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Russell K. Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective"

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During the past decade, debate has intensified about the role of long-term opioid therapy in the management of chronic nonmalignant pain. Specialists in pain management have discussed the issues extensively and now generally agree that a selected population of patients with chronic pain can attain sustained analgesia without significant adverse consequences. This perspective, however, is not uniformly accepted by pain specialists and has not been widely disseminated to other disciplines or the public. Rather, the more traditional perspective, which ascribes both transitory benefit and substantial cumulative risk to long-term opioid therapy, continues to predominate. According to this perspective, the inevitability of tolerance limits the possibility of sustained efficacy, and other pharmacological properties increase the likelihood of adverse outcomes, including persistent side-effects, impairment in physical and psychosocial functioning, and addiction. If accurate, these outcomes would indeed justify the withholding of opioid therapy for all but the most extreme cases of chronic nonmalignant pain.

Two sets of observations have been the strongest impetus for a critical reexamination of the evidence supporting the traditional view of opioid therapy. First, experience gained during the management of cancer pain has demonstrated the potential for highly favorable outcomes from long-term opioid therapy. Second, evidence has accumulated that the laws and regulations intended to reduce illicit use and misuse may have unintended adverse effects on legitimate prescribing. These observations provide a context for further analysis of the controversy surrounding the use of opioids for nonmalignant pain.

Implications of opioid therapy for cancer pain

Experience in the cancer population contrasts starkly with the negative view of opioid drugs. Numerous surveys indicate that long-term opioid therapy provides adequate relief to 70 to 90 percent of patients with cancer pain. Rather than contributing to distress or dysfunction, the relief of pain in this population is associated with an improved quality of life. On this basis, long-term treatment with opioid drugs has been strongly advocated by pain specialists and both national and international medical organizations.

This experience in the treatment of cancer pain has produced observations that belie accepted dogma about opioid therapy. For example, patients rarely demonstrate euphoric responses to opioid drugs, and neither analgesic tolerance nor physical dependence is a significant clinical problem. Moreover, patients without concurrent brain pathology seldom experience persistent neuropsychological toxicity (such as somnolence or mental clouding). Most important perhaps, addiction is extremely rare among cancer patients with no prior history of substance abuse who are administered opioids for pain. These observations justify the need to examine conventional thinking about the role of these drugs overall, including their potential utility in chronic nonmalignant pain.

Implications of opioid regulation

The prescription of opioids is scrutinized by regulatory and law enforcement agencies, which are responsible for preventing drug diversion and eliminating inappropriate prescribing practices. In pursuing these functions, these agencies have no statutory or regulatory interest in impeding the legitimate use of opioids by physicians. Physicians understand the need to monitor and regulate controlled prescription drugs, and must be assured that prescribing behavior that is within the bounds of accepted medical practice will not lead to investigation or sanction. If a proper balance were struck between the intrusions necessary to regulate these potentially abusable drugs and protecting patients' access to them, there would be no need for concern.

Unfortunately, evidence indicates that this balance has not been achieved.6 Regulatory policies contribute to the undertreatment of pain both directly, by impeding access to controlled prescription drugs, and indirectly, by negatively influencing prescribing behavior. Impediments to access are exemplified by regulations in

some states that limit the number of tablets that can be prescribed at one time. Such a regulation may force patients with a legitimate need for high opioid doses, most of whom have cancer pain, to obtain multiple prescriptions per week, which may be exhausting to both the patient and prescriber.

The adverse impact of regulation on legitimate prescribing is less concrete but probably far more widespread. In a recent survey, a majority of physicians admitted that concerns about regulatory scrutiny at least occasionally impel a change in the prescription of a controlled drug. Not surprisingly, the degree of concern about regulatory oversight was greatest with the drugs most often used in the management of severe pain, such as morphine.

Analysis of multiple copy prescription programs offers additional evidence of the influence of regulatory policies on physician prescribing. These programs, which monitor physician behavior through the use of a special prescription form for controlled drugs, offer point-of-sale data that are strongly favored by those in the regulatory and law enforcement communities. Every state that has initiated a multiple copy prescription program has recorded a greater than 50 percent reduction in the prescribing of the regulated drugs. Although proponents contend that this change reflects a lower rate of abuse, these claims have been disputed by pain specialists and others. Data from the federal Drug Abuse Warning Network have not confirmed that multiple copy prescription programs curtail prescription drug abuse, and surveys in Texas and New York suggest that the increased awareness of regulatory oversight associated with these programs reduces legitimate prescribing of the regulated drug and increases prescribing of substitute drugs that may be less preferred for the indication in question.

These observations indicate that clinicians may perceive some degree of personal risk in prescribing opioids, even if medical judgment supports this use. The reality of this perception has been buttressed by a nationwide survey of members of boards of medical examiners, which revealed that a substantial proportion of these regulators would potentially recommend investigation of a prescriber solely in response to the knowledge that an opioid had been administered to a patient with nonmalignant pain for more than six months.

Decision making by physicians within the broad parameters of conventional medical practice should not be unduly influenced by federal or state laws, regulations, policies, or communications that restrict patient access to controlled prescription drugs or incite fear of inappropriate scrutiny or sanction by regulators or those in law enforcement. In an area of therapeutics that is continuing to evolve, like long-term opioid therapy, a clear need exists for dialogue between regulators and clinicians that can define the shifting parameters of conventional practice and continually reassure legitimate prescribers. This dialogue has not taken place and efforts are needed to support it. A critical reevaluation of the role of opioid therapy in the management of chronic nonmalignant pain can be a useful element in this process.

Published experience

Opioid therapy has been evaluated in a small number of controlled clinical trials that assess brief periods of dosing in specific populations with nonmalignant pain. Most of these trials evaluate one or two weeks of treatment in patients with arthritis. The results largely, but not uniformly, support the efficacy of the therapy, but their relevance to long-term management is dubious. None demonstrates the development of abuse behaviors during the brief treatment periods. One controlled trial had an open-label extension phase, during which treatment benefit was maintained.

The most relevant controlled trial published to date evaluated six weeks of morphine therapy in patients with chronic musculoskeletal pain. This study, which used a crossover design, compared the opioid against an active placebo (benztropine) to ensure blinding of the therapy and evaluated a broad range of outcomes related to subjective effects and function. The results demonstrated a significant reduction in pain during morphine therapy, without change in physical or psychological functioning, and without evidence of psychological dependence (measured on a "drug liking" scale) or aberrant drug-related behavior.

Numerous surveys have also been published during the past decade. Some have described the favorable experience of clinicians who have administered opioid drugs to selected patients with nonmalignant pain. One large survey, for example, described 100 patients with diverse pain syndromes who received dihydrocodeine, buprenorphine, or morphine for prolonged periods. More than half these patients maintained greater than 50 percent analgesia for at least one month and performance status increased

overall, with the largest improvement observed among those with the greatest relief of pain. No incidents were reported of serious toxicity or drug-related behaviors suggestive of addiction or abuse.

In another survey, patients treated for sickle cell disease at a single university-based clinic were offered liberalized prescribing of opioids modeled on the treatment of cancer pain. During a two-year follow-up period, emergency room visits declined by 67 percent and hospital admissions decreased by 44 percent. No increase in opioid abuse was reported.

In contrast to these favorable surveys, others depict negative outcomes associated with long-term opioid therapy. These generally originate from multidisciplinary pain management programs and suggest that opioid use may predispose to heightened pain and functional impairment, neuropsychological toxicity, prevarication about drug use, and poor treatment response. Many of the patients described in these reports improve (at least functionally, and sometimes even in terms of pain) when opioids are tapered and discontinued within the context of a more comprehensive pain treatment program.

The limited number of controlled trials, combined with the disparities and inherent biases of the survey literature, preclude definitive conclusions about the risks and benefits of long-term opioid therapy. Nonetheless, it is reasonable to infer from these conflicting results that there is a spectrum of patient responses. On one end of this spectrum is a "successful" subpopulation that achieves sustained partial analgesia without the development of treatment-limiting toxicity, functional deterioration, or aberrant drug-related behaviors. Some of these patients achieve functional gains as pain declines. On the other end is a subpopulation that deteriorates during opioid therapy. This deterioration can be characterized by worsening pain and disability, the development of aberrant drug-related behaviors, or both.

Most pain specialists endorse this view of opioid therapy and, consequently, no longer debate the role of opioid therapy in absolute terms. For pain specialists, the issue is not whether opioid drugs should ever be used in the treatment of chronic pain, but when and how. Although this shift in consensus may not be shared by all specialists, and has certainly not disseminated widely to other professional disciplines, it is noteworthy, and suggests that the use of opioid therapy for chronic nonmalignant pain must now be evaluated as a potentially salutary therapeutic option for carefully selected patients. From this vantage, all those who might become involved in this therapy--clinicians, pharmacists, regulators, and patients--could benefit from a clear understanding of the evidence that defines its risks and benefits.

Opioid therapy for nonmalignant pain: critical issues

The risks and benefits of opioid therapy can be addressed by examining the diverse literature that relates to several critical issues, specifically efficacy, the potential for adverse pharmacological effects, and addiction liability.

Therapeutic efficacy

The efficacy of opioid therapy can be discussed in terms of the responsiveness of different patient subgroups, the durability of the response, and the appropriateness of therapy in the context of larger treatment goals.

Opioid responsiveness

Experience in the management of cancer pain has focused attention on the concept of *opioid responsiveness*. Opioid responsiveness refers to the probability that "adequate" analgesia (that is, satisfactory relief without intolerable and unmanageable side-effects) can be attained during dose titration. After opioid therapy is initiated, most patients undergo gradual escalation of the dose until a favorable balance between analgesia and side-effects is reached, or treatment-limiting toxicity precludes further dose adjustments. The balance between analgesia and side-effects varies from patient to patient given the same opioid, and from opioid to opioid within the same individual.

The large individual variability in the responsiveness to opioid drugs can be ascribed to a variety of patient-related and pain-related factors. The existence of one or more of these factors can relatively increase or decrease the likelihood that optimally administered opioid therapy will yield a favorable balance between

analgesia and side-effects. No factor has ever been shown to impart complete resistance to opioid analgesia. For example, a neuropathic mechanism may reduce the overall responsiveness to opioid drugs, but does not exclude a favorable response in any individual case. No characteristic of the patient or pain syndrome can predict the overall benefit of opioid therapy.

These observations resonate well with clinical experience. They indicate that opioid therapy may or may not provide adequate pain relief to any individual patient. The only method for determining outcome is through a therapeutic trial. At present, the predictors of opioid response are not strong enough to exclude patients as candidates for treatment on the presumption of inefficacy.

Durability of response

Clinicians and patients alike commonly express concern that the inherent pharmacology of opioid drugs, specifically the potential for tolerance, limits the potential for long-term efficacy. *Tolerance* is a pharmacological property defined by the need for increasing doses to maintain effects. The term does not imply a specific mechanism or mechanisms, but does indicate that exposure to the drug is the driving force for the change in response.

Although tolerance can be readily demonstrated in animal models, these models have limited relevance to the complex clinical setting. During opioid therapy, tolerance to adverse effects, such as respiratory depression, somnolence, and nausea, appears to occur routinely. This is a favorable outcome that allows dose escalation to levels associated with analgesia. In contrast, clinically significant tolerance to analgesic effects appears to be uncommon. Most patients who are receiving opioid drugs for chronic pain attain stable doses associated with a favorable balance between analgesia and side-effects for prolonged periods. Dose escalation, when it is required, usually has an obvious alternative explanation, such as worsening of a painful lesion.

Analgesic tolerance, therefore, seldom compromises the efficacy of therapy. Fear of tolerance does not justify a decision to withhold or delay a therapeutic opioid trial.

Therapeutic appropriateness

The treatment of chronic nonmalignant pain is usually guided by the dual goals of enhanced comfort and improved physical and psychosocial functioning. Although conventional thinking assumes that opioid therapy compromises functional restoration, the surveys described previously present a more complex situation. Some patients with nonmalignant pain can receive opioids and apparently capitalize on improved comfort by increasing function, whereas others receive the same drugs and develop worsening disability.

This variability in the response to opioid therapy highlights the heterogeneity of patients with chronic pain. Reports from multidisciplinary pain management programs that suggest a high likelihood of opioid-related functional disturbances may reflect the population referred to such programs, which is characterized by higher levels of psychosocial distress and functional impairment than other patients with chronic pain. The appropriateness of opioid therapy for all patients with chronic nonmalignant pain cannot be generalized from any selected population.

Furthermore, pain specialists do not advocate opioid therapy as a substitute for a comprehensive pain management approach that may incorporate psychological and rehabilitative treatments for appropriate patients. It is even possible that some patients who are candidates for multidisciplinary pain management programs could benefit from opioid therapy as a complementary treatment. Opioid treatment may also be an approach that could be implemented by the individual practitioner as part of a multimodality treatment strategy for patients who have disabling pain and are not candidates for specialized pain treatment programs, lack access to such programs or the resources to attend them, or continue to experience severe pain after completing such a program. Persistent pain is common following participation in a multidisciplinary pain management program, even if functional benefits are initially gained, and many patients continue to use opioid drugs.

Adverse pharmacological outcomes

The risk of adverse pharmacological outcomes can be evaluated in terms of major organ toxicity, persistent side-effects, and the potential problems posed by physical dependence.

Major organ toxicity

There is no evidence of major organ toxicity during long-term opioid therapy in either the cancer population or the methadone-maintenance population. Case reports have described the occurrence of pulmonary edema in dying cancer patients who received very high opioid doses, but this clinical situation is extreme and the connection between the drug and the adverse event is unproven. Longitudinal studies in the methadone-maintenance population have demonstrated that the occurrence of liver disease relates to concurrent alcohol use or another medical disorder, rather than ingestion of the opioid.

Recent studies in animal models have revealed the existence of opioid-related dysimmune effects. Human data relevant to this issue of immune alteration are very limited, and no worrisome clinical observations have been made in the cancer population or the methadone-maintenance population. Although the potential for adverse immune effects is a serious concern that awaits clinical evaluation, it would not be appropriate to consider any practical changes in the therapeutic use of opioid drugs in the absence of additional data.

Theoretically, continuous exposure to an exogenous opioid could produce long-lasting changes in central nervous system mechanisms that are mediated by endogenous opioids and their receptors. These mechanisms could involve the processing of nociceptive information or any of the other diverse homeostatic functions mediated by these compounds. It is even possible, of course, that exposure to an opioid drug at critical periods could change the vulnerability to the aberrant processes that underlie addiction. Future studies should continue to evaluate the possibility of such outcomes. To date, no clinical evidence indicates that these phenomena are occurring.

Persistent side-effects

Many of the diverse clinical effects produced by opioids could be manifest as morbid side-effects during pain treatment. Persistent constipation, somnolence, or cognitive impairment, for example, can become problematic and limit the utility of the therapy. Constipation is the only persistent side-effect that commonly occurs in the cancer population, but a few patients experience other adverse effects. In the methadone-maintenance population, approximately 10 to 20 percent of patients complain of persistent constipation, insomnia, and decreased sexual function; a somewhat higher percentage report persistent sweating.

The potential for cognitive impairment is particularly important in the use of opioids for chronic nonmalignant pain. Overt impairment could compromise rehabilitation efforts and place the patient at risk (for example, during driving). Conceivably, mild impairment could have the same effect and even go unrecognized by the patient or others.

Although cognitive impairment and disturbances in psychomotor functioning are commonly observed following acute administration of opioids to nontolerant patients or dose escalation in those on chronic therapy, these effects typically wane with stable long-term therapy. In opioid-treated patients with cancer pain, small impairments in reaction time have been observed, but the clinical significance of this finding is not clear. A recent study of cancer patients receiving long-term morphine therapy revealed only minimal effects on cognitive and psychomotor functions related to driving. Another study of cancer patients suggested that tolerance to the adverse neuropsychological effects that occur immediately after opioid dose escalation develops within two weeks.

In patients without cancer, the data are more conflicting. Several surveys of patients admitted to pain programs and surveys of heroin addicts and methadone-maintenance patients have demonstrated clinically evident sedation or abnormalities on neuropsychological testing. All these populations were subject to selection bias, however, and no survey controlled for the possible confounds of prior head injury or concurrent administration of other centrally acting drugs. Some studies of methadone-maintained patients have not observed cognitive impairment, and a small study that compared a group of chronic pain patients treated with opioids alone with a group treated with benzodiazepines noted significant cognitive effects only in the latter group. Also reassuring, surveys of driving records performed in methadone-maintained populations have not revealed an increased rate of infractions or accidents.

Thus, the data cannot adequately characterize the risk of subtle neuropsychological impairment among patients with chronic nonmalignant pain. Additional investigations in this area are needed. In the cancer population, conventional clinical practice views long-term opioid use as fully compatible with normal function in most cases. Patients are encouraged to be active and there is no admonition to limit driving or other activities unless overt impairment is observed. Clinical experience in the methadone-maintenance population is similar. In the absence of definitive studies, however, clinicians who administer opioids to patients with nonmalignant pain must carefully assess the potential for subtle cognitive impairment over time. Occasionally, this may require formal neuropsychological testing.

Risk of addiction and abuse

The potential for iatrogenic addiction is a major issue in the use of opioid drugs for the management of chronic non-malignant pain. To assess this potential, the definitions of phenomena relevant to drug dependence must be clarified.

Definition and implications of physical dependence

Physical dependence is a physiological phenomenon defined solely by the development of an abstinence syndrome (opioid withdrawal) following abrupt discontinuation of therapy, substantial dose reduction, or administration of an antagonist drug. No studies have been conducted of physical dependence in patients who are receiving opioids for pain, and clinical observation suggests that the dose and duration of treatment required to produce the phenomenon vary remarkably across patients. To be prudent, clinicians generally assume that patients are physically dependent (that is, have the capacity for an abstinence syndrome) after a few days of repeated opioid doses.

Great confusion exists among clinicians about the differences between physical dependence and addiction. This continues despite the widespread acceptance among addiction specialists of the critical distinctions between these phenomena. Although physical dependence, like tolerance, has been suggested to be a component of addiction (specifically, the avoidance of withdrawal has been postulated to lead to drug-seeking behavior), the clinical experience gained in the population with chronic pain strongly affirms that addiction should be defined in a manner that fully distinguishes it from physical dependence. Physical dependence alone does not preclude the uncomplicated discontinuation of opioids in the medical setting, as amply demonstrated by the success of opioid detoxification by multidisciplinary pain programs and the routine cessation of opioids in cancer patients who become fully analgesic following a pain-relieving neurolytic procedure. Indirect evidence for this distinction between physical dependence and addiction is even provided by animal models of opioid self-administration, which have demonstrated that persistent drug-taking behavior can be maintained in the absence of physical dependence.

The fundamental distinction between addiction and physical dependence implies that clinicians should never label patients who are presumed to be at risk for an abstinence syndrome (that is, physically dependent) as *addicted*. Such a description misrepresents reality and stigmatizes the patient. For the same reason, use of the imprecise general term *dependent* should be avoided. Clinicians should use *physically dependent* when this fits the intended meaning.

Physical dependence is often perceived to be clinically unimportant as long as an abstinence syndrome is avoided. It must be acknowledged, however, that the possibility of adverse effects, such as psychological and physical morbidity related to the syndrome of protracted abstinence or the potential for psychological distress driven by a fear of withdrawal, has not been investigated. These possible outcomes require additional evaluation.

It has also been postulated that subtle abstinence syndrome phenomena could contribute to a "downhill spiral" in which pain is sustained or maladaptive behaviors are perpetuated as a result of opioid use. Some type of similar process has also been suggested to explain "rebound" headache, a syndrome of refractory pain ascribed to frequent use of short-acting analgesics. Although no systematic study has been done of this putative phenomenon, the problematic nature of opioid therapy in some patients is unquestionable, and, in these individuals, the impact of all possible outcomes related to treatment, including physical dependence, should be carefully assessed. In some cases, this assessment can only be performed if opioid therapy is discontinued for a period of weeks to months, so that patient responses independent of the drug can be monitored.

Definition of addiction

Standard definitions of addiction have been developed from experience with substance abusers, but are difficult to apply to patients who are receiving a prescribed therapy for an appropriate medical indication. The definition in a major pharmacology text incorporates "relapse after withdrawal" and the definition promulgated by the World Health Organization includes a reference to physical dependence. These definitions could be applied to opioid-treated patients generally. Similarly, the definitions for psychoactive substance dependence in the third and fourth editions of *Diagnostic and Statistical Manual of Mental Disorders* include criteria based on chronicity of use, physical dependence, and tolerance. Such criteria also fail to distinguish patients who receive chronic opioid therapy for pain from those who are addicted. The definition developed by a task force of the American Medical Association appears to be most relevant to patients ("compulsive use of a substance resulting in physical, psychological or social harm to the user and continued use despite that harm"), but requires additional detail to be useful.

In the clinical setting, *addiction* should be defined as a psychological and behavioral syndrome characterized by (1) loss of control over drug use, (2) compulsive drug use, and (3) continued use despite harm. These phenomena must be described in a manner appropriate to patients with chronic pain by reference to specific aberrant drug-related behaviors that may be encountered in practice (see Table 1). These behaviors are familiar to clinicians, but have not been empirically studied. A *priori*, they can be placed along a spectrum, in which some (such as repeated visits to an emergency room against medical advice or the demand for a specific opioid) are worrisome, but less likely to indicate addiction than others (such as injection of an oral formulation or acquisition of illicit opioids to supplement prescribed drugs).

Although the diagnosis of addiction may be relatively straightforward in the patient who engages in highly aberrant behaviors, the more common situation, in which the patient occasionally demonstrates a less egregious behavior, is far more challenging to assess. In this circumstance, true addiction actually appears on a "differential diagnosis," which must be resolved through a careful evaluation. This differential diagnosis includes *pseudoaddiction*, for example, which is a term that describes the development of aberrant behavior in cancer patients who are experiencing unrelieved pain; with better analgesia, the behaviors cease. Other diagnoses include specific psychiatric disorders, such as some personality disorders, that can be characterized by impulsive drug use. Occasionally, problematic behaviors reflect an encephalopathy with confusion about the therapeutic regimen. Irresponsible drug-related behavior rarely indicates criminal intent.

Given this complexity, the diagnosis of addiction can only be entertained following a careful assessment of specific drug-related behaviors. This assessment must first ascertain if the behaviors can be fairly labeled as aberrant. In some cases (for example, the patient who consumes less of the drug when pain spontaneously remits and consumes more than prescribed when pain flares), this may involve consideration of the instructions given to the patient.

If aberrant drug-related behavior has occurred, the clinician must explore its nature and implications. An episode volunteered by the patient and perceived to be transitory and impulsive, perhaps related to a period of unrelieved symptoms, does not warrant a diagnosis of addiction, whereas behaviors that have occurred repeatedly and suggest a more profound loss of control over drug use should be appropriately labeled as such. If the meaning of the behavior is not clear, some time may be required to assess the patient correctly and observe the reaction to additional requirements, such as frequent clinic visits or periodic drug screens.

Risk of addiction

If a true addiction syndrome were a common occurrence among patients who are administered opioids for nonmalignant pain, the approach could not be justified. Indeed, therapeutic decision making about this therapy should be influenced by the potential for any management problems, including those that could potentially be classified as pseudoaddiction. Unfortunately, published surveys have failed to report the prevalence of the various aberrant drug-related behaviors, and a critical evaluation of the current literature can only begin to clarify the occurrence of more severe disturbances consistent with addiction. Specific information about the prevalence and impact of all aberrant drug-related behaviors is needed.

Early surveys of individuals undergoing treatment for addiction yielded data that appeared to suggest a substantial risk of iatrogenic addiction during opioid therapy for pain. In one report, more than one-quarter

of some addict groups stated that addiction began as a result of prescribed opioid treatment. Combined with reports of high recidivism rates among detoxified addicts, and theoretical writings that linked addiction to the pharmacological properties of tolerance and physical dependence, these data supported the view that the mere exposure to an opioid could induce and sustain an addiction.

These surveys were unable to elucidate the risk of addiction during long-term opioid administration to patients without a known history of substance abuse, or patients with varying histories of abuse or addiction. Indeed, the biases inherent in these surveys limit the utility of the information they provide. Surveys of actual pain patients are more relevant, but these, too, are subject to the potential for selection bias and observer bias. The relatively high rate of aberrant drug use observed among patients referred to multidisciplinary pain management programs, for example, is difficult to interpret due to variability in the definitions applied to drug-related outcomes in these settings and the highly selected nature of the populations.

In the absence of well-conducted longitudinal surveys of otherwise unselected populations with nonmalignant pain, other data have been adduced to clarify addiction liability during opioid therapy. For example, although it is widely believed that opioids produce the reinforcing experience of euphoria, surveys of cancer patients, postoperative patients, and normal volunteers indicate that elation is uncommon following administration of an opioid; dysphoria is observed more typically, especially in those who receive meperidine. The rare occurrence of euphoria in patients without a history of abuse suggests that fundamental processes may predispose to addiction and are uncommon among patients who have not previously demonstrated abuse behaviors. It can be speculated that the lack of prior substance abuse, combined with the lack of a euphorigenic response to a therapeutic opioid, signals a particularly low risk of addiction.

Several patient surveys are also relevant. The Boston Collaborative Drug Surveillance Project, for example, identified only four cases of addiction among 11,882 hospitalized patients with no history of substance abuse who received at least one dose of an opioid. A nationwide survey of burn units found no cases of addiction in the information obtained about 10,000 patients treated for burn pain, and a survey of patients treated at a large headache center could only identify three problem cases among 2,369 patients who had access to opioid analgesics. Recent studies of patients who were allowed to self-administer an opioid for a period of weeks to treat mucositis pain following bone marrow transplantation observed patterns of drug-taking behavior that were inconsistent with the diagnosis of addiction. The latter finding is consistent with clinical experience, which indicates that addiction is an exceedingly rare outcome during long-term opioid treatment of cancer pain.

Although these surveys of patients with pain are reassuring, they, too, are limited by various sources of bias and a lack of generalizability to the diverse populations with chronic nonmalignant pain. Moreover, the interpretation of all survey data requires comparison to U.S. population prevalence rates for alcoholism (3 to 16 percent) and other forms of substance abuse (5 to 6 percent). Obviously, surveys of pain patients that demonstrate rates of substance abuse much lower than population base rates must be interpreted cautiously.

Overall, these surveys provide evidence that the outcomes of drug abuse and addiction do not commonly occur among patients with no history of abuse who receive opioids for medical indications. Other epidemiological data similarly contradict the notion that exposure to opioid drugs alone reliably leads to escalating use and recidivism after detoxification. The existence of so-called "chippers," individuals who occasionally use heroin recreationally, belies the inevitability of the full addiction syndrome even in those who consume the drugs for purposes other than pain control. More interesting, perhaps, is the evidence that a large proportion of soldiers who abused heroin in Vietnam stopped this activity abruptly on return to the United States and subsequently demonstrated a low rate of relapse. This finding highlights the importance of situational factors in the pathogenesis of addiction.

Some direct evidence even indicates that a genetic factor may be important in the development of addiction. A genetic predisposition has been demonstrated convincingly in alcoholism, and it has been postulated that the development of alcoholism in a small minority of those who imbibe parallels the development of addiction in a small proportion of those exposed to opioids.

Together, these data suggest that the development of addiction cannot be ascribed solely to the reinforcing properties inherent in a drug. Rather, addiction requires predisposing psychological, social, and physiological

(possibly genetic) factors, which presumably interact in some complex fashion during drug exposure. Based on the limited information available, it is highly unlikely that patients without a significant history of substance abuse will become addicted during long-term opioid treatment of chronic pain.

This risk should not be assumed to be nil, however, and assumptions concerning addiction should not be assumed to extend to all types of aberrant drug-related behavior. Indeed, it is probable that patients without prior abuse vary in the risk of aberrant behavior. For example, it can be speculated that the risk of aberrant behaviors (including those consistent with addiction) is probably greater among those with severe character pathology associated with impulsivity and among those who are relatively young. A brief, five-item screening tool has recently been validated and suggests that the number of alcoholic drinks per day, acknowledged use of cannabis, a history of smoking, and age may be important predictors of opioid abuse; further experience with this instrument is needed to determine its predictive validity, and hence its utility in clinical practice. Although the risk of problematic drug taking, and perhaps addiction, is probably higher among those with a known history of substance abuse, it is likely that this risk also varies with the type and frequency of abuse, the history of substance abuse treatment, current psychosocial supports, and other factors. Additional studies are needed to confirm the low risk of addiction or abuse among those with no history of significant abuse and to clarify the predictive value of specific patient characteristics.

Conclusions

Pain specialists now generally agree that a subpopulation of patients with chronic nonmalignant pain can attain favorable outcomes for prolonged periods using opioid drugs. These outcomes are characterized by sustained analgesia, relatively stable doses, tolerable side-effects, functional gains (or at least no demonstrable functional decline), and highly responsible drug taking (that is, no evidence of significant aberrant drug-related behavior). These outcomes substantively mimic those observed in the typical cancer patient.

On the basis of clinical experience and the foregoing analysis, guidelines for the use of opioid therapy in nonmalignant pain have been proposed (see Table 2). These guidelines, which attempt to balance the potential for salutary effects and the possibility of serious morbidity, will likely evolve as additional data become available.

Given the evidence that opioid therapy can be discontinued without difficulty in virtually all patients, treatment can be initiated in the form of a therapeutic clinical trial. Prior to such a trial, the patient should be fully informed and consent to the therapy. As treatment is administered, close monitoring of the relevant outcomes (specifically pain relief, side-effects, physical and psychosocial functioning, and the development of aberrant drug-related behaviors) can clarify its benefit.

Once begun, opioid therapy requires a working knowledge of the pharmacological techniques described in the cancer pain literature. These guidelines optimize the likelihood of successful therapy by emphasizing individualization of therapy through a process of assessment and dose adjustment. Although some clinicians support specific approaches for all patients with nonmalignant pain, such as the use of long-acting drugs and no access to supplemental doses, these recommendations are derived solely from anecdotes and are better applied on a case-by-case basis.

Escalation of the opioid dose until satisfactory analgesia occurs, or intolerable and unmanageable side-effects supervene, is the standard for cancer pain management and would presumably optimize analgesic outcomes during the treatment of patients with nonmalignant pain as well. Adherence to this principle may pose a problem, however, if excessive focus on therapy limits rehabilitation, or increases the discomfort of the clinician who is managing a controversial therapy in a highly regulated environment. Previous experience also suggests that the need for repeated dose escalations is uncommon among patients with nonmalignant pain who have a favorable response to opioid treatment. Thus, the need for a higher dose should engender a careful evaluation of the medical and psychosocial status of the patient. The clinician may find it useful to seek additional consultations with specialists in pain management at such times.

Long-term opioid therapy must be accompanied by ongoing assessment of aberrant drug-related behaviors. This assessment should determine the impact of pain and psychological factors on drug-related behaviors and distinguish the development of an addiction disorder from a less serious problem. If the diagnosis of addiction is supported, a targeted therapeutic approach is needed and consultation with a specialist in

addiction medicine is recommended. If the diagnosis of addiction would not be appropriate and the decision is made to continue therapy, a highly structured response to the aberrant behaviors is still required. These may incorporate new explicit instructions for dosing (perhaps with a written contract), more frequent visits, smaller prescriptions, periodic urine screens, ongoing psychotherapy, or other interventions. Consultation with a specialist in addiction medicine may again be helpful. Patients who are perceived to have a relatively high risk of aberrant behaviors (such as those with a previous history of substance abuse) should have these controls incorporated into the treatment from the start. These patients are also candidates for a conservative approach to therapy, which might apply some of the anecdotal recommendations noted previously (for example, use of long-acting drugs, no supplemental "as needed" doses, and avoidance of parenteral doses).

The available data do not permit doctrinaire pronouncements about the role of opioid therapy for nonmalignant pain. Rather, the assessment of this therapy is slowly evolving as experienced is gained. Although additional controlled clinical trials of long-term opioid therapy are needed, the lack of these trials should not exclude the empirical use of this approach when medical judgment supports it and treatment is undertaken with appropriate monitoring. This monitoring should repeatedly evaluate analgesia, incidence and severity of opioid side-effects, current physical and psychosocial functioning, and the occurrence of any aberrant drug-related behaviors. Given the complexities of this therapy, documentation of these endpoints in the medical record is essential.

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Douglas J. Pisano, "Controlled Substances and Pain Management: Regulatory Oversight, Formularies, and Cost Decisions"

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Pharmacists, physicians, and other health care personnel practice within an integrated system of laws and regulations that influence many treatment modalities. Capitation, managed care, and other controls strain these relationships by mandating greater oversight of how health care is delivered. From a pharmacist's perspective, any use of medication requires knowledge of three omnipresent factors: regulatory control, formularies (product selection), and economic decision making. My objective is to raise awareness of these issues as they relate to the prescription of pain medication and to pain management generally.

Federal drug law

All practice-oriented drug law and regulation is based on the federal Controlled Substances Act of 1970. The Act, also known as Title II, is part of a much larger piece of legislation, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CSA). CSA was enacted to regulate the manufacturing, distribution, dispensing, and delivery of drugs or substances that are subject to, or have the potential for, abuse or physical or psychological dependence. These drugs are designated *controlled substances* because they are "controlled" under CSA.

CSA falls under the regulatory authority of the Drug Enforcement Administration (DEA), which controls access to regulated substances through the federal registration of all persons in the legitimate chain of manufacturing, distribution, or dispensing of controlled substances, except the ultimate user. The "ultimate user" is defined as (1) the patient who is competent to use these drugs as prescribed by a practitioner, or (2) the patient's caregiver who administers them to the incompetent patient, for example, the parent of a sick child. All health care providers who deal with controlled substances are subject to CSA as well as to

those drug control laws of the state in which they are licensed and practicing (unless such practice is exclusively in a federal facility, for example, a Veteran's Administration hospital).

CSA empowers DEA to register all persons, businesses, and institutions conducting any activity that involves controlled substances. DEA does this by issuing registration numbers. Each DEA number must be renewed tri-annually. In addition, CSA establishes a closed system of record keeping that controls and tracks the flow of controlled substances through the health care system. For example, if a practitioner who has a DEA registration wants to order a controlled substance from a wholesaler or manufacturer, very specific record-keeping provisions exist depending on how the drugs ordered are categorized or scheduled. All registrants who order, fulfill an order, store, distribute, or dispense a controlled substance must report this activity to DEA and also maintain their own records for a period of two years.

CSA classifies medicinal substances into schedules based on their potential for abuse, psychological or physiological dependence, and medical use. These substances include narcotics, amphetamines, and barbiturates, and they are denoted CI, CII, CIII, CIV, and CV (see Table 1). Scheduling provisions also include prescription dispensing limitations.

Much of what appears in the Controlled Substances Act also appears in state acts and regulations, which also contain more stringent modifications. For example, in Massachusetts, prescriptions issued for medications listed in Schedule II must be filled by a pharmacy within five days of the date of issue. Drugs listed in Schedule II or III are only fillable for a thirty-day supply on any single filling. In addition, Massachusetts considers any prescription drug not included in a federal schedule to be designated as Schedule VI. Therefore, in Massachusetts, an antihypertensive medication or prescription eye drops are controlled substances.

Federal versus state laws and regulations

Each state has enacted various laws and regulations and has a counterpart to a federal administrative agency that controls the manufacture, distribution, and sale of drugs within the state and that regulates the practice of health care professionals. Because one state's drug control laws may vary greatly from the federal, certain basic principles must be followed by health professionals in order to comply. Joseph Fink et al. suggest the following.

> (1) Health professionals are responsible for compliance to the same degree with both federal and state laws and regulations that govern their practice.
> (2) A state drug control law or regulation may be more stringent than its federal counterpart.
> (3) Health professionals must comply with a state drug control law or regulation when it is stricter than federal law or when there is no similar prohibition or requirement under federal law.
> (4) If a federal drug control law or regulation is more stringent than the comparable state law or regulation, the federal regulation must be followed.

Generally, most heath care professionals do not make meaningful distinctions between federal and state laws and regulations in their day-to-day practice.

Prescription basics

Federal laws and regulations as well as those of many states require that prescriptions be dispensed with all requisite information (see Figure 1). Prescriptions must be written in ink, indelible pencil, or typewritten. Information can be entered onto a prescription by a designee, called an agent, of the prescriber or by a pharmacist when a clarification is needed. The only information required to be in the prescriber's own handwriting is a personal signature. Federal law also allows prescriptions from Schedules III-V to be given orally or telephoned into pharmacies from prescribers or their agents; pharmacists are then required to record the name of that person onto that prescription. These oral prescriptions must then be supplemented with a written hard copy within seven days of issuance. This hard copy back-up is the prescriber's responsibility. Pharmacists who do not receive the back-up within seven days are required to report this missing information to DEA. If the pharmacist does not report missing information, he is in violation of DEA regulations and therefore subject to penalties.

As mentioned, federal law categorizes prescription medications into schedules based on their abuse potential. As a result, these drugs need to be handled by prescribers and pharmacists in very specific ways. Schedule II controlled substances, which are generally used for moderate to severe pain, have the most restriction. Prescriptions written for medications listed in Schedule II can only be refilled with a written prescription.

Prescriptions for Schedule II controlled substances may be partially filled for quantities less than those prescribed if the pharmacy is out-of-stock or a patient requests less, provided that the pharmacy dispenses the remainder to the patient within seventy-two hours. If this is not possible, the prescription becomes void and the prescriber is so informed. Pharmacists may dispense partial quantities of Schedule II medications to patients in long-term care facilities or to the terminally ill for up to sixty days from the original date of the prescrip-tion's issuance. The dispensing pharmacist is required to record that the patient is in a long-term care facility or is terminally ill, along with the date of dispensing, quantity dispensed and remaining, and with the dispensing pharmacist signature on the back of the prescription.

Schedule II medications also have restrictions on oral or telephone transmissions. CSA allows prescribers to call pharmacies and orally transmit prescriptions for Schedule II drugs only in an emergency. An "Emergency Situation," as stated under CSA, means that immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user; no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under Schedule II of CSA; and, it is not reasonably possible for the prescribing physician to provide a written prescription to be presented to the person dispensing the substance, prior to dispensing.

In an emergency, a pharmacist may dispense a controlled substance in Schedule II on receiving the orally transmitted authorization of a prescribing practitioner, provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency. The prescribing practitioner must then provide a written prescription for the emergency quantity. The written prescription must be delivered or postmarked to the dispensing pharmacist within seventy-two hours after authorizing an emergency oral prescription. The prescription must also have written on its face "Authorization for Emergency Dispensing." On receipt of the written prescription, the dispensing pharmacist must attach the prescription to the oral one. If the prescribing practitioner fails to deliver a written prescription within seven days, the pharmacist must notify DEA.

The regulations for emergencies can be cumbersome for home infusion pharmacies, hospice, and long-term care pharmacies. Frequent dosage modifications of parenteral or controlled-release narcotic substances for patients who require these services can place pharmacies and prescribers at a regulatory disadvantage because the pharmacy would have to enforce the existing regulations. However, DEA has provided an easier mechanism for handling prescriptions for Schedule II pain medications. In May 1994, DEA issued a rule that allows controlled substance prescription orders to be transmitted from a prescriber to a dispensing pharmacy by facsimile. The rule covers all controlled substance prescriptions. DEA allows pharmacies to receive facsimile prescriptions for intravenous pain therapy and to retain them as the original prescription, thereby substantially reducing the need for oral emergency prescriptions in these settings. One must note that these rules do not apply to oral dosage forms.

Prescriptions written for Schedules III and IV are regulated somewhat less stringently. They are refillable up to five times if so authorized, or for six months from their date of issue, whichever terminates first; and, when filled with a partial quantity, they must have the quantity recorded on the back, along with the date of refilling and the dispensing pharmacist's initials. Prescriptions for Schedule V are also refillable. However, the number of refills is not set by law, and the authorized number of refills depends on the professional judgment of both the prescriber and the pharmacist.

Pharmacists and prescribers are co-liable for prescriptions written for patients. This is called corresponding responsibility. A prescription for a controlled substance must be issued in good faith and for a legitimate medical purpose by a practitioner in the usual course of his professional practice; likewise, pharmacists have the corresponding responsibility to ensure that the prescription is issued and dispensed in good faith for a legitimate medical purpose by a practitioner acting in the usual course of his practice.

For instance, a pharmacist receives a prescription written by a radiologist for her child. Radiologists are medical doctors with a specialty. They may prescribe medication outside their specialty provided that the prescription is written in good faith, for a legitimate medical purpose, and in the usual course of medical

practice. If the radiologist has conducted all of the medically required tests and generated a patient record, thereby establishing a physician-patient relationship, the pharmacist may fill the prescription under federal law. Pharmacists will question prescriptions such as this in order to protect themselves and their patients.

Product selection

Product selection causes pharmacists and prescribers much anguish. Product selection can be divided into two categories: (1) the substitution of products that are pharmaceutically equivalent and are bioequivalent, that is, a brand name product and a generic copy; and (2) the substitution of chemically dissimilar products that are in the same therapeutic class, that is, two therapeutic moieties that treat the same medical condition.

The substitution of products with the same active ingredients is well defined in the regulations of many states. Generally, substitutable products used by pharmacists and sanctioned by the states are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*), published since 1979 by the Food and Drug Administration (FDA). This federal publication is a guide to health care professionals for making product selection decisions. It lists marketed drug products that are considered by FDA to be safe and effective and it provides information on therapeutic equivalence evaluations for approved multisource prescription drug products.

The *Orange Book* rates drugs based on their therapeutic equivalence. For a product to be therapeutically equivalent, it must be both pharmaceutically equivalent (that is, the same dose, dosage form, strength, and so on) and bio-equivalent (that is, the rate and extent of its absorption are not significantly different from the rate and extent of absorption of the drug with which it is to be interchanged).

FDA allows pharmaceuticals to be considered bio-equivalent in one of two methods. The first method studies the rate and extent of absorption of a test drug, which may or may not be a generic variation, and a reference or brand name drug under similar experimental conditions and in similar dosing schedules, where the test results do not show significant differences. The second approach uses the same method to determine whether a difference exists in the test drug's rate and extent of absorption, but the difference is considered to be medically insignificant for the proper clinical outcome of that drug.

> Bioequivalence of different formulations of the same drug substance involves equivalence with respect to the rate and extent of drug absorption. Two formulations whose rate and extent of absorption differ by 20% or less are generally considered bioequivalent. The use of the 20% rule is based on a medical decision that, for most drugs, a 20% difference in the concentration of the active ingredient in blood will not be clinically significant.

The *Orange Book* uses a letter coding system to help practitioners determine which drug products are therapeutically equivalent. The first letter, either an A or a B, indicates a drug product's therapeutic equivalence rating. The second describes dose forms and can be designated by any one of a number of different letters.

For example, in the *Orange Book*, A codes are described as follows:

> Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which:
> 1) there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP or AT, depending on the dose form; or
> 2) actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. These are designated AB.

A B-code rating is much less desirable than an A rating. Products rated B may be commercially marketed; however, they may not be considered therapeutically equivalent. B codes are defined as follows:

> Drug products that FDA at this time does not consider to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the

problem is with specific dosage forms rather than with the active ingredients. These are designated BC, BD, BE, BN, BP, BR, BS, BT, or BX.

FDA has adopted an additional subcategory of B codes. The designation B* is assigned to former A-rated drugs "if FDA receives new information that raises a significant question regarding therapeutic equivalence."

Not all drugs are listed in the *Orange Book*. Drugs obtainable only from a single manufacturing source, DESI-drugs, or drugs manufactured prior to 1938 are not included. Those that do appear are listed by generic name. Drug products with an A rating that are determined by FDA to be therapeutically equivalent may be substituted. Drug products with B ratings that are not considered by FDA to be therapeutically equivalent may not be substituted. However, because the Orange Book is merely a guide to therapeutic equivalence, state agencies, for instance, the Massachusetts Department of Public Health, have the option to allow some B-rated products to be substituted if a determination can be made that bioequivalence is not essential. The only practical way for health professionals to determine whether a drug is listed is to consult both the Orange Book and other reference material available from the appropriate agency in one's home state.

Currently, at least thirteen states require pharmacists to substitute one product for another, depending on how a prescription is written. This is called *mandatory substitution*. Thirty-nine states allow *permissive substitution* where patients may be asked if they want to substitute a product based on cost or pharmacist suggestion. Many states also have a *positive formulary* where pharmacists may only dispense substitutable products from an established list of drugs. Others have a *negative formulary* where pharmacists may substitute any product provided it *does not* appear on the established list.

The substitution of products within a therapeutic category in which two therapeutic moieties can be used alternatively to treat the same medical condition is problematic for pharmacists. Hospital pharmacy and therapeutics committees, managed care organizations (MCOs), and others who control a formulary are constantly searching for the most therapeutic and cost-effective medication to treat patients. At issue is the great breadth of medications available. A pharmacist would have many choices that might be considered optimal were it not for the product cost. Therefore, medication management decision-makers must make choices about which medications will be used for particular medical conditions or patients based on overall clinical effectiveness and cost. These decisions lead into the discussion of pharmacoeconomics.

Pharmacoeconomic decision making

Pharmacoeconomics is a very pervasive term in much of the pharmacy literature. Pharmacoeconomics explains pharmacy and therapeutics in terms of cost and patient outcomes, and helps decision-makers make the best possible decision regarding the use of available resources and pharmacy dollars.

According to Lyle Bootman et al., pharmacoeconomic research helps health care providers:

- determine which drugs should be included in a hospital formulary;
- evaluate clinical pharmacy services to assess cost and outcomes; and
- determine whether particular drug therapy decisions improve patients' quality of life.

For example, an MCO administrator is asked to evaluate two competing pharmaceuticals for possible inclusion in its closed formulary. One product will be listed, the other will not. Both are used to treat the same disease. Each has different side-effects. One is dosed daily, the other four times daily. Both cost approximately $4.00 per day of therapy.

If the administrator selects one product over the other without first evaluating one against the other, the decision may be short sighted. Is it cost effective for the health plan to select a once-daily product that has known side-effects which cause such severe gastrointestinal irritation that patients become noncompliant, resulting in additional physician visits and new medications prescribed to sicker patients? Or, is it cost effective to prescribe the product dosed four times daily, which requires a significantly longer therapy but has fewer severe side-effects? Both considerations may have ancillary issues that need to be evaluated before a product goes into the formulary.

Pharmacists use various methods to answer such product-selection issues arising in daily practice (see Figure 2). The most often used include the following:

- cost-benefit analysis;
- cost-effectiveness analysis;
- cost-minimization analysis; and
- cost-utility analysis.

Cost-benefit analysis

Cost-benefit analysis is a method by which a pharmacist assigns a dollar value to all of the benefits of the medication, and then subtracts all of the costs to supply those benefits. When done with two or more products, comparison of the data is beneficial.

For example, a pharmacist must evaluate several pain medications. He needs to determine two things: first, how much are the perceived benefits worth monetarily; and second, how much the drug "really" costs. The monetary value of the benefit may include the addition of several months of pain-free life, which may result in extra income to the patient's family. The pharmacist determines the costs by calculating the price of the medication, its administration, hospital time, and so forth, and then subtracts the difference for each medication. The product with the highest present value has the highest cost-benefit. However, not all benefits easily lend themselves to a dollar value, for instance, the value of increased patient satisfaction when the patient can continue to work while undergoing pain management therapy. Some allocations may very well be up to the decision-maker's own values.

Cost-effectiveness analysis

Cost-effectiveness analysis is a method used to assess value among a group of alternatives. For example, drug A and drug B are equally effective in managing cancer pain. Drug A can be purchased at a lower price than drug B. However, drug B requires less administration time and is better tolerated by the patient. Drug B is more cost-effective. This methodology is beneficial when one wants to determine the best overall value from a group of drugs.

Cost-minimization analysis

Cost-minimization analysis is used to determine the least expensive of those drug products that provide equal benefit. An example of this analysis is evaluation of equivalent drug products where the selection of one over the others is primarily based on lowest acquisition cost.

Cost-utility analysis

Cost-utility analysis is a more humanistic methodology. Like cost-effectiveness analysis, it measures the cost of something relative to its effectiveness, from some perspective, many times that of the patient. But in cost-utility analysis, an intervention, for instance, the cost of pain management therapy, is also measured in terms of the quality of health care outcomes, such as how a patient feels about his life after the treatment. In broader terms, cost-utility analysis puts into economic perspective the patient's feelings regarding how much a few more years of productive life is worth relative to how much the therapy costs.

Case study

Below, I apply the four analyses to demonstrate how each operates in practice.

> A sixty-eight-year-old male is diagnosed with pancreatic cancer. He initially presents with abdominal discomfort, not yet described as acute pain. The patient refuses all attempts at chemotherapy. The patient requests only to be kept comfortable at all stages of his illness. The physician may have many alternatives available, all of which will manage the patient's pain equally.

The overall treatment goal for this patient is achievement of a pain-free existence at a minimal cost. Can one methodology determine how to treat this patient and yield a similar or more positive therapeutic outcome of pain control at a lower cost? Health care professionals base their therapeutic decisions primarily on therapeutic outcomes. Health care administrators, however, may take an entirely different view, such as determining the least costly way to achieve the desired outcome. Total treatment costs need to be considered, and they may include nursing and medical staff time, administration supplies, and all other costs related to home or hospice care.

A cost-effectiveness strategy requires the physician to evaluate several treatment modalities and consider the price of the product and the required administration time to achieve the desired pain control outcome. An oral, long-acting opioid can be chosen over an intravenous alternative because it may have greater savings to the health system in that the patient can self-administer an oral dosage without the additional costs of professional homecare. This savings is the value.

A cost-minimization strategy requires the physician to evaluate the price of the available products. The decision to prescribe is based solely on the least expensive therapeutic alternative.

A cost-benefit strategy requires the physician to calculate the net dollar value benefits relative to the cost of each alternative therapy. If the cost of one drug is greater than the others (after the inclusion of product, administration, time, and so on), but the value of the benefits to the patient is greater (less inconvenience or greater compliance), then that product would be a better cost-benefit choice.

A cost-utility strategy includes the calculation, from the patient's perspective, of the net costs of the products used to keep him pain-free. A cost-utility strategy might include presenting the patient with a list of alternatives and an explanation of the benefits and side-effects of each medication. The patient would be allowed to decide which best fits his needs and treatment goals.

Several other issues need to be addressed. Initially, at the community pharmacy level, patients at home receive prescriptions from their prescriber. The pharmacy might be required by federal or state law to dispense a less expensive drug, possibly a generic alternative to the medication written. The patient's medical insurer may also require substitution if legal. Frequently, physicians prescribe certain medications that are then substituted due to insurers' cost-minimization policies. In many states, pharmacies must comply.

Changes in therapy might be needed to accommodate breakthrough pain. For community pharmacies, the issue is one of record keeping and explaining therapeutic duplication to insurers. The physician may feel that the patient's needs are best met by a fentanyl patch applied once every three days. The question then becomes whether the patient's insurer will pay for it. Cost-effectiveness analysis could be conducted in this situation to make the case that the patch is the proper treatment modality.

One cannot help notice that each of these methodologies can be employed, with varying degrees of difficulty, in most medical situations. Pharmacy and therapeutic issues readily lend themselves to economic assessment due to the high cost of drugs. Pharmacoeconomic research is one way to ensure that patients benefit from the most cost-justified treatment modalities.

Conclusion

Pain management, from the pharmacist's perspective, is dominated by regulations, formularies, and cost controls. Regulatory issues are cumbersome due to the volume of record-keeping provisions imposed by both federal and state agencies. Failure by pharmacists and other health care providers to keep accurate records can result in a $25,000 fine imposed by DEA. Health care institutions who treat large numbers of pain management patients are certainly at risk for great financial exposure.

Product selection expands the concerns of health care practitioners. FDA allows substitution of products based on therapeutic equivalence. Many states and third-party payers promote product substitution based on their own economic or therapeutic criteria. Prescribers and pharmacists must be aware of these localized dilemmas.

Decision-makers in today's health care market are increasingly influenced by operating costs. Data that can be used to generate information which results in knowledge is a valuable commodity to them. Pharmacy is in a unique position to capture and produce clinical, economic, and risk management data. This data can produce timely information to inform clinical decision-makers about how to provide proper patient management. It is important for health professional pharmacists and administrators not only to focus on clinical information in drug product decision making, but also to include broader health economics considerations under the rubric of clinical decision making for modern selection of drug therapy.

Project on Legal Constraints on Access to Effective Pain Relief, "The Pain Relief Act"

Journal of Law, Medicine & Ethics, 24, no. 4 (1996): 317-18.

Short Title

Sec. 1. This Act may be cited as the Pain Relief Act.

Definitions

Sec. 2. For the purposes of this Act:

1. "Board" means [insert the appropriate list of state licensure, registration, or disciplinary boards or agencies that have disciplinary authority over physicians, nurses, physician assistants, pharmacists, and any other health care professionals covered under this Act].

2. "Physician" means a licensee of the [insert the name of the board or boards licensing M.D.s and D.O.s].

3. "Nurse" means a licensee of the [insert the name of the state board of nursing], including advanced practice nurses.

4. "Pharmacist" means a licensee of the [insert the name of the state board of pharmacy].

5. "Physician assistant" means a licensee or registrant of the [insert the name of the state board regulating physician assistants, which may include the board of medicine].

6. [Include, with definition, any other professionals who should fall within the protection of this Act.]

7. "Intractable pain" is a state of pain, even if temporary, in which reasonable efforts to remove or remedy the cause of the pain have failed or have proven inadequate.

8. "Clinical expert" is one who by reason of specialized education or substantial relevant experience in pain management has knowledge regarding current standards, practices, and guidelines.

9. An "accepted guideline" is a care or practice guideline for pain management developed by a nationally recognized clinical or professional association, or a specialty society or government-sponsored agency that has developed practice or care guidelines based on original research or on review of existing research and expert opinion. If no currently accepted guidelines are available, then rules, policies, guidelines, or regulations issued by the Board may serve the function of such guidelines for purposes of this Act. Such Board rules, policies, guidelines, or regulations must conform to the intent of this statute. Guidelines established primarily for purposes of coverage, payment, or reimbursement do not qualify as "accepted practice or care guidelines" when offered to limit treatment options otherwise covered within this Act.

10. "Therapeutic purpose" is the use of pharmaceutical and nonpharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

11. "Disciplinary action" includes both informal and formal, and both remedial and punitive actions taken by a Board against a health care provider.

12. "Health care provider" is a licensed professional as defined in Subsections 2, 3, 4, 5, and 6 of this section.

Sec. 3.

1. Neither disciplinary action nor state criminal prosecution shall be brought against a health care provider for the prescription, dispensing, or administration of medical treatment for the therapeutic purpose of relieving intractable pain who can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline and with the standards of practice identified in Section 4 below. The showing of substantial compliance with an accepted guideline may be rebutted only by clinical expert testimony.

2. In the event that a disciplinary action or criminal prosecution is pursued, the board or prosecutor shall produce clinical expert testimony supporting the finding or charge of violation of disciplinary standards or other legal requirements on the part of the health care provider. Evidence of noncompliance with an accepted guideline is not sufficient alone to support disciplinary or criminal action.

3. The provisions of this section shall apply to health care providers in the treatment of all patients for intractable pain, regardless of the patient's prior or current [chemical dependency or addiction]. The Board may develop and issue [regulations,] rules, policies, or guidelines establishing standards and procedures for the application of this Act to the care and treatment of chemically dependent individuals.

Sec. 4. Nothing in this Act shall prohibit discipline or prosecution of a health care provider for:

a. failing to maintain complete, accurate, and current records documenting the physical examination and medical history of the patient, the basis for the clinical diagnosis of the patient, and the treatment plan for the patient;

b. writing false or fictitious prescriptions for controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 et seq. [or applicable state statute];

c. prescribing, administering, or dispensing pharmaceuticals in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 et seq. [or applicable state statute]; or

d. diverting medications prescribed for a patient to the provider's own personal use.

Sec. 5. The Board shall make reasonable efforts to notify health care providers under its jurisdiction of the existence of this Act. At a minimum, the Board shall inform any health care provider investigated in relation to the provider's practices in the management of pain of the existence of this Act.

Sec. 6. Nothing in this Act shall be construed as expanding the authorized scope of practice of any health care provider.

Sandra H. Johnson, "Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act"

Journal of Law, Medicine & Ethics, 24, no. 4 (1996): 319-27.

> The problem is pain. Patients and their families tell the story:
>
> He is your son. You love him. You want to help him in every way you can, but when he is in that kind of pain, you are helpless in a sense.... I'm his daddy. It was--what was I supposed to do for him? I felt, you know, helpless.
>
> It terrifies you. You want to run away from it. Pain is something you wish would kill you but does not. Agony results from the pain that does not have the decency to knock you out.
>
> [W]e had a good family, but how much can you watch? How much suffering can you watch from your child, your 7-year-old child, and still keep your mind?
>
> I am a forty-six-year-old registered nurse who specializes in oncology care and education. I am also a patient who suffers from chronic nonmalignant pain, and this malady has been the most frightening, the most humiliating, and the most difficult ordeal of my life....
> The general tenor of the medical advice that was given to me was this: I would just have to learn to live with the pain....
> ... I found myself begging, as though I were a criminal. Defensive and angry and yet in such great need, I would beg forgiveness for having this pain. I became withdrawn, completely disabled by my terrible, relentless pain. I was unable to function professionally. I was unable to be much of a wife or a mother, a daughter or a friend....
> ... Now, when I see unnecessary suffering caused by intractable, "mismanaged" chronic pain, I am disgusted. As a health care provider, I am ashamed.

Debilitating pain is a widespread problem that cuts across many patient populations. For example, 75 percent of cancer patients in one study reported suffering pain, with 40 to 50 percent reporting moderate to severe pain and 25 to 30 percent reporting severe pain. This occurs even though 90 percent of cancer pain can be relieved through "relatively simple means." Chronic nonmalignant pain has been described as "an extremely prevalent problem." Over two-thirds of nursing home residents experience serious chronic pain. Moreover, the elderly, minorities, women, children, and those unable to speak for themselves due to disability bear the brunt of ineffective care and are undertreated at even higher rates than others. But despite the development of effective pain management interventions and the overall human and financial cost, pain is neglected and undertreated.

The ethical duty to relieve pain is well established. The Agency for Health Care Policy and Research (AHCPR) founds its pain management guidelines on this principle: "The ethical obligation to manage pain and relieve the patient's suffering is at the core of a health care professional's commitment."

Health care professionals offer many reasons for the undertreatment of pain, and an effective response to the problem requires an effort on several fronts. Health care professionals require much more effective education and training in the treatment of pain. Institutions must remove unnecessary institutional barriers to pain relief and should ensure that effective pain management is an institutional priority. Payment systems should realize the costs of pain and adequately support pain control. Patients and caregivers must also be informed and assured that pain relief is to be expected and that fears of addiction are unfounded.

One source of the problem, according to physicians, is the threat of legal sanctions for treating patients in pain, especially when that treatment must rely on the use of controlled substances. Doctors have reported that they undertreat for pain, in part, from fear of legal penalties, especially disciplinary action. In a California survey, 69 percent of respondents said that the potential for disciplinary action made doctors more conservative in their use of opioids in pain management, and a third reported that their own patients may be suffering from untreated pain. Another review of published research on the undertreatment of pain concluded that "available data suggest that medical decision-making regarding the use of opioids continues to be unduly influenced by regulatory policies and fear of regulators."

Doctors' fears of disciplinary action and criminal prosecution are justified. There is no evidence that large numbers of physicians are sanctioned for their treatment of patients in pain, but the impact of the process on those physicians who are only investigated, or only charged but not disciplined, or only warned or cautioned but not penalized is severe. The prosecutorial stance stimulated by a "war on drugs" and by increasing public scrutiny of disciplinary agencies may unintentionally interfere with adequate pain relief because it has intensified and criminalized investigations and later proceedings. Descriptions of the investigation of physicians engaged in the treatment of pain patients with controlled substances present a scenario that would easily intimidate most people. Some evidence also suggests that many state medical boards have not adapted to more current approaches to the use of controlled substances in pain management and that they may rely solely or too heavily on dosage and length of treatment as indicators of inappropriate and illegitimate prescription practices. Greatly increased enforcement efforts in Medicaid programs may also have an impact on prescribing practices in the treatment of pain, though these are still being evaluated.

Review of the case law involving disciplinary actions against physicians for their prescriptive practices also reveals that the disciplinary process is not entirely successful in distinguishing between "good doctors" who are providing effective medication to patients experiencing pain and "bad doctors" who are providing controlled substances to patients when it is not appropriate. Brief discussion of two cases illustrates the point.

In a 1995 opinion, the Louisiana Court of Appeals in *In the Matter of DiLeo* reviewed the case of a physician whose license had been suspended by the State Board of Medical Examiners for his treatment of seven chronic pain patients with controlled substances. The prosecution's expert witness testified that the physician maintained more detailed medical records on his patients than most physicians in general practice did; that the patients did suffer legitimate chronic pain; and that the dosages used were not excessive. The sole basis for the expert's testimony against the physician was the length of time during which the medication was prescribed. Citing only the *Physician's Desk Reference*, the expert indicated that the drugs were only intended for short-term use. The expert, an addictionologist, testified that the drugs were addictive over the long term. The appellate court rejected the board's suspension of the doctor's license. The court concluded that he had acted in good faith and reasonably believed that the patients were suffering pain; that his patients had suffered serious injury or medical complications that warranted the use of pain medication; and that there was no evidence of diversion or improper use. The physician had first been charged with a violation of the state medical practice act in May 1992, and the board's appeal of this 1995 court of appeals decision was denied in February 1996, nearly four years later.

In 1996, the Florida Court of Appeals reviewed a disciplinary action in *Hoover v. Agency for Health Care Administration*, where the state board had imposed a $4,000 fine, had required the doctor to complete continuing medical education on the prescription of "abusable" drugs, and had placed the physician on two years' probation. In this case, the board had assessed these penalties despite the fact that the administrative hearing officer found that the board had failed to prove any of its charges. The board had presented two physicians who testified as experts at the administrative hearing in support of the board's charges; but neither had examined any of the patients or their medical records, and they testified solely on the basis of pharmacy records of the drug and the amount prescribed. The appellate court, in its review, noted that these testifying physicians themselves did not treat chronic pain patients. The court concluded that "[d]espite this paucity of evidence, lack of familiarity, and seeming lack of expertise" the state's physicians testified that the defendant had prescribed "excessive, perhaps lethal amounts of narcotics, and had practiced below the standard of care." The court set aside the board's penalties. The court further noted that it was "surprising to see agency disciplinary action based upon such a paucity of evidence after [the court's] admonitions" in a case some years earlier, concerning inadequacy of evidence in cases involving treatment decisions.

These cases evidence substantial problems in the process and the proof used to prosecute the defendant physicians. As would be expected, the number of such appellate cases is not large, in part because very few cases are litigated to the appellate level. In addition, the number of judicial opinions may be small because disciplinary agencies and prosecutors may undertake investigations and impose no official sanction while limiting the professional's practice or requiring remedial action as a consensual resolution to the threat of disciplinary action. Further, it appears likely that the number of physicians actually penalized for their prescriptive practices in treating patients for pain is not large, although the state agencies interviewed for the Project on Legal Constraints on Access to Effective Pain Relief (the Project) were not able to separate actions against physicians treating patients for pain from the more general disciplinary category of abuse of

prescription drugs. As described earlier, however, the threat of disciplinary action or prosecution is itself severe because of the burdens imposed by the investigation and proceedings themselves.

Investigations and hearings are a necessary part of effective professional discipline and criminal prosecution for suspected illegal drug activity or incompetent care. But even if the health care provider is exonerated in the end, the investigations and proceedings almost unavoidably cause substantial injury to the provider, in terms of financial, professional, and emotional consequences. The licensee's ultimate success in defending his/her actions after lengthy proceedings does not ameliorate these effects. Effective early evaluation or stopping points must be built into the system if fear of legal sanction is to be mitigated as a cause of ineffective care of patients in pain. The actual risk of an inappropriate legal sanction against physicians treating patients in pain is likely somewhat less than physicians imagine; but the severity of the consequences of disciplinary or criminal processes may lead doctors to weigh the risks very heavily.

The Pain Relief Act responds to the problem of neglected pain by addressing the risk of inappropriate legal sanctions against health care professionals. In protecting them, however, the Act accounts for legitimate goals underlying discipline and prosecution.

Disciplinary and prosecuting agencies are concerned with impaired providers who self-prescribe controlled substances or divert drugs to their own use. They are concerned with professionals who are incompetent or fraudulent in their prescriptive practices, because such practitioners present a physical or financial threat to their patients by prescribing controlled substances where the medication is believed to be ineffective or dangerous. Prosecutors are concerned with abuses of government health care programs, including Medicaid. State disciplinary boards are also involved, often in collaboration with criminal prosecutors, in the war against drugs, penalizing providers who prescribe controlled substances that can be diverted to street use or who themselves deal drugs using their prescriptive authority. Unfortunately, disciplinary and prosecutorial efforts to achieve these regulatory goals may be discouraging health care professionals from providing ethically and medically necessary care.

A number of approaches may contribute to resolving the tension in policies underlying disciplinary actions and prosecutions relating to treatment for pain. Important work has been done by some boards of medicine, for example, in developing internal policy statements concerning their disciplinary stance toward the issue. A statutory approach makes a unique contribution.

Why a statute?

Written administrative policies can neutralize the fear of legal sanction if these policies are broadly disseminated among the health care professions and are observed at all levels of the state professional disciplinary agency. A legislative response to the impact of legal sanctions on effective treatment for pain is, however, desirable under many circumstances. A state statute can serve several purposes.

State agencies are charged with achieving a number of public policies in their legal actions against health care professionals for the prescription of controlled substances. Among these clearly stated policies are decreasing the illicit supply of drugs and reducing the costs of certain government-supported health care programs. A statute clearly removing the threat of adverse government action for competent pain management will establish authoritatively a state policy of ensuring access to effective relief of pain. This would allow a pro-pain-relief policy to take its place among other statutorily expressed and easily understood policies. A legislative statement of public policy may also be used by the courts in cases related to pain management in other legal contexts. A statute can be a powerful step in placing pain control at the same level as drug control in state policy making.

A state statute may exert a greater influence over prosecutors and over the lawyers representing the boards in investigations, hearings, and appeals than a policy statement. State government agencies, including disciplinary boards and prosecutors' offices, often experience significant staff and membership turnover, including their legal representation. A clearly articulated statute provides legal continuity across these staff, membership, and representation changes. In an interview survey of a number of state medical boards, the Project found senior staff with responsibility for professional discipline who were not aware of appellate court opinions in their own states even when the opinion had set an evidentiary standard for disciplinary actions relating to treatment for pain and that had directed the boards to alter their practices.

Adoption of a pain-relief policy by a single professional state disciplinary agency governs that agency's own actions, and such a policy may satisfy professionals governed by that board. But effective pain management, including the prescribing, dispensing, and administering of controlled substances, involves other professionals. The successful policy making accomplished by one board may have to occur across several state agencies and with the prosecutors who have discretion to act under state criminal law, to ensure that their policy effectively protects all providers who are significantly involved in pain management.

A pain relief statute also provides an external standard by which board policies and actions can be reviewed. In a state that is up to date on its controlled-substances policy in medical treatment, the Act would not impede effective discipline. In a state that persists in very restrictive policies or in formal or informal activity that works against effective treatment, a statute gives a court a legal basis on which to review the board's policies, standards, investigative activity, and both formal and informal actions. Where health care professionals are faced with repeated investigations or letters of concern that appear to threaten but never actually proceed to formal action, a statute may provide them, or the organizations that employ them, with a basis for a declaratory judgment action.

Several states have already enacted "intractable pain" statutes, and others are considering them. These statutes vary widely among the states. The Pain Relief Act is compared with these existing state statutes in the last section of this commentary.

The Pain Relief Act

The following discussion reviews the major provisions of the Pain Relief Act. The first section outlines the operation of the Act. The second section offers a detailed discussion of the Act's major provisions.

Structure

The primary goal of this Act is to terminate actions against providers engaging in justifiable pain management practices as early as possible in the disciplinary or criminal process. The objective is to prevent unnecessary investigations, protracted proceedings, and inappropriate legal sanction. To this end, the Act provides that disciplinary action or state criminal prosecution cannot be brought against a health care provider under certain circumstances. Where such action is brought, the Act sets a procedural and substantive standard for the evaluation of the professional's practices.

The structure used to create this shield for providers engaged in appropriate treatment practices is a form of rebuttable presumption. A provider meeting the standards specified in the Act is presumed to be in compliance with disciplinary standards and criminal law; however, the disciplinary board or prosecutor may rebut the provider's demonstration of compliance with the Act's standards with clinical expert testimony.

Any legislation or rule that distinguishes acceptable from unacceptable practices must make reference to some standard of practice. For example, living will statutes that provide immunity to physicians who comply with a patient's advance directive frequently require simply that the physician act in "good faith." The Pain Relief Act does not adopt a good-faith standard for its protection of health care professionals because that standard would allow professionals who provided incompetent pain management to escape disciplinary action or prosecution.

Statutes or rules regulating professionals often require that the professional conform to "accepted standards of practice" or "customary practice." Similarly, a statute designed to shield health care professionals from inappropriate legal sanction could expressly provide that only those professionals who conform to the standard of care or to customary practice are shielded. Such standards are counterproductive in regulating pain management because current professional practices are generally viewed as inadequate, with undertreatment and mistreatment being significant problems.

The use of very broad terms such as "standards of practice," "accepted medical practice," or "customary practice" presents a second problem because they require extensive proof and testimony to fill in the specific content. Reference to standards of practice or customary practice may be ambiguous because the legal connotation of standards of practice can include both "customary," "best," and "accepted" practices. Reliance on a standard that requires extensive proof or that is ambiguous would defeat the Act's purpose of avoiding protracted proceedings and terminating disciplinary and criminal proceedings as early as possible

where appropriate. Less ambiguous standards should provide professionals with more confidence that their treatment of patients for pain will not trigger investigation for disciplinary action or criminal prosecution.

Providing a shield for providers who act in good faith may too easily protect incompetent providers. Providing a shield for providers who engage in accepted medical practice can codify inadequate practices and require physicians to stay well within the mainstream instead of adopting current more aggressive approaches to pain management.

The Pain Relief Act incorporates accepted practice/care guidelines as the standard for a shield from disciplinary or criminal actions. The Act does not require compliance with accepted practice guidelines, however. In fact, it specifically states that departure from accepted guidelines is not sufficient evidence on its own to support adverse action against the provider. Instead, compliance with accepted practice guidelines provides only a defense to disciplinary action or criminal prosecution.

To receive the protection of the Act, the professional must be in substantial compliance with accepted practice guidelines. Substantial compliance, as a legal term, means conformity with essential requirements. It requires considerably more than minimal but less than absolute compliance. Requiring strict or absolute conformity with guidelines places a severe burden on a provider and is inconsistent with the structure and form of practice guidelines generally.

Those providers who educate themselves about current guidelines available in their field for the treatment of pain patients--and observe those guidelines in their own practices--receive the benefit of protection from discipline and criminal prosecution. On the other hand, accepted guidelines only play a protective role, and evidence of noncompliance is insufficient to support action against the provider. In other words, accepted guidelines can be used as a shield, not a sword, against the health care professional.

To be protected under the Act, the provider must also comply with the standards of practice specifically identified in the Act, including maintenance of accurate and complete medical records, physical examination of the patient, documentation of a treatment plan, among other criteria. The Act also prohibits false or fictitious prescriptions and diversion of medication prescribed for a patient to the provider's own use. These standards have been viewed in the case law as important indicators of good-faith treatment for pain. Applying these statutory standards would screen effectively for the most serious violators of ordinary standards of practice.

The Act requires that a board or prosecutor produce testimony of a clinical expert to rebut a provider's demonstration of compliance with an accepted guideline for care of patients with pain. The requirement that the board or prosecutor involve a qualified expert (as defined in the Act) early in the process operates as an important check on inappropriate enforcement actions. The Act also requires a board or prosecutor to provide testimony of a clinical expert to support its finding or charge of violation should proceedings be pursued.

Specific provisions

Language in brackets in the text of the Act indicates the point at which individual states should provide language that reflects their own statutory framework. For example, in Section 2, the Act does not identify the individual boards by title but rather brackets that item for insertion of the appropriate identifier in each state.

"Health care providers"

The Pain Relief Act reaches all licensed health care providers whose prescription, dispensing, or administration practices in pain relief may trigger disciplinary action or prosecution. It is not limited to physicians, as are current statutes and policies.

This broad scope is particularly important because many states are now recognizing prescriptive authority for advanced practice nurses and physician assistants. Further, the delivery of much of health care has shifted to settings such as long-term care, nursing homes, home care, and hospice, where most of the direct pain care is performed by nurses rather than physicians, even in the absence of prescriptive authority for

controlled substances. In collaborative practice settings, nurses and physician assistants remain accountable to their own professional discipline boards, independent of the boards of medicine that regulate physicians.

"Intractable pain"

The Act uses intractable pain because that term is commonly used in similar state statutes. The Act does specify that intractable pain can be temporary, and this is consistent with the ordinary meaning of intractable, although the connotation of the term is sometimes taken to be long term only. The statutory definition is not limited to particular physical conditions and so would apply to chronic nonmalignant pain and other pain states.

"Clinical expert"

It is important that the provider who more aggressively treats patients in pain consistent with newer standards of care be evaluated only by professionals who themselves are knowledgeable about effective pain relief. Current law in many states does not require that a disciplinary board engage an expert in proving a claim of violation of disciplinary standards. Where an expert is required, the courts generally afford the board wide latitude in the qualifications of the expert. In criminal prosecutions, qualifying the experts who will evaluate the provider's practices for the jury is key. Both of the appellate court cases described earlier can be viewed as actions in which the board's experts were inadequate to prove that the defendant physician had violated the law.

Under the Pain Relief Act, the board or criminal prosecutor is required to provide a qualified clinical expert to support the case against the provider. By the specific terms of this Act, the expert is one who "by reason of specialized education or substantial relevant experience in pain management has knowledge concerning current standards, practices, and guidelines." The licensee is not required to provide expert testimony.

"Accepted guideline"

The Act protects a health care professional from the threat of legal sanction if the professional substantially complies with accepted guidelines for the treatment of pain. As discussed previously, substantial compliance with such guidelines provides a shield against legal penalty. The Act specifically states, however, that a health care provider is not to be penalized for noncompliance with accepted guidelines.

The Act limits the statutory recognition of accepted guidelines to those produced by nationally recognized clinical or professional associations, specialty societies, and government agencies. A number of organizations would satisfy the statutory description, including AHCPR, the American Pain Society, the American Society of Clinical Oncology, and so on. The Medical Board of California, for example, has specifically referred to AHCPR guidelines, "which have been endorsed by the Board as a sound yet flexible approach to the management of [trauma, surgery and cancer] pain."

The Act excludes guidelines developed primarily for coverage, payment, or reimbursement because those guidelines may be issued for cost-containment purposes. Although cost containment is a legitimate goal, it does not serve the purposes of this Act.

The Act allows the provider to select from multiple sources for guidance in fashioning or defending his/her own practices, allowing for diverse practices of professionals and medical specialties. Allowing guidelines from multiple sources to function within the Act also addresses potential resistance from health care providers, and especially physicians, toward practice or care guidelines. Providers continue to have the freedom to select the patterns of practice that best serve their patients.

The use of accepted guidelines should also address another deficiency in pain management practices by raising the awareness of current standards of pain management within the professions. Physicians and nurses give many reasons for undertreating pain, including lack of knowledge. The Act's recognition of substantial compliance with accepted guidelines as a defense to disciplinary action or criminal prosecution provides a substantial incentive for health care professionals to increase their knowledge of pain management techniques and strategies.

Guidelines are not currently available for all areas of pain management. Where guidelines are undeveloped, the statute specifically gives a board authority to develop its own policies and rules, but these must be consistent with the goals of the Act. The Act itself may in fact prompt boards to fill in the gaps through rule making or policy making rather than through adjudication of individual cases. Case-by-case enforcement, absent statutory or administrative standards, has the unfortunate consequence of testing basic principles and standards at the expense of individual providers. This increases fear of sanction and fear of scrutiny.

It is important, though, that the Act does not place the burden on boards to develop practice or care guidelines. In 1991, the Government Accounting Office reported that medical specialty societies spent one to three years and up to $130,000 on a single guideline development project, a cost that did not include the value of time donated to the professional society. Boards are not able to bear such a burden under current restrictive state budgets.

"Disciplinary action"

Disciplinary interventions frequently result in informal resolution. If the Act is to protect and encourage providers whose practices comply with an accepted guideline and specific statutory practice standards, informal resolutions should meet the same standards of good practice. The Act, therefore, reaches both formal and informal actions and both remedial and punitive actions.

Chemically dependent patients

Pain does not discriminate. Patients who are drug-dependent may experience severe pain unrelated to their dependency. They are equally or perhaps more likely to contract painful diseases such as AIDS or to experience injuries or disabilities that may cause chronic pain. Using the patient's preexisting condition as a serious obstacle to adequate treatment of intractable pain is punitive of their status and causes avoidable suffering.

Current legal restrictions on the treatment of chemically dependent patients in pain penalize patients suffering from intractable pain, as well as the licensed professionals directing their care. These legal restrictions are not always well designed and may use inaccurate, inadequate, or ambiguous definitions of dependency or addiction. Restrictions on access to pain medications may also have a severe and adverse effect on the treatment of AIDS patients and an adverse impact by race.

The Act, therefore, expressly extends its protection to providers in their treatment of chemically dependent or addicted patients for pain. The Act, however, specifies a broader authority on the part of the boards to establish both standards and procedures for the application of the Act to this patient population. This structure will accommodate variation in state law and policy in this particular area, although standards and procedures developed by the boards must be consistent with the Act's purpose of encouraging the provision of effective pain relief.

Comparison to current statutes

Several states have enacted pain statutes, or are considering legislation. The Pain Relief Act differs from some statutes in significant ways, and attempts to address shortcomings in existing statutes.

The Pain Relief Act is broader in its scope than all current state statutes in two aspects. First, the Act reaches all professions with significant involvement in the treatment of pain; it is not confined to physicians. Second, the Act reaches both disciplinary action and criminal prosecution. Of course, states may choose to modify the Act by reducing its scope to certain professions or to disciplinary actions only.

Conversely, the Act is narrower than some state statutes in its scope of protection because it does not provide absolute immunity for professionals treating patients in pain; instead it provides significant protection to health care providers who can show substantial compliance with certain standards of practice. At the same time, however, the Act does not penalize providers who cannot demonstrate compliance with any practice guideline. Noncompliance cannot provide the basis of adverse action against any provider.

California's statute provides that "no [doctor] shall be subject to disciplinary action ... for prescribing or administering controlled substances in the course of treatment ... for intractable pain" as long as prescription of controlled substances is for a "therapeutic purpose" and meets requirements similar to those in Section 4 of the Act. Similar statutory immunity provisions relating only to disciplinary action and only for physicians have been adopted by Nevada, Oregon, and Texas. Although such statutes appear to afford physicians broader protection, the standards with which the physician must comply are comparatively nondeterminative. For such statutes to be effective, the boards must take appropriate action through rule making or other such activity to rectify the ambiguities of the statutory standard. Where boards have taken such action, the more ambiguous statutory standard may operate effectively; but absent such action, such a statute may provide little encouragement for effective treatment of pain in the face of legal uncertainty.

Virginia's statute simply states that a physician may use controlled substances for the treatment of patients in pain. This statute does not specify what legal effect this statement is to have. It does not directly address standards to be used in disciplinary action, except to state that the statute does not grant immunity. It does not establish a legal standard that effectively responds to fear of disciplinary action.

Several current state statutes rely on general standards of medical practice in the treatment of pain. For example, Florida's statute simply refers to the "level of care, skill, and treatment recognized by a reasonably prudent physician under similar circumstances." Nevada's statute similarly refers to "accepted standards for the practice of medicine." The Pain Relief Act, because it aims to terminate disciplinary proceedings or criminal action at an early point in the process and because it aims to communicate a predictable and reliable standard to professionals concerned about the risk of legal sanction, uses a more specific standard.

The Act is similar to the existing state statutes in specifying other required standards of practice. These include the maintenance of written patient records; physician examination of the patient; the establishment of a treatment plan; and other clinical and practice management actions.

The Act does not require a second medical opinion about the cause of the patients' pain, although a few of the current statutes do. California's statute, for example, requires evaluation by "the attending physician or surgeon and one or more physicians or surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of pain." Requiring a second medical opinion, especially from a specialist, may create significant access and payment problems for pain patients.

The Pain Relief Act differs from current statutes in its treatment of patients who are chemically dependent. At least three state statutes (North Dakota, Texas, and California) specifically exclude persons who are being treated by the physician for chemical dependency. Some provide that the physician may not provide controlled substances to "a person the physician or surgeon knows to be using drugs or substances for nontherapeutic purposes."

The Pain Relief Act, in contrast, specifies that the provisions of the Act do apply to patients who are chemically dependent or addicted. The Act specifically includes the treatment of patients who are chemically dependent in order to offset restrictions that may negatively influence physicians in their treatment of patients who might be inappropriately considered "chemically dependent" because of their long-term use of opioids for the treatment of pain. Specific inclusion should encourage, rather than discourage, professionals in treating chemically dependent patients in pain.

The Oregon statute stands alone in requiring the patient's written consent to pain medication. It requires that before beginning treatment for intractable pain, "the physician shall provide to the person and the person shall sign a written notice disclosing the material risks associated with the prescribed or administered controlled substances to be used in the course of the physician's treatment of that person." The Pain Relief Act does not establish a special statutory requirement of written consent because treatment for pain is governed by the ethical and legal framework already in existence for informed consent to treatment. A specific statutory requirement for written consent treats medication for pain differently than other medications and so continues the notion that it is necessarily riskier or more dangerous. Requiring written consent would raise significant issues for incompetent patients and may raise questions of cultural diversity that are currently being studied in regard to consent and advance directives.

Intractable pain statutes are not the only state statutes that currently limit legal sanctions against physicians in their treatment of patients in pain. Most living will or advance directive statutes include

direction to the physician that measures necessary for the relief of pain be employed. Several of these statutes, or the statutory forms provided within the statute, direct that pain relief be provided even if it might hasten death. Good-faith compliance with such an advance directive, within the terms of the state statute, usually confers immunity from civil and criminal liability. Living will statutes tend to be of limited application, however; they are almost always restricted to incompetent patients and, in most states, by the medical condition of the patient. Still, they provide a statement of state policy supportive of the alleviation of pain.

Conclusion

Needless human suffering from untreated but treatable physical pain is caused by a number of factors influencing health care professionals, health care institutions, payment systems, and patients and families themselves. Fear of legal sanction is one reason for neglect of treatment. The Pain Relief Act, and similar statutory and administrative responses, can minimize fear of legal penalty for effective treatment of patients in pain. The Act identifies pain control as a priority for state health policy, and allows pain control to join drug control as an expressed policy of the state.

Efforts to align a state's professional regulatory system and other enforcement activity behind the goal of relieving treatable pain must also examine the processes used to investigate professionals charged with legal violations in relation to treatment of patients in pain. New models must be developed to shift oversight of pain management from a quasi-criminal context to another context more conducive to patient protection. Earlier in the history of professional regulation, the regulatory posture toward substance-abusing or otherwise impaired physicians changed significantly with the introduction of diversion and impaired-physician programs. Such physicians are no longer handled in a criminalized process. Nor are physicians who are charged with negligence. The regulatory approaches toward impaired physicians or toward disputes over treatment may offer other models for the investigation and prosecution of health care professionals who meet at least minimum standards in their treatment of patients in pain.

David L. Ralston, "Pain Management: Texas Legislative and Regulatory Update"

Journal of Law, Medicine & Ethics, 24, no. 4 (1996): 328-37.

My purpose is to provide an update on recent Texas regulatory and statutory changes adoptedsince the passage in Texas of the Intractable Pain Treatment Act in 1989 (Pain Act) (see Table 1). First, I describe the rules adopted by the Texas State Board of Medical Examiners (TSBME) that authorize physicians to prescribe opioids for the treatment of pain (Pain Rules) (see Table 2). Second, I detail recent statutory changes that pertain to education of physicians and medical students about pain treatment. All of these changes attempt to create a better legal environment for the treatment of chronic pain in Texas.

Background

Rules or policy statements?

Before describing the Pain Rules adopted in Texas, the question "Why adopt rules, rather than simply ask TSBME to issue a policy statement?" must be answered. Many states, most notably California, have issued policy statements that clarify for physicians the parameters within which they may treat pain. Policy statements, unlike administrative regulations, do not have the force of law.

Perhaps even more important, policy statements may change with any change in the political winds of the government agency issuing the policy statements. For instance, before adoption of the Pain Rules, Texas had previously issued three policy statements on appropriate prescribing practices. Unfortunately, these three statements were inconsistent in how each approached the issue. In 1988, TSBME stated in its newsletter:

> The Board is obligated by statute to receive and investigate complaints alleging that a licensee is prescribing or administering what could be excessive quantities of drugs to persons who may be addicted to the medications.

Then, in 1992, without referencing the adoption of the Pain Act, TSBME placed the following pertinent statements on the front page of its newsletter:

> The Board does not wish to inhibit the proper treatment of pain. However, the Board will continue to be concerned about the inappropriate use of narcotics in non-malignant conditions in which physical therapy measures, exercise techniques, or relaxation and stress control techniques have not been utilized.

At this point in 1992, it appeared as if TSBME not only focused on "excessive quantities of drugs to persons who may be addicted to the medications," but also required "physical therapy measures, exercise techniques, or relaxation and stress control techniques" to be used first with patients with nonmalignant conditions. In the last TSBME pronouncement before the adoption of the Pain Rules, TSBME no longer focused on "excessive quantities of drugs" as a sole indicator of inappropriate prescribing, nor did it require different treatment modalities for malignant and nonmalignant pain. Instead, referencing the International Narcotic Control Board, Section 21 of the Code of Federal Regulations, and the Pain Act, TSBME stated that

> opioids (narcotics) and other Scheduled Controlled substances are indispensable for the treatment of pain; and, are useful for relieving and controlling many other distressing symptoms patients may suffer. It is the position of the Board that these drugs be prescribed for the treatment of these symptoms in appropriate and adequate doses after an appropriate diagnosis is made.

Additionally, this time TSBME stated the "[q]uantity and chronicity of prescribing will be judged on the basis of the diagnosis and treatment of the targeted symptoms and neither of these factors are prima facie evidence of inappropriate or excessive prescribing." After the publication of these three policy statements, the need for a simple, straightforward, and binding administrative rule became apparent.

Physicians also had a specific need for the Pain Rules. The incidence of pain is high, yet inferior pain relief occurs due to Texas physicians' perceived regulatory barriers to treating pain adequately. Specifically, 68 percent of those physicians responding to a statewide survey of licensed Texas physicians conducted in 1995 stated that they believed TSBME influences pain treatment some or even quite a lot. Yet, 61 percent of these same physicians did not know TSBME standards for opioid prescribing and 68 percent of them did not believe these standards could easily be determined.

Why the Texas Medical Practice Act is insufficient

The Texas Medical Practice Act (MPA) currently does not adequately address the discipline of physicians for prescribing practices. The stated purposes of MPA include "eliminating ... ineffective provisions ... and restating the law in more modern language where possible." Currently, MPA provides for disciplinary action relating to the inappropriate prescribing of controlled substances. Specifically, physicians in Texas have been disciplined by TSBME under various provisions of MPA relevant to prescribing practices. First, physicians have been disciplined for prescribing or practicing medicine in a manner *not consistent with public health and welfare*. Second, physicians have been disciplined by TSBME for "prescribing or administering a drug or treatment that is *nontherapeutic in nature or nontherapeutic in the manner* the drug or treatment is administered or prescribed." Unfortunately, none of these MPA provisions is defined in the Texas MPA.

The Pain Rules provide more guidance in referencing the definitions used in the Code of Federal Regulations (CFR). CFR requires prescriptions by a physician for a controlled substance to be issued for "a legitimate medical purpose in the usual course of professional practice." That requirement originated in the regulations implementing the Harrison Narcotic Act of 1914. It is used in the federal regulations implementing the Controlled Substance Act (CSA) and in interpretations of CSA by the Department of Justice. These three usages are explained below.

Regulatory usage

The original Harrison Narcotic Act regulations

The Harrison Narcotic Act of 1914 (the Act) established a registration and taxation system to control the use of narcotics. The regulations implementing this Act required all dispositions of opioids to be accompanied by an order form unless the disposition was (1) by a duly qualified and registered practitioner *in the course of his professional practice*, or (2) pursuant to a properly executed prescription *for a legitimate medical purpose*. Additionally, all prescriptions under the Act had to be issued *for a legitimate medical purpose*.

The U.S. Senate floor debate reveals the care with which Congress drafted the Act. A senator from the then rural state of Ohio asked to exempt physicians from the bill because of the hardships it imposed on the rural practice of medicine. He compromised on requiring the licensing of physicians to distribute narcotics, but exempted physicians from the record-keeping requirements of the bill. He pleaded:

> We must have a cure for the drug habitue, but we must not forget the innocent sufferer on his or her bed of sickness and pain. Let us protect the country from the physician or druggist who is encouraging the drug habit for purely commercial purposes; but let us not by too much red tape hinder the physician in the proper practice of his profession. We can prevent the abuse of the drugs without unduly hampering its proper use.

Therefore, the original intent of the language was to balance the needs of law enforcement with adequate pain relief for patients. The intent of the Pain Rules is to carry this balance forward.

Drug Enforcement Administration manual

The Diversion Control Division of the Drug Enforcement Administration issued a manual in 1990 to assist physicians' understanding of CSA. The manual states:

> Controlled substances and, in particular, narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or chronic disorder. These drugs have a *legitimate clinical use* and the physician should not hesitate to prescribe, dispense or administer them when they are indicated for a *legitimate medical purpose*. It is the position of the Drug Enforcement Administration that these controlled substances should be prescribed, dispensed or administered when there is a *legitimate medical need*.
>
> It is my opinion that the difference between permitting prescribing for *legitimate medical purpose*, as used here, and restricting prescribing for a *nontherapeutic* use or prescribing *not consistent with public health and welfare*, as used in the Texas MPA, is twofold. First, a positive statement of the law allows for the changes in medical practice as more research is done. The negative statements *nontherapeutic use* and *not consistent with public health and welfare* do not. Second, cultural and societal biases can be used to interpret *nontherapeutic use* and *public health and welfare*. This may lead to underprescribing of opioids. For instance, when opioids are prescribed for certain chronic nonmalignant painful conditions, many people do not believe this is culturally and socially acceptable. Further, the phrase *nontherapeutic use* and *efficacy* might be confused. For example, certain chronic painful conditions (neuropathic pain) may respond poorly to opioids. However, is relieving only some aspects of neuropathic pain a nontherapeutic use? Restating the law in this area replaces a vague provision with language that more appropriately addresses the issue of adequate pain relief.
>
> *Controlled Substance Act and the Code of Federal Regulations*
>
> Congress states in the legislative findings section of CSA that "many of the drugs included within this title have a useful and *legitimate medical purpose* and are necessary to maintain the health and general welfare of the American people." Indeed, the regulation implementing CSA states that "for a controlled substance to be effective [a prescription] must be issued for a *legitimate medical purpose* by a practitioner acting *in the usual course of professional practice.* " Texas law now conforms to these established standards. It is hoped this improved legal standard will provide guidance to Texas physicians prescribing opioids and lead to improved prescribing practices.

Federal and state case law usage

Federal case law

Requiring all prescriptions to be issued for a "legitimate medical purpose in the usual course of professional practice" has a long and well defined history in the area of narcotics regulation. In fact, as described below, review of the federal case law reveals that three factors determine whether a physician is prescribing for a legitimate medical purpose in the usual course of professional practice. In many cases, the "facts ... were so blatant that a statement of clear cut criteria in a form useful in other cases would have been superfluous to the decision." However, within the case law, several factors repeat with regularity. The following factors, therefore, can be characterized as determining that a physician is not prescribing for a "legitimate medical purpose in the usual course of professional practice."

> (1) Lack of medical treatment by the physician--
> (a) no medical history and no physical exam;
> (b) physician ignores results of tests made; and
> (c) no charge for medical services, but instead a graduated fee according to the number of pills desired.
>
> Lack of medical judgment by the physician--
> (a) inordinately large number of drugs given or prescriptions issued;
> (b) excessive frequency of prescriptions;
> (c) no logical relation between drugs prescribed and treatment of alleged condition;
> (d) physician allows patient to request a specific drug, rather than prescribing a drug based on a medical history and diagnosis;
> (e) prescriptions issued in exchange for sexual relations with the patient; and
> (f) physician ignores presence of track marks on patient for whom injectable drugs are prescribed.
>
> (2) Awareness of a nonlegitimate purpose on the part of the physician--
> (a) physician tells patient to fill prescriptions at different pharmacies;
> (b) physician writes more than one prescription at a time, then post-dates some of them to avoid the appearance of overprescribing;
> (c) physician erases names in record book to avoid scrutiny;
> (d) physician asks patient to use a fictitious name for prescription or agrees to write prescription in the name of someone who is not the patient;
> (e) physician uses street slang rather than medical terminology for drugs prescribed;
> f) prescriptions issued to patient known to be distributing them to others or to be using them for other than legitimate medical purposes; and
> (g) physician tells patient names of disease he/she can claim to suffer if pharmacist questions him/her.

The standard used in *United States v. Rosen* to analyze whether a physician distributed or dispensed a controlled substance for other than legitimate medical purposes in the usual course of professional practice is as follows:

> A physician is restricted to dispensing or prescribing drugs in the bona fide treatment of a patient's disease, including a dispensing of a moderate amount of drugs to a known addict in a good-faith attempt to treat the addiction or to relieve conditions or suffering incident to addiction. However, under the guise of treatment a physician cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict. Congress did not intend for doctors to become drug "pushers." In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options. Hence, what constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.

This standard clearly reveals flexibility in the law, which is important when dealing with unsettled medical issues such as treatment of nonmalignant pain with opioids. Physicians are given the latitude of "available options" and are judged based on the "evidence and attending circumstances."

Texas case law definitions

An additional basis for the change from the Texas standard, which restricts prescribing for *nontherapeutic use* or prescribing *not consistent with public health and welfare*, to the federal standard, which requires the prescription to be for a *legitimate medical purpose in the usual course of professional practice*, is the paucity of Texas case law providing clarification to the terms *nontherapeutic use or consistent with public health and welfare*. The Texas MPA states: "Any term, word, word of art, or phrase that is used in this [MPA] and not otherwise defined in this [MPA] has the meaning as is consistent with the common law." However, only four applicable cases exist in Texas. Only one reported case can initially be found where the defendant lost his license due to a "professional failure to practice medicine in an acceptable manner consistent with public health and welfare." In *Balla v. Texas State Board of Medical Examiners*, an appellate court upheld the revocation of Dr. George Balla's medical license for issuing "patient prescription orders for amphetamine and amphetamine-like drugs through the mail ... without 'a proper medical examination to determine if such drugs were medically necessary or medically indicated for treatment of any illness or medical condition.'" Although Dr. Balla's actions were clearly not acceptable, one case does not provide direction for physicians who want to practice medicine that is consistent with both accepted scientific and medical standards and the less well defined standard of "public health and welfare."

The common law definition of "prescribing or administering a drug that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed" is also very limited. Only three reported cases rely on this section of MPA and only one of them resulted in the revocation of a physician's license. In the other two cases, the courts overruled the Texas Board of Medical Examiners because it lacked the expert testimony necessary to uphold the license revocation.

Finally, no cases in Texas have relied on "prescribing, administering or dispensing in a manner not consistent with public health and welfare dangerous drugs ... or controlled substances...." Therefore, Texas common law has not provided adequate assistance in defining these three phrases in the Texas MPA.

How Texas regulations might have changed a recent Florida disciplinary action

Sometimes having case law that addresses the issues of pain management can initially create the worst possible outcome. Indeed, the reason for drafting clear guidelines regarding the treatment of pain rather than leaving it up to the courts to decide is best demonstrated in a recent physician disciplinary action in Florida, *Hoover v. Agency for Health Care Administration*. On June 26, 1996, a Florida district court reversed the Florida Board of Medicine's reprimand and civil fine of a physician alleged to have "inappropriately and excessively" prescribed various Schedule II controlled substances. The court's reversal turned on the fact that the Florida Board of Medicine substituted its own judgment for a hearing officer's findings of fact and conclusions of law without proving a violation of the Florida Medical Practice Act by clear and convincing evidence.

At a formal hearing requested by the physician, Board of Medicine experts testified that "the doctor had prescribed excessive, perhaps lethal amounts of narcotics, and practiced below the standard of care." One of these physicians also stated that "the amounts prescribed constituted a 'tremendous number of pills.'" However, the expert physicians did not treat patients with chronic pain and

> 'candidly testified that without being provided with copies of the medical records for those patients, they could not evaluate [the physician's] diagnosis of what alternative modalities were attempted or what testing was done to support the use of medication chosen by [the physician] to treat [her patients].'

The physician under investigation, on the other hand, testified in great detail

> concerning the condition of each of the patients, her diagnoses and courses of treatment, alternatives attempted, the patients' need for medication, the *uniformly improved function of the patients with the amount of medication prescribed*, and her frequency of writing prescriptions to allow her close monitoring of the patients. She presented corroborating physician testimony regarding the appropriateness of the particular medications and the amounts prescribed and her office-setting response to the patients' requests for relief from intractable pain.

The hearing officer found the physician's prescribing practices to be appropriate, based on "(1) the doctor's testimony regarding the specific care given, (2) the corroborating testimony of her physician witness, and (3) *the fact that the doctor's prescriptions did not exceed the federal guidelines for the treatment of intractable pain in cancer patients.* "

Essentially, the Board of Medicine supplanted the hearing officer's findings of fact and conclusions of law by finding the doctor in violation of the Florida Medical Practice Act. The board stated that (1) the federal guidelines were irrelevant because they were directed to treatment of cancer pain and that (2) the board's experts testified the physician's prescribing practices were below the standard of care. The hearing officer, however, found that the federal guidelines referenced "have been issued for the use of Schedule II controlled substances to treat intractable pain and that although these guidelines were established to guide physicians in treating cancer patients, *those are the only guidelines available at this time*."

This case originated before the effective date of the intractable pain treatment law in Florida. However, if a similar case were presented to TSBME with the assistance of the Pain Rules, it might not require a formal hearing to reach the same conclusion as the Florida district court. The possible savings, in terms of money and a physician's professional reputation, are substantial over time. The applicability of the Pain Rules to the facts of the Florida case is twofold. First, the Pain Rules state:

> Quantity of pharmaceuticals and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this chapter.

Therefore, having experts testify that the number of pills prescribed is outside accepted medical practice would not be enough in Texas. Additionally, the Pain Rules state:

> Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated *to a great extent by the treatment outcome*, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

Therefore, when patients uniformly display improved function with the amounts of medication prescribed, this treatment outcome should greatly reduce the risk of investigation in Texas. Thus, physicians in Texas are now able to use the Pain Act and the Pain Rules to improve pain treatment for Texas patients.

Recent legislation and educational efforts

In addition to the Pain Rules, education must play a part in improving pain management. In 1995, the Texas legislature addressed the pain management education of Texas physicians by enacting legislation to encourage physicians who treat pain to take continuing medical education (CME) courses in pain management. The Texas Cancer Council was charged with maintaining a list of CME courses for Texas physicians. And, the legislature authorized a survey of Texas medical schools to determine the content and amount of course work offered in pain treatment and management.

The results of this survey were tabulated and reported to the Texas Higher Education Coordinating Board-Division of Health Affairs (Coordinating Board). The survey asked to what extent each medical school addressed specific instructional elements identified in the statute. There are seven allopathic medical schools and one osteopathic medical school in Texas. The preliminary report from the Coordinating Board indicates that the schools had difficulty in determining what courses actually contained specific pain instructions, and a wide diversity of courses and hours were reported to be devoted to pain treatment instruction among the

schools. By innuendo, claims were made that pain treatment tended to thread itself into almost all courses offered. Absent from the report was an agreed pain treatment course standard among the schools. In clinical courses, which often follow an apprenticeship model, concern was raised as to who the "master" was for the course and how much he/she knew about pain management so that the quality of instruction could be ensured. One thing was very clear in the report: no one department, entity, or teaching unit had the responsibility of providing an integrated, comprehensive course in pain treatment. Nor were formal courses offered on the duty of physicians to relieve pain and other distressing symptoms associated with diseases of aging that surely deserve a more prominent role in the undergraduate medical curricula as a result of our changing older population demographics. The major recommendation from the Coordinating Board was that all Texas medical schools should define collectively what a standardized curriculum component in pain treatment education should represent. These results will now be reviewed by various interest groups to determine what legislative action, if any, may now be appropriate.

Besides medical school curriculum, other pain treatment educational efforts have been carried on by various organizations and institutions in Texas. The Texas Pain Society, made up of physicians specializing in pain treatment, conducts formal training sessions for physicians several times each year. The Texas Cancer Pain Initiative (TCPI) has sponsored stand-alone meetings as well as lectures by pain treatment experts at hospital grand rounds and other hospital staff-related activities throughout the state. Through grants from the Texas Cancer Council, TCPI has also conducted role-model all-day sessions for groups consisting of a physician, nurse, and pharmacist from designated geographical areas throughout Texas. Since 1995, the Texas Medical Association has sponsored meetings on proper pain treatment and regulatory issues relating to prescribing opioids for pain of both malignant and nonmalignant origin.

Surveys of Texas physicians reveal a need for these educational efforts. For instance, almost three-quarters of physicians recently surveyed believe patients who take opioids chronically are addicts. Over half of those surveyed state that the greatest barrier to pain treatment is physician reluctance to prescribe opioids. Therefore, to provide a greater opportunity for patients to receive adequate pain relief, educational efforts for Texas physicians and medical students should be a high priority. With the latest information in pain management and treatment, physicians are more likely to treat patients based on sound medical principles rather than cultural biases and fear.

Conclusion

The Pain Rules and the various educational efforts in Texas are aimed at improving the treatment and management of pain by Texas physicians. These changes, along with the Pain Act, are the first steps in an on-going effort to improve the regulatory environment in a way that will further encourage adequate pain treatment.

Chris Stern Hyman, "Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment"

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The current debate about physician-assisted suicide and the question of whether patients would ask for such help if their pain were adequately controlled place in sharp focus the issue of undertreated pain. Studies have repeatedly documented the scope of the problem. A 1993 study of 897 physicians caring for cancer patients found that 86 percent of the physicians reported that most patients with cancer are undermedicated for their pain. A 1994 study found that noncancer patients receive even less adequate pain treatment than patients with cancer-related pain, and that minority patients, the elderly, and women were more likely than others to receive inadequate pain treatment. Although the problem of undertreatment of pain is multifaceted, I only address how state medical boards contribute to the problem and suggest possible remedies.

The literature on palliative care describes the numerous barriers that impede effective pain management and that result in the inadequate prescribing of pain-relieving drugs for terminally and chronically ill

patients. One of the significant impediments is physicians' fear that prescribing an adequate quantity of opioids will result in an investigation by the state medical board, the Drug Enforcement Administration (DEA), or the state agency responsible for regulating controlled substances. Another is the woeful lack of knowledge of some physicians about how to treat intractable pain and their inaccurate perception about what is and is not legal. Even members of state medical boards do not have a clear understanding of what is legally and medically acceptable in using opioids to treat pain.

The most effective antidote to the physicians' fear is ensuring that state medical boards are not investigating and disciplining physicians who treat pain appropriately and that state medical boards and physicians are well informed about effective pain management. Is this best accomplished by statute, regulations, or guidelines, or by using experts and education? Statutes and regulations can give physicians some reassurance, but the key to appropriate enforcement is the level of knowledge about pain management of state medical boards' members and staffs. In attempting to remove barriers to effective pain management, state medical boards should take the following steps.

(1) Objectively assess the medical board's level of knowledge of effective pain management and the extent of the undertreatment of pain in their state.
(2) Enlist the assistance of physicians who are experts in pain management to review cases under investigation and to serve as expert witnesses in hearings.
(3) Consider how the regulatory process can be used to improve pain management.
(4) Evaluate how best to inform and educate licensees about pain management.

Assess the board's knowledge of pain management and the extent of undertreatment of pain

Each state board needs to assess objectively whether its members are sufficiently knowledgeable about pain management. To do so, the Federation of State Medical Boards of the United States (FSMB) could assist the state medical boards by creating a self-assessment questionnaire for all boards. If, on the basis of evaluations, the level of knowledge is found to be inadequate, then training by qualified experts is essential. Experts should be hired as consultants and used to train board members as well as licensees throughout the state.

Members of state medical boards have an obligation to be knowledgeable about all aspects of medical practice. Each physician obtains a medical license from the state medical board to practice in that particular state. In the United States, we have sixty-eight state medical boards (some states have more than one board--one for allopathic physicians, one for osteopathic physicians, or one for licensure and one for discipline). In return for granting a license, the state medical board gains jurisdiction over that physician's professional conduct and has the authority to investigate and bring a disciplinary action against a physician who fails to meet the acceptable level of conduct--in other words, that physician commits misconduct. In every state, statutes and regulations define physician misconduct and the process by which physicians are disciplined.

Enlist pain management experts to review cases under investigation and to serve as witnesses

State medical boards must enlist the expertise of physicians who are knowledgeable about pain management and must use their expertise to train investigators and attorneys, so that accurate decisions will be made about whether misconduct has occurred in a particular case. Without this expertise, the perception and, in some instances, the reality that appropriate treatment of pain exposes one to risks of disciplinary action will continue. Each state medical board should develop a list of pain management experts who will, as consultants, review cases under investigation and who will testify in a disciplinary hearing when necessary. The absence of this expertise has resulted in disciplinary actions being overturned by state courts and perpetuates the perception that physicians who appropriately prescribe controlled substances, particularly Schedule II drugs, for relief of intractable pain will face disciplinary action.

For example, in Arkansas and Tennessee, appellate courts have reversed disciplinary actions taken by the state medical boards for excessive prescribing of controlled substances for relief of pain. In each case, the state board failed to produce an expert physician to testify at the disciplinary hearing about the appropriate standard of care and the extent to which the accused physician deviated from that standard. In Florida, the district court of appeals reversed the decision of the state medical board which had found that a physician had excessively prescribed Schedule II controlled substances for intractable pain. The hearing officer, after

the disciplinary hearing, found that the state board had failed to meet its burden of proof on all charges and that the physician's prescribing practices were appropriate. In this instance, the hearing officer found that the state experts had never examined the medical records of the patients who were the subject of the misconduct allegations. The experts had only examined the computer printouts obtained from the pharmacies. The state medical board rejected the findings of the hearing officer and disciplined the physician. The appellate court held that the board is not free to reject the hearing officer's findings and to substitute its own when the findings are based on competent and substantial evidence. The court was also disturbed that this disciplinary decision was based on such a "paucity of evidence" after reversals in two prior cases for the state board's failure to prove that the physician had prescribed excessive amounts of controlled substances.

Reversals such as these clarify why statutory protection from unwarranted disciplinary action is considered essential by its proponents, but it is questionable whether statutory protection from discipline is the best way to ensure that state medical boards function as they should.

If a state court overturns a disciplinary action for lack of substantial evidence in the record to support a medical board's conclusion that the treatment of pain by a physician was inappropriate, then that state medical board and its attorneys would have to assess carefully their own level of expertise in pain management. Are experts in pain management available to the state medical board to serve as expert witnesses? Are its investigators and attorneys sufficiently knowledgeable about pain management to discern which cases to pursue and which to close? Are the correct cases being prosecuted? A statute, like those discussed below, should not be required to ensure appropriate enforcement by regulatory authority and it will not correct the paucity in knowledge about pain management and procedural rules.

Consider how the regulatory process can improve pain management

Each state must evaluate what will be most efficacious in improving pain management. In some states, amendments to the statutes regulating controlled substances are needed. In prescribing controlled substances, two overlapping regulatory processes govern a physician's conduct. One is the federal system for regulating the prescribing, administering, dispensing, and distribution of controlled substances, which is defined in federal statutes and regulations and enforced by DEA. The other is each state's statutes and regulations, which also govern the use of controlled substances. Some of these statutes contain barriers to effective pain treatment.

Several experts have pointed out that the terms *addict* and *addiction* are defined inadequately in many state controlled-substances statutes. If *addict* is defined as a person who habitually uses a narcotic drug and becomes dependent on it, then the definition should be changed because it is equally applicable to a patient with nonmalignant pain who is being appropriately treated with opioids. New York has such a definition and the New York State Department of Health has tried unsuccessfully for the last several years to amend the statute to restrict the definition to a person who habitually uses a controlled substance for a nonmedical or unlawful purpose. These inaccurate definitions contribute to the misunderstandings of health care professionals and their fears about addiction. Many do not understand the distinction between drug abusers who are psychologically dependent on and compulsive users of a drug *and* pain patients who are physically, but not psychologically, dependent on a drug. The federal Controlled Substances Act contains a positive statement recognizing the useful and legitimate medical purpose of many controlled substances. Amendments to state statutes modeled on this federal language would balance the necessary restrictions with recognition of the therapeutic importance of these drugs.

Some states have opted for statutes on intractable pain, others for regulations and/or guidelines. As of September 1996, eleven states have statutes (see Table 1). Ten states have enacted statutes that affirmatively permit prescribing of controlled substances for intractable pain, and six of them give additional reassurance by offering protection from disciplinary action with language, such as California's, that

> No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

These unusual statutes seem to be addressed both to the regulated and to the regulators. To the regulated, reassurances are given that appropriate pain management will not result in a disciplinary action; to the

regulators, an admonition not to discipline for appropriate treatment. In some states, as discussed above, this admonition is necessary.

The Project on Legal Constraints on Access to Effective Pain Relief, conducted by the American Society of Law, Medicine & Ethics, proposes a Pain Relief Act for adoption by state legislatures. It provides in Section 3.1 that

> Neither disciplinary action nor state criminal prosecution shall be brought against a health care provider for the prescription, dispensing, or administration of medical treatment for the therapeutic purpose of relieving intractable pain [when that provider] can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline....

This statute seeks to protect health care providers from unwarranted disciplinary actions and state criminal prosecutions if appropriate pain management occurred. The model statute defines *accepted guidelines* as including practice or care guidelines for pain management developed by nationally recognized organizations, specialty societies, and government-sponsored agencies, policies, guidelines, or regulations adopted by state boards.

Given the persistence of the problem of undertreatment of pain, a statute that affirmatively endorses the treatment of intractable pain is appealing. However, regulatory statutes that encourage specific conduct and protect those who engage in it present problems when grafted onto an existing statutory framework. Why should legislators extend immunity from prosecution for pain management and not for any other treatment? Usually, medical practice statutes put physicians on notice of what conduct is not permitted. In New York, the state with which I am most familiar, and in most other states, state medical practice acts define the conduct that is not permitted, thus the terminology, misconduct. The Model State Medical Practice Act developed by FSMB conforms to this format. It sets forth thirty-five definitions of misconduct, all of which are prohibited actions.

The statutes on intractable pain deviate from this format in that they affirmatively permit specific conduct. State legislators and medical board executives and members will ask why pain management should be singled out for different statutory treatment. Proponents of these statutes will need persuasive data to convince skeptical state legislators and regulators that the problem can best be solved by enactment of a statute.

In addition to the statutes, a number of states have adopted guidelines or regulations for pain management. Nine states have guidelines and three have regulations (see Table 2) that give varying degrees of guidance to physicians. The guidelines and regulations seek to raise the consciousness of the medical profession and to reassure licensees that they should treat pain, malignant and nonmalignant, with the appropriate medications.

Regulations and guidelines can contribute to effective pain management by giving guidance in how to treat patients, but they raise two issues. One is how to give practitioners sufficient specificity so that the guidance is useful and, at the same time, sufficiently flexible to allow altering the specifics as additional information is made available by experts. For the twelve states that have adopted regulations or guidelines on intractable pain, the regulations and guidelines typically address assessment of symptoms, treatment, record keeping, informed consent, and the problems of under- and overprescribing. Some are more complete than others, and this variability raises the question of whether a sufficiently high level of specificity can be achieved through the process of individual states adopting guidelines or regulations.

The other issue is what amount of regulatory authority should be invested in this standard of care. The Pain Relief Act proposes "accepted guidelines," which include those developed by nationally recognized organizations, specialty societies, and so forth; but some states may not cede to an organization the authority to create guidelines.

A distinct legal difference also exists between the regulatory authority of guidelines and regulations. Guidelines have no force of law. Guidelines are merely suggestions for conduct. *Black's Law Dictionary* defines *regulation* as a "rule or order having force of law issued by executive authority of government." In evaluating the relative utility of guidelines versus regulations, regulations have the advantage of being legally enforceable. They give patients reassurance that physicians must treat pain according to a standard

of care or face consequences from the state medical board. Regulations can give the state medical board the authority to discipline a physician who fails to treat pain as well as provide guidance on how to treat. Guidelines cannot be enforced.

On the other hand, regulations are more cumbersome to change than guidelines. Each state has a legally mandated process for amending regulations, which does not apply to guidelines. Nevertheless, given the novelty of state medical boards requiring a course of conduct for a given therapeutic treatment and the work required to create such a document, if a medical board is weighing the relative merits of a regulation versus a guideline, a regulation is preferable because it is enforceable.

Evaluate how best to inform and educate licensees about pain management

Michigan has opted for a statute that requires continuing education in pain management for health care professionals as part of the license renewal process. The state has created an interdisciplinary advisory committee to review the effectiveness of these requirements for the legislature. The Massachusetts legislature established a commission in May 1993 to study how pain is managed in that state. The commission's report was issued in January 1997; it contained a series of recommendations, including statutory amendments. Some states, for example, Minnesota, have held training sessions with panels of experts to discuss current practices in prescribing controlled substances. Many state medical boards have published articles in their newsletters about pain management and about prescribing opioids to treat intractable pain. However, systemic educational efforts are needed to ensure that physicians become knowledgeable and willing to treat pain patients.

The fear of unwarranted prosecution, which is at the heart of physicians' concerns, can be counteracted only if the actions of state medical boards are appropriate and if these boards educate physicians about pain management. Educational efforts by the boards will have the effect of both increasing the physicians' knowledge and reassuring physicians that the boards understand what the appropriate treatment of pain is.

Conclusion

No patient should suffer in pain because of unnecessary barriers to treatment. The responsibility and initiative to educate health care professionals about effective pain management must be shared by all institutions and organizations that deliver health care, regulate health care delivery, train health care professionals, and represent health care professionals and consumers. Attention should also be paid to ensuring that medical students understand the importance of pain management and are knowledgeable about effective treatments as well as regulatory procedures. Research should be conducted or existing research examined, so that each state has documentation about the undertreatment of pain in its health care systems and about the difficulty patients have in obtaining effective pain management. State controlled-substances statutes that inaccurately define addict and addiction should be amended.

State medical boards can do their part by educating their members and their licensees, by taking the steps necessary in their states to eradicate barriers to more effective pain management, and by ensuring that they are not contributing to the barriers. Statutes that affirmatively endorse the treatment of intractable pain are problematic. Regulations and guidelines may focus attention on the undertreatment of pain, but they are unlikely to correct serious deficiencies of knowledge among state medical board members and their staffs. The use of pain management experts to train board members and their staffs and to serve as expert witnesses in disciplinary hearings would immediately improve the quality of the decisions made in cases involving the prescribing of controlled substances, particularly opioids, for the treatment of pain.

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David E. Joranson, Aaron M. Gilson, "Improving Pain Management Through Policy Making and Education for Medical Regulators"

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Physician concern about regulatory scrutiny as a barrier to appropriate prescribing for pain management has been identified and studied. A 1991 Pain Research Group survey demonstrated a need to provide updated information about opioids and pain management to state medical board members. Indeed, a national survey even showed a need to provide more education about pain management to oncology physicians. Two approaches for responding to these concerns have been undertaken in several states by the state medical boards and the pain management community: (1) the development and adoption of administrative policies designed to bring disciplinary standards in line with clinical practice; and (2) the creation of education programs for state medical board members and staffs. Each can have a substantial impact on removing real and perceived regulatory barriers to effective pain relief.

Guidelines

State medical boards have a duty to protect the public from improper prescribing, but they also have an interest in promoting public health. Although the use of opioid analgesics to manage chronic noncancer pain is being reassessed clinically and scientifically, some state medical boards have already recognized and responded to the need to clarify their policies regarding prescribing for pain. Policy making and clarification by the boards themselves, especially when produced through collaboration with the pain management community, can significantly contribute to harmonizing clinical practice and regulatory policy.

In some instances, boards have adopted guidelines on the use of controlled substances in pain management to address inappropriate uses of opioids and unprofessional prescriptive practices. More recently, however, some boards have begun using guidelines to address physicians' fear of board investigation or discipline for prescribing opioids for chronic noncancer pain. Indeed, respondents to the 1991 national survey of U.S. medical board members supported a call for medical boards to clarify their policies. Most members who were surveyed said, at that time, they would discourage a physician from prescribing opioids for a patient with chronic noncancer pain, and approximately one-third said they would investigate the practice as a potential violation of law.

Medical board guidelines vary considerably. The attitudes of medical boards toward the use of opioids ranges from "It is generally accepted in current medical therapy that it is inappropriate to treat nonmalignant pain with narcotics on a routine basis" to "[T]he Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable nonmalignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed."

The conditions and qualifications in medical board policies on opioid use also vary considerably. The pain management community may not support some provisions, such as: a requirement that two physicians diagnose intractable pain; the recommendation or requirement of "drug holidays"; the use of undefined terms such as *addict or habitue*; or restrictions on prescribing to the entire class of people who use drugs nontherapeutically, even if they have pain.

In 1993, the Medical Board of California (MBC) undertook a review of "malprescribing." A special task force on appropriate prescribing heard testimony that physicians avoid prescribing controlled substances, including "triplicate" drugs, for patients with intractable pain out of fear of discipline by MBC. As will be illustrated, MBC then took several actions to emphasize that it supports appropriate prescribing of opioids for pain, including intractable pain.

MBC initially provided information about the then new Agency for Health Care Policy and Research clinical practice guidelines on acute and cancer pain to all state physicians and encouraged them to apply the guidelines in clinical practices. MBC cosponsored the California Summit on Effective Pain Management held in 1994, which recommended that the triplicate prescription system be replaced with a less invasive and more efficient system. Further, MBC adopted a proactive policy statement, "Prescribing Controlled Substances for Pain," and announced that it would publish guidelines to help physicians avoid investigation

when they used opioids to manage intractable pain. The resulting guidelines were issued in 1994 and have been used as a model by other medical boards.

The new California guidelines were constructed on the fundamental principles that guide professional medical practice, as generally recognized by medical boards. The MBC guidelines do not establish specific prescribing or pain management parameters; rather, they afford California physicians a framework within which a physician may prescribe without concern about interference from regulatory agencies. Drafts of the guidelines were reviewed by medical and legal experts, adopted unanimously by MBC, and disseminated to all California physicians. The American Pain Society (APS) endorsed the California guidelines in 1995.

Subsequent to the development of the MBC guidelines, complementary guidelines were adopted by the boards of nursing and pharmacy. Similar guidelines were then adopted by the medical boards in Florida, North Carolina, and Washington. Further guidance for state policy is contained in the recently approved "Consensus Statement on the Use of Opioids for the Treatment of Chronic Pain," available from the American Academy of Pain Medicine and APS. This statement was developed by a joint task force of the two organizations chaired by Dr. J. David Haddox.

Legislation

Legislative activity has also led to policy addressing pain management; it presents special risks. Some benefits might be gained from legislation in increased public and professional awareness that opioids can legitimately be used to treat chronic pain. Legislation may also help to ease some physicians' fears of ultimate disciplinary action, though perhaps not board investigation and its attendant legal costs. However, standards of medical practice would be established by elected officials, for example, who may or may not involve organizations that represent medicine and science in the drafting process. Opening the door to legislative consideration of medical issues must be carefully considered because this process is political and complex, and the consequences are difficult to foresee. A serious concern is whether legislatures and some regulatory boards might even further restrict rather than expand access to opioids for chronic pain management. Conversely, some policies focus exclusively on use of opioids and fail to acknowledge the legitimate use of nonpharmacological methods of pain management.

Unfortunately, some specific restrictions could create problems for good clinical practice if they are uniformly applied or enforced. These restrictions include: (1) defining medical use of opioids for intractable pain as a therapy of last resort (as is the case in many current intractable pain statutes); (2) application of intractable pain treatment acts to all intractable pain patients, including those with cancer; (3) implying that opioids may be used for pain only in cases where the cause of pain cannot be removed; (4) excluding pain patients who use drugs for nontherapeutic purposes; (5) requiring an evaluation of every patient by a specialist in the organ system believed to be the cause of pain; and (6) requiring a signed informed consent form in every case where controlled substances are used to relieve pain.

State legislatures will probably continue to consider intractable pain policy. With the national focus on assisted suicide likely to return to the states following the United States Supreme Court decision, state legislators may become even more interested in legislative action to improve pain management. With the development of model pain legislation by the American Medical Association, it is possible that state and local medical societies will become interested in such legislation. Professional pain organizations should closely monitor the development of state pain policy and provide information and assistance to their elected representatives.

Alternatively, once a particular state has identified inadequate treatment of pain as a problem, a state pain commission could be established. Such a commission could enlist the assistance of other state agencies, could produce a careful study of the problem, and could guide the development of a variety of needed responses, including educational programs and administrative policy making. This process can provide a foundation for change. However, the greatest risk with government studies is the lack of funding for follow-up and implementation.

Education for medical boards

Discussions of the findings of the 1991 survey of medical board members with the Federation of State Medical Boards of the United States (FSMB) led to cooperative efforts to sponsor educational workshops,

"Pain Management in a Regulated Environment." The workshops provided various state medical boards with an educational forum in which to review and discuss advances in knowledge and practice and to develop board guidelines concerning the appropriate medical use of opioids in pain management and related disciplinary policy. Six workshops were presented between 1993 and 1996: one for the Alabama Board of Medical Examiners in 1993, four regional workshops for board members from various state medical boards in 1994 and 1995, and one for the North Carolina Board of Medical Examiners in 1996. A total of 125 board members attended these workshops, and they represented thirty-two state medical boards and approximately 20 percent of the total number of board members. The seminars were sponsored by FSMB in cooperation with the Pain Research Group (now the Pain & Policy Studies Group). Members of APS and the American Society for Addiction Medicine served as faculty.

Such workshops may stimulate a change in policy. For example, following these workshops, the medical boards in Alabama and North Carolina developed and disseminated new guidelines for prescribing controlled substances for pain. In most cases, the purpose of these post-seminar guidelines has been to clarify that the medical board accepts use of opioids to manage chronic noncancer pain. They also outline each board's basic expectations of prescribers.

Conclusion

Medical board guidelines, like intractable pain treatment statutes and regulations, can encourage better management of intractable pain. Guidelines vary from state to state, and some ultimately restrict appropriate prescribing. Before medical boards issue new guidelines for prescribing opioids for intractable pain, they should evaluate the situation in their state and systematically review the issues, seeking advice from experts who can provide accurate information about current clinical practice and pharmacology. New guidelines, if needed, should reflect current knowledge about pain management and permit flexibility in the management of patients with intractable pain. The present positive dialogue that is developing among medical boards, pain clinicians, and addiction specialists should be enhanced in order to ensure the development of rational and consistent intractable pain treatment guidelines at the state level.

In our experience, professional licensing boards are keenly interested in improving public health. As the demand for better pain management increases and medical boards learn about medical advances in pain management, they may revise their disciplinary policies. But these revisions should take place systematically and in consultation with members of the pain management community.

Acknowledgment

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Linda Farber Post, Jeffrey Blustein, Elysa Gordon, Nancy Neveloff Dubler, "Pain: Ethics, Culture, and Informed Consent to Relief"

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As medical technology becomes more sophisticated, the ability to manipulate nature and manage disease forces the dilemma of when *can* becomes *ought*. Indeed, most bioethical discourse is framed in terms of balancing the values and interests *and* the benefits and burdens that inform principled decisions about how, when, and whether interventions should occur. Yet, despite advances in science and technology, one caregiver mandate remains as constant and compelling as it was for the earliest shaman--the relief of pain. Even when cure is impossible, the physician's duty of care includes palliation. Moreover, the centrality of this obligation is both unquestioned and universal, transcending time and cultural boundaries.

Although universally acknowledged, pain is a complex phenomenon for both the patient and the caregiver, influenced as much by personal values and cultural traditions as by physiological injury and disease. The multiplicity of factors that influence the perception and expression of pain take on special importance in the

health care setting, where pain becomes an interpersonal experience between the sufferer and the reliever. How pain is signified by the patient and understood by the provider determines in large measure how it is valued and, ultimately, how it is treated.

If the perception of and response to pain are to be understood in a useful way, they must be examined in the context of culture, gender, imbalances of power, morality, and myth. This paper will not address the anthropological dimensions of pain--how patients of different cultural and ethnic backgrounds experience and express pain. Rather, we focus on professional attitudes toward pain management, and we suggest there is a moral imperative for relieving pain that transcends (1) the expressed wish to be treated, and (2) the informed consent process. Even though informed consent has become the lens for viewing the doctor-patient relationship, it is not a singularly useful model in the treatment of pain. We argue that the ethical duty of beneficence is sufficient justification for providers to relieve the pain of those in their care absent rejection of analgesia by a capacitated patient.

Accordingly, this discussion will be framed by the following questions:

- What is the philosophical significance of pain and how is it reflected in the physician's obligation to relieve pain?
- Do ethnicity, gender, age, and race make a significant difference in how people perceive, experience, and react to pain?
- Do the differing values placed on the expression and relief of pain affect the interaction between patients and providers, or the effectiveness of care giving?
- How are the ethical principles of autonomy and beneficence implicated in the pain experience?
- How is the process of informed consent changed by incorporating issues of pain?

The moral imperative to relieve pain

Pain, suffering, and choice

During the past thirty years, the ethic of medical care in the United States has changed radically. The traditional paradigm was largely paternalistic--the doctor would decide what was medically appropriate and present it to the patient, not for consent, but for assent. Today, the governing ethic is anti-paternalistic. Bioethicists, philosophical and legal scholars, physicians, and judges all have made a powerful case for patient autonomy and have objected to paternalistic medicine on the grounds that it supplants patient values and preferences with those of the provider.

Given personal idiosyncrasies, frequent denial of reality, and greater or lesser dependence on others for strength and direction, autonomy becomes very complex. Because it focuses primarily on self-determination and liberty, with less attention to the needs for support, autonomy alone cannot provide a sufficiently rich doctrine to inform the doctor-patient relationship. In defining the moral framework for this relationship, we must consider other values.

Principled analyses of the doctor-patient relationship suggest that it is the dual obligation of physicians to respect and promote the autonomy of their patients and to protect and enhance their well-being. This obligation of beneficence requires physicians to do good and prevent harm, the list of goods typically including prolongation of life, restoration of function, and relief of pain and suffering. Whether something is counted as a good or a harm depends on the specific circumstances, the patient's values, and some shared notions of suffering and well-being.

Despite its subjective quality, the experience of pain is both real and reverberating. As one writer describes it,

> Pain is dehumanizing. The severer the pain, the more it overshadows the patient's intelligence. All she or he can think about is pain: there is no past pain-free memory, no pain-free future, only the pain-filled present. Pain destroys autonomy: the patient is afraid to make the slightest movement. All choices are focused on either relieving the present pain or preventing greater future pain, and for this, one will sell one's soul. Pain is humiliating: it destroys all sense of self-esteem accompanied

> by feelings of helplessness in the grip of pain, dependency on drugs, and being a burden to others. In its extreme, pain destroys the soul itself and all will to live.

The lay, medical, and bioethics literatures tend to equate pain and suffering, and most people assume that the greater the pain, the greater the suffering. However, as Dr. Eric Cassell points out, pain and suffering are, in fact, distinct phenomena. He gives as an example childbirth: although the pain can be extreme, many women regard the experience as joyous and life-enhancing. Conversely, some people may suffer greatly even when they are not in great (physical) pain, perhaps in anticipation of pain.

When pain and suffering are closely related, Cassell claims, it is for one or more of the following reasons: the pain is overwhelming; the patient does not believe the pain can be controlled; the source of the pain is unknown; or the pain is apparently without end. Suffering is preeminently a threat to the personhood of patients--a threat not merely to their lives, but also to "their integrity as persons." Only when one's continued existence is threatened in this way can the experience of pain properly be said to cause suffering. Thus, when patients are told their pain cannot be managed, diminished, or controlled, they frequently experience suffering because they believe their personal intactness is jeopardized. In some instances, emotional isolation adds to patients' suffering, as when the physician suggests that the pain is only imagined.

Common parlance often distinguishes among physical, spiritual, or emotional pain, that is, between pain that is physiological or psychological in origin. But, whether we speak of different kinds of pain or of pain and suffering, the relief of physical pain is regarded as a primary moral goal of medicine because of its intimate connection with patient well-being.

As a threshold matter then, it is necessary to understand this relationship between pain and well-being, and why the obligation to serve patient well-being encompasses the obligation to relieve pain. "No one wants to be in pain," is a rather careless way of expressing a commonly shared assumption. It is important to distinguish between (1) wanting to live a life that is free of pain, and (2) wanting to be relieved of the pain one is currently experiencing. Given a choice between living pain-free and living with some admixture of pain and pleasure, it would not seem wise to choose the former. A life without pain would be rather shallow and uninteresting, and would leave one vulnerable to the injury and disease that pain often signals.

The obligation of physicians to relieve pain is what moral philosophers call a prima facie or conditional obligation, something physicians ought to do unless some other duty or moral consideration takes precedence. One such consideration is the refusal of a decisionally capacitated patient to have her pain relieved. Pain control may be welcomed by some who are capable of choosing, while others may view it as yet another instance of unwarranted physician paternalism. For example, if a patient with the capacity to make health care decisions says she wants the pain to continue because for her it has redemptive meaning, then the obligation to relieve pain is overridden. The patient is saying that, although in pain, she is not suffering or that the suffering is chosen and accepted.

A more common reason for electing to experience pain is the choice of cognition and affective response over relief. Many patients refuse higher doses or more potent pain medication because they do not want chemically to compromise their intellectual and emotional awareness. For these individuals, the choice is a deliberate and delicate value-based balance between relief of pain and erosion of personality.

But suppose a patient is incapacitated and clearly in pain. Should efforts always be made to provide relief? Does the incapacity automatically abrogate choice? Although honoring the wishes of a capable individual shows respect for the person, withholding relief from one who cannot decide or communicate is a form of abandonment, indefensible for caregivers. Compassion, then, is the basis of a moral presumption favoring pain relief. It will always tip the balance in favor of pain relief if the patient can no longer choose or if the patient's intent is in question. Pain is not always devalued, but it is something we need a compelling reason not to treat. The most humane approach, and the one to which caring physicians are disposed, is to relieve pain until evidence of patient refusal is forthcoming.

The response of caregivers to patients' pain behaviors

Just as patients' attitudes about and responses to pain are affected by their personal and cultural values, so are those of their caregivers. For example, physicians' clinical judgments about pain are influenced by

group-based factors, including age, gender, race, and ethnicity, as well as physical appearance, with the more attractive patients perceived as experiencing less pain than those who are physically unattractive.

The effect of age and gender stereotyping on how patients are medicated for pain was studied by Karen Calderone. Because physicians and nurses saw women as more emotionally labile and prone to exaggerating pain complaints, they were given analgesia less frequently and sedatives more frequently than male patients. These gender distinctions were not related to the patients' sensory perceptions, only to their overt expressions of pain, with women seen as more expressive. Both men and women under sixty-one years of age received more frequent pain medication than their elders; younger men were medicated most frequently and older women least frequently.

A 1993 study by Knox Todd et al. of patients treated for long-bone fractures at the UCLA Emergency Medicine Center found that Hispanics were twice as likely as non-Hispanic whites to receive no medication for pain. Todd et al. explain the distinction as (1) culturally influenced expressions of pain, and (2) the failure of health care professionals to recognize the presence of pain in patients whose cultural backgrounds differ from their own. The study suggests that the difference in how doctors managed the two groups may occur either when pain is assessed or when analgesia is ordered. A subsequent study of the same population found that, although physicians did not assess pain differently in the two groups, their estimates of pain in both were consistently lower than those of the patients themselves. The ethnically based inequity in pain treatment was found again in the follow-up study, with Hispanics receiving analgesia less often than non-Hispanic whites. Nevertheless, Todd et al. reject the notion that cultural bias among physicians aware of similar pain in two patient groups could account for their undertreating one group.

The balance of power between provider and patient is yet another theme in the pain management interaction. So long as therapeutic control is vested in the caregiver, the patient remains the passive victim of pain. In examining the "regularly and systematically inadequate" treatment of severe pain in hospitalized patients, Dr. Marcia Angell asserts that the standard "prn" (administer as needed) regimen makes patients powerless supplicants, forcing them to endure pain until the next scheduled opportunity to ask for medication. Even then, she concedes, the request might be inhibited by the patient's "desire to please the medical staff and not be a nuisance." The result is an adversarial, rather than a therapeutic, relationship. Dr. Angell suggests a more flexible regimen, which prevents rather than treats pain and better balances the treatment benefits and risks.

Caregivers' responses to their patients' pain are also shaped by their understanding--often misunderstanding--of pain and the agents for its relief. Numerous studies have demonstrated that inadequate professional education and the susceptibility of health care providers to misconceptions and unfounded fears about opioid addiction and related regulation undermine effective analgesia. These misconceptions are also shared by the lay public. A 1993 survey found that 92 percent of Americans accept pain as an inevitable part of life, with most having either experienced severe pain or observed it in someone close to them. Even so, most Americans were found to reject what they believe to be effective medicinal pain relief because they fear overreliance and/or addiction. These fears, plus concerns about legal liability, are reflected in the stringent laws regulating drug prescription and the suspicion of health care providers who see patient requests for pain relief as drug-seeking behavior related to addiction. The unsurprising result is the routine undermedication of even terminally ill patients.

These interesting and counterintuitive findings may have their roots in beliefs that are not peculiarly American, but common to Western cultures generally. Commenting on the Agency for Health Care Policy and Research practice guidelines on pain, Patricia Crowley asserts that the current health care standard of treating acute pain retroactively rather than preventively stems from two well established myths of Western culture: (1) enduring pain is a character-building, moral-enhancing endeavor, and (2) patients who receive pain medication will become addicted to the drugs.

Pain, suffering, and death

An article by Dr. Timothy Quill presents the obligation of health care providers to help terminally or severely ill patients achieve a "good death." He focuses on the needless suffering of those whose experiences have left them terrified of a bad (painful, prolonged, lonely) death. He argues that it is the provider's duty to relieve pain, suffering, terror, and fear of abandonment. Dr. Quill notes that, given data that 50 to 100 percent of pain can be effectively relieved, dying patients must be reassured and then provided effective pain control while being helped to remain as alert as possible.

An oft-quoted article by Dr. Sidney Wanzer et al. about the care of hopelessly ill patients examines an array of accepted treatment policies, their implementation and deficiencies, including pain management. Dr. Wanzer et al. assert that not only should patients be treated aggressively with pain medication, as much and as often as necessary, but they must also be reassured early in the terminal disease process that they will not be allowed to suffer.

Physician-assisted suicide, a subject of growing concern within the lay, medical, and legal communities, also has implications for any discussion of pain attitudes, behavior, and management. A substantial body of evidence indicates that many if not most people who request assistance in ending their lives are really seeking their doctors' help in ending their pain, and that what patients fear more than the prospect of death is the prospect of life with unrelieved pain. The clear implication is that severe and unremitting pain may make even death seem preferable, and that such a request may in fact signal the need for more aggressive palliation rather than assisted suicide.

Decision making, informed consent, and pain

Autonomy, beneficence, and consent to pain relief

The ethical principles that classically inform a bioethical analysis are *autonomy* (respecting the privacy and self-determination of the individual), *beneficence* (providing benefits and balancing risks or burdens against those benefits), *nonmaleficence* (avoiding harm), and *justice* (fairly distributing the risk, burdens, and benefits). Pain and its relief implicate especially autonomy and beneficence, and discussions of pain management and informed consent highlight the tension between the two principles.

Autonomy underlies decision making that gives priority to the values and wishes of the individual when they are not legitimately restricted by the rights of others. It is only when the individual's wishes are obscure, inaccessible, or overridden by competing principles that the judgment of others is substituted. This concept of the individual and independent self is accorded near reverence in Western cultures. Indeed, commentators challenge the attempt of American bioethics to define its concepts and frame its discourse in terms so unbiased and culturally neutral as to create the impression of universality. In fact, its principles reflect mainly Western values and it is asserted that patient autonomy is almost exclusively a product of the Western preoccupation with individuality and self-control.

The principle of beneficence underlies obligations to benefit others and the ways in which these obligations are fulfilled. These behaviors include actions that defend, prevent harm, and rescue those in danger. Beneficence is the principle with arguably the greatest resonance for care-givers, whose mission is to provide patients with therapeutic benefit and shelter from harm. These notions of nurturing and protecting reach fullest expression in caring for those who are the most vulnerable, conferring a special responsibility on those who care for the very young, the very old, those who are suffering, and those who are incapable of looking after themselves.

In the health care setting, autonomy is reflected most prominently in the doctrine of informed consent. This paradigm of self-determination is the process of knowledgeable and expressed choice whereby a decisionally capacitated individual, who has been apprised of the risks and benefits of a proposed treatment, grants explicit permission for or rejects a particular intervention. It is by now well established theory, although not always well established practice, that the contemporaneous or prior expression of treatment wishes by a capacitated individual controls the health care decision. The doctrine of informed consent represents the legal embodiment of the right to self-determination in health care. In addition, it guides the process of medical decision making by defining the parameters of the patient-physician dialogue.

The roots of informed consent

The ethical and legal roots of informed consent provide the basis for its power. The notion of informed consent was initially grounded in the law of assault and battery, holding that any unconsented-to touching constituted an unlawful act. The subsequent trend toward negligence rather than battery reflected judicial dissatisfaction with the artificial notion that consent either did or did not happen. The doctrine of negligence permits a nuanced examination of whether the discussion reflected the risks and benefits that were material to this patient. Although modern law treats failure to disclose as an action in negligence, the patient's right to make knowledgeable health care decisions has expanded the focus to make the informed consent process

act as a protection of privacy and autonomy, rather than as a barrier to negligent failure of a "duty to warn." Finally, in the current climate of malpractice, cost containment, and managed care, informed consent has become a defensive weapon of risk management.

Courts hearing negligence cases based on absence of informed consent tend to rely on an objective reasonable person standard, which assumes that the reasonable person is one holding Western values and favoring Western-defined approaches to medical decision making. In contrast, a subjective standard requires physicians to disclose information relevant to the particular patient and judges whether *that* individual would have reached the same decision absent disclosure. Ultimately, a subjective standard evokes a richer notion of informed consent by considering the diverse ways and the different contexts in which patients and physicians communicate and make decisions. Although courts have not adopted a pure subjective standard, recent statute and case law have considered the importance of patients' particular values in making medical decisions and suggest a trend toward a more patient-centered notion of informed consent.

During the past thirty years since the explosion of the various rights movements, the ethical principle of autonomy has become the major support for individual empowerment and self-determination. In virtually every social sphere, the aim has been to level the playing field by eliminating power imbalances caused by race, gender, class, and education. In the health care setting, the twin notions of patient as partner in medical decision making and patient as informed health care consumer reflect patient autonomy as the controlling principle. Simultaneously, malpractice litigation involving informed consent placed the wishes of the patient, rather than the conventions of physician practice, at the core of possible liability for negligent disclosure. In time, patients came to see informed consent as their offensive security against physician overreaching, while doctors perceived it as their defensive protection against charges of malpractice--the medical equivalent of a pre-nuptial agreement. The unfortunate result is an adversarial rather than therapeutic climate, with informed consent as the weapon of choice.

Because of its ethical and legal supports, informed consent is now broadly accepted as indispensable to patient rights, the violation of which essentially invalidates the legal and ethical propriety of medical treatment. However, autonomy itself is a doctrine that may be imposed on individuals whose values support a more communally experienced ethic. The elevation of patient autonomy to its preeminent position has increased the potency of explicit patient permission to the point where it effectively trumps all other avenues for determining and implementing what is in the patient's best interests. Exalting the patient's right to exercise autonomy has correspondingly restricted the doctor's discretion and opportunities for therapeutic intervention. Ironically, the pursuit of greater patient power has actually devalued the physician's duty of beneficence. The obsession with autonomy has led to a fetish of informed consent that substitutes delivery of consumer-chosen health care for the provision of patient-oriented health *caring*.

Barriers to a universal and inflexible informed consent requirement

Although the principle of autonomy, manifested through knowledgeable consent, is routinely required for therapeutic interventions, we argue that, for at least two reasons, informed consent should not be invoked in decisions about pain management. Substantial evidence confirms that the key elements in the pain experience (the perception and expression of pain; the relief-seeking behavior and response to it; and the capacity or willingness to assume decisional responsibility) are highly complex and dependent on numerous variables. The informed consent doctrine depends entirely on the elevation and expression of self-determination. Under these conditions, requiring that pain management rely exclusively on or be constrained by an affirmative act of patient consent threatens to undermine the very foundations of the caregiver duty of beneficence.

Legally valid informed consent can only be provided by a decisionally capable individual. The presence or absence of decisional capacity is evaluated according to the specific decision under consideration, with a higher level of capacity generally required for those decisions carrying greater risks. If a person clearly has the capacity to understand and process his situation, reference values, consider the consequences, and make his wishes known, then his decision should control and his consent is required.

This analysis does not apply to the formerly capable and communicative individual. Often, when choices must be made, age or illness has destroyed the abilities of reasoning and expression. If this incapacitated individual, while still capable, had articulated treatment wishes prospectively through advance directives (by

appointing a health care proxy agent, by executing a living will, or by leaving explicit oral instructions), those directions should be respected and implemented even though capacity has lapsed.

Likewise, people unable to grant informed consent either because they have lost capacity through age or infirmity and left no advance directives, or because they never were capacitated (such as newborns, children, and mentally retarded adults) are excluded from the requirement to provide consent. Their health care decisions must be made by surrogates using substituted judgment (based on what is known about the patient's values and preferences) or the best interest standard (based on the surrogate's evaluation of the patient's welfare). For these individuals, many of whom require pain control, the informed consent requirement is fulfilled by others acting on their behalf, although some notion of their assent may be important. In these situations, surrogate refusal of pain treatment is ethically problematic, especially if it is based on fear of addiction. Consider, for example, the young man who is dying of end-stage AIDS. He is wasted, obtunded, and writhing in pain. His mother, who cannot accept either his diagnosis or his prognosis, refuses to allow him to be given pain medication because she does not want him to become addicted. In this instance, the caregivers would have to overrule a mother's misplaced attempt to protect her son in order to do what is, in fact, in his best interests.

The second reason why informed consent cannot always frame health care determinations about pain is that individual autonomy is not the universal paradigm for decision making. The architecture of informed consent represents a legal attempt to find and secure the patient's voice in medical deliberations and to equalize the balance of power between patients and their physicians. It is also increasingly a risk management strategy to protect the institution from later liability by demonstrating that the risk of negative outcomes was known and accepted by the patient. The patient voice sought, however, echoes a notion of autonomy based on Western cultural values that favor the individual over the community, self-reliance over dependence, action over passivity, scientific rationality over spirituality, and forthrightness over harmony. This doctrine focuses on the right--often, it seems, the obligation--of the individual to make decisions concerning medical treatment. In addition, it advocates candor and assertiveness regarding the disclosure of medical prognosis, treatment options, and their risks and benefits. Finally, it promotes the active participation of the individual patient, rather than family, community, or other surrogates, in medical treatment decisions.

It is important to bear in mind that this preoccupation with patient autonomy does not apply universally. Western values often clash with world-views held by non-Western cultures that may place greater emphasis on spirituality, family and community, or authority and social stratification. These communitarian ethics may value less assertive decision-making processes and encourage deference to physician judgment. By mechanically applying narrow Western-defined doctrines of autonomy and informed consent, American law deprives non-Western cultures of their proper position of power and actually devalues the notion of autonomy. The very meanings of health, illness, and healing are shaped by cultural values. Sensitivity to these distinctions encourages critical thinking about how they affect medical care discussions and decisions, as well as the experience and expression of illness, disability, and discomfort--issues that form the essential background for considerations of pain control.

Finally, it has been suggested that, when a person is in extreme pain, truly informed *consent* may not be possible. Caregivers have an ethical obligation to inform the capacitated patient about the salient effects and side-effects, benefits and risks of pain management options, especially those related to use of narcotics, to help the patient to reach an informed *decision* about treatment. But, despite the best efforts to provide relevant information and elicit the patient's values and wishes, severe pain may erode an individual's cognition and autonomy. A patient suffering such pain often can think of nothing except relief and will agree to anything that will provide it. For such patients, truly free and informed consent may be an illusion.

Exceptions to informed consent

Inevitably, the rigid express permission requirement has necessitated the invention of ways to get around it in order to provide patients with the care they need. These loopholes are embodied in three well established exceptions to the informed consent requirement: medical emergency, therapeutic privilege, and waiver.

In an emergency, the patient might be precluded from consenting because of unconsciousness or incapacity, and life-saving treatment delay or failure would result in harm so grave as to outweigh any potential harm of a proposed treatment. Under these critical conditions, courts agree that physicians may dispense with informed consent, so long as they conform to practices customary in such emergencies. Some courts even hold that in emergencies, consent is implied.

The second exception falls within therapeutic privilege, under which information may be withheld from the patient when, in the physician's judgment, disclosure of the information would itself be harmful to the patient. Some commentators strongly criticize this exception, arguing that it risks destroying the theory of informed consent and signals a return to medical paternalism.

The third recognized exception, waiver, provides either statutory or judicial support for patients to give up their right to receive and to act on medical information. The notion of waiver acknowledges that some patients lack the confidence to analyze risk data or prefer to depend on their physician's professional judgment; others simply prefer not to hear adverse information, or choose to depend on family judgment. Patients may waive their right to receive relevant information, and they may also waive the right to make a specific decision or any decision at all. As a result, the waiver mechanism accommodates diverse cultural values by respecting alternative approaches, such as family-centered decision making and deference to physician authority. Because the patient remains in control of the decision-making process by choosing when to allow others to make the actual treatment decision, the waiver also upholds the value of self-determination. In theory, then, the law allows patients who understand their right of waiver to relinquish their right to grant informed consent so long as the waiver is given with full information and without coercion. In fact, in the health care setting, waiver is rarely used because risk management concerns require the patient's expressed consent to protect the institution from liability.

In addition to these customary exceptions, it has been necessary to create other varieties of nonexpressed consent to validate the notion that treatment has been authorized. Most relevant are *presumed consent*, derived from a general theory about the way rational people behave, and *implied consent*, inferred from the actions of a particular individual in a specific circumstance. The presumption underlying both exceptions appears to be that, because people will invariably opt for treatment to restore health, individuals who are physically or cognitively incapacitated can also be presumed to prefer health and would consent to therapeutic intervention if they were able to do so. Thus freed from the need to obtain expressed informed consent, the physician's twin duties of beneficence and nonmaleficence trigger a default posture that supports treatment.

Informed consent and the management of pain

Predating the current emphasis on patient autonomy, the duty of beneficence has been a core value of the healing professions, incorporating the relief of pain as well as the promotion of healing. It has been claimed that relieving pain is a "moral duty, based on both beneficence and respect." And yet, despite this ethical mandate, it has been repeatedly demonstrated that caregivers routinely, often deliberately, undermedicate patients in pain.

Aside from the few exceptions noted, informed consent is required for most treatment interventions, especially those that are invasive or carry more than minimal risk. It is interesting, therefore, that pain control interventions are traditionally exempt from this requirement. As a matter of practice, physicians are expected to ask patients about drug allergies and inform them about the proper dosages and potential side-effects of prescribed pain medications, and pharmacists are required to enclose warning labels and information about synergistic effects; but there is no formal requirement that patients give informed consent for analgesia. It is true that pain medication is routinely given on a prn basis, which requires patients to request the medication and thereby affirmatively signal their consent to receive it. Recently, patients have also been given the option of patient-controlled analgesia, whereby they actively participate in the decisions about and administration of their own pain medication, usually through a self-regulated intravenous pump. Finally, it is certainly plausible that a patient who does not want pain medication at all and is able to communicate that preference would have that refusal honored. The crucial point here is that these circumstances apply only to patients who are decisionally capacitated or at least alert and articulate enough to determine and communicate whether they want pain relief.

The more challenging situation involves those patients who are decisionally incapacitated or unable to communicate, and who require surrogate decision-makers to authorize treatment interventions. Perhaps an individual has left an advance directive stating that, should he become incapacitated and be in pain, no analgesia is to be administered. Even in the absence of contemporaneous refusal or explicit advance instructions, enough may be known about him, about his values and beliefs, to determine that he is or was the sort of person who finds meaning in pain.

However, the duty to honor the refusal of analgesia issued prospectively by a currently incapacitated patient is significantly weaker than the duty to honor the contemporaneous refusal of a capacitated patient. It has even been argued that the currently incapacitated patient may be so different from the formerly capacitated one that they are in effect two distinct people with different interests. However, when there is no advance directive and inferences must be drawn about what the patient would want, not making an effort to relieve the patient's current pain is even more ethically problematic than proceeding without expressed instructions. It would be both irrational and inhumane to withhold relief because of inability to request it. Analgesia is routinely given when patients are *understood* to be in pain. Physicians and nurses, using their well developed skills of observation and clinical judgment, evaluate patients' body language, cardiac and respiratory function, facial expressions, emotional signals, and verbal and nonverbal cues, and do what they believe their patients would want done for them.

Applying the primacy of patient autonomy to the issue of pain management, one could argue for yet another exception to the informed consent requirement that would be applicable to an incapacitated patient in pain. It is generally acknowledged that, except for the rare instances when pain is believed to have some character-building or redemptive quality, people desire to be rid of the pain they are currently experiencing, even though some may choose to endure it as the only alternative to diminished consciousness. If *presumed consent* is that which can be expected of most people, then the incapacitated postoperative, terminally ill, or grievously wounded person can be presumed to consent to pain relief intervention. Likewise, if *implied consent* is that which can be inferred from an individual's conduct, then the incapacitated person writhing and moaning in pain certainly can be believed to consent to the administration of analgesia. It is a short step from there to the concept of an implied waiver by which an incapacitated patient in pain is understood to delegate decisional authority regarding analgesia. It could even be argued that an individual who seeks medical attention is, by definition, seeking relief of the presenting pain and/or implying consent to the relief of any pain resulting from treatment.

Although it is tempting to subscribe to these arguments and suggest that pain management requires no expressed informed consent because the patient is believed to have given presumed or implied consent, or waived consent altogether, we decline the opportunity to use such flimsy contrivances. Rather, we submit that providing relief from pain is central to the very notion of healing and, for that reason alone, it requires no exceptions or intellectual artifice for its validity. Indeed, we agree with the following sentiments regarding implied consent:

> [I]t is quite obvious that implied consent is a legal fiction. Clearly there is no consent in this [emergency medical] situation. Rather, the law gives physicians a *privilege* to provide treatment in emergencies, even in the absence of consent, in order to promote other important societal goals besides individual choice--namely, the preservation of life or the restoration of health.... [I]n such a situation a physician has an obligation to do what is best for the patient.

We do not accept the proposition that the caregiver's twin duties of respect for persons and beneficence are mutually exclusive in the realm of pain management or even necessarily conflicting. Rather, we argue that principled and compassionate caring embraces both the respect for and the protection of persons. It has been claimed that beneficence can legitimately outweigh autonomy when it is clearly in the best interests of the patient and, especially, when the treatment interventions are consistent with the patient's own therapeutic goals. We would go further and argue that the current obsession with patient autonomy risks courting a form of patient abandonment in which healers are prevented from healing, and those in pain are denied relief because expressed consent is lacking. To succumb to such reasoning demonstrates a lack of respect for patients and places caregivers in danger of sacrificing beneficence on the altar of autonomy.

The persuasive argument that the individual's diminishing cognitive capacity changes her needs and goals carries the implicit notion that decisions, such as advance health care directives, made by a formerly capacitated person are not necessarily appropriate for the now incapacitated person, and caregivers should not be bound to honor these directives if they are clearly contrary to the patient's current best interests. The implications for pain management are compelling. The person who, never having experienced severe pain, says, "No matter what happens, I do not want pain medication," may feel very different about the need for analgesia when experiencing an attack of renal colic. The caregiver might well be justified in giving more weight to the individual's current relief-seeking behavior than any prior theoretical statements. Likewise, an incapacitated patient's signals of pain can and should speak as clearly as any articulated request for relief.

Conclusion

Pain, although universally acknowledged, is experienced in ways that vary with ethnicity, gender, age, class, and condition. The implications for health care are obvious. If culture is a lens through which the world is perceived and understood, each refraction will depend on the particular prism employed. People bring their culturally determined values and behaviors to all consequential experiences, especially interpersonal encounters. The meaning pain holds for sufferers and the person(s) attending them determines the intensity with which it is perceived and the response it calls forth. Substantial differences among patients, families, and caregivers in their perceptions of and reactions to pain can affect significantly the ways in which pain is expressed, the ways in which relief is requested, and how it is administered.

The importance of decision making is nowhere more striking than in the health care setting. Issues of control and choice, influenced by cultural background, current illness, and perceived obligations, are brought into sharp focus as people from different vantage points grapple with complex and emotion-laden dilemmas. The twin duties of autonomy and beneficence assume special significance in this context. Self-determination, valued most highly in Western cultures, is articulated in the doctrine of informed consent, required for almost every therapeutic intervention. Yet, the duty of beneficence, reflected in the caregiver mandate to relieve pain, can be seen to transcend boundaries of culture and even self-determination. Ultimately, compassion speaks in the most forceful and universal tongue to relieve pain.

Robyn S. Shapiro, "Health Care Providers' Liability Exposure for Inappropriate Pain Management"

Journal of Law, Medicine & Ethics, 24, no. 4 (1996): 360-64.

Recent studies have exposed the startling inadequacy of health care providers' knowledge about and practice of effective pain management. For example, in one study, it was reported that 79 percent of a random sample of 454 medical-surgical inpatients experienced pain during hospitalization, and that 58 percent of patients with pain considered the pain horrible or excruciating. In another study, 67 percent of 2,415 randomly selected hospitalized patients had pain during the twenty-four hours prior to being interviewed, and 50 percent reported pain at the time of the interview. In a study of seriously ill hospitalized patients reported in 1996, half of the patients complained of pain, and one-sixth reported that they experienced extremely severe pain at least half the time. According to one literature review, 75 percent of cancer patients have reported suffering pain, and one study estimates that 25 percent of cancer patients die with severe unrelieved pain. Chronic nonmalignant pain has been described as "an extremely prevalent problem," and over two-thirds of nursing home residents experience serious pain.

Yet, despite the clinical data, experts contend that pain can be controlled for a great percentage of patients. For example, a study evaluating the World Health Organiza-tion's guidelines for the relief of cancer pain reported that only 3 percent of the 401 dying patients in the study experienced severe pain at the time of death, and recent articles in the clinical literature contend that in up to 90 percent of cancer patients, pain can be controlled by relatively simple means.

Decisions in two recent lawsuits suggest that proper pain management is beginning to evolve as an element of the standard of care required of health care providers. A North Carolina jury awarded $15 million in damages to the family of a patient whose dying days were made intolerable on account of pain mismanagement; and the Georgia Supreme Court affirmed a patient's right not only to have unwanted medical treatment discontinued but also to receive medication to manage his pain at the time. Moreover, in coming years, pain management practice guidelines, the Pain Relief Act of the Project on Legal Constraints on Access to Effective Pain Relief, and continued professional and public recognition of the importance of pain control likely will broaden liability exposure of health care providers who inappropriately manage pain.

Malpractice considerations for providers

In any professional negligence action, the claimant must prove (1) that the provider owed a duty of care to the patient; (2) that the provider violated that duty by failing to exercise reasonable care in providing treatment; (3) that the patient's injury was proximately caused by the provider's negligent conduct; and (4)

that the patient suffered a compensable injury. The scope of the provider's duty to the patient, referred to as the *standard of care*, is the degree of care customarily exercised by providers who are qualified by training and experience to perform similar services under comparable circumstances. In other words, the standard of care is defined, in large part, by reference to the customs of the profession.

Typically, a jury or other fact-finder determines case-by-case the standard of care that should have governed the provider's conduct, by evaluating evidence, often conflicting, about what standard of care should have been followed in the treatment of the patient. Evidence introduced to assist the fact-finder in determining the standard of care is primarily the testimony of experts, which in turn relies on learned treatises, articles in medical journals, and research reports.

Case law to date

In a 1990 North Carolina negligence lawsuit, for the first time a health care provider was held liable for failure to treat pain appropriately. In this case, *Estate of Henry James v. Hillhaven Corp.* , the jury awarded $15 million in damages to the family of Henry James, whose dying days were made intolerable by the decision of a nurse and her employer, a nursing home, to withhold or reduce pain medication ordered by the patient's physician. Mr. James was admitted to the nursing home with prostate cancer that had metastasized to his left femur and to his spine. When Mr. James entered the nursing home, he was not expected to live more than six months. The patient's personal physician prescribed 7.5 cc of oral morphine elixir every three hours as needed for pain. However, a nurse employed by the nursing home assessed Mr. James as being "addicted to morphine," and, on that basis, without the advice, consent, or orders of a physician, instituted an alternative "pain-management" plan. This plan minimized the use of pain medication by substituting a mild tranquilizer and delaying or withholding altogether the administration of analgesics.

The lawsuit focused on health care providers' responsibilities to ensure the proper administration of pain medications in appropriate doses. Mr. James's family proved that the failure of the nurse and her employer, the nursing home, to meet this responsibility caused Mr. James to experience physical pain and suffering as well as emotional and mental anguish--"inhuman treatment" inflicted "without regard to the consequences and without care as to whether or not the patient received analgesic relief and without care that the result and procedures were torture of the human flesh."

During the trial, medical and nursing experts testified about the proper standard of care for the administration of opioid analgesics and specifically about the administration of morphine for the relief of intractable pain. In addition, a nurse specializing in quality assurance for nursing homes testified that health care institutions have an obligation to ensure that their health care providers properly manage pain.

The $15 million jury verdict was resolved by settlement among the parties in an undisclosed amount. In his summary statement approving the settlement, Judge Cy A. Grant reiterated that:

> "[Mr. James's family] does not allege that the conduct of the defendants caused the death of [Mr. James], but only that the conduct of the defendants caused [him] increased pain and suffering...."

State v. McAfee also illustrates the law's recognition that pain management is an integral component of appropriate medical care. In this case, Mr. McAfee, a quadriplegic who was incapable of spontaneous respiration, sought court approval for discontinuation of his respirator. The Georgia Supreme Court affirmed his right to refuse medical treatment and held that he was also entitled to have a sedative administered at the time:

> Mr. McAfee's right to be free from pain at the time the ventilator is disconnected is inseparable from his right to refuse medical treatment. The record shows that Mr. McAfee has attempted to disconnect his ventilator in the past, but has been unable to do so due to the severe pain he suffers when deprived of oxygen. His right to have a sedative (a medication that in no way causes or accelerates death) administered before the ventilator is disconnected is a part of his right to control his medical treatment.

Although the focus of this case was the patient's right to refuse unwanted medical care, this ruling implies that at least in Georgia, providers may be held accountable for not providing measures that will help to ensure the patient's comfort.

The impact of clinical practice guidelines

Aside from these cases, courts may in the future be more inclined to include proper pain management in the standard of care required of health care providers because of the development and publication of pain management practice guidelines. The U.S. Department of Health and Human Services Agency for Health Care Policy and Research (AHCPR) was created in 1989 to "enhance the quality, appropriateness, and effectiveness of health care services and access to such services." To that end, under the authority of the Office of the Forum for Quality and Effectiveness in Health Care, AHCPR develops clinical practice guidelines to help physicians, educators, and health care practitioners prevent, diagnose, and treat diseases and other health conditions in the most effective and appropriate manner. AHCPR guidelines are developed by multidisciplinary panels of health professionals and consumers, on the basis of systematic reviews of relevant scientific evidence as well as professional judgment.

In 1992, AHCPR released its *Acute Pain Management Guidelines*, and in 1994 it released its *Cancer Pain Management Guidelines*. Both guidelines call (1) for a collaborative, interdisciplinary approach to the care of patients with pain, (2) for an individualized pain-control plan developed and agreed on by patients, their families, and providers, (3) for ongoing assessment and reassessment of patients' pain, (4) for the use of both drug and nondrug therapies to manage pain, and (5) for explicit institutional policies on pain management. The guidelines also include specific pain management approaches and techniques, sample pain assessment tools, discussion of pain control in special populations, and scientific evidence regarding pain management interventions.

Practice guidelines addressing a variety of medical matters have been used in malpractice litigation as evidence of the standard of care. For example, in *Davenport v. Ephraim McDowell Memorial Hospital*--a malpractice action against a hospital, an anesthesiologist, and others--one of the plaintiff's proposed exhibits was *Guidelines for Standards of Care and Management Standards in the Post Anesthesia Care Unit*, published by the American Society of Post Anesthesia Nurses. The appellate court indicated that such a document did not rise to the level of a learned treatise; nonetheless, it agreed with the trial court's ruling that the document would be helpful as a guide for measuring care. Similarly in *Rodriguez v. Jackson*, the court held that a government manual concerning tuberculosis treatment was admissible but not conclusive evidence about the standard of care; and in *Cornfeldt v. Tongen*, the Minnesota Supreme Court held that the trial court had committed a clear error by refusing to admit into evidence the Joint Commission on the Accreditation of Healthcare Organizations' guidelines on administering anesthesia.

The admissibility of practice parameters to establish a standard of care was recently bolstered by the U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* In that case, the petitioners, two minor children and their parents, alleged that the children's birth defects had been caused by their mothers' prenatal ingestion of Bendecdin, an anti-nausea prescription drug marketed by the respondent. The respondent moved for summary judgment, claiming that Bendecdin did not cause birth defects in humans. Merrell Dow supported its claim with the affidavits of a physician and an epidemiologist who reviewed various studies involving patients who had taken the drug and concluded that Bendecdin was not a factor. The petitioners produced eight experts who concluded that Bendecdin could cause birth defects. This conclusion was based on animal studies, chemical structure analysis, and the unpublished reanalysis of previously published human statistical studies. The district court ruled that the petitioners' expert opinion evidence was inadmissible because it was not based on technique generally accepted as reliable in the scientific community, and so it granted summary judgment for Merrell Dow. The U.S. Court of Appeals for the Ninth Circuit affirmed, citing *Frye v. United States* for the rule that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community. The U.S. Supreme Court reversed and remanded, however, noting that at least in a federal trial, the "general acceptance" test is not a prerequisite for the admissibility of evidence. Rather, the Court said, in accordance with the Federal Rules of Evidence, that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," a witness qualified by knowledge, skill, experience, training, or education may testify thereto. As a result of *Daubert*, it appears that the evidentiary standard for scientific testimony is now more flexible, and that this could lead to wider admissibility of practice parameters to establish the standard of care in medical malpractice lawsuits.

Some state statutes expressly accommodate the admissibility of practice guidelines as evidence of the standard of care. A Vermont statute on malpractice arbitration panels, for example, provides that guidelines drafted by professional organizations, licensed hospitals, or quality assurance programs recognized by state law are admissible as evidence on whether the provider satisfied the standard of care.

In other states, health care providers in malpractice actions have been permitted to use compliance with practice guidelines as a conclusive defense. In Maine, for instance, although claimants may not rely on the fact that a physician failed to adhere to practice parameters drafted by statutorily created "medical specialty advisory committees" to establish negligence, physicians may be absolved of any negligence if they prove that they did follow the parameters.

Absent specific statutory direction, the evidentiary weight of practice parameters admitted as evidence in a malpractice case will vary according to (1) the degree of acceptance and authority of the practice parameter; (2) how closely the parameter fits the clinical situation at hand; and (3) the validity of the research and analysis underlying the parameter. In light of AHCPR's reputation and comprehensive guideline development methodology, it is likely that its pain management guidelines (if applicable to the situation) would be admitted and carry substantial evidentiary weight in proving the standard of care in a pain management malpractice case.

The impact of state intractable pain statutes, the Pain Relief Act, and enhanced professional and public awareness

In addition to pain management guidelines, growing numbers of state intractable pain statutes, the Pain Relief Act, the development of institutional pain management policies, and enhanced public recognition of the importance of pain management will broaden liability exposure of health care providers who mismanage pain.

Several states have enacted statutes that address pain management. The provisions of these statutes vary. Some provide that physicians may treat patients *other than* chemically dependent persons for pain with controlled substances; others specify that a physician may administer controlled substances for intractable pain if he/she does so in accordance with accepted medical practice standards; and one statute requires patients' prior written consent to pain medication.

The Pain Relief Act, developed by the Project on Legal Constraints on Access to Effective Pain Relief, a research project of the American Society of Law, Medicine & Ethics, will help to improve and further this state legislative movement. The Act's most significant provisions simply state that

> Neither disciplinary action nor state criminal prosecution shall be brought against a health care provider for the prescription, dispensing, or administration of medical treatment for the therapeutic purpose of relieving intractable pain [when that provider] can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline....

Health professionals undertreat pain for different reasons, one of the most important being their fear of legal penalties, especially disciplinary action. Sixty-nine percent of physician respondents in a California survey stated that the potential for disciplinary action had made them more conservative in their use of opioids in pain management, and one-third reported that their patients may be suffering from neglected, treatable pain. In addition, Dr. Russell Portenoy's recent review of the literature finds that "available data suggest that medical decisionmaking regarding the use of opioids continues to be unduly influenced by regulatory policies and fear of regulators."

The Pain Relief Act aims to increase patient access to effective pain management by removing the threat of inappropriate legal liability and disciplinary action against health care professionals. To the extent that the Act is adopted by states and is successful in its goal, it will alter pain management practice and, accordingly, the standard of care as established by clinicians' expert testimony in malpractice litigation.

The growing incidence of pain management policies in hospitals and long-term care facilities, and enhanced public consciousness about the ability and need to manage pain are additional factors that will help to change clinical practice and, consequently, the standard of care. Analogously, in recent years, public awareness was important in establishing the legal presumption against the use of restraints in nursing homes. Until recently, the practice of using restraints was ubiquitous in nursing homes. In the past several years, however, professional and public perceptions have shifted, and use of physical restraints in many instances is now considered unnecessary, improper, or even abusive. With numerous epidemiological studies demonstrating significantly increased chances of bad clinical outcomes with prolonged use of restraints, and subsequent professional association initiatives, consumer advocacy activities, and federal law specifying

residents' rights to be free from unnecessary restraints, more institutional long-term care facilities have moved toward reduced restraints.

Along the same lines, it appears that changing attitudes toward pain management are changing pain management practices, and that these changed practices will set the standard of care in malpractice litigation. Increasingly, expert testimony will reflect that appropriate pain management is an integral component of professional custom, leaving the health care professional who deviates from that standard exposed to claims of negligence.

Conclusion

AHCPR's *Acute Pain Guidelines* note the ethical obligation to manage pain and relieve suffering, which is at the core of the health care professional's commitment to his/her patients. The standard of care to which health care professionals are held in law should mirror their ethical obligations to patients. Pain management guidelines, the Pain Relief Act, and growing recognition among health care providers and the public about the possibilities and importance of pain control will help establish appropriate pain management as a component of the standard of care--which will help to ensure patients of more competent and compassionate care.

Loring Conant, Arlene Lowney, "The Role of Hospice Philosophy of Care in Nonhospice Settings"

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Many advances in public health and medical technology have contributed to the improved well-being and overall longevity of Americans. Such benefits, however, have been offset by a change in the nature and prolongation of the dying process. Daniel Callahan offers a challenge to caregivers in his observation of "violent death by technological attenuation," and he sets an agenda to identify a more appropriate approach to the needs of the dying.

Over the past quarter century, hospice has increasingly been used as a resource for care at the end of life. However, according to 1995 estimates by the National Hospice Organization (NHO), hospice care presently accounts for only about 15 percent of the care of terminally ill patients in the United States. We will review issues of access and use of hospice services and examine the various institutional, professional, societal, and cultural barriers to hospice principles of care, and consider various options to promote optimal care at the end of life. We think the underlying principles of an interdisciplinary hospice model of care provide a framework of care for the dying patient and are applicable in various settings.

Terms

Several terms require definition. *Hospice services* provide support and care for persons in the last phases of incurable disease so that the dying may live as fully and comfortably as possible. Hospice recognizes dying as part of the normal process of living and focuses on maintaining the quality of remaining life; it neither hastens nor postpones death. An underlying tenet of hospice is that with appropriate care and a caring community sensitive to their needs, patients and their families may be free to attain a degree of mental and spiritual preparation for death that is satisfactory to them. The hospice team is an interdisciplinary group of professionals, with expertise in palliative pain and symptom control, who attend to the psychosocial needs of both the patient and the family.

According to the World Health Organization (WHO), *palliative care* is the active total care of patients whose disease may not respond to curative treatment. The goal of palliative care is to achieve the best possible quality of life for patients and their families. It affirms life and regards the dying process as normal. It emphasizes relief from pain and other distressing symptoms, integrates the physical, psychological, and spiritual aspects of patient care, offers a support system to help the patient live as actively as possible until death, and helps family members cope during the patient's illness and in their own bereavement.

The terms *hospice* and *palliative care* are used interchangeably in the literature, and represent the shared goals of meticulous attention to optimal pain and symptom management. Hospice care is distinguished from palliative care in that hospice care is rendered at the end of the palliative care spectrum. From its roots as a social movement, hospice has nurtured the evolution and maturation of palliative care.

Hospice and palliative care

Points of entry to hospice and palliative care differ. Admission criteria for Medicare- and Medicaid-funded hospice programs require that a physician's prognosis be six months or less, that care be delivered mostly in the home, and that the patient no longer be pursuing curative interventions. In contrast, palliative care can be initiated earlier in the disease process, while the patient may be receiving aggressive curative treatments, with the opportunity to benefit from skilled symptom management and supportive services. Hospice remains the appropriate option when the burden of treatment outweighs the benefit to the patient and the patient's prognosis is less than six months.

Although growing in public and professional awareness, palliative care is not commonplace in academic medicine, due to lack of knowledge about the needs and care of the dying and to inadequate funding for palliative care research and education. As a result, the provision of hospital-based palliative care services for those with advanced disease has been a relatively novel concept until recently.

Access and use

NHO estimates that 390,000 patients and their families were cared for in the United States by hospice programs in 1995. This represents only a small percentage (15 percent) of the approximately 2.4 million Americans who die each year. Dr. Christine Cassel and Bruce Vladeck cite several reasons why only a relatively small percentage of dying patients are served by hospices: beyond the obvious problem of limited availability, many physicians are reluctant to articulate the realities of terminal illness because they feel it robs patients of hope. More relevant, perhaps, are the declining lengths of stay: one recent study reported a median stay for 6,450 hospice patients in five states as being only thirty-six days. Our societal aversion to death also contributes to our inability to integrate hospice and palliative care into our health care system on a large scale. Other recent studies demonstrate that hospice services are underutilized, that referrals to hospice service are made very late, and that patients are uninformed about the availability of appropriate terminal care.

According to recent studies, the predominant racial group among hospice patients is Caucasian, totaling 85 percent, followed by African-American at 9 percent, and Hispanic at 3 percent. The remaining 3 percent are not identified. These percentages, which are consistent with other data, reflect a significant issue of minority access to hospice services. Hospice programs face a formidable challenge to represent their diverse communities, in board and staff makeup, and in patient populations served.

Challenges

The Robert Wood Johnson Foundation funded the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT), a research project including over 9,000 patients at five major teaching hospitals. Significant deficiencies were identified in the care given to the dying in those hospitals. Close to 60 percent of the population still dies in hospitals.

Although the SUPPORT project encouraged the use of advance directives and nurse advocacy to guide and communicate treatment decisions, patients' preferences were either unknown to their physicians or ignored. Comprehensive attempts to change the practice of professionals caring for the dying were profoundly ineffective. In the last three days of life, more than 50 percent of the patients in the study were in moderate to severe pain more than half of the time, and 38 percent of the study population spent at least ten days in an intensive care unit (ICU) on life-support systems.

A central tenet of American health care is the patient's right to refuse treatment. The health care professional's ethical responsibility is to relieve pain and to prevent unnecessary suffering. The goals of care are to address the patient's physical comfort and peace of mind, and to provide the opportunity for a peaceful death, including those patients "who have serious and eventually fatal conditions, regardless of their likely survival time."

But despite the goals of medicine, a disparity exists between patient preferences and actual practice, and it is reflected in the poor outcomes for the majority of dying patients studied in a variety of settings. Mildred Solomon and her researchers found that the majority of nurses and physicians they surveyed agreed with the patient's right to forgo treatment, yet the same study also revealed that the majority of dying patients were overtreated with technology but their pain was undertreated. The results of Solomon et al. and SUPPORT present both a challenge to and an opportunity for hospice professionals to assist in developing a new paradigm for optimal terminal and palliative care programs in hospital, long-term, and home care settings.

Moreover, a questionnaire, given to 864 physicians participating in the Eastern Cooperative Oncology Group, revealed that 50 percent of the physicians sampled rated the pain management in their own practice settings to be fair to very poor. This 1993 study, surveying attitudes and practices in cancer pain management, observed that the major barriers to optimal pain management included inadequate pain assessment, and a combination of physician reluctance to prescribe opioids and patient reluctance to report pain and take opioids, in the context of a common phenomenon: nurses and physicians not always believing their patients when they report pain.

According to Dr. Charles Cleeland et al., four factors predict health caregivers' underassessment and undermedication for pain: (1) opposite gender, (2) age greater than seventy years, (3) minority status, and (4) an appearance of well-being, that is, not appearing distressed.

Dr. Kathleen Foley and her colleagues have provided a thoughtful framework for those caregivers attending terminally ill patients, which is applicable to care settings outside the tertiary care center. Their Taxonomy of Suffering addresses seven "Common Shortcomings" in terminal care, all of which have been well documented in the literature:

(1) inadequate physical symptom control;
(2) undiagnosed depression or anxiety (major depression occurs in up to 25 percent of terminally ill patients);
(3) unaddressed existential distress;
(4) untreated psychological distress in family members;
(5) untreated family fatigue (which is particularly critical because the greatest fear of the dying is being an intolerable burden on caregivers);
(6) lack of skill in effective communication, particularly where cultural differences exist; and
(7) unrecognized professional health care provider fatigue and/or moral distress.

The interdisciplinary model

The hospice interdisciplinary model has been implemented in various settings: home, nursing home, and hospice residence. The challenge is to provide such a model of comprehensive services for the terminally ill in acute and long-term care settings, where patients enter for diagnosis, treatment of disease, and palliation.

The Cleveland Clinic Palliative Care Program (PCP) was the first program in the United States to provide comprehensive and coordinated care for those with advanced disease in outpatient, inpatient, home health, and hospice care settings. Implemented in 1987, PCP began as an inpatient consultation service. In 1988, an outpatient clinic, research program, and community board of advisors were added, and thereafter a hospice home care service, a cancer home care service, and a dedicated inpatient unit. The mission of PCP is to provide excellent care for patients with advanced cancer and their families throughout illness and grieving. A business plan to monitor costs and reimbursements and a marketing approach to improve referrals and education have been developed.

Another model program, the Palliative Care Consultation Service of the Medical College of Wisconsin, began clinical activities in 1993. Its goals are to provide symptom control, to assist with end-of-life decision making, and to serve as a resource for appropriate discharge planning for all dying patients. Pain and end-of-life decision making are the most frequent reasons for consultation. The service's clinical and educational roles have received widespread acceptance by the medical, nursing, and support staffs.

JoAnn Dalton and colleagues have demonstrated in North Carolina how palliative principles of care can be successfully implemented in a rural setting. And for those communities where the hospital remains the focus of care for the terminally ill, Betty Ferrell et al. propose creation of the position of pain resource nurse to direct the interdisciplinary palliative care team and to provide a hospital-wide network of support.

A two-year quality improvement project on dying in various settings has recently been initiated at three hospitals in Vermont and New Hampshire. A principal investigator, Dr. Sarah Goodlin, is identifying patient and family values and other aspects of the dying experience to help define appropriate and desirable goals of care. Critical pathways are being developed with a focus on coordinating care in hospital, nursing home, home health, and hospice settings. Dr. Goodlin recommends collaboration of ethics committees with professionals in their agencies to improve care of the dying.

Conclusion

Optimal care at the end of life can be offered in a variety of settings, including the home, the skilled nursing facility, the subacute unit, and the residential and assisted living setting. For those who die in the hospital, step-down units and palliative care centers can offer more appropriate levels of care where the focus changes from curative to palliative symptom control. With such care integrated into community and tertiary health care systems, major barriers to timely referrals may be overcome. In addition, the hospice palliative care model offers enormous potential for enhancing the educational opportunities for nurses, physicians, social workers, chaplains, therapists, and allied caregivers.

The burdens of technology and institutional standards that prolong pain and suffering make dying a more complex, protracted, and fearful process. Dying well requires changing unrealistic goals of cure and life prolongation to the reasonable goal of a peaceful death.