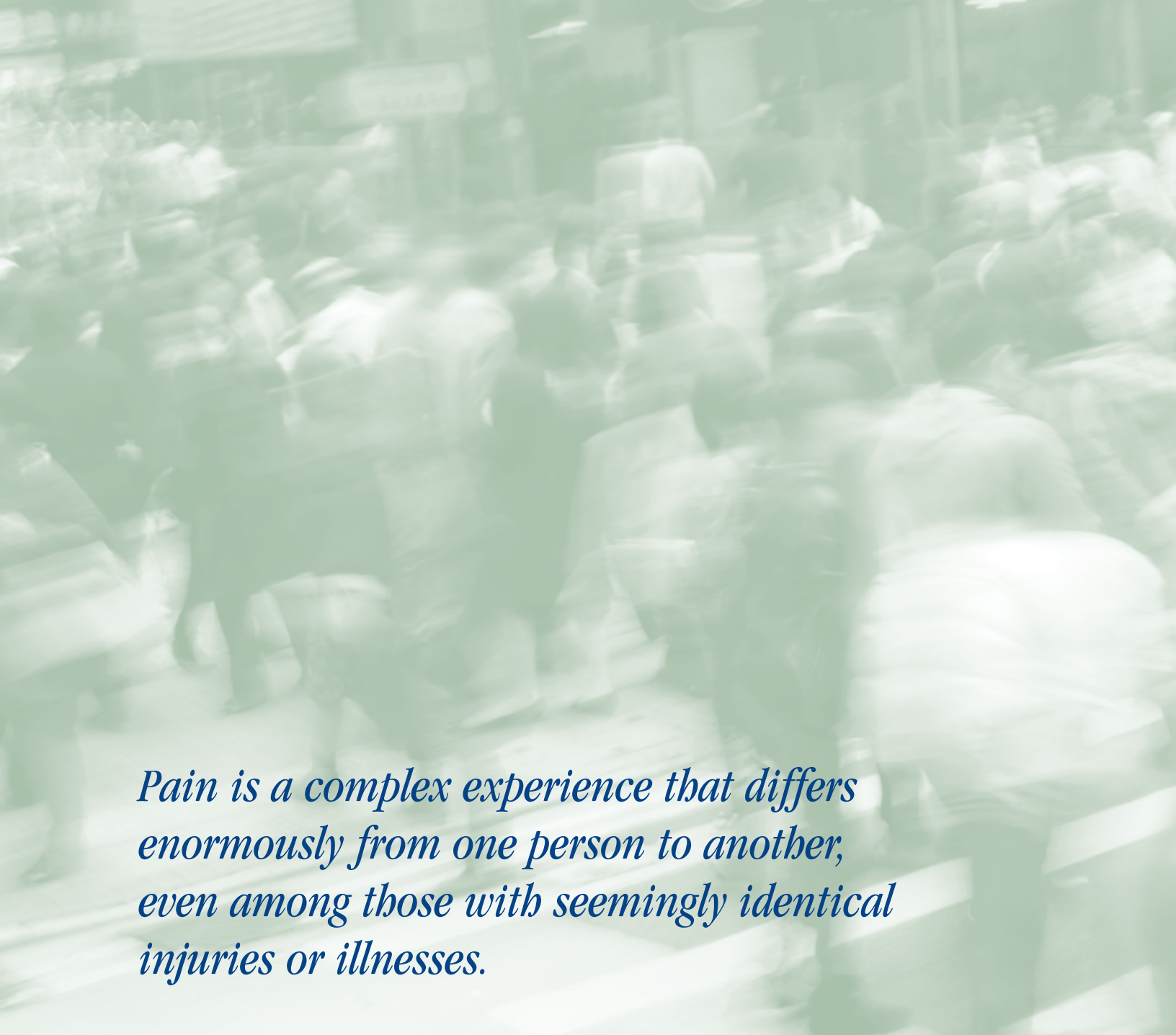


A Policymaker's Guide to Understanding Pain & Its Management



American Pain Foundation

A United Voice of Hope and Power over Pain



Pain is a complex experience that differs enormously from one person to another, even among those with seemingly identical injuries or illnesses.

ABOUT THE AMERICAN PAIN FOUNDATION

Founded in 1997, the American Pain Foundation (APF) is an independent, nonprofit 501(c)3 and the largest national advocacy organization serving people affected by pain. APF speaks out with people living with pain, caregivers, health care providers and allied organizations, working together to dismantle the barriers that impede access to quality pain care for all.

OUR MISSION

The American Pain Foundation educates, supports and advocates for people affected by pain.

A Policymaker's Guide to Understanding Pain & Its Management

PURPOSE OF THIS GUIDE

Policymakers within the federal or state government and regulatory agencies must keep in mind that they represent Americans who live with pain, many of whom have pain every day of their life.

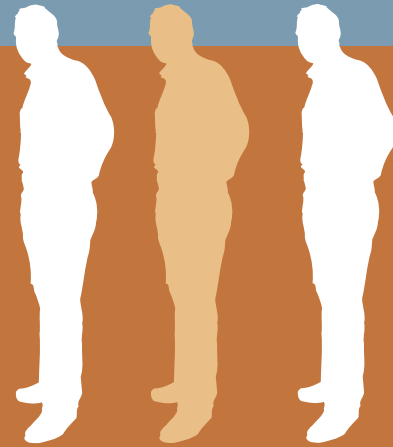
Because pain can and should be treated as a legitimate medical condition just like diabetes, hypertension, obesity and cancer, the American Pain Foundation (APF) has developed this guide as a primer on pain and its management to help meet the informational needs of busy policymakers and their staff members. We know pain is a complex topic, and hope you will find this to be a useful resource in your work to help shape positive, balanced pain policies.

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PAIN AFFECTS EVERYONE

Chronic pain affects
1 in 3
Americans, according to
the Institute of Medicine.



Consider the following...

- Most Americans — eight in 10 — will suffer from back pain at some point in their lives.
- As we age, arthritis hinders the normally smooth sliding motion of our joints and connective tissues, resulting in stiffness and discomfort. Arthritis is the leading cause of disability in people over the age of 55.
- Pain associated with pediatric immunizations is a significant source of anxiety for children receiving immunizations, and evidence suggests that the way children and parents cope can set the stage for future pain responses.
- Damage to or dysfunction of the central nervous system due to stroke, multiple sclerosis and brain or spinal cord injuries also stimulates pain pathways. Undertreated or poorly treated acute pain can manifest as chronic pain for the same reasons.
- An estimated 30 to 50 percent of individuals undergoing active treatment for cancer and 70 percent of those with advanced stages of the disease experience significant levels of pain and may be reluctant to discuss their pain with their health care providers.
- Pain continues to rank among the top medical complaints of active duty military personnel and veterans. An estimated nine out of 10 Iraq and Afghanistan veterans reportedly return home with some type of pain.

Sources: The American Academy of Physical Medicine and Rehabilitation, Arthritis Foundation, Mayday Fund, National Institute of Neurological Disorders and Stroke, National Cancer Institute.

Introduction

Everyone has experienced pain — whether it is a pounding headache at the end of a long day, a throbbing toothache warning of a cavity or infection, a cut or sprained ankle from a fall, or a stinging burn from touching a hot pan. There are also hundreds of pain syndromes, and pain is often a chief complaint with most chronic medical conditions, including cancer, diabetes, arthritis, fibromyalgia and a host of neurological disorders.

While acute pain serves as nature’s biological red flag that something is wrong, pain that persists beyond the expected point of healing has no physiological value — in a sense, the nervous system has broken. For many Americans, pain is a constant and unwanted companion and it’s only when someone is in the grips of pain that they truly know how agonizing and life-limiting it can be.

If untreated, pain can significantly infringe on a person’s quality of life and productivity. Aside from the human suffering, untreated pain exacts a tremendous financial toll on individuals and society at large.

COMMON TYPES OF PAIN

Acute Pain — usually has a clear cause and signals a problem

- Postoperative pain
- Dysmenorrhea (severe menstrual pain)
- Chest pain signaling a heart attack
- Post-traumatic pain: Cuts, scrapes, bruises, fractures
- Mild stress or sinus headache
- Epigastric pain from cardiac problems, gastroesophageal reflux disease (GERD) or other digestive disorder
- Sudden, severe headache signaling stroke or brain aneurysm

Chronic — continues beyond the expected point of recovery

- Persistent back or neck pain from an injury
- Migraine
- Arthritis
- Phantom limb pain
- Shingles/postherpetic neuralgia
- Neuropathic pain due to damage to the central nervous system from diabetes, cardiovascular disease, cancer treatment (surgery, chemotherapy, radiation therapy), spinal cord injury, stroke, blast injury

BURDEN OF PAIN IN AMERICA: AN EVOLVING PUBLIC HEALTH CRISIS

Pain is a serious and costly public health issue. Chronic pain affects 116 million American adults — that’s one out of every three — yet it remains misunderstood. It afflicts more people than diabetes, heart disease and cancer combined, and is a leading cause of disability in the United States. Even though pain is one of the most common reasons patients consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering and poor patient outcomes.

Untreated or poorly managed pain can compromise every aspect of life including a person’s:

- physical and mental health,
- social and intimate relations,
- ability to sleep and perform everyday tasks,
- work productivity, and
- financial well-being.

Chronic pain is not only emotionally and physically debilitating for the individual, it also places a tremendous burden on family members and caregivers, and contributes to excessive health care costs. Pain costs the U.S. an estimated \$635 billion in health care expenses and lost productivity each year.¹

Health care providers and policymakers will soon see a substantial increase in the number of people needing treatment for chronic pain when the 75 million baby boomers move into their late 60s and 70s in the coming years. This uptick will not only affect providers, but it is also expected to increase the cost of chronic pain in the U.S.

¹Institute of Medicine of the National Academies. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. June 2011 brief report. Available at www.iom.edu/relievingpain.



Treating and managing pain is an integral part of clinical care in primary care settings and across all specialties. Pain management matters; **it guards against needless suffering, improves quality of life and productivity and can cut health care costs.**

Even though pain is one of the most common reasons patients consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering and poor patient outcomes. It also costs the nation \$635 billion in medical treatment and lost productivity every year.

SOME COMMON MISCONCEPTIONS ABOUT PAIN

Pain is “all in your head.” Although our brains process the perception of pain, this does not mean that pain is imaginary when the source of pain is not well understood. Pain is all too real to the person who lives with it on a daily basis.

Pain is inevitable; you must learn to tolerate it and suffer in silence. Pain traditionally has been viewed as an inevitable consequence of a disease or condition. The fact is most pain can be relieved with proper pain management.

Pain is a natural part of growing older. While pain is more common as we age, because conditions that cause pain (e.g., arthritis, degenerative joint diseases, cancer, shingles, osteoporosis) are more frequent in older adults, it should not be something people have to endure untreated.

All pain is the same. Many studies failed to find that similar pain stimuli will produce the same pain level intensity. There is an individual difference when sensation is first recognized as painful (pain threshold). There is a difference with pain intensity that each person is able to accept (pain tolerance). Identical injuries can be described differently by sensation and intensity.

The best judge of pain is the physician or nurse. There is little relationship between what a physician or nurse might “guess” about a person’s pain and their actual pain experience. The person with pain is the authority on the existence and severity of his/her pain. His or her self-report is the most reliable indicator.

Seeking medical care for pain is a sign of weakness. Pain carries a stigma, and many people are hesitant to talk about their pain and how it affects their daily life; they also don’t want to be considered a “bad” or high-maintenance patient.

Use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit www.painsafe.org.

Pain is complex and frequently misunderstood by the public, policymakers, and even health care providers. The issue of pain is riddled with myths and misconceptions, which makes the task of informing and educating people about pain and its management that much more challenging.

Unfortunately, too many Americans are not getting the pain care they need and deserve.

Some common reasons for difficulty in obtaining adequate care include:

- Lack of access to care because of too few trained professionals and problems with insurance coverage.
- Limited or no professional training in pain management, which leaves health care providers ill-equipped to respond effectively to their patients’ reports of pain.
- Cultural norms and the stigma associated with admitting pain.
- Restrictive or ambiguous state laws governing health care practice relating to pain care.
- Misconceptions about opioid addiction.
- Concerns among providers about prescribing pain medications for chronic pain, and fears of scrutiny by regulators or law enforcement.
- Persisting disparities leaving certain populations vulnerable to denials of appropriate pain treatment (e.g., infants and children, women, minorities and certain ethnic groups, the elderly, the institutionalized including those in the prison system).

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While pain is a symptom of many chronic diseases and is expected after many surgical procedures, persistent pain should not be viewed simply as a symptom. Ongoing pain is a sign that something is wrong in the body.

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POLICY AFFECTS PAIN MANAGEMENT PRACTICE

Regulation and legislation can have a significant effect on the practice of pain management and access to care, much like it does for other health conditions such as HIV/AIDS and breast cancer. Policymakers and health care regulators play an active role in the development of laws governing pain treatment; however, a number of factors can influence the content and messages of such policies, affecting public access to pain care treatment options. For example, availability of prescription opioid analgesic medications especially may be hindered by restrictive state policies, and therapeutic switching and/or step therapies imposed by insurance companies may limit pain treatment options.

KEY CHALLENGES TO CONSIDER WHEN WORKING TO IMPROVE PAIN-RELATED POLICY

- Persisting social stigma of pain management and the medical use of opioid pain medications, especially among legal and government regulatory bodies.
- Lack of awareness of current state policy content.
- Predominant focus on abuse and diversion of opioid analgesics. While abuse and diversion of prescription pain medication is certainly a problem that can have tragic consequences, so too are policies that hinder access to safe and effective pain care for those with legitimate medical need. The little attention paid to access to care for those with addictive disease or mental health disorders compound this issue.
 - As a group, lawmakers, educators, health care providers, the pharmaceutical industry, and caregivers could address the dual public health crises of the undertreatment of pain and rising prescription drug abuse together.²
- Outdated terminology that confuses physical dependence with addiction and has the potential to stigmatize people with pain as addicts and restrict prescribing practices.
- Lack of sufficient treatment resources and no clear definition of what constitutes a pain expert.
- Lack of reimbursement or support for pharmacological and nonpharmacological treatments for pain. Yet, there is increasing evidence that a multimodal treatment approach leads to better outcomes, gets people back to work sooner and costs less over the long run.
- Poor communication and/or implementation of policy that may unintentionally harm patients or limit access to pain therapies. Even if the substance of a policy upholds pain treatment as integral to the provision of quality medical care, sometimes the implementation of a policy can negatively affect the clinical practice of pain care. Intractable pain treatment acts are one example (see APF's *Pain Care Policy Topic Brief* for more information).

² American Pain Foundation. Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management — A Roundtable Discussion. April 2008. Available at www.painfoundation.org.

A Primer on Pain and Its Management

BURDEN OF PAIN IN AMERICA: AN EVOLVING PUBLIC HEALTH CRISIS

Pain is a serious and costly public health issue. It affects more American adults than diabetes, heart disease and cancer combined, and is a leading cause of disability in the United States. Even though pain is one of the most common reasons people consult a health care provider, it is often inadequately assessed and treated, resulting in needless suffering, poor outcomes and reduced quality of life and productivity.

Pain is a complex perception that differs enormously from one person to another, even those with seemingly identical injuries or illnesses.

Untreated or undertreated or inappropriately treated pain can compromise every aspect of life, including a person's physical and mental health, social and intimate relations, ability to sleep and perform everyday tasks, work productivity and financial well-being.

Persistent pain is not only emotionally and physically debilitating for patients, it also places a tremendous burden on families and caregivers, and contributes to excessive health care costs. Chronic pain costs the nation an estimated \$635 billion in medical treatment and lost productivity each year. As the 75 million baby boomers move toward retirement, the epidemic of untreated or undertreated pain is expected to rise.

Chronic pain affects 1 out of 3 Americans — or an estimated 116 million adults, according to the Institute of Medicine.

PAIN BASICS

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. In 1968, Margo McCaffery, RN, a pioneer in the field of pain management nursing, stated pain is “whatever the experiencing person says it is, existing whenever and wherever the person says it does.”

COMMON PAIN CONDITIONS

In a National Center of Health Statistics survey, the following are common types of pain:

- low back pain (27 percent)
- severe headache or migraine pain (15 percent)
- neck pain (15 percent)
- facial ache or pain (4 percent)

See:

<http://www.painfoundation.org/media/resources/pain-facts-figures.html>.

At its best, acute pain is the body’s natural alarm system, alerting us to injury (or further injury if already injured). It prompts us to stop a harmful behavior or seek medical attention. For example, lifting too much weight might result in a piercing pain in a person’s back. Within moments of touching a hot surface, the fiery sensation of a burn warns us to quickly pull away. Worsening abdominal pain may be a sign of appendicitis or other serious infection. The experience of pain also beckons the injured person to rest, promoting healing.

At its worst, persistent pain robs people of their livelihood and well-being. When pain persists, it is often a sign that the body’s alert system has broken down. In other words, pain signals remain active. Over time, this heightened response may:

- Harm the nerves, blood vessels and organs
- Suppress immune function
- Result in excessive inflammation
- Delay healing

Since the brain remembers pain, pain may be imprinted into the nerve tissue and continue to send pain sensations even in the absence of painful stimuli. This change in the nervous system means that pain has now evolved into disease state with no physiological meaning or value.

Chronic Pain-Brain Connection

New research is unraveling how chronic activation of the biological pathways transmitting pain is associated with structural and chemical changes in the brain. A recent study suggests that constant pain signals can result in mental rewiring that affects the frontal cortex — the area of the brain mainly associated with emotion and attention. According to researchers, this provides the first objective proof of brain disturbances in people with chronic pain that is unrelated to the sensation of physical pain. Functional magnetic resonance imaging reveals changes in brain activity and sensitization in people with pain.

TYPES OF PAIN

	Acute	Chronic
Cause	Generally known	May be known, but often unknown
Duration	Short, well described	Prolonged beyond healing ≥ 3 months
Onset	Usually sudden	Sudden or gradual development
Treatment	Resolve underlying cause; self-limiting	Focus on underlying cause, if known, and pain disorder: pain reduction, function improvement, minimize side effects
Prognosis	Total relief typically possible	Total relief often impossible

Acute pain occurs suddenly due to illness, inflammation, injury or surgery. It has a short duration that subsides when the injured tissue heals. The cause of the pain can usually be diagnosed and treated.

Persistent (chronic) pain is pain that lasts long enough (after normal healing or for at least three months), or is intense enough, to affect a person's normal activities and well-being. Failure to treat acute pain promptly and appropriately at the time of injury, during initial medical and surgical care or at the time of transition to community-based care, contributes to the development of chronic pain syndromes. Every time someone undergoes surgery in which nerves and tissue are cut, he or she is at risk for ongoing pain if their initial pain is not addressed or their pain processing is altered during healing.

With chronic pain, pain signals may remain active in the nervous system for weeks, months or even years. Unlike acute pain, chronic pain has no value or benefit; it is a disease in its own right. It can also be especially challenging to treat.

PAIN ASSESSMENT



Timely access to quality pain management is the best way to minimize the suffering and disability often associated with undertreated pain and to avoid additional problems down the road.

Most hospitals, nursing homes and other health care facilities are now required to assess and treat pain. To correctly diagnose pain, a health care professional will:

- Perform a thorough physical exam
- Complete a pain assessment
- Ask detailed questions about the individual's medical history and lifestyle
- Order blood work, X-rays, electrical tests to detect nerve damage, or other diagnostic and laboratory tests

Pain is a subjective experience, and it is critical for health care providers to have a complete picture of the patient's pain history. He/she may ask about seven characteristics of pain to help LOCATE the pain and make the correct diagnosis.

- L** the exact Location of the pain and whether it travels to other body parts
- O** Other associated symptoms such as nausea, numbness or weakness
- C** The Character of the pain, whether it's throbbing, sharp, dull or burning
- A** Aggravating or Alleviating factors. What makes the pain better or worse?
- T** the Timing of the pain, how long it lasts, is it constant or intermittent?
- E** the Environment where the pain occurs, for example, while working or at home

The type of pain someone is experiencing is often a clue to its cause; for example, persistent pain that is burning or tingling is often the result of nerve disease (neuropathy).

EFFECTS OF UNRELIEVED PAIN ON PHYSICAL AND MENTAL HEALTH

If untreated, pain can have serious physiological, psychological and social consequences. It can:

- Limit the ability to work, sleep, exercise or perform everyday tasks (for example, dressing, going to the grocery store, lifting a child)
- Reduce mobility
- Impair strength
- Diminish appetite
- Make it difficult to recover from an injury or fight infection by weakening the immune system
- Aggravate other health problems
- Lead to depression and/or anxiety, which often worsen pain sensations
- Make it difficult to concentrate or reason
- Place added strain on relationships and interfere with intimacy
- Result in a loss of self-esteem and independence

Pain intensity scales are additional tools available to help individuals with pain describe only one feature of their pain, its intensity. These assessment tools help health care providers better understand the level of pain experienced at rest, during activities and how it varies throughout the day. These include numeric, verbal or visual scales.

With **numerical scales**, patients use numbers from 0 to 10 (0 being no pain and 10 being the worst pain ever) to rate the intensity of the pain.

Verbal scales contain commonly used words such as “mild,” “moderate” and “severe” to help patients’ describe the severity of the pain.

Visual scales use aids like pictures of facial expressions, colors or gaming objects, such as poker chips, to help explain the severity of pain. One type, the Wong Baker Faces Pain Rating Scale, shows six different facial expressions from happy (no hurt) to agony (hurts the worst) to help show health care providers how much pain a patient feels. Body diagrams may also be used to help pinpoint where the pain occurs.



From Hockenberry MJ, Wilson D, Winkelstein ML: *Wong's Essentials of Pediatric Nursing*, ed. 7, St. Louis, 2005, p. 1259. Used with permission. Copyright, Mosby.

Multidimensional pain assessment tools, such as the McGill Pain Questionnaire (MPQ) and the Brief Pain Inventory (BPI), have been developed to quantify different aspects of pain, including location and quality of pain and its effect on mood and function. However, these take longer to administer than the simpler scales and some patients who are cognitively impaired or poorly educated may find them difficult to complete. They are generally used in pain research, and have been adapted for clinical use in many settings.

The processing of pain is complex. A basic explanation is that the pain signals of acute pain are initiated when receptors on the skin, within an organ, tissue or nerve are triggered by injury or disease, known or unknown. A series of events follow: an electrical impulse, or pain message, is generated that is then carried on nerve fibers to the spinal cord. The spinal cord transmits the pain signal to various levels of the brain for interpretation and response. At any time during the transport of pain messaging, these noxious signals can be blocked, enhanced or modified. Signaling associated with chronic pain is much more complicated than acute pain as science is beginning to show.

TREATING PAIN

Successful pain management aims to:

- 1) lessen the pain,
- 2) improve functioning and
- 3) enhance quality of life.

Pain treatment should be:

- patient-centered — tailored to the individual
- multimodal — use a variety of pain treatment options
- multidisciplinary — involve a team of health care providers working directly with the person with pain, caregivers and family members as needed

Not one treatment strategy will work for everyone — a “cookie cutter” approach to pain care is ineffective.

Treatment options may include:

- Medication (anti-inflammatory medicines, opioids or other classes of medications called adjuvants)
- Psychosocial interventions (cognitive-behavioral counseling, guided imagery)
- Rehabilitative approaches (exercise, application of heat/cold, myofascial release, occupational therapy, if needed)
- Complementary alternative medicine (massage, acupuncture, hypnosis)
- Injection or infusion therapies

- Implantable devices and surgical procedures

Research shows that pain can affect one’s emotions and behavior and interfere with the ability to concentrate, manage everyday tasks and cope with stress. Likewise, stress and emotional pressures can make pain worse, provoking “flare ups” and contributing to alterations in the immune system response. These relationships are not always easily recognized or readily fixed by medical procedures or medications alone.

New treatments under investigation are aimed at the physical, psychological and environmental components of chronic pain. Research is also examining the role of genetic predisposition and the immune system in mitigating pain signals.

For a detailed description of the different treatment modalities for managing pain, please refer to the America Pain Foundation’s *Treatment Options: A Guide for People Living with Pain*.

PainSAFE (Pain **S**afety & **A**ccess for **E**veryone), www.painsafe.org, includes information and tips for consumers and clinicians on the safe and appropriate use of pain therapies.

MEDICATIONS & PAIN MANAGEMENT

Medications play an important role in the treatment of pain. There are three major classes of medications for pain control:

Non-opioids: nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen

Opioids: morphine, oxycodone, methadone, codeine and fentanyl are examples

Adjuvant analgesics: a loose term referring to the many medications originally used to treat conditions other than pain, but now are used to help relieve specific pain problems; examples include some antidepressants and anticonvulsants. Some of these medications have been shown to work well for specific types of pain.

Medications that have no direct pain-relieving properties may also be prescribed as part of a pain management plan. These include medications to treat insomnia, anxiety, depression and muscle spasms, and can help a great deal in the overall management of pain in some individuals.

Topic Brief

THE FDA, REMS AND THE POTENTIAL IMPACT ON ACCESS TO PAIN TREATMENTS



The U.S. Food and Drug Administration (FDA) regulates new drug approvals, product labeling for both prescription and over-the-counter (OTC) medications and the manufacturing process. When reviewing new drug applications, the agency carefully weighs the benefits and risks of each medication.

New laws also give the FDA authority to regulate these products after they have been approved. Such expanded jurisdiction over prescription and OTC medications is well-intended to help ensure additional oversight of medications after they come to market and provide extra safeguards for medication safety.

Because of its role in regulating controlled substances, including ingredients in pain medication, the Drug Enforcement Agency (DEA) is also influential in shaping federal pain policy and regulations. The non-medical use and abuse of prescription drugs has become a serious public health issue. Both FDA and DEA are involved with pain medication regulation in an attempt to curb the misuse and diversion of these medications, while at the same time ensuring access for people with legitimate medical need.

The challenge — and concern — is that new policies to curb the non-medical use of various prescription medications could end up interfering with legitimate access to treatments for certain patient populations, most notably people living with persistent pain.

POST-APPROVAL DRUG REGULATION

In 2007, the Food and Drug Administration Amendments Act (FDAAA) gave the FDA authority to regulate drugs after they are approved.

As part of this charge, the FDA has been working with the pharmaceutical industry and consumer stakeholders to develop Risk Evaluation and Mitigation Strategies, or REMS, for a number of classes of medications, including opioid analgesics. Opioids are often a necessary part of a comprehensive pain management plan for certain patients with moderate to severe pain to help alleviate pain, restore functioning and improve quality of life. See APF's *Chronic Pain and Opioid Therapy Topic Brief* for more information.

In February 2009, the FDA sent letters to the manufacturers of 24 short- and long-acting opioid medications announcing they will be required to institute REMS to ensure the benefits of the

medications outweigh the risks, such as those related to misuse, abuse and overdose. New opioid medications will require REMS; some of the long-acting and rapid-onset opioids that are currently available by prescription already have REMS.

As of March 2010, more than 100 medications have REMS in place. Strategies for reducing risk of harm or misuse can range from providing basic patient and prescriber information and education packets or mandating continuing education for pharmacists and prescribers to restricting channels of distribution for certain medications and requiring patients to sign on to a registry.

It is well documented and widely understood that pain is undertreated or poorly treated for millions of people. FDAAA states that REMS should not place undue burden on access to care for those with legitimate need. The REMS process is well-intended and is meant to ensure

the safe use of medications in part by helping to ensure proper patient selection (an opioid tolerant individual who has low risk for misuse or becoming addicted) and requiring patient education on how to safely store and dispose of these medicines so they don't fall into the wrong hands. However, the American Pain Foundation (APF) — along with other leading consumer and provider organizations in the pain community — is concerned that the REMS process, while well-intentioned, will erect new barriers to timely and appropriate pain care.

REMS MAY UNINTENTIONALLY THREATEN ACCESS TO CARE FOR PEOPLE WITH PAIN

While well-intentioned, REMS have the potential to further limit access to opioid pain medication. There is not clear evidence that the proposed strategies will reduce abuse or misuse of prescription medication. Such strategies may cause people living with pain to

not receive the medications that are most appropriate for their needs.

Currently, REMS recommended by the FDA would only be required for long-acting opioids – not short-acting. This can affect prescribing choices. By making it more difficult for a health care provider to prescribe one class of medication and easier to prescribe another, prescribers may gravitate toward less stringently-regulated products. In some cases where a long-acting opioid could greatly improve the life of a person with pain, they may be prescribed a short-acting opioid because it is “easier” for the prescriber, yet more burdensome and less efficacious for their patient. This is not optimal pain care and may diminish the quality of life for the person in pain. It also does not address the underlying problem of prescription drug abuse, as those with substance use disorder or participants in criminal diversion will simply move to products that have fewer restrictions and are easier to obtain.

Additionally, from the clinician perspective many may choose not to treat people with pain who require opioid therapy amid such onerous requirements. These protocols serve to reinforce the fear that their medical license and livelihood are at risk each and every time they write a prescription. Regulations can be so restrictive that they deter health care professionals from the practice of pain care altogether.

A CALL FOR BALANCE

Prescription drug abuse is a serious public health issue — one that may make it more difficult for people with pain to access medication that can make their lives worth living; ideally, REMS

can be a part of the solution in terms of making abuse and misuse of pain medication more difficult. However, regulations designed to reduce prescription drug abuse should not come at the expense of people with a legitimate medical need.

As such, REMS must protect and not interfere with patient access to these important medicines. Negative stereotypes about individuals with pain and fear of ramifications of opioid prescribing can prevent early and effective treatment. Any strategies that further interfere with the ability of prescribers and other appropriate health care practitioners to responsibly develop, provide and adjust pain management regimens for their patients, including regimens that use opioid medication, will prove detrimental to patient care and are financially burdensome.

The cost of pain not only includes direct costs associated with health care provider visits, diagnostics and medication, but indirect costs such as lost wages and productivity of people with pain, as well as family members and caregivers. Aside from stealing livelihoods, untreated pain has been shown to shorten the lives of those who suffer. Some, who no longer consider their lives worth living, see suicide as their only option. These lives and livelihoods lost to pain are worth no less than lives and livelihoods lost to prescription drug misuse or abuse.

RATIONAL AND OUTCOME-BASED SOLUTIONS DESPERATELY NEEDED

Access to appropriate medicines should not be disrupted. As REMS evolve, the elements or strategies included should be proven to reduce the risk of abuse, misuse or diversion.

APF endorses recommendations made to the FDA to provide a balanced solution that will measurably curb the non-medical use and diversion of opioids, while ensuring and protecting patient access to opioid pain medications for those who medically need them. Recommendations include:

- 1) REMS should not interfere with the ability of prescribers and other appropriate health care practitioners to responsibly develop, provide and adjust pain management regimens for their patients.
- 2) REMS elements should be designed so they can be measured to determine their effectiveness in reducing risk of abuse, misuse and overdose.
- 3) Appropriate metrics are needed to determine successful outcomes for patient care as well as abuse, misuse, and diversion. Success thresholds should be predefined, reasonable and achievable. The following questions should be answered:
 - a. Is there convincing data to show a direct link between the non-medical use and abuse of prescription drugs to the prescribing behaviors of responsible health care professionals and use by people with pain who legitimately require opioids as part of their pain treatment plan?
 - b. Does the increase in prescriptions for legitimate medical use provide a surplus of prescription opioid analgesics in medicine cabinets and mailboxes for others to divert?

For example:

- To differentiate accidental overdose by those who are prescribed opioids and overdoses caused as a result of non-medical use, abuse or diversion, REMS metrics should capture more detail about prescribers and patients (similar to cancer, stroke, or trauma registries) so there is insight on who is prescribing (family practice, rural, urban, etc), at what doses, and to what types of patients.
 - Improved metrics are needed to better understand the national prevalence data that separates out incidents of accidental overdose due to inadequate knowledge (of the prescriber and their patients), misuse, abuse and diversion by the patient population as compared to the non-medical use by the public at large.
 - More information is needed to identify sources for non-medical access to prescription medications, as it relates to unintentional and intentional overdose, misuse, abuse and diversion.
 - Impact on access to pain care from REMS requires data collection and analysis to monitor for unintentional harm to people living with pain who require opioid therapy as one of their pain treatment options.
- 4) Short-acting opioids should also be subject to the class-wide REMS to eliminate any inclination to substitute short-acting for long-acting opioids.
 - 5) New patient registries should not be a part of REMS for opioids. Restrictive, punitive systems such as patient “registries” further stigmatize people with pain and create additional hardships and new barriers to effective pain care.
 - 6) Prescriber and dispenser risk mitigation education should be conducted as effectively as possible, and tied to DEA registration requirements or otherwise incentivized to encourage responsible prescribing and ensure compliance. Educational efforts directed to the prescriber, the dispenser and the intended end user need to focus on the safe use, safe storage and safe disposal of medicines to prevent prescription opioid medication from entering illicit channels of distribution.
 - 7) Patient education materials can be developed for individual products to help prescribers and dispensers provide patients with appropriate use, storage, and disposal information, as well as any specific precautions relating to individual products.

Conclusions/Next Steps

Regulators, health care providers and people with pain all face a difficult challenge in the current environment. Balancing policies in such a way that they effectively address two concurrent and sometimes conflicting public health crises is extraordinarily difficult. REMS is not the sole solution to this dilemma, but it can be one incremental step in the direction of resolving it. For this to happen, it is necessary for policymakers to continually remind themselves that there are two groups of people at risk of morbidity and even mortality in this situation, and to continually ask if policy proposals will serve the needs of both groups.

In part, this challenge is so difficult because we have never addressed a pair of problems so diametrically opposed and have never thoroughly evaluated the outcomes to determine the extent to which the solutions were, in fact, solutions. It is imperative that such outcome studies be conducted with any REMS for opioids, so that we implement policies that protect both the millions of people with chronic pain and the millions of people with substance use disorders. Failure to conduct such an evaluation could leave us spending huge amounts of time and effort — not to mention money — implementing policies that are, in fact, harmful rather than helpful. Intervening in the manner evidence indicates is best is not just necessary in the practice of medicine, but also in the practice of public policy.

As FDA implements the new REMS for long-acting opioids and evaluates its effect, it is important to recognize that the lives and livelihoods lost to uncontrolled pain are worth no less than those who misuse or abuse prescription medications.

For more information, visit www.painfoundation.org.

STATE-BASED PAIN CARE POLICY

A Snapshot of State-Based Policies Affecting Pain Care

Untreated pain is a silent epidemic in America. Chronic pain significantly and negatively affects the lives of an estimated one out of every three Americans, and costs the nation as much as \$635 billion in added health care expenses and lost productivity each year, according to the Institute of Medicine. This figure does not begin to cover the physical, emotional and economic strain of pain on the individual and caregivers.

As with efforts to advance the prevention, diagnosis and treatment of other diseases — for example HIV/AIDS and cancer — legislative and regulatory policies can strengthen or hinder efforts to improve pain care — a fundamental tenet in medicine.

In June 2011, the Institute of Medicine (IOM) released a seminal consensus report, “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,” and called for a comprehensive, population-level strategy to address pain as a complex disease, not just a symptom of injury or illness.

Included among the IOM’s recommendations to improve pain management are:

- **Developing a comprehensive plan by the U.S. Department of Health and Human Services** with specific goals, actions and timeframes by the end of 2012;
- **Reducing barriers** to access — whether legal, regulatory, reimbursement or cultural;
- **Educating the public** on prevention, treatment and self-management;
- **Improving professional education** across the spectrum of disciplines, and throughout the continuum of undergraduate, graduate and continuing health professions training; and
- **Focusing pain research efforts at the National Institutes of Health (NIH)**, and coordinating that research with other government agencies and the private sector to speed the development of **new therapies**, foster **interdisciplinary approaches**, increase **longitudinal research** of people in pain, and **increase the number of pain researchers**.

For more information, see IOM (Institute of Medicine) 2011. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, Washington, DC; The National Academies Press. Available at <http://iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>.

Of course, federal and state elected officials, along with members of regulatory and licensing bodies, play a role in many of these areas and help shape the practice of pain management throughout the United States through the passing of federal and state policy.

At the same time, the non-medical use and diversion of prescription medications — including opioid analgesics — is also an important public health and safety issue that has influenced many policies in this area. For this reason, most of the policies discussed in this topic brief relate to the medical use of opioids, and the restrictions affecting the safe and appropriate provision of opioids for the treatment of moderate to severe pain. This in no way diminishes the importance of a multidisciplinary, multimodal therapeutic approach to pain management; opioids are only one tool within a broad range of treatment options. Indeed, many policies governing opioid therapy recognize the benefits of a multidisciplinary clinical approach. Moreover, policy responses to prevent the non-medical use of any therapy should not only protect the public from harm, but also maintain access to treatment for those with legitimate medical needs.

State-based Legislation and Regulatory Policy

State governments have the authority to adopt policies that provide the legal basis for health care practice, including professional practice relating to pain management and the medical use of opioids. Legislatures create statutes that are broad and general, and then depend on the relevant regulatory agency to interpret and implement the statutes through regulations. In the field of medicine, for example, the state legislature grants authority to the state medical board to define and implement its laws through regulations that are consistent with legislative provisions.

Although these laws can establish requirements and prohibitions affecting treatment decisions about pain care, including chronic non-cancer pain, regulations are designed to be revised periodically to keep pace with changing practice standards. Conversely, legislation has been slow to change

in reaction to updated professional standards. Please refer to the section below titled *Challenges to Policies Promoting Safe and Effective Use*, which provides examples of pain-related statutes or regulations relating to opioid prescribing that contain potentially restrictive or ambiguous language.

Well-crafted pain policy promotes acceptable medical treatment, including pain management and the appropriate use of pain medications, and assures that the non-medical use of medications is clinically monitored and addressed effectively. However, overly restrictive prescribing requirements or prohibitions may create barriers to adequate pain treatment. Policies relating to the access of pain medications, therefore, must balance the public's health with protecting public safety through appropriate and effective drug control. Minimizing drug abuse and diversion must not interfere with the availability of medications for legitimate medical and scientific purposes.

Policies that promote the safe and effective use of pain medications are adopted and implemented within the context of two public health issues: (1) the under-treatment of pain and (2) the abuse of prescription pain medications. The story most commonly communicated to the public is too often focused on fears of substance abuse and diversion of opioids.

When the perception of undue risk outweighs therapeutic benefit, detrimental clinical consequences will occur. People with pain will be unable to access pain treatment options that enable them to be more functional and have an optimal quality of life. On the other hand, the abuse and diversion of opioids constitute a serious public health problem, and policies must be developed to reduce the resultant morbidity and mortality.

For more information, read the [American Pain Foundation \(APF\) Chronic Pain and Opioid Therapy](#) topic brief.

POLICIES CAN AND DO INFLUENCE PAIN CARE

Policies of any kind may either directly or unintentionally stigmatize individuals and/or make it harder for them to get appropriate pain care, which is already difficult to obtain for clinical or systemic reasons. In addition, health care professionals generally are hesitant to engage in policy change activities because of a lack of guidance about how best to approach and interact with policymakers around these issues.

Furthermore, good policy does not necessarily equal good practice. Once good policy is in place, a number of actions must follow to translate it into practice. Policymakers, health care professionals and people with pain must understand what constitutes good pain management and what certain policies allow. Any policy responses must be thoughtfully approached and uphold access to humane care that prevents needless suffering and improves quality of life.

A Snapshot of State Pain Laws and Policies that Influence Pain Management

The ability to effectively and responsibly manage pain is influenced by federal laws, state statutes, regulations, regulatory guidelines and policy statements.

The following provides a snapshot of some of the existing policies that can affect pain care at the state level.

Some state-based laws and policies that can influence the provision of pain care:

- Prescription Monitoring Programs
- Professional Licensing Board Regulatory Policies
- Mandated Continuing Education in Pain/Palliative Care
- Intractable Pain Treatment Acts
- Controlling Pharmaceutical Costs in Medicaid Programs
- Workers' Compensation
- Step Therapy (Fail First) and Therapeutic Switching Insurance Policies



• Prescription Monitoring Programs (PMPs, also called prescription drug monitoring programs [PDMPs])

PDMPs are state-based programs that aim to reduce the abuse and diversion of prescription medications. These programs track controlled substances prescribed by authorized practitioners and dispensed at pharmacies. PDMPs can help identify individuals who obtain similar medications from multiple prescribers or pharmacies (also called “doctor shopping” or “pharmacy hopping”). Not only can PDMPs provide early warnings of drug abuse hot spots (especially when considered with other data) and help investigators uncover diversion and insurance fraud, they also can be a useful clinical practice tool to improve patient care.

By mid-2011, 36 states had operational PDMPs; another eight states have adopted laws authorizing the creation of these programs.

In its recent report, “Epidemic: Responding to America’s Prescription Drug Abuse Crisis,” the White House supports the expansion of state-based PDMPs to all 50 states as a “promising approach” to help curtail prescription drug diversion and abuse (See http://www.whitehousedrugpolicy.gov/publications/pdf/rx_abuse_plan.pdf), but also recognizes the need for improvements, stating that “more work is needed to determine how to maximize their effectiveness.” In particular, PDMPs currently are limited by their inability to:

- Share inter-state data to determine whether an individual has obtained medications from other states (although this may soon change);
- Authorize electronic access to prescribers; or
- Provide “real-time” data to prescribers and dispensers.

There also is a need to effectively promote the appropriate use of PDMPs when they become available so that prescribers can better utilize the PDMP data to inform their treatment decisions when prescribing opioids. For information about the current status of PDMPs, visit <http://www.aapainmanage.org/aboutus/Advocacy.php>.

APF outlines key considerations for policymakers when drafting or reviewing PDMP legislation, and calls for research to study the effect of PDMPs on physician prescribing practices, pain management and drug diversion and misuse. To read APF’s statement, visit <http://www.painfoundation.org/about/position-statements/pmp.html>.

• Professional Licensing Board Regulatory Policies

Most states have avoided enacting pain legislation. Instead, states promote health care regulatory board regulations, guidelines or policy statements.

These policies typically promote the message that pain management and the safe and effective use of controlled substances is an accepted part of professional practice. Another goal of such policies is to reassure clinicians that they have nothing to fear from their licensing agency if reasonable professional practices are followed when using controlled substances for patient care. Much of this recent policy activity was prompted in 2004 by the Federation of State Medical Boards’ creation of the model policy to promote consistency in state medical board policy (see http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf). Now, 45 states have some type of medical board policy to address pain relief.

Other states have joint statements on pain management, palliative care or end-of-life care adopted by health care boards. Examples are:

- Minnesota:
<http://www.phcybrd.state.mn.us/forms/jspm.pdf>;
- Kansas:
http://www.state.mn.us/mn/externalDocs/BMP/BMP_Joint_Policy_Statement_091404112418_Joint%20Statement%20on%20Pain%20Management.htm;
- Oregon:
<http://www.painpolicy.wisc.edu/domestic/states/OR/joint.pdf>;
- South Carolina:
<http://www.painpolicy.wisc.edu/domestic/states/SC/scjoint.pdf>

- **Mandated Continuing Education in Pain/Palliative Care**

Some legislatures and regulatory boards either mandate or strongly encourage that continuing education (CE) for health care professionals to renew their license include pain and palliative care education. Such policies have been deemed necessary based on evidence that many health care professionals lack knowledge about pain management and receive little training in medical school.

These mandates should incorporate outcomes research to demonstrate the value of CE, including data to show whether and to what extent the curriculum and teaching methods improved pain treatment. Such research also may suggest how CE programs could be modified to increase their effectiveness.

- **Intractable Pain Treatment Acts (IPTAs)**

IPTAs are a class of statutes intended to provide immunity to health care professionals who prescribe opioids to treat intractable pain. Although the intent of IPTAs is commendable, the statutes historically have contained restrictions or ambiguities that may limit clinical decision-making practices. For example, these laws may require people living with pain to have a consultation with one or more health care professionals before their pain can be treated when the goal should be to make it easier for clinicians to treat pain.

Additional problematic language includes implying that opioids are outside legitimate professional practice; providing immunity only for individuals living with persistent pain that does not respond to other treatment options; prohibiting prescribing to people with substance use disorder; and confusing addiction with physical dependence. IPTAs also tend to omit clear statements supporting enhanced pain management and access to care.

In recognizing these issues, several states have repealed such requirements and ambiguities — including the term and definition of “intractable pain,” in effect extending the immunity of this law to treating all types of pain.

- **Controlling Pharmaceutical Costs in Medicaid Programs**

Medicaid programs control which medications are on a drug formulary by establishing preferred drug lists (PDLs) to accomplish cost containment. Medications not included on the PDL remain available only with prior approval, which can delay access to the medically recommended medication. Pharmaceutical companies are often required by Medicaid to provide supplemental rebates to have their product included in the formulary.

Ideally, states should make decisions based on safety, clinical efficacy, and cost, rather than solely on the cost as the primary criteria in determining which medications are included in a PDL.

“The struggle for pain relief can ill-afford any more unnecessary obstacles, even those masquerading as fiscal responsibility. It is never responsible to exchange pain and suffering for a per-pill cost ledger. Without also taking efficacy, expediency, and safety into account along with overall cost, this committee will also need to be accountable for unnecessary pain and suffering among the most vulnerable citizens in Maryland, a toll for which each member can justly feel responsible.”

— 2005 Maryland P & T Committee Testimony by F. Michael Glotch, III, MD.

Another mechanism that can be used by Medicaid to both control costs and enhance patient safety is a “lock-in” program, in which an individual may be assigned a single practitioner and single pharmacy from which to obtain pain medication.

The premise behind lock-in programs is that heightened tracking helps ensure Medicaid recipients receive appropriate treatment, while controlling costs by reducing visits to hospitals, clinics, physician offices and emergency rooms, as well as duplicative or unnecessary prescriptions. North Carolina enacted a lock-in program specific to opioid pain medication in 2010. Other states, like Wisconsin, monitor controlled substances, including benzodiazepines and stimulants as well as opioids. Lock-in requests can be made by pharmacists when the prescription recipient is suspected of non-medical use.

- **Workers’ Compensation**

Workers’ compensation, like Medicaid, is a very expensive area for government health care funding. Some states have established extensive guidelines for workers’ compensation-related pain treatment, as a means of controlling both costs and the risk of non-medical use of medications and diversion. Unfortunately, some of these guidelines are extremely restrictive and run the risk of impeding effective and appropriate pain treatment.

For example, in Washington state, the Health Technology Clinical Committee has denied coverage of several pain care devices and treatments for those enrolled in state-paid medical

plans: Medicaid, workers’ compensation and Uniform Medical. As of May 2011, coverage denials include the use of intrathecal pumps, transcutaneous electrical nerve stimulator (TENS) units and spinal cord stimulators. The decisions to deny reimbursement for these three chronic pain devices affects approximately 330,000 public employees and retirees, 70,000 individuals in the Basic Health Program, 900,000 in the Medicaid program, and 2.5 million workers with approximately 130,000 claims (Labor & Industries, Workers’ compensation).

This is a complex area of work — one that deserves more focused attention from the pain community and policymakers alike. Third-party payer policies and practices that usurp the “doctor-patient” relationship, deny pain care access to vulnerable groups, or are developed primarily for cost savings supersede the best interest of patient care. These actions serve as an inappropriate and unacceptable form of health care rationing.

For more information, read [APF’s Access to Care Position Statement](#).

- **Step Therapy (Fail First) and Therapeutic Switching — Insurance Policies**

Step or fail first therapy requires alternate medications, which in some cases includes over-the-counter medication, or other therapies to be used before the health care provider-recommended medication is approved for reimbursement. These patients can be required to “fail” numerous other

treatment options before the insurer will grant reimbursement access to the treatment option that was originally prescribed by the clinician. This protocol is used as a cost-saving measure for the insurer.

Step therapy often sets the stage for forced “off-label” use of medications that may no longer be appropriate nor provide optimal efficacy for an individual’s medical condition. This policy can actually increase costs for the insurer because the delay in recommended care may decrease the person’s response to treatment or cause other health complications.

Therapeutic switching (or “therapeutic substitution”) is when the *insurer* substitutes less expensive medications or alternate medications. These are not the medications prescribed by the health care professional and the individual is not usually aware of the change until he or she arrives at the pharmacy to pick up their medication. These medications may have more side effects or be less effective for the person with pain. Pharmacists and clinicians are put in the unfortunate predicament of confronting insurers to defend the medication therapy that they prescribed. This is different than “therapeutic interchange,” where exchanges are in accordance with previously established and *medical* staff-approved written guidelines or protocols, within a drug formulary system.

It is understandable that insurance companies try to cut costs and avoid unnecessary medical interventions; however, the clinical judgment of the direct care provider to an individual’s health care must not be undermined. Legislative and

regulatory ruling must help correct this by placing prescribing power back in the hands of health care professionals in charge of their patient's care. APF supports the American Medical Association's official statement on this issue:
...[T]he AMA accepts the concept of therapeutic *interchange*, i.e., the authorized

exchange of therapeutic alternates in accordance with previously established and medical staff-approved written guidelines or protocols, within a drug formulary system. ...[T]he AMA clearly differentiates therapeutic interchange from therapeutic *substitution*, i.e. the act of dispensing a therapeutic

alternate for the drug product prescribed without prior authorization of the prescriber, and reaffirms its strong opposition to therapeutic substitution in any patient care setting.

For more information, read APF's position statements on therapeutic switching and step therapies.

Challenges to Policies Promoting Safe and Effective Use

Pain generally is poorly understood by the public, policymakers, and even many health care professionals. An integral part of pain care policy is educating people — and in some cases reeducating people — about how pain affects lives, its cost to society and the tremendous toll it can exact on families, the workplace and the community. Such efforts to improve the awareness and understanding of pain treatment issues, however, may be undermined by policies included in the previous section and also by requirements and language found in other policies.

Addiction terminology

One of the most common problematic provisions remaining in state policy today is archaic terminology that confuses physical dependence with addiction. As of mid-2011, 41 states have adopted language clarifying the distinction between these clinical phenomena. Such up-to-date terminology is typically contained in health care regulatory guidelines or policy statements; however, the statutes of 14 states and the health care regulations in two states continue to classify physical dependence as synonymous with addiction. As a result, these states have conflicting standards about what constitutes addiction, which may create ambiguity and has significant clinical implications.

When such archaic standards are applied in practice, they have the potential to stigmatize people with pain as “addicts” and restrict prescribing practices, leading to inadequate pain management for those who need opioid pain medication for management of their pain condition.

ADDITIONAL RESOURCES FOR APPROPRIATE DEFINITIONS

American Pain Foundation issued an At-a-glance page defining each of these terms in its *Chronic Pain and Opioid Therapy* topic brief.

The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine released a consensus document about this issue. These professional organizations recognize the following definitions and recommend their use. See <http://www.ampainsoc.org/library/bulletin/mar99/president.htm> for additional information.

- **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.

- **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.

- **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.

For additional resources, see the Federation of State Medical Boards' influential Model Policy for the Use of Controlled Substances for the Treatment of Pain. Responsible Opioid Prescribing: A Physician's Guide at www.fsmb.org/pain-model-policy.html.

Reporting People Who are Prescribed Opioids

The laws in some states contain problematic language relating to the reporting of people being treated with opioids. For example:

- In Pennsylvania, pharmacies must report the identity of every person being treated with schedule II controlled substances to the state attorney general (28 Pennsylvania Code § 25.131).
- A law in North Carolina requires all health care practitioners who treat “drug dependent persons” to report their patients to the state Department of Health and Human Services. This law may

classify individuals as “drug dependent” if they are taking opioids for a legitimate medical purpose and are physically dependent on the medication.

It seems, therefore, that practitioners prescribing opioids to treat people with pain could be subject to this requirement (North Carolina General Statutes § 90-109.1(c)).

- Finally, the California Department of Justice can assign a physician to examine any person taking a schedule I, II, or III medication, or who has an addiction to a controlled substance. The person must submit to the examination, or

could be found guilty of a misdemeanor (California Health & Safety Code § 11453).

Excessive Prescribing

A frequent dictate on health care practice is the creation of ambiguous practice standards, such as defining unprofessional conduct to include “excessive prescribing” without operationalizing the term or defining how it would be determined. Such vague standards need to be clarified in or removed from state laws.

Pain Management and the Legal System

Prescribers frequently cite fear of prosecution and loss of license as reasons they fear treating people with pain. If legal or regulatory sanction is perceived as a significant risk, it presents a barrier to proper pain management. All health care professionals need to know how to assess and treat pain knowledgeably. Prescribers must know how and when to add opioid-based medications to

the pain treatment plan. They must be aware of federal and state laws governing the prescribing and handling of controlled-substance pain medications to avoid contributing to abuse and diversion. At the same time, legislators and regulatory officials should successfully address prescription drug abuse and diversion without limiting the availability of any pain treatment option, including opioid analgesics that are warranted for legitimate medical use.



HOW POLICIES MAY HAVE UNINTENDED CONSEQUENCES

In Washington state, three policies have been problematic for people living with pain and their health care professionals:

- ESHB 2876 — a new opioid prescribing law that went into effect in June 2011, adds barriers to prescribing opioids to people living with pain by adding burden and cost to practitioners and patients.
- HTA— Washington state’s Health Technology Assessment Committee denied coverage of three technologies (spinal cord stimulation, intrathecal drug delivery systems and TENS units) for people with pain in the public payer system and voted to cover four out of five spinal injections in early 2011.
- HB1311— proposes the creation of a committee that may decide to limit options for pain care, contributing to this disturbing climate in Washington state. In each of these instances, well-intentioned laws can have consequences not only for people with pain and those with a substance use disorder, but also for anyone receiving a controlled substance to treat a medical condition.

Ironically, this policy activity was promoted as an effective response to the abuse and overdose deaths related to prescription pain medications, without evidence that such public health issues result from inappropriate prescribing by health care professionals. Of course, initiatives to safely and successfully reduce the non-medical use of prescription opioids are essential, but only to the extent that they avoid undermining clinical decision-making practices and legitimate patient care. Unfortunately, such policy activity encourages similar policy adoption in other states before its impact either on non-medical use and overdose deaths or on the treatment of patients with legitimate medical conditions is known.

Non-Governmental Regulations Promoting Good Pain Management

Not all policy affecting pain management comes from government agencies. The Joint Commission, a voluntary, independent, not-for-profit organization, provides accreditation services to more than 18,000 health care facilities and programs in the United States. Joint Commission accreditation is, in many ways, the “gold standard” of achievement for health care organizations, and recognizes the adherence to high standards in many aspects of patient care.

In 2001, thanks largely to the efforts of Dr. June Dahl and her colleagues from the University of Wisconsin, the Joint Commission issued its first set of standards focused specifically on a symptom or disorder: pain. The standards for pain assessment and treatment required organizations to

- regularly assess and document the presence, severity, and qualities of pain;
- provide appropriate treatment for pain when it is present;
- educate patients, their caregivers, and practitioners about pain treatment; and
- engage in performance improvement efforts related to pain management, among other standards.

These standards resulted in many institutions adopting “pain as a fifth vital sign” policies.

Evaluating State Policies

Pain advisory committees (also known as pain commissions or pain task forces) play a role in evaluating state pain care policies. These state-level workgroups are used to improve pain management practices by evaluating state laws and regulations that could interfere with access to adequate pain care and to develop recommendations for corrective action.

To be most effective, pain advisory committees should comprise a multidisciplinary team of individuals representing state agencies and health care organizations, health care professionals with pain expertise, people with pain, caregivers and public citizens. They should also serve an advisory and educational function, surveying the status of pain policy and practice in the state and recommending changes to policymakers about achieving better balance in policy and improved practice of pain management. As a result, successful collaborations between committee members and policymakers can influence a state's legislative or regulatory agenda to diminish or avoid establishing barriers to pain management, as well as reduce the non-medical use and diversion of prescription pain medications. One successful model to consider is the pain management commission for the state of Oregon, established in 1999 (see <http://www.oregon.gov/OHA/OHPR/PMC/index.shtml/>).

In addition, the University of Wisconsin Pain & Policy Studies Group (PPSG) created a criteria-based evaluation related to opioid analgesics to quantify and assign grades representing the quality of each state's pain policies aimed at

preventing drug abuse, regulating professional practice, and improving patient care. These criteria can then be used to compare all states and track policy changes over time. Five evaluations over an eight-year period by PPSG show continuous improvement in state policies governing the medical use of opioid medications. See: http://www.painpolicy.wisc.edu/Achieving_Balance/PRC2008.pdf

Grades range from A to F, including mid-point grades (e.g., B+, C+, D+). Higher grades are associated with state policies that are more balanced and consistent with modern medicine. A lower grade means that a state's policies contain potential barriers to patient

pain relief (i.e., language that creates ambiguous practice standards or contradicts current medical knowledge, policies that are not consistent with the policy guidance recommendations from authoritative sources and fail to communicate the appropriate messages about pain management to professionals, patients and the public). See the table below for a list of states' most recent grades related to the content of statutes, regulations, and health care regulatory board guidelines/policy statements involving opioids.

State Grades for 2008

State	2008 Grade	State	2008 Grade
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+
Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

PPSG provides a database of state statutes, regulations and other government policies affecting pain management. Visit www.painpolicy.wisc.edu/matrix.htm to find pain management policies in your state.

What's Next to Improve Policy Content Related to Pain Care

We all must thoughtfully consider existing and proposed legislation and regulatory policies to find requirements that might unduly impede access to pain management, while also maintaining the potential to protect against harm from the inappropriate use of any treatment modality. To guide efforts within a state to create new or modify existing policies that both promote the safe and effective treatment of pain and minimize the public health consequences of the non-medical use of prescription opioids, we encourage policymakers to:

- Identify the policy needs/issues in your state by engaging with the constituencies governed/affected by such policy
- Ask questions of pain experts and people affected by pain
- Focus on removing archaic or ambiguous language/requirements
- Avoid legislation that establishes standards that are slow to change in reaction to professional developments
- Anticipate how policies, even if not directly related to pain management, could influence pain care
- Support efforts to evaluate outcomes of policy change to determine if the intended goals were met, if unintended consequences need to be addressed, and if there is a way to modify policy to achieve more intended and fewer unintended consequences.
- Use available resources to guide policy changes/recommendations, such as the American Pain Foundation (www.painfoundation.org) or the Pain & Policies Study Group state policy evaluation findings (http://www.painpolicy.wisc.edu/Achieving_Balance/EG2008.pdf). These resources could provide an idea about what other states may have done to address similar issues, or could point to the existence of policy templates that are available.

STATE POLICY WATCH

State policies influencing pain management continue to evolve. Policymakers, health care professionals and the public need to be mindful about unintended consequences that could introduce hardships for prescribers, dissuade well-meaning health professionals from providing pain and palliative care, and hinder access to quality and timely pain care. Experts expect the following to be ongoing policy topics in the years to come:

- Expanding and improving consistency of prescription monitoring programs, especially efforts to link these programs across state lines and evaluate outcomes to make them more effective.
- Shutting down “pill mills,” which contribute to prescription drug trafficking, endanger individuals receiving medications from these illegal clinics and threaten the communities where they are located, through dedicated legislation.
- Increasing the number of community-based take back programs to ensure proper disposal of expired and unused prescription medications and, in turn, prevent diversion and non-medical use.
- Developing regulatory policies aimed at health care professionals to promote the safe and effective treatment of pain.
- Creating policies aimed to curb morbidity and mortality from prescription medication abuse that might impede efforts to protect access to quality pain management.

LEGISLATORS CAN USE THE FOLLOWING TIPS AND QUESTIONS, DEVELOPED BY PPSG, TO HELP IMPROVE PAIN MANAGEMENT IN THEIR STATES.

What can state legislatures do to improve pain management?

First, study the problem. Create a multidisciplinary task force, commission or committee with public hearings to study carefully the barriers to pain management for all types of pain in the state (cancer, chronic non-cancer, post-surgical, sickle cell, AIDS, etc.); review relevant state policies outlined below; make and implement recommendations in legislation, leadership, public information, education, training, program development, etc.

1. Drug, pharmacy, controlled substances policy

- Does the state controlled substances act recognize the essential medical uses of controlled substances as in federal law and as recommended by the National Conference of Commissioners on Uniform State Laws?
- Does state law or regulations unduly restrict prescribing of controlled substances, e.g., government-required prescription forms; exclusion of addicts even if they have pain; require second opinion, consultation or informed consent; legal terminology confusing addicts with pain patients/addict reporting, limit number of dosage units of controlled substances (e.g., opioids) that can be prescribed at one time, or limit unrealistically the period of validity of a prescription for a scheduled substance?
- Does state policy allow physicians and pharmacists to take full advantage of the flexibility in federal controlled substances regulation regarding faxing and partial dispensing of controlled substances prescriptions?

2. Medical policy

- Does the medical practice act or regulations contain any policies with regard to prescribing controlled substances which are unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain? (i.e., no prescribing to addicts, even if they have pain?)
- Does the medical board have a policy statement or guidelines which clarifies that the board recognizes that the use of controlled substances for the treatment of chronic pain is accepted

medical practice and clarifies the principles which a physician can follow to confidently avoid the risk of discipline or arrest by any agency in the state?

3. Facility regulation (hospice, nursing home, home care, etc.)

- What is the attitude of the state facility regulators: is pain a priority or is the priority only reducing the use of controlled drugs?
- Do certification and inspection criteria include assessment and treatment of pain and training of patient care staff; is technical assistance on pain and symptom management available?

4. State health policy

- Does the state cancer control program include a funded emphasis on pain management and palliative care for cancer patients in the state?
- Is there a state pain initiative and does it have adequate support?
- Does the public have access to information about pain and symptom management including chronic non-cancer pain, and where to go for help?
- Do toll free numbers for other chronic conditions, like cancer or diabetes, include information about pain management?
- Do managed care organizations have adequate policies: pain assessment, treatment, reimbursement, appropriate access to specialists?
- Does state Medicaid policy reimburse the controlled medications used in pain and symptom management?
- Does workers' compensation adequately address the needs of people with chronic severe pain?

5. Drug enforcement policy

- Do the agencies in the state which are involved in drug law enforcement and monitoring of controlled substances prescribing, dispensing and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who prescribe and dispense legitimate controlled substances?

CHRONIC PAIN AND OPIOID THERAPY

Effective management of chronic pain often requires a step-wise, coordinated and integrated trial of different treatment options, a team of health care providers and social support from family and friends. Health care providers may start with behavioral and non-pharmacological interventions (e.g., hot/cold therapy, physical therapy, relaxation techniques) when devising pain treatment plans. Strong prescription pain relievers like opioid analgesics may be recommended as one of the treatment options to help reduce moderate to severe pain so that function and quality of life can be improved. According to the American Pain Society, the American Academy of Pain Management and the American Geriatrics Society, individuals with severe or functionally limiting pain that is not sufficiently relieved by other means should be considered for a trial of opioid therapy.

Key Issues

- An estimated 116 million Americans suffer with chronic pain.¹ The consequences of unmanaged persistent pain are devastating for individuals and their families. Sadly, many people with chronic, debilitating pain are made to feel as though the pain is “just in their head.”
- For some people, opioids are a necessary and integral part of a comprehensive pain management plan to help relieve pain, restore functioning and improve quality of life.^{2,3}
- Unfortunately, access to these medications may be hindered by unduly restrictive state policies, persisting social stigma surrounding their use, as well as therapeutic switching and/or step therapies imposed by insurance companies. For more information about policies that directly or unintentionally affect access to pain care, read the *State-Based Pain Care Policies Topic Brief*.
- Unless a person with pain has a past or current personal or family history of substance abuse, the likelihood of addiction is low when opioids are appropriately prescribed, taken as directed and monitored by a responsible and knowledgeable health care provider. Although more well-controlled studies are needed, current evidence indicates that addiction prevalence in pain patients may be no different from prevalence of addiction in the general U.S. population.^{4,5}
- Rising rates of non-medical use of prescription medications and emergency room admissions related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide.⁶ The main source of drug diversion is from theft by family members, friends and workers in the home or from the sharing and selling of medications though often with good intentions.⁷
- Diverse players (e.g., lawmakers, educators, health care providers, the pharmaceutical industry, caregivers) must come together to address the dual public health crises of the undertreatment of pain and rising prescription drug abuse.⁸
- Alleviating pain remains a medical imperative — one that must be balanced with measures to address rising non-medical use of prescription drugs and to protect the public health.⁸

Opioids 101

Opioids include morphine, oxycodone, oxymorphone, hydrocodone, hydromorphone, methadone, codeine and fentanyl. Opioids are classified in several ways, most commonly based on their origin and duration of effects.⁹

Common classifications for opioids^{9,10}

SOURCE	Natural or semisynthetic: Contained in or slightly modified (semisynthetic) from chemicals found in poppy resin	Synthetic: Synthesized in the laboratory
DURATION OF RESPONSE	Short-acting: Provide quick-acting pain relief and are used primarily as “rescue medication,” as in acute pain	Long-acting: Provide longer duration of pain relief and are most often used for stable, chronic pain

One of the advantages of opioids is that they can be given in so many different ways. For example, they can be administered by mouth, oral mucosal or sublingual delivery systems, rectal suppository, intravenous injection (IV), subcutaneously (under the skin), transdermally (in the form of a patch) or into a region around the spinal cord. Patches, IV injections and infusions are very important for patients who cannot swallow, or whose GI tracts are not working normally.¹¹

Opioids are believed to work by binding to specific proteins (opioid receptors), which are found in specialized pain-controlling regions of the brain and spinal cord. When these compounds attach to certain opioid receptors, the electrical and chemical signals in these regions are altered, ultimately reducing pain.⁹

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain¹²

However, some types of pain, such as pain caused by nerve compression or destruction, do not appear to be relieved by opioids.¹⁰

Adverse Effects

Side effects of opioids result primarily from activation of opioid receptors outside and within the nervous system. Activation of opioid receptors in the gut, for example, may cause constipation,

nausea and vomiting, and other gastrointestinal effects. Tolerance to nausea and vomiting usually develops within the first few days or weeks of therapy, but some people are intolerant to opioids and experience severe adverse side effects.¹⁰ Other side effects include drowsiness, mental clouding and, in some people, euphoria.⁹ Recent research shows that genetic variations may influence opioid metabolism.

Depending on the amount taken, opioids can depress breathing. However, this effect usually is not present after someone has taken opioids over time. The risk of sedation and respiratory depression is heightened when opioids are taken with other sedating medications (e.g., antihistamines, benzodiazepines), reinforcing the need to carefully monitor individuals who are taking such combinations.

Careful Monitoring and Open Communication

People taking opioids must be carefully selected and monitored by a knowledgeable and responsible prescriber. People with pain should speak openly with their health care provider about noticeable improvements in functioning, as well as side effects and other concerns (e.g., constipation, fears of addiction).

The American Pain Foundation's *Targeting Chronic Pain* materials help facilitate open dialogue between people who live with pain and their health care team, and give prescribers tools for selecting, monitoring and following their patients. To access these resources, visit www.painfoundation.org and click on Publications under the Learn about Pain tab.

The Four "A's"

The Four "A's" of pain management are used by clinicians to measure key treatment outcomes — pain relief, psychosocial functioning, side effects and addiction-related outcomes.

Analgesia – Is the pain relief clinically significant? Is there a reduction in the pain score (0-10)?

Activity levels – What is the patient's level of physical and psychosocial functioning? Has treatment made an improvement?

Adverse effects – Is the patient experiencing side effects from pain relievers? If so, are they tolerable?

Aberrant behaviors – Are there any behaviors of concern such as early refills or lost medication? Does the patient show signs of misuse, abuse or addiction? What is the plan of action?

Source: Passik & Weinreb, 1998; Passik & Portenoy, 1998

**Dual Public Health Crises:
Balancing Medical Imperative to
Relieve Suffering and Protect
Public Safety**

Pain affects more Americans than diabetes, heart disease and cancer combined, and it is one of the leading causes of disability in the United States. Recognition of pain as a growing public health crisis has led to the establishment of specialized pain clinics, treatment guidelines for certain types of pain, as well as greater use of treatment strategies to effectively alleviate pain and improve functioning, including prescription pain medicines.

As the therapeutic use of opioids has increased to appropriately address pain, there has been a simultaneous and dramatic rise in non-medical use of prescription drugs.¹³ When misused — that is, taken by someone other than the person for whom the medication was prescribed, or taken in a manner or dosage other than what was prescribed — prescription medications can produce serious adverse health effects and can lead to addiction, overdose and even death.

People who abuse opioids typically do so for the euphoric effects (e.g., the “high”); however, most abusers are **not** patients who take opioids to manage pain.¹⁴ Rather, they are often people within the social network of the person who possesses a lawful prescription. In fact, 71 percent of people abusing prescription pain relievers received them from a friend or family member without a prescription.⁷ Prescription pain relievers are frequently illegally stolen from medicine cabinets, purchased or shared in schools, or simply given away.

Picture of Prescription Drug Abuse in America

- In 2009, 16 million Americans 12 years of age and older had taken a prescription pain reliever, tranquilizer, stimulant or sedative for non-medical purposes at least once in the previous year.¹⁴
- The rate of non-medical use of medications has risen among teenagers. In fact, prescription drugs are now the second most abused category of drugs behind marijuana.¹⁵
- In 2007, 93 percent of unintentional poisoning deaths in the U.S. were caused by drugs. Opioid pain medications, such as methadone, hydrocodone, or oxycodone, were most commonly involved, followed by cocaine and heroin.¹⁶
- Most people who use prescription drugs nonmedically (7 out of 10) get them from friends or family; very few obtain them from drug dealers or the Internet.¹⁴

Nonmedical use includes misuse, abuse or otherwise not taking a drug as prescribed.

The growing prevalence of prescription drug abuse not only threatens the lives of abusers; concerns about misuse, abuse and diversion may also jeopardize effective pain management by impeding appropriate access to opioids for legitimate medical need. Concern about scrutiny by regulators or law enforcement, and specific action by some agencies, has had a “chilling effect” on the willingness of some doctors, nurse practitioners and physician assistants to prescribe opioids.^{8,17} Moreover, high profile reports of drug abuse, diversion and addiction, or of legal actions taken against prescribers have helped perpetuate a negative — and

often false — picture of chronic pain management.⁸ Over time, these reports overshadow the stories of people with pain — those whose lives have been shattered by unrelenting pain — who get needed pain relief from these medications. Understanding the difference between tolerance, physical dependence, abuse and addiction is also critical to telling the story. According to medical experts, use of the term “narcotic” in news reports may further reinforce the myths and misconceptions of this class of drugs, given the negative connotation.⁸

“Clinicians continue to approach opioid prescribing with a spectrum of highly diverse practices, from complete avoidance to alacrity. Both extremes ignore either patient-specific indications and context for opioid therapy or the risks associated with such therapy. Idiosyncratic approaches need to give way to principles-based practices, focusing on well-established therapeutic goals and clinical indications, risk stratification and matched structuring of care, titration and stabilization, ongoing monitoring and outcomes (safe and effective use).”

— Perry Fine, MD, Topics in Pain Management

Strategies to Address Twin Public Health Crises

Systematic and targeted approaches are essential to address the growing prevalence and complexity of the non-medical use of prescription drugs, while simultaneously ensuring that people with legitimate medical needs receive effective treatment.

These approaches can generally be categorized as follows:

- Legislative strategies to create balanced and consistent laws and improve state-based prescription drug monitoring programs.
- Educational efforts to raise awareness about prescription drug abuse and its dangers among schools, families, health care providers, patients and potential abusers.
- Greater public awareness and acceptance of pain and the need to be able to access appropriate treatment with medical oversight.
- Medical strategies to help identify and monitor people with pain who require opioid management, incorporating risk

management into the treatment plan (e.g., informed consent, appropriate pain assessment, diagnostic testing and monitoring, transition planning, collaborative practice with addiction medicine and behavioral health specialists as indicated).

- Pharmaceutical industry strategies to help prevent misuse, abuse and diversion by developing new tamper resistant packaging and/or formulations (e.g., tamper-resistant bottles, electromagnetic chips to track medication, new formulations that could resist or deter common methods of opioid abuse).

For additional recommendations, see the American Pain Foundation’s report outlining critical barriers to appropriate opioid prescribing for pain management, *Provider Prescribing Patterns and Perceptions: Identifying Solutions to Build Consensus on Opioid Use in Pain Management*. This 16-page report calls for a more balanced perspective of the risks and benefits of these medications in practice and policy and summarizes key challenges and actionable solutions discussed by leading pain experts at a roundtable meeting hosted by APE.

Making the Grade: Evaluation of State Policies

The Pain & Policy Studies Group (PPSG) report “Achieving Balance in State Pain Policy: A Progress Report” graded states on quality of its policies affecting pain treatment and centered on the balance between preventing abuse, trafficking and diversion of controlled substances and simultaneously ensuring the availability of these medications for legitimate medical purposes. PPSG researchers evaluated whether state pain policies and regulations enhance or impede pain management and assigned each state a grade from ‘A’ to ‘F.’

State Grades for 2008

State	2008 Grade	State	2008 Grade
Alabama	B+	Montana	C+
Alaska	C+	Nebraska	B+
Arizona	B+	Nevada	C
Arkansas	B	New Hampshire	B
California	B	New Jersey	C+
Colorado	B	New Mexico	B+
Connecticut	B	New York	C
Delaware	C+	North Carolina	B
District of Columbia	C+	North Dakota	B
Florida	B	Ohio	B
Georgia	B	Oklahoma	C+
Hawaii	B	Oregon	A
Idaho	B	Pennsylvania	C+
Illinois	C	Rhode Island	B+
Indiana	C+	South Carolina	C+
Iowa	B	South Dakota	B
Kansas	A	Tennessee	C
Kentucky	B	Texas	C
Louisiana	C	Utah	B+
Maine	B+	Vermont	B+
Maryland	B	Virginia	A
Massachusetts	B+	Washington	B+
Michigan	A	West Virginia	B
Minnesota	B+	Wisconsin	A
Mississippi	C+	Wyoming	C+
Missouri	C+		

Source: The Pain & Policy Studies Group, http://www.painpolicy.wisc.edu/Achieving_Balance/PRC2008.pdf.

At a Glance: Differentiating physical dependence, tolerance, abuse and addiction

Unfortunately, confusion between normal physiological responses to opioids (physical dependence and analgesic tolerance) and pathological phenomena such as addiction or substance abuse persist. Such misunderstandings not only reinforce the stigma surrounding medical use of these medicines, they also fuel fears of addiction and, in turn, may impinge on access to these medications for legitimate medical need. Although opioids have an abuse liability, clinical studies have shown that the potential for addiction is low for the vast majority of individuals using opioids for the long-term management of chronic pain.¹⁹ As with any medication, there are risks, but these risks can be managed.

“Universal agreement on definitions of addiction, physical dependence and tolerance is critical to the optimization of pain treatment and the management of addictive disorders.”

— Consensus document from the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine

Physical dependence is characterized by biological changes that lead to withdrawal symptoms (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) when a medication is discontinued. Physical dependence differs from psychological dependence, or the cravings for the euphoria caused by opioid abuse. Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation.⁹

Analgesic tolerance is a biological process in which a patient requires increasing amounts of a medication to achieve the same amount of pain relief. Dose escalations of opioid therapies are sometimes necessary and reflect a biological adaptation to the medication. Although the exact mechanisms are unclear, current research indicates that tolerance to opioid therapy develops from changes in opioid receptors on the surface of cells.⁹ Thus, the need for higher doses of medication is not necessarily indicative of addiction.³

Addiction is a disease characterized by preoccupation with and compulsive use of a substance, despite physical or psychological harm to the person or others.³ Behaviors suggestive of addiction may include: taking multiple doses together, frequent reports of lost or stolen prescriptions, and/or altering oral formulations of opioids.

Abuse is the intentional self-administration of a medication for a non-medical purpose, such as to obtain a high.³ Both the intended patient and others have the potential to abuse prescription drugs; in fact, the majority of people who abuse opioids do not suffer from chronic pain.¹⁴

Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately “drug seeking,” which may be misidentified as addiction by the patient’s physician. Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.³

MISUSE VS. ABUSE

- **Medication Misuse:** Legitimate use of a valid personal prescription but using differently from provider's instruction, such as taking more frequently or higher than the recommended doses. Use may be unintentional and considered an educational issue.
- **Medication Abuse:** Using a valid personal prescription for reasons other than its intent, such as to alleviate emotional stress, sleep restoration/prevention, performance improvement, etc. Use may be unintentional and considered an educational issue.
- **Prescription Drug Misuse:** Intentional use of someone else's prescription medication for the purpose of alleviating symptoms that may be related to a health problem. The use may be appropriate to treat the problem but access to obtain this drug may be difficult/untimely or may have been provided from a well-intentioned family member or friend.
- **Prescription Drug Abuse:** Intentional use of a scheduled prescription medication to experiment, to get high or to create an altered state. Access to the source may be diversion from family, friends or obtained on the street. Inappropriate or alteration of drug delivery system, used in combination with other drugs or used to prevent withdrawal from other substances that are being abused are included in this definition.

Source: Carol J. Boyd PhD, MSN, RN; Director: Institute for Research on Women and Gender, Substance Abuse Research Center, University of Michigan

Risk factors for opioid addiction include, but are not limited to:^{2,3}

- Personal or family history of prescription drug or alcohol abuse
- Cigarette smoking
- History of motor vehicle accidents
- Substance use disorder
- Major psychiatric disorder (e.g., bipolar disorder, major depression, personality disorder)
- Poor family support
- History of preadolescent sexual abuse

NOTE: Unless an individual has a past or current history of substance abuse, the potential for addiction is low when opioid medications are appropriately prescribed by a licensed health care provider and taken as directed. Those with chronic pain and addictive disease deserve the same quality of pain treatment as others and will require greater structure and resources in their care.

WEB RESOURCES

PainSAFE

www.painsafe.org

Opioid RX

http://pain-topics.org/opioid_rx/

Tufts Health Care Institute Program on Opioid Risk Management

<http://www.thci.org/opioid/>

Emerging Solutions

http://www.emergingsolutionsinpain.com/index.php?option=com_continued&cat=37&Itemid=303

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Topic Brief

PAIN MANAGEMENT & DISPARITIES

The undertreatment of pain in America is a growing public health crisis, especially among underserved populations, including ethnic minorities, women, older Americans and those who are socioeconomically disadvantaged.

Despite an overall improvement in health for most Americans, certain segments of the population continue to experience poor health status.¹ There is compelling evidence that minorities are less likely to have access to routine, coordinated medical care or health insurance than whites. They are also more likely to receive inappropriate or insufficient care, resulting in poorer health outcomes.

As the U.S. population becomes increasingly diverse, there is an urgent need to eliminate health disparities. Patients have a right to appropriate assessment and treatment of their pain without regard to race, ethnicity or other factors.

“Of all the forms of inequality, injustice in health is the most shocking and the most inhumane.”

—Martin Luther King, Jr.

Health Disparities Defined

According to the National Institutes of Health, health disparities are defined as “differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States.”

Disparities in health care are complex and multifaceted resulting from:

- Patient/personal factors (e.g., low socioeconomic status, communication barriers)
- Health care provider factors (e.g., bias, cultural insensitivity)
- Systematic/health system factors (e.g., health insurance status, access to care)



Snapshot of U.S. Population, An Older and More Diverse Nation

According to projections by the U.S. Census Bureau:

- Minorities now comprise roughly one-third of the U.S. population.
- By 2023, more than half of all children will be from minority groups.
- Minorities are expected to become the majority in 2042.
- In 2050, the nation is projected to be 54 percent minority.
- The Latino population, already the nation’s largest minority group, will triple in size between 2005 and 2050.
- The nation's population of elders will more than double in size from 2005 through 2050 as the baby boom generation enters traditional retirement years.

Source: U.S. Census Bureau, 2008, <http://www.census.gov/PressRelease/www/releases/archives/population/012496.html>; Pew Hispanic Center.

Disparities in Pain Care

Pain is widely recognized as an undertreated health problem in the general population.² However, a growing body of research reveals even more extensive gaps in pain assessment and treatment among racial and ethnic populations, with minorities receiving less care for pain than non-Hispanic whites.^{3,4,5,6}

Differences in pain care occur across all types of pain (e.g., acute, chronic, cancer-related) and medical settings (e.g., emergency departments and primary care).^{3,4,5,6,7} Even when income, insurance status and access to health care are accounted for, minorities are still less likely than whites to receive necessary pain treatments.^{3,4,8}

Minorities are less likely to:

- Have access to pain management services and treatments
- Have their pain documented by health care providers
- Receive pain medications

And more likely to:

- Use the emergency department for pain care, but less likely to receive adequate care
- Experience greater severity of pain
- Experience and report physical disability
- Experience poorer health and quality of life related to pain

There are clear variations in the way pain is assessed and managed among all minority populations. Significant gaps exist in the provision of effective quality pain care due to the lack of research and medical training focused on pain care disparities.^{3,4,9}

Research also shows gender differences in the experience and

RESEARCH ON DISPARITIES IN PAIN CARE HAVE SHOWN:

- Blacks were less likely than whites to receive pain medication and had a 66 percent greater risk of receiving no pain medication at all.^{5,6,7,9}
- Hispanics were twice as likely as non-Hispanic whites to receive no pain medication in the emergency department (55 percent of Hispanics received no pain medication vs. 26 percent of non-Hispanic whites).^{7,10}
- Minority patients were less likely to have pain recorded relative to whites, which is critical to providing quality patient care.¹¹
- Only 25 percent of pharmacies in predominantly nonwhite neighborhoods had opioid supplies that were sufficient to treat patients in severe pain, as compared with 72 percent of pharmacies in white neighborhoods.¹²
- In a study of minority outpatients with recurrent or metastatic cancer, 65 percent did not receive guideline-recommended analgesic prescriptions compared with 50 percent of nonminority patients ($P < 0.001$). Hispanic patients in particular reported less pain relief and had less adequate analgesia.¹³

treatment of pain. Most chronic pain conditions are more prevalent among women; however, women's pain complaints tend to be poorly assessed and undertreated.³

Additionally, gender differences have been identified in patient responsiveness to analgesics and pain stimuli. While estrogen and progesterone play a role in how pain signals are received in men and women, psychology and culture may also account for some of the difference. For example, children may learn how to respond to pain later in life depending on how their pain complaints were treated in their formative years (e.g., receiving comfort and validation versus being encouraged to tough it out or dismiss the pain).¹⁴ For more information, see the *Special Considerations: Pain in Specific Populations Topic Brief*.

In response to the overwhelming discrepancies in pain treatment among minority groups, the Joint Commission issued a statement recognizing the rights of all patients to receive appropriate assessment and management of pain, and the World Health

Organization has declared that pain relief is a human right.

Patient and provider factors drive pain disparities

Multiple factors contribute to racial and ethnic disparities in pain care, including beliefs about pain, preconceived bias and cultural insensitivity and poor patient-provider communication.

Positive physician-patient interaction and communication is critical in accurate pain assessment.² Some research has shown that patients take a more active role in their own pain treatment when their health care providers are of similar ethnic backgrounds.^{3,4}

“Pain is a complex, subjective response with several quantifiable features, including intensity, time course, quality, impact, and personal meaning. The reporting of pain is a social transaction between caregiver and patient.”¹⁵

Patient sources of racial and ethnic disparities:³

- Low socioeconomic status
- Patients’ attitudes or beliefs regarding pain and patient-level decision making and preferences
 - Stoicism and the belief that pain is an inevitable part of disease
- Minority patients more likely to:
 - Refuse recommended pain therapies
 - Poorly adhere to treatment regimens
 - Delay seeking medical care
- Mistrust of physicians or previous negative experiences with health care system
- Limited health literacy
- Language barriers that hinder communication with providers

Physician sources of racial and ethnic disparities:³

- Perceptions of race and ethnicity
- Racism or bias
- Poor cross cultural communication skills/cultural insensitivity
- Underrepresentation of physicians from racially/ethnically diverse backgrounds/lack of cultural sensitivity

HOT TOPICS

Disparities & Pain: HOT TOPICS

- Aging and increasingly diverse U.S. population could lead to greater disease burden if pain remains untreated
- Undertreatment of minorities in emergency departments
- Minority pain complaints receive less attention than others
- Impact of pain on productivity and quality of life among minority patients
- Pain relief as a human right

Minorities lack access to effective pain care

Limited access to pain care services is a key contributor to poorer pain treatment among minorities.

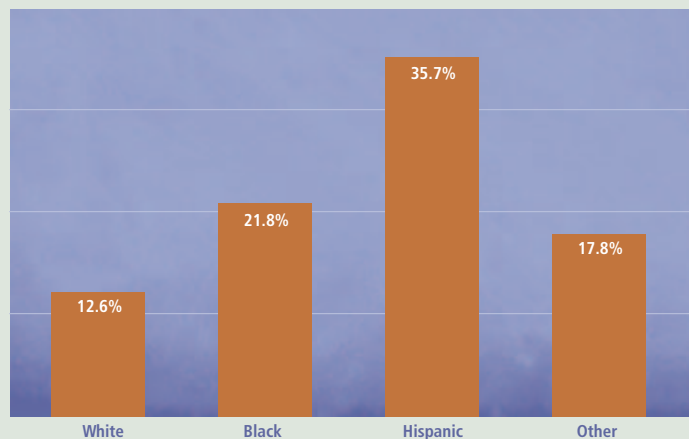
- Overall, minorities tend to be financially poorer than non-Hispanic whites.
- Socioeconomic factors can impede access to health insurance and primary health care services, and minorities are less likely to have access to pain treatment services than the general population.^{3,4,7,16,17}
- Racial and ethnic minorities are at increased risk of having their pain complaints ignored by health care providers, thereby limiting their options for accessing appropriate pain treatment.^{3,4,6,7}

According to the Robert Wood Johnson Foundation, 46 million

Americans, including 9 million children, are living without health care coverage. More than eight out of 10 are from working families. The consequences of being uninsured are widely recognized and include: lack of access to health care, poor quality care, lost economic productivity, as well as financial burdens on individuals and society overall. As the minority population in the U.S. continues to grow, it becomes increasingly important to address the numbers of uninsured and underinsured among racial and ethnic groups.

Barriers also exist in patient access to pain medications. Research shows that physicians may be less likely to prescribe pain medications for minority populations^{6,7,16,18} and pharmacies in neighborhoods with large minority populations often do not carry opioid medications.^{3,4,12}

PERCENTAGE UNINSURED AMONG THE NONELDERLY POPULATION BY RACE AND ETHNIC ORIGIN, 2006



Sources: Employee Benefit Research Institute estimates from the March Current Population Survey, 2007 Supplement. Cover the Uninsured, www.covertheuninsured.org.

“Inequities in access can contribute to and exacerbate existing disparities in health and quality of life, creating barriers to a strong and productive life.”

— The Commonwealth Fund

More extensive research needed to close disparities gap

While national attention has become increasingly focused on health disparities, less attention has been given specifically to inequities in pain care.^{19,20} However, the growing interest in health disparities in general provides pain treatment providers, researchers and advocates with an opportunity to raise awareness about disparities in pain management and the need for additional pain disparities research. Currently, the social impact of pain on patients, their families and communities is largely absent in most federal research plans.^{3,4}

Additional studies and a comprehensive pain research agenda are needed to:

- Understand the role of stereotypes and bias in doctor-patient interactions
- Improve training for health care providers
- Plan educational interventions for patients
- Understand the differences in patient behaviors that may contribute to pain care disparities
- Develop culturally sensitive pain assessment tools
- Raise consciousness about disparities in pain management and barriers to effective health care overall

WEB RESOURCES

CDC Office of Minority Health and Health Disparities

<http://www.cdc.gov/omhd/>

Cover the Uninsured: a Project of the Robert Wood Johnson Foundation

<http://covertheuninsured.org/>

American Pain Society: Racial and Ethnic Identifiers in Pain Management: The Importance to Research, Clinical Practice, and Public Health Policy

<http://www.ampainsoc.org/advocacy/ethnoracial.htm>

Agency for Health care Research and Quality: Addressing Racial and Ethnic Disparities in Health Care

<http://www.ahrq.gov/research/disparit.htm>
<http://www.ahrq.gov/qual/nhdr03/nhdrsum03.htm>

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SPECIAL CONSIDERATIONS: PAIN IN SPECIFIC POPULATIONS

Although pain is a significant problem among all Americans, certain populations are more susceptible to and at greater risk for undertreatment, including children, minorities and those with advanced, life-limiting medical illness. Studies conducted in emergency departments suggest that women receive less attention in response to reports of severe pain than men. Also, due to military training and culture which teaches service members to be tough, and the complex nature of pain and post-traumatic stress, active duty military personnel and veterans tend to experience greater challenges achieving optimal pain relief than the civilian population.

In order to provide the most effective pain care possible and minimize pain-related morbidity, characteristics of vulnerable populations must be taken into consideration when performing pain assessment and implementing treatment plans. Health care professionals must also become aware of their own biases and understand that, regardless of demographic or social position, every individual with pain requires evaluation and treatment tailored to his or her specific clinical circumstances.

Children and Pain

Every child will experience pain at one time or another, whether it's from everyday bumps and bruises, or more chronic conditions such as headaches, gastrointestinal problems or diabetes. In fact, chronic pain affects up to 38 percent of children.¹

Pediatric pain stems from a wide range of chronic conditions. For example:

- Each year, 1.5 million children have surgery, and many receive inadequate pain relief. In 20 percent of cases, the pain becomes chronic.²
- Of children aged 5 to 17 years, 20 percent suffer headaches.²
- More than one-third of children complain of abdominal pain lasting two weeks or longer.³
- Juvenile arthritis, which causes joint inflammation and aches, affects nearly 250,000 people under the age of 16 years.⁴
- About one in 1,000 U.S. children are cancer survivors and may have to deal with late and long-term effects of treatment (e.g., chronic fatigue and pain syndromes, nerve damage).²
- Recent evidence reveals reduced pain sensitivity is a common feature of children with autism

and Asperger's syndrome.²

- Musculoskeletal pain can result from "growing pains," a normal occurrence in about 25 to 40 percent of children.⁵

COMMON CAUSES OF PAIN IN CHILDREN

- Abdominal pain (e.g., irritable bowel syndrome, ulcerative colitis)
- Headaches
- Scrapes and bruises
- Needlestick pain from immunizations (most children receive up to 24 immunizations by their 2nd birthday)
- Sports injuries (e.g., sprains, concussion, fractures)
- Chronic illnesses (e.g., sickle cell disease, type I diabetes)

According to the American Medical Association, children and infants are at increased risk of inadequate pain management, with age-related factors playing a major role. Physical and psychological changes that occur during childhood development can make understanding and managing pain in children significantly more complicated than treating pain in adults. Many things affect the way a child experiences, communicates

and responds to pain, including their:

- age
- beliefs and understanding of what is causing the pain
- ability to cope
- activity and anxiety levels
- previous experiences with pain and how they learned to respond
- support from parents and siblings
 - parental pain, stress and family functioning may also play a role in pediatric pain
 - preliminary data suggest that a mother's anxiety may be transmitted more strongly to her daughters than her sons, resulting in increased anxiety and pain in girls, but not boys.⁶

If pain is not addressed and treated early on, it can greatly impact a child's quality of life by interfering with mood, sleep, appetite, school attendance, academic performance, and participation in sports and other extracurricular activities. Furthermore, if unrelieved, childhood pain can pave the way to more pain later in life.⁷ It is essential that health care providers

begin to approach pediatric pain so that appropriate strategies can be devised to target and reduce children’s distress and pain-related disability.

Unaddressed pain can also result in significant financial stress for families who not only have to cover health care expenses, but who may also have to miss work to care for a sick child.⁸

Inadequate prevention and relief of pediatric pain are still widespread. Many obstacles exist to providing appropriate pain care to children and adolescents:¹⁰

- Beliefs and attitudes about the experience of pediatric pain.
- General lack of understanding about the best course of action for treating children in pain.
- Belief that pain should be treated less aggressively in children than adults.
- Pediatric pain management research has not been effectively translated into routine clinical practice.
- Pain in children with disabilities or other special health care needs may be more difficult to assess.

MYTHS AND TRUTHS ABOUT PAIN IN CHILDREN

MYTH: Children who are playing or sleeping must not be in pain.
TRUTH: Children cope with pain by distracting themselves, often through play. Sleep may also be a coping mechanism, and/or because they are exhausted.

MYTH: Young infants do not feel pain because their nervous systems are immature and unable to perceive and experience pain the way adults do.

TRUTH: Decades ago it was believed that a newborn couldn’t feel pain, and surgery was routinely performed on infants without anesthetic. Today, we know that the central nervous system of a 26-week-old fetus has the capability of experiencing pain. There is strong evidence that children experience increasing anxiety and perception of pain with multiple procedures or painful stimuli.⁸

MYTH: Children can easily become addicted to pain medications.

TRUTH: Less than 1 percent of children treated with opioids become addicted.⁹

MYTH: Children will tell adults when they are having pain.

TRUTH: Children may not have the words to express pain (e.g., hurt, “ouch”) or know to point to where it hurts. They may also be afraid of the consequences (e.g., extra visits to the pediatrician, shots, medicine). There are many tools available to assess pain in children. Adults need to recognize how children of different ages express pain in both behaviors and words.

Potential barriers to the effective treatment of pain in children¹⁰

- The myth that children, especially infants, do not feel pain the way adults do;
- Lack of routine assessment for the presence of pain in children;
- The idea that treating pediatric pain takes too much time and effort;
- Fears of adverse effects of analgesic medications, including respiratory depression and addiction;
- Differing personal values and beliefs of health care professionals about the meaning and value of pain in the development of the child (e.g., the belief that pain builds character).

WEB RESOURCES

American Pain Society
www.ampainsoc.org

**International Association for the Study of Pain
 Pain in Children**
<http://childpain.org>

UCLA Pediatric Pain Program
www.mattel.ucla.edu/pedspain/home.php

American Academy of Pediatrics
www.aap.org

Whole Child Foundation
www.wholechildla.org

Gender and Pain

Although it has long been thought that women and men have similar pain experiences, recent research reveals significant differences in the way male and female brains process pain,¹ as well as in women's expression of pain and their responsiveness to analgesics and pain stimulus.^{2,3}

Historically, women have been categorized as being emotional and overly sensitive; often influencing the way physicians assessed and managed their pain.⁴ Even though research now shows that chronic pain conditions are generally more prevalent among women, they continue to be treated less aggressively for their pain than men.^{5,6} And while women are more likely than men to seek treatment for their pain, they are less likely to receive it.⁷

Women report pain more often than men do and in more body regions, and they also tend to have more severe, recurrent and persistent pain, as well as a reduced pain threshold when compared with men.³ However, despite their increased pain burden, women reportedly cope with pain better than men, possibly due to the fact that they experience pain more often throughout the course of their lives (e.g., menstruation, pregnancy and child birth, and other health issues specific to women).³

Female hormones are also likely to play a role in pain perception. Some pain conditions like migraine tend to vary with a woman's menstrual cycle, and many of the observed gender differences in pain appear to diminish following the reproductive years.⁸

Hormones May Influence Pain Experience

- Estrogen administration in women and in men can increase the incidence of chronic pain conditions.^{9,10}
- Variations in women's estrogen levels, like those that occur during the menstrual cycle or during pregnancy, may regulate the brain's natural ability to suppress pain.¹¹
- Some pain conditions such as migraine and fibromyalgia tend to fluctuate with a woman's menstrual cycle.
- Observed gender differences in pain appear to diminish following menopause.

Additionally, cultural conditioning may impact the expression of pain among women and men. As children, girls are more likely to be permitted to express pain and show emotion than boys, and attitudes about the social acceptability of gender and pain often carry into adulthood.³

Potential Sources of Gender Differences in Pain

Biological factors including:

- sex hormones
- genetics
- anatomical differences

Psychosocial influences including:

- emotion (e.g., anxiety, depression)
- coping strategies
- gender roles
- cultural conditioning
- health behaviors
- use of health care services

As advances in brain imaging technology provide further insights into gender variations in the experience of pain, it is becoming evident that different pain experiences among men and women will call for different approaches to pain management.

Ongoing research is essential to achieve:

- A better understanding of the biological and psychosocial factors that influence gender differences in pain
- A greater appreciation of the different health needs of men and women
- More effective and targeted pain treatments for women

PAIN DISORDERS WITH HIGHER PREVALENCE IN WOMEN

- Migraine
- Irritable bowel syndrome
- Fibromyalgia
- Chronic pelvic pain
- Interstitial cystitis
- Temporomandibular joint disorder (TMJ)
- Breast pain (mastalgia)
- Autoimmune disorders (e.g., lupus and chronic fatigue syndrome)
- Rheumatoid arthritis
- Osteoarthritis

WEB RESOURCES

International Association for the Study of Pain: Real Women, Real Pain
www.iasp-pain.org

National Institutes of Health: Gender & Pain
http://painconsortium.nih.gov/genderandpain/summary.htm

HealthyWomen.org
www.healthywomen.org/

Society for Neuroscience: Gender & Pain
www.sfn.org/index.cfm?pagename=brainBriefings_gender_and_pain

Older Adults and Pain

As we age, pain becomes a more common problem due to the high prevalence of chronic and progressive pain-producing conditions associated with aging. It is estimated that up to 50 percent of older persons living in the community have pain that interferes with normal function, and 59 to 80 percent of nursing home residents experience persistent pain.^{1,2} Alarming, being older than 70 is the leading risk

factor for inadequate pain management.³

Diagnosing and treating pain in older adults can be challenging. Those 65 and older often present with multiple medical and nutritional problems, take multiple medications and have many potential sources of pain. Older persons with dementia or communication problems are at even greater risk of undertreatment of pain due to difficulties

communicating their pain.⁴ Use of certain medications in older persons becomes problematic because of physiological changes.⁵

The most common cause of persistent pain in older adults is musculoskeletal in nature, typically from osteoarthritis or other bone, joint and spine disorders. According to the Arthritis Foundation, arthritis affects up to 80 percent of older adults, who report being fearful of recurring pain and disability. But the predilection for painful conditions does not mean that older adults need to live with uncontrolled pain. Quite the opposite; older adults can be effectively treated, and in so doing, pain-related morbidity — and even premature mortality — can and should be obviated.

COMMON PAIN CONDITIONS IN OLDER ADULTS

- Arthritis
- Lower back and neck pain; vertebral compression fractures from osteoporosis
- Abdominal pain (e.g., gallstones, bowel obstruction, peptic ulcer disease, abdominal aortic aneurysm)
- Cancer-related pain (symptom of disease or effect of nerve damage from treatments)
- Neuropathic pain due to diabetes, herpes zoster ("shingles"), kidney disease or other medical problems
- Muscle cramps, restless leg pain, itchy skin and sores due to circulatory problems or vitamin D deficiency
- Fibromyalgia
- Complex regional pain syndrome (CRPS), a neuropathic pain condition which can develop after an illness or injury and often affects the extremities
- Injuries, especially from falls



WEB RESOURCES

Handbook of Pain Relief in Older Adults — An Evidence-Based Approach

By Gloth III, F. Michael

http://www.amazon.com/Handbook-Pain-Relief-Older-Adults/dp/1607616173#reader_1607616173

**American Medical Association
Assessing and Treating Pain in Older Adults**

http://www.ama-cmeonline.com/pain_mgmt/module05/index.htm

**American Geriatrics Society Foundation
The Management of Persistent Pain:
Resources for Older Adults and Caregivers**

http://www.healthinaging.org/public_education/pain

End-of-life and Pain

Pain control is one of the most challenging aspects of end-of-life care.¹ Terminal illness is often accompanied by severe pain, and a significant number of people suffer needlessly at the end-of-life. While the goal of end-of-life care should be making the terminally ill more comfortable, the health care system has been designed to take a curative approach to disease, rather than focusing on symptom relief.² Hospital research reveals that health care providers continue to inadequately treat pain, and tend to under-medicate terminal pain.

Individuals at end-of-life may have their pain undertreated for variety of reasons, including a lack of knowledgeable and experienced physicians and myths about addiction to pain medication, leading unnecessarily to patient and family suffering.³

Despite advances in research on end-of-life pain treatment, health care providers remain influenced by social and legal concerns, as well as misconceptions about medications including addiction, overdose, lasting side effects and diminished physical capacity.⁵ The terminally ill and their families may also hesitate to begin using pain medications as they often associate such treatment with imminent death, thereby allowing patient suffering to worsen and continue.⁴

However, thorough and ongoing pain assessment, paired with well-

designed and aggressive medication plans, as well as counseling for patients and their families can have a significant impact on pain relief and side effects among dying patients.^{4,5}

END-OF-LIFE PAIN MAY BE EXACERBATED BY MANY OTHER SYMPTOMS INCLUDING:

- Dry mouth
- Nausea
- Water retention and swelling
- Lack of appetite
- Shortness of breath
- Mental distress and anxiety caused by fear or denial of impending death

Effective pain management at the end-of-life requires addressing the total pain experience, including physical causes, as well as interpersonal and spiritual pain.^{3,4}

Pain associated with terminal illness often requires special treatment that can be best provided by hospice and palliative care programs available in many medical facilities. Hospice focuses on relieving symptoms and supporting patients who are nearing the end of their life, while palliative care is designed to provide comfort and pain relief at any time during a person's illness.⁷ The goal of both programs is to alleviate physical, emotional, spiritual pain and suffering while respecting the dignity of the individual with a life-limiting illness.

“Suicidal wishes in patients with advanced disease are closely linked to unrelieved pain and to mood alterations such as depression and anxiety, which like pain, frequently respond to clinician treatment if the clinician identifies and addresses them.”^{2,6}

Essential Components of End-of-life Care⁸

- Continual assessment and management of pain and other physical symptoms
- Assessment and management of psychological and spiritual needs
- Helping the individual identify personal goals for pain treatment and end-of-life care
- Assessment of the person's support system

WEB RESOURCES

American Academy of Family Physicians: Challenges in Pain Management at the End of Life

www.aafp.org/afp/20011001/1227.html

American Pain Society: Treatment of Pain at the End of Life

www.ampainsoc.org/advocacy/treatment.htm

Discovery Health Center: End of Life Q&A with Dr. Scott Fishman

<http://health.discovery.com/centers/pain/endoflife/endoflife.html>

National Hospice and Palliative Care Organization

www.nhpco.org/i4a/pages/index.cfm?pageid=3254

“When someone is dying, time is a luxury and wait-and-see is not an option. What matters most in the final days is that patients are free of crippling pain and unbearable suffering so that they can finish their lives in ways that bring comfort, peace, and completion. Concerns about lasting side effects or diminished physical capacity from months of using a drug become secondary to making a patient comfortable. No one has to die in pain.”

— Dr. Scott Fishman

Military/Veterans and Pain¹

Pain is a major issue among military personnel and veterans, who are at heightened risk for injury and combat wounds. Although modern body armor and rapid evacuation to medical care is saving lives, there are more maimed and shattered limbs than ever before, with instances of amputation nearly doubling since before the Vietnam War. Hundreds of thousands of returning veterans will seek medical care and claim disability compensation for a wide variety of injuries and health problems they sustained during their tours of duty. It is estimated that the U.S. will be paying the cost of related medical care and disability claims for the next 40 years.

Veterans are more likely to experience psychological distress and other medical conditions, including post-traumatic stress disorder, depression, amputations, traumatic brain injuries, substance abuse and other injuries, which further complicate effective pain management.

COMMON PAIN CONDITIONS AMONG MILITARY MEMBERS

Post-traumatic stress disorder (PTSD) commonly affects soldiers returning from war, and is triggered by exposure to a situation or event that is or could be perceived as highly threatening to a person's life or those around him/her. PTSD may not emerge for years after the initial trauma.

It is a normal reaction to an abnormal situation. Not every service member will be diagnosed with a disorder, but most will experience some level of post-traumatic stress which can exacerbate pain conditions.

Chronic pain symptoms and PTSD frequently co-occur and may intensify an individual's experience of both conditions. Together, they result in fear, avoidance behaviors, anxiety and feelings of isolation.

Amputations have long been a tragic, unavoidable consequence of combat — "one of the most visible and enduring reminders of the cost of war," according to the Amputee Coalition of America. While there have been major advances in medicine, prosthetics and technologies that allow amputees to lead more independent lives, most of these patients continue to need specialized long-term or lifelong support. Managing wound, post-operative, phantom and stump pain is important to reduce suffering and improve quality of life.

A **traumatic brain injury (TBI)** is a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain and is a major cause of lifelong disability and death. Managing pain in veterans with TBIs may be complicated by memory lapses affecting medication management, difficulty organizing and following complicated and sometimes even simple pain management regimens, and difficulty learning new coping skills. Rehabilitation should incorporate efforts to relieve associated pain.

Veterans have significantly worse pain than the general public, and while military medical care is among the best in the world, there are still long-term problems and challenges with managing disability and chronic pain.

Military culture may also present a significant barrier to appropriate pain care. The persisting stigma around pain and pain treatment is particularly pronounced in the military, and pain is often perceived as a sign of weakness leading many individuals to choose to suffer in silence. Seeking mental health care for PTSD and depression, which so often accompany pain is important; pain is best managed when depression and PTSD are treated simultaneously.

A recent analysis found that the Veterans Health Administration (VHA) is already overwhelmed by the sheer number of returning veterans and the seriousness of their health care needs. Without increased staffing and funding for veterans medical care, it will not be able to provide quality care in a timely fashion.

However, after the 2009 passage of the military and veterans pain care laws, the Department of Defense and the Veterans Health Administration have begun to work together to improve pain care for service members. They jointly developed a pain management task force and issued a report: *Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize the Care for Warriors and their Families* outlining more than 100 recommendations to improve pain care within these health care systems. To find out more, visit http://www.health.mil/Libraries/HA_Policies_and_Guidelines/11-003.pdf.

Barriers to optimal pain management among veterans and military personnel may include fears about:

- No longer being physically capable of fulfilling their duties
- Being discharged and no longer having a sense of purpose
- Letting down or losing the respect of their peers
- Becoming addicted to pain medications
- Experiencing personality changes or problems with sexual relations due to pain medications
- Losing their benefits/pension if they acknowledge a pain condition

The U.S. Veterans Health Administration is instructing physicians and nurses who treat veterans to regard pain as a “fifth vital sign,” to be routinely assessed along with blood pressure, pulse, temperature and respiration.

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WEB RESOURCES

American Pain Foundation:

Military/Veterans and Pain

www.painfoundation.org

www.exitwoundsforveterans.org

Amputee Coalition of America

www.amputee-coalition.org

Defense and Veterans Brain Injury Center

www.dvbic.org

Disabled American Veterans (DAV)

www.dav.org

U.S. Department of Veterans Affairs

www.va.gov

HOT TOPICS

Children & Pain

- Maternal anxiety influencing daughters' experience of pain
- Some neonatologists still do not treat pain in pre-term low birth weight babies because they "won't remember it"
- Investigations into "chronic daily headaches" in children
- Unraveling pediatric pain conditions and their impact into adulthood (e.g., whether complex regional pain syndrome in children leads to adult CRPS, whether irritable bowel syndrome in adolescents is this the same as IBS in adults)
- Complementary and alternative medicine: how and what is safe to use in children with chronic pain?
- Factors leading to pain-related disability in children (e.g., missing school, not sleeping, avoiding physical and social activities, not eating)

Gender & Pain

- Prevalent pain conditions in women (e.g., fibromyalgia, chronic pelvic pain)
- Interface of hormones and the pain experience
- Brain imaging, uncovering routes of pain transmission and tolerance
- Differential effects of medicines across genders
- Impact of chronic pain on sexuality and self-image



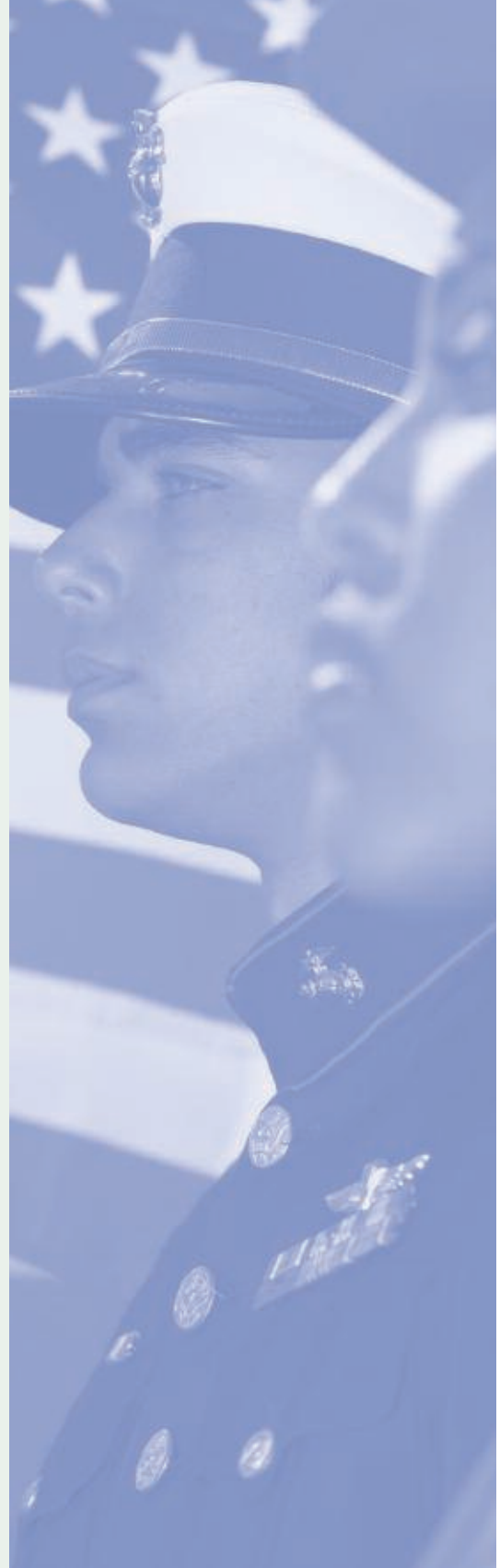
HOT TOPICS

Older Adults and End-of-life Care & Pain

- False belief that pain is an inevitable part of aging
- Vitamin deficiencies and musculoskeletal pain
- Limited consumer awareness of the options that exist other than traditional “acute care” approaches (e.g., doctor’s office visits, ER visits, hospitalizations)
- Insufficient numbers of adequately trained and skilled health care professionals to manage the myriad issues confronting patients/families with advanced medical illness; limited number of providers with specialty in geriatrics
- Variability in delivery of hospice and palliative care services across the country
- Lack of clinical research data on pain care among elders

Military/Veterans & Pain

- DOD/VA responds to the Military and Veterans Pain Care Acts of 2009
- Emerging Options: Interdisciplinary approaches to pain care
- Acupuncture now being incorporated into treatment plans at Walter Reed Army Medical Center
- Competitive athletics as a form of therapy



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