INTRODUCTORY LECTURES

Regulatory Barriers for Adequate Pain Control

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Abstract

In 1961 the "Single Convention on Narcotic Drugs" was adopted by the United Nations to explicitly address the need for narcotic drugs to curtail suffering and keep the distribution of these drugs in the control of health professionals. Fifty years later, neither goal has been reached for a variety of reasons. Governments have avoided putting in place systems to assure adequate supplies to relieve the suffering of those with severe pain, drug enforcement agencies maintain restrictive regulations and physicians are intimidated by threats of legal action if their prescribing patterns do not conform to arbitrary standards. There is a shortage of pain control consultants and the training for most health care providers is deficient when it comes to the management of chronic pain. Some of the regulatory barriers have been successfully addressed through advocacy efforts and the expertise deficiencies improved through targeted educational programs.

Keywords: Single Convention on Narcotic Drugs - regulatory barriers - international responsibility

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Regulatory Barriers to Adequate Pain Control

Prevalence of Pain

The prevalence of pain among adults with advanced cancer ranges between 75% in the outpatient clinic to 80% for people receiving end-of-life care. (McKegney 1981; Cleeland et al., 1994) Even under relatively ideal cancer management, approximately 40 to 50% of patients fail to achieve pain control and this is unacceptable considering our medical responsibility to provide adequate care.(Cherny and Portenoy, 1994) In the Netherlands, ineffective pain management was even seen with patients receiving curative cancer treatment and there was an increased association among those with a low education.(van den Beuken-van Everdingen et al., 2007a; 2007b) In developed countries patients receiving curative therapy and those with incurable cancer deserve better pain management. In other countries, with fewer resources available for cancer care, the proportion of the population destined to die of their disease who require pain management as part of end-of-life care is even greater. In another study, it was found that patients in an outpatient setting with a combination of cancer and non-cancer pain were at significant risk for under-treatment of their pain (Valeberg et al., 2008). A prevalence study of pain in older adults demonstrated how pain caused disability and reduced function, particularly in older women (Miro et al., 2007). In a pain prevalence study among hospitalized cancer patients in Norway, approximately 30% reported severe pain and were not receiving opioids or in some cases no analgesic therapy (Holtan et al., 2007). The presence of inadequately treated pain in countries with excellent medical resources and adequate supplies of opioid analgesics (often referred to as “narcotics”) underscores the problems imposed by educational deficiencies and regulatory barriers imposed on the healthcare system. WHO estimated that 80% of the World's population had no access to adequate treatment for severe pain (WHO 2007).

International responsibility

In 1961 the "*Single convention on narcotic drugs*" was adopted by member states confirming in its major thesis statement that narcotic drugs were critical for the relief of pain and adequate medicinal narcotic drugs should be made available (UN 1961). The WHO developed a pain relief guideline more than two decades ago and has continued to recognize the critical importance of morphine and other opioids for the treatment of severe pain (WHO 2000). To withhold, impede access to, or delay treatment for severe pain can be considered a form of passive torture that warrants appropriate corrective attention. Unfortunately there are economic, bureaucratic, educational, and drug supply barriers that require attention if there is any hope of achieving extensive application of these pain control guidelines.

These guidelines were developed to promote and improve the standard of care for severe pain. Many of those suffering severe pain are receiving end-of-life care and are therefore the most vulnerable; neither those patients nor their family caregivers are in a position to challenge their political leadership to solve the systems’ problems, namely: the shortage of available expertise, restrictive overregulation, inadequate drug supplies and widespread under-treatment of patients with severe pain.

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Successful programs have occurred internationally and both Uganda and Vietnam are examples of what can be done to overcome the dominant inertia working against these necessary improvements (Lohman et al., 2010).

Complex interactive Impediments for: sufferers, health care providers, legislators and regulators.

Pain and suffering have been part of the religious practices for man since the beginning of recorded history. The story of "Job" told in the Old Testament of the Bible, is a narration of an inexplicable painful test of faith. Self-flagellation and other self-inflicted pain as punishment for perceived unacceptable behavior or as a cleansing rite persist even today (Morris, 1994). From sensitivity to stoicism, there is a wide range of individual reactions to pain. Unless specifically queried about their pain, many patients will not reveal their pain experience and may even shield the attendant health care professionals from pain as one of their major problems. Others may overreact and be considered unreliable historians about the cause or severity of their pain. Misunderstanding about and fear of addiction, and concern about side effects [e.g. loss of control] may negatively influence the patient, supportive family members or even their health care providers (Ward et al., 1993). The ambiguity in the pain experienced by the patient and the quality of the communication with the provider can interfere with timely and effective pain assessment and management. In environments where the government interferes with access and supply of pain medications, the path of least resistance is often to accept the pain with a level of fatalism. The government is expected to facilitate an adequate supply of effective pain medications, but this is not always the outcome.

Prescriber burden in today's environment.

When prescribed responsibly, opioid analgesics are inexpensive, safe and highly effective medicines for relieving suffering (WHO, 2007). But these controlled substances also tend to trigger dueling policy challenges for health care professionals, who must consider the interface between providing safe, effective pain relief for their patients through responsible prescribing and curbing drug diversion, misuse and abuse (Woodcock, 2009). As a result, far too many patients are left to suffer because they and their health care professionals do not have access to morphine or other opioid analgesics needed to provide pain control. This is the case despite the fact that the UN drug conventions recognize that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes."

Because of practice demands physicians may not have adequate time to assess the severity of each patient's pain, consider the potential interactions of analgesics with other medications, or educate the patient and family about effective pain management and the safe use of prescribed medicines. These drugs have a known narrow therapeutic index and their delayed metabolism may have cumulative adverse effects. Inadequate training in the management of severe pain, the lack of accessible consultative expertise and concerns about patient costs for expensive medications also contribute to the lack of optimal outpatient management of pain. Further impeding access, local pharmacies may be reluctant to carry inventories of opioid analgesics because of their fear of robbery, particularly in medically underserved neighborhoods. In some states in the US, duplicate or triplicate specialized prescription forms required for controlled substances make writing prescriptions for opioids onerous both in terms of time to write them, as well as a burdensome record keeping requirement. In the few states where these forms are still used, fewer opioid analgesic prescriptions are written because of the inconvenience, but with no correlative evidence demonstrating that these forms have made any impact on reducing drug abuse and diversion.

Therefore, the selection of less effective or inexpensive analgesics may result in the under-treatment of the patient's pain. In addition, some physicians reduce their pain prescribing because they are concerned that they may be subjected to regulatory oversight which could prove both time-consuming and a threat to their professional status (Fishman, 2007). Physicians must invest the amount of time necessary to assure that they know how to and do assess and treat pain in the most responsible and effective manner for every patient.

Substance Abuse in the United States.

While the dangers of prescription pain medications and their misuse often hit the news headlines, we hear far less often about the other side of the story – the individual patients who are suffering and need these medications to ease their cancer pain. Efforts to promote safe, responsible prescribing of controlled substances and prevent diversion and abuse of opioid analgesics are very important and necessary. But those efforts should not interfere with medical practice and patient care. Drug control policies must be balanced so they do not restrict medical decision-making and the availability of controlled substances for legitimate medical purposes. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical (Joranson and Gilson, 2006).

Unfortunately, the attendant publicity related to drug trafficking, morbidity and associated criminal behavior receives maximal attention from the news media. The overt suffering of individuals is unpleasant, resulting in the public as a whole not appreciating the magnitude of the problem. The abuse of prescriptive medications resulting in the deaths of celebrities such as Michael Jackson and violent crimes associated with illegal drug use, influences both the attitudes and beliefs of many members of the legislative bodies and the public. These attitudes are reinforced by law enforcement agencies resulting in more oppressive regulations in the name of crime control.

The problem of substance abuse among the young Americans is significant. Survey information tells us that about 47% of the high school graduates have tried an illicit drug (Johnston, 2008). Approximately half of those

individuals have used an illegal drug other than marijuana. On the positive side, 57% of high school seniors have not ever tried marijuana. High school students have reported the ready availability of a variety of illicit drugs. Approximately 1/2 of all students state that cocaine is readily available and other illicit narcotics are available to approximately 1/3 of the students (see Table 1). For a comparable period of time the number of narcotics violation records for physicians in the United States remained constant until the appointment of a reactionary new attorney general of the United States (Bolin, 2006). This mixture of medicine with politics resulted in doubling the number of violation records over the subsequent four years. Conservative politicians interfered with the expected death of highly publicized unfortunate individuals such as Terry Schiavo, a lady with documented irreparable brain damage in a vegetative state. Political interventions have generated an atmosphere of fear among some physicians concerned about the inappropriate scrutiny of their controlled substance prescriptions by the US drug enforcement agency. This underscores the need to educate both the members of the executive branch of government as well as those responsible for promulgating the laws and regulations relevant to the availability of controlled substances.

There appear to be five major areas that contribute to the inadequate management of pain that could be remedied with the right programmatic approach (Gilson et al., 2005; Gilson, 2010).

Strategies for Improvement

1. Raise awareness about the importance of providing adequate pain management and improve understanding about the benefits and risks of pain control medications by adopting and communicating uniform, easily understood definitions of addiction, tolerance and dependence such as those developed and adopted by the Federation of State Medical Boards in the United States in its 2004 Model Policy for the Use of Controlled Substances for the Treatment of Pain.
2. Develop adequate drug supply systems by the government bodies responsible for controlling opioids. This appears to be a major problem in many countries whose leaders publicly endorse better pain control but are unable to provide the supply of drugs necessary to safely accomplish optimal pain control.
3. Examine and revise restrictive public policies relevant to pain management to ensure policies are balanced and do not interfere with safe pain prescribing and practice required to ease suffering.
4. Expand the pool of healthcare workers with pain management expertise through government facilitated programs.
5. Enact policies that recognize the importance of pain management and safe opioid prescribing as an essential component of quality care and limit the threat of unwarranted legal sanctions and the added administrative burden imposed on health professionals forced to defend appropriate cancer management. Selected patients may require large amounts of opioid analgesics or prolonged treatment with these medications to assure optimal pain control.

Table 1. A Depiction of the Illicit Drug Environment

Year	Cocaine	Other Narcotics	NPDB Reports
92	53	45	215
93	49	34	210
94	47	34	190
95	48	35	160
96	48	32	180
97	49	34	150
98	51	36	100
99	48	32	120
00	48	34	130
01	46	32	125
02	45	29	235
03	43	28	440
04	48	30	330

Based on the per cent of high school students who knew where to get illicit drugs (Johnston, 2008) and the number of narcotics reports filed in the National Practitioner's Data Bank (NPDB) There appeared to be an increase in which practicing physicians were reported during the tenure of two Attorney Generals of the US. (Bolin 2006)

Drug enforcement and pain control - the RIGHT balance

Effective drug management using agents with a narrow therapeutic index is a major responsibility for healthcare providers. In the United States there is widespread non-medical misuse of prescription pain relievers. An estimated 5.2 million people did so in one month alone in 2007 according to one report. (Woodcock 2009) Similarly, it is estimated that in 2006 there were approximately 57,000 emergency department visits in the US for the non-medical use of a variety of opioid analgesics, and 9179 children in a three-year period from 2003 were treated for the accidental exposure to prescriptive opioids. (Woodcock 2009) It is imperative that along with the ability to manage pain using the most potent and effective drugs, health care providers must also do so responsibly, essentially becoming "risk managers" when considering each prescription for opioids.

Developing benchmark indicators for the safe and adequate use of opioid analgesics for pain control is not easy, but looking at the UN data for a standardized mortality from cancer per hundred thousand people for a few selected European countries (a surrogate for need for

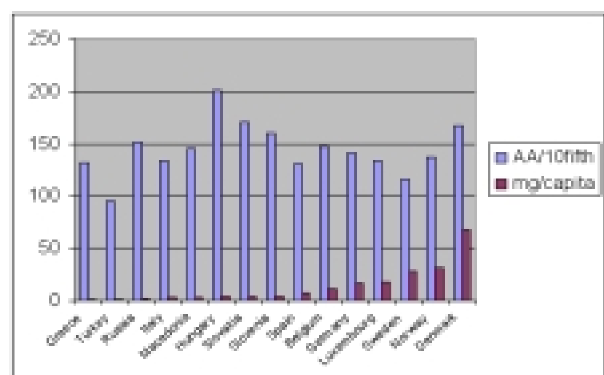

Figure 1. The Age-adjusted Cancer Mortality for Selected Countries. (Provided to show proportional demand for narcotics) and the per capita Consumption of morphine for the year 2000 (UN 2000)

pain management) along with the estimated milligrams per capita of opioids consumed, provides a confusing picture of disparities. (UN 2000). Ranking the countries based on opioid consumption suggests the Northern European Countries consume more opioids which may mean better pain control. Deficiencies for some of the countries have been and are being addressed. Information such as this stimulated Italy to address changes in their existing system using a work group appointed by the Ministry of Health (Blengini et al., 2003).

One of the well-documented major fears of patients with advanced cancer is a painful death. Balanced pain policies are critical to assure virtually all patients will not have to experience such terminal pain. Since 2000 policy statements have increased by 55% while there has been a minimal increase in the number of relevant laws and regulations (Gilson et al., 2007). The University of Wisconsin Pain and Policy Studies Group (PPSG) developed a state-by-state report card, which, similar to the Italian experience, resulted in positive policy changes. The process included the evaluation of all state laws and regulations for prescribing, dispensing and administering controlled substances as well as providing guidance to state medical and pharmacy licensing boards. These efforts were guided by the central principle of " balance". This is a long-standing national and international consensus statement : "efforts to control abuse and diversion of opioid analgesics should not interfere with relieving patients' pain and suffering and that regulatory policy should not contradict current medical and scientific knowledge." Balanced state policies should not impede appropriate patient pain management and should not sanction the use of controlled substances outside of the control of licensed healthcare professionals. The PPSG generated a 16 item policy evaluation criteria composed of a list of eight positive and eight negative items based on language found in existing state policies. States were then ranked based on a grading system. Following the publication of performance, strategic legislative advocacy resulted in 35 states making positive changes in their policies. Between 2006 and 2008 alone, 15 state policy grades improved (2008). Ongoing pain advocacy efforts will yield even more balanced policies in the future (Brawley et al., 2009).

Examination of government policies resulted in healthcare professional organizations pushing for positive changes: legal, financial, systems and other barriers. The use of outside consultants and educators experienced in developing the necessary local expertise to affect the political and clinical change necessary will add to the likelihood of success. It is critical to identify an executive or legislative champion prepared to gather a workgroup capable of addressing the existing policies in an unbiased manner. Using advocacy tools, such as those developed by the American Cancer Society Cancer Action Network, the advocacy affiliate of the American Cancer Society, have proved successful in various environments and could be adapted to save time and effort (Kirch, 2003). There are other organizations that have been successful in stimulating positive changes and they should be called upon for help whenever necessary.

We owe it to ourselves as potential sufferers of pain and all other patients in the future, to improve the existing situation, striving for the best pain management possible with our present medications, until the science of the future provides a superior option.

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