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CONTROLLED SUBSTANCES AND PAIN MANAGEMENT: A NEW FOCUS FOR STATE MEDICAL BOARDS

The publication of the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (elsewhere in this issue of the *Bulletin) is* a vital contribution to improving pain management in the United States. This article reviews why model guidelines are needed and why it is an improvement over most current medical board guidelines. Suggestions regarding implementation of guidelines are offered to the Federation and to state medical boards.

WHY MODEL GUIDELINES ARE NEEDED

INADEQUATE PAIN MANAGEMENT

A number of health authorities have concluded that pain often is inadequately treated in a wide range of patient groups, including trauma and surgery patients, patients with cancer, those who are dying, as well as those who are living with a variety of chronic painful conditions.[1] In addition to the direct effects of pain on health and quality of life, unrelieved chronic pain may result in unscheduled hospital admissions; excessive use of emergency rooms; loss of employment, spouse, and family; and loss of life itself when some chronic pain patients commit suicide.[2] Jack Kevorkian, the US Supreme Court, and the State of Oregon recently have focused particular attention on the need for action at the state level to improve pain management.

PAIN MANAGEMENT IS BECOMING A HIGHER PRIORITY

In 1986, the World Health Organization (WHO) began its global initiative to relieve pain due to cancer using a three-step approach that required the use of opioid analgesics like morphine.[3] At about the same time, efforts began in the United States to document and respond to the inadequate treatment of cancer pain. To date, these efforts include, among others not listed:

- health care providers
- patient advocacy groups
- state cancer pain initiatives
- state government pain commissions
- state summit meetings and task forces
- state legislatures and medical boards
- the National Institutes of Health
- the US Agency for Health Care Policy and Research
- the Institute of Medicine of the National Academy of Sciences
- the US Cancer Pain Relief Committee
- the American Pain Society (APS)
- the American Academy of Pain Medicine (AAPM)
- the American Society of Law, Medicine & Ethics (ASLME)
- the Joint Commission for Accreditation of Health Care Organizations
- foundations such as the Robert Wood Johnson Foundation, the Mayday Foundation, the Kornfeld Foundation, and the Project on Death in America

In 1986, the national consumption of opioids for medical use began to increase significantly in the United States due to increased prescribing, and continues to increase.[4] The extensive clinical experience with the use of opioid analgesics for managing chronic severe cancer pain challenged traditional views that dosing of opioids was necessarily limited by side effects, such as sedation and tolerance. Both clinicians and researchers reported that the dose of opioid agonists could be increased for escalating pain, sometimes to levels that previously would have been considered either dangerous or excessive. While the patient became physically dependent, such prescribing rarely, if ever, led to documented psychological dependence or addiction. The management of pain due to cancer began to improve.

Experience in cancer pain precipitated a scientific and clinical reappraisal of the use of opioids for chronic non-cancer pain. The traditional view that opioids should not be used in the management of chronic non-cancer pain has given way to acceptance of a role for opioids, especially among pain specialists.[5] There remains a need, however, to clarify the criteria for patient selection and clinical management. In early 1997, the AAPM and the APS published an unprecedented Consensus Statement on *The Use of Opioids for the Treatment of Chronic Pain*[6] modeled in part after the 1994 guidelines of the Medical Board of California titled *Guidelines for Prescribing Controlled Substances for Intractable Pain.*[7]

In 1997, the Federation began to consider developing model guidelines that could be recommended to state medical boards. The objectives of the guidelines were to encourage effective pain management, to serve as an alternative to legislative action, and to achieve a degree of consistency among the states with respect to pain and controlled substances policy. At the same time, there was an effort to recognize and maintain a balance of improved pain relief with the medical boards–responsibility to protect public health and safety from the misuse of controlled substances.

Guidelines from state medical boards are needed for several reasons. State medical boards, reflecting traditional views about the risks of opioids, have in the past discouraged the use of opioids for patients with chronic pain. Indeed, state laws typically lack recognition (as in federal law) that controlled substances are necessary for public health and may be prescribed for pain. Past efforts to address prescription drug abuse and diversion sometimes have focused more on the potential street value of amounts prescribed to patients over a period of time, rather than on evaluating the outcome of treatment. Some boards have issued statements that opioids are not appropriate for the treatment of chronic pain.

As physician and patient interest in use of opioid analgesics began to develop after 1986, there was friction. A process of dialogue and policy change began.

Studies to describe regulatory impediments to the use of opioids for pain management began in Wisconsin as a cooperative effort of the Wisconsin Cancer Pain Initiative, the state's Controlled Substances Board, and the University of Wisconsin. In a survey, Wisconsin physicians said they would reduce the amount or prescribe less controlled drugs to avoid regulatory scrutiny, especially when prescribing for chronic pain.[8]

This and other surveys demonstrated that many physicians perceived a risk of regulatory scrutiny, especially when prescribing opioids for chronic non-cancer pain. To study this

situation further, in 1991 we surveyed all state medical board members in the United States.[9] This survey demonstrated that only 12% of medical board members believed that the use of opioids for chronic non-cancer pain was legal and accepted medical practice, and the rest would either discourage the practice, or investigate it as a possible violation of law.

These findings were reported in the *Federation Bulletin* in 1992, and at the Federation's 1991 annual meeting in Seattle, Washington, leading to a series of workshops for state medical boards. Sponsored by the University of Wisconsin's Pain and Policy Studies Group (PPSG) in cooperation with the Federation and the medical boards in Alabama and North Carolina, these workshops helped to increase communication between medical boards and advocates for pain management. As boards' awareness of the pain problem and physicians' concerns grew, medical boards began to adopt guidelines to recognize the use of opioids for the treatment of pain, including chronic non-cancer pain.[10] Several boards have gone beyond the development of guidelines by disseminating information about pain management and the board's guidelines through the media, as well as by sponsoring physician and public education programs about pain management.[11] These boards have expressed satisfaction with such programs.

The trend among state medical boards to adopt guidelines was paralleled by a trend in state legislatures to adopt intractable pain treatment acts (IPTA). IPTA's are usually prompted in states where a conflict between physicians or patients about prescribing opioids for chronic non-cancer pain has emerged. However, some of these new laws may inadvertently impede pain management because they contain restrictive provisions, including

- exclusion of prescribing for persons who use drugs non-therapeutically even if the person has pain,
- defining the prescribing of controlled substances for intractable pain as a last resort and not within the ordinary practice of medicine, and *requiring*
- written informed consent and
- a consultation with a specialist for every patient receiving opioids for intractable pain.

Legislative involvement in establishing medical policy can be fraught with risks[12]; the Federation's model guidelines are preferable to legislative establishment of pain policy.

THE ADVANTAGES OF THE FEDERATION'S MODEL GUIDELINES

The Federation's model guidelines have advantages over most current medical board guidelines or policy statements from individual states. Such advantages are outlined as follows:

1. The drafting of the Federation's model guidelines profits from experience with the first generation of medical board guidelines, and also takes advantage of national input. The drafting process involved a national group of representatives of the Federation and several state boards which had extensive experience with medical board policy generally, and with pain guidelines specifically. The group also included representatives from the APS, the AAPM, the ASLME, and the University of Wisconsin PPSG. These organizations previously worked with state medical boards on pain-related education and policy projects.

2. The review and approval process for the model guidelines was national in scope; the Federation sponsored a forum to take testimony on the model guidelines from a variety of organizations representing boards, patient advocacy groups, and the US Drug Enforcement Administration. The Federation's model guidelines were reviewed by members of the following organizations:

- American Academy of Pain Medicine
- American Medical Association
- American Pain Society
- American Society for Action in Pain
- American Society of Law, Medicine & Ethics
- Compassion in Dying Federation
- Drug Enforcement Administration
- Forensic & Educational Consultants
- Kansas Association of Osteopathic Medicine
- National Association of State Controlled Substances Authorities
- New York Board for Professional Medical Conduct
- US Public Health Service, Office of Substance Abuse Treatment
- University of Wisconsin Pain & Policy Studies Group

The drafting group met again to incorporate recommendations from these organizations, and produced a final draft that was reviewed and adopted by the Federation's House of Delegates May 2, 1998.

3. The drafting process was informed by a content analysis performed by researchers at the PPSG. Twenty-four guidelines and policy statements, issued by state medical boards from 1989 to 1997, were finally evaluated (the Virginia guidelines were not received in time to be included).

A coding scheme and an evaluation form were developed to assess the presence of a number of variables, including the guidelines' stated purpose(s), a board's position on the use of opioids, the use and definition of terms relating to addiction, the criteria by which a board will judge the validity of prescribing, and the recommended parameters of good medical practice in pain management. Results from the evaluation identified extensive variability in the guidelines, for example, in whether opioids are accepted for pain management, and inconsistencies in the use and definitions of pain- and addiction-related terms.

New state guidelines should reflect current knowledge about pain management and permit flexibility in the management of patients with pain. The present positive dialogue among medical boards, pain clinicians, and addiction specialists should be enhanced to ensure the development of rational and reasonably consistent pain treatment guidelines at the state level. The Federation's model guidelines should be of interest to state medical boards that do not have guidelines, as well as those boards that would like to update their guidelines; the Federation's model guidelines contain language that would be an improvement over current board guidelines in several respects:

1. Purpose: The model guidelines

- state that effective pain management is part of good medical practice,
- address physicians' concerns about regulatory scrutiny by clarifying the board's policy,
- explain how the board distinguishes legitimate medical practice from unprofessional conduct, and
- encourage physician education by providing references to clinical practice guidelines that are available.

Many existing guidelines do not address these important purposes. The model guidelines also emphasize the need to protect public safety by preventing drug abuse while, at the same time, encouraging effective pain management.

2. Opioids: The model guidelines recognize that opioids may be necessary for the treatment of pain and accepts their use for the management of acute cancer and chronic non-cancer pain. Some existing guidelines do not contain such direct statements of recognition.

3. Addiction-related terms: The model guidelines use and define correctly terms such as tolerance, physical dependence, addiction, and pseudoaddiction. Many existing guidelines do not use terms consistently and either provide no definitions or definitions that are incorrect.

4. Board criteria used to judge practice: The model guidelines explain that the board will judge the validity of a particular prescribing practice based on the outcome of the physician's treatment of the patient rather than on the amount and duration of prescribing. Previous guidelines have at times used amount and duration as the basis for such judgments or have provided no indications about how such judgments will be made.

5. Parameters: The model guidelines provide a reasonable set of recommended parameters based on principles of good medical practice for physicians' use of controlled substances for pain management. In brief, the parameters are

- a complete medical history and physical examination,
- development of a treatment plan with objectives that will be used to monitor progress, as well as the documentation of a recognized medical indication for the use of a controlled substance,
- informed consent and patient agreement to treatment,
- periodic review,
- consultation when appropriate,
- documentation of the aforementioned treatment steps, and
- compliance with both federal and state controlled substances laws and regulations.

Some existing guidelines are less complete than the model, while others recommended "drug holidays" or make many requirements that could limit a physician's treatment discretion. Further, the model guidelines allow a physician to deviate from the outlined requirements or recommendations for good cause shown.

SUGGESTIONS FOR THE FEDERATION AND TO STATE MEDICAL BOARDS

The development and adoption of medical board guidelines, by themselves, will not improve pain management. We urge boards to assess the situation in their state, seeking advice from experts who can provide accurate information about current issues and clinical practices. Once adopted, guidelines should be incorporated into board investigation and disciplinary practices. The effectiveness of guidelines in reducing physician concern about regulatory scrutiny and encouraging the appropriate use of opioids will depend on thorough and repeated dissemination and incorporation into medical education. Medical boards can work with other groups such as state medical societies and academic organizations to sponsor educational programs. It is only through physician knowledge of the information contained in the guidelines that the objectives of the policy can be fulfilled.

CONCLUSION

State medical boards have the authority to regulate medical practice and are in a position to encourage pain management and to address some of the barriers to pain management, including physicians' concerns about being investigated. The model guidelines from the Federation are an improvement over existing guidelines and should be considered by all state medical boards. Representatives of national and state organizations with interest in pain management appreciate and are eager to continue the dialogue that has been established with state medical boards and the Federation.

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