The Politics of Pain:

Balancing Vigilance and Compassion

Report of the
Texas Pain Summit
Improving Pain Care in Texas

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2006-2007

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American Cancer Society®

Texas Medical Association

Physicians Caring for Texans

TxPEC

Texas Partnership for End-Of-Life Care

LIVESTRONG™

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Texas Pain Society

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From the Chairman

"This obligation of beneficence requires physicians to do good and prevent harm, the list of goods typically including prolongation of life, restoration of function, and relief of pain and suffering."

Post, et al., 1996[1]

Pain is the most common reason that Texans access our healthcare system. Extrapolating from national data, about 11 million Texans may live with unrelenting pain. Injured people may have acute pain that becomes a lasting problem. Those with chronic disease may suffer from persistent pain related to their illness. Cancer patients may have pain from tumors or from side effects or aftereffects of treatment. In the last days of their lives, people may suffer from unrelenting pain that robs them of their dignity.

Uncontrolled pain compromises quality of life, decreases productivity, is a major cause of disability, and is a leading contributor to healthcare costs in the U.S. Most painful conditions can be relieved with proper treatment, yet many people in pain along with their healthcare practitioners often face barriers that prevent its appropriate management. More than half of patients get inadequate treatment that slows recovery and diminishes quality of life. The elderly, women, and racial and ethnic minorities often suffer disproportionately from inadequate pain treatment.

Several factors appear to account for the disparity in treatment. First, patients may be reluctant to report pain for various reasons. In addition, many practitioners have inadequate education and training to properly assess and manage pain or they may misunderstand policies. Finally, fear of excess scrutiny by regulatory agencies or law enforcement authorities may inhibit the appropriate treatment of pain.

The epidemic of unrelieved pain in the U.S. has proven severe enough to warrant government involvement. Within the last seven years, the U.S. Congress has passed a major initiative – the Decade of Pain Control and Research (2001-2010). Further, the Congress is considering the National Pain Care Policy Act of 2007. Both of these are intended to improve pain care research, education, training, access, awareness, outreach, and clinical care. These initiatives make special provisions for reducing disparities associated with pain care in underserved populations.

Far from watching from the sidelines various stakeholders including state government, regulators, law enforcement, and health professionals from all disciplines have actively pursued solutions for pain-suffering Texans. In August 2006, concerned professionals from across the state convened the Texas Pain Summit. The Summit consisted of a concentrated day of education and consensus building and focused on 1) improving Texas pain care policy; 2) fostering dialogue among healthcare professionals and regulatory and licensing agencies; and, 3) promoting a balanced regulatory system in which the prevention of prescription drug diversion and abuse is complementary to high-quality pain treatment and management.

In an effort to improve the lives of Texans suffering from severe pain, the Texas Legislature recently established an interim study committee (SB1879). Its mission is to examine relevant statutes and aid the Legislature in developing effective policies that balance vigilance and compassion in pain management.

This document contains key information and data from the Summit as well as surveys of Texas households and healthcare practitioners. It offers insights into a broad spectrum of issues surrounding the experience of pain by Texans. It also sheds light on the attitudes and knowledge of Texas healthcare professionals regarding pain and its treatment. Our goal and sincere hope is that that the information in this summary will be instrumental in improving pain care for all Texans.

Larry C. Driver, MD
Chair, Texas Pain Summit

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No enterprise of the scope and scale of the Texas Pain Summit can be successful without support from many organizations and individuals giving freely and extensively of their time, expertise, talent, and resources. We wish to acknowledge these fine people and their organizations. Without their community-minded spirit and dedication to assuring that all those who suffer from pain have access to appropriate treatment, the summit and this plan for improving pain care in Texas would not be possible.

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Executive Summary

"Pain is dehumanizing. The severer the pain, the more it overshadows the patient's intelligence. All she or he can think about is pain: there is no past pain-free memory, no pain-free future, only the pain-filled present.

Pain destroys autonomy: the patient is afraid to make the slightest movement. All choices are focused on either relieving the present pain or preventing greater future pain, and for this, one will sell one's soul.

Pain is humiliating: it destroys all sense of self-esteem accompanied by feelings of helplessness in the grip of pain, dependency on drugs, and being a burden to others.

In its extreme, pain destroys the soul itself and all will to live."

-Post, et al., 1996.[2]

An Historical Perspective

In a landmark piece of legislation in 1989, Texas became the first state in the nation to pass an Intractable Pain Treatment Act (IPTA) designed to address barriers to good pain management. It declared that pain management is an integral part of medical practice and that the use of opioid medications to treat intractable pain is a part of professional practice.

The IPTA attempted to create a safe haven for physicians, to allay their fears of regulatory scrutiny about using the right medication, in the right amount, and at the right time to treat pain. It affirmed that people with a history of substance abuse are no less deserving of compassionate care for pain than those without such problems. [3] In concert with this effort, Texas' regulatory boards also updated their policies and guidelines.

In 2001, the Texas State Board of Pharmacy issued a position statement asserting that a cornerstone of quality care for Texans dictated access to *"appropriate and effective pain relief."* The Board encouraged pharmacists to become knowledgeable about effective methods for treating pain including the use of opioids whether for acute or chronic, cancer or non-cancer pain. Further, the board declared that pharmacists should not fear disciplinary action for dispensing controlled substances, including opioids, for the treatment of pain.[4]

Both the IPTA and the Board of Pharmacy's statement attempted to strike a balance between assuring that people with pain had access to appropriate treatment while at the same time preventing diversion and abuse of opioid medications.

Notwithstanding these ground-breaking actions, mounting evidence indicates that both acute and chronic pain continue to be undertreated in Texas. Despite the fact that Texas was the first state to enact comprehensive pain management legislation, recent "report cards" indicate that Texas has lost its position as a pain management leader.

Last Acts®, a national program instituted by the Robert Wood Johnson Foundation to improve end-of-life care, rated Texas' pain policies a "D" in 2002.[5] The Pain & Policy Studies Group (PPSG) Progress Report in an analysis of Texas laws and regulations gave Texas a "C" in 2000 and showed no improvement in its subsequent reports of 2003 and 2006.[6]

Building Momentum for the Future

In August 2006, striving to return Texas to its standing as a national leader in quality pain management, the American Cancer Society, Lance Armstrong Foundation, Texas Medical Association, Texas Pain Society, and Texas Partnership for End-of-Life Care, with additional financial support from the Alliance of State Pain Initiatives, Purdue Pharma L.P., and Endo Pharmaceuticals, hosted the Texas Pain Summit, the first of its kind in our state. A major goal of the Summit was to foster dialog between healthcare professionals and the state's licensing and regulatory bodies in order to create a "balanced" regulatory system. Such a system fosters the appropriate medical use of opioid analgesics and other controlled substances that are essential for pain control while preventing their diversion and abuse for inappropriate, non-medical purposes.

Working groups constructed from Summit attendees (more than 70 healthcare professionals from a wide variety of disciplines, and including academicians, regulators, government officials, and law enforcement officers) assembled at the Summit. Working groups used a consensus-building model to identify recommendations

for improving pain care in Texas. While the groups reached consensus, it cannot be inferred that consensus represents individual opinions or the opinions of their respective organizations.

Subsequently, summit participants, leadership, and advisors, were asked their opinions of each recommendation's ability to improve pain management in Texas and ease of implementation within five years. The Summit Committee then developed a plan of action aligned with major strategies, objectives, actions, and measures.

The committee sought feedback on the action plan from summit participants, leadership, national advisors, and a thoughtfully selected group of key stakeholders and organizations from across Texas. Using the feedback received from all respondents, the committee developed a set of sharply focused initiatives designed to improve quality and accessibility of appropriate care for pain-suffering Texans.

To complete the picture of pain management in Texas, between 2006 and 2007, the Summit Committee commissioned knowledge, attitude and practice surveys of Texas physicians, nurses, and pharmacists, and a knowledge and attitude survey of Texas adult householders.

The Texas household survey revealed that an estimated eleven million Texans have experienced noteworthy levels of pain on at least a monthly basis.[7] Texans overwhelmingly described their pain as moderate or severe with more than half having had pain for longer than a year. Completed in October 2006, this survey utilized probability sampling techniques and may be the first realistic indicator of the state of pain in Texas.

The surveys revealed among healthcare professionals a fundamental lack of knowledge about what is legal and considered a legitimate part of practice and about addiction and the medical use of opioids for the treatment of pain. The surveys also exposed conflict between disciplines and the struggle of Texas' healthcare professionals to balance the needs of their patients in pain with regulatory uncertainty.[8,9]

Today and Tomorrow

The surveys commissioned by the Summit underscore the significance of the PPSG Progress Report 2007, released on July 17, 2007, which showed that Texas was not among the thirty-four states that had improved their grade from 2000 to 2007. Further evidence of the lack of progress in Texas is seen in the failure of recent legislative and regulatory efforts to improve the PPSG rating.

In 2006, the Board of Medicine, in collaboration with the Texas Pain Society, revised Chapter 170 regulations removing all negative language, adding affirming language, and bringing clarity to the clinician's responsibilities to their patients with pain.[10]

Texas also passed Senate Bill 1879 which establishes electronic monitoring for prescription medications in Schedules II through V, a key determinate in achieving balanced pain policy. SB1879 eliminates the 7-day prescription validity rule and establishes an advisory committee to the Texas Department of Public Safety comprised of representatives from the Boards of Medicine, Nursing, and Pharmacy and others.

Furthermore, SB1879 establishes an interim study committee on pain (Pain Treatment Review Committee) that is responsible to the legislature. This committee is comprised of clinicians, health organization representatives, and members of government with advice from regulatory boards, the Texas Department of Public Safety, and the Department of Aging and Disability Services. The committee is charged with examining Texas' statutes which impact a person's ability to obtain pain relief and with reporting recommendations for needed changes to the next regular legislative session.

Major deterrents to progress in Texas are outdated language contained in the IPTA and continuance of special serialized Government Issue prescription forms for Schedule II drugs. Texas is now the only state in the nation with such a requirement.

While the original impetus for the Summit was to address policy-related issues, the plan of action presented here spans a full complement of issues and barriers to quality care. This multi-faceted, multi-year plan includes public policy initiatives, provider/professional education, advocacy, public awareness, media outreach, and collaboration with law enforcement and regulatory bodies. Moreover, the plan addresses access to care, disparities in care, and support for implementation as crosscutting issues.

The challenge now exists for caring and concerned healthcare professionals, healthcare systems and organizations, and a caring and concerned government to bring them to fruition.

Fran Di Giacomo, artist, author, and 23-year cancer survivor, suffers from chronic pain.

"I Haven't Got Time for the Pain."

"Science has control of pain."

Inscribed on the gravestone of William T. G. Morton
Demonstrated the use of ether as an anesthetic
at Massachusetts General Hospital in 1846

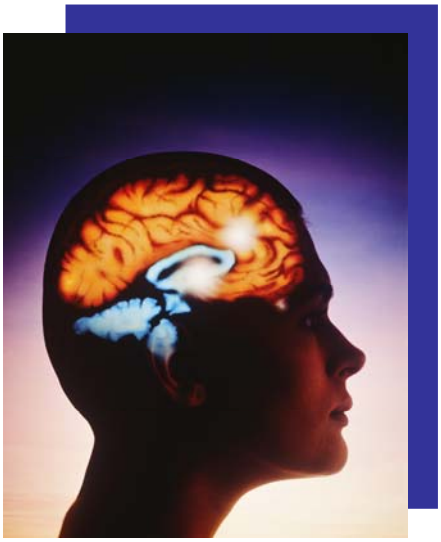
More than 150 years after Morton's death, scientists and healthcare professionals stand at the threshold of making his dream of controlling pain a reality. Potent tools for managing pain include new medicines and innovative ways to administer them, complementary methods acknowledging the mind-body connection, and a deeper understanding of how the body and the brain react to pain. The Decade of Pain Control and Research – a major Congressional initiative – has resulted in advances in pain management and 21st century treatment of pain presages techniques specifically tailored to the individual.

In addition, healthcare professionals increasingly have recognized the need to assess and treat pain. In 1999, the Veterans' Health Services recognized pain as the Fifth Vital Sign and required its assessment along with blood pressure, temperature, pulse, and respiration rate. The Joint Commission now requires routine pain assessment and management as a part of the accreditation criteria for healthcare facilities.

In spite of advances in our ability to manage pain, millions of Americans continue to report unrelieved pain of significant duration. Part of the reason so many Americans suffer is the number of disease states that produce pain. More troubling, however, is the massive failure of the healthcare system overall to assess and treat pain with already proven and relatively effective measures.

What Is Pain?

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage."[11] In other words, pain is any sensation that hurts. Pain can be useful by serving as a protective function that alerts us to illness or injury. However, pain left untreated, or treated inadequately, can be harmful by slowing recovery and compromising our quality of life.



Pain management experts divide pain into two distinct clinical types—nociceptive and neuropathic.[12] Nociceptive pain occurs when damage to the body such as muscle or connective tissues surrounding bony joints or in the soft internal organs and tissues stimulates nerve endings, or nociceptive neurons. When the nociceptor encounters painful stimulus, a message is sent into the spinal cord and nerve tracts that carry the pain signal to the brain are activated. When pain messages reach the brain, they may or may not rise to the level of conscious thought. If they do, we feel pain.[13,14] Pain of this nature is often described as stabbing, dull, aching, throbbing, cramping, gnawing, or squeezing.

Neuropathic pain is often described as sharp, burning, or shooting and can be accompanied by numbness or tingling in arms, hands, legs or feet, and results from injury directly to the central nervous system (spinal cord and brain). Damage can be trauma related (car accidents, combat related injury), disease related (diabetes, environmental toxins), or caused by a tumor pressing against or invading the nerves in the brain or spinal cord. Neuropathic pain also can result from damage caused by certain medical interventions, such as chemotherapy, radiation, or surgery. Neuropathic pain can be very difficult to treat because it is often resistant to more conventional treatments and medications.[15]

In addition, pain is categorized by its duration: transient, acute, chronic,[16] and breakthrough. Transient pain is short-lived and serves to prevent lasting damage to the body. We experience transient pain in response to specific hurtful stimuli such as extremes in temperature or pressure or exposure to harmful chemicals. Mild sunburn is an example of transient pain. This type of pain often motivates us to stop the harmful activity causing it. People rarely seek medical attention for transient pain.[17]

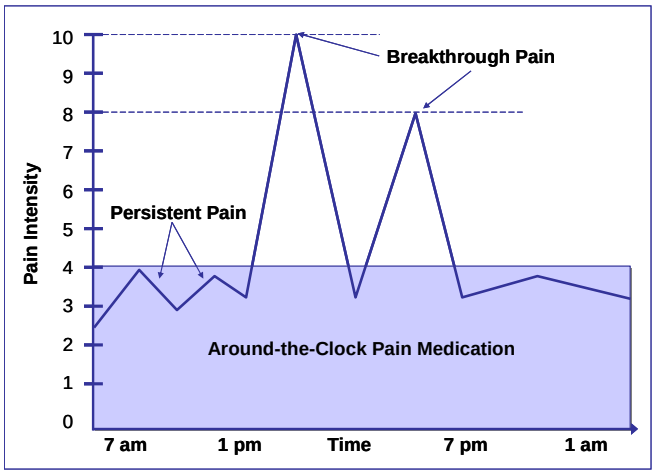
In contrast, acute pain lasts longer than transient pain but typically less than three months (although acute continuous pain caused by cancer can last longer). A broken bone or severe burn is an example of acute pain. This type of pain may also be caused by medical interventions such as surgery. People normally seek medical treatment for acute pain in order to aid the body's natural healing power and to seek relief from discomfort.[18]

Chronic pain is defined as pain without apparent biologic value that has persisted beyond the normal healing time (usually defined as greater than three months).[19] For example, a person may continue to feel pain long after the surgically induced wound produced by the amputation of a limb (This is known as phantom limb pain). Other examples of chronic pain include injury to the back or neck, arthritis, fibromyalgia, diabetic neuropathy and cancer. The increased likelihood of developing chronic pain is an underappreciated risk of therapies that promote survivorship of cancer patients and trauma victims.[20,21] The type of injury sustained influences whether the chronic pain is classified as nociceptive or neuropathic. Chronic pain may last for many months or even many years and affects multiple domains of life. People almost always seek help from their healthcare providers for chronic pain.

Even when persistent pain is managed stably with an around-the-clock medication, flares of pain termed breakthrough pain may occur. Within 3-5 minutes, breakthrough pain may reach maximum intensity (often moderate to severe pain). An episode of breakthrough pain may last an average of 30 to 60 minutes and may occur several times per day. While episode duration is shorter in persons with chronic cancer related pain, the flares occur more frequently. For example, the median frequency of breakthrough pain in cancer patients is 4-7 episodes per day and two per day in non-cancer pain, e.g., arthritis, low back pain, and diabetic neuropathy.[22,23]

Figure 1 graphically demonstrates how an individual receiving around-the-clock pain medication can experience breakthrough pain of varying intensities. Breakthrough pain requires assessment and treatment independent from the persistent pain.[24]

Figure 1. Breakthrough pain[25,26]



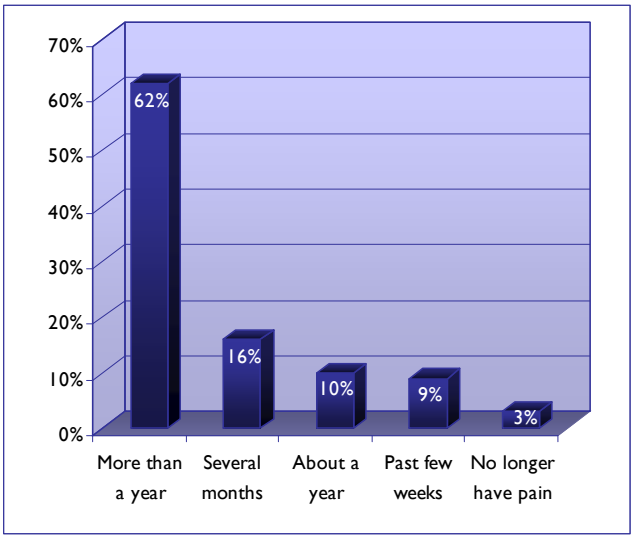
Prevalence of Pain

The sheer volume of diseases and injuries that produce pain as well as improvements in promoting survivorship contribute to the prevalence of pain in the United States. The results from the 2003 Research!America Survey on Pain were startling. Fully, fifty-seven percent of adults age 20 and older—translating into more than 122 million people—reported having chronic or recurrent pain either currently or in the past 12 months (Table 1). Even more troubling, the vast majority (62%) of those suffering with pain reported doing so for more than a year (Figure 2).[27]

Table 1. Have had chronic pain in the past year

All Adults	57%
Men	55%
Women	60%
Age	
18-34	54%
35-49	56%
50-64	63%
65+	57%

Figure 2. Duration of pain

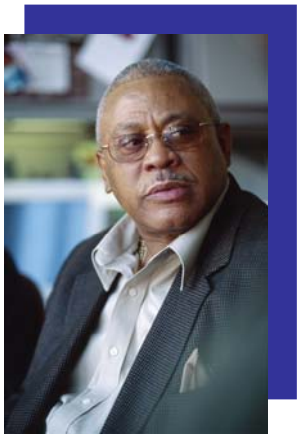


An estimated eleven million Texans have experienced noteworthy levels of pain on at least a monthly basis. Results of a survey of adults from 503 randomly selected Texas households (the Texas household survey) indicated that 43% of Texans suffer pain on a daily basis, with 56% having done so for three or more years. On overwhelming number of Texans – 63% – characterized their pain as moderate or severe.[28]

Pain in Vulnerable Populations

"The only thing necessary for the triumph of evil is for good men to do nothing."

-Edmund Burke (attributed)



The overall prevalence of pain tends to be higher among vulnerable populations – the elderly, the poor, women, children, and those of racially or ethnically diverse populations. Among elderly Americans residing in nursing homes, 43.4% report pain at least some of the time. The rate of daily pain of among nursing home residents nationally is 15.8%, and with a diagnosis of cancer, this rate rises to 21.6%.[29]

About one out of four nursing home residents with daily pain receive no treatment at all for their pain – ***not even Tylenol®***. For residents with cancer less than one out of three receive at least some treatment for pain. Despite guidance from the American Academy of Pain Medicine emphasizing the ethical responsibility of healthcare providers and organizations to ensure effective pain and symptom management at the end of life, almost half of residents who die in nursing homes receive only minimal pain treatment (over-the-counter analgesics such Tylenol® or aspirin) or none at all. Elderly residents with cognitive impairments are even less likely than those without such impairments to receive pain medication.[30]

While the management of excruciating daily pain experienced by Texans residing in nursing homes compares favorably against national rates (2.2% vs. 3.7%), a more disturbing picture emerges when examining the rate of chronic severe pain. In 2001, nearly 45% of this population reported persistent severe pain at first assessment and again at a second assessment at least 60 days later compared with the national rate of 41.6% (Table 2). Notably, trend data for Texas indicated erosion in quality of pain care provided to nursing home residents, while the national rate remained stable.[31]

Table 2. Persistent severe pain among nursing home residents in Texas as compared with the U.S. [32]

		1999	2000	2001
Excruciating daily pain among all nursing home residents	TX	2.7%	2.3%	2.2%
	US	3.9%	3.6%	3.7%
Persistent severe pain (at first assessment & at a second assessment at least 60 days later)	TX	42.4%	42.0%	44.2%
	US	41.5%	41.7%	41.6%

Recent information gathered on acute pain indicates there may be gender variances in both pain intensity and tolerance. Women tend to suffer from certain painful conditions more often than men.[33] However, women being treated for cancer are at greater risk for inadequate prescription of pain medicines and 1.5 times more likely to receive inadequate pain management.[34] Moreover, while women are more likely to seek medical attention for pain, they also are more likely to encounter disbelief and have their pain discounted by their physicians.[35] In a covert clash with the traditional medical model, women report it is *"hard work"* to make their symptoms viable, visible, and credible to their physicians, while at the same time they engage in an intricate ballet of not appearing *"too weak or too strong, too healthy or too sick, or too smart or too disarranged."*[36]

The poor also suffer disproportionately from unmanaged pain. According to the National Center for Health Statistics, people in households with incomes that are less than 200% of the Federal Poverty Level report pain more often than those in higher income households.[37]

In the U.S., poverty is inextricably linked with race and ethnicity. Between 2002 and 2004, nearly one out of every four African-Americans lived in poverty compared with only 8.3% of Whites. Poverty rates among Hispanics are also higher than those of Whites with just over one out of five classified as poor by the federal government.[38]

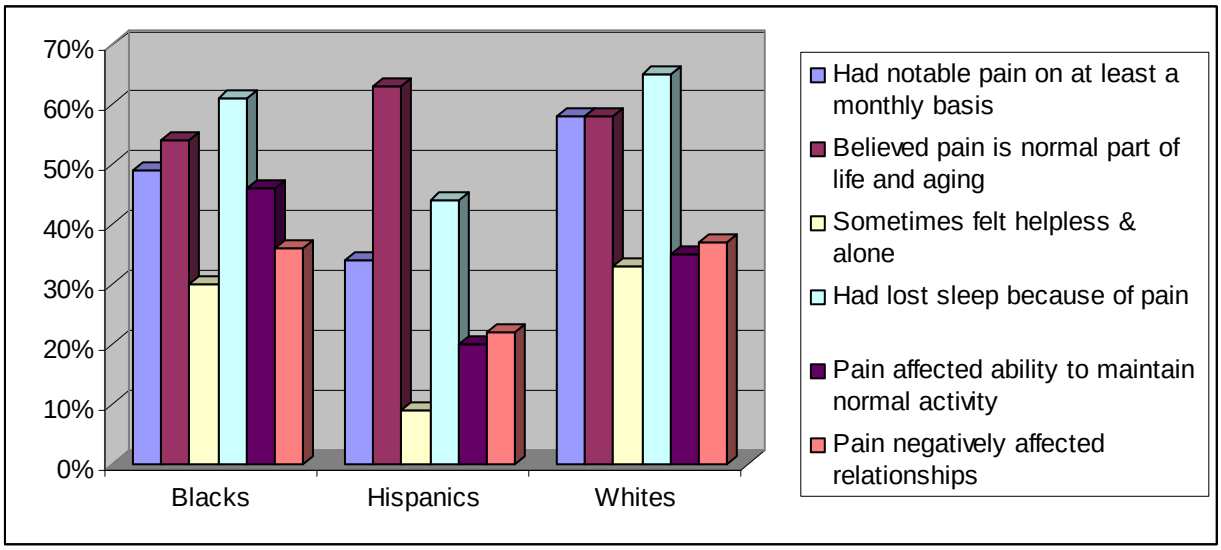
Racial and ethnic disparities in how pain is perceived, assessed, and treated are found in all healthcare settings and across all types of pain – acute and chronic, malignant and non-malignant.[39] Recent research indicates that African-Americans and Hispanics continue to receive substandard medical treatment for a broad range of illnesses. Moreover, the disparity in treatment persists even after adjusting for health insurance coverage, socioeconomic status, stage and severity of the disease and type of medical facility.[40] The reasons for such disparities are complex and involve patient and healthcare provider knowledge, attitudes, and communication styles, healthcare provider decision-making practices, and healthcare system barriers such as lack of adequate access to medicines for treating pain.

Surveys of Texas physicians, nurses, and pharmacists, conducted in 2006 and 2007 and referred to as the Texas healthcare professional surveys when cited collectively, suggest these are important concerns (See Appendix C). About a third of Texas physicians and nearly half of nurses believe that a patient's payment source affects the way a person's pain is managed. Moreover, at least seven out of ten Texas pharmacists agreed that the patient's culture, race, or ethnicity may affect treatment options for pain.[41]

Results from the Texas household survey illustrate the complex interplay of cultural factors and perception of pain and reveal interesting differences in attitudes towards pain and its impact on the individual (Figures 3). A clear majority of Texas' major ethnic groups (Hispanics, Blacks, and Whites) agreed that "Pain is just a normal part of life and aging." However, only one out of three Hispanics indicated that they experienced notable pain on a monthly basis, while substantially more than half of Whites and about half of Blacks indicated the same. Fewer than one out of ten Hispanics indicated that their pain sometimes left them feeling helpless and alone, as opposed to about a third of Whites and Blacks.[42]

Six out of ten Whites and Blacks asserted that their pain caused them to lose sleep. However, a much smaller percentage of Hispanics (44%) reported losing sleep because of pain, and, only 20% of Hispanic pain sufferers indicated that pain affected their ability to maintain their normal activity levels. At least one out of five Hispanics reported that their pain negatively affected relationships with loved ones and friends compared with nearly two out of five of Whites and more than a third of Blacks.[43] Given there is no physiological reason for these variances based on ethnicity, these results suggest that strong family support systems in the Hispanic community somewhat assuage the individual's suffering.

Figure 3. Ethnic differences in the experience and perception of pain among Texans



Diseases and Conditions that Produce Pain

Americans report suffering from a number of different types of pain: back pain, neck pain, chronic headaches, cancer pain, nerve-related pain (neuropathic), total body pain, AIDS-related pain, and others which are typically associated with a broad spectrum of diseases and conditions. Like cancer, pain is no respecter of persons, and most of us will either experience pain personally or know someone who does (Table 3).

Table 3. U.S. prevalence of diseases/conditions that produce significant pain

Disease/condition	Overall prevalence (in millions)
Back pain	54.6 [44]
Arthritis*	46.4 [45]
Headache/migraine	33.9 [46]
Diabetes	20.8 [47]
Cancer	10.7 [48]
Osteoporosis	10.0 [49]
Fibromyalgia	10.0 [50]
HIV/Aids	1.2 [51]
Sickle cell disease	.07 [52]

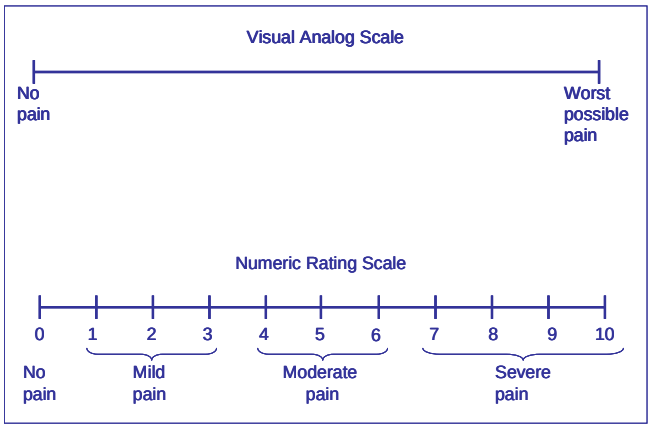
*Includes 2.1M with rheumatoid arthritis

Assessing Pain

Clinicians have a variety of tools with which to assess the intensity of pain experienced by their patients. Validated in scientific literature for more than two decades, standardized pain questionnaires and pain intensity scales serve to help patients and healthcare professionals communicate more effectively about pain and assists clinicians in determining the most appropriate treatments. Questionnaires currently used for research purposes include the Brief Pain Inventory[53], the Memorial Symptom Assessment Scale[54], the Edmonton Symptom Assessment Scale[55] and a variety of pain intensity scales.

Pain intensity scales have been developed for all patient populations including infants 0 to six months and for those with verbal and cognitive impairments. Most commonly used among adults are the visual analog scale (VAS) and the 0-10 Numeric Rating Scale.[56] In a VAS, the patient is asked to place a mark on a 100mm line in between "no pain" and "worst possible pain" indicative of the current level of pain the patient is experiencing. In a typical numeric rating scale, 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, and 7-10 = severe pain. Examples of a visual analog scale and numeric rating scale are depicted in Figure 4.

Figure 4. Examples of pain intensity scales



Among children and adults who may not be able to relate to a numerical scale, the Wong-Baker Faces Pain Rating Scale is a commonly used assessment tool.[57] This scale depicts a series of faces in increasing distress from "no hurt" (0) to "hurts worst" (10).

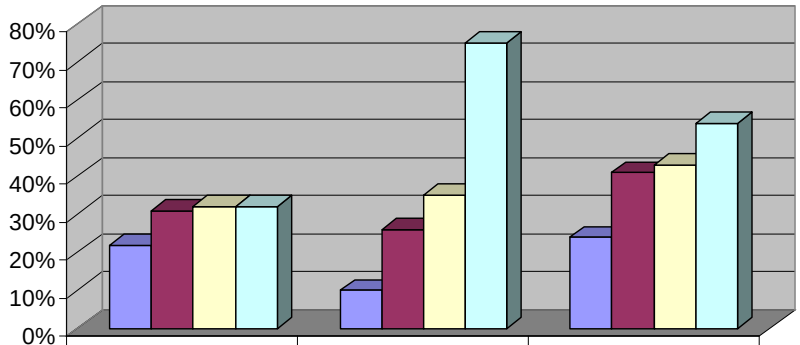
As reported in the Texas healthcare professional surveys, most Texas health professionals used the 0-10 numeric rating scale to assess pain. Regardless of which scale was used, though, only 66% of physicians and 83% of nurses who used a pain scale found it useful or accurate to evaluate pain in their patients. It is notable that 14% of Texas physicians and 9% of nurses used a scale even though they did not believe it was useful or accurate, particularly in view of reports that time limitations are a major barrier to pain management.[58]

Even though health professionals have the tools, the Texas survey indicates that many physicians and nurses do not assess for pain. At least one out of every five Texas physicians reported that they do not routinely assess their patients' pain. While it is possible that these patients have their pain assessed by a nurse, this finding suggests that there is a substantial portion of the population who is not regularly evaluated for this problem.

Perhaps more alarming is the frequency of pain assessment. Fewer than half of responding physicians assessed pain at each patient visit. While assessment was more frequent among nurses, still less than half reported assessing pain at every visit. Just under one out of four pharmacists reported that they do not routinely assess pain.[59] This finding may be related to pharmacists working in a public retail setting where pain assessment might be impractical.

Conceivably the failure to regularly assess patient pain is linked to beliefs about the "normalcy" of pain and aging (Figure 5). About a third of physicians, one out of four nurses and four out of ten pharmacists believe that pain is just a normal part of life. Similarly, roughly a third of physicians, over a third of nurses, and at least four out of ten of pharmacists believe that pain is inevitable with aging. It follows, of course, that if something is unavoidable then there is not much that can be done. In spite of their beliefs regarding the normalcy of pain, Texas physicians indicate that about a third of their patients present with some form of pain, while nurses think that three-quarters of their patients do, and pharmacists think more than half do. The great disparity between physicians' and nurses' perceptions about the number of their patients presenting with pain is likely related to the higher rate of nurses (83%) who do routinely assess for pain vs. 66% of physicians.[60]

Figure 5. Texas healthcare professionals' assessment of and beliefs about pain



	Physicians	Nurses	Pharmacists
Pain is not routinely assessed	22%	10%	24%
Pain is a normal part of life	31%	26%	41%
Pain is inevitable w/ aging	32%	35%	43%
Patients presenting w/ pain	32%	75%	54%

In Search of Treatment

> *"Pain is whatever the patient says it is, existing whenever the patient says it does."*
>
> Margo McCaffery, RN, MS, FAAN

Once pain has reached a certain threshold, people will seek medical attention. Nationally, nine out of ten pain sufferers have consulted some type of health professional because of their pain. Over 60% have seen their family doctor, while many others (40%) consulted a specialist, such as an orthopedist. Only 15% had seen a physician specializing in pain management. A significant number of Americans also relied on help from outside mainstream medicine. One out of four Americans were treated by a chiropractor, while one out of ten reported having seen complementary and alternative medicine practitioners, such as acupuncturists or herbalists.[61]

In many cases, a single practitioner was unable to address the patient's problem fully. Nearly four out of ten patients reported having to consult more than one practitioner for pain treatment; almost one out of five patients has visited two practitioners, 14% have tried three, and 6% have seen four.[62]

Patients often offered mixed reviews about their pain treatments (Table 4). Nearly 60% of those taking prescribed medications indicated they were fairly effective, while only 41% of those taking over-the-counter medications experienced the same level of relief. Chiropractic treatments and traditional physical therapy provided effective relief for about half of patients; however, the other 50% experienced less than satisfactory results. Those who sought surgical treatment for pain experienced similar outcomes. Overall, less than six out of ten current chronic pain sufferers indicated that they were satisfied with the treatment of their pain.[63]

Table 4. Effectiveness of pain treatments

Treatment type	Tried treatment	Rated treatment as very/fairly effective
Over-the-counter medications	79%	41%
Prescription medications	69%	58%
Physical therapy	48%	48%
Chiropractic treatments/therapies	39%	54%
Surgery	32%	54%
Other treatments or therapies, such as acupuncture or aromatherapy	20%	40%

A substantial number of Texans expressed concern about suffering pain some time in the future. Nearly one out of four Texans indicated a high degree of concern. Fewer than 70% were "very" confident that their health provider would address their concerns and treat them with dignity and respect while only six out of ten were "very" confident their pain would be properly assessed and promptly treated.[64]

Among Texans who sought medical assistance for pain, just over half rated their treatment "very" effective. Even though the vast majority of pain sufferers were largely satisfied with the discussion of treatment options they received from their healthcare providers, greater than 60% reported requiring the services of more than one provider before their needs were adequately addressed.

The vast majority of Texans indicated they were unaware of a pain specialist in their community. Most Texans were treated by family physicians or hospital personnel (30%). Only a quarter reported having seen a pain-specialist.

Barriers to Effective Treatment

> *"It really boils down to this: that all life is interrelated. We are all caught in an inescapable network of mutuality, tied into a single garment of destiny. Whatever affects one directly, affects us all indirectly."*
>
> -Dr. Martin Luther King, Jr.
> December 1967

Even though our understanding of the mechanisms of pain and its effective treatment has steadily improved, a number of barriers exist that prevent people from obtaining relief. These barriers are typically associated with the structure of the healthcare system overall, the attitudes and knowledge base of healthcare professionals, patient attitudes and beliefs about pain, or some combination of the three.[65]

Structure of the Healthcare System. Healthcare system barriers include low priority given to pain and the lack of negative sanctions for poor pain management.[66] The strict regulation of certain pain medications also acts as a hurdle for many patients. Opioids may not be available in a local pharmacy, forcing patients to travel extra distances to fill prescriptions. This may be especially significant in poor neighborhoods—particularly those which are racially diverse—and in areas with high crime rates.

The lack of universal coverage as well as cost containment strategies by health insurance providers also serve as hurdles for patients seeking effective pain treatment.[67,68] Many treatments are simply too costly for patients lacking health insurance. For those who are covered, the most effective treatment or medications may not be reimbursed by health insurance companies or may be inadequately reimbursed.

The experiences of Texas doctors and nurses appear to support the extent of this problem. About a third of physicians (32%) and nearly half of nurses (48%) indicated that they believe payment source affects the way a patient's pain is managed.[69]

Healthcare Professionals. Barriers to effective pain management are also manifest in the attitudes, knowledge, and practice constraints of the healthcare professionals who provide treatment. National studies indicate that commonly identified barriers among professional practitioners include inadequate assessment of the patient's pain,[70] insufficient knowledge of pain management techniques, concerns about patient addiction, and fear of practice scrutiny associated with the prescription of opioids.[71]

Results from the Texas healthcare professional surveys underscore these findings.[72] However, they also point to the disparity in viewpoints between physicians, nurses, and pharmacists regarding the various barriers (Table 5). The top three barriers to effective pain management identified by Texas physicians were 1) lack of time for proper assessment, 2) the attitudes of patients and their families regarding pain treatment, and 3) the fear of practice scrutiny by regulators and law enforcement.

In contrast, nurses most commonly identified patient and family attitudes as an impediment, followed by physician attitudes toward pain management, and cultural differences with patients. Pharmacists most frequently pointed to prescriber attitudes, followed by time limitations, and lack of provider education. Only 20% of pharmacists reported fear of regulatory scrutiny.

Table 5. Texas healthcare professionals' reported barriers to pain management

Physician Barriers	%	Nurse Barriers	%	Pharmacist Barriers	%
Time limitations	53%	Patient/family attitudes	52%	Prescriber attitude	48%
Patient/family attitudes	46%	Physician attitude/practice	40%	Time limitations	47%
Fear of practice scrutiny	38%	Cultural differences	35%	Lack of education	38%

There were also clear differences between doctors and nurses in pain assessment. At least one out of five physicians and one out of ten nurses reported that they do not routinely assess patients for pain. It is not clear whether this is a result of time constraint or is simply not a routine practice. Guidelines for routine assessment and management of pain are included in policies and procedures for their organization according to 85% of nurses, but only 38% of physicians. This finding suggests that organizations do not expect physicians to assess and manage pain or, perhaps, physicians are unaware of it if they do. Assessment and management guidelines were part of policies and procedures for over half of pharmacists; 22% did not know if they were.[73]

Less than a third of the surveyed doctors and nurses in Texas viewed education on pain management as a concern. About a third of physicians and nurses reported that lack of knowledge or training was a barrier to advocating for their patients' analgesia needs. The majority of these professionals reported receiving training on pain management in school. However, more Texas nurses and pharmacists reported exposure than physicians.[74] This finding is not surprising given the evidence that pain management is not well-represented in professional medical education curricula.[75] Just over 60% of physicians reported receiving education on pain management in school compared with 78% of nurses and 75% of pharmacists. Interestingly, most physicians *reported opposition* to mandatory continuing education on pain management for re-licensure. In contrast, a wide majority of nurses and pharmacists indicated they *would support* such a requirement.[76]

Like their patients, healthcare providers also are concerned about addiction, tolerance, and management of analgesic side effects.[77] Four out of ten Texas physicians and at least one out of ten nurses admitted to belief that the use of opioids causes addiction.[78] However, a limitation of the physician and nurse surveys is that it does not differentiate between beliefs that opioids cause addiction in persons with acute pain, cancer pain, or chronic pain.

Awareness of a history of drug abuse by a patient appears to have a direct impact on the physician's treatment decisions. Nearly 45% of Texas physicians indicated they would limit pain medication dose and frequency to patients with such a history while 13% reported they would not prescribe any pain medication.[79] The differences among true addiction (a psychological condition), pseudoaddiction (relief-seeking – not drug-seeking – behavior), and dependence and tolerance (physical conditions) may not be well understood by Texas healthcare professionals in general.

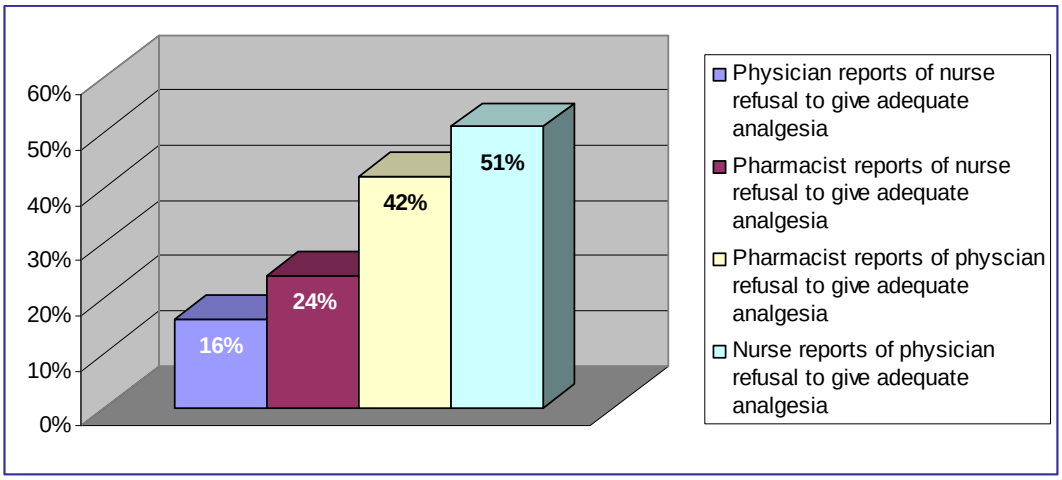
Half of Texas nurses surveyed reported situations where physicians refused to give adequate analgesia while only 16% of physicians reported the same of nurses.[80] Similarly, four out of ten pharmacists reported knowing firsthand of a situation when a physician refused to give adequate analgesia and a quarter reported the same for nurses (Figure 6).[81]

Almost eight out of ten Texas pharmacists admitted to belief that there is a risk for addiction in patients using opioids for pain; about a third believed that the risk depends on the underlying condition. At least one out of ten pharmacists would refuse to fill a prescription for a patient with a history of substance abuse, and 15% would recommend limiting the dose and dosing frequency.[82]

Additionally, almost half of Texas pharmacists reported knowing of a pharmacist other than themselves who had refused to fill a prescription for opioids. The three most common reasons were 1) same drug and dose recently filled, 2) altered prescription form, and 3) the prescription was out of date.[83]

Just over half of Texas pharmacists admitted that they had ever refused to fill a prescription for opioids. The three most common reasons were 1) the prescription form had been altered, 2) the same drug and dose had recently been filled, and 3) the prescription was out of date—these findings suggest that limits on Schedule II prescription validity are an important barrier.[84]

Figure 6. Reports of healthcare professional refusal to give adequate pain management



Patients. Over the last two decades, several studies have shown that patients are reluctant to report pain to their healthcare team and/or are reluctant to take prescribed pain medications. Some people believe that pain is merely a normal part of life that is typically associated with aging and simply take no action on their own behalf. Others believe that pain is a sign of a worsening disease or condition. Some people worry about "bothering" their physician and want to be viewed as a "good" patient. Dealing with the side effects may also impede a patient's willingness to take pain medications.

Patient attitudes and beliefs regarding addiction may also raise formidable barriers to effective pain management. Many patients fear becoming an addict or developing tolerance to medication. Others fear being labeled an addict—perhaps a larger concern for people of different races and ethnicities.[85] Regardless of the type of patient level barrier, the end result tends to be poor adherence to the treatment regimen outlined by healthcare professionals.[86]

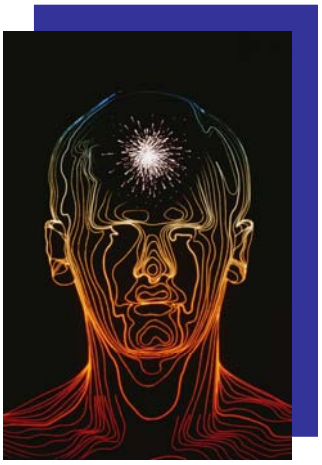
The significance of these barriers is evident in the results from the Texas household survey.[87] At least seven out of ten Texans surveyed indicated that pain sufferers seem to be unaware that pain should be treated as a distinct condition. A large proportion reported a belief that people with pain avoid treatment because they fear the underlying cause. Three-quarters of those surveyed also concurred with the notion that most people do not realize that pain, if untreated, will likely worsen. An overwhelming majority (85%), however, believed that the body heals faster when pain is properly treated.

Unfortunately, fewer than 70% of the Texans surveyed expressed belief that pain can be effectively managed with good treatment. Coupled with fatalistic views related to pain and aging, patient and family attitudes appear to play a significant role in deterring Texans from seeking relief at least early on, when pain might be managed more easily or when underlying conditions causing pain might be diagnosed and treated early.

Consequences of Unrelieved Pain

> *"Pain is a more terrible lord of mankind than even death itself."*
>
> -Albert Schweitzer, MD

The consequences of unrelieved pain translate into major lifestyle changes affecting employment, residence, or personal freedom for 20% of all Americans.[88] The American Productivity Audit determined that 13% of the total workforce had a loss in productive time at work due to common pain syndromes such as 1) headache, 2) back pain, 3) arthritis pain and, 4) other musculoskeletal pain. The time lost from work due to a pain condition was a mean of 5.2 hours per week. Reduced performance at work, not absence from work, accounted for 76.6% of lost productive time.

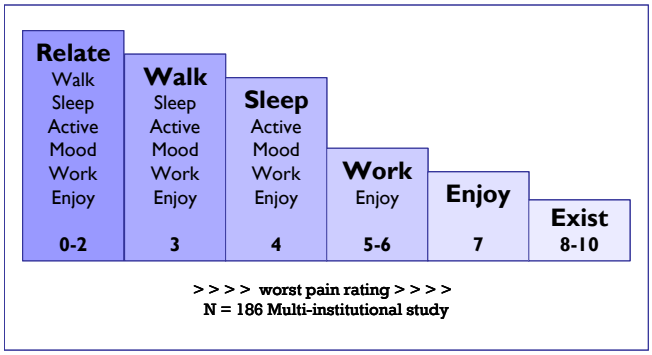


While these data translate into an estimated 61.2 billion dollars per year, this figure does not include pain associated with dental, cancer, gastrointestinal, neuropathy or menstruation. Nor does it include pain-induced disability leading to absences of one week or more, healthcare costs, secondary costs from hiring and training replacement workers, or the effect on productivity of co-workers.[89] Cost to employers of back pain in workers 40-65 years of age is estimated to be $7.4 billion/year with 71.6% of the cost due to exacerbations in back pain.[90] Comprehensive management of pain is one mechanism to improve work productivity and decrease healthcare costs for employees and employers alike.

Unrelieved pain impacts not only the ability to hold a job and engage in personal relationships, but if severe enough pain can prohibit even the most basic activities of daily living such as bathing, dressing, toileting, and feeding. Persistent pain correlates to alterations in both mood and immune function affecting both mental and physical health (Figure 7).

When pain is nonexistent or at minimal levels (0-2), the individual is able to relate well to family and friends, walk, sleep, engage in physical activity, have a positive mood, work as a productive member of society, and enjoy life. Human resiliency is seen even at severe pain levels (7); if a patient has developed effective coping strategies, they can still experience some life enjoyment. However, by the time pain reaches its most intense levels (8-10), one can only exist.

Figure 7. Increasing pain results in decreased activity and impaired quality of life[91]



There is significant impact on the quality of life among Texans suffering with pain. Two in three reveal their suffering sometimes causes them to feel anxious, irritable or depressed and results in their losing sleep. Nearly one in three pain-suffering Texans has a relationship with a loved one or friend negatively affected to a significant degree, cannot engage in many of the activities they once could, and sometimes feels hopeless or alone.[92]

Pain impacts one's ability to get enjoyment from life, impairs activities of daily living, causes less life-involvement, and overall diminishes quality of life. This is particularly tragic for patients with chronic pain, malignancy, or terminal illness. As pain continues or intensifies, fear, anxiety, depression, and hopelessness often occur. These are people for whom each remaining moment counts. The presence of pain compromises their ability to enjoy time with loved ones and deal with the spiritual and psychosocial issues that accompany chronic and catastrophic illness.

Comprehensive Pain Management

> *"The experience of pain is an overwhelming, whole-person experience with devastating effects on the experiencing person, the family witness, and the nurse. Reflection on the meaning of pain and the meaning of nursing's responsibility to respond to pain is a challenging endeavor. We are guided by essential concepts of respect, relationship, and compassion through an ethical perspective of feminist scholars. It is through a deeper view of pain as Alice Walker might say, "moving from lavender to purple," that we may become the fullest of professionals and moral agents providing relief of pain and suffering."*
>
> Betty J. Ferrell, PhD, FAAN, 2005[93]

A comprehensive approach to pain management includes the following considerations: medication management (opioid and non-opioid), interventional procedures, demonstrated complementary methods, and psychosocial services. In 1997, the American Academy of Pain Management (AAPM) and the American Pain Society (APS) developed a consensus statement outlining principles of good medical practice for the prescription of opioids which included:

1. Evaluation of the patient
2. Development of a treatment plan tailored to the patient's needs and problems
3. Consultation, as needed, with appropriate specialists (pain medicine, psychologists, psychiatrists)
4. Periodic review of treatment effectiveness
5. Documentation to support pain treatment plan[94]

Healthcare professionals should routinely convey to the patient and family that pain is important and can usually be well controlled with many options. Additionally, healthcare professionals should convey to their patients that there is no benefit to suffering and that morphine and other opioids are frequently prescribed to help manage pain. Patients and families also need to know that addiction is rarely a problem among those being treated for pain and that most side effects can be managed.

The World Health Organization (WHO) encourages healthcare professionals to use a three-step Analgesic Method as a guide for the pharmacologic treatment of pain (Figure 8).[95] Also called the "Three-Step Analgesic Ladder", this model promotes the sequential use of pain medications which are gradually increased in strength and matched to pain intensity in an effort to achieve effective pain relief.

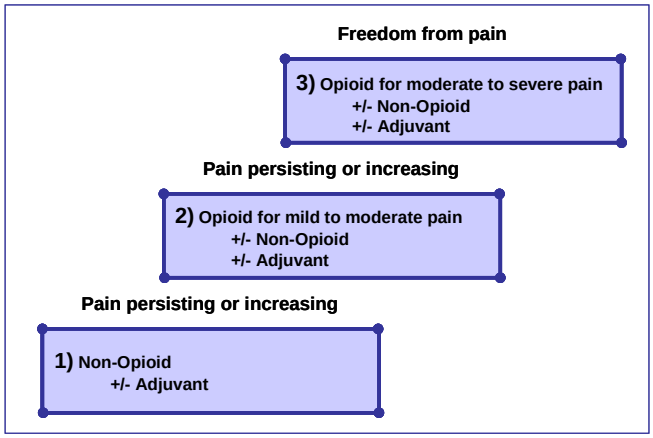
The first step consists of the use of some type of non-opioid medication – aspirin, acetaminophen, ibuprofen or others. If the pain persists, a mild opioid such as codeine is added. If the combination of mild opioid and non-opioid medications fails to achieve effective analgesia, then a stronger opioid such as morphine or other medication in this therapeutic group should be substituted. Other medications, sometimes called adjuvants, may be given at any time during treatment to enhance pain relief, to relieve the adverse effects of analgesics, and to treat associated psychological symptoms such as insomnia, anxiety, and depression.

A newer paradigm suggests that rather than sequential steps, each category of treatment should be available to the patient whenever indicated and tailored to their individual needs. Also important is integrating non-pharmacologic approaches to pain management earlier in treatment along with cognitive and behavioral therapies, complementary medicine, and recognition of individual spiritual values at any time the patient may need them.[96]

Whatever the method used to treat pain, the following goals should be paramount in the minds of prescribers when using pharmacological agents to treat pain:

1. Reduce or eliminate pain and pain-related interference with activities
2. Reduce other pain-related symptoms
3. Reduce opioid requirements
4. Treat with agents that have a adequate duration of effect
5. Treat with agents that have an acceptable cost to the payer

Figure 8. Three-step analgesic ladder



Consumer Protection and Pain Treatment

"The time to act on this is now. Speaking from the perspective of my own generation, there are few among us who, within the next decade, will be spared from having to advocate on behalf of ourselves, our parents or our loved ones for the right to competent end-of-life care and pain management. This is an issue that cannot be ignored. "

-General William H. Sorrell
President 2004, National Association
of Attorneys General

Consumer protection may be described as assuring that consumers have access to safe products and services. Do we protect citizens if they do not have adequate access to services or practices that relieve pain? How can we improve access to effective pain management practices for our citizens?

Attorneys General in each state are charged with protecting constituents in matters affecting the public interest, including consumer protection of those who are dying.[97] The National Association of Attorneys General (NAAG) began an initiative in 2004 to encourage state Attorneys General offices to become even more actively engaged in helping to improve end-of-life care for the citizens of their states.

The NAAG End-of-Life Healthcare Project has focused on three principal areas of concern in which Attorneys General may play a major role:

1. Pain management
2. Acknowledgement and respect for the wishes of those who are dying
3. Ensuring competent end-of-life care

In 2003, NAAG adopted a resolution calling for a balanced approach to promoting pain relief and preventing abuse of pain medications. The resolution affirms that "it is crucial that public health, law enforcement, and government officials continue to develop strategies and methods to prevent the abuse and diversion of prescription drugs while safeguarding the right of those suffering from severe and chronic pain to continue to have access to appropriate medications".

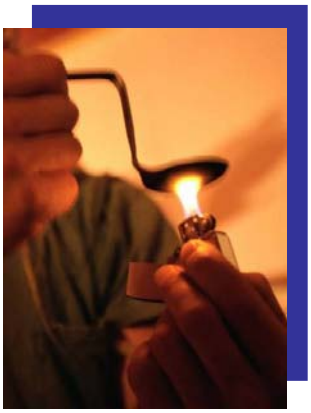
Attorneys General have been actively working to ensure a balance between drug abuse enforcement and ensuring availability of prescription pain medications for those who need them.[98] To this end, Attorneys General Drew Edmondson (Oklahoma); J. Joseph Curran Jr., (Maryland); and William Sorrell (Vermont) met with Drug Enforcement Administrator Karen Tandy to offer the assistance of state Attorneys General in promoting an understanding and commitment to a balanced drug enforcement policy.[99]

Although the State of Texas has been charged with "consumer protection of those who are dying" from their national organization, and the resources to assist with implementing programs and services toward this end are available, the State Attorney General has not yet adopted this recommended initiative as a priority.

Diversion and Abuse of Pain Medications

"Human health does not depend only on treatment by physicians. Social and political circumstances profoundly influence the health and well-being of all people."

-American Academy of Pain Medicine
Ethics Charter, 2003



Effective pain management is problematic from numerous perspectives, but drug diversion presents unique challenges for patients, healthcare practitioners and law enforcement agencies. There is no question that the illegal diversion and abuse of prescription pain medicines do cause public harm.

In an attempt to determine the source of pain medication diversion, the Pain and Policy Studies Group (PPSG) published in 2005 an analysis of Drug Enforcement Agency (DEA) data from 22 eastern states for the time period of 2000 to 2003. Data from these states were all that were analyzable from the electronic database provided by the DEA from Form 106 ''Report of Theft or Loss of Controlled Substances.'' Over the 4-year period, almost 28 million dosage units of all controlled substances were diverted. Of these total diversions, just fewer than 6.5 million dosage units (23%) were attributable to the theft or loss of six prescription pain medications: fentanyl, hydromorphone, meperidine, methadone, morphine, and oxycodone.

Theft was an important source of diversion of pain medications with the greatest proportion of drug theft/losses being from pharmacies (89.3%). A much smaller proportion was attributed to medical practitioners, manufacturers, distributors, and addiction treatment programs. Study authors, Joranson and Gilson, conclude that *"pain medications, regardless of schedule, are being stolen from the drug distribution chain prior to being prescribed, contributing to their illicit availability, abuse, and associated morbidity and mortality."*[100]

In Texas, the Health & Safety Code, Code of Federal Regulations, Texas Administration Code, and the Occupations Code mandate regulations for diversion control, including rules for registration, monitoring, reporting, and issues related to violations and sentencing.

According to the Texas Department of Public Safety Narcotics Service website, the following are the most commonly diverted controlled substances as of 2007.[101]

1. Hydrocodone products (Vicodin and Lortab)
2. Oxycodone (Percocet, Percodan and Tylox)
3. Ritalin
4. Soma
5. Anabolic Steroids
6. Dextroamphetamine
7. Fentanyl
8. Methamphetamine
9. Diazepam
10. Alprazolam

The Texas Department of Public Safety also clearly defines the practitioner's responsibilities which include:

1. Legal and ethical responsibility to uphold the law and to help protect society from drug abuse
2. Professional responsibility to prescribe controlled substances appropriately, guarding against abuse while ensuring the medication is used for legitimate medical and scientific purposes
3. Personal responsibility to protect your practice from becoming an easy target for drug diversion. You must become aware of the potential situations where drug diversion can occur and of the safeguards that can help prevent it[17]

While laws and regulations are meant to control diversion and illegal drug use, they may also have hampered good intentions of practitioners in implementing effective pain management strategies due to, among other factors, rigid rules on time limitations for prescriptions (Schedule II drugs), burdensome prescription forms, and misconceptions among healthcare professionals regarding what is legal and illegal with regard to using opioids for treating pain.

Data from the Texas healthcare professional surveys corroborate these problems. At least a quarter of Texas pharmacists (27%) indicated belief that the use of opioids for more than six months in persons with acute pain who also had a history of substance abuse is a violation of the law and 4% believed it is a violation to treat a person with chronic cancer pain and a history of substance abuse. More than one out of ten (13%) believed that it is a violation of law to use opioids for more than six months to treat persons with acute pain *and no history of substance abuse.* For chronic non-cancer pain, 17% of Texas pharmacists reported belief it is illegal to use opioids for at least six months in persons with chronic nonmalignant pain and a history of substance abuse.

The data on what Texas pharmacist believed is lawful but not generally accepted as a part of professional practice is also eye-catching. Nearly half of respondents think it is not acceptable to use opioids for at least six months to treat people with acute pain and a history of substance abuse. A third believed it is unacceptable to use opioids for more than six months to treat persons with acute pain and no history of substance abuse, those with chronic non-cancer pain, and those with chronic cancer pain.

At least a quarter of Texas pharmacists expressed concern about regulatory oversight (somewhat concerned – 22%, very concerned – 2%, and extremely concerned – 2%). However, just 4% had actually been investigated, and yet a third of the respondents indicated that they knew firsthand of someone who had been investigated.

Addiction Issues

> *"In the depth of winter, I finally learned that there was within me an invincible summer."*
>
> -Albert Camus

Definitions Related to the Use of Opioids for the Treatment of Pain

Opioids have an important role in the treatment of pain. Use of opioids has often been limited by concerns about addiction, misuse and possible diversion for non-medical uses. Lack of a common definition of addiction has often hampered discussions among scientists, clinicians, regulators and the lay public. To overcome this problem, the American Academy of Pain Medicine (AAPM), the American Pain Society (APS) and the American Society of Addiction Medicine (ASAM) issued a joint consensus statement, *Definitions Related to the Use of Opioids for the Treatment of Pain* (2001), to clarify terminology relevant to the use of opiates for the appropriate medical treatment of pain (Figure 9).[102]

Figure 9. Clarification of physical dependence, tolerance and addiction

I. Addiction: Addiction is a primary, chronic, neurobiologic 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.

II. Physical Dependence: Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

III. 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.

-AAPM/APS/ASAM, 2001.

For many patients, there is the fear of addiction with pain treatment which leads to inadequate or even no treatment of pain.[103] For practitioners, caring for patients with drug addictions in acute care situations[104] and for those needing chronic pain management[105] can be profoundly challenging. An estimated 5-7 million people with an addiction experience pain. Ineffective treatment of pain or lack of treatment may be significant contributing factors to drug diversion.[106]

Major factors that contribute to the problem of effective pain management in the past have included:

1. Lack of formal healthcare professional education[107,108]
2. Healthcare provider stereotyping of individuals that cause fear of mistreatment by patients[109]
3. Lack of valid tools to accurately predict a person's risk for addiction[110]
4. Lack of mutual trust between patient and healthcare provider due to physician fears of deception: the physician may be unsure if the opiates that are requested are for the addiction or for actual acute care situation/actual pain[111]
5. Physician discomfort and uncertainty in dealing with a patient's pain in the face of patient addiction can lead to ineffective communication between physician and patient[112] and in turn resulting in inconsistent and ineffective care

> *"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction."*
>
> -Federation of State Medical Boards, May 2004[113]

Pain management and the issue of addiction and abuse of opioids is an active area of education for healthcare professionals and pharmacists. Pain and addiction can co-exist and the opioids used to treat chronic pain can be a solution or a problem, or both. Many healthcare professionals lack the skills needed for treating addiction disorders.[114]

Principles for screening patients for medication abuse in a busy primary care clinic include the following.[115]

1. Watch for aberrant behavior that may be associated with abuse or diversion
2. Be familiar with the individual risk factors for opiate abuse
3. Use assessment tools to evaluate diagnose, and possibly predict abuse or addiction in patients

Significant differences exist in the patient seeking opiates for control of persistent pain and a person seeking opiates to support an addiction. Pain patients may also present with "pseudoaddiction" where potentially drug seeking behavior (early refills, requesting higher doses of opiates) reflects inadequate pain control (Table 6).[116]

Table 6. Comparison of attributes between physical dependence and addiction

	Physical Dependence	Addiction
Out of control with medications	No	Yes
Medications improve quality of life	Yes	No
Use continues in spite of problem	No	No
Denial about any problems	No	No

Pseudoaddiction is a term used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated."[117] Even though pseudoaddiction may cause the patient to appear to be drug-seeking, the reality is they are simply seeking pain relief.

Addiction is characterized by aberrant drug-taking behaviors that include one or more of the following

- Control over drug use is impaired
- Compulsive use
- Continued use despite harm
- Craving

Other factors contributing to the problem of effective pain management in a patient with a substance abuse disorder include patient lack of readiness for addiction treatment and lack of accessibility to resources for treatment.[118] Texas also currently has policies in place that restrict prescriptions for patients with pain and concurrent addictive disease.[119]

> *"A practitioner may prescribe methadone or any other narcotic to a narcotic addict for analgesic purposes."*
>
> -Drug Enforcement Administration
> April 2004[120]

Risk factors for the incidence of addiction and relapses to addictive behavior include stress, drug availability, and repeated exposure to environmental cues previously associated with taking the drug.[121] A major cause of stress in the substance abuse patient population includes the undertreatment or no treatment for pain, leading to illegal drug use or legal, e.g., alcohol abuse.[122]

Managing drug abuse, addiction and diversion in chronic pain patients presents unique challenges. Kirsh and Passik suggest principles that help to provide structure to ensure appropriate monitoring and to promote prescribing without prejudice.[123] A multidisciplinary team approach including mental health professionals that specialize in addiction is critical to developing strategies for management and treatment compliance.

Formal and clinical education regarding effective pain management in both medical and nursing curricula is essential to meet the needs of diverse populations experiencing pain. This action may only occur with policy mandates. In addition, standardized approaches to the assessment and treatment of pain in acute care settings for addicted patients in pain and/or in opiate withdrawal are needed, which would help make treatment more consistent and effective.[124] Because addiction can only be diagnosed over time through observation of behaviors, a 10-step "universal precautions" approach would also be a safe way to facilitate effective pain management, reduce stigma and minimize risk.[125]

According to the AAPM/APS/ASAM Consensus Document of 2001, the following behaviors are suggestive of addiction.[126]

1. Inability to take medications according to an agreed upon schedule
2. Taking multiple doses together
3. Frequent reports of lost or stolen prescriptions
4. Doctor shopping
5. Isolation from family and friends
6. Use of non-prescribed psychoactive drugs
7. Use of analgesic medications for other than analgesic effects
8. Non-compliance with recommended non-opioid treatments or evaluations
9. Insistence on rapid-onset formulations/routes of administration
10. Reports of no relief whatsoever by any non-opioid treatments

For ongoing monitoring of chronic pain patients on opioids, practitioners may find it helpful to apply the "4 A's" of pain medicine. The 4 A's outlined below address domains proposed to be most relevant: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors (Figure 10).[127]

Significant knowledge deficits and misperceptions are major factors contributing to ineffective pain management in Texas. Innovative education programs that reflect comprehensive content regarding pain management issues, e.g., barriers, measures for effective pain management, cultural and ethnic diversity, minority and economic factors, addiction/dependency/diversion and regulatory factors, as well as common myths and stereotypes for healthcare professionals are needed to correct this gap.

A major avenue for achieving this will necessitate policy mandates through credentialing, licensing, and regulatory boards. Education must not be limited only to those specializing in pain management, but to all healthcare professionals.

Figure 10. 4 A's of pain management outcome assessment

Analgesia: "On a scale of 0 to 10, how much pain are you having today?"

Activities of Daily Living: Be specific in asking how far a patient can walk, etc.

Adverse drug effects and side effects: Ask about constipation and other side effects

Aberrant behavior that typically evolves over time: Is the patient on schedule with medications? Document medication losses, early refills, unapproved dose escalations, etc.

Balancing Drug Control Policy with Quality Pain Treatment

> *"…there is a Central Principle that should guide efforts to establish a balanced regulatory environment for pain management. Achieving this goal does not mean that all state policies must look alike; rather, laws must strike an appropriate balance between appropriately governing controlled medications and those who prescribe and dispense, and ensuring their availability for those who legitimately need them for the relief of pain and suffering."*
>
> -Pain & Policy Studies Group, 2006

A major goal of the Texas Pain Summit was to foster dialog between healthcare professionals and the state's licensing and regulatory bodies in order to create a "balanced" regulatory system. Such a system fosters the appropriate medical use of opioid analgesics and other controlled substances that are essential for pain control while preventing their diversion and abuse for inappropriate, non-medical purposes.

The challenge of using opioid analgesics for pain control. Opioids are the drugs of choice for the management of moderate to severe acute and cancer pain. They may also be essential for selected patients who suffer from persistent pain not related to cancer. Their abuse has long been of concern, but it has been heightened in the past several years by a significant increase in their diversion and abuse, an increase that has occurred in the context of the increasing use of these drugs for pain control.[128] Many feel that physicians are the source of the problem, that careless prescribing has led to their availability on the illicit market and has increased the problem of addiction. However, theft from pharmacies is the main contributor to diversion of medications legitimately used for the treatment of pain.[129]

Medical decisions may be influenced by fears of regulators. Because opioid analgesics have the potential to be abused, their prescribing and dispensing are subject to legal and regulatory controls at the federal and state level. Federal law governs the drugs themselves and their distribution from the supplier to the end user. While nothing in federal law prevents the appropriate use of opioids for pain control, it does place these drugs in schedules based on their potential to be abused. Schedule I drugs, with the highest potential for abuse, are not approved for medical use (marijuana, cocaine, etc.) Schedule II drugs include morphine, oxycodone, and similar medicines essential for relief of severe pain. Hydrocodone with acetaminophen is in Schedule III. States regulate professional practice but they have also promulgated laws and regulations aimed at preventing drug diversion and abuse. Texas has long had a Prescription Monitoring Program (PMP) to specifically track Schedule II opioid use. Some assert that this program has had a chilling effect on opioid prescribing for pain control, and that it makes clinicians hesitant to prescribe, dispense and administer these essential pain medications. Unfortunately, there are no data to support the supposition that a PMP affects the quality of pain management provided to patients, nor do the data demonstrate that a PMP reduces diversion and abuse.

Recommendations. Medical decisions about opioid use are influenced by fears of addicting patients as well as fears of regulatory policies and regulators. Barriers in Texas State laws and regulations have been identified and are discussed in detail in the next section. Efforts should be directed at removing these barriers. In addition, efforts must be directed at the misperceptions and inappropriate attitudes of healthcare professionals, regulators and members of the law enforcement community because they also constitute barriers to effective pain control. It is essential to focus on reshaping values so that effective pain control can be a reality for all Texans.

Issues for Policy Makers

"Government cannot relieve from toil. Do the day's work. If it be to protect the rights of the weak – whoever objects – do it."

Governor Calvin Coolidge, 1920
on the *Duty of Government*

It is undeniable that the undertreatment of pain is a public health problem in Texas, as well as across the nation. Adults living in families with income less than twice the poverty level report pain more often than higher income adults.[130] Pain that is not well managed may drive people, including the uninsured or underinsured, into medical care and acute care facilities probably resulting in an increased burden on the state's public health and emergency response services.

Policy makers must deal with the public health issue of drug addiction and attempts by some to divert prescription drugs from their legitimate medical use for illicit purposes. Attempts to address this issue can take the form of federal and state laws, regulations, and guidelines – such as drug control laws and health professional regulations.

Unfortunately, if the laws to prevent prescription drug diversion are out of balance with the regulations and policies designed to facilitate effective pain management by medical professionals, they become a barrier between medical professionals and their patients. Medical professionals can become reluctant to prescribe pain medications for fear of regulatory scrutiny and legal prosecution and their patients suffer even though effective therapies to treat pain are available. Regulatory scrutiny can be of special concern for medical professionals in pain management because judgment about what is considered appropriate prescribing may be based on norms for all practitioners in the state, many of whom seldom treat pain patients.

As a state, policy makers can ensure that the laws, regulations, and guidelines put into place strike a balance between prescribing pain medicines and preventing drug diversion, keeping in mind that at the heart of this issue are people with legitimate pain and suffering that the medical community has the ability to manage effectively if they are educated and empowered to do so. Medical professionals need to be able to put their patients' needs first without the chilling effect that comes with regulatory uncertainty.

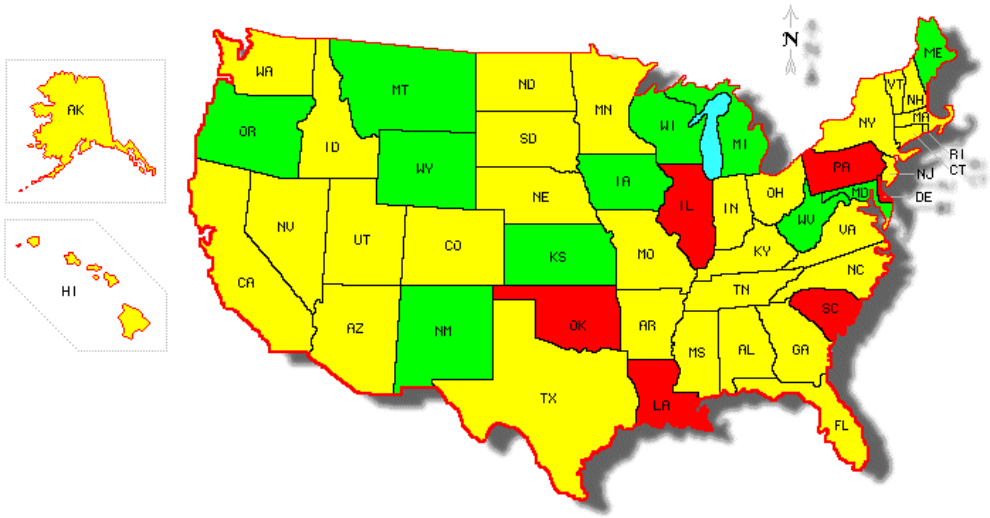
Policy makers must truly understand the scope of drug diversion in Texas and examine the effectiveness of efforts to prevent prescription drug abuse. It is critical that objectivity be maintained in this area so as to not overcompensate in statute for what is often sensationalized media coverage of alleged or actual cases of pain medication abuse or diversion.

How States Measure Up

In 2006, the American Cancer Society, Lance Armstrong Foundation and Susan G. Komen for the Cure, the nation's leading information and advocacy groups for people with cancer, announced joint funding of the Pain & Policy Studies Group (PPSG) to continue its evaluation of pain management policies in the U.S. In addition, the ACS developed a tracking mechanism for scoring a state's progress in pain policy and in practice (Figure 11). These criteria build upon the PPSG's evaluation and include the following.

1. Existence of state pain commission, task force or advisory council
2. Nurse Practitioner authority to prescribe all controlled substances for pain
3. Health Professional Licensing Board(s) (medical, nursing, pharmacy) has adopted pain management policies
4. Pain management provisions included in state comprehensive cancer control plan
5. Improvements made toward achieving more balanced state pain policy between 2000 and 2006 (PPSG state grades)

Figure 11. How states measure up



Map Color Key
Green - Well balanced policies and good practices that enhance pain management, with opportunities for additional improvements to achieve better pain management
Yellow – Moderately balanced policies and practices; action required to address some policy and practice barriers that impede pain management
Red – Numerous policy and practice barriers exist that impede pain management and require concerted action to address Pain & Policy Studies Group 2007 Progress Report

The Pain & Policy Studies Group (PPSG) at the University of Wisconsin began a comprehensive policy research project in 2000 to analyze and evaluate federal and state pain policies based on what has become known as the *"Central Principle of Balance"* defined by the PPSG as follows.

> *"The Central Principle of Balance represents a dual imperative of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability.*[131]

PPSG evaluated hundreds of state and federal policies against sixteen criteria used to identify policy language that could potentially enhance or impede patient access to opioid analgesics, referred to as "positive" and "negative" provisions. The PPSG published its findings in a landmark document, entitled *Achieving Balance: A Guide to Evaluation of Federal and State Policies* (Evaluation Guide 2000). The Evaluation Guide 2000 presented its evidence in the form of policy profiles for each state and for the Federal government.

A *Progress Report* that grades all states based on the quality of their policies related to pain management tracks changes over time; each state has a policy grade for 2000, 2003, 2006 and 2007. The Progress Report 2007 and the Evaluation Guide 2007 can be found at the Pain & Policy Studies Group's web site: http://www.painpolicy.wisc.edu/Achieving_Balance/index.html.

Evaluation Criteria

State grades are based on the frequency with which policy provisions meet the following sixteen evaluation criteria *(recreated with permission, PPSG, 2007).*[132]

Positive provisions *(Criteria that identify policy language with the potential to enhance pain management*

1. Controlled substances are recognized as necessary for the public health
2. Pain management is recognized as part of general medical practice
3. Medical use of opioids is recognized as legitimate professional practice
4. Pain management is encouraged
5. Practitioners' concerns about regulatory scrutiny are addressed
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing
7. Physical dependence or analgesic tolerance are not confused with "addiction"
8. Other provisions that may enhance pain management
   Category A: Issues related to healthcare professionals

Category B: Issues related to patients
Category C: Regulatory or policy issues

Negative provisions *(Criteria that identify policy language with the potential to impede pain management)*

9. Opioids are considered a treatment of last resort
10. Medical use of opioids is implied to be outside legitimate professional practice
11. Physical dependence or analgesic tolerance are confused with "addiction"
12. Medical decisions are restricted
    Category A: Restrictions based on patient characteristics
    Category B: Mandated consultation
    Category C: Restrictions regarding quantity prescribed or dispensed
    Category D: Undue prescription limitations
13. Length of prescription validity is restricted
14. Practitioners are subject to additional prescription requirements
15. Other provisions that may impede pain management
16. Provisions that are ambiguous
    Category A: Arbitrary standards for legitimate prescribing
    Category B: Unclear intent leading to possible misinterpretation
    Category C: Conflicting (or inconsistent) policies or provisions

Separate grades are calculated for the frequency of both positive and negative provisions, and then averaged to produce an overall grade for each state. The overall grade is what is discussed in this report.

Highlights of the 2007 Progress Report

- Thirty-one states received a grade of B or above, while 18 states including Texas received a grade of C+ or C. Only one state, Georgia, received a below average grade (D+); no state received a D or F (Figure 12 and Table 8)
- Kansas, Michigan, Virginia, and Wisconsin, comprising 9% of the U.S. population, are the only states to receive an A
- The 28 states with a B or B+ encompass almost 50% of the U.S. population including California, Florida, and Ohio (the 1st, 4th, and 7th most populated states)
- Almost 40% of the U.S. population lives in the 18 states that have a grade of C or C+, including the following states with large populations (Illinois, New Jersey, New York, Pennsylvania, and Texas)
- Kansas and Wisconsin improved to an A in 2007
- No state's grade decreased from 2000 to 2007
- Thirty-four states improved their grade from 2000 to 2007 – Texas was not among them

Figure 12. State grades map
(Recreated with permission, PPSG, 2007.)

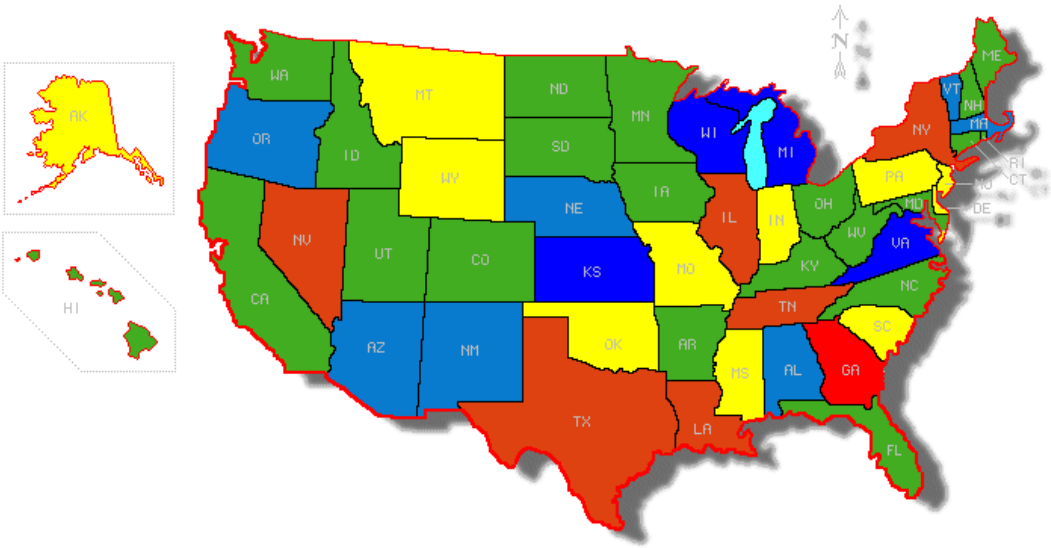


Table 7. State grades for 2007 by grade

(Recreated with permission, PPSG, 2007.)

A Represents 9% of US pop.	B+ Represents 8% of US pop.	B Represents 41% of US pop.	C+ Represents 16% of US pop.	C Represents 23% of US pop.	D+ Represents 3% of US pop.
Kansas	Alabama	Arkansas	Alaska	Illinois	Georgia
Michigan	Arizona	California	Delaware	Louisiana	
Virginia	Massachusetts	Colorado	Dist. of	Nevada	
Wisconsin	Nebraska	Connecticut	Columbia	New York	
	New Mexico	Florida	Indiana	Tennessee	
	Oregon	Hawaii	Mississippi	Texas	
	Vermont	Idaho	Missouri		
		Iowa	Montana		
		Kentucky	New Jersey		
		Maine	Oklahoma		
		Maryland	Pennsylvania		
		Minnesota	South Carolina		
		New Hampshire	Wyoming		
		North Carolina			
		North Dakota			
		Ohio			
		Rhode Island			
		South Dakota			
		Utah			
		Washington			
		West Virginia			

Measuring Change over Time

In order to reflect changes in a state's policy over time, the PPSG developed a research methodology to grade each state based on the quality of its pain policy and recalculated the 2000 and 2003 grades using the 2006 methodology. The 2006 methodology also was used to evaluate states in 2007 (Table 7). One should note that grades in the 2006 report are in some cases not the same as those in the first progress report, which is now obsolete.

Table 8. State grades 2000 to 2007

(Recreated with permission, PPSG, 2007.)

States	2000 Grades	2003 Grades	2006 Grades	2007 Grades	States	2000 Grades	2003 Grades	2006 Grades	2007 Grades
AL	B	B	B+	B+	MT	C+	C+	C+	C+
AK	C	C+	C+	C+	NE	B+	B+	B+	B+
AZ	B	B	B	B+	NV	D+	C	C	C
AR	C+	C+	B	B	NH	C	C+	C+	B
CA	C	C	C	B	NJ	D+	C	C+	C+
CO	C	C	C+	B	NM	B	B+	B+	B+
CT	C	C	C+	B	NY	D	C	C	C
DE	C+	C+	C+	C+	NC	B	B	B	B
DC	D+	D+	C+	C+	ND	C	C	B	B
FL	B	B	B	B	OH	B	B	B	B
GA	D+	D+	D+	D+	OK	C+	C+	C+	C+
HI	C	C	B	B	OR	C+	C+	B+	B+
ID	C	C+	B	B	PA	C+	C+	C+	C+
IL	C	C	C	C	RI	D+	D+	B	B
IN	C	C+	C+	C+	SC	C+	C+	C+	C+
IA	C+	B	B	B	SD	B	B	B	B
KS	C+	B+	B+	A	TN	D	C	C	C
KY	D+	C+	B	B	**TX**	**C**	**C**	**C**	**C**
LA	C	C	C	C	UT	C+	C+	B	B
ME	B	B	B	B	VT	C	C+	B+	B+
MD	C+	B	B	B	VA	B	B	A	A
MA	C	B	B	B+	WA	B	B	B	B
MI	B	A	A	A	WV	C+	B	B	B
MN	C+	C+	B	B	WI	C	C+	B	A
MS	C	C	C+	C+	WY	C	C	C+	C+
MO	D+	C+	C+	C+					

As was the case in the Progress Report 2006, the Progress Report 2007 indicates that policy improvements occurring between 2006 and 2007 resulted most often from state healthcare regulatory boards that adopted policies encouraging pain management and/or palliative care and, although less often, from state legislatures that repealed restrictive or ambiguous language from statute and/or regulation. In 2000, fewer than half of all states (49%) received above a C. By 2003 this had increased to 67% of states, 84% in 2006, and 86% in 2007.

How Did State Grades Change?

- Twenty –three states (45%) including Texas changed their policies. However these changes resulted in a grade change in only 8 states with California and Wisconsin showing the greatest improvement.
- While Texas did make changes in its Medical Board regulations (Chapter 170) which increased positive indicators and removed all negative indicators, these changes were insufficient to result in a grade change.
- California repealed a total of eight provisions with restrictive or ambiguous language in several statutes resulting in a B grade, and Wisconsin's Medical Board adopted a pain management policy that fulfilled seven positive criteria resulting in an A grade.
- 43 states made no policy changes from 2006-2007 sufficient to make a difference in their grade (Table 10).

Table 9. Grade change in state pain policy between March 2003 and March 2006

(Recreated with permission, PPSG, 2007.)

Positive Change – 8 states	No Change – 43 states		
Arizona	Alabama	Maryland	Oregon
California	Alaska	Michigan	Pennsylvania
Colorado	Arkansas	Minnesota	Rhode Island
Connecticut	Delaware	Mississippi	South Carolina
Kansas	District of Columbia	Missouri	South Dakota
Massachusetts	Florida	Montana	Tennessee
New Hampshire	Georgia	Nebraska	Texas
Wisconsin	Hawaii	Nevada	Utah
	Idaho	New Jersey	Vermont
	Illinois	New Mexico	Virginia
	Indiana	New York	Washington
	Iowa	North Carolina	West Virginia
	Kentucky	North Dakota	Wyoming
	Louisiana	Ohio	
	Maine	Oklahoma	

Evaluation of Texas Pain Policies

The following charts recreated from the Evaluation Guide 2007 depict the occurrence of language found in Texas' statues, regulations, and other governmental policies that relate to the PPSG evaluation criteria. There can be both positive and negative provisions in the same statute, regulation, or policy. Table 10 charts positive language contained in Texas policies and blanks represent opportunities to add positive language.

Table 10. Provisions that may ENHANCE pain management

(Recreated with permission, PPSG, 2007.)

Criteria	1	2	3	4	5	6	7	8
	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Professional Practice Act*								
Intractable Pain Treatment Act		●	●	●	●			●
Medical Practice Act								●
Pharmacy Practice Act			●					●
REGULATIONS								
Controlled Substances*								
Medical Board		●	●		●	●	●	●
Pharmacy Board			●					●
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Policy Statement		●	●	●	●		●	
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Texas Cancer Council								●
Licensing of Hospitals								●
Licensing of Home and Community Support Services Agencies								●

*Note: A dot indicates one or more provisions were identified. * No provisions were found in this policy*

Table 11 charts instances of negative language contained in Texas' policies. Their deletion would represent opportunities for Texas to remove restrictive or ambiguous policy language. Because Texas already has a grade of "A" for positive provisions, but an "F" for negative provisions, it is recommended that legislative and regulatory efforts focus on removing negative provisions in order to improve the state's overall grade.

Table 11. Provisions that may IMPEDE pain management

(Recreated with permission, PPSG, 2007.)

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act					●	●		
Professional Practice Act*								
Intractable Pain Treatment Act		●				●		●
Medical Practice Act				●				
Pharmacy Practice Act*								
REGULATIONS								
Controlled Substances						●		
Medical Board								
Pharmacy Board						●		●
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement*								
Pharmacy Board Policy Statement*								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Texas Cancer Council*								
Licensing of Hospitals*								
Licensing of Home and Community Support Services Agencies*								

*Note: A dot indicates one or more provisions were identified. * No provisions were found in this policy.*

Following is a brief on Texas' specific statues, regulations and policies that either enhance or detract from good pain management. The source for this brief is the PPSG Evaluation Guide 2007.

Statutes

Controlled Substances Act
Tex. Health & Safety Code § 481.002
While this statute clearly defines opioids as a part of professional practice, it also limits the length of prescription validity. Further, the statute places undue restrictions on prescribing by requiring a special prescription form only for Schedule II medications. It also requires the intended use of the controlled substance or the diagnosis for which it is prescribed be documented on the prescription form. Federal Controlled Substances law does not require the diagnosis of the patient on a controlled substance prescription. Questions of confidentiality are raised.

Intractable Pain Treatment Act (IPTA)
Tex. Occ. Code § 107.001
For all its forward-thinking good intentions, the IPTA also contains some problematic and contradictory language. It contains numerous positive criteria declaring pain management is part of medical practice and that opioids are part of professional practice. It attempts to provide a secure environment for physicians prescribing in their healthcare facility. However, this only applies to prescribing for intractable pain patients and not patients in general. The IPTA encourages pain management and addresses fear of regulatory scrutiny. It recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management, which is authorized for all patients in §107.102.

Conversely, some language in the IPTA also implies opioids are not part of professional practice and suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia. Additionally, the act makes undue prescription requirements compelling the physician to monitor the patient to ensure that controlled substances are used only for the treatment of the patient's painful medical condition. Although it is reasonable to expect physicians to avoid knowingly issuing prescriptions that would contribute to diversion, an absolute requirement is unrealistic.

Medical Practice Act
Tex. Occ. Code § 153.014
The Medical Practice Act charges the State Board of Medical Examiners with responsibility for providing practitioners with information and education about pain management, the appropriate use of pain medicines, and the differences between addition, pseudo-addiction, tolerance and physical dependence. The act encourages physicians to include education in pain treatment among the hours of continuing medical education required for re-licensure. However, this statute also restricts medical decision-making based on patient characteristics, e.g. the patient with addictive disease or a history of addiction unless they are in treatment for addiction or declared in "intractable" pain.

Pharmacy Practice Act
Tex. Occ. Code § 551.003
The Pharmacy Practice Act declares that opioids are part of professional practice and charges the State Board of Pharmacy with responsibility for providing practitioners with information and education about pain management, the appropriate use of pain medicines, and the differences between addition, pseudo-addiction, tolerance and physical dependence.

Texas Cancer Council
Tex. Health & Safety Code § 102.009
This statute charges the Texas Cancer Council with responsibility to provide to physicians a listing of available continuing medical education courses in pain treatment offered by accredited Texas medical and osteopathic schools, hospitals, healthcare facilities, or professional societies or associations for physicians.

Regulations

Controlled Substances Regulations
37 TAC § 13.73
These regulations place undue restrictions on prescribing by requiring a special serialized government issued prescription form only for Schedule II medications.

Medical Board Regulations
22 TAC § 170.1 - 170.3
These regulations legitimize pain management as a part of medical practice and the use of opioids to treat pain as a part of professional practice. They recognize that the goals of pain treatment should include improvements in patient functioning and quality of life. Additionally, Medical Board regulations identify pseudoaddiction as a possible consequence of inadequate pain management and do not confuse physical dependence and analgesic tolerance with "addiction." The regulations address the fear of regulatory scrutiny acknowledging that prescription amount alone does not determine legitimacy and stating that *"Proper pain treatment is not a matter of how much drug therapy is used, as long as that therapy is based on sound clinical judgment."* Further, the regulations allow for additional flexibility for physicians as long as their prescribing maintains the standards of good medical practice. And, finally, these regulations recognize that

inadequate pain treatment is subject to disciplinary action just as other substandard practices would be.

Pharmacy Board Regulations
22 TAC § 281.7
These regulations legitimize the use of opioids to treat pain as a part of professional practice and the treatment of "narcotic drug dependent" persons for their addiction or for intractable pain. However, they also set arbitrary standards for legitimate prescribing implying there is a limit to the amount prescribed, even though the limit is not set. Additionally, the regulations appear to inhibit off-label prescribing, a common practice at times necessary for difficult cases. The exclusion provided for treatment of "narcotic drug dependent" persons mentioned above does not include other people with addictive disease or a history of addiction. Further, there are undue prescription restrictions requiring the use of a special prescription form for Schedule II drugs only.

Licensing of Hospitals
25 TAC § 133.42
The regulations establish a responsibility for hospitals to ensure that pain management is an essential part of patient care. There are no changes recommended for these regulations.

Licensing of Home and Community Support Services Agencies
40 TAC § 97.403
These regulations establish a mechanism (comprehensive health assessment and care plan) for hospices to ensure that pain management is an essential part of patient care. There are no changes recommended for these regulations.

Other Governmental Policies and Policy Changes

Texas State Board of Pharmacy Position Statement on the Treatment of Pain
This policy statement encourages pain management declaring pain management is a part of medical practice and legitimizes the treatment of pain with opioids as a part of professional practice. The policy states that tolerance and physical dependence are normal consequences of sustained use of these medications and should not be confused with addiction and addictive behaviors. In addition, the policy addresses fear of regulatory scrutiny. This policy could be strengthened by broadening its definition of the inappropriate treatment of pain to include undertreatment as well as nontreatment, overtreatment and the continued use of ineffective treatments.

Repeal of the Term "Intractable Pain"
Texas repealed the term "intractable pain" from policy. The definition of "intractable pain" used in Texas, because it occurred in law, implied that the medical use of opioids is outside legitimate professional practice (Criterion #10) and suggested that physicians would not qualify for the immunity provided by the law if they prescribe opioids as a treatment of first choice for patients, even if the patient is suffering from severe pain (Criterion #16: Category B).

Expansion of Prescription Monitoring
Texas also adopted a law (SB 1879) to expand its prescription monitoring program to cover multiple schedules of medications (e.g., Schedules II-IV), which recognizes that these programs are created to prevent the illegal use of controlled substances and are not to infringe on legitimate professional practice and patient care; this statement directly supports the Central Principle of Balance. However, Texas continues to have a government-issued prescription form requirement for Schedule II controlled substances only, now the only state in the nation with this provision.

Pain Treatment Review Committee

SB1879 also establishes a Pain Treatment Review Committee comprised of healthcare professionals and healthcare system representatives, government officials, and law enforcement. The Boards of Pharmacy, Medicine and Nursing along with the Department of Public Safety and Department of Aging and Disability Services will serve as advisors.

The committee is charged with the study of relevant provisions in Texas laws that relate to the administration of prescription medication, controlled substances, and the needs of patients for effective pain control and management. The committee will examine how the statutes affect public health needs, the professional medical community, and persons affected by acute, chronic, or end-of-life pain and will by September 1, 2008, report any changes recommended to the statutes to the Lieutenant Governor, the Speaker of the House, and the appropriate standing committees in the Senate and the House of Representatives that have jurisdiction over the issues studied by the committee.

Improving Pain Care in Texas: The Texas Action Plan to Relieve Pain

"No action, no change. Limited action, limited change. Lots of action, change occurs."

-Catherine Pulsifer, *An Inspirational Thought, Motivational Thought – Change*, 2007

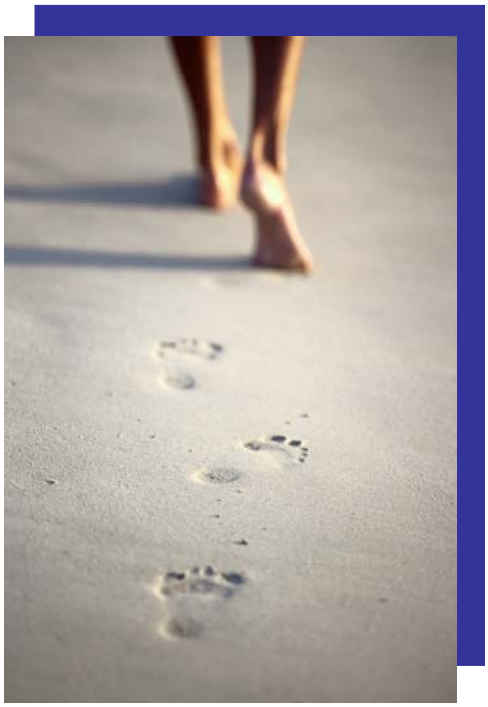
Definitions

Comprehensive pain management. Includes medical management, interventional procedures, complementary and integrative approaches, psychosocial services, and rehabilitation services

Champion. Patients, families, healthcare providers, and others who can articulate the pain story including recognition that pain is a multi-faceted condition requiring comprehensive assessment and collaborative management, and how lives are transformed by appropriate assessment and management

Empowerment. Clinical professionals have the moral and ethical obligation to have pain management education and skills and apply those skills at the bedside and pain patients, families, and caregivers have the knowledge and skills to communicate effectively their needs and the level of relief provided

Pain education strategies. Combination of didactic and skill demonstration



Major Goal

Ensure high quality pain management for people of all communities and cultures in Texas through public policy initiatives, public awareness campaigns, and patient and provider education

Major Strategies

I. Public Policy Initiatives for Consumer Protection
II. Healthcare Professional/Provider Education and Empowerment
III. Advocacy for Better Patient Care
IV. Public Awareness and Media Relations
V. Law Enforcement and Regulatory Agency Collaboration and Education

Strategy I: Public Policy Initiatives for Consumer Protection

Objective 1: Educate policy makers on pain management issues

Action 1: Support the multidisciplinary Pain Treatment Review Committee created by Senate Bill 1879 to develop plans for improving pain care in Texas as measured by: 1) Committee established; 2) Plan to improve Texas policies established; 3) Texas score improved to "A"

Objective 2: Remove restrictive or ambiguous language from Texas laws, statutes, regulations, and/or policies as recommended in the Pain and Policy Studies Group 2006 Evaluation Guide

Action 1: Establish a work group to engage the licensing boards in discussion and adoption of consistent pain management policies as measured by: All licensing boards adopt consistent pain management policies

Action: 2 Workgroup disseminates Pain and Policy Studies Group recommendations for removal of restrictive or ambiguous language as measured by: Recommendations for change implemented into Texas laws, statutes, regulations, and policies

Action 3: Communicate clear and unambiguous regulatory expectations regarding the prescribing of controlled substances to practitioners and healthcare providers as measured by: Licensing boards adopt and communicate pain policy statements

Action 4: Advocate for the Texas Attorney General to adopt the National Association of Attorneys General initiative on pain management as a Texas priority as measured by: 1) Texas Attorney General identifies pain management as a priority consumer protection initiative; 2) Texas Attorney General appoints liaison to pain initiatives

Objective 3: Remove additional prescription requirements related to Schedule II drugs

Action 1: Secure funding for and implement a global electronic prescription monitoring program in Texas that will monitor all drug schedules as measured by: 1) Funding secured; 2) Electronic prescription monitoring program implemented

Action 2: Advocate for removal of additional Schedule II prescription requirements as measured by: 1) Elimination of 7-day rule; 2) Elimination of specialized prescription form; 3) Elimination of diagnosis requirement on Schedule II scripts

Action 3: Advocate for improved prescribing privileges for Advanced Practice Nurses and Physician Assistants to improve access to pain care for diverse and underserved populations as measured by: Advance Practice Nurses and Physician Assistants able to write Schedule II prescriptions

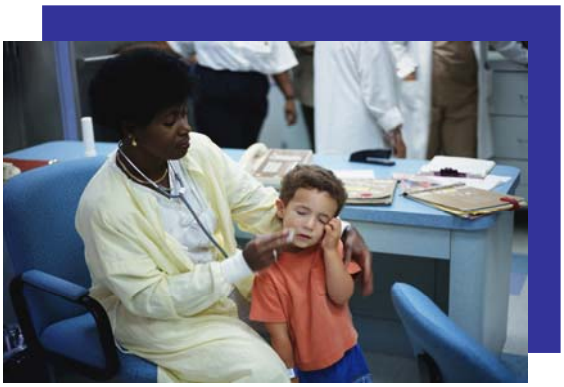
Objective 4: Support an initiative for all health profession licensing boards to develop and release a joint consensus statement regarding the individual's right to assessment and management of pain

Action 1: Establish a work group to engage the licensing boards in discussion and adoption of the joint consensus statement as measured by: 1) All licensing boards adopt patient bill of rights regarding assessment and management of pain; 2) Joint statement is issued

Objective 5: Advocate for reimbursement plans that recognize the complex nature of pain and compensate for high quality pain management

Action 1: Distribute published data on impact of pain management on the cost of healthcare as measured by: 1) Creation summary document; 2) Number distributed to policy makers

Action 2: Advocate for reimbursement of comprehensive pain management that includes medication management, interventional medicine, proven complementary methods, and psychosocial services, as measured by: 1) Public and private insurers provide coverage for comprehensive pain management



Strategy II: Healthcare Professional and Provider Education and Empowerment

Objective 1: Provide practitioners and healthcare providers with a way to obtain best practices information on pain management, including the prescribing of Schedule II drugs

Action 1: Establish a web-based, Texas-specific, best practices clearinghouse on pain management as measured by: 1) Website with links to credible sources is created, monitored and kept up to date; 2) Licensing boards refer to website; 3) Number of hits on website; 4) Number of unique visitors; 5) Topics viewed; 6) Duration of visit

Objective 2: Promote evidence based interdisciplinary approaches to coordinated pain management care plans including clinical outcome measures

Action 1: Create summary document of best practices in interdisciplinary approaches to coordinated pain management care plans as measured by: 1) Summary document created and posted on website; 2) Number of hits to webpage; 3) Number of organizations utilizing summary document practices

Action 2: Promote the development of clinical outcomes tracking to measure effectiveness of pain management care plans as measured by:

Number of programs with outcomes in place with an evaluation plan

Objective 3: Establish professional licensure requirements that include comprehensive education on pain management with accurate information on addiction and abuse

Action 1: Establish an interdisciplinary workgroup that identifies minimum pain management education required for licensure and re-licensure as measured by 1) Minimum pain management education identified; 2) Education modules established; 3) Curriculum adopted by healthcare profession schools and licensing boards

Action 2: Introduce legislation that would establish minimum standards for professional education in pain management as measured by 1) Legislation introduced; 2) Legislation adopted

Action 3: Promote adoption of curriculum that supports comprehensive pain management as measured by: 1) Annual survey of healthcare profession schools for adoption of curriculum; 2) Curriculum demonstrates evidence based quality indicators for comprehensive pain management as established by accrediting organizations; 3) Program incorporates pain education strategies

Strategy III: Advocacy for Better Patient Care

Objective 1: Provide clear, concise messages concerning patient rights to assessment and management of pain to practitioners, patients and families

Action 1: Adopt/adapt a patient bill of rights regarding assessment and management of pain as measured by: Document adopted/adapted

Action 2: Distribute bill of rights to health professionals in Texas as measured by: 1) Number of published in healthcare professional publications; 2) Number of materials distributed to be used as education tool with patients; 3) Number of educational programs including bill of rights in program

Action 3: Distribute bill of rights to patient and consumer groups in Texas as measured by: 1) Number of patient and consumer organizations supporting the principles in the bill of rights; 2) Annual survey of patient and consumer organizations for utilization of bill of rights

Action 4: Distribute bill of rights to consumer media outlets in Texas as measured by: 1) Number of press releases forwarded to consumer print and broadcast media outlets; 2) Number of articles published in consumer print media outlets; 3) Number of interviews and news stories in broadcast media

Objective 2: Mobilize pain patients, families, and healthcare providers to advocate for better care through advocacy training and networks.

Action 1: Promote awareness of patients, families, and healthcare providers of existing pain advocacy networks and how to access them as measured by: 1) Number of resources documented and posted on website; 2) Number of hits on webpage

Action 2: Promote the development of advocacy training for patients, families, and healthcare providers by existing pain advocacy networks as measured by: 1) Number of training programs; 2) Number educated

Strategy IV: Public Awareness and Media Relations

Objective 1: Generate consumer demand for better pain management through public awareness campaigns

Action 1: Develop a consumer engagement campaign as measured by: 1) Consumer campaign developed; 2) Number and type of campaign materials produced; and, 3) Number and type of campaign materials distributed

Action 2: Secure funding to support comprehensive public awareness campaign as measured by: Campaign fully funded

Action 3: Publicize the Texas Pain Summit Report as measured by: 1) Report published and 2) Number of reports disseminated

Action 4: Identify high profile champions as measured by: Number of champions active in campaign

Strategy V: Law Enforcement and Regulatory Agency Collaboration and Education

Objective 1: Promote development of a collaborative action plan among healthcare professionals, law enforcement agencies, and regulatory and licensing agencies

Action 1: Complementary education of law enforcement, regulatory and licensing agencies, and healthcare providers regarding their individual perspectives on pain management and diversion and abuse issues as measured by: 1) Program developed; 2) Number of programs offered; 3) Number educated

Action 2: Collaborate with the state Narcotics Regulatory Program in the development of a database for pharmacies & prescribers to communicate prescribing of controlled substances as defined in Senate Bill 1879 as measured by: 1) Funding received to implement law; 2) Database developed and implemented; 3) Outcomes defined and measured e.g. decreased diversion and pharmacy crimes

Action 3: Collaborate with licensing boards to standardize knowledge base of board members about pain management concepts and the impact of poor pain management on the economy and the well being of the population as measured by: 1) Program developed; 2) Number of programs offered; 3) Number educated

Crosscutting Strategy I: Access

Objective 1: Heighten awareness of access issues related to effective pain management

Action 1: Consolidate research on poor access into a document suitable for the public as measured by: 1) Document produced; 2) Document posted on website

Action 2: Identify impact of poor access to pain care on the cost of healthcare as measured by: 1) White paper on cost of poor pain care; 2) Document posted on website

Action 3: Educate healthcare professionals and other groups about access issues as measured by: 1) Number of organizations offering programs; 2) Number of programs; 3) Number of attendees

Action 4: Secure Texas specific data on poor access to pain care, e.g. map opioid availability, geographic availability of pain specialists, and pain centers

Action 5: Share data on poor access to pain care in Texas and its impact with the Interim Study Committee established by Senate Bill 1879 as measured by data distributed to the committee

Action 6: Share data on poor access to pain care in Texas and its impact with employers as measured by 1) Number of employers receiving data

Action 7: Share data on poor access to pain care in Texas and its impact with communities 1) Number distributed to media outlets; 2) Number of media publications/broadcasts

Crosscutting Strategy II: Disparities

Objective 1: Heighten awareness of disparities in pain care among diverse cultures and communities

Action 1: Consolidate research on disparities into a document suitable for the public as measured by: 1) Document produced; 2) Document posted on website

Action 2: Identify impact of disparities in pain care on the cost of healthcare as measured by: 1) Paper on cost implications of disparities in pain care; 2) Document posted on website

Action 3: Educate healthcare professionals and other groups about disparities issues as measured by: 1) Number of organizations offering programs; 2) Number of programs; 3) Number of attendees

Action 4: Secure Texas specific data on disparities in pain care, e.g. map opioid availability, geographic availability of pain specialists, and pain centers as measured by data secured

Action 5: Share data on disparities in pain care in Texas and its impact with the Interim Study Committee established by Senate Bill 1879 as measured by data distributed to the committee

Action 6: Share data on disparities in pain care in Texas and its impact with employers as measured by 1) Number of employers receiving data

Action 7: Share data on disparities in pain care in Texas and its impact with communities 1)Number distributed to media outlets; 2) Number of media publications/broadcasts

Crosscutting Strategy III: Support and Commitment

Objective 1: Secure support and commitment for implementing the Texas Action Plan for Pain

Action 1: Secure organizations' support and adoption of the Texas Action Plan for Pain as measured by: 1) Number of organizations adopting plan and committing to action; and, 2) Texas Action Plan for Pain implemented

Action 2: Hold a stakeholders meeting as measured by: 1) Meeting held and 2) Number of stakeholders attending

Action 3: Secure five years funding for initiatives as measured by: $500,000 secured to fund project initiation

Appendix A: Texas Pain Summit Participants

Faculty

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Appendix B: Summit Working Groups

Table 12. Summit working groups membership

Working Group A: Prescription Monitoring and Quality Pain Care	Working Group B: Provider Education and Public Awareness
Leadership: Allen W. Burton, MD & Andy Miller, MHSE, CHES	Leadership: Mark Redrow, MD & Karen Torges
Members	Members
Barb Barber, LPN, BS	Mary Lou Adams, PhD, RN, CS, FN
Pamela Bennett, BSN, RN	Sandra Balderrama, MPA, BSW
Kelli Cox	Grady Basler
June Dahl, PhD	Mary Bennett, MFA
Carol Fisher, RPh, MPA	H. Paul Cooper, Jr., MA
Eric Gourley, MD	Larry C. Driver, MD
Kay Kamm	Stephanie Gonzalez, MHA
Sandra Kienitz, RN-C, FNP, CLNC	Sherry Hill
Christopher Ruud, MD	Alice Inman, PsyD, RN
Virginia Sicola, RN, AOCN, PhD	Jan Maville, EdD, RN, CNS
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Debra K. Ucci, RN, FNP, ACNP	Anne Moore, LMSW
Mike Van Doren	Billy U. Philips, Jr, PhD, MPH, FACE
Rachel Wunsch, RN, MSN, FNP-C	Peggy Phillips, BSN, RN-C
	Kathy Plakovic, MSN, APRN-BC
	George Wharton, MD

Working Group C: Collaboration between Healthcare and Regulatory Communities to Improve Pain Care in Texas	Working Group D: Improving the Texas Scorecard
Leadership: Lisa Robin & Gay Lindsey, MSN, RN, OCN	Leadership: Matt Bromley & Suze Miller, LMSW
Members	Members
Leonides G. Cigarroa, Jr., MD	Susan Boucher, RN
Ronald Crossno, MD, CMC, FAAHPM	Gloria Duke, PhD, RN
Kristi Dover, PharmD	Salvatore LoCoco, MD
Johnny Hatcher	Linda Barefoot
Richard Evans	Myra Christopher
Larry Farrow	Robert Fine, MD
Michael Fitzpatrick, MD	Lewis Foxhall, MD
Melanie Fowler, RN, FNP	James Gray
Lewis Hellerstein, MD, FACP	Pat Kelly
Anne Kimbol, JD	Jody Patterson
Gerald W. Lee	Linda Schickedanz, RN, MSN, CNS
Jodie Pepin, PharmD	Jay Silver
Kathy Webster, PharmD, PhD	Jenee Gonzales Garza
	Debora Treu

Appendix C: The Texas Healthcare Professional Surveys

The Texas physician and nurse surveys, *TalkBack 26: Survey of Physicians and Nurses on Pain Management Issues*, were conducted in the summer of 2006 by the Physician Oncology Education Program (POEP) of the Texas Medical Association in collaboration with the Nurse Oncology Education Program (NOEP) of the Texas Nurses Association/Foundation. POEP and NOEP are funded projects of the Texas Cancer Council.

The physician survey utilized a convenience sample of 1,000 physicians randomly selected from the population of all primary care physicians for whom the Texas Medical Association (TMA) had an e-mail address and who had not been invited to participate in a survey during the previous 12 months.

Nurses from all fields of practice who were subscribers to the NOEP electronic newsletter (4,000+) were invited to participate in the nurse survey, a parallel to the physician survey.

The Texas Pain Summit, in collaboration with the Texas Pharmacy Association and Texas Society of Health-system Pharmacists, conducted the *Texas Survey of Pharmacists on Pain Management* in early 2007.

Pharmacists from all practice settings who were members of the Texas Pharmacy Association (TPA) (3,500+) and the Texas Society of Health-system Pharmacists (TSHP) (1,420), and who provided an email address to their respective organizations, were invited to participate in the survey.

Sampled healthcare professionals were e-mailed the invitation to participate. Non-responders were e-mailed once (pharmacists) or twice (physicians and nurses) with follow-up requests to participate. Additionally, the TPA and TSHP both included the survey announcement in their respective electronic newsletters.

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