Medical Education Systems, Inc.

PAIN

Pain

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Learning Objectives

Upon successful completion of this continuing education course, you will be able to:

1. Define and discuss the term *pain*, including the different *t*
2. *ypes* of pain experienced by patients.
3. Discuss the *etiology* of pain.
4. Identify and discuss the various medications and protocols recommended today for the care of patients in pain.
5. Identify and discuss the new standards issued by the JCAHO regarding the management of pain in a variety of settings.
6. Compare the protocols and philosophies regarding pain management found in the U.S. and several other Western countries.
7. Identify and discuss the various state, local, and federal regulations relating to the management of pain.

Introduction

Pain in Medical Care Today

How to define "Pain" and how it should be "managed" is currently a very ***topical issue*** of interest among those in the health care profession all around the world. Patients in pain are now seen to have well-defined rights to receive adequate relief from their suffering. Both patients and care providers have been protesting the antiquated approaches to the care provided in relation to pain in recent years. Today, things are changing dramatically, and this Continuing Education Unit explores those changes, why they are happening, and how they may affect you.

In Chicago, Illinois, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has announced new standards and requirements for the assessment of pain in accredited hospitals and other healthcare settings. The new standards are impacting hospitals, nursing homes, home health care agencies, behavioral health facilities and health plans.

This CEU provides you with updated information on a wide variety of *pain-related* issues, including: definitions, etiology, medications, protocols (current and proposed), government regulations at all levels, international standards, and provides you with an in-depth look at the newly developed standards from JCAHO.

Some facts you should know about pain and the scope of the problem in the United States:

- 90% of all diseases may be associated with pain
- 65 million Americans suffer painful disabilities at any given time
- 61% of medical directors of pain centers are anesthesiologists
- It is estimated that of all pain practitioners, fewer than 10% are proficient in more than 8 out of 130+ diagnostic or therapeutic (treatment) procedures relative to pain
- It is possible that an individual that is untrained and unskilled in the treatment or surgery that is being offered can legally treat you!
- 75% or more of patients in hospitals hurt and suffer more than they should.
- Thirty-one million Americans have low back pain at any given time. One half of all working Americans admit to having back symptoms each year. One third of all Americans over age 18 had a back problem in the past five years severe enough for them to seek professional help. And the cost of this care is estimated to be a staggering $50 **Billion** yearly--and that's just for the more easily identified costs! (Data according to the American Chriropractic Association)
- 40 million visits to health care providers and prolong hospital stays are due to pain. (Last two items according to NIH)

When dealing with such an enormously complex topic such as “pain” one finds it necessary to look at how pain impacts the life process from the **beginning** to the **end**. From the birthing process to the now often drawn out process of dying. Regarding birth, there are some issues on which healthcare profession don’t always agree:

Management of labor pain: promoting patient choice - Editorial

American Family Physician, Sept 15, 2003

In 2001, the Nature and Management of Labor Pain symposium (see Leeman, et al., (1) in this issue) brought together family physicians, obstetrician--gynecologists, nurse-midwives, childbirth educators, and anesthesiologists for a critical analysis and discussion of systematic reviews on labor pain. (1) The symposium occurred in the context of the increasing use of epidural analgesia, which is now used in almost two thirds of labors in the United States. (2) Presentations showed that epidural analgesia is a more effective pain-relief method than intravenous narcotics, (3,4) the second most common pharmacologic method of pain relief (used in 30 percent of labors). (2,5) In the First National U.S. Survey of Women's Childbearing Experiences, (2) 78 percent of women rated epidural analgesia as very helpful.

Most women in the United States deliver infants in hospitals where epidural analgesia or intravenous narcotics are the only pain-relief options.

Alternative pharmacologic methods for pain relief, including nitrous oxide and paracervical blocks, are used infrequently in the United States. Despite numerous studies showing that use of doulas and continuous labor support results in a de-creased need for medical intervention, improved maternal and newborn outcomes, and increased maternal satisfaction, few women are afforded this option. (6)

Although epidural analgesia clearly is a highly effective and popular method of providing labor analgesia, it has significant potential side effects. Symposium presentations showed that epidural analgesia may increase the length of labor, the need for operative vaginal delivery, and the likelihood of perineal laceration. (4,7) Epidural analgesia can cause maternal fever, with consequent increased use of neonatal antibiotics and sepsis evaluations. (4,7) Whether epidural analgesia results in a higher rate of cesarean delivery or is a confounder based on its use in "difficult" labors remains a point of controversy. Physicians who frequently use epidural analgesia may have a maternity practice style that leads to higher cesarean rates as a result of earlier hospital admission, increased use of oxytocin augmentation, and decreased presence of the physician. (8)

The childbirth survey showed that many women are poorly informed about the potential side effects of epidural analgesia. (2) To make an informed choice, women should be told of the risks and benefits during prenatal care rather than in the midst of labor. Symposium participants acknowledged the scarcity of data about the effects of epidural analgesia on newborn behavior, breastfeeding, and maternal-infant bonding, and they highlighted the need for future research in these areas.

A technologic birthing model that uses labor induction, epidural analgesia, continuous electronic fetal monitoring, and cesarean delivery increasingly dominates labor and delivery wards in the United States and other industrialized countries. Conference participants expressed concern that when institutional epidural rates are high, other methods of labor support, such as childbirth classes, doulas, nurses trained in supporting nonmedicated childbirth, and availability of other pain control modalities, may not be offered. In many hospitals, labor pain management options are limited to epidurals, parenteral analgesics, or rudimentary labor support from overextended nurses. An anesthesiologist at the symposium remarked that "While there may be problems with high epidural usage, in the presence of our nursing shortages and economic or business considerations, having a woman in bed, attached to an intravenous line and continuous electronic fetal monitor and in receipt of an epidural may be the only realistic way to go."

Access to professional labor support is considered a luxury for patients in most U.S. hospitals, and lack of access to epidural analgesia may result in legal action. (9) The issue of patient choice is being used as a pretext for increasing technologic intervention in the birth process. A past president of the American College of Obstetricians and Gynecologists called for the right of a patient to choose cesarean delivery in the absence of maternal or fetal indications, (10) and the American Society of Anesthesiologists suggests closing smaller hospitals that are unable to support universal access to epidural analgesia. (11) However, neither organization advocates a broader range of labor support and pain management options to promote patient choice.

Brazilian women are "choosing" cesarean delivery partly out of concern that they won't receive adequate medical care during labor. (12,13) Similarly, in many hospitals, American women may feel that epidural analgesia is the only real choice they have.

Family physicians providing maternity care may feel "out of the loop" as a result of the predominant use of epidural analgesia for labor pain. The request for epidural analgesia may be conveyed to the anesthesiologist by the nursing staff, with only a perfunctory nod from the primary caregiver. In contrast to this inappropriate trend, the request should be viewed as a consultation. (14) As with any consultation, the family physician has the responsibility to be a knowledgeable advocate for the patient--taking the time to learn which epidural drugs and techniques are used in a specific hospital and understanding their effectiveness, potential side effects, and limitations.

Family physicians can seek ways to learn alternative approaches to epidural analgesia and incorporate them into practice. They, along with other maternity care providers, should be knowledgeable about and supportive of a range of pain management options in their hospitals, birthing centers, and communities. The Family-Centered Maternity Care course sponsored by the American Academy of Family Physicians (www.aafp.org/x14376. xml) offers sessions on labor support, labor positions, and sterile water injections for women with "back labor." Family physicians should support prenatal childbirth preparation and education; these steps are essential to set appropriate expectations for an event that can be a sentinel experience for many women and their families.

Labor and delivery units should not operate on the expectation that every woman will use epidural analgesia during labor. Other choices, such as labor support and doulas, nonpharmacologic pain-relief methods, and pharmacologic pain-relief methods other than intravenous narcotics or epidurals, should be available. We await research into which pain-relief options women would choose if they had a greater range of choices, how these methods can be used most effectively, and how all methods affect the birthing woman, her labor, and her infant. (15)

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When it comes to **"end of life"** there are similarly "issues" to be explored. At the end of 2001, the National Cancer Policy Board released a report entitled "*Improving Palliative Care for Cancer*" in which it stated:

"This year, over 550,000 Americans will die from cancer. At least half will experience pain, nausea, difficulty breathing, depression, fatigue, and other physical and psychological conditions that vastly diminish the quality of their remaining days. Too often, clinicians and hospitals are not trained or mandated to provide good symptom control and supportive therapy to cancer patients, particularly those who are dying. With federal research and training efforts centering largely on trying to cure patients, palliative care is often overlooked."

The report went on to say that, "Despite billions of dollars spent on research in cancer biology and cancer therapeutics, there has been little investment in research that might significantly alleviate the physical and psychological distress of patients at the end of life. The types of distress experienced by these patients are shared, in a temporary or more lasting fashion, with patients being treated for cancer and, at least to some extent, by some who survive the disease....

Patients with advanced cancer typically experience multiple symptoms related to cancer and cancer treatment. These symptoms can include physical (e.g., nausea, dyspnea), cognitive (e.g., delirium, memory problems, impaired concentration), and affective (e.g., depression, anxiety) experiences associated with the disease and its treatments. Symptom severity is related to the extent of disease and the aggressiveness of therapies such as surgery, chemotherapy, radiotherapy, and biological therapies. Common symptoms of cancer and cancer treatment significantly impair the daily function and quality of life of patients. Pain is a good example. When pain is present, it adversely affects patients' mood, activity, and ability to relate to others (Serlin et al., 1995). Similarly, fatigue, gastrointestinal symptoms, cachexia, anorexia, shortness of breath, and psychological distress add tremendously to the distress that patients experience.

At present, the severe distress, multiple symptoms, and inadequate treatment faced by many patients at the end of life are well documented. Several studies have examined cancer-related symptoms in patients with advanced disease. Coyle and colleagues found that fatigue, weakness, pain, sleepiness, and cognitive impairment were frequent symptoms of patients with terminal disease enrolled in a supportive care program. Fatigue (58percent) and pain (54 percent) were the most prevalent symptoms. Donnelly and colleagues prospectively studied the prevalence and severity of these symptoms in 1,000 patients with advanced cancer. Pain, fatigue, and anorexia were consistently found to be among the 10 most prevalent symptoms at all 17 primary cancer sites studied. When pain, anorexia, weakness, anxiety, lack of energy, severe fatigue, early satiety, constipation, and dyspnea were present, a majority of patients rated them as moderate or severe.

As part of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT), McCarthy and colleagues (2000) evaluated more than 1,000 cancer patients during the three days before death and also at one to three months before death, and three to six months before death. As expected, as they progressed toward death, their estimated six-month prognosis decreased significantly and the severity of their disease worsened. Patients' functional status also declined significantly as they approached death, such that most patients had four or more symptoms within the three days before death. Patients with cancer experienced significantly more pain and confusion as death approached. Severe pain was common; more than one-quarter of patients with cancer experienced significant pain three to six months before death and more than 40 percent were in significant pain during their last three days of life. However, dying patients were only modestly depressed and anxious during their last three days of life.

Recent studies have described the prevalence and severity of pain due to cancer and have documented that pain is often under-treated with available analgesics. These studies present a model for the study of other major symptoms, such as depression and fatigue. Approximately 55 percent of outpatients with metastatic cancer have disease-related pain, and 36 percent have pain of sufficient severity to impair their function and quality of life despite current analgesic therapy. Despite national and international guidelines for its management, many patients with pain are not prescribed an analgesic appropriate to the severity of their pain. Evidence suggests that patients in minority groups may have an even greater risk for under-treatment of pain.

Two studies of outpatients with metastatic or recurrent cancer receiving treatment at Eastern Cooperative Oncology Group (ECOG) institutions found that more than 40 percent of those with pain were not prescribed analgesics strong enough to match the severity of their pain A discrepancy between the physician's and patient's rating of the severity of the pain was a major predictor of under-medication for pain. Pain has to be appreciated before it can be treated. In addition, patients seen at centers that treated predominantly minority patients were three times more likely than those treated elsewhere to have inadequate pain management. Other factors that predicted inadequate pain treatment included age of 70 years or older, female sex, and better performance status. These results support the opinion of oncology physicians that poor assessment of symptoms is a major barrier to adequate symptom management.

A recent study (Cleeland et al., 2000) repeated the ECOG study format with physician members of the Radiation Therapy Oncology Group. On average, physicians estimated that two-thirds of cancer patients suffered pain for longer than one month. Assessing a case scenario, 23 percent would wait until the patient's prognosis was six months or less before starting maximal analgesia, indicating a very conservative approach to pain management. Adjuvants and prophylactic side-effect management were underutilized in the treatment plan for the case presented. Perceived barriers to good pain management were very similar to the ECOG study, with poor pain assessment being ranked number one. Compounded by inadequate training for physicians in the palliative treatment of cancer, these problems influence decisions made in the management of incurable cancer and profoundly affect end-of-life care.

In spite of recent concerns over symptom management at the end of life, provoked in large part by the debate over euthanasia, there is substantial evidence that symptoms that could, in principle, be well managed are under-treated, especially for patients who are still in active treatment. There is evidence that many symptoms could be controlled more adequately if we systematically applied the knowledge that we now have about symptom management."

As you can see from the information above, pain presents complex issues for medical professionals from birth to death! Now, let's take a look at what makes **pain** such a complex topic.

Some Definitions and Concepts

Before going into more detailed issues and controversies regarding ***pain,*** we should look some definitions and concepts related to pain:

Pain, unpleasant sensory and emotional experience caused by real or potential injury or damage to the body or described in terms of such damage. Scientists believe that pain evolved in the animal kingdom as a valuable three-part warning system. First, it warns of injury. Second, pain protects against further injury by causing a reflexive withdrawal from the source of injury.

Finally, pain leads to a period of reduced activity, enabling injuries to heal more efficiently.

Pain is difficult to measure in humans because it has an emotional, or psychological component as well as a physical component. Some people express extreme discomfort from relatively small injuries, while others show little or no pain even after suffering severe injury. Sometimes pain is present even though no injury is apparent at all, or pain lingers long after an injury appears to have healed.

Physiology of Pain

The signals that warn the body of tissue damage are transmitted through the nervous system. In this system, the basic unit is the nerve cell or neuron. A nerve cell is composed of three parts: a central cell body, a single major branching fiber called an axon, and a series of smaller branching fibers known as dendrites. Each nerve cell meets other nerve cells at certain points on the axons and dendrites, forming a dense network of interconnected nerve fibers that transmit sensory information about touch, pressure, or warmth, as well as pain.

Sensory information is transmitted from the different parts of the body to the brain via the spinal cord, which is a complex set of nerves that extends from the brain down along the back, protected by the bones of the spine. About as wide as a finger, the spinal cord is like a cable packed with many bundles of wires. The bundles are nerve pathways for transmitting information. But the spinal cord is more than just a message transmitter, it is also an extension of the brain. It contains neurons that process incoming sensory information, and generates messages to be sent back down to cells in other parts of the body.

Information being transmitted between and within the brain and spinal cord travels through the nervous system using both chemical and electrical mechanisms. A message-carrying impulse travels from one end of a nerve cell to another by means of an electric signal. When the electric signal reaches the terminal end of a nerve cell, a gap called a synapse prevents the electric signal from crossing to the next cell. The electric signal triggers the cell to release chemicals called neurotransmitters, which float across the synapse to the neighboring nerve cell. These neurotransmitters fit into specialized receptors found on the adjacent nerve cell, much as a key fits into a lock, generating an electric impulse in the neighboring cell. This new impulse travels to the end of the long cell, in turn triggering the release of neurotransmitters to carry the message across the next synapse. Not all neurotransmitters initiate a message in a neighboring nerve cell. Some specialize in preventing neighboring cells from generating an electrical signal, while others function as helpers, facilitating the message's journey to the brain.

While most of the sensory nerves in the skin and other body tissues have special structures covering their nerve endings, those nerves that signal injury have free nerve endings.

These simple nerve endings specialize in detecting noxious stimuli—a catchall term for injury-causing stimuli such as intense heat, extreme pressure, or sharp pricks or cuts. The nerve endings that detect pain are called nociceptors, and the process of transmitting pain signals when harmful stimulation occurs is called nociception. Several million nociceptors are interlaced through the tissues and organs of the body.

In general, pain can be divided into two categories:

1. nociceptive pain
2. neuropathic pain

Nociceptive pain is that which travels through a normal intact nervous system. Nociceptive pain is often treated successfully with simple pain relieving drugs such as acetaminophen, aspirin, ibuprofen or opioids.

Neuropathic pain is that which travels through an injured nervous system. It is as if the nervous system is reporting its own injury. Patients often describe neuropathic pain as burning, or electric shock-like.

Neuropathic pain is not as responsive to pain-relieving drugs that work in nociceptive pain. However, other drugs such as the antidepressants and anticonvulsants work on neuropathic pain. When evaluating a cancer patient, we often try to determine if the pain is nociceptive or neuropathic. So do not be confused if your doctor starts you on an antidepressant for pain management. Your doctor is not treating depression but is treating your pain with these drugs. In addition to the physical component of the pain, we also evaluate the patient's psychosocial response to the pain. Our pain psychologists are very helpful in treating the emotional response to pain. So if a psychologist is recommended as part of the treatment plan, this does not mean your doctor feels your pain is in all in your head. Psychological counseling together with the medical management of pain can be very effective

With nociceptive pain, an injury triggers pain signals in two types of nociceptors, one with large, insulated axons known as A-delta fibers and one with small, uninsulated axons known as C fibers. The large A-delta fibers conduct signals quickly, and the smaller C fibers transmit information slowly. The difference in the functions of these two fibers becomes obvious to a person who stubs a toe. At first the injured person is aware of a sharp, flashing pain at the point of injury. Generated by the A-delta fibers, this short-lived pain intrudes upon the thoughts and perceptions occurring in the brain. Just as this first pain subsides, a second pain begins that is vague, throbbing, and persistent. This sensation is derived from the C fibers.

Pain information from the A-delta and C fibers travels through the spinal cord to the brain. When it receives the pain message, the spinal cord generates impulses that travel back down to muscles, which lead to a reflexive contraction that pulls the body away from the source of injury. Other reflexes may affect skin temperature, blood flow, sweating, and other changes.

While this reflex action is underway, the pain message continues up the spinal cord to relay centers in the brain. The sensory information is routed to many other parts of the brain, including the cortex, where thinking processes occur.

Psychology of Pain

When messages from pain-generating nerve endings finally reach higher centers in the brain, they are processed much like other forms of perception—that is, the sensory information is integrated with memories, expectations, emotions, and thoughts in order to form a complete perceptual experience. While it seems convenient to think of pain as a simple message that sounds an alarm in the brain, contemporary understanding stresses that pain is much more complicated. The emotional aspects of an injury may be more significant than the extent of the physical damage in determining the perceived intensity of pain.

Each person perceives pain a little differently, and as a result, each person also responds to painful stimulation differently. Pain research specialists have observed a wide variety of subtle variations in pain response. For instance, children are quicker to cry after a relatively minor injury than are adults. Learned cultural behaviors often dominate the way individuals express pain. Older children and young adults are often taught that crying, sometimes viewed as a sign of weakness, is inappropriate behavior, while younger children have no such understanding. Some people are more willing to express pain than others, but this does not mean they hurt more.

Broad cultural differences in pain responsiveness have also been documented. In some aboriginal societies, people undergoing important rituals often incur extreme tissue injury willingly, and typically, pain is not expressed. Male Australian aborigines, for instance, traditionally celebrated passage into manhood with a ritual that involved circumcision, extensive scarring of the chest, and extraction of the two upper front teeth. The initiate was expected to show no reaction to the injury. It may be that the person undergoing the rite managed to suppress expressions of suffering, but it may also be that the individual was able to perceive less pain by making use of natural pain control mechanisms.

Pain Control

The body has many mechanisms that amplify or reduce pain. When cells are damaged, they release chemicals, such as bradykinins and prostaglandins. These chemicals intensify pain sensation both by making nociceptor nerve endings more sensitive and by causing inflammation around the damaged cells. Without these chemicals, nociceptors would cease transmitting pain information as soon as the source of injury was removed. Some scientists suspect that bradykinins activate nociceptors in the first place.

Other mechanisms reduce pain sensation by blocking, or *inhibiting*, the transmission of the pain message to the brain. To alter the pain sensation, the brain and spinal cord release specialized neurotransmitters called endorphins and enkephalins.

These chemicals interfere with pain impulse transmission by occupying the nerve cell receptors required to send the impulse across the synapse. By making the pain impulse travel less efficiently, endorphins and enkephalins can significantly lessen the perception of pain. In extreme circumstances, they can even make severe injuries nearly painless. If an athlete is injured during the height of competition, or a soldier injured during combat, they may not realize they have been injured until after the stressful situation has ended. This happens because the brain produces abnormally high levels of endorphins or enkephalins in periods of intense stress or excitement.

In addition to the body's own mechanisms, humans have devised many different ways to manipulate the body's ability to control pain. Drugs that relieve pain, known as analgesics, usually interfere with pain impulse transmission in the nervous system. Narcotic analgesics, such as codeine, have chemical structures that are similar to the pain-blocking neurotransmitter endorphin. Other drugs that relieve pain alter the way damaged nerves transmit information. Nonsteroidal anti-inflammatory drugs, such as aspirin and ibuprofen, are analgesics that reduce pain by inhibiting the synthesis of prostaglandins, the body chemicals that intensify pain and cause inflammation.

Another way humans control pain is by injection of drugs that temporarily deaden the nerves that transmit pain signals. These drugs bring about anesthesia, a loss of sensation that renders the body completely or partially insensitive to pain, or even touch. Local anesthetics, such as procaine, deaden nerves in a particular area of the body but interfere little with other body functions. General anesthesia renders people unconscious so they do not feel pain at all. People who undergo general anesthesia also have no memory of events that occurred while they were unconscious.

Many people learn to control their pain with strategies that do not rely on drugs or surgery. Some people control the normally involuntary components of pain message transmission using a behavior modification technique called biofeedback. Acupuncture is widely used for pain relief. Many scientists now believe that this ancient medical procedure may trigger the release of endorphins and enkephalins, the body's own pain-inhibiting neurotransmitters. Others suspect that the pain-relieving attributes of acupuncture are due, in part, to a patient's expectation of relief. Although it is not completely understood, physicians and pain specialists have found that when a person suffering from pain expects that a particular procedure—in this case acupuncture—will make their pain subside, it actually does.

In cases where no treatment effectively relieves pain, doctors may recommend a surgical procedure in which pain-transmitting nerves in the brain or spinal cord are severed. Only a small fraction of pain sufferers need such surgical treatment. Another pain-relieving procedure involves placing electrical stimulators on the skin, nerves, spinal cord, or brain to reduce pain sensation.

Some injuries take a long time to heal, and even then, pain does not always completely subside. People suffering from this condition, known as chronic pain, may continue to experience debilitating pain for years, without having any apparent tissue damage. This may be the result of permanent damage to the nervous system.

There is new evidence that the nerves in the spinal cord and brain can alter their connections after severe pain—that is, even after healing, the nervous system never returns to normal. Pain that subsides and then returns periodically, such as headaches or low back pain, also falls under the category of chronic pain. In their search for pain relief, many chronic pain sufferers become dependent on strong painkilling medicines, and they often fall into an endless cycle of pain, depression, and inactivity.

The complexity of human pain often requires a combination of pain therapies to achieve relief. Pain management specialists are usually medical doctors with specialized training in neurology, psychiatry, or surgery who have restricted their practice to the analysis and treatment of pain. Psychologists are usually important members of a pain management team. Many people are turning to alternative healthcare practitioners, such as those that specialize in acupuncture or chiropractic, for pain relief. Often, pain management specialists and practitioners of alternative pain therapies join forces in multidisciplinary pain clinics.

Some Thoughts About Pain

Pain is universal. You can trace its trail through time--from a toothache evident in fossil remains of a human jawbone to today's drugstore shelves packed with pain relievers. Almost half of all Americans seek treatment for pain each year, 7 million from newly diagnosed back pain alone.

Pain is complex. Sometimes it's beneficial. A sharp stab alerts you to injury when you burn your finger, hurt your back or break a bone. But other pain--the day-after-day ache of arthritis or the anguish of cancer--serves no useful purpose, and its relentlessness can become overwhelming.

Above all, pain is unique. The varieties of misery are as many as its sufferers. Your pain is an interplay of your own particular biological, psychological and cultural makeup.

Pain remains the most common source of *suffering.* Its relief—the relief of all symptoms—is the hallmark of care aimed at the relief of suffering. However, it remains true that adequate relief for severe and continuing pain is **unusual** in the modern hospital. There is no longer any excuse, however, for doctors and other health care providers not to relieve pain because so much has been written on the subject—and now even the JCAHO is stepping in.

New insight into these components is changing the concept of pain management. Pain is no longer seen as just a companion of disease or injury. It can become a damaging process in its own right that requires early and aggressive treatment.

In addition, effective management increasingly focuses on attitude as well as medication and other therapies. You must understand the reasons for pain and how to control it.

By working closely with their doctor and health-care team, patients can learn to manage pain and enjoy a more fulfilling family, work and leisure life.

Exercise, relaxation techniques, and physical, occupational and psychological therapies play important treatment and prevention roles. And new drug-delivery systems can keep some types of pain under continuous control. But despite these advances, some painful conditions are still inadequately treated.

The Physical Sensation of Pain

Most pain originates when special nerve endings, called nociceptors (no-si-SEP-turs), detect an unpleasant stimulus. Humans have millions of nociceptors in your skin, bones, joints, muscles and internal organs. There may be as many as 1,300 in just one square inch of skin.

Some nociceptors sense sharp blows, others heat. One type senses pressure, temperature and chemical changes. Nociceptors can also detect inflammation due to injury, disease or infection. Nociceptors use nerve impulses to relay pain messages to networks of nearby nerve cells (your peripheral nervous system). Messages then travel along nerve pathways to your spinal cord and brain (the central nervous system). Each cell-to-cell relay is almost instantaneous, thanks to chemical facilitators called neurotransmitters. These chemicals flow from one nerve cell to the next in less than a thousandth of a second.

Some nerve pathways are faster than others. One type makes connections with many surrounding nerve cells en route. They transmit more slowly. People feel this type of pain as dull, aching and generalized. Another type relays impulses almost instantaneously and signals sharp pain focused in one spot.

Scientists believe that pain signals must reach a threshold before they're relayed. This "gate control" theory holds that specialized nerve cells in your spinal cord act as gates that open to allow pain messages to pass, depending on the strength and nature of the pain signal.

A message-routing section in the brain

Pain signals travel from the peripheral nerves to the spinal cord to your thalamus, a message sorting and switching station in your brain. The thalamus sends two types of messages. One goes to the cerebral cortex, the thinking part of the brain, which assesses the location and severity of damage. The second is a "stop-pain" message back to the injury site to tell local nociceptors to stop sending any more pain messages. Once alerted, the brain doesn't need additional warning. But sometimes, this mechanism fails and pain persists

Meanwhile, the cerebral cortex relays the pain message it received to the brain's limbic center. The limbic center produces emotions, such as sadness or anger, in response to pain messages. The limbic center can affect the way the cerebral cortex perceives pain messages, and can lessen or intensify the pain.

The cerebral cortex also sends messages to your autonomic nervous system, which controls vital body functions such as breathing, blood flow and pulse rate.

Several types of neurotransmitters (proteins and hormones produced in the brain or nervous system) can increase or decrease pain signals. A hormone--one of the prostaglandins--speeds transmission of pain messages and makes nerve endings more sensitive to pain. And a protein called substance P continuously stimulates nerve endings at the injury site and within the spinal cord, increasing pain messages.

Serotonin and norepinephrine (nor-ep-i-NEF-rin) seem to decrease pain by causing nociceptors to release natural pain-relievers called endorphins.

The emotional component

Pain is not simply a matter of passing messages up and down the spinal cord. When a pain signal reaches the brain, it passes through a filter of personal experience. The emotional and psychological state at the moment, memory of past pain experiences, outlook and stress level all affect how a person interprets a pain message and their ability to tolerate it. Upbringing and cultural attitude toward pain also play a role. And age, level of information about the pain, and even lack of sleep may have an impact.

The emotional responses of shock, fear and anxiety can increase the perception of pain. For example, a minor pain sensation, such as a dentist's probe, combined with anxiety can cause undue pain.

But the emotional state can also diminish major pain messages. One pain study compared survivors of a major battle in World War II with men in the general population of a major U.S. city, matched injury for injury. The combat veterans required less pain relief than those in the general population.

People who learn from upbringing and cultural background that the normal response to pain is great suffering and distress actually experience more pain than people who grow up in an environment where pain is often ignored. The common expressions "suffer in silence," "bite the bullet," "grin and bear it," and "no pain, no gain" point to American cultural patterns that discourage acknowledgment of pain.

Types and characteristics of pain

In general, pain is divided into two general categories--acute and chronic.

- ***Acute***--Acute pain is temporary, related to the physical sensation of tissue damage. It can last from a few seconds to several months, but generally subsides as normal healing occurs. Examples include a burn, a fracture, an overused muscle, or pain after surgery. Cancer pain may be long-lasting but acute due to ongoing tissue damage.
- ***Chronic***--Chronic pain lingers long beyond the time of normal healing. Some chronic pain is due to damage or injury to nerve fibers themselves (neuropathic pain). Although it may begin as acute pain, neuropathic pain often develops gradually and becomes chronic pain that's difficult to treat.

  Chronic pain can result from diseases, such as shingles and diabetes, or from trauma, surgery or amputation (phantom pain). It can also occur without a known injury or disease. Like a gate that's blocked open, nerves continue to send pain messages even though there is no continuing tissue damage.

  Chronic pain ranges from mild to disabling and can last from a few months to many years. Significant emotional and psychological components may develop. The essential ingredient is that the chronic pain changes behavior. For example:

A person experiences the actual physical sensation of acute pain--the immediate, sharp stab in arthritic finger joints as they try to open a lid. Next is the emotional response--anger and frustration with fumbling fingers. Eventually, behavior changes may occur. A person may avoid using aching fingers and hands. Hands become weak from inactivity, and the person in pain depends on others for assistance.

Chronic pain can result in lowered self-esteem, sadness, anger and depression. Over the long term, a sense of helplessness to control chronic pain can lead you to develop characteristic "pain behavior." Behavioral changes can become habitual--crutches that can undermine the ability to effectively manage pain.

Evaluating pain

Pain is subjective, but there are ways to measure it. Doctors and other care providers may use questionnaires, have patients fill out a pain-rating scale, or have them select words that best describe their pain.

When repeated attempts to find a cause fail, and treatments aren't effective, the patient may benefit from a team approach offered by a pain clinic. A thorough evaluation may involve specialists in anesthesiology, neurology, psychology and psychiatry, rheumatology, physiatry and physical therapy. The goal is to treat all facets of the pain.

Specialized tests can evaluate how the body senses nerve impulses and how the impulses travel through the nervous system. Imaging techniques, such as X-rays, computed tomography (CT), magnetic resonance imaging (MRI), bone scans and ultrasound, may help detect problems in bones, muscles, joints and soft tissue.

Treat pain early and aggressively

For many years, standard practice called for treating moderate to severe acute pain with injections of narcotic medication "as needed." This method often resulted in delays and widely varying levels of pain relief. Pain rose and fell based on the dose timing. For most people, pain relief was effective only part of the time. Even today, pain is often under-treated.

Inadequate pain control can occur for many reasons. The choice, dose and timing of medication are critical in obtaining effective relief. Also, patients and their care providers may be unduly concerned about the use of narcotics in treating acute pain. But addiction is rare when narcotics are used for short-term relief of acute pain. It may become a problem when narcotics are inappropriately used for chronic pain relief. Addiction is not an issue in treatment of pain from a terminal illness.

Adequate acute pain control following surgery is important because it can allow patients to recover their strength faster and start walking earlier. This can help avoid problems, such as pneumonia and blood clots, due to inactivity.

Inadequately treated acute pain can prolong recovery and make you more susceptible to chronic pain. Continued pain messages enhance subsequent pain responses. Peripheral pain receptors become more sensitive. And continued pain may cause long-lasting modifications in nerve cells along spinal cord pain pathways. These changes make established pain harder to suppress.

As pain persists, feelings of anxiety, stress, anger, helplessness and depression can worsen. Tension and pain may initiate a downward pain spiral that's difficult to break. Early, aggressive treatment, and working with care providers to prepare a pain plan, can help prevent this.

Pain-relieving medications

Pain treatment often includes medications and non-drug therapies. Over-the-counter pain-relieving (analgesic) drugs include:

- *NSAIDs*--Nonsteroidal anti-inflammatory drugs, or NSAIDs (en-SAYDS), are used to treat acute pain from inflammation, such as from arthritis. They relieve pain by inhibiting production of pain-intensifying neurotransmitters activated by tissue damage. NSAIDs include aspirin (Anacin, Bayer, Bufferin), ibuprofen (Motrin, Advil, Nuprin), naproxen sodium (Aleve) and ketoprofen (Orudis KT). All can cause gastrointestinal bleeding. All are also available in prescription form.

- *Acetaminophen*--Acetaminophen (Tylenol) is used to treat pain and control fever, but has only a limited effect on inflammation. It doesn't cause gastrointestinal bleeding like NSAIDs. Prolonged, high-dose use can cause kidney and liver damage.

  Drugs available only by prescription include:
- *Narcotics*--These drugs are the most effective medication for moderate to severe pain. They're used for cancer pain and acute pain when the cause is known and other medications are ineffective. Narcotics also have an important role in the treatment of pain associated with terminal illness. They're not approved for chronic pain. Narcotics include drugs derived from opium (opiates), such as morphine and codeine, and synthetic narcotics (opioids), such as oxycodone, methadone and meperidine (Demerol).
- Side effects can include drowsiness, nausea, constipation, mood changes, and with prolonged use, addiction.
- *Antidepressants*--These medications may offer some relief for people with chronic pain, whether or not they also have depression. Amitriptyline (Elavil), trazodone (Desyrel) and imipramine (Tofranil) may be used with other analgesics. These drugs aren't addicting. They're especially useful for neuropathic, head and cancer pain. Side effects can include drowsiness, constipation and mouth dryness.
- *Anticonvulsants*--Developed for epilepsy, these drugs, such as phenytoin (Dilantin) and carbamazepine (Tegretol), can also help control chronic nerve pain. Side effects include drowsiness and confusion.

Other drugs may be used for specific types of pain. Corticosteroid medications may help relieve pain due to inflammation and swelling. Prolonged use can result in widespread problems, such as bone thinning, cataracts and increased blood pressure.

Tramadol (Ultram) is a synthetic analgesic used primarily for chronic pain, but is also prescribed for acute pain. Side effects may include dizziness, drowsiness, nausea, constipation and sweating.

Sumatriptan (Imitrex), now available in tablet form, may reduce pain from migraine headache by constricting blood vessels in your brain. Because the drug may increase blood pressure and constrict arteries to your heart, it's not used for people with uncontrolled high blood pressure or heart disease.

Capsaicin (Zostrix), a topical cream made from an extract of red peppers, can help relieve skin sensitivity resulting from shingles. It's also used to treat pain from arthritis, cluster headaches, diabetic neuropathy and pain after mastectomy. You may have an initial burning sensation where the cream is applied. Benefits are temporary so you'll need repeated application. Capsaicin probably relieves pain by interrupting transmission of pain messages from nociceptors.

Managing pain

Short-lived acute pain generally responds to medication and goes away with healing but persistent pain can lead to depression, inactivity, de-conditioning and increased dependence on others.

Chronic pain can interfere with sleep and eating habits, exercise, social activity and work. Breaking this cycle usually requires a coordinated approach offered in a pain rehabilitation program. Physical, occupational and behavioral therapies, and assistance with the psychological components of chronic pain, are the cornerstones of successful treatment. Here are some strategies for coping with chronic pain:

- *Relaxation techniques*--Stress increases muscle tension and worsens pain. Relaxation techniques--such as meditation and yoga--involve activities in which you focus on something other than the pain. Patients can do many at home. Listening to music, visualizing a relaxing scene, trying a new hobby or visiting a friend may also help. These techniques can alter peripheral and central pain processes and are especially effective for chronic headache and muscle tension.

  Biofeedback may also help by teaching patients to be aware of autonomic pain responses such as skin temperature, muscle tension, blood pressure and heart rate, and how to modify these.

  Patients need to ask their doctor or other care givers about where to find help in learning relaxation and biofeedback techniques.

- *Occupational therapy*--This helps patients return to ordinary tasks around the home and work. Focusing on home responsibilities, work or volunteer activities--perhaps for limited hours at first--is a first step in pain rehabilitation.
- *Physical therapy and exercise*--Patients may fear exercise will increase pain, but if they start gently and increase gradually, exercise usually doesn't cause injury or additional pain. A regular program should include stretching, strengthening activities and aerobic exercise, such as walking, swimming or cycling. Slow stretching can relax muscles and release tension. If the patients have chronic back pain, you they get enough relief from muscle-strengthening exercises alone, thereby avoiding surgery.
- *Family therapy*--Chronic pain can change personalities and unravel relationships. The person with pain feels guilt and family members become stressed taking over additional responsibilities and new roles. The key is to maintain their normal responsibilities and roles as much as possible.

Pain may be universal--perhaps even unavoidable. But it doesn't have to control a person’s life. The keys to successful pain control are early treatment, ongoing assessment, and clear communication between care givers and their patients.

New Hospital Pain Policy Standards from JCAHO

There have been several extremely important events in the world of pain management.

1. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has announced new standards and requirements for the assessment of pain in accredited hospitals and other healthcare settings. The new standards are a product of a collaborative effort between the Department of Standards of the Joint Commission and the Pain Management Improvement Group at the University of Wisconsin-Madison Medical School headed by Dr. June Dahl. Hospitals, Nursing homes, home health care agencies , behavioral health facilities and health plans will be called upon to:

a. Recognize the right of patients to appropriate assessment and management of pain
b. Assess pain in all patients
c. Record the results of the assessment in a way that facilitates regular reassessment and follow up
d. Educate relevant providers in pain assessment and management
e. Determine the competency in pain assessment and management during the orientation of all new clinical staff
f. Establish policies and procedures which support appropriate prescription or ordering of pain medications
g. Assure that pain does not interfere with participation in rehabilitation, educate patients and their families about the importance of effective pain management
h. Include patients' needs for symptom management in the discharge planning process and
i. Collect data to monitor the appropriateness and effectiveness of pain management.

The new standards explicitly acknowledge that pain is a co-existing condition with a number of diseases and injuries, and requires explicit attention. For example, a patient with breast cancer should effectively be treated not only for the actual illness but also for any associated pain.

"Unrelieved pain has enormous physiological and psychological effects on patients. The Joint Commission believes that the effective management of pain is a crucial component of good care," says Dennis S. O'Leary, MD, president of the Joint Commission. "Research clearly shows that unrelieved pain can slow recovery, create burdens for patients and their families, and increase costs to the healthcare system."

The pain management standards - along with examples of compliance - were included in 2000-2001 standards manuals for the Joint Commission accreditation programs. The standards were first scored for compliance in 2001.

"These standards are put the importance of pain management at center stage, ensuring that health care providers and professionals will take pain management in a serious way," says Russ Portenoy, MD, president of the American Pain Society, which has endorsed these standards.

(To view the new standards, please visit the Joint Commission website: www.jcaho.org)

An article published in the Journal of The American Medical Association (JAMA) challenge the conventional wisdom that drugs used for the relief of severe pain - such as morphine - are widely abused. Research done at the Pain & Policy Studies Group of the University of Wisconsin Comprehensive Cancer Center found that while there were significant increases in the amounts of opioids prescribed by physicians in the U.S., it also found that abuse of opioids was low and stable. In contrast to a 109% increase in abuse with cocaine and heroin, abuse with opioids increased only 6.6% from 1990 to 1996. David Joranson, lead author of the article, noted that, "at a time when abuse of illicit drugs continues to increase, it is reassuring that abuse of opioid pain medications is a small part of the U.S. drug problem."

One of the reasons for inadequate pain management is that health professionals fear opioid medications will be abused. The JAMA report states that increased use of opioids resulting in abuse may be based more on myth than reality. These results suggest that the U.S. can be a model for how to achieve a balanced controlled substances policy, that is, one that can improve the availability of pain relief while limiting abuse. Research has disproved the widespread belief that the use of opioids results in addiction. A statistically insignificant number of cases of addiction (14 out of 10,000 cases) were determined in previous research quoted on the Wisconsin website. This article can be viewed at The Pain & Policy Studies Group, University of Wisconsin website: www.medsch.wisc.edu/painpolicy

It should be remembered that it took the medical profession 37 years to accept the hypothesis of Anton Simmelweis, MD, that the failure to wash hands before delivering infants caused the widespread incidence of "childbirth fever" by Austrian physicians. It is the deepest hope of the National Foundation for the Treatment of Pain that scientific knowledge will replace mythology more rapidly in the management of pain.

The argument can now be made that, with the universal availability of standards and guidelines for the treatment of pain; no medical practitioner can credibly defend failure to adequately treat pain relief, except for a frank lack of expertise and/or training. We will discuss the new standards at greater length in this CEU.

A number of medical groups have weighed in on the issues relating to pain management and the changes needed to create a more humane and effective way to deal with patients. What follows here is a compendium of some of those viewpoints and recommendations:

Perspectives in Intractable Pain Management
An analysis of current diverging viewpoints

Introduction

Across America, two opposing attitudes or paradigms of thinking currently exist in regards to the medical management of intractable pain. Empirical, long-range medical research has brought new light into the darkness of the Old Paradigm. However, despite

the studies that support the New Paradigm, millions of people in our country continue to suffer needlessly because regulatory agencies and healthcare professionals deny safe, medical treatment to them. The Old Paradigm ignores three decades of international studies that support opioid pain treatment in cancer pain patients and severe intractable pain patients. An important goal of the National Foundation for the Treatment of Pain is to make public this new information that will bring the Old Paradigm thinking into the New Paradigm.

The Old Paradigm believes:

- It is not safe or prudent to prescribe pain medication on a continual basis.
- Opioid pain medicine is addictive and can cause long-term damage to internal organs.
- Pain patients should be tough and learn to live with pain.
- When pain patients continue to ask for increased pain medication, they are exhibiting addictive behavior.
- Physicians who prescribe pain medicine are no different than illicit drug dealers and should be treated as such.

The New Paradigm knows (supported by three decades of empirical medical research):

- Opioid pain treatment is safe and effective when monitored by licensed physicians.
- Less than 1% of chronic pain patients become addicted or experience long-term physiological damage as a result of prolonged, controlled opioid pain treatment.
- When pain patients receive adequate pain treatment that relieves their chronic pain and associated depression, patients can lead relatively normal, productive lives. Their friends and families frequently give positive reports of an increased "quality of life," previously thought impossible.
- When pain patients continue to ask for increased pain medication, they are not addicted but experiencing increased pain. Once patients receive adequate doses of appropriate pain treatment, patients stop asking for increased levels of medication.
- There is a world of difference between licensed medical professionals who prescribe pharmaceutical drugs for legitimate pain patients in a medically controlled environment and illicit drug dealers who sell drugs in an uncontrolled, nonmedical environment.

The Old Paradigm continues to influence many healthcare perspectives despite overwhelming evidence and medical association endorsements that support the New Paradigm. Also, documentation and clinical studies exist that support adequate pain management and the steps that are being taken to move the thought processes from the Old Paradigm to the New.

Definitions and Background Information

What is intractable pain?

Intractable pain is a pain state in which the cause of the pain cannot be removed or otherwise treated and which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physicians and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of pain

What are the ailments often associated with intractable pain?

The following is a list of ailments that may result in intractable pain:

- Lower back pain
- Cancer
- Severe burns
- Tension and migraine headaches
- Arthritis
- Myocardial ischemia
- Renal colic
- Gout

What is the recommended treatment for severe intractable pain?

The recommended treatment for severe intractable pain is opioid therapy. Opioids are classified as drugs that are either natural derivatives or synthetic forms of opium.

Examples of opioids are:

- Morphine
- Hydromorphone
- Oxycodone
- Codeine
- Meperidine
- Methadone
- Levorphanol
- Fentanyl
- Propoxyphene

Who is affected by intractable pain?

Thirty-four million Americans suffer from intractable pain every year. What's more there are medications available that can relieve their pain, but certain barriers created by societal stigmas and taboos continue to block pain patients from receiving the relief they need.

What's the problem?

Although opioids have been recommended for moderate to severe pain by pain researchers over the past three decades, five audiences—governments, state medical boards, physicians, patients, and insurance companies—have perpetuated the old paradigm in thinking that opioids taken for intractable pain treatment are unsuitable at high dosage levels and for an extended period of time.

The new paradigm in thought advocates for the use of opioids for intractable pain by gearing dosage levels and treatment durations specific to the levels of pain experienced by each individual patient. By allowing physicians to work with their patients to determine the appropriate pain treatment for each case, more patients will be adequately treated. Once adequately treated, most patients regain a healthy quality of life.

Governments' and State Medical Boards' Perspectives

Three layers of governmental authority prepare laws and guidelines that supervise availability of prescription drugs:

1. International treaties
2. Federal laws and regulations
3. State laws and regulations

Regarding opioid use for intractable pain, international treaties and federal laws recognize the necessity of balance between providing adequate amounts of opioids for intractable pain and controlling drug abuse.

State laws, on the other hand, tend to place additional restrictions upon opioids to control drug diversion (using prescription drugs for recreational use); however, the restrictions usually interfere with intractable pain patients' receiving adequate amounts of opioids for pain relief.[1,2] The factors that contribute to states' interfering with adequate opioid treatment are:

a. ambiguously defined terms for addiction
b. opioid dosage unit limitations
c. multiple copy prescription programs
d. electronic monitoring systems
e. falsely perceived illegality of opioids for intractable pain

International Treaties

Because drug abuse and inadequate treatment of intractable pain are international health problems, international treaties have been established to pose as models for nations to develop their own laws stipulating the need for opioid pain treatment while controlling drug diversion.

The most important international treaty regulating narcotic drugs is the 1961 Single Convention. This treaty was formed to decrease international drug abuse and increase support for opioid use in pain treatment.[3] The preamble states that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes." [4]

Commentary on the 1961 Single Convention, written by the Secretary-General of the United Nations, suggested that prescription drugs be placed into different categories or schedules, according to abuse and therapeutic potential, to aid in drug regulation.

Also, the Secretary-General stated that healthcare providers should not be required to track each individual acquisition and disposal of a controlled drug, and pharmacists should not be obligated to record each sale as both instances may pose a burden on effectively ensuring availability of opioids for pain treatment.[5]

You will find in the state laws and regulations section below that state laws do not follow this international treaty as most require both physicians and pharmacists to track each opioid prescription while the state monitors their prescribing patterns. State laws place these restrictions on opioids to monitor for physicians who may be selling opioid prescriptions to drug abusers. Unfortunately, these restrictions tend to limit the amount of opioids physicians are able to prescribe for intractable pain. As a result, healthcare providers do not prescribe adequate amounts of opioids to relieve intractable pain for fear of regulatory scrutiny.[2,6,7]

Federal Laws and Regulations

In response to the 1961 Single Convention, the United States Congress passed the Controlled Substances Act (link) and the Controlled Substances Import and Export Act (link) in 1970. Both of these acts categorize prescription drugs into schedules, according to abuse and therapeutic potential, and specify the means to regulate each schedule. Five schedules were established on a scale, beginning with Schedule I containing illegal drugs and ending with Schedule V containing the least regulated drugs. According to the Controlled Substances Act, opioids are categorized under Schedule II and Schedule III.

Drugs listed in Schedule II are described as follows:[8]

- The drug has a high potential for abuse
- The drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions

- Abuse of the drug may lead to severe psychological or physical dependence

Drugs listed in Schedule III are described as follows:[8]

- The drug has a potential for abuse less than the drugs in Schedules I or II.
- The drug has a currently accepted medical use in treatment in the United States.
- Abuse of the drug may lead to moderate to low physical dependence or high psychological dependence.

Congress initiated the Drug Enforcement Administration (DEA) as the federal agency responsible for enforcing the Controlled Substances Act. To uphold federal guidelines that stipulate opioids as medically necessary for intractable pain, the DEA states in its regulations that it does not want to "impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs…to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." [9]

The DEA also states[10] "A physician is allowed to exercise his medical judgment and to dispense or administer narcotics to an individual for extended periods for the purpose of relieving intractable pain in which no other relief or cure is known. An example of this would be terminal cancer patients or patients with painful chronic disorders."

As you will see in the state laws and regulations section below, the DEA does not uphold their allowance of physicians to exercise their medical judgment for prescribing narcotics for chronic pain for extended periods of time. On the contrary, the DEA works with the state medical boards to monitor opioid prescribing. If the DEA or state medical boards discover any physicians whom they deem to be over-prescribing opioids, often they work together during the investigations and prosecutions.

Politics of Reform

In the more “innocent” pre-9/11-Iraq war times, there was a time of much debate regarding a national policy regarding pain. In its November 2000 Newsletter, the National Foundation for the Treatment of Pain discussed the “politics” associated with pain relief reform:

The on-going tumult surrounding the Presidential Election has significant implications for the treatment of intractable pain. One would think that the subject of pain treatment would transcend political differences, as pain has no regard for party affiliation. But strangely enough, politics does play a major role. Take, for example, the subject of the treatment of the pain of terminally ill patients.

The Hyde-Nickels Act was a legislative watershed for political differences. This Act would mandate a radical change in the politics of pain treatment. Always before, the management of medical practice has remained in the hands of the states. The Boards of Medical Examiners and the Boards of Pharmacy of each state previously have always retained the right to review the standards of medical care. This has not been any particular advantage to promoting proper pain treatment, because in many states

regulatory prosecution has remained a major factor in the denial of opioid medications to pain patients. The majority of physicians have remained intimidated by the perceived risk of state prosecution, loss of reputation and licensure. In fairness, however, the National Federation of State Medical Boards unanimously adopted a model Intractable Pain Act in the spring of 1998, which has encouraged protective legislation in several states since. The Hyde-Nickels Act would for the first time intervene the authority of the Federal government, under the auspices of the Justice Departments Drug Enforcement Agency, into the picture.

The Republican sponsored Hyde-Nickels Act would direct the DEA to examine the medical charts of all terminal patients, to determine if the prescribing physician had any "intent" to hasten the death of the patient with federally controlled medical substances. If found guilty the doctor would be subject to a minimum, mandatory sentence of 20 years in prison, plus significant fines. Virtually all physicians agree that this would have a chilling effect on the willingness of physicians to prescribe. The bill lingers before Congress, placed in the back of other legislation, which would provide a "Trojan Horse" for this bill. The NFTP has joined with over 40 other national organizations in opposing the bill. We will keep you posted.

In another area of political controversy, literally at the midnight hour, the 2000 session of the Florida Legislature voted to make hydrocodone medications schedule II, requiring a written prescription and precluding phone-in prescriptions. Urged by the Florida Medical Association and other interested parties, on August 29, 2000, the Attorney General filed an emergency rule reclassifying drug products containing no more than 300 mg of hydrocodone per 100 ml and not more than 15 mg per dose as schedule III. The emergency rule will remain in place 90 days. What the future holds is uncertain. What is clear is that there is little rationality involved in this matter. Florida, awash in heroin, cocaine, marijuana, crystal methamphetamine, black market uppers, downers, Ecstasy, and other designer drugs, is not threatened by the legitimate prescription of hydrocodone. Making hydrocodone class II would only create a greater black market for these drugs, as it would be far more complicated to see a doctor for the medication than buying it off the street. Are these legislators working for the international drug-smuggling cartels, working past midnight to create new franchises for them? It can seem very bizarre.

State Laws and Regulations

State laws are similar to federal laws in that they both allow controlled substances to be prescribed for specific medical purposes. States, however, are allowed to add additional restrictions to federal laws, and in the case of opioid treatment for intractable pain, most states do not recognize the legitimacy of opioids for intractable pain.[1]

Several factors contribute to states' lack of recognition of opioid legitimacy for intractable pain, over-regulation of opioid treatment for intractable pain, the prosecution of legitimate physicians, and the under-treatment of intractable pain patients. These include:[1]

a. <u>ambiguously defined terms for addiction</u>

b. opioid dosage unit limitations
c. multiple copy prescription programs
d. electronic monitoring systems
e. falsely perceived illegality of opioids for intractable pain

State medical boards (consisting mostly of physicians) and the DEA work together to regulate opioid prescribing; however, their lack of knowledge of the pharmacological effects of opioids for intractable pain, their fear of addiction, and their fight against drugs as a whole in our society has compelled them to over-regulate drugs that adequately treat intractable pain. In order for states to allow physicians to provide adequate amounts of opioids to intractable pain patients, state medical boards and the DEA need to become better educated about the advancements being made in intractable pain management.

Some state medical boards have reached a turning point in their knowledge of adequate intractable pain treatment and have made steps toward ensuring safe opioid treatment. To create an ideal atmosphere that supports adequate opioid treatment, states would need to strive to:

- **Define addiction terminology more accurately** so that healthcare providers do not falsely associate addiction with opioid pain treatment[1,11]
- **Remove dosage limitations from the laws** so that pain patients receive adequate amounts of opioids to relieve their pain[1,2,12]
- **Eliminate multiple copy prescription programs** so that legitimate physicians do not compromise their patients' pain treatment for fear of regulatory investigation[3,14-16]
- **Support electronic monitoring systems but discourage adding more schedules to state medical board regulations** so that further stigmas toward opioid treatment do not develop
- **Create an educational effort to teach themselves on the legality of opioids for intractable pain** so that they do not over-regulate and therefore restrict patients from receiving the correct amount of pain medication[11]

Some definitions and problems associated with those definitions

A. Addiction

To understand how addiction is ambiguously defined in state laws, we must first understand how addiction and its components are defined correctly.

The American Society of Addiction Medicine recently defined terms associated with addiction and the physiologic responses associated with opioid treatment for intractable pain. The terms defined below reflect current thought on the differences between addiction and opioid pain treatment.[17]

> Physical dependence upon an opioid is a physiological state in which abrupt cessation of the opioid, or administration of an opioid antagonist, results in a withdrawal syndrome. Physical dependency on opioids is an expected occurrence in all individuals in the presence of continuous use of opioids for therapeutic or for nontherapeutic purposes. It does not, in and of itself, imply addiction.
>
> Tolerance is a form of neuroadaptation to the effects of chronically administered opioids (or other medications), which is indicated by the need for increasing or more frequent doses of the medication to achieve the initial effects of the drug. Tolerance may occur both to the analgesic effects of opioids and to some of the unwanted side effects, such as respiratory depression, sedation, or nausea. The occurrence of tolerance is variable in occurrence, but it does not, in and of itself, imply addiction.
>
> Addiction in the context of pain treatment with opioids is characterized by a persistent pattern of dysfunctional opioid use that may involve any or all of the following:
>
> - adverse consequences associated with the use of opioids
> - loss of control over the use of opioids
> - preoccupation with obtaining opioids, despite the presence of adequate analgesia
>
> Individuals who have severe, unrelieved pain may become intensely focused on finding relief for their pain. Sometimes such patients may appear to observers to be preoccupied with obtaining opioids, but the preoccupation is with finding relief of pain, rather than using opioids per se. This phenomenon has been termed ‘pseudoaddiction’ in the pain literature.

Aaron Gilson, Researcher at the Pain and Policy Studies Group at the University of Wisconsin, narrows down the definition of addiction as "drug use despite harm". This would not apply to pain patients as taking opioids actually increases their quality of life.

Ambiguous definition of addiction

According to the American Society of Addiction Medicine, "The clinical implications and appropriate management of physical dependence, tolerance and addiction differ. It is therefore important that clear definitions be established to facilitate identification and appropriate management of these occurrences.[11,17]

Because many members of state medical boards continue to believe that physical dependence and tolerance associated with opioid pain treatment is the same as addiction, numerous states’ regulations fail to recognize the difference between physiological responses to opioids for intractable pain and the physiological and psychological responses to recreational drug abuse.[1,17]

A survey conducted by The Pain and Policy Studies Group at the University of Wisconsin, confirmed state medical boards' false belief that physiological responses to opioids are the same for addiction and intractable pain treatment. One question in the survey asked state medical board members to select terms that encompass the definition of addiction and physiological responses to opioid pain treatment. Physical dependence and tolerance held a large majority of the vote.

Table 1. Terms that state medical board members included within their definition of addiction. Each member was required to choose one or more of the following terms to define addiction: physical dependence, psychological dependence, tolerance, other, and don't know.[11] (A question from a survey conducted by The Pain and Policy Studies Group at University of Wisconsin)

Choose the terms that define addiction	
physical dependence	85%
psychological dependence	71%
tolerance	41%
physical dependence only	10%
psychological dependence only	10%
tolerance only	1%

As a result of the confusion with the definition of addiction, and specifically with the assumption any type of physical dependence or tolerance is associated with addiction, states fail to establish the difference between intractable pain patients and drug addicts and between physicians and drug dealers. State medical board members need to understand that physical dependence and tolerance are not always associated with addiction, thus opioids taken for intractable pain rarely if ever result in addiction. Once this is done, over-regulation and prosecution of legitimate physicians may subside to allow for more adequate intractable pain treatment.

B. Opioid dosage unit limitations

Federal regulations and the DEA state that no limitations should be set for healthcare professionals to administer or dispense opioids for intractable pain patients.[9] Yet, some state medical boards insist upon regulating pain treatment by using opioid dosage unit limitations, limitations that result in under-treatment of pain because patients may not be able to access the amount of drugs necessary to relieve extreme levels of pain. Many states have dropped dosage unit limitations from their legislature; however several still remain. According to Aaron Gilson of the Pain and Policy Studies Group at the University of Wisconsin, nine states continue to support dosage unit limitations. The states are listed in Table 2.

Table 2. State restrictions for Schedule II controlled substances, including opioids. Note: Many states are ambiguous about their definition. One dosage unit may mean one pill, or it may mean the amount taken at one time.

Massachusetts	30-day supply (Schedule II & III)
Missouri	30-day supply (Schedule II)
New Hampshire	34-day supply or 100 dosage units, whichever is less (Schedule II & III)
New Jersey	30-day supply or 120 dosage units, whichever is less (Schedule II)
New York	30-day supply (Schedules II-V)
Rhode Island	30-day supply or 250 dosage units (Schedule II)
South Carolina	30-day supply or 120 dosage units, whichever is less (Schedule II)
Utah	1-month supply (Schedule II)
Wisconsin	34-day supply (Schedules II-IV)

To average citizens, these amounts may seem like a lot; but for intractable pain patients, most dosage unit limitations add up to only a fraction of what they need to relieve their pain. For example, one pain patient featured on *60 Minutes* in 1997 said that he takes 60 pills per day—400 pills per week—to relieve his pain. If this pain patient lived in one of the above states, he wouldn't receive the amount of medication necessary to relieve his pain. Also, pain patients who need to prescribe medication on mail order may be restricted by dosage unit limitations from a state in which they don't live.

Dr. William Hurwitz, a pain specialist, said, "If it takes 100 pills a day or 200 pills a day to relieve the pain, that's what it takes. There's just no way for me to say, 'Let's undertreat them. Let's make them suffer.' " [12]

Not only do pain patients continue to suffer due to restricted dosage unit limitations, but they also acquire increased expenses. Restricted dosage unit limitations require severe intractable pain patients to make multiple visits to their physicians to obtain opioid prescriptions if their required dosage exceeds the states' allotted dosage amount. As a result of acquiring more prescriptions, pain patients then pay additional dispensing fees at the pharmacy.[2]

Also, patients suffer due to restricted dosage unit limits because healthcare providers and state medical boards mistake their continual search for pain relief—pseudoaddiction—with addictive behavior. New York State, for example, requires physicians to report their patients who take opioids for an extended amount of time as addicts—a mistake in the definition of addiction and in requiring dosage unit limitations.[1]

Ultimately, all of these restrictions result in poor pain management, created and perpetuated by state medical boards and the DEA.

C. Multiple copy prescription programs

In an attempt to discourage drug diversion, some states have adopted a multiple copy prescription program (MCPP). An MCPP typically requires physicians to purchase prescription pads from the state to prescribe controlled drugs under Schedule II, in which most opioids are categorized. When a Schedule II prescription is written, the physician, the pharmacist, and the Narcotics Division of that state each keep a copy for two years.[3] The Narcotics Division, in turn, cooperates with the DEA and the state medical board, state and county attorneys, physicians, pharmacists, dentists, and veterinarians to investigate "irregular" prescribing patterns and ultimately contribute to the prosecution of suspected "overprescribing" offenders.[3] Those states who have MCPPs are listed in Table 3.

In a July 1998 letter to the National Foundation for the Treatment of Pain, the DEA stated that it encourages the development of MCPPs because the data collected from them can be used to:

- develop medical education programs to heighten professional awareness to prescription drug abuse and abuse trends
- target doctor shoppers (patients who seek opioids without a medical reason) and script rings (doctors who sell opioid prescriptions to drug abusers)
- eliminate the need for investigators to spend limited resources searching prescription data by visiting every pharmacy, looking through prescription files, and thus creating an air of suspicion regarding a possible investigative target
- provide a system whereby practitioners can inquire about patients that could potentially be doctor shoppers

Table 3. A list of states with prescription monitoring programs, compiled by the DEA.

State	Program	Year Enacted	Schedules Covered
California	Triplicate / Electronic	1940	Schedule II
Hawaii	Duplicate / Electronic	1943	Schedule II and Hydrocodone
Idaho	Duplicate / Electronic	1967	Schedules II, III, IV
Illinois	Triplicate	1961	Schedule II
Indiana	Electronic	1995	Schedules II
Kentucky	Electronic	1998	Schedules II, III, IV
Massachusetts	Electronic	1992	Schedule II
Michigan	Single Copy / Electronic	1989	Schedule II
Nevada	Electronic	1997	Schedule II, III, IV
New Mexico	Electronic	1994	Schedule II
New York	Triplicate	1977	Schedule II and Benzodiazepines
Oklahoma	Electronic	1990	Schedule II
Rhode Island	Electronic	1979	Schedule II, III, Needles and Syringes
Texas	Triplicate / Electronic	1985	Schedule II

Utah	Electronic	1995	Schedules II, III, IV, V
Washington	Triplicate	1989	N/A
West Virginia	Electronic	1995	Schedule II

Multiple copy prescription programs (MCPPs) do offer an immediate and drastic decrease in the amount of Schedule II drugs prescribed in each state. When states began their multiple copy prescription programs, the following reductions in Schedule II drugs resulted: Texas - 64%, Rhode Island - 57%, New York - 54%, Idaho - 50%.[13]

The problem with these numbers is that there is little chance that approximately half of the physicians in those states stopped prescribing opioids because they were afraid of getting caught selling drugs on the black market. Rather, these reductions in opioid prescribing resulted from physicians' fear of prosecution,[3] not because they are drug dealers but because they know their state will interpret their prescribing as such.

Physicians' fear of being prosecuted results in one of two behaviors—simply not prescribing any pain medication or prescribing less regulated pain medication that causes further, more dangerous side effects than opioids.[14,16,18,19] In fact, a 1996 study, comparing analgesic prescribing patterns between physicians whose states had MCPPs and those without, showed that the "MCPP status is a strong influence in predicting the type of analgesic used…the presence of a state MCPP exerts a negative influence on the probability that a Schedule II analgesic will be prescribed in an office visit, and a strong positive effect on the probability of Schedule III opioid analgesic receipt…If rates of use of Schedule II medications are indeed lower in the MCPP states, patients in those states may experience greater levels of pain than their counterparts in non-MCPP states." [19]

The less regulated drugs that are most often used as alternatives are anti-inflammatory drugs. When taken over extended periods of time as required for intractable pain treatment, anti-inflammatory drugs can cause internal bleeding, ulcers, and kidney, liver, or stomach damage.[14,16] Even worse, one study showed that 17,000 deaths resulted from these opioid alternatives in one year, whereas deaths resulting from opioids was described as "vanishingly small" by Dr. Brian Goldman, a University of Toronto researcher who has studied prescription drug diversion.[14]

Ultimately, the MCPPs perpetuate a stigma against adequate opioid treatment that results in the intimidation and prosecution of legitimate physicians who adequately treat intractable pain. Because of these unwarranted prosecutions, the DEA contradicts its conviction that physicians are allowed to exercise their medical judgment to dispense or administer narcotics for extended periods of time for chronic pain.

D. Electronic monitoring systems

The National Foundation for the Treatment of Pain had a conversation with Susan Peine from the DEA, in which she spoke about the DEA's recommendation that all states', with or without MCPPs, develop an electronic monitoring system. Using this electronic monitoring system, state medical boards and the DEA can continue to monitor

prescribing patterns but on an electronic level. Peine suggested the advantage of the electronic monitoring system is that investigators will no longer visit physicians' offices to investigate prescribing. Rather, their prescribing patterns will be on file and searchable electronically, allowing for a less intrusive investigation.

As Aaron Gilson, Researcher at the Pain and Policy Studies Group at the University of Wisconsin, points out, however, these programs tack on additional drug schedules to monitor. As you can see in Table 3, all of the states that monitor multiple schedules of drugs have electronic monitoring systems in place. Gilson agrees that these electronic monitoring services are better in the fact that they are less intrusive; however, these electronic monitoring services may be worse than MCPPs because they may perpetuate further stigmas towards opioids that are not only in Schedule II but Schedule III as well.

E. Falsely perceived illegality of opioids for different categories of intractable pain

The Pain and Policy Studies Group at the University of Wisconsin conducted a survey of state medical boards to determine how they perceived the legality and medical appropriateness of opioid treatment for different categories of pain patients for an extended period of time. Approximately 6 board members from 49 states responded. (Massachusetts was not represented.) Seventy-five percent of the respondents were physicians, 15% were public members, 12% were members of osteopathic boards.[11] Their responses to this survey are listed in Table 4.

Table 4. State medical board perception of legality and medical appropriateness of opioid treatment for different categories of pain patients for an extended period of time.[11] Note: Rows do not total 100% because respondents could give more than one response.

Patient History	**Level of perceived legality**				
	Lawful and generally acceptable medical practice	Lawful, but generally not acceptable medical practice; should be discouraged	Probable violation of medical practice laws and regulations; should be investigated	Probable violation of federal / state controlled substances laws; should be investigated	Don't know
Cancer pain only	75%	14%	5%	5%	7%
Cancer pain with history of opioid abuse	46%	22%	14%	12%	16%
Chronic, non-malignant pain only	12%	47%	32%	27%	7%
Chronic, non-malignant pain with history of opioid abuse	1%	25%	58%	50%	6%

Adapted from *Fed Bull.* 1992;79(4):15-49.

As you can see from these state medical board responses, opioid treatment is generally accepted for cancer pain only, but very few members understand that opioid treatment is recommended for severe, intractable pain whether due to cancer or not. Some even believe that prescribing opioids for non-malignant intractable pain is a crime worth investigating.

Treating cancer and non-malignant pain in patients who have a history of drug abuse is a controversial and often confusing topic in opioid treatment. One study showed that the patients who abused alcohol alone and who had a support system through family, friends, and/or Alcoholics Anonymous showed no signs of opioid abuse.[20] Those patients who abused several substances, which may or may not have included opioids, and did not have a support system through family, friends, or AA tended to abuse opioids during treatment. The signs that the study observed for opioid abuse were:[20]

- unauthorized dose escalations occurring more than once in a 3-month period
- frequent telephone calls to the clinic numbering more than two calls per month
- "doctor shopping" or receiving opioids from any other physician or from any emergency room visit
- losing or reporting prescriptions as "stolen"
- more than three visits to the clinic without an appointment during a 1-year period
- multiple so-called drug allergies, or intolerance to attempts to change a patient's opioid to another opioid

Turning point for patients: state laws and guidelines that encourage adequate pain relief

Some states have become more aware of the necessity of opioid treatment for intractable pain and have either passed legislation known as Intractable Pain Acts (IPAs) or have prepared guidelines on how board members should review physician prescribing patterns. These laws and/or guidelines generally:[21]

- advocate for patients' rights to receive adequate pain treatment
- provide medical boards with specific definitions of addiction
- provide medical boards with guidelines that allow them to identify more easily who is a legitimate physician and who is a physician selling drugs on the black market
- allow physicians to provide adequate amounts of pain relief to their patients
- sometimes provide physicians protection from state medical board discipline

Tables 5 and 6 identify those states that have created IPAs or guidelines that outline treatment for intractable pain.

Table 5. States that have IPAs and when they were initiated.[21]

California	1990

Colorado	1992
Florida	1994
Missouri	1995
Nevada	1995
Oregon	1995
Texas	1989
Virginia	1988
Washington	1993
Wisconsin	1996
Adapted from *APS Bull.* 1997;7(2):7-9.	

Table 6. States that have guidelines on intractable pain treatment and when they were initiated.[21]

Alabama	1994
Arkansas	1993
Arizona	1990
California	1994
Colorado	1996
Florida	1996
Georgia	1991
Idaho	1995
Massachusetts	1989
Maryland	1996
Minnesota	1988
Montana	1996
North Carolina	1996
Oregon	1991
Texas	1993
Utah	1987
Washington	1996
Wyoming	1993
Adapted from *APS Bull.* 1997;7(2):7-9.	

Benefits and risks of Intractable Pain Acts (IPAs)

As explained earlier, IPAs provide many benefits to all parties involved in opioid treatment for intractable pain, including:[21]

- recognizing that there is a legitimate place for opioids in the treatment of chronic pain

- providing immunity provisions that may protect physicians from discipline (although not from investigation and its attendant legal costs)
- enhancing public awareness of the inadequacies present in today's treatment of pain

Although quite minor, risks exist with the development of legislation governing medical practice with IPAs that could further restrict rather than expand access to opioids for intractable pain, including:[21]

- defining the medical use of opioids for intractable pain as a therapy of last resort
- applying laws to all intractable pain patients, even if they have cancer
- implying that opioids may be used for pain only in cases where the cause of pain cannot be removed
- excluding pain patients who use drugs "for nontherapeutic purposes"
- requiring an evaluation of every pain patient by a specialist in the organ system believed to be the cause of the pain
- requiring a signed informed consent from in every case (some IPAs)

All-in-all, IPAs are beneficial to state medical boards, physicians, and patients because they create an atmosphere of acceptance for adequate intractable pain treatment.

California guidelines as model guidelines for other states

The Medical Board of California (MBC) guidelines on prescribing controlled substances for intractable pain continue to serve as a model for state medical boards across the country that seek adequate pain treatment for their citizens. Built on principles of good medical practice, the MBC created a prescription framework for physicians, allowing them to prescribe controlled substances without concern of regulatory scrutiny or dosage unit limitations. These guidelines were reviewed and adopted unanimously by pain and legal experts. After adoption and distribution of the MBC guidelines, the American Pain Society endorsed them.[21]

The MBC guidelines state:[22]

> While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.
>
> Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is

> severe. Extended therapy may be necessary if the pain is chronic. The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed.
>
> The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for nonmedical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitués merely because they are being treated with opioids.
>
> Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them.

To better treat intractable pain patients, all parties involved in providing adequate amounts of opioids for intractable pain, whether physician, pharmacist, nurse, patient, state medical board member, or DEA agent, should aim to work together to appropriately manage drug diversion while stipulating a medical need for adequate pain relief.[21]

Healthcare Professionals Transition into the New Paradigm of Pain Management

As advancements in pain management gain awareness throughout the healthcare community, opioids will gain acceptance as a safe, effective form of treatment for intractable pain. To bring about this awareness, healthcare providers, state medical boards, and the DEA need to understand that:

- addiction is rarely if ever associated with opioid treatment for intractable pain
- formal pain management curriculum must be introduced into medical schools to avoid customary prescribing behavior
- opioids should be prescribed and distributed at levels proportional to the levels of pain the patient is experiencing no matter what the age or ethnicity of the patients may be
- regulatory programs perpetuate inadequate pain treatment

Because this transition into the new paradigm of adequately treating intractable pain would take an enormous effort on the part of the healthcare community, the American Academy of Pain Medicine and the American Pain Society recommended guidelines for opioid treatment for intractable pain.[21] They urge healthcare providers to push state legislators for much needed reform on opioid prescribing that will mimic the guidelines they have prepared. Regulators have also asked for these guidelines to help them distinguish between legitimate and illegitimate prescribing behaviors.

Also, physicians and other health care professionals at all levels can follow these steps to eliminate fear of regulatory scrutiny:[20]

- help bring state laws and regulations up-to-date
- seek clarification if risk of sanctions is perceived
- communicate with the regulatory and licensing officials in each state
- join the debate about multiple copy prescription programs
- become involved in efforts to prevent diversion
- get the multiple copy prescription forms if your state requires them

All parties involved in prescribing—clinicians, state medical boards, DEA—need to become educated about appropriate opioid therapy for intractable pain. Once they understand the medical need for opioids for intractable pain, they can begin to work together, instead of against each other, to relieve patients of their patients of their pain.

Lack of Knowledge of Opioid Pharmacological Effects

False notions of addiction in pain management results from clinicians' ignorance of opioids' pharmacological effects for intractable pain. It's true that decades of studies have supported the use of opioids for intractable pain, yet most clinicians today still do not prescribe and distribute the appropriate analgesics to match their patients' severity of pain.[12] Healthcare providers continue to under-treat intractable pain patients because they learn pain management through customary prescribing behavior, which in turn creates an atmosphere for inappropriate prescribing and under-treatment of pain in different populations.

Customary prescribing behavior

Physicians continue to under-treat pain patients due to a cyclical phenomenon known as customary prescribing behavior.[8] Customary behavior is behavior that is perpetuated by community thought as opposed to individual outcomes. This behavior is passed down from physicians to medical school graduates as graduates enter training in hospitals. Medical school graduates accept the prescribing patterns that they learn in training hospitals because they do not receive formal pain management training in their medical school curricula.

The house staff that train medical school graduates believe that they treat pain via the "bedside experience." However, if this were true, they would not continuously ignore two outcome variables that could help them treat their patients' pain adequately—their

consistent failure to treat pain and the fact that they have rarely seen patients become addicts.[8] Customary prescribing behavior creates a situation in which clinicians ignore the results of their inadequately treating pain and, instead, focus on treating patients as physicians before them have done.[13]

PRN prescribing patterns

Another reason that clinicians inadequately relieve pain is their continued support of PRN (*pro re nata*, or as needed) prescribing. PRN was once thought to be effective in relieving patients' pain because PRN requires patients to receive pain medication when they absolutely need it therefore avoiding "addiction." PRN prescribing is no longer thought to be effective for analgesia because:

- PRN requires patients to experience unnecessary pain before receiving relief [4,14]
- clinicians tend to label patients as addicts because patients continuously ask or even beg for pain relief [7]
- once the dose is finally given, the pain could be so severe that the medication does not treat it, and a higher dose becomes necessary. If higher doses are not given gradually, side effects, such as mental clouding and nausea usually result [7,14]

In fact, PRN prescriptions are contraindicated for pain relief because the roller coaster incidence of pain does not minimize tolerance and addiction but actually exaggerates them.[4,15]

Under-treatment in different populations

Children, elderly, and minorities tend to receive lesser relief of pain than the rest of the population. The reasoning is not founded upon discrimination, but a belief system that: children don't feel pain like adults [7,16]; the elderly are believed to feel less pain than they had before and don't report their pain like younger patients [7,16]; and minorities are treated in a customary behavior founded on the thought that minorities are at a greater risk of addiction.[17]

The truth is everyone, despite age or ethnicity, feels pain. The difference between the levels of pain felt does not result from age or ethnicity but from disease progression.[4] Therefore, no boundaries should be set for appropriate levels of pain management based on anything except reported pain levels experienced by each, individual patient. Also, it is the responsibility of each patient to report their pain to their healthcare provider in order to receive adequate amounts of pain treatment.

Fear of State Medical Board/DEA Investigation

Seven million people suffer intractable pain that requires opioids for pain relief; however, only 4,000 physicians in the United States are willing to prescribe opioids for these people.[10] One of the key reasons for this nationwide hesitation to prescribe opioids results from the increasing fear that legitimate physicians will be investigated and disciplined by state medical boards and the DEA.[3,18,19,20]

Investigating and disciplining physicians and pharmacists

State medical boards and the DEA monitor opioid prescribing patterns and sometimes mistake physicians treating pain patients with large amounts of opioids for physicians selling opioid prescriptions to drug addicts. These mistaken identities usually cost physicians their medical licenses, leaving them out of jobs and patients without adequate pain treatment. Because of regulatory scrutiny, physicians resort to learning regulatory avoidance tactics so as not to look suspicious and ultimately lose their licenses. Unfortunately, these avoidance tactics come at the cost of treating patients ineffectively and inappropriately.

Since most physicians already underprescribe opioids for intractable pain relief, whether due to unfounded fear of addiction or lack of knowledge of opioid pharmacological effects, the physicians who do prescribe the correct amount of opioids required to relieve certain levels of intractable pain look even more suspicious to authorities.[20] As a result, 900 physicians' licenses were revoked or suspended in 1995 and 1996 because their state medical board deemed that they were prescribing too many opioids.[21] The scare of medical board and DEA investigation has run so rampant that some doctors go so far as putting signs in their offices saying, "Do not ask me to refill pain medications" or "Don't ask for opioids."[10]

Pharmacists are also investigated by the DEA for dispensing too many opioids. In a Department of Health and Human Services report, the American Association of Hospital Pharmacists, the American Pharmaceutical Association, and the National Association of Boards of Pharmacy said that pharmacists may fail to provide adequate levels of analgesia because they fear harassment or prosecution by enforcement agencies, usually at the local or state level.[15,20]

Harmful alternatives and multiple copy prescriptions

One form of drug regulation in some states is multiple copy prescriptions. State medical boards to monitor prescribing patterns of several drugs, including opioids, in order to discourage drug diversion, created these programs.

The problem with multiple copy prescriptions is that it points out the physicians who are prescribing correct amounts of opioids and allows state medical boards to interpret their prescribing patterns as inappropriate and reason for investigation.

The irony of these multiple copy prescription programs is that there is no proof that all physicians who prescribe "too many" opioids are contributing to drug abuse, but there is proof that physicians turn to less-regulated drugs as alternatives that are not indicated for moderate to severe pain and cause more side effects and deaths than opioids.[4]

The most prescribed alternatives for opioids are anti-inflammatory agents (drugs that are indicated only for mild to moderate pain not intractable pain). When taken over extended periods of time, as required for intractable pain, anti-inflammatory agents cause internal bleeding, ulcers, and kidney, liver, or stomach damage.[4,10] Even worse, one study showed

that 17,000 deaths resulted from these alternatives in one year, whereas deaths resulting from opioids was described as "vanishingly small" by Dr. Brian Goldman, a University of Toronto researcher who has studied prescription drug diversion.[10]

DEA's rationale for investigation

Why do state medical boards and the DEA continue to investigate physicians and pharmacists when it seems so obvious that most are providing opioids to relieve intractable pain? Some say that the DEA's war on drugs has found an easy target with healthcare professionals who prescribe and distribute opioids because the authorities can monitor prescribing patterns; they can't monitor drug dealers as easily.

As logical as this type of monitoring and investigation of physicians' prescribing to discourage diversion may seem to state medical boards, the fact of the matter is, there is little evidence that suggests the opioids physicians and pharmacists provide are those that are ultimately sold on the streets. In fact, DEA officials have stated that most of the drugs in the black market are those that originated from illegal, foreign manufacturers.

Major New Approach at DEA

In 2001, there were major advances in the campaign to improve how pain is perceived and managed. The Drug Enforcement Administration, Last Acts Partnership, and the Pain & Policy Studies Group at the University of Wisconsin joined forces in 2001 to develop a consensus statement, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act."

This consensus statement, which was joined by numerous other health care organizations, called for a balanced policy addressing both the necessity of medical access to prescription pain medications and active approaches to stem abuse, addiction and diversion:

"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act
A Joint Statement From 21 Health Organizations and the Drug Enforcement Administration

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need.

Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical.

Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients[1] ability to receive the care they need and deserve.

This consensus statement is necessary based on the following facts:

- Under-treatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively.

- For many patients, opioid analgesics when used as recommended by established pain management guidelines are the most effective way to treat their pain, and often the only treatment option that provides significant relief.

- Because opioids are one of several types of controlled substances that have potential for abuse, they are carefully regulated by the Drug Enforcement Administration and other state agencies. For example, a physician must be licensed by State medical authorities and registered with the DEA before prescribing a controlled substance.

- In spite of regulatory controls, drug abusers obtain these and other prescription medications by diverting them from legitimate channels in several ways, including fraud, theft, forged prescriptions, and via unscrupulous health professionals.

- Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated generating a sense of fear rather than respect for their legitimate properties.

- Helping doctors, nurses, pharmacists, other healthcare professionals, law enforcement personnel and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.

American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Pain Medicine
American Alliance of Cancer Pain Initiatives
American Cancer Society
American Medical Association
American Pain Foundation
American Pain Society
American Pharmaceutical Association
American Society of Anesthesiologists

American Society of Law, Medicine & Ethics
American Society of Pain Management Nurses
American Society of Regional Anesthesia and Pain Medicine
Community-State Partnerships to Improve End-of-Life Care
Drug Enforcement Administration
Last Acts
Midwest Bioethics Center
National Academy of Elder Law Attorneys
National Hospice and Palliative Care Organization
Oncology Nursing Society
Partnership for Caring, Inc.
University of Wisconsin Pain & Policy Studies Group

After that statement was released, the group met to discuss the need for education of both the health care community, and the law enforcement and regulatory community. Although educational programs that promoted the philosophy, science and practical issues surrounding the policy of balance had begun to appear, there was a compelling need for a clear and concise educational product, which would be targeted to both health care professionals and professionals in the law enforcement and regulatory communities. The group met several times during the last year to review existing educational material and ultimately decided to produce a highly readable "Frequently Asked Questions" that would cover the clinical and regulatory issues surrounding the prescribing of controlled drugs.

These Frequently Asked Questions (FAQs) were produced by a Principal Working Group, which included the experts who developed the consensus statement, and a Review Committee, which included experts from the fields of nursing, neurology, psychiatry, pharmacology, pharmacy and addiction medicine. The material represents a consensus, supported by the available literature and by the laws and regulations that govern the use of controlled prescription drugs.

When this document, the Frequently Asked Questions document, **Michele G. Sullivan** from a national news agency's *Mid-Atlantic Bureau* wrote a story titled **DEA Clarifies Policy on Opiod Use, Misuse, Fraud—The guidelines attempt to strike a balance between the needs of physicians and those of the DEA:**

Physicians who appropriately prescribe opioids to treat chronic pain can rest assured that they will not be investigated by federal agents, according to new guidelines for pain management issued jointly by the Drug Enforcement Agency and national pain experts.

But the guidelines also stress that physicians have a responsibility to make sure that their patients aren't "doctor shopping" to hoard the drugs for personal use or illegal sale.

The document "Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel," will be distributed to physicians who prescribe opioids

and to DEA field agents. Its question and answer format includes guidelines on diagnosing pain, assessing patients' risk for addiction, and proper documentation. The guidelines also include information on laws and regulations, and clear descriptions of how and why the DEA may prosecute a prescriber.

The guidelines are an attempt to “strike a balance” between physicians' need to feel safe when prescribing these drugs and DEA's need to aggressively investigate allegations of drug diversion and fraud, said David Joranson, senior scientist and director of the Pain and Policy Studies Group at the University of Wisconsin, Madison.

Medical and law enforcement personnel have “symmetrical responsibilities,” Mr. Joranson said at a press briefing. “Prescribers have a responsibility not to contribute to abuse, and the DEA has a responsibility not to interfere with patient care.”

About 40% of patients with chronic pain are undertreated, said Russell Portenoy, M.D., the project's lead pain expert. This is partly because of physicians' lack of knowledge of these drugs and their inability to accurately assess pain patients. “Physicians tend to overestimate the risks (associated with opioids) and accept the stigma that has evolved around these drugs.”

“So the inference is that they are used much less than they should be in these populations,” said Dr. Portenoy of Memorial Hospital for Cancer and Allied Diseases, New York.

Another factor in undertreatment is physicians' fear of federal investigation into their prescribing habits, Mr. Joranson said. “The medical and regulatory environment for pain management seems to be worsening. Physicians are concerned about being investigated if they prescribe controlled substances, and they are even more cautious because of high-profile arrests and investigations that can damage or end their careers,” even if any charges are later dismissed.

“The result is that patients can't find a doctor who will prescribe opioids. Some pharmacies don't even carry them. In some ways, pain management has become a crime story when it should be a health care story,” Mr. Joranson said.

The new document is DEA's attempt to strengthen relations with prescribers and clarify the agency's role with regard to opioids, said Patricia Good, chief of DEA's liaison and policy section. “Our hope is to create a sense of perspective and reinforce the fact that the majority of practitioners have nothing to fear from the drug enforcement community.”

In fact, Ms. Good said, concerns about DEA investigations into medically sound prescribing have been overblown. “Much has been made of our ‘aggressive tactics,’ and there are many misconceptions about DEA's role and fundamental beliefs about our position on this. This has led to fears that doctors who prescribe opioids are singled out for observation.”

This is untrue, she said. In 2003, the DEA arrested only 50 clinicians for fraud or diversion, a decrease from 70-80 arrests annually in prior years.

In an effort to educate the entire DEA community, she said, the document will be made available to all investigators. “Our goal to make sure we have adequately trained our diversion employees in the differences between addiction and physical dependence. We want them to understand what good treatment is, so they will understand diversion and abuse when they see it.” With reinforcement, investigators will get the message, Dr. Portenoy said, but it may take a while for a complete sea change.”

In outline form, here are the topics covered by this important document (FAQs):

Contents

12. Can more than one opioid at a time be prescribed to a patient?

13. What is “opioid rotation,” and when is it appropriate?

14. What are “tapering” and “drug holidays”? Is a written agreement between the clinician and the patient required before instituting treatment with an opioid?

15. What should be documented when prescribing opioids?

Section V: Risks in the Medical Use of Opioid Analgesics

16. What is the extent of prescription opioid abuse?

17. What are the common ways opioids are diverted to illicit uses?

18. How can clinicians assess for risks of abuse, addiction, and diversion and manage their patients accordingly?

19. What behaviors are potential indicators of problems for patients on long-term opioid therapy?

20. If a patient receiving opioid therapy engages in an episode of drug abuse, is the physician required by law to discontinue therapy or report the patient to law enforcement authorities?

21. Is it legal and acceptable medical practice to prescribe long-term opioid therapy for pain to a patient with a history of drug abuse or addiction, including heroin addiction?

22. What strategies can be used to treat pain successfully in patients who are currently abusing drugs?

Section VI: Other Legal and Regulatory Considerations

23. What requirements must physicians and pharmacists meet to comply with federal and state laws regulating opioids?

24. What regulations do physicians need to know and observe when prescribing opioid analgesics for pain?

25. Can methadone be used for pain control and, if so, is a clinician required to have a special license to prescribe it?

26. Under what circumstances will the federal Drug Enforcement Administration (DEA) investigate and prosecute a doctor or pharmacist or refer cases to other agencies?

27. Should efforts to address diversion avoid interfering with medical practice and patient care?

28. When should a law enforcement officer turn to a pain medicine specialist for advice?

29. Does the number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, or the duration of therapy with these drugs by themselves indicate abuse or diversion?

While there is not space in this CEU to include the entire document, we do offer the highlights here because there is so much important and clarifying information contained in this FAQs document:

SECTION I
INTRODUCTION

The purpose of this document is to provide information to health care professionals and professionals in the law enforcement and regulatory communities about the medical treatment of pain. The goal is to achieve a better balance in addressing the treatment of pain while preventing abuse and diversion of pain medications. The authors of this document stand committed to the core principle of balance that was expressed in the 2001 joint consensus statement by the U.S. Drug Enforcement Administration and numerous health care organizations:

> Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical (DEA et al., 2001).

Controlled substances that are prescription drugs, such as opioids, are essential for the care of patients but carry a risk that goes beyond the usual clinical concern about toxicity. These drugs can become the object of abuse and addiction or be a target for diversion to an illicit market. This potential for abuse, addiction, and diversion raises concern among all clinicians, including physicians and pharmacists, and those in law enforcement, drug regulation, and policy makers.

When potentially abusable drugs are also necessary medicines, assessment and management of drug-related problems can be complex. The parameters of acceptable medical practice include patterns of drug prescription—such as long-term administration of an opioid drug at escalating doses and administration of more than one controlled prescription drug—that may raise a “red flag” for both clinicians and regulators. Problematic drug-related behavior takes many forms and has many causes in the clinical

setting. Even relatively severe drug-seeking behaviors in the context of a legitimate medical need, such as uncontrolled pain, cannot immediately be ascribed to addiction. The desperate search for pain relief, and the complex psychosocial disturbances accompanying chronic pain, may influence the phenomenology of drug use and greatly complicates the assessment of drug-related problems.

At the same time, however, even patients with severe pain can develop patterns of abuse or addiction, or engage in criminal activity. Physicians who encounter such patients must control the behaviors, diagnose the comorbidities, and react in a way that is both medically appropriate and consistent with the laws and regulations that apply to the medical use of controlled drugs. Although physicians have expressed concern about criminal prosecution when treating such patients, the arrest and indictment of a physician cannot occur unless he or she can be shown to have knowingly and intentionally distributed or prescribed controlled substances to a person outside the scope of legitimate practice.

Drug abuse exacts a huge social cost, and some have been tempted to address prescription drug abuse by greatly limiting access. When drugs are needed for legitimate medical purposes, such as pain management, this action may have unintended consequences that could be just as harmful to the public. Surveys have found that chronic pain is highly prevalent and exacts a huge toll in terms of lost productivity, health care costs, and human suffering. As the U.S. population ages, people will live longer with chronic, often painful, diseases. Even if opioids are appropriate for only a small proportion of these patients, nothing should be done to limit access to the drugs when they are needed, or to increase the reluctance of prescribers to recommend them.

Society has a compelling interest in ensuring ***both*** the ready access to controlled prescription drugs when medically needed ***and*** ongoing efforts to minimize their abuse and diversion. These two goals are not in conflict; they coexist and must be balanced. Those who are licensed to prescribe, dispense and administer these drugs, and those in the law enforcement or regulatory communities need continual education to improve their ability to balance these goals. There should be an ongoing dialogue between practitioners and those in law enforcement and regulation.

The FAQs in this document support the need for dialogue and reflect an effort to answer basic questions about the appropriate use of opioids given their unquestioned medical value, as well as their potential for abuse, addiction, and diversion. The goal is to provide medically and legally sound and balanced education to practitioners, law enforcement, and regulators.

Clinical items have been drafted by experts in pain management, and the items addressing regulatory issues have been drafted by members of law enforcement and experts in the regulation of controlled substances. All responses derive from the fundamental view that practitioners must try to relieve pain, but also must obey laws and regulations, and avoid contributing to diversion, while law enforcement personnel and regulators must address the sources of diversion, but do so in a manner that never interferes in clinical pain management.

Important Disclaimer

Although the FAQs reflect a consensus view of an expert panel, lack of strict adherence to these suggestions does not imply that a particular practice is outside the scope of legitimate medical practice. The FAQ is not intended to be used as medical practice guidelines or standards or as legal advice with regard to specific practices or cases for which clarification should be obtained by consulting relevant practice guidelines, laws, and regulations; the agencies that administer them; and experts in law and in pain and addiction medicine. Practitioners, law enforcement, and regulators should always keep abreast of changes in federal and state statutes, in regulations, and in other policies relevant to pain management.

Relevant Resources:

Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. (2000). *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.* Washington, DC: Last Acts. (Available at http://www.medsch.wisc.edu/painpolicy/dea01.htm.)

Research America. (2003). *Chronic Pain Pervasive in All Age Groups, New Study Shows*. Alexandria, VA, September 4. (Available at http://www.researchamerica.org/opinions/pain.html.)

SECTION III
PAIN AND ITS TREATMENT

2. Why is pain management important?

Uncontrolled pain is an enormous public health problem in the United States. Already accounting for many tens of billions of dollars of needed health care and lost productivity, it is expected that the costs will grow dramatically as the population ages and people live longer with chronic diseases. Equally important, unrelieved pain has a devastating impact on the physical, emotional, social, and economic well-being of patients and their families. Diagnosing and treating pain is, therefore, fundamental to the public health. Many medical and regulatory organizations have recognized the imperative to relieve pain in official statements and guidelines.

Relevant Resources:

American Geriatrics Society Panel on Persistent Pain in Older Persons. (2002). The management of persistent pain in older persons. *Journal of the American Geriatric Society* 50 (6 suppl): S205-S224. (Available at http://www.americangeriatrics.org/education/manage_pers_pain.shtml.)

American Pain Society. (1999). *Guideline for the Management of Acute and Chronic Pain in Sickle Cell Disease. Clinical Practice Guideline Number 1*. Glenview, IL: American Pain Society.

American Pain Society. (2002). *Guideline for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. Clinical Practice Guideline Number 2*. Glenview, IL: American Pain Society.

Arnold R, Berger A, Billings JA, et al. (2004) *Clinical Practice Guidelines for Quality Palliative Care*. Brooklyn, NY: National Consensus Project for Quality Palliative Care. (Available at <http://www.nationalconsensusproject.org/guideline.pdf> http://www.nationalconsensusproject.org/guideline.pdf).

Cancer Pain Management Policy Review Group.(2001). *American Cancer Society Policy Statement on Cancer Pain Management*. National Government Relations Department, American Cancer Society.

Federation of State Medical Boards of the United States Inc. (2004). *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org.)

Foley, K. M., and H. Gelband (eds). (2001). *Improving Palliative Care for Cancer*. Washington, DC: National Academy Press. (Available at http://www.nap.edu/catalog/10149.html.)

Institute of Medicine Committee on Care at the End of Life. (1997). *Approaching Death: Improving Care at the End of Life*. Washington, DC: National Academy Press. (Available at http://books.nap.edu/catalog/5801.html.)

National Institutes of Health Consensus Development Program. (2002). *Symptom Management in Cancer: Pain, Depression and Fatigue*. Statement prepared following a National Institutes of Health State-of-the-Science Conference on Symptom Management in Cancer; Bethesda, MD, July 15–17. (Available at http://consensus.nih.gov/ta/022/022_intro.htm.)

Research America. (2003). *Chronic Pain Pervasive in All Age Groups, New Study Shows*. Alexandria, VA, September 4. (Available at http://www.researchamerica.org/opinions/pain.html.)

Rich, B. A. (2001). Physicians' legal duty to relieve suffering. *Western Journal of Medicine* 175:151–152.

Tucker, K. L. (2001). A new risk emerges: Provider accountability for inadequate treatment of pain. *Annals of Long-Term Care* 9 (4): 52–56.

Tucker, K. L. (2002). Anatomy of a claim for failure to treat pain adequately: $1.5M jury verdict in first case to be tried. *Progress in Palliative Care* 10 (1): 14-15.

3. What are the goals of pain management?

The goals of pain treatment are to reduce pain and suffering, enhance quality of life, and increase the ability to function—all while minimizing the risk of adverse effects. These goals are the same for all pain patients regardless of addiction history. To accomplish these goals, pain management may involve any of a broad array of interventions, one of which is drug therapy. There are numerous options for analgesic drug therapy, including opioids. When drug therapy is one of the strategies used to address pain, the primary goal is to reduce pain without causing distressing side effects or other drug-related problems. Functional restoration may be another important goal and clinical decisions about the ongoing use of analgesic drugs typically require a careful assessment of all outcomes.

4. How can a clinician assess a patient's pain?

Pain assessment is a critically important component of pain treatment because it can yield a pain diagnosis (usually described in terms of etiology, pathophysiology and/or syndrome) that may clarify the need for further evaluation, guide the selection of treatments, suggest prognosis, and indicate the status of coexisting diseases. A documented pain assessment provides a clinical basis for prescribing controlled substances and a recorded baseline against which to measure progress during treatment. The measurement of pain intensity is an important aspect of the pain assessment. Self-report is the "gold standard" for pain measurement. This should be done with a tool appropriate for the patient's cognitive development, language, culture, and preferences; the same tool should be used in subsequent assessments to allow for reliable evaluation of change. Pain measurement tools include numeric scales, visual analog scales, and verbal rating scales. In addition to pain measurement, the assessment should describe the pain in terms of location, temporal characteristics (onset, duration, course, and fluctuation), quality, and factors that increase and decrease pain. The assessment also should evaluate the impact of the pain on physical and psychosocial functioning. Other tools, such as body maps, daily diary records, and multidimensional pain scales, may be used to capture some of this additional information.

A comprehensive pain assessment also includes a physical examination, which can help define the etiology and pathophysiology of the pain. The need for a physical examination is most compelling when a patient with pain is initially evaluated. The extent of this examination is considered to be a matter of clinical judgment and is determined by the nature of the clinical problem; the physician's discipline; and the availability of

previously documented examinations, imaging, and laboratory findings relevant to the pain problem. At the end of an examination, the physician should have sufficient information about the physical status of the patient to support a reasonable diagnostic formulation and decide on next steps. Whether further physical examination is required on subsequent visits also is a matter of clinical judgment, based on the need to confirm or monitor specific findings, track specific treatment effects, or assess comorbidities.

Relevant Resource:

Miaskowski C, Cleary J, Burney R, Coyne,P.; Finley,R.; Foster,R.; Grossman,S.; Janjan,N.; Ray,J.; Syrjala,K.; Weissman,S.; Zahrbock,C. (2004) *Guideline for the Management of Cancer Pain in Adults and Children*. Glenview, IL: American Pain Society.

Simon, L.S., AG Liman, and A Jacox et al. (2002). *Guideline for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. Clinical Practice Guideline Number 2*. Glenview, IL: American Pain Society.

5. When should a primary care physician turn to a pain medicine specialist to manage a patient's pain?

Treatment of pain is an expected part of good medical practice, and all physicians should address the problem to the best of their abilities. Physicians have an obligation to 1) know about the range of therapies used to manage acute and chronic pain; 2) recognize their own level of expertise in pain assessment, treatment selection, and management; 3) understand the nature of the consultative resources in the community; and 4) refer appropriately. Consultation may be needed to obtain a more comprehensive evaluation, to clarify the optimal therapeutic strategy, to implement a therapy that is outside of the referring physician's expertise, or to respond to the patient's desire for another opinion.

If the use of a controlled prescription drug, such as an opioid, is considered to be a potentially useful element in the therapeutic strategy, the physician may consider consultation for any of a variety of specific reasons. Consultation is considered part of good medical practice and is encouraged by the Federation of State Medical Boards' "Model Policy for the Use of Controlled Substances for the Treatment of Pain" (available at http://www.fsmb.org/). Specialist input may be helpful to clarify the appropriateness of therapy; define the optimal regimen or monitoring approach; assist in the evaluation of problematic behavior, or evaluate specific recommendations, such as a switch from "PRN" to fixed scheduled dosing, or from a short-acting to a long-acting drug.

In all cases, the decision to request a consultation should be based on both a critical self-evaluation on the part of the physician and an assessment of the clinical challenges posed by the patient. The physician's self-evaluation should define which types of patients or therapies can be implemented without additional help, which can be implemented with guidance through consultation, and which are better left to a specialist. Where these lines are drawn depends on existing knowledge and skills, and the availability of support

systems for monitoring. Ideally, most patients who undergo evaluation by the specialist will then return to the primary physician for ongoing treatment.

In some situations, consultation prior to, or during, opioid therapy may be requested solely to address the concern that specialist review would be reassuring to a regulator should the therapy ever be questioned. Although this is not a medical justification per se, it may be appropriate given the evolving nature of opioid therapy in medical care.

Consultation is not required under federal law, but some states do require consultation when treating patients with pain (see http://www.medsch.wisc.edu/painpolicy/2003_balance/ for examples). Some states have done away with this requirement.

If the patient is referred to a specialist or pain treatment center to receive treatment, the referring physician should understand whether the expertise needed is in fact available. Not all pain specialists are knowledgeable or experienced in opioid therapy, for example, and not all provide access to psychological or rehabilitative treatments. The referring physician should understand the nature of the consultative services in the community before sending a patient for evaluation or care. A searchable list of credentialed pain specialists can be found at the American Academy of Pain Medicine's website: http://www.painmed.org/membership/; a searchable list of pain clinics can be found at http://www.pain.com/frameindex.cfm.

SECTION IV
MEDICAL USE OF OPIOID ANALGESICS

6. How are opioids used to manage chronic pain?

There are many approaches to treating chronic pain that should be considered based on a comprehensive assessment of the pain syndrome and its impact, the level of disability, and the existence of medical and psychiatric comorbidities. In some cases, specific treatment targeting the cause of the pain is available and appropriate. For example, good glycemic control is central to the treatment of painful diabetic neuropathy and joint replacement can eliminate pain due to severe osteoarthropathy. When pain becomes chronic, there are numerous specific therapies that may be appropriate to lessen discomfort or address the need for functional restoration. On the basis of the assessment, pain treatment may emphasize or de-emphasize pharmacotherapy and incorporate any of a variety of non-drug treatments. These may include physical therapy or other rehabilitative approaches; cognitive and behavioral strategies; interventional treatments such as injections or implantation of spinal cord stimulators and pumps; or numerous complementary approaches such as acupuncture and massage.

Drug treatments include nonopioid medications, such as acetaminophen, aspirin and the nonsteroidal anti-inflammatory drugs (NSAIDs); numerous drugs known collectively as the adjuvant medications (including antidepressants, antiseizure medications, and others);

and opioid analgesics. Like the decision to use any other treatment, the decision to try an opioid, or to continue opioid therapy on a long-term basis, should be based on a careful evaluation of the issues specific to this approach.

Opioid therapy is accepted around the world as the most important approach to managing severe, acute pain (such as pain after surgery), moderate to severe chronic cancer pain, and moderate to severe chronic pain caused by other life-threatening diseases (such as AIDS). The use of opioid therapy to treat chronic nonmalignant pain has been more controversial and is still being actively discussed by medical experts. The consensus now is that some patients with chronic pain should be considered as candidates for long-term opioid therapy, and some will gain great benefit from this approach.

The controversy over the use of opioid drugs to treat chronic pain is multifaceted. To some extent, it is related to limited scientific literature that does not yet clearly define the most appropriate patient subpopulations, best treatments, and range of outcomes. More research is seriously needed to address these questions.

The controversy also stems from a lack of education about these drugs on the part of clinicians, regulators, law enforcement, policy makers, patients and the public at large. The scientific literature that does exist is often poorly recognized. This literature is generally viewed by pain specialists as having established the effectiveness of opioid therapy in selected patients. It also has helped define the risks and range of benefits that are associated with the approach.

There also is substantial confusion about the meaning of, and the true risks associated with, drug-related phenomena such as physical dependence, tolerance, and addiction (see Appendix A for definitions). This confusion can lead to the withholding of opioid medication because of a mistaken belief a patient is addicted when he or she is merely physically dependent. It can lead to inappropriate targeting of practitioners and patients for investigation and prosecution, and to excessive and unfounded fear of opioid use among patients and the public. This confusion must be resolved to settle the important medical questions relating to patient selection, treatment goals, dosing, and monitoring. The answers to these questions should be informed by research.

Ideally, the clinician's decision about how to treat a patient's pain is based on a full understanding of the likelihood of both benefit and harm from reasonable treatment alternatives. However, there are few data on risks and benefits for many treatments, including the long-term use of opioids. Nevertheless, it is widely agreed that opioids are an option for long-term pain treatment and that a trial may be a reasonable step for patients who have moderate to severe chronic pain. To make this decision, the assessment should attempt to answer the following questions:

- *What is conventional medical practice in the treatment of this type of pain?* If there is widespread acceptance of an approach, such as trials of nonsteroidal anti-inflammatory drugs in painful osteoarthropathy, then the decision to use an opioid may require documentation that the accepted approach has been tried and failed, or carries an unacceptably high risk in the specific patient.

- *Are there other treatments that may be effective and feasible, and have a risk-to-benefit profile as good as, or better than, the opioids?* This question is difficult to resolve, given the lack of comparative data from clinical trials. Nonetheless, the clinician who is considering the administration of an opioid, particularly long-term administration, should carefully consider whether there are other treatment options that are likely to work as well in the specific case, at the level of risk associated with opioid therapy.
- *Is the patient particularly vulnerable to opioid side effects?* The analysis of risk-to-benefits shifts in those who are predisposed to severe opioid side effects.
- *Is the patient likely to take medications responsibly or, if problems seem likely, could a plan for structuring the therapy and monitoring it be successful?* Risk assessment and management should be considered a fundamental aspect to long-term opioid therapy. An assessment that reveals characteristics, such as a history of substance abuse in the recent past, that suggests a relatively high risk of problematic drug-related behaviors may influence the decision to initiate treatment or lead to more intensive monitoring if opioid therapy is still indicated.

Based on the answers to these questions, the clinician should be able to make an informed judgment about the potential value of an opioid trial in a particular patient.

Opioid treatment options include short-acting opioids, such as codeine, hydrocodone, hydromorphone, morphine, or oxycodone. Some of these drugs are available in combination with aspirin, acetaminophen or ibuprofen; in this case, caution is needed to avoid toxicity from the nonopioid component. Long-acting opioids, such as one of the modified-release opioids (e.g. fentanyl, morphine, or oxycodone) or the long half-life drug methadone are preferred for chronic pain because they are more convenient and may provide more consistent pain relief. Less frequent dosing with long-acting or controlled-release opioids also can improve adherence to the therapy (fewer missed doses). In appropriate patients, a short-acting opioid may be prescribed on a "PRN" basis in combination with fixed scheduled administration of a long-acting drug to assist in the management of "breakthrough" pain.

For more information on the use of opioids in the management of pain, see:

- American Academy of Pain Management
- http://www.aapainmanage.org/education/Education.php
- American Academy of Pain Medicine
- http://www.painmed.org/cme
- American Academy of Physician Assistants
- http://www.mecgeducation.com/jaapa/pain_management/default.asp
- American Board of Pain Medicine
- http://www.abpm.org/index.htm
- American Headache Society
- http://www.ahsnet.org
- American Medical Association
- http://www.ama-assn.org/ama/pub/category/10171.html
- American Pain Society

- http://www.ampainsoc.org
- Beth Israel Department of Pain Medicine and Palliative Care http://www.stoppain.org/
- California Academy of Family Physicians http://www.familydocs.org/
- National Pain Education Council http://www.npecweb.org

Relevant Resources:

American Society of Addiction Medicine. (1997). *Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain*. Chevy Chase, MD: American Society of Addiction Medicine. (Available at http://www.asam.org/ppol/opioids.htm.)

Gourlay, G. K. (2002). Clinical pharmacology of opioids in the treatment of pain. In M. A. Giamberadino (ed.), *Pain 2002—An Updated Review: Refresher Course Syllabus*. Seattle: IASP Press, pp. 381–394.

Graven, S., H. C. W. deVet, M. van Kleef, and W. E. J. Weber (2000). Opioids in chronic nonmalignant pain: a criteria-based review of the literature. In M. Devor, M. C. Rowbotham, and Z. Wiesenfeld-Hallin (eds.), *Proceedings of the 9th World Congress in Pain Research and Management* 16, Seattle: IASP Press.

Kalso, E. (2000). Opioids for chronic noncancer pain. In J. O. Dostrovsky, D. B. Carr, and M. Koltzenburg (eds.), *Proceedings of the 10th World Congress on Pain*, Seattle: IASP Press, pp. 751–765.

Passik, S. D., and H. J. Weinreb Managing chronic nonmalignant pain; Overcoming obstacles to the use of opioids. *Advances in Therapy*17: 70–80.

Savage, S. R. (2003). Opioid medications in the management of pain. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith et al. (eds.). *Principles of Addiction Medicine* (3rd ed.). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp.1451–1463.

Zacny, J., G. Bigelow, P. Compton et al. (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. *Drug and Alcohol Dependence* 69: 215–232.

7. What outcomes should be assessed when judging whether opioid therapy is successful?

Opioid analgesics have the ability to relieve pain. Improved comfort may be associated with better physical and psychosocial functioning, and enhanced quality of life. Opioids also have the potential for side effects and adverse effects (including abuse or addiction). Given the variation in the responses associated with this therapy, the management of

opioid therapy should include ongoing evaluation of a range of outcomes. The relevant categories include:

- *pain relief;*
- *side effects;*
- *functioning, both physical and psychosocial (and overall quality of life); and*
- *problematic drug-related behaviors (which may suggest misuse, abuse, addiction, or even diversion).*

Pain intensity, or the extent of pain relief, should be measured over time and documented in the medical record. This may involve questions using a simple verbal rating scale (none, mild, moderate, severe), a numeric scale ("0 to 10"), or some other type of measure. Documentation in the medical record that pain is being followed over time is important evidence of the appropriateness of therapy.

Although opioids can provide pain relief, complete pain relief is uncommon during the treatment of chronic pain. Pain measurements during the treatment of chronic pain are seldom "zero," and in some cases, can fluctuate at relatively high levels. In the clinical setting, the overall benefit, or success, of opioid therapy often cannot be determined by pain scores alone. Although clinical studies have suggested that meaningful pain relief is associated with defined reductions in pain scores (e.g., two points on a 0 to 10 scale or 30% on a visual analogue scale), these values are helpful in research but do not capture the complexity of the clinical situation. For some patients, pain relief may be "meaningful" when specific tasks can be performed, mood improves, sleep is better, or relationships with others can occur. The monitoring of pain intensity is important but the clinician should be prepared to assess all these outcomes in an effort to understand the overall effects of therapy.

Side effects are common during opioid therapy. The potential for side effects should be explained to the patient and anticipated, assessed, and managed. With the exception of constipation, side effects are usually of short duration and can be expected to lessen with time as the body adapts to the opioid (see Question 9 for more information on side effects).

Although a large clinical experience suggests that most patients use opioid drugs responsibly—following instructions, communicating with the clinician, and avoiding actions that would be worrisome to the prescriber—some patients engage in problematic drug-related behaviors. These problematic behaviors are very diverse and may reflect any of a wide array of clinical disorders (including addiction); they could potentially reflect diversion as well. Practitioners who prescribe controlled prescription drugs, such as the opioids, should monitor drug-related behavior. This may be done through history-taking,

or if indicated, through more structured plan that includes behavioral assessments. Such a structured approach is most clearly indicated if the patient has a known history of addiction or significant substance abuse (see Question 23).

In summary, pain treatment with opioids should be evaluated over time by assessing improvement in pain and the extent to which this outcome is associated with side effects,

gains in function and quality of life, and the occurrence of any problematic behaviors. These outcomes are important to assess in all cases, regardless of their history.

Relevant Resources:

Gourlay, G. K. (2002).Clinical pharmacology of opioids in the treatment of pain. In M. Giamberadino (ed.), *Pain 2002—An Updated Review: Refresher Course Syllabus*.Seattle: IASP Press, pp. 381–394.

McQuay, H. J. (1999). How should we measure the outcome? Opioid Sensitivity of Chronic Noncancer Pain. In E. Kalso, H. J. McQuay, and Z. Weisenfeld-Hallin (eds.), *Progress in Pain Research and Management* 14. Seattle: IASP Press, pp. 371–383.

Rowbotham, M. C. (2001). Editorial: What is a "clinically meaningful" reduction in pain? *Pain* 94: 131–132.

8. Where can clinicians find educational material on prescribing opioid analgesics?

- American Academy of Pain Management
  http://www.aapainmanage.org/education/Education.php
- American Academy of Pain Medicine
  http://www.painmed.org/cme
- American Academy of Physician Assistants
  http://www.mecgeducation.com/jaapa/pain_management/default.asp
- American Geriatrics Society
  http://www.americangeriatrics.org/education/manage_pers_pain.shtml
- American Medical Association
  http://www.ama-assn.org/ama/pub/category/10171.html
- Beth Israel Department of Pain Medicine and Palliative Care
  http://www.stoppain.org/
- California Academy of Family Physicians
  http://www.familydocs.org/
- National Pain Education Council
  http://www.npecweb.org

9. What are the common side effects associated with opioid therapy, and how can they be managed?

It is very important that physicians anticipate, recognize, and treat side effects when patients are receiving opioids for pain. Common side effects at the start of therapy or after dose escalation include somnolence or mental clouding, nausea, and constipation. Uncommon side effects include fatigue; itching; adverse mood change; dry mouth, loss of appetite, bloating, or heartburn; urinary hesitancy; sweating; sexual dysfunction; and headache. Although any side effect can persist, the most common long-term side effect is

constipation. With overdose, opioids can cause serious respiratory depression, the risk of which is again highest in the setting of limited or no ongoing opioid therapy.

Physicians should periodically inquire about side effects. If side effects are present and are not tolerated well, treatment should be adjusted. The drug or how it is administered can be changed, or a specific treatment can be given for the side effect. Typically, successful therapy depends on achieving and maintaining a favorable balance between analgesic effects and side effects.

Constipation is very common during opioid therapy, particularly among those patients who are predisposed (the elderly, patients taking other constipating drugs, patients with diseases that affect the gastrointestinal track). Tolerance may not develop to opioid-induced constipation, and laxative therapy may be needed throughout the course of treatment.

Somnolence and mental clouding are common when therapy is initiated or the dose is increased. Although these effects typically decline over time, some patients experience persistent impairment. The risk presumably is higher among those who are concurrently using other CNS depressants and those with diseases associated with encephalopathy. Selected patients with analgesia compromised by somnolence or mental clouding may be candidates for specific therapy with a psychostimulant drug.

Nausea and vomiting may be treated with antiemetics such as phenothiazines, butyrophenones, or metoclopramide. When nausea is due to motion-related vestibular effects, a trial of an antihistamine, such as meclizine or scopolamine, should be considered. If opioid-induced gastroparesis is suspected (postprandial nausea, bloating, reflux symptoms), metoclopramide is a preferred drug because of its positive effects on gastrointestinal motility. To help manage nausea, it may be worthwhile to consider switching to a nonoral route of administration, at least for a time.

Itching, which results at least in part from the release of histamines triggered by opioids, usually resolves within a few days. If itching persists, it may be treated with an antihistamine. Among the commonly used opioids, and fentanyl and oxymorphone have a relatively low propensity to release histamine.

Respiratory depression is a rare adverse effect during chronic opioid treatment. Respiratory depression is possible if dose escalation occurs very quickly, beyond the ability of compensatory mechanisms to adjust; if some intercurrent cardiopulmonary event occurs (for example, pulmonary embolism or pneumonia), or if something happens to eliminate the source of the pain (for example, a nerve block). Except in rare circumstances, respiratory depression is preceded by somnolence and slowed breathing. Respiratory depression that occurs from some intercurrent cardiopulmonary event may be partially reversed by naloxone. Accordingly, a response to naloxone does not mean that the opioid was the primary problem. When patients develop respiratory depression in the setting of stable dosing, a prompt search for another cause usually is indicated, even if the patient improves with naloxone.

Because the administration of naloxone carries substantial risks in the physically dependent patient (severe withdrawal), it should not be used unless clinically significant respiratory depression is feared. Naloxone should not be given for somnolence in the absence of existing or impending respiratory effects. If the time of peak effect of the drug has passed, and the patient has adequate respirations, it is safer to observe for a period of hours than to treat with naloxone. If naloxone must be given, it is safer to give small doses repeatedly and monitor effects.

Relevant Resources:

American Pain Society. (2003). *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain* (5th ed.). Glenview, IL: American Pain Society.

Fohr, S. A. (1998). The double effect of pain medication: Separating myth from reality. *Journal of Palliative Medicine* 1 (4): 315–328.

10. What information do patients need about using opioids for chronic pain?

Informing patients about issues surrounding pain management and the use of opioid analgesics is good medical practice. Sometimes, this is accomplished as part of informed consent, which is recommended and, in fact, required in some states (to see if your state requires informed consent, refer to http://www.medsch.wisc.edu/painpolicy/matrix.htm).

Physicians can provide information through discussions with the patient or by distributing a handout, booklet, or medication agreement. Patients and their caregivers also can gain access to valuable information by using the Internet to reach a number of organizations (see links provided below).

Although not a complete list, patients should understand this information:

- Patients' rights
  - Patients have the right to have their pain assessed and treated.
  - Accredited medical facilities should recognize this right.
- Diagnosis and treatment plan

  Patients should:
  - know the diagnosis and as much as possible about reasons for the pain.
  - know the goals of treatment and how the physician will measure progress to achieve the goals.
  - know why opioid analgesics are part of the treatment plan and how and when to take them.
  - know the realistic expectations for sustained pain relief and improved functioning, and that it may not be possible to relieve all their pain.
  - realize that opioids are only one part of a treatment plan that may include other treatments such as physical therapy or psychological techniques.
  - recognize that decisions about starting, changing, or stopping opioid treatment should be made with patient input.

- know that they can ask for changes in treatment or a consultation with a specialist if pain relief is not adequate.

- Side effects

  Patients should:

  - know what side effects to expect and how to manage them.
  - understand that most side effects are transitory, but any effect can persist and potentially compromise the long-term value of the treatment.
  - recognize that concurrent therapies for side effects may be recommended.
  - know that the occurrence of intolerable and untreatable side effects means that the treatment is not appropriate and must be changed.
  - know that opioids may impair thinking and alertness at first and, if this occurs, the patient should avoid driving or other similar activities until these effects dissipate.

- Abuse, addiction, physical dependence, and tolerance

  Patients should:

  - know the definitions of physical dependence, tolerance, and addiction.
  - understand that the use of an opioid in a manner different from what is instructed is a form of drug abuse, and that the clinician must continually assess whether this is occurring and take steps to prevent it or, should it be identified, stop it.
  - know that the use of alcohol and any other prescribed drugs during opioid therapy must be assessed by the clinician, and should the use of these substances be perceived to be problematic, the clinician must assess the situation and take appropriate actions.
  - recognize that the use of illicit drugs can be a significant problem, and that the clinician must monitor the patient for this occurrence and act appropriately if it is discovered.
  - know that addiction is a serious illness, and that the clinician must monitor drug-related behaviors in part to make sure that this problem is not developing; if there is a possibility that problematic behaviors surrounding medicines are due to an addiction, the physician must treat this.
    - know that true addiction is believed to be a rare occurrence in patients who receive opioids for a medical reason and have no history of drug abuse or addiction; clinicians must monitor drug-related behaviors in all patients, however, have accurate and balanced information about addiction and how it is assessed.
  - know that physical dependence, which is the capacity for withdrawal, is normal during opioid therapy, does not prevent discontinuation of the therapy if the pain stops, and, most important, is not addiction.
  - know that analgesic tolerance occurs when a stable dose of pain medication has a decreasing effect over time and does not indicate addiction.

- Some “Dos” and One “Don’t” for Patients

  - Do talk to the doctor and other health care professionals involved in your pain care about the pain; keep notes and write down questions to ask about the pain.
  - Do talk to the doctor if the medication is not working.
  - Do talk to the doctor if there are problems with side effects.

- Do talk to the pharmacist openly about this therapy if he or she could potentially help with information about the pain or the management of side effects.
- Do keep the medications in a safe place and out of children's reach.
- Do look for another physician, or request referral to a specialist, if the pain is not taken seriously.
- Do use the medication only as it is prescribed and handle the therapy with a high level of responsibility.
- Do notify the physician if you are planning to become pregnant or are already pregnant.
- Don't allow others to use the prescription medication; the patient is the only person who is legally permitted to have the prescribed opioids.

For more information about pain, patients' rights, communicating with the physician, and support:

American Alliance of Cancer Pain Initiatives
http://www.aacpi.org
American Cancer Society
http://www.cancer.org/docroot/home/index.asp
American Chronic Pain Association
http://www.theacpa.org
American Pain Foundation (homepage)
http://www.painfoundation.org/
American Pain Foundation (brochure "Finding Help for your Pain")
http://www.painfoundation.org/downloads/FindingCare.pdf
Cancer Information Service
http://cis.nci.nih.gov/
National Chronic Pain Outreach Association
http://www.chronicpain.org/
National Pain Foundation
http://www.painconnection.org

11. What kinds of problems might patients encounter when obtaining opioid prescriptions, in having them filled, or in taking the medications properly?

- Some physicians may be reluctant to prescribe pain medications due to uncertainty about the medical appropriateness, inadequate or inaccurate knowledge about pain management, limited information about opioid pharmacology, concern about the development of problematic drug-related behavior or addiction, and fear of scrutiny by regulatory and law enforcement agencies and the insurance industry. Physician communication with regulatory agencies, as well as information disseminated by organizations such as medical boards, can help to overcome these problems.

- Pharmacists sometimes react with suspicion to patients who are prescribed opioid drugs because of concern about drug abuse or lack of information about the proper role of opioid therapy in pain management. Some pharmacists even refuse to dispense controlled substances, and some do not understand what the law allows. Communication between the physician and pharmacist, as well as consultation with and information disseminated by pharmacy boards, can reduce these problems.
- Some pharmacies do not stock pain medications due to high cost, poor reimbursement, low prescription demand, and concerns about theft or robbery; clinicians may recommend certain pharmacies or may call ahead to be sure that the prescribed medication is in stock.
- Pharmacies sometimes provide drug information, including computer printouts, that provide an inaccurate perspective of the benefits and risks of opioid drugs, reinforcing patient concerns about the medicine.
- Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate, media coverage about abuse of opioid pain medications.

Relevant Resources:

Joranson, D. E., and A. M. Gilson (2001). Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association* 41 (2): 213–220. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/01japhak/index.htm.)

Morrison, R. S., S. Wallenstein, D. K. Natale et al. (2000). "We don't carry that"—Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine* 342 (14): 1023–1026.

12. Can more than one opioid at a time be prescribed to a patient?

The physician may determine that it is beneficial for the patient to use more than one opioid at a time. In the treatment of cancer pain, the typical approach involves the prescription of a long-acting opioid to relieve baseline pain plus a short-acting opioid (known as the "rescue" dose) to be taken as needed for episodes of breakthrough pain. Many pain specialists now apply this approach to the management of chronic noncancer pain. The use of this rescue medication should be considered on a case-by-case basis. Some patients appear to be good candidates because their pain fluctuates, opioids help, and there is a reasonable expectation of responsible drug use; others may benefit more from administration of a single drug according to a fixed schedule. Other nonopioid controlled substances also may be coadministered during opioid therapy (see Question 9). A separate prescription form should be used for each opioid or other controlled substance prescribed.

13. What is "opioid rotation," and when is it appropriate?

Opioid rotation refers to a switch from one opioid to another. It is a common strategy to address the occurrence of intolerable side effects during opioid therapy. When a switch is made, the starting dose of the new drug is selected based on the information in an "equianalgesic dose table." Versions of this table are widely available, and the values it contains should be considered a broad guide to selecting the dose. In most cases, the dose of the new opioid is reduced from the calculated equianalgesic dose because cross-tolerance between opioids is incomplete and there is substantial variation in the dose-response across individuals. This reduction reduces the risk of side effects from a calculated dose that may be, in effect, too high for the patient. The extent of the dose reduction varies with the specific drug and the clinical situation of the patient. The usual 30-50% reduction in the calculated equinalgesic dose is increased (usually to 75-90%) when the switch is to methadone, and is decreased (sometimes to no reduction at all) when the switch is to transdermal fentanyl; the reduction is increased if the patient has significant opioid side effects or is medically frail, and it is decreased if the patient has a high level of pain. After treatment with the new drug is initiated, the dose usually must be adjusted, often repeatedly, to optimize the balance between pain relief and side effects.

Relevant Resources:

Anderson, R., et al. (2001). Accuracy in equianalgesic dosing. Conversion dilemmas. *Journal of Pain and Symptom Management* 21 (5): 672–687.

Arnold, R., and D. E. Weissman (2003). Calculating opioid dose conversions #36. *Journal of Palliative Medicine* 6 (4): 619–620.

Pereira, J., et al. (2001). Equianalgesic dose ratios for opioids. A critical review and proposals for long-term dosing. *Journal of Pain and Symptom Management* 22 (2): 672–687.

Southern California Cancer Pain Initiative. *Pocket Card*. (Available at http://sccpi.coh.org/.)

14. What do the terms "tapering" and "drug holiday" mean?

Tapering (or "weaning") is when the physician discontinues a pain patient's opioid therapy by progressively reducing the dose to prevent withdrawal symptoms. If opioid therapy must be stopped, the dose should be tapered rather than being discontinued abruptly. The observation that opioid therapy can be discontinued without uncomfortable abstinence by carefully tapering the dose supports the view that opioid therapy can be initiated as a *trial*. If the patient benefits, treatment can be continued; if the patient does not benefit, or benefits for a time but then develops problems, the treatment can be stopped without risk of the significant physiologic perturbations associated with withdrawal.

Tapering of a patient being treated for pain is legally distinct from "detoxification" of a patient being treated for addiction. Physicians who are directing the taper of a therapy do not need a separate DEA registration as do those who are directing detoxification programs under Title 21 of the U.S. Code of Federal Regulations §1306.07. There are no federal or state regulations governing the tapering from opioids of a patient being treated for pain.

A "drug holiday" usually means the cessation of opioid therapy for reasons other than inadequate pain relief, unacceptable adverse effects, or decreased quality of life. There is no medical justification for an enforced drug holiday of an opioid in the management of ongoing pain.

15. Is a written agreement between the clinician and the patient required before instituting treatment with an opioid?

Although not required by federal regulations, written agreements regarding opioid treatments can be an important part of treatment for some patients and may be required or considered the standard of practice in some states. Pain specialists have differing opinions about the contents and use of agreements, but some believe they should be used whenever long-term opioid therapy is instituted. Some clinicians use agreements as routine office policy for every patient receiving chronic opioid therapy. Written agreements should advance a positive therapeutic relationship, reflect a willingness to have an open dialogue about the responsibilities and risks associated with opioid therapy, and contain clear and accurate information and instructions for the patient. Such agreements—a copy of which is kept by both physician and patient—may be useful to:

Describe the treatment goals and plan.

- Clarify the responsibilities and expectations of both physician and patient.
- Serve as a reference point if there is any disagreement about expectations and responsibilities.
- Serve as written informed consent regarding the possible side effects and risks of opioid medications.
- Establish parameters for opioid use and consequences for misuse.
- Aid in the diagnosis of problematic drug-related behavior, should it occur.

Examples of such agreements can be found at:

- American Academy of Pain Management http://www.aapainmanage.org/literature/Articles/OpioidAgreements.pdf.
- American Academy of Pain Medicine http://www.painmed.org/productpub/statements/

Relevant Resource:

Gitlin, M. C. (1999). Contracts for opioid administration in the management of chronic pain: a reappraisal. *Journal of Pain and Symptom Management*18: 6–8.

16. What should be documented when prescribing opioids?

Requirements for documentation when prescribing opioids for the treatment of pain vary from state to state, but there are several features that endorsed commonly:

- The medical record should have evidence that the treatment is taking place within the standards of medical practice.
    - For an initial evaluation, this includes a history and physical examination, a pain assessment, and a treatment plan.
    - For follow-up visits, this includes an appropriate interim history and focused examination when indicated, pain reassessment, and reevaluation of the treatment plan.
- The medical record should reveal evidence that the physician has evaluated the nature of the pain complaint, earlier treatments, impact of the pain, important comorbidities, and alcohol and drug history.
- The medical record should show that a range of outcomes have been repeatedly assessed during the course of opioid therapy, including:
    - pain intensity;
    - physical and psychosocial functioning;
    - side effects of therapy; and
    - drug use behaviors (that is, whether any problematic behaviors occur).

The Federation of State Medical Boards of the United States (FSMB) "Model Policy for the Use of Controlled Substances for the Treatment of Pain" provides more detailed direction on documentation at http://www.fsmb.org/. State requirements can be obtained from your state medical board (directory provided at http://www.fsmb.org) and from state pain policies for each state and can be found at http://www.medsch.wisc.edu/painpolicy/matrix.htm.

SECTION V
RISKS IN THE MEDICAL USE OF OPIOID ANALGESICS

17. What is the extent of prescription opioid abuse?

It is difficult to measure with precision trends in the abuse of prescription controlled substances, including the opioid analgesics. Several information systems exist and are described in the references below. Some useful perspective can be obtained from one nationally representative information system, the Drug Abuse Warning Network (DAWN), although periodic changes in data collection methodology make its interpretation difficult over time. According to *The DAWN Report* (January 2003), published by the Substance Abuse and Mental Health Services Administration:

Concern about the abuse of prescription painkillers has risen dramatically in the U.S. Of particular concern is the abuse of pain medications containing opiates (also known as narcotic analgesics), marketed under such brand names as Vicodin®, Oxycontin®, Percocet®, Demerol®, and Darvon®. According to the Drug Abuse Warning Network (DAWN), the incidence of emergency department (ED) visits related to narcotic analgesic abuse has been increasing in the U.S. since the mid-1990's, and more than doubled between 1994 and 2001.

The DAWN system collects data from EDs about the number of times drugs are mentioned[1] in drug overdoses. In 2002, the total number of DAWN ED mentions was 1,209,938. These included:

- 17% alcohol-in-combination with other drugs (24% increase from 1995);
- 16% cocaine (47% increase from 1995);
- 10% marijuana (164% increase from 1995);
- 10% all narcotic analgesics combined (163% increase from 1995); and
- 8% heroin (34% increase from 1995).

Of the opioid analgesic category:

- Codeine: 4,961 mentions; a decrease of 43% from 1995
- Fentanyl: 1,506 mentions; an increase of 6745% over 1995
- Hydrocodone: 25,197 mentions; an increase of 160% over 1995
- Hydromorphone data not available

[1]A drug mention refers to the number of times a drug is mentioned as being involved in a drug-related emergency room visit.

- Meperidine: 722 mentions; a decrease of 31% from 1995
- Methadone: 11,709 mentions; an increase of 176% over 1995
- Morphine: 2,775 mentions; an increase of 116% over 1995
- Oxycodone: 22,397 mentions; an increase of 560% over 1995
- Propoxyphene: 4,676 mentions; a decrease of 25% from 1995

Given the well accepted limitations of DAWN data, this report should not be considered a detailed or comprehensive accounting of the epidemiology of drug abuse. Nonetheless, the DAWN system has been used for many years as an indicator of drug abuse patterns. From this indicator and other data, there is a high likelihood that prescription drug abuse has increased substantially during the past decade.

Relevant Resources:

Brookoff, D. (1993). Abuse potential of various opioid medications. *Journal of General Internal Medicine* 8: 688–690.

Gilson, A. M., K. M. Ryan, D. E. Joranson, and J. L. Dahl (in press). A reassessment of trends in the medical use and abuse of opioid analgesics. *Journal of Pain and Symptom Management*.

Ling, W, D. R. Wesson, and D. E. Smith (2003). Abuse of prescription opioids. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith, R. K. Ries, and B. B. Wilford (eds.), *Principles of Addiction Medicine* (3rd ed). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp. 1483–1492.

Zacny, J., G. Bigelow, P. Compton et al. (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. *Drug and Alcohol Dependence* 69: 215–232.

18. What are the common ways opioids are diverted to illicit uses?

"Diversion" refers to the unlawful transfer of prescription drugs from legitimate to illicit channels of distribution, often resulting in episodes of abuse. Opioids are diverted in many ways, all of which are illegal. At the top of the distribution chain, there are thefts from drug manufacturers and wholesalers. The most common type of diversion at this level is from in-transit losses. Depending on the size of the "heist," this source could account periodically for a large number of opioids reaching the illicit market.

At the retail level, there are thefts from pharmacies, also a potentially large source of diversion. The most common pharmacy theft is the "night break-in." There are also numerous reports of armed robbery of pharmacies. The individuals who commit these crimes can be dangerous and may be motivated by their own addiction or to sell the drugs on the illicit market. Diversion from pharmacies also includes employee pilferage and customer theft. There is also "Internet" diversion, where drugs are illegally purchased online from foreign and domestic websites.

Some physicians knowingly and intentionally prescribe opioid medications for profit or other personal gain and others may become involved in "prescription fraud," which occurs whenever prescriptions for controlled substances are obtained under false pretenses, including when prescriptions are forged or altered to authorize additional quantities or refills, or when prescriptions are called in to pharmacies by individuals posing as patients or claiming to represent a physician. Patients sometimes sell their prescription forms or medications to others, and nonpatients may steal a patient's prescriptions or medications. Some physicians unwittingly contribute to diversion by careless prescribing or failure to maintain control over their prescription pads. To reduce these occurrences, practitioners should write prescriptions in a way that precludes alteration, keep prescription forms in a secure location, and contact local law enforcement if prescription forms are ever stolen.

Drug abusers may visit multiple physicians and present themselves convincingly so that physicians who are unfamiliar with drug abuse may inadvertently contribute to drug diversion. This method of diversion is called "doctor shopping." Skilled "professional patients" seek out physicians and use them, willingly or unwillingly, as suppliers of drugs that are then diverted to the illicit market. Any physician can be duped, and physicians are encouraged to familiarize themselves with how to spot a drug abuser (see answer to Question 19) or go to DEA website for "Don't be scammed by a drug abuser,"

http://www.deadiversion.usdoj.gov/pubs/brochures/index.html), while at the same time ensuring that their pain patients receive the pain relief they need.

There are few data about the extent to which these various sources contribute to overall diversion and abuse. The source of diversion for which there is the most consistent and reliable data comes from DEA registrants, including pharmacies, who are required to report all significant losses and thefts to the DEA. (An example of pharmacy theft data can be found on the DEA website, http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycodone.htm).

Relevant Resource:

Gilson, A. M., K. M. Ryan, D. E. Joranson, and J. L. Dahl (in press). A reassessment of trends in the medical use and abuse of opioid analgesics. *Journal of Pain and Symptom Management*.

19. How can clinicians assess for risks of abuse, addiction, and diversion and manage their patients accordingly?

Some patients engage in aberrant drug-related behavior during treatment with an opioid or another controlled substance prescription drug. In some cases, this abuse is relatively minor and transitory, but in others, it is serious and persistent. Clinicians should recognize that these behaviors may have any number of causes, including addiction. It is recommended that clinicians adopt a "universal precautions" approach to the use of potentially abusable drugs, including opioids, as discussed below. This approach monitors behaviors over time and structures prescribing consistent with the degree of risk of abuse, addiction, and diversion. By establishing treatment expectations for each patient, and structuring therapy appropriately, physicians can identify those patients who are at risk for abuse, addiction, or diversion; help those who may need controls to manage the therapy responsibly; and provide the monitoring that is needed for safe and effective prescribing.

Clinicians should consider the following approaches in developing a "universal precautions" approach:

1. In assessing patients for opioid therapy, take a detailed history and perform an appropriate physical examination (see Question 4). The medical history should include a history of controlled prescribed drug use and alcohol, cannabis and nicotine use. Screen for addictive behaviors of other family members. Take into consideration any social, psychological, or work-related factors that may indicate a potential for abuse, addiction, or diversion. Identify concurrent psychiatric illness, especially where poor impulse control is a feature.
2. Establish diagnoses for the pain problem and for relevant comorbidities, and record these in the chart. Base the diagnosis on appropriate evaluations and review of patient records, if available. A patient's unwillingness to allow contact with previous providers should be evaluated and documented.

3. Consider multiple approaches to the treatment of chronic pain. Nonpharmacological and nonopioid analgesic approaches may be preferred. Some states have special requirements for treatments that should be tried before opioids.
4. Consider opioid therapy for all patients with chronic moderate to severe pain, but evaluate the answers to the following questions first and make case-by-case decisions about the appropriateness of an opioid trial (see Question 6):
    - *What is conventional medical practice in the treatment of this type of pain?*
    - *Are there other treatments that are effective and feasible and have a risk-to-benefit profile as good as, or better than, the opioids?*
    - *Is the patient particularly vulnerable to opioid side effects?*
    - *Is the patient likely to take medications responsibly or, if problems seem likely, could a plan for structuring the therapy and monitoring it be successful?*
5. Recognize that opioid therapy is as much a "therapeutic trial" as any other treatment. If the benefits are not clear, or the risks of adverse effects are not easily managed, the therapy can be modified or stopped.
6. One practitioner should have primary responsibility for management of chronic pain in patients with a known or suspected history of abuse, addiction, or diversion.
7. When a patient has a known history of abuse, addiction, or diversion, it is particularly important that the clinician be clear from the beginning about expectations in the treatment plan. The treatment plan may include a written agreement with the patient describing the requirements (see Question 15 regarding agreements), such as limited quantities of medication, routine urine screens, consultation with a specialist**,** and the consequences of not adhering to the agreement.

If the clinician decides to initiate opioid therapy, it is appropriate to begin by titrating the amount of opioid to ensure that maximum therapeutic effect can be reached. Continuation of therapy is justified if the benefit is demonstrably greater than the adverse outcomes; this should be clearly documented. Once adequate pain relief has been achieved, a successfully treated patient is one who remains responsible over time, follows the agreement for use of the opioids and exhibits neither drug abuse behaviors nor indications of addiction, and experiences enhanced comfort and an improved quality of life.

At the other extreme, patients who manifest the disease of addiction exhibit a range of maladaptive behaviors and experience a decreased quality of life. They do not follow the agreement for use of opioids, do not conform to the agreed-upon dosing schedule; and may lose prescriptions, repeatedly seek early refills, or obtain additional supply from other sources. They continue or escalate medication use despite adverse consequences; appear unaware of, or in denial about, abuse of the medication; and may always have a "story." In some cases, such a patient will "doctor shop" or alter prescriptions to increase his or her supply of the medication. (See answers to Question 22 and Question 23 for more information).

A "universal precautions" approach to the prescribing of controlled prescription drugs does not mean that all patients who have the capacity to engage in abuse or diversion will be identified, or prevented from these behaviors over time. Nonetheless, the approach emphasizes the value of ongoing assessment and close monitoring, which are essential aspects to the appropriate, safe and effective use of these over time.

Relevant Resources:

Compton, P., J. Darakjian, and K. Miotto(1998). Screening for addiction in patients with chronic pain and "problematic" substance use: Evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Covington, E. (2001). *Lawful Opioid Prescribing and Prevention of Diversion*. Dannemiller Education Foundation CD ROM, October.

Drug Enforcement Administration. (1999) "Recognizing the Drug Abuser." (Available at http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm.)

20. What behaviors are potential indicators of problems for patients on long-term opioid therapy?

Patients who received opioids or other controlled prescription drugs for legitimate medical purposes may engage in problematic drug-related behaviors. The range of behaviors is broad and their meaning may be difficult to clarify. Some behaviors that are clear-cut indicators of abuse or addiction when they occur in those with no legitimate medical problem become more challenging to interpret when there are unrelieved symptoms that are the target of therapy. In all cases, problematic drug-related behaviors must be carefully assessed, even as efforts are undertaken to eliminate or limit them. The differential diagnosis of problematic behavior includes addiction and diversion, but also pseudoaddiction (see Appendix A), confusion related to organic brain disease, and numerous psychiatric disorders associated with impulsive or self-destructive drug use.

Some of the problematic drug-related behaviors that occur in populations with chronic pain should be noted, and managed, by clinicians, but are generally recognized as relatively less egregious, and therefore, probably less likely to be predictive of addiction. These include:

- complaints about need for more medication;
- drug hoarding;
- requesting specific pain medications (others "don't work");
- openly acquiring similar medications from other providers;
- occasional unsanctioned dose escalation; and
- nonadherence to other recommendations for pain therapy.

These behaviors are not acceptable and could lead to any of a number of responses on the part of the clinician, including the decision to taper and discontinue treatment. Clinicians also should be aware that some of these types of behaviors, such as the effort to acquire

medications from other providers, may be violating the laws of some states. It is important to recognize, however, that these behaviors cannot be perceived to be an immediate reflection of addiction. Rather, the assessment may reveal other potential explanations, including the possible effects of unrelieved pain.

The following behaviors are more egregious, and as such, are more probable indicators of abuse, addiction, or diversion (see DEA website, http://www.deadiversion.usdoj.gov/pubs/brochures/index.html):

Deterioration in functioning at work, in the family, or socially

Illegal activities, such as selling medications, forging prescriptions, stealing drugs from other patients, buying prescription drugs from nonmedical sources

- Injection or snorting of medication
- Multiple episodes of "lost" or "stolen" prescriptions
- Resistance to changes in therapy, regardless of adverse effects
- Refusal to comply with random urine drug screens or referral to specialist
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians and pharmacies

These behaviors also cannot be assumed to be diagnostic of addiction, but they do indicate a relatively greater degree of pathology and presumably signal a higher likelihood of this disorder. Even if the criteria for addiction are not met, the severity of these problems emphasizes the need for a competent assessment and appropriate management, possibly including referral to a specialist in addiction medicine.

Several recent surveys suggest that the occurrence of problematic drug-related behaviors of one sort or another is very common in populations treated with long-term opioid therapy. As a result, monitoring for problematic behaviors must be considered to be an essential aspect of the long-term management of opioid therapy. These behaviors should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated. Rather, they indicate the need for assessment, informed diagnosis and appropriate management. Management may or may not include continuation of therapy, depending on the circumstances (see Question 21). If the decision is made to terminate the physician-patient relationship, there must always be a good faith effort to avoid patient abandonment by providing referrals.

Pharmacists, whose principal professional obligation is to provide medications to the patient, and to counsel the patient on safe and effective use of the medications, must evaluate whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the course of professional practice. The main indicator that pharmacists should watch for is whether the prescription appears to be forged or altered. Pharmacists also should check patient profiles for seemingly duplicative or excessive controlled substance use and communicate with the prescribers in such cases. In addition, DEA says that the following signs should also be considered:

- Unsettling patient presentation

- A pattern of early requests for prescription refills (that is, more than a few days before the patient should be running out)

- Unreasonable quantities
- Time of prescription presentation, that is, weekends or after hours
- Patient unknown to pharmacist
- Prescriber unknown to pharmacist

These "red flags" do not mean that drug abuse or diversion is occurring. Patients are the focus of the practice of pharmacy, so professional judgment must serve the patient's needs first and foremost. Stereotypes of what an abuser "looks like" can harm legitimate patients because people who abuse prescription medicine can exhibit some of the same behaviors as patients who have unrelieved pain (see Appendix A for definition of pseudoaddiction).

Physicians and pharmacists should expect some degree of interaction with law enforcement authorities if their patients are involved in illegal activities, especially when patients sell the drugs that have been prescribed for them or when there is a need to substantiate prescription forgeries.

Relevant Resources:

Brushwood, D. B. (2003). Drug control policy out of balance. *Pain & The Law*. (Available at http://www.painandthelaw.org/mayday/brushwood_090403.php.)

Compton, P., J. Darakjian, and K. Miotto (1998). Screening for addiction in patients with chronic pain and "problematic" substance use: evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Drug Enforcement Administration. (2003). *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970* (8th ed.). Washington, DC: U.S. Department of Justice. (Available at http://www.deadiversion.usdoj.gov/pubs/manuals/index.html.)

Passik, S. D., K. L. Kirsh, M. V. McDonald et al. (2000). A pilot survey of aberrant drug-taking attitudes and behaviors in samples of cancer and AIDS patients. *Journal of Pain and Symptom Management* 19 (4): 274–286.

Portenoy, R. K. (1996). Opioid therapy for chronic nonmalignant pain: Clinicians' perspective. *Journal of Law Medicine & Ethics* 24 (4): 296–309. (Available at http://www.painandthelaw.org/aslme_content/24-4c/portenoy.pdf.)

21. If a patient receiving opioid therapy engages in an episode of drug abuse, is the physician required by law to discontinue therapy or to report the patient to law enforcement authorities?

Federal drug laws do not require physicians to report to law enforcement authorities patients who have engaged in drug abuse. The controlling federal legal standard is that the physician must issue prescriptions for controlled substances only for legitimate medical purposes and in the usual course of professional practice. However, some state policies state that a physician should not prescribe, administer, or dispense opioid

analgesics to a person the physician knows or should know is using controlled substances for nontherapeutic purposes. State laws and regulations should be consulted on whether a report of patient drug abuse is necessary or use of opioids must cease under such circumstances.

In states with no specific legal requirements on this subject, if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended (see the answer to Question 23).

Incontrovertible evidence of criminal activity, such as diversion, is grounds for termination of the doctor-patient relationship.

22. Is it legal and acceptable medical practice to prescribe long-term opioid therapy for pain to a patient with a history of drug abuse or addiction, including heroin addiction?

It is within the scope of current federal law to prescribe opioids for pain to patients with a history of substance abuse or addiction. However, some state policies may be more restrictive than federal law (see the answer to Question 21 as well as http://www.medsch.wisc.edu/painpolicy/2003_balance/).

In general, pain patients fall into three groups. The first includes patients whose pain is not complicated by current addiction or a history of substance abuse. This group includes the majority of patients.

The second group comprises those patients who have histories of substance abuse or addiction but are in established recoveries. Some of these patients are receiving substitution therapy (methadone or buprenorphine), and some are in drug-free recovery. It is prudent to consult with a specialist in addiction medicine when considering long-term opioid therapy for patients who fall into this group. Therapy for patients in this group typically includes more controls than does therapy for those with no such history.

The third group, which includes those who are actively abusing substances, poses the greatest challenge. These patients require care of an advanced nature, which may not available in the primary care setting (see Question 23 for guidance about treating pain in patients who are currently abusing drugs, and Question 26 regarding the need to distinguish between the use of methadone for analgesia or substitution treatment). Referral of such patients to an addiction medicine specialist is appropriate (see state lists of addiction medicine specialists at www.asam.org).

Relevant Resources:

Compton, P., J. Darakjian, and K. Miotto (1998). Screening for addiction in patients with chronic pain and "problematic" substance use: evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Dunbar, S. A., and N. P. Katz (2001) Chronic opioid therapy for nonmalignant pain in patients with a history of substance abuse: report of 20 cases. *Journal of Pain and Symptom Management* 11 (3): 163–171.

Gilson, A. M., and D. E. Joranson (2002) U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain* 18 (4 suppl): S91–S98. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/02cjpn/index.htm.)

23. What strategies can be used to treat pain successfully in patients who are actively abusing drugs?

Federal law and regulations do not prohibit the use of opioids to treat pain if a patient is abusing controlled substances. However, state policies vary with respect to this therapy. Some states' policies discourage, if not prohibit, physicians from prescribing opioid analgesics to patients whom they know or should know are using controlled substances for nontherapeutic purposes (see answer to Question 21).

Using opioids to treat pain in such patients is very challenging. Physicians who proceed with this treatment should consider the following suggestions:

- Refer the patient to an addiction medicine specialist for concurrent treatment.
- Work closely with the addiction medicine specialist to coordinate the patient's care.
- Use a written agreement to outline treatment plan, including expectations and consequences.
- Structure the treatment in a manner that maintains the safety of the patient, and increases both the patient's ability to maintain control and the clinician's ability to identify medication misuse. Depending on the specifics of the case, this structure may include the prescribing of small quantities, frequent visits, the use a single drug (typically a long-acting opioid), pill counts, the use of a single pharmacy, defined contacts with historians other than the patient (e.g., family members or employers), required attendance at a drug-treatment program, and regular screening of urine toxicology (to provide evidence of therapeutic adherence and non-use of other drugs). The structure of the treatment plan should be tailored to reflect the clinician's assessment of the severity of drug abuse risk. Clear and regular communication between the clinician and the patient is an extremely valuable part of the treatment plan.

Continued drug abuse despite repeated interventions may, in some cases, indicate the need to discontinue prescribing of potentially abusable drugs, and in other cases, provide the impetus for termination of the physician-patient relationship. The clinician should be

prepared to respond in these ways, and should understand both the options for nondrug therapies and the approach to termination without abandonment.

Relevant Resources:

Dunbar, S. A., and N. P. Katz (2001). Chronic opioid therapy for nonmalignant pain in patients with a history of substance abuse: report of 20 cases. *Journal of Pain and Symptom Management* 11 (3): 163–171.

Gilson, A. M., and D. E. Joranson (2002). U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain* 18 (4 suppl): S91–S98. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/02cjpn/index.htm.)

Gourlay, D., H.A. Heit, and Y. Caplan (2002). Urine drug testing in primary care, dispelling the myths & designing strategies. *California Academy of Family Physicians (CAFP)*. PharmaCom Group, Inc. Stamford, CT. (Available at http://www.familydocs.org/UDT.pdf)

Heit, H.A., and D. Gourlay (2004). Urine drug testing in pain medicine. *Journal of Pain and Symptom Management* 27 (3): 260-67.

Savage, S. R. (2002). Assessment for addiction in pain-treatment settings. *Clinical Journal of Pain* 18: S28–S38.

Savage, S. R. (2003). Principles of pain management in the addicted patient. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith et al. (eds.), *Principles of Addiction Medicine* (3rd ed.). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp. 1405–1419.

Wesson, D., W. Ling, and D. E. Smith (1993). Prescription of opioids for treatment of pain in patients with addictive disease. *Journal of Pain and Symptom Management* 8: 289–296.

SECTION VI
OTHER LEGAL AND REGULATORY CONSIDERATIONS

24. What requirements must physicians and pharmacists meet to comply with federal and state laws regulating opioids?

For a physician to apply for a federal controlled substances registration to administer, prescribe, and/or dispense controlled substances, the physician must be licensed to practice medicine. In addition, some states require a state controlled substance registration.

If a physician loses or has restrictions placed upon his or her state-granted authority to use controlled substances, or is convicted of a drug-related felony or has lost his or her authority to participate in federal health care programs, there may be a legal impact on the physician's DEA registration status.

Physicians are legally authorized to administer, dispense, and/or prescribe controlled substances only for legitimate medical purposes, and the prescription must be issued in the usual course of a professional practice in the context of a doctor/patient relationship. DEA regulations (http://www.access.gpo.gov/nara/cfr/) affecting prescriptions include the following:

- Schedule II prescriptions must be signed by the physician or nurse practitioner unless there is an emergency.
- In the case of a bona fide emergency, the physician may telephone a pharmacy and authorize a prescription; however, a signed prescription must be forwarded to the pharmacy within seven days to account for the emergency prescription.
- Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.
- Prescriptions written for controlled substances in schedules III, IV, and V may be refilled up to five times within six months. They may be telephoned or transmitted via facsimile to the pharmacy. Office staff may communicate the information to the pharmacy when acting as an agent of the registered physician.
- The amount of a controlled substance prescription is not limited by federal regulations to a maximum quantity or a specific period, although some states do have such limitations.
- Federal regulations do not require physicians to maintain prescribing records for controlled substances, although many states do.

Federal regulations are being developed that will provide a legal basis for the secure transmission of prescription information electronically, including via the Internet, between physicians and pharmacies. Practitioners should also be aware that an individual state's requirements for controlled substance prescriptions might be more restrictive than federal provisions.

Dispensing physicians are also subject to the following DEA regulations:

- Physicians who purchase controlled substances or who receive controlled substances as complimentary samples must maintain records to account for the receipt and use of the controlled substances.
- Physicians must physically inventory the drugs once every two years and have a copy of the inventory available for inspection by DEA diversion investigators.
- An official DEA order form must be used to obtain or transfer Schedule II drugs. The records of receipt and distribution (dispensing) must clearly identify the source of the drugs and the recipient (patient).

These are the basic requirements. Physicians should consult with DEA field offices if they have questions about the separate registration needed for the use of opioids to treat

opioid-dependent patients, or if they have multiple offices or special situations that require clarification. A list of the DEA's field offices with staff contacts can be found at the DEA diversion website, http://www.deadiversion.usdoj.gov/.

Pharmacists filling a prescription for controlled substances have a corresponding responsibility under the law to ensure that the prescription was written by a properly authorized prescriber and that it was written for a valid medical purpose. Pharmacists must be familiar with both state and federal requirements and are encouraged to document their efforts to ensure they have fulfilled their responsibilities under the law. They are also encouraged to develop a working relationship with their state pharmacy board (contact information can be found at http://www.nabp.net/) and DEA representatives to achieve open channels for communication. Finally, pharmacists are encouraged to read the DEA's *Pharmacist Manual* for guidance about the Controlled Substances Act and its implementing regulations, at http://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Relevant Resources:

Good, P. M. (2003). *DEA Policy Concerning the Legality of a Practitioner Issuing Several Schedule II Prescriptions on the Same Date for the Same Medication for a Stable Patient*. Letter from Chief of the Liaison and Policy Section, DEA Office of Diversion Control, to Dr. Howard Heit, January 31. (Available at http://www.asam.org/pain/federal_regulations_for_prescrib.htm.)

Joranson, D. E. (1993). Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances. In J. R. Cooper, D. J. Czechowicz, S. P. Molinari, and R. C. Petersen (eds.). *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Monograph 131*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse, pp. 18–34. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm.)

Public Policy Statement on the Rights and Responsibilities of Healthcare Professionals in the use of Opioids for the Treatment of Pain (2004) Adopted by the American Society of Addiction Medicine's Public Policy Committee, the American Academy of Pain Medicine, and the American Pain Society. (http://asam.org/) Power Point slides of Federal Regulations of Prescribing a Controlled Substance.

25. What regulations do physicians need to know and observe when prescribing opioid analgesics for pain?

State level: The privilege of prescribing drugs, including controlled substances, is based on having a license to practice medicine or osteopathy issued by a licensing and disciplinary board in each of the states where a practitioner wishes to practice. Some states also require an additional registration for prescribing controlled substances. (information about how to contact state controlled substances authorities can be obtained at http://www.nascsa.org/HOME.htm.) State statutes and regulations list prohibited controlled substances activities. Most states also have issued a regulation, guideline, or policy statement that provides guidance and, in some cases, a standard of care, for

prescribing opioid analgesics for pain (http://www.medsch.wisc.edu/painpolicy/matrix.htm).

Federal level: Once a practitioner has satisfied state requirements of licensure and registration, the DEA issues a federal controlled substances registration, enabling the prescribing of controlled substances for legitimate medical purposes. The specific requirements for prescribing controlled substances are listed in Title 21, Parts 1300–1999 of the Code of Federal Regulations (http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1) and are summarized in a presentation format (http://www.asam.org/pain/federal_regulations_for_prescrib.htm). Further information about controlled substances and prescribing requirements can be obtained at http://www.deadiversion.usdoj.gov/.

Prescribing opioids (referred to as narcotic drugs in federal regulations) for pain, including "intractable" pain, *is lawful* when there is a physician-patient relationship established by an examination, a treatment plan, and medical records.

26. Can methadone be used for pain control, and, if so, is a clinician required to have a special license to prescribe it?

Methadone is approved by the Food and Drug Administration as safe and effective for medical use as an analgesic. Although its low cost and effectiveness in some settings is driving increasing use, it is important to emphasize that its unique pharmacology is associated with a relatively higher risk of unintentional toxicity. This relates to a long and variable half-life and the potential for a greater-than-expected potency when a switch is made from an alternative opioid. The safe use of methadone requires knowledge of these characteristics and an ability to monitor therapy closely after it is initiated or changed.

State and federal regulations do not restrict the use of methadone to treat pain. It is recommended that the physician note in the chart that the methadone is for analgesia only. Any physician who has a DEA registration for controlled substances that includes Schedule II can prescribe methadone, just as any other Schedule II opioid medication, for pain. An additional separate DEA registration is needed only when dispensing methadone for outpatient maintenance or detoxification, not when prescribing it for pain, and the supply and records must be separate from its use for analgesia.

Relevant Resources:

Anderson, R., et al. (2001). Accuracy in equianalgesic dosing. Conversion dilemmas. *Journal of Pain and Symptom Management* 21 (5): 672–687.

Dole, V. P. (1988). Implications of methadone maintenance for theories of narcotic addiction. *Journal of the American Medical Association* 260: 3025–3029.

Garrido, M. J., and I. F. Troconiz (1999). Methadone: A review of its pharmacokinetic/ pharmacodynamic properties. *Journal of Pharmacological and Toxicological Methods* 42 (2): 61–66.

Gazelle, G., and P. G. Fine (2003). Methadone for the treatment of pain #75. *Journal of Palliative Medicine* 6 (4): 620–621.

Pereira, J., et al. (2001). Equianalgesic dose rations for opioids. A critical review and proposals for long-term dosing. *Journal of Pain and Symptom Management* 22 (2): 672–687.

27. Under what circumstances will the federal Drug Enforcement Administration (DEA) investigate and prosecute a doctor or pharmacist or refer cases to other agencies?

According to the DEA, the vast majority of DEA-registered practitioners are honest, ethical people who strive to satisfy their legal and regulatory responsibilities. The targets of DEA complaint investigations are the small number of practitioners who operate with criminal intent. For a physician to be convicted of illegal sale, the authorities must show that the physician knowingly and intentionally prescribed or dispensed controlled substances outside the scope of legitimate practice.

The DEA focuses its limited manpower and resources on the most flagrant violators. To understand the DEA's intent and practices, it is important to keep in mind that:

- State and local agencies, including licensing boards, police departments, Medicaid fraud units, etc., also conduct investigations related to controlled substance diversion, fraud, or improper medical practice.
- The DEA investigates only a small number of physicians[2] (for example, during fiscal year 2003, the DEA initiated a total of 732 investigations concerning doctors, 584 of which resulted in some form of sanction. In short, approximately *0.075%* of all physicians registered with the DEA were the subject of some type of DEA investigation during the year.)
- A significant number of theses investigations were initiated because the physician in question was no longer licensed to practice medicine and was therefore no longer entitled to DEA registration. In 424 such cases, the physicians elected to surrender their DEA registrations. This represents 72.7% of the 584 "sanctions" imposed by the DEA.

[2]The term "physician" includes dentists, osteopaths, podiatrists, veterinarians, medical doctors and a small number of mid-level practitioners. In May of 2004, there were 972,008 practitioners registered with the DEA. Medical doctors account for 71 percent of the total physicians registered with the DEA. Osteopaths account for another 4.6 percent. Dentists account for 13.3 percent. Veterinarians account for 5.1 percent.

- In 34 cases, physicians' DEA registration was revoked.
- During fiscal year 2003, the DEA arrested 50 physicians whose activities were deemed to be knowingly and intentionally beyond the scope of medical practice, that is, criminal. This represents 0.005% of physician registrants.
- Most frequently, the DEA responds to complaints, allegations of diversion, or some other impropriety. Depending on the content, most of these are referred to state medical boards or local police.
- Joint investigations may occur when local police and state or federal agencies seek out the DEA for its expertise.
- The DEA does use administrative sanctions (for example, Letters of Admonition, Memoranda of Understanding) rather than criminal investigations when the complaint or allegation relates to such activities as faulty record keeping. In fact, of the 584 actions mentioned above taken during fiscal year 2003, 67 were of this nature.

Following receipt of information concerning a physician or pharmacist, an investigator would make inquiries to ascertain the validity of the allegation. *Practitioners should be aware that a preliminary inquiry does not necessarily mean that wrongdoing has occurred*. The nature of the inquiry varies based on the type of information received. For example, if the allegation pertains to a doctor prescribing controlled substances without conducting medical examinations, the investigator would be required to obtain information about the doctor's prescribing habits. In the absence of a prescription-monitoring program, investigators would be required to visit pharmacies to review prescription files. If the complaint pertained to a pharmacist, a review of the pharmacy's prescriptions and possibly an audit would be conducted.

An investigation that uncovers inappropriate activity may be resolved through a variety of administrative, civil, or criminal actions. Factors that are considered when law enforcement personnel are determining what action to take include the opinion of medical experts, the egregiousness of the violations, and whether the practitioner is thought to have engaged in the violation knowingly or intentionally. The legal system does not allow practitioners to consciously disregard indications that illegal drug-related activities might be occurring.

A DEA criminal investigation may involve a search warrant, but only if the DEA has sufficient evidence to convince a federal judge or magistrate that it is warranted. Although a search is not a charge and may not result in an arrest, it is a very serious matter, and normal police protocol involves control of the premises and safety of the participants.

Cases generally would be referred to other agencies if a practitioner's activities are found to be outside the course of professional practice, but not significant enough to warrant federal prosecution.

28. Should efforts to address diversion avoid interfering with medical practice and patient care?

To avoid interfering with legitimate medical practice and patient care, there needs to be a balanced approach between physicians and regulators. The principle of *balance*, which should be fundamental to national and state drug control policy, asserts that efforts to prevent abuse of opioid analgesics, while necessary, should not interfere with medical practice and patient care. Health professionals should avoid contributing to diversion, and law enforcement and regulatory authorities should avoid interfering in pain management.

A 2003 comprehensive evaluation of all relevant federal and state policies according to the principle of balance can be found at http://www.medsch.wisc.edu/painpolicy/2003_balance/.

Key law enforcement and regulatory organizations endorse the principle of balance. For example:

- In 1998, the Federation of State Medical Boards of the U.S. issued model guidelines that state regulatory boards can use to encourage better pain management, address physicians' concerns about regulatory scrutiny, and maintain compliance with existing legal requirements for prescribing (http://www.fsmb.org). These guidelines have been endorsed by the National Association of Boards of Pharmacy, the National Association of State Controlled Substances Authorities, and the U.S. Drug Enforcement Administration. The guidelines have since been revised as a model policy in 2004.
- In 2001, the DEA and many leading health care groups issued a joint statement, titled "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act." It has been endorsed by 43 organizations and can be accessed at http://www.lastacts.org/briefingoct01/endorse.html.
- In its 2003 report, "Improving End-of-Life Care: The Role of Attorneys General," the National Association of Attorneys General stated its support for the concept of balance, recognizing the need for a positive regulatory environment for pain management and emphasizing that law enforcement efforts should not affect provision of patient care.

For law enforcement to stop diversion, it is necessary to accurately identify the sources of diversion. The sources are individuals who unlawfully divert prescription controlled substances to other than legitimate medical purposes. When an individual is suspected of robbing a pharmacy, there is little chance that apprehension and prosecution will interfere with medical practice and patient care; indeed, solving such crimes protects good medical care. When the suspect is a physician, pharmacist, or patient, the need for law enforcers to distinguish the medical use of opioid analgesics to manage pain from unlawful activities is critically important. This FAQ presents information that can be valuable to enforcement personnel in such situations. In some cases, consultation with a pain medicine specialist may be useful to law enforcement and regulatory officials (see answer to Question 29).

Relevant Resources:

Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group et al. (2001). *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts. (Available at http://www.medsch.wisc.edu/painpolicy/dea01.htm.)

Federation of State Medical Boards of the United States Inc. (1998). *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org.)

Federation of State Medical Boards of the United States Inc. (2004). *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org.)

Joranson, D. E. (1993). Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances. In J. R. Cooper, D. J. Czechowicz, S. P. Molinari, and R. C. Petersen (eds.), *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Monograph 131*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse, pp. 18—34. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm.)

National Association of Attorneys General. (2003). *Improving End-of-Life Care: The Role of Attorneys General*. Washington, DC: National Association of Attorneys General.

Pain & Policy Studies Group. (2003). *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (2nd ed.). Madison, WI: University of Wisconsin Comprehensive Cancer Center. (Available at http://www.medsch.wisc.edu/painpolicy/2003_balance/.)

29. When should a law enforcement officer turn to a pain specialist for advice?

The timing of a consultation with a pain specialist varies, according to the information needed by an investigator. The identified specialist should have current knowledge about pain management, including the use of opioids. In consulting with a pain specialist, an investigator may seek confirmation that prescriptions are being issued for legitimate medical purposes and that the care being provided is within the bounds of professional practice. There is great potential for misunderstanding at the interface of pain treatment, addiction, and the therapeutic use of controlled substances.

Consequently, investigators are encouraged to consult a pain specialist or addiction medicine specialist whenever there are questions about using controlled substances to treat pain. The following questions are examples:

- How can you tell this patient has a chronic pain problem?
- Is there justification for the drugs that have been prescribed?
- Are the prescribed amounts appropriate?
- If a patient is displaying drug-seeking behaviors, is this a sign of under-treated pain, addiction, or involvement in diversion?

Relevant Resource:

Andrew, L. B. (2003). The ethical medical expert witness. *Federation Bulletin, Journal of Medical Licensure & Discipline* 89 (3): 125—131.

30. Do the number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, or the duration of therapy with these drugs by themselves indicate abuse or diversion?

The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem**,** and they should not be used as the sole basis for an investigation by regulators or law enforcement. However, these factors, combined with others, may indicate that prescriptions are being issued or dispensed for other than legitimate medical purposes or not in the course of professional practice. Characteristics of a practitioner or pharmacy that warrant further inquiry that could lead to an investigation include:

- A large proportion of prescriptions being paid for in cash.
- Large distances between the doctor, patients, and pharmacy, particularly if a sizable proportion of a doctor's prescriptions are being filled at a pharmacy not conveniently located to either the doctor or the patients.
- Drugs and doses being prescribed are not individualized.
- One physician writing multiple prescriptions for numerous patients that are filled consecutively in one pharmacy, indicating that either one person is presenting multiple prescriptions, or several people are filling similar prescriptions at the same time.
- A high frequency of prescriptions to replace lost prescriptions or medications.
- Frequent premature renewal or refilling of prescriptions.
- Frequent prescribing of unusual combinations of drugs, such as stimulants and depressants.

APPENDIX A: Terms

Abuse: A term used in the psychiatric ("Substance Abuse") nomenclature to describe a maladaptive pattern of substance use, not related to a therapeutic purpose, resulting in recurrent and significant adverse consequences. Repeated nontherapeutic use of a

substance causes harm that can manifest in physical or social impairment but does not meet the criteria of compulsive use despite harm. In common parlance, “abuse” may also refer to the use of a substance, including a controlled prescription drug, that is outside of social norms (including the norm of adherence to prescribed drug treatments).

Addiction: A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Addiction is considered distinct from, though sometimes interrelated with, tolerance and physical dependence. Neither physical dependence nor tolerance to prescribed drugs is sufficient evidence of addiction. Unlike tolerance or physical dependence, addiction is not a predictable effect of drug exposure but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals, for which drug exposure is only one of the etiologic factors. Simple exposure to opioids does not produce addiction.

Narcotic: A legal term that refers to all those substances covered by the Single Convention on Narcotic Drugs, 1961, and the 1972 Protocol amending that Convention, including opiates, opioids as well as cocaine and marijuana.

Opiate: A substance that is produced from the poppy plant, such as codeine and morphine.

Opioid: A scientific term that refers to both natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems, including codeine, morphine, oxycodone, and fentanyl.

Physical Dependence: A state of adaptation that is manifested by a specific withdrawal syndrome that can be produced by abrupt cessation of dosing, rapid dose reduction, and/or administration of an antagonist. Most patients on long-term opioid therapy develop physical dependence, which is not predictive of addiction.

Pseudoaddiction: A term used to describe an iatrogenic phenomenon in which a patient with under-treated pain is perceived by health care professionals to exhibit behaviors similar to those seen in addiction but is not true addiction. Patients may become focused on obtaining medications, may “clock watch,” and may otherwise seem inappropriately “drug seeking.” The term has been used to describe even such behaviors as illicit drug use and deception, if they appear to be primarily driven by the patient’s efforts to obtain relief. It is believed that pseudoaddiction can be distinguished from true addiction because the behaviors resolve and do not recur when pain is effectively treated. Clinicians should be aware that abuse or addiction, and pseudoaddiction can co-exist, and a pattern of maladaptive drug-related behaviors could signal the presence of addiction, under-treated pain, or both.

Tolerance: Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time. Tolerance often occurs in the absence of addiction, as when drugs are used therapeutically over a period of time, and usually requires increased doses of the drug to produce the pharmacologic
effects initially resulting from smaller doses.

* The definitions of addiction, physical dependence, and tolerance are from American Academy of Pain Medicine, American Pain Society, and American Society of Addiction Medicine (2001). *Definitions relate to the use of opioids for the treatment of pain.*

Relevant Resources:

American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine (2001). *Definitions Related to the Use of Opioids for the Treatment of Pain*. Glenview, IL: AAPM, APS, ASAM. (Available at http://www.ampainsoc.org/advocacy/opioids2.htm.)

Savage, S. R., D. E. Joranson, E. C. Covington et al. (2003). Definitions related to the medical use of opioids: Evolution towards universal agreement. *Journal of Pain and Symptom Management* 26 (1): 655–667. (Available at http://www.medsch.wisc.edu/painpolicy/biblio.htm.)

Weissman, D. E., and J. D. Haddox (1989). Opioid pseudo-addiction—an iatrogenic syndrome. Pain 36: 363–366.

Heit, H.A., (2003) Addiction, Physical Dependence, and Tolerance: Precise Definitions to Help Clinicians Evaluate and Treat the Patient with Chronic Pain. Journal of Pain and Palliative Care Pharmacotherapy.

As you can see, this *Frequently Asked Questions Document* goes a long way towards clarifying what had been a somewhat murky and mistrustful relationship between the DEA and the medical profession. Hopefully is has answered many of your questions too!

Patients' Perspective

One out of six households in America contains a member with severe, intractable pain.[1] Unfortunately, most of these patients go under-treated because healthcare providers do not provide adequate amounts of opioids to relieve their pain.

Ironically, some patients also perpetuate their own under-treatment of pain because they:

- don't always report their pain to their doctor[2-4]
- are reluctant to take opioids for intractable pain treatment[2,3,5]

Whether patients report their pain or not, however, under-treatment of pain is usually inevitable. Eventually, unrelieved pain patients may head into a downward spiral of depression[4-8] and, perhaps, begin to consider suicide.[4,5,9,10]

The New Paradigm creates a new transition in thought that educates patients about pain treatment, empowers patients to seek appropriate relief, and helps patients avoid depression and thoughts of suicide.

Healthcare Reimbursement System's Perspective

As intractable pain management remains a low priority in healthcare, so does it remain a low priority in healthcare reimbursement.[1,2] In the United States, many intractable pain patients are not able to comply with their intractable pain treatment because they don't have the appropriate healthcare coverage to pay for their medication or equipment.

The United States is one of few developed countries that does not provide healthcare coverage for its citizens[3]; therefore, economic status ultimately determines the quality of care that patients receive.[4] The following pattern has developed between patients' economic status and the quality healthcare that is readily available to them:

- patients' economic status reflects the amount of insurance affordable to them
- the type of insurance patients have determines the amount of healthcare coverage they will receive
- the amount of healthcare coverage patients receive determines how well they will comply with their prescribed treatment

Steps to overcome healthcare reimbursement limitations

Steps to Overcome Healthcare Reimbursement Limitations

Low priority given to the accountability of pain and pain management coupled with limited access to opioid pain treatment perpetuates inadequate intractable pain relief.[1,2] Education of pain's medical validity is necessary for government healthcare services,

private reimbursement services, healthcare providers, and patients to increase opioid compliance.

Researchers have suggested steps to overcome dependency of pain treatment on healthcare reimbursement services that include:6

- establishing public education programs on opioid pain treatment and drug abuse
- urging for an increase in validity of pain management and encouraging increased opioid reimbursement
- increasing communications between physicians and pharmacists in prescribing pain treatment
- encouraging physicians to constantly examine the pain treatment they prescribe to be that it is best suited for each patient's pain relief and optimum prescription reimbursement
- providing medication free of charge or subsidizing prescriptions to pain patients over 60 years of age

JCAHO Pain Management Standards

Overview

Before showing you where to find the JCAHO's actual Pain Management Standards, we present you with some overview thoughts:

Excuses for inadequate pain control appear to have run their course and will no longer be accepted because poor pain control is unethical, clinically unsound, and economically wasteful.

This was the prevailing notion underlying the spring 2000 Chicago Leadership Summit on Pain Management sponsored by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Pain Society (APS). The second such meeting was held in Los Angeles.

Dennis S. O'Leary, MD, president of the JCAHO, said that appropriate pain management is good medicine because it results in quicker clinical recovery, shorter hospital stays, fewer readmissions, and improved quality of life, leading to increased productivity. He said that the "mystique of pain" the long-held notion that because pain is subjective it eludes objective measurement has given way to evidence-based medicine as newer methods of assessing and controlling pain have emerged.

"Pain control has become a problem because of confusion as to who is responsible [for it], a general lack of knowledge about pain, and misconceptions about drug tolerance and addiction," said O'Leary hence the development of standards that place responsibility for pain management on health care organizations.

With the motto "The pain management paradigm is about to shift," the JCAHO says the change will occur in four ways: by making it a patient rights issue as well as an education and training issue, emphasizing the quantitative aspects of pain (placing it on a 10-point scale), encouraging systematic assessment, and emphasizing safe management.

All this adds up to a heightened awareness of pain as the **"fifth vital sign"** (as originally designated by the Department of Veterans Affairs) that should be monitored with the same vigilance as blood pressure, pulse, temperature, and respiratory rate. It also means a shift from traditional pain control practices, as exercised by individual patient and physician decision making with unspecified follow-up, to a more systematic approach by multidisciplinary teams of individuals with specified responsibilities.

C. Richard Chapman, PhD, a clinical psychologist at the University of Washington and president of the APS, discussed the magnitude of clinical pain. Based on his knowledge of a number of studies, he said that in only about one in four of the 23 million surgical operations done in the United States annually does the patient receive adequate relief of acute pain, he said. In addition, Americans incur about 65 million traumatic injuries, including 2 million burns, each year, and millions more have diseases that produce acute pain.

Of the 50 million people in this country with chronic pain, Chapman said that four in 10 with moderate-to-severe pain cannot find adequate relief. More than 26 million people 20 to 64 years of age have frequent or persistent back pain, and one in six has painful arthritis. Only about 30% of all cancer patients with pain get adequate relief, he said.

Barriers to Pain Control

Perry G. Fine, MD, professor of anesthesiology at the University of Utah School of Medicine and associate medical director of the Pain Management Center in Salt Lake City, summarized the shortcomings of current pain control. He said they constitute a series of barriers that may reflect physicians' attitudes (interest, open-mindedness or lack thereof, sense of personal priority) or aptitudes (knowledge and skills). Briefly, the barriers are as follows:

Attitude Barriers

Interest. Medical school curriculums spend little time on pain management despite the ethical imperative to relieve pain and suffering. Time constraints cause physicians' interest in helping patients with pain to wane because control procedures are complex and time consuming. Compared with other procedures, pain control offers physicians little in the way of reimbursement and financial incentives.

Open-mindedness. "These include negative reinforcement during clinical training, in which residents are punished for attending to personal pain [of patients] while being rewarded for measuring potassium levels. Cultural biases toward complainers, crooks [such as people seeking drugs for resale rather than pain relief], and drug seekers interfere with prescribing pain drugs. Then there are the hassle factors of documentation,

prescription refills, frequency of visits, telephone calls, and so forth. In addition, physicians fear regulatory scrutiny and reprisal and may have 'opiophobia' (fear of addiction). The truth," Fine said, "is that crossover in the drug culture world and those in need of medicine is very small."

Priority. During residency training, experience with pain is limited and empathy is not part of the medical culture. Furthermore, medical students have limited positive mentoring experiences with regard to pain control. "Management of pain is not valued within the established medical culture as a credible or highly respected discipline or specialty," Fine said. "Pain control is not respected in the medical community, and we are told that if we get involved in the pool of suffering, we will lose our objectivity."

Aptitude Barriers

Knowledge. There are many of these barriers, including limited undergraduate didactic and pre-clinical course work, as well as a limited clinical focus. And a universal symptom like pain is not universally addressed in postgraduate training. "We spent many hours memorizing the [blood] clotting cascade, but none on the pain cascade," Fine said, adding, "Half the population may go through a pregnancy, yet 100% of all medical students have to pass boards on obstetrics and gynecology. On the other hand, 100% of the population is at risk for pain, but how many have to pass qualifications for pain management? Zero percent!"

Skills. "People and organizations get good at what they practice and concentrate on."

The elimination of these barriers, Fine said, will require taking several steps. "The first step is recognition of the problems, which is where we are today. But interest alone is not enough. The next step is commitment of resources and alignment of incentive. We're on the verge of taking this step."

New Standards

Richard S. Frankenstein, MD, an internist in Garden Grove, Calif, and a commissioner of the JCAHO, where he chairs the Standards and Survey Procedures Committee, said the new pain management standards (see sidebar) reflect the consensus of an expert panel of physicians, nurses, pharmacists, therapists, and representatives of other health care organizations. Consistent with pain management guidelines issued by the Agency for Healthcare Research and Quality and the APS, the new JCAHO standards which go into effect in January emphasize a collaborative and interdisciplinary approach, individualized pain control plans, assessment and frequent reassessment of pain, use of pharmacologic and non-pharmacologic strategies, and establishment of a formalized approach.

The JCAHO is surveying institutions that have begun programs to assess problems that have emerged. The results of this process will be reviewed, and appropriate recommendations will be made for each accreditation setting. Pain management standards for each manual are posted on the JCAHO's Web site at http://www.jcaho.org.

In addition, Joint Commission Resources, Inc, a subsidiary of the JCAHO, has published an overview of the standards along with examples of implementation from organizations with successful pain assessment and management approaches. The publication, Pain Assessment and Management: An Organizational Approach, is available for $35 from the Web site listed above or by calling (630) 792-5800.

Carole H. Patterson, RN, director of the JCAHO Standards Interpretation Group, described the six standards chapters as follows:

Rights and Ethics. Recognize the right of individuals to appropriate assessment and management of pain. This standard represents the organizational commitment to pain management. Health care organizations may make this commitment explicit through their mission statements, their patient/client bill of rights, or detailed service standards.

Assessment of Persons With Pain. Assess the existence and, if so, the nature and intensity of pain in all patients, residents, or clients. This standard represents the organizational recognition that pain is a common experience and that unrelieved pain has negative consequences. To comply with the standard, the organization incorporates pain assessment into its procedures. It develops procedures for recording assessment results and for ongoing reassessment and follow-up. As part of this standard, the organization also determines and ensures staff competency in pain assessment and management, and incorporates training on pain assessment and management in the orientation of new clinical staff.

Care of Persons With Pain. Establish policies and procedures that support the appropriate prescribing or ordering of effective pain medications. This standard asserts that the goal of care is treating symptoms that may be associated with a disease, condition, or treatment, including pain. In the context of pain management, it focuses on appropriate prescription and administration of patient-controlled analgesia, spinal-epidural or intravenous medications, and other pain management techniques.

Education of Persons With Pain. Educate patients, residents, and clients and families about effective pain management. This standard specifies that the organization is responsible for helping patients, residents, and clients understand the importance of pain management as a part of treatment, as well as the influence that cultural and belief systems have on shaping conceptions of pain and pain control. In particular, organizations must present individuals with balanced and accurate information on pain medication, since many misconceptions exist about them.

Continuum of Care. Address the individual's needs for symptom management in the discharge planning process. This revised standard includes pain as a symptom that should be addressed when considering an individual's needs after discharge.

Improvement of Organization Performance. Incorporate pain management into the organization's performance measurement and improvement program. This revised standard specifies that as the organization collects data to monitor its performance, it should consider the appropriateness and effectiveness of its pain management program.

Here are some samples of how the new Standards read:

Patient Rights and Organization Ethics chapter
Note: New language is underlined.

RI.1.2.7
Patients have the right to appropriate assessment and management of pain.

Intent of RI.1.2.7
Pain can be a common part of the patient experience; unrelieved pain has adverse physical and psychological effects. The patient's right to pain management is respected and supported. The organization plans, supports, and coordinates activities and resources to assure the pain of all individuals is recognized and addressed appropriately.

This includes

- initial assessment and regular reassessment of pain;
- education of relevant providers in pain assessment and management;
- education of patients, and families when appropriate, regarding their roles in managing pain as well as the potential limitations and side effects of pain treatments; and
- after considering personal, cultural, spiritual, and/or ethnic beliefs, communicating to patients and families that pain management is an important part of care.

Examples of Implementation for RI.1.2.7

1. The ambulatory care organization includes a commitment to pain management in its mission statement, patient and family bill of rights, or service standards (for example, "Patients have the right to expect a quick response to reports of pain").
2. The following statement on pain management is posted in all examination rooms and waiting areas at a large multispecialty clinic:

Patient Rights

As a patient at this clinic, you can expect

- your reports of pain will be believed,
- information about pain and pain relief measures,
- a concerned staff committed to pain prevention and management,

- health professionals who respond quickly to reports of pain, and
- effective pain management.

Patient Responsibilities

As a patient at this clinic, we expect that you will

- ask your doctor or nurse what to expect regarding to pain and pain management,
- discuss pain relief options with your doctors and nurses,
- work with your doctor and nurse to develop a pain management plan,
- ask for pain relief when pain first begins,
- help your doctor and nurse assess your pain,
- tell your doctor or nurse if your pain is not relieved, and
- tell your doctor or nurse about any worries you have about taking pain medication.

3. Pain is considered the "fifth" vital sign. Pain intensity ratings are recorded along with temperature, pulse, respiration, and blood pressure.
4. The clinic identifies patients with pain or at risk for pain according to criteria developed by the quality improvement committee overseeing pain assessment and treatment. Further assessment is then completed for patients identifying pain or at risk for pain.
5. All new patients and their families receive information verbally and in an electronic or printed format that effective pain relief is an important part of their treatment.
6. A clinic demonstrates its commitment to pain management by holding annual staff awareness events focused on pain assessment and management.
7. Educational materials about pain management are supplied to all ambulatory surgery patients prior to the day of surgery.

Scoring for RI.1.2.7
Does the organization address the patient's right to assessment and management of pain, including all items listed in the intent?

Score 1 Yes

Score 3 Sometimes

Score 5 No

PE.1.4
Pain is assessed in all patients.

Intent of PE.1.4
In the initial assessment, the organization identifies patients with pain. When pain is identified, the patient can be treated within the organization or referred for treatment. The scope of treatment is based on the care setting and services provided. A more comprehensive assessment is performed when warranted by the patient's condition. This assessment and a measure of pain intensity and quality (for example, pain character, frequency, location, duration), appropriate to the patient's age, are recorded in a way that facilitates regular reassessment and follow up according to criteria developed by the organization.

Examples of Implementation for PE.1.4

1. All patients in the initial evaluation are asked the following screening or general questions about the presence of pain: Do you have pain now? Have you had pain in the last several weeks or months? If the patient responds "yes" to either question, additional assessment data are obtained about the following elements:

    - Pain intensity (use a pain intensity rating scale appropriate for the patient population; pain intensity is obtained for pain now, at worst, and at best or least; if at all possible, make every attempt to use the same rating scale each time pain is assessed);
    - Location (ask the patient to mark on a diagram or point to the site of pain);
    - Quality, patterns of radiation, if any, character (elicit and record the patient's own words whenever possible);
    - Onset, duration, variation, and patterns;
    - Alleviating and aggravating factors;
    - Present pain management regimen and effectiveness;
    - Pain management history (including a medication history, presence of common barriers to reporting pain and using analgesics, past interventions and response, manner of expressing pain);
    - Effects of pain (impact on daily life, function, sleep, appetite, relationships with others, emotions, concentration, and so forth);

- The patient's pain goal (including pain intensity and goals related to function, activities, quality of life); and
- Physical exam/observation of the pain site.

2. When clinicians consistently observe discordance between verbal self-report of pain and associated behaviors and ability to function, further assessment is done to ascertain the reason for the discordance. The discordance may be due to a variety of causes, such as stoicism, learned coping skills, expectations about the conditions necessary for adequate analgesia, previous experience that the medication will be immediately discontinued if pain is rated as improved, family dysfunction, or adversarial relationships among the patient, family, and health care team. A clinic may want to appoint an interdisciplinary team to consult on such patients, including representatives from social work, psychology, and chronic disease specialists.
3. A clinic decides to use the 0-10 pain scale (0 representing no pain, 10 representing the worst pain imaginable) as its standard measure of pain intensity. However, certain populations may not be able to use this numeric scale, so the clinic may need to use other pain scales for special patient populations such as infants and children, older adults, and the cognitively impaired. Developmental stage, chronological age, functional status, cognitive abilities, and emotional status should be considered in the choice of assessment methods and tools. To ensure continuity, the clinic encourages its affiliated hospital, home health and hospice program, and nursing home also to adopt the same pain intensity measures.
4. Patients often have more than one site of pain. An assessment system or tools with space to record data on each site is provided on the assessment sheet.
5. Pain intensity scales are enlarged and displayed in all examination rooms and waiting areas. There may be a need to use more than one pain intensity measure. An organization selects pain intensity measures to ensure consistency across departments, for example, the 0-10 scale, which adult patients are encouraged to use. If they cannot understand or are unwilling to use it, the Wong-Baker FACES pain rating scale (smile-frown) or the verbal descriptor scale may be used. For example, a clinic serving both children and adults selects a scale to be used with each of those patient populations. Assessment of cognitively impaired patients may also require assessment of behavioral factors signaling pain or discomfort.
6. Staff are educated about pain assessment and treatment including the barriers to reporting pain and using analgesics. Staff encourage the reporting of pain when a patient and/or family member demonstrates reluctance to discuss pain, denies pain when pain is

likely to be present (for example, post-operative, trauma, burns, cardiac emergencies), or does not follow through with recommended treatments.

Scoring for PE.1.4
Is pain assessed when warranted by the patient's condition as outlined in the intent?

Score 1 Yes

Score 2 With a few, minor exceptions

Score 3 Not consistently

Score 4 Rarely

Score 5 No

And to find out more specifics on the Standards, see your hospital's copy of the JCAHO Manual or go to: http://www.partnersagainstpain.com/index-hs.aspx?sid=22

To give a "summary" flavor to this rather wide-ranging course, we offer you the following (along with a fervent hope that this course has broadened your knowledge of the topic: pain.

Seven Tips for Managing Pain Patients after they Return from the Specialist

Bill McCarlberg, MD Founder, Chronic Pain Management Program, Kaiser Permanente Escondido, Calif. *Pain Medicine News* November/December 2004, volume 2, number 6

A specialty consult is often needed for a complex medical problem such as diabetes or congestive heart failure. When the patient is returned to the primary care provider, the condition has been evaluated, the work up completed, treatment initiated and the problem stabilized. If difficult or complex treatment strategies are offered as in HIV or cancer, the patient is often followed on a long-term basis by the specialist. In chronic pain patients, the pain does not disappear after specialty referral. Aggressive strategies maybe employed including injections, complex drug regimens, and high dose opioid management, yet the long term care responsibilities lie with primary care. The differences seen in pain care vs. other specialty care for complex problems result from many factors

including unfavorable reimbursement from 3rd party payers. To provide quality, continuing care for these complicated pain patients, the following tips may help.

1) Developing a relationship with the referral doctor will help guide your future care. Make sure the specialist delineates what is the best course to follow with a patient for their continued care or during pain flares. Should breakthrough medication be used, or should the patient return to the specialist during these times of crisis? Discussing the treatment plan with the specialist such that the expected course and follow up arrangements will lead to consistent quality care. The pain specialist will also understand what level of comfort and expertise you have in dealing with these patients. Future referrals will be returned at the appropriate time in treatment and with the necessary care information.

2) All pain treatment is ultimately aimed at improving patient function. When patients return with continued pain, certainly ask about their pain, but concentrate on function. Be sure to document pain levels and improved function in the chart, and emphasize to the patient the need for functional gains.

3) When the specialist has exhausted all treatment strategies, continued pain is often distressing and fearful for the patient. Returning to the primary care provider can be particularly stressing when cure is not achieved. Reassurance and compassionate listening are often very therapeutic. When cure is not anticipated, patients expect us to validate their discomfort, answer concerns about alternative therapies, and not abandon care. Avoid statements like: "there is nothing more I can do" for example. Another referral to physical therapy or updating an MRI will not likely help after specialty care is complete. You can continue an impactful therapeutic relationship with simple reassurance, caring and hope.

4) Keep patients active. Exercise in any form that is practiced regularly improves function, sleep, sense of well being and depression. Continue to ask about exercise in your patients and encourage this active.

5) Interdisciplinary specialty care providers use a variety of treatment strategies including medication, physical rehabilitation, injections, activity modification, exercise etc. As with any chronic disease, successful self-management is the key. Passive, unmotivated patients expecting to be taken care of or cured do not improve and are stressful for us to treat. Self-management skills (relaxation, exercise, pacing, strategic rest etc.) give better outcomes than passive therapies. Emphasize the importance of self-management skills with your patients.

6) Psychosocial issues including depression and anxiety are commonplace in chronic pain patients. Inadequate assessment and treatment of the psychosocial comorbities occur even after specialty evaluation due to many factors including reimbursement strategies and managed care carve-outs for psychosocial services. Be alert to these lingering problems. We all provide psychosocial treatments for our patients; chronic pain patients require a high index of suspicion.

7) Regularly scheduled appointments for chronic pain patients are vital rather than waiting until a pain problem spirals out of control and becomes much more difficult to treat. Even if we have difficulty dealing with patients with, for example, fibromyalgia, hoping that they will not make their own appointments is unrealistic. Regularly scheduled appointments help keep the complaint lists manageable. Patients may not be as anxious or feel as abandoned if you welcome them with a regular appointment. Even though this may sound like more work for you, the result will be shorter, more productive interactions.

Chronic pain patients are suffering not just from pain but fear, depression, and isolation among many other issues. Primary care can use the pain specialist for help but the continuing care will ultimately return to us. We must provide quality, empathetic care for our patients. I believe we are uniquely trained with broad medical knowledge and longevity with our patients to be able to provide the best care.

APPENDIX 1: JCAHO Dosing Guidelines and Equlanalgesic Charts

site:

http://www3.us.elsevierhealth.com/PAIN/charts.html

Equianalgesic Charts for Printing
Note: to read and print these files, you must have the Adobe Acrobat Reader installed, which is free and available for download from the Adobe site.

Chart 1a: Approximate equivalent doses of opioids for moderate to severe pain

Chart 1b: Approximate equivalent doses of opioids for moderate to severe pain (cont'd)

Chart 2: Dosing Guidelines for Acetaminophen and Selected NSAIDs.

Then you could add:

For an excellent Resource For Integrating the Revised JCAHO Pain Assessment and Management Standards, go to this site:

http://www3.us.elsevierhealth.com/PAIN/jcaho_index.html

Equianalgesic Chart: Approximate equivalent doses of opioids for moderate to severe pain.

ANALGESIC	PARENTERAL (IM, SC, IV) ROUTE1,2 (mg)	PO ROUTE1 (mg)	COMMENTS
MU OPIOID AGONISTS			
MORPHINE	10	30	Standard for comparison. Multiple routes of administration. Available in immediate-release and controlled-release formulations. Active metabolite M6G can accumulate with repeated dosing in renal failure.
CODEINE	130	200 NR	IM has unpredictable absorption and high side effect profile; used PO for mild to moderate pain; usually compounded with nonopioid (e.g., Tylenol #3).
FENTANYL	100 µg/h parenterally and transdermally ~= 4 mg/h morphine parenterally; 1 µg/h transdermally ~ = 2 mg/24h morphine PO	—-	Short half-life, but at steady state, slow elimination from tissues can lead to a prolonged half-life (up to 12 h). Start opioid-naive patients on no more than 25µg/h transdermally. Transdermal fentanyl NR for acute pain management. Available by oral transmucosal route.
HYDROMORPHONE (Dilaudid)	1.5	7.5	Useful alternative to morphine. No evidence that metabolites are clinically relevant; shorter duration than morphine. Available in high-potency parenteral formulation (10 mg/ml) useful for SC infusion; 3 mg rectal ~= 650 mg aspirin PO. With repeated dosing (e.g., PCA), it is more likely that 2-3 mg parenteral hydromorphone = 10 mg parenteral morphine.
LEVORPHANOL (Levo-Dromoran)	2	4	Longer acting than morphine when given repeatedly. Long half-life can lead to accumulation within 2-3 days of repeated dosing.
MEPERIDINE	75	300 NR	No longer preferred as a first-line opioid for the management of acute or chronic pain due to potential toxicity from accumulation of metabolite, normeperidine. Normeperidine has 15-20 h half-life and is not reversed by naloxone. NR in elderly or patients with impaired renal function; NR by continuous IV infusion.
METHADONE (Dolophine)	10	20	Longer acting than morphine when given repeatedly. Long half-life can lead to delayed toxicity from accumulation within 3-5 days. Start PO dosing on PRN schedule; in opioid-tolerant patients converted to methadone, start with 10-25% of equianalgesic dose.
OXYCODONE	—-	20	Used for moderate pain when combined with a nonopioid (e.g., Percocet, Tylox). Available as single entity in immediate-release and controlled-release formulations (e.g., OxyContin); can be used like PO morphine for severe pain.
OXYMORPHONE (Numorphan)	1	10 rectal	Used for moderate to severe pain. No PO formulation.

1 Duration of analgesia is dose dependent; the higher the dose, usually the longer the duration. (Continued.)

2 IV boluses may be used to produce analgesia that lasts approximately as long as IM or SC doses. However, of all routes of administration, IV produces the highest peak concentration of the drug, and the peak concentration is associated with the highest level of toxicity, e.g., sedation. To decrease the peak effect and lower the level of toxicity, IV boluses may be administered more slowly, e.g., 10 mg of morphine over a 15 minute period or smaller doses may be administered more often, e.g., 5 mg of morphine every 1-1.5 hours.

FDA = Food and Drug Administration; NR = not recommended; ~ = roughly equal to

Equianalgesic Chart: Approximate equivalent doses of opioids for moderate to severe pain. (cont'd)

ANALGESIC	PARENTERAL (IM, SC, IV) (mg)	PO ROUTE1 (mg)	COMMENTS ROUTE1,2
AGONIST-ANTAGONIST OPIOIDS:			Not recommended for severe, escalating pain. If used in combination with mu agonists, may reverse analgesia and precipitate withdrawal in opioid-dependent patients.
BUPRENORPHINE (Buprenex)	0.4	—-	Not readily reversed by naloxone; NR for laboring patients.
BUTORPHANOL (Stadol)	2	—-	Available in nasal spray.
DEZOCINE (Dalgan)	10	10	60
NALBUPHINE (Nubain)			
PENTAZOCINE (Talwin)			

—-—-180

Selected References

For more complete information and additional references, see: Pasero C, Portenoy RK, McCaffery M: Opioid analgesics. pp. 161-299.In: McCaffery M, Pasero C: **Pain Clinical Manual**, St. Louis, 1999, Mosby, pp. 241-243.

American Pain Society (APS): **Principles of analgesic use in the treatment of acute and cancer pain**, ed. 3, Glenview, IL, 1992, APS.Lawlor P, Turner K, Hanson J, et al: Dose ratio between morphine and hydromorphone in patients with cancer pain: a retrospective study, **Pain** 72(1,2):79-85, 1997.Manfredi PL, Borsook D, Chandler SW, et al: Intravenous methadone for cancer pain unrelieved by morphine and hydromorphone: clinical observations, **Pain** 70:99-101, 1997.Portenoy RK: Opioid analgesics. In Portenoy RK, Kanner RM, editors: **Pain management: theory and practice**, Philadelphia, 1996, FA Davis Company, pp. 249-276.

ANALGESIC	PO DOSAGE (MG)
Nonopioids	
Acetaminophen	650
Aspirin (ASA)	650
Opioids† Codeine	32-60
Hydrocodone††	5
Meperidine (Demerol)	50
Oxycodone†††	3-5
Propoxyphene (Darvon)	65-100

† Often combined with acetaminophen; avoid exceeding maximum total daily dose of acetaminophen (4000 mg/day).
†† Combined with acetaminophen, e.g., Vicodin, Lortab.
††† Combined with acetaminophen, e.g., Percocet, Tylox. Also available alone as controlled-release OxyContin and immediate-release formulations.

A Guide to Using Equianalgesic Charts

- Equianalgesic means approximately the same pain relief.
- The equianalgesic chart is a guideline. Doses and intervals between doses are titrated according to individual's response.
- The equianalgesic chart is helpful when switching from one drug to another, or switching from one route of administration to another.
- Dosages in the equianalgesic chart for moderate to severe pain are not necessarily starting doses. The doses suggest a ratio for comparing the analgesia of one drug to another.
- For elderly patients, initially reduce the recommended adult opioid dose for moderate to severe pain by 25% to 50%.
- The longer the patient has been receiving opioids, the more conservative the starting doses of a **new** opioid.

Selected References: For more complete information and additional references, see: McCaffery M, Portenoy RK: Nonopioids: Acetaminophen and nonsteroidal
antiinflammatory drugs. pp. 129-160. In: McCaffery M, Pasero C: **Pain: Clinical Manual**, St. Louis, 1999, Mosby, p. 133.American Pain Society (APS): **Principles of analgesic use in the treatment of acute pain and cancer pain,** ed. 3, Glenview, IL, APS, 1992.Kaiko R, Lacouture P, Hopf K, et al: Analgesic efficacy of controlled-release (CR) oxycodone and CR morphine. **Clin Pharmacol Ther** 59:130, 1996.

Dosing Guidelines for Acetaminophen and Selected NSAIDs

Generic (Brand) Name(s)	Recommended Starting Oral Dose (mg)*	Dosing Schedule	Maximum Oral Dose (mg/day) Recommended**	Comments
acetaminophen (Tylenol, many others)	650	q4-6h	4000-6000	No platelet or GI toxicity.
aspirin (Bayer, many others)	650	q4-6h	4000-6000	May not be well tolerated.
choline magnesium trisalicylate (Trilisate)	500-1000	q12h	4000	No effect on platelet aggregation. Available as a liquid.
diclofenac [Cataflam (immediate-release) Voltaren Delayed Release, Voltaren-XR, (extended-release)]	25	q8h	150	
diflunisal (Dolobid)	500	q12h	1500	
ibuprofen (Motrin, Advil, many others)	400	q6h	3200	Available as a suspension.
ketoprofen (Orudis, Oruvail Extended-Release)	25	q6-8h	300	Available rectally and as a topical gel.
ketorolac (Toradol)	10	q6h	40	Use limited to 5 days.
nabumetone (Relafen)	1000	q24h	2000	Minimal effect on platelet aggregation.
naproxen (Naprosyn, Aleve)	250	q12h	1025-1375	
salsalate (Disalcid)	500-1000	q12h	4000	Minimal effect on bleeding time.

fold here

* Should be reduced by one-half to two-thirds in the elderly, those on multiple drugs, or those with renal insufficiency.**Data are lacking, but the dose listed is thought to be the maximum needed by most patients for analgesia and the dose beyond which side effects are more likely.

Some patients require or tolerate less or more. h = hour; q = every

For references, see: McCaffery M, Portenoy RK: Nonopioids: Acetaminophen and nonsteroidal antiinflammatory drugs. pp. 129-160. In: McCaffery M, Pasero C: **Pain: Clinical Manual,** St. Louis, 1999, Mosby, pp.139-140.

Indications for nonopioid analgesics:

- **Mild pain.** Start with a nonopioid. Acetaminophen or a NSAID alone often provides adequate relief.
- **Moderate to severe pain.** Pain of any severity may be at least partially relieved by a nonopioid, but a NSAID alone usually does not relieve severe pain.
- **Pain that requires an opioid.** Consider adding a nonopioid for the opioid dose-sparing effect.

Gastroprotective therapies for prevention of ulcers in patients taking NSAIDs:

- •Misoprostol (Cytotec).
- •Famotidine (Pepsid) 40 mg bid.
- •Combination of H2 blocker, e.g., ranitidine (Zantac), sucralfate (Carafate), and antacids.

Preventive strategies when bleeding is a concern:

- •Use NSAIDs that have minimal or no effect on bleeding time, such as choline magnesium trisalicylate (Trilisate), salsalate (Disalcid), and nabumetone (Relafen).
- •Use acetaminophen instead of a NSAID.
- •To decrease bleeding associated with operative procedures, stop aspirin therapy one week before surgery, and stop most other NSAIDs 2 to 3 days before surgery.

■ From McCaffery M, Paser

Pain CEU Exam

Select the ***best*** answer to each of the following items. Mark your responses on the Answer form.

1. In the United States, the _____ has announced new standards and requirements for the assessment of pain in accredited hospitals and other healthcare settings.

a. American Hospital Association
b. American Medical Association
c. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
d. HICFA

2. According to figures cited in the CEU, _____ of all diseases may be associated with pain.

a.10%
b. 25%
c. 70%
d. 90%

3. _____**,** unpleasant sensory and emotional experience caused by real or potential injury or damage to the body or described in terms of such damage

a. Disease
b. Pain
c. Suffering
d. Pathology

4. Pain is difficult to _____ in humans because it has an emotional, or psychological component as well as a physical component.

a. cure
b. measure
c. describe
d. diagnose

5. The signals that warn the body of tissue damage are transmitted through the _____.

a. pancreas
b. thalamus
c. nervous system
d. hypothalamus

6. While most of the sensory nerves in the skin and other body tissues have special structures covering their nerve endings, those nerves that signal injury have _____.

a. free nerve endings
b. inflammatory secretions
c. collagen coverings
d. synaptic damage

7. Pain information from the A-delta and C fibers travels through the _____ to the brain.

a. thalamus
b. pancreas
c. pituitary gland
d. spinal cord

8. To alter the pain sensation, the brain and spinal cord release specialized neurotransmitters called endorphins and _____.

a. collagen
b. neurons
c. enkephalins
d. axons

9. Drugs that relieve pain, known as_____, usually interfere with pain impulse transmission in the nervous system

a. analgesics
b. neuoroblockers
c. nociceptions
d. bradykinins

10. _____ analgesics, such as codeine, have chemical structures that are similar to the pain-blocking neurotransmitter endorphin.

a. Trigliceride
b. Fast acting
c. Narcotic
d. Nonsteroidal

11. In cases where no treatment effectively relieves pain, doctors may recommend a surgical procedure in which pain-transmitting nerves in the brain or spinal cord are _____.

a. repaired
b. enhanced
c. severed
d. spliced

12. Some injuries take a long time to heal, and even then, pain does not always completely subside. People suffering from this condition, known as _____.

a. intractable
b. chronic pain
c. incurable
d. acute

13. According to your CEU, it remains true that adequate relief for severe and continuing pain is _____ in the modern hospital.

a. always available
b. usually available
c. the norm
d. unusual

14. Most pain originates when special nerve endings, called _____, detect an unpleasant stimulus.

a. sensors
b. nociceptors
c. axons
d. C-fibers

15. A protein called _____ continuously stimulates nerve endings at the injury site and within the spinal cord, increasing pain messages.

a. substance A
b. substance C
c. substance P
d. substance K

16. For many years, standard practice called for treating moderate to severe acute pain with injections of narcotic medication _____.

a. automatically
b. only with the patient's permission
c. "as needed"
d. after peer review

17. _____ anti-inflammatory drugs, are used to treat acute pain from inflammation, such as from arthritis.

a. Prostaglandin
b. Nociceptor
c. Narcotic
d. Nonsteroidal

18. _____is a synthetic analgesic used primarily for chronic pain, but is also prescribed for acute pain.

a. Amitriptyline (Elavil)
b. meperidine (Demerol)
c. Tramadol (Ultram)
d. Imipramine (Tofranil)

19. _____, now available in tablet form, may reduce pain from migraine headache by constricting blood vessels in your brain.

a. Amitriptyline (Elavil)
b. Sumatriptan (Imitrex)
c. Tramadol (Ultram)
d. Imipramine (Tofranil)

20. _____, a topical cream made from an extract of red peppers, can help relieve skin sensitivity resulting from shingles.

a. Tramadol (Ultram)
b. Imipramine (Tofranil)
c. Sumatriptan (Imitrex)
d. Capsaicin (Zostrix)

21. _____may help by teaching patients to be aware of autonomic pain responses such as skin temperature, muscle tension, blood pressure and heart rate, and how to modify these

a. Accupuncture
b. Education programs
c. Biofeedback
d. Relaxation therapy

22. Research done at the Pain & Policy Studies Group of the University of Wisconsin Cancer Center found that while there were significant increases in the amounts of opioids prescribed by physicians in the U.S., it also found that abuse of opioids was low and stable. In contrast to a 109% increase in abuse with cocaine and heroin, abuse with opioids increased only _____ from 1990 to 1996

a. 2%
b. 6.6%
c. 12%
d. 30%

23. _____ pain is a state in which the cause of the pain cannot be removed or otherwise treated and which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physicians and surgeon and one or more physicians and surgeons specializing in the treatment of the

a. Chronic
b. Acute
c. Intractable
d. Nonresponsive

24. Tolerance is a form of _____to the effects of chronically administered opioids (or other medications) which is indicated by the need for increasing or more frequent doses of the medication to achieve the initial effects of the drug.

a. addiction
b. neuroadaptation
c. dependence
d. resistance

25. Aaron Gilson, Researcher at the Pain and Policy Studies Group at the University of Wisconsin, narrows down the definition of addiction as _____.This would not apply to pain patients as taking opioids actually increases their quality of life.

a. “over use”
b. “lack of control”
c. "drug use despite harm"
d. “nonresponsiveness to the drug”

26. Many members of state medical boards continue to believe that physical dependence and tolerance associated with opioid pain treatment is the same as _____.

a. addiction
b. abuse
c. criminal action
d. non-compliance

27. In an attempt to discourage drug diversion, some states have adopted a _____.

a. narcotic review policy (NRP)
b. peer review drug policy (PRDP)
c. multiple copy prescription program (MCPP).
d. zero tolerance policy (ZTP)

28. Some states have become more aware of the necessity of opioid treatment for intractable pain and have either passed legislation known as _____.

a. Multiple Copy Prescription Program (MCPP).
b. Intractable Pain Acts (IPAs)
c. Peer Review Drug Policy (PRDP)
d. Patient Bill of Rights Acts (PBRA)

29. Physicians continue to under-treat pain patients due to a cyclical phenomenon known as _____.

a. customary prescribing behavior
b. first do no harm policy
c. respond with maximum caution policy
d. code blue policies

30. Another reason that clinicians inadequately relieve pain is their continued support of _____ prescribing.

a. defensive
b. ADA (anti-drug addiction)
c. PRN (*pro re nata,* or as needed)
d. code blue policies

31. The difference between the levels of pain felt does not result from age or ethnicity but from _____.

a. past experience with pain
b. stress levels
c. perceptions
d. disease progression

32. Low priority given to the accountability of pain and pain management coupled with limited access to opioid pain treatment perpetuates _____.

a. patient antipathy
b. inadequate intractable pain relief
c. disease progression
d. high medical costs

33. Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

a. True
c. False

34. The legal system does not allow practitioners to consciously disregard indications that illegal drug-related activities might be occurring.

a. True
c. False

35. . Physical dependency on opioids is an expected occurrence in all individuals in the presence of continuous use of opioids for therapeutic or for nontherapeutic purposes. It does not, in and of itself, imply addiction.

a. True
c. False

36. “Diversion” refers to the unlawful transfer of prescription drugs from legitimate to illicit channels of distribution, often resulting in episodes of abuse. Opioids are diverted in many ways, all of which are illegal.

a. True
b. False

37. Some physicians unwittingly contribute to diversion by careless prescribing or failure to maintain control over their prescription pads.

a. True
b. False

38. In assessing patients for opioid therapy, take a detailed history and perform an appropriate physical examination. The medical history should NOTinclude a history of controlled prescribed drug use and alcohol, cannabis and nicotine use.

a. True
b. False

39. Pseudoaddiction: A term used to describe an iatrogenic phenomenon in which a patient with under-treated pain is perceived by health care professionals to exhibit behaviors similar to those seen in addiction but is not true addiction. Patients may _____.

a. may “clock watch b. may otherwise seem inappropriately “drug seeking
b. focus on obtaining medications d. All of the above

40. Some of the problematic drug-related behaviors that occur in populations with chronic pain should be noted, and managed, by clinicians, but are generally recognized as relatively less egregious, and therefore, probably less likely to be predictive of addiction. These include:

a. complaints about need for more medication b. unsanctioned dose escalation
b. drug hoarding d. All of the above

41. Seven million people suffer intractable pain that requires opioids for pain relief; however, only 4,000 physicians in the United States are willing to prescribe opioids for these people.

a. True
b. False

42. Opioid treatment options include short-acting opioids, such as codeine, hydrocodone, hydromorphone, morphine, or oxycodone.

a. True
b. False

43. The Republican sponsored Hyde-Nickels Act would direct the DEA to examine the medical charts of all terminal patients, to determine if the prescribing physician had any "intent" to _____ with federally controlled medical substances.

a. addict
b. overmedicate
b. avoid harming
d. hasten the death of the patient

44. The 2000 session of the Florida Legislature voted to make _____medications schedule II, requiring a written prescription and precluding phone-in prescriptions.

a. NSAID
b. methadone
b. hydrocodone
d. carbamazepine (Tegretol)

45. Following the motto _____,the JCAHO says the change will occur in four ways: by making it a patient rights issue as well as an education and training issue, emphasizing the quantitative aspects of pain (placing it on a 10-point scale), encouraging systematic assessment, and emphasizing safe management.

a. “No more pain”
b. “The pain management paradigm is about to shift"
c. “Zero pain tolerance”
d. “Do no harm, allow no unresolved pain”

46. According to Perry G. Fine, MD, professor of anesthesiology at the University of Utah School of Medicine and associate medical director of the Pain Management Center in Salt Lake City "Management of pain is _____ within the established medical culture as a credible or highly respected discipline or specialty,"

a. now featured
b. not valued
c. often neglected
d. changing

47. According to officials at the_____, “During residency training, experience with pain is limited and empathy is not part of the medical culture.”

a. AMA
b. ANA
c. JCAHO
d. AHA

48. According to the JCAHO, it is important to :”Address the individual's needs for symptom management in the _____. “

a. admission process
b. emergency room
c. discharge planning process
d. all the above

49. The argument can now be made that, with the _____ for the treatment of pain; no medical practitioner can credibly defend failure to adequately treat pain relief, except for a frank lack of expertise and/or training.

a. universal availability of standards and guidelines
b. technology available today
c. JCAHO regulations
d. new paradigm

50. According to the JCAHO, The **goal** of the care of patients _____is to provide individualized care in settings responsive to specific patient needs.

a. in the hospital
b. function
c. rights
d. well being