WEST VIRGINIA Department of Health & Human Resources
Bureau for Medical Services

DUR Capsules

News and Information for West Virginia Providers from the West Virginia Bureau for Medical Services (WVBMS)

Considerations when Using Controlled Substances to Treat Chronic Pain

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Impact of Chronic Pain

Acute pain is the body's response to environmental dangers, and it helps protect people from harm.[1] Chronic pain, which is defined by the International Association for the Study of Pain as "pain that persists beyond normal tissue healing time" (approximately three months), serves no physiologic purpose.[2] A survey conducted by the American Pain Society found that 9% of the adult American population suffers from moderate to severe, chronic noncancer pain.[1] Chronic pain negatively affects a patient's quality of life and also has significant impacts on society. It is the leading cause of disability and results in high healthcare costs. For example, a patient with chronic back pain has healthcare expenditures that are approximately 60% higher than someone without chronic pain. The annual economic costs of chronic pain are estimated to be over $86 billion.[1] The management of chronic pain is a balance between treating pain adequately and minimizing the risks involved with opioid therapy for both the patient and the provider.

Trends in Opioid Use

Americans consume approximately 80% of the world's opioid supply, yet only account for 4.6% of the world's population. Despite concerns with drug abuse and addiction, over 90% of patients presenting to and receiving treatment in a pain management setting are given opioids.[1] Opioid prescription drug sales have substantially increased over the last decade (Figure 1). From 1997 to 2006, methadone usage increased 1,177%, oxycodone usage increased 732%, hydrocodone usage increased 244%, and morphine usage increased by 196%.[1] The only opioids with a decline in use were codeine and meperidine (-25% and -28%, respectively). In 2006, the most commonly prescribed opioid was oxycodone. This was followed by hydrocodone, codeine and then morphine. With so many patients taking prescription opioids, it is more important than ever to ensure that these medications are used safely and effectively.

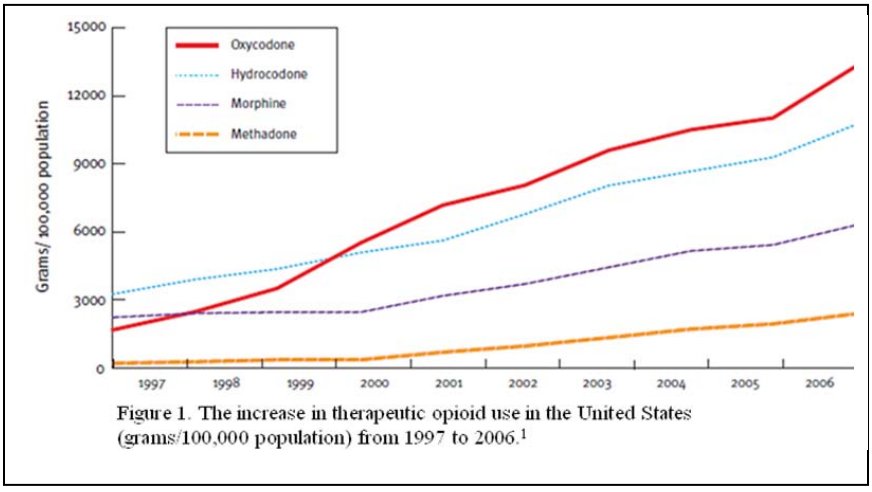

Figure 1. The increase in therapeutic opioid use in the United States (grams/100,000 population) from 1997 to 2006.[1]

Opioid Therapy Risks

With the increased use of opioids for treating conditions like chronic pain, there have also been increases in the incidence of poisonings, emergency department (ED) visits, and substance abuse. From 1999 to 2007, the number of poisoning deaths in the U.S. involving any opioid analgesic more than tripled (from 4,041 to 14,459), and accounted for 36% of the total poisoning deaths in 2007.[3] During 2004 to 2008, the estimated number of ED visits for the nonmedical use of opioid analgesics increased 111% (from 144,600 to 305,900 visits). The highest numbers of ED visits were recorded for oxycodone, hydrocodone, and methadone.[4] Although most people use prescription medications responsibly, an estimated 48 million Americans aged 12 years or older have used prescription drugs for nonmedical reasons in their lifetimes. This represents approximately 20 percent of the U.S. population.[5] According to a national survey in 2007, 5.2 million Americans aged 12 years or older were current nonmedical users of opioid pain relievers.[6]

Treatment Options

Short-Acting versus Long-Acting Opioids

Short-acting opioids (SAOs) are most frequently used for transient types of pain such as acute or intermittent pain. SAOs are often preferred for initial opioid therapy due to the fast onset of action and faster titration to effect. If the patient's pain is continuous, SAOs need to be dosed around the clock to maintain plasma levels of the medication and avoid end of dose effects like pain breakthrough. When SAOs are dosed around the clock, effective analgesia requires meticulous adherence by the patient, and it can increase a patient's pill burden substantially.[7-9] Once a daily dose of SAO has been titrated to effect and the pain is optimally controlled, switching to a long-acting agent may be appropriate.

Long-acting opioids (LAOs) are specially formulated to release a steady, controlled amount of medication into the bloodstream for an extended period of time making them ideal for persistent pain conditions. Potential benefits of LAOs include a more convenient dosing schedule, reduced pill burden, improved medication adherence, improvement in sleep, and more consistently controlled analgesia.[7-9] Many SAOs also have a long-acting formulation (i.e., buprenorphine, fentanyl, hydromorphone, morphine, oxycodone, tramadol, and oxymorphone),[10] thereby facilitating the transition from a short- to long-acting agent.

Treatment regimens for chronic pain often include both a long-acting and short-acting opioid.[8] The long-acting component is used to achieve a baseline level of adequate pain control, while the short-acting component is used on an as needed (PRN) basis for breakthrough pain or acute worsening of the chronic pain condition.[7-9] However, if the SAO is being utilized disproportionately to the LAO, then a regimen adjustment should be considered after determining the cause for the increased utilization. It may be due to an acute event or because the LAO is not achieving an adequate level of baseline pain control. It may also be due to misuse or abuse of the SAO.

Potential for Adverse Drug Events with Combination Products

In one study, 60% of unintentional acetaminophen overdoses involved the use of a combination drug product.[11] Codeine, hydrocodone, oxycodone, and tramadol are all available as combination products with acetaminophen. Hydrocodone and oxycodone are also available in formulations with ibuprofen. The maximum adult daily doses of acetaminophen and ibuprofen are 4000 mg and 3200 mg, respectively.[10] Theoretically, most opioids have no maximum or ceiling dose. However, when used in a combination product, the amount of opioid that can be used becomes limited by the amount of acetaminophen or ibuprofen (Figure 2).[2] Because patients have access to acetaminophen and ibuprofen in over-the-counter products, they may inadvertently exceed the daily maximum doses when using these products with a combination opioid formulation. In an effort to improve patient safety, the U.S. Food and Drug Administration (FDA) has asked drug manufacturers to limit the strength of acetaminophen in prescription drug products to 325 mg per tablet, capsule, or other dosage unit.[12] This will involve reformulation of many combination opioid products before January 14, 2014.

Select Combination Opioid & Acetaminophen Products[10]					
	Strength(s) of Opioid Component Per Tablet	Amount of Acetaminophen Per Tablet	**Max Tablets Per Day**	Corresponding Daily Dose of Acetaminophen	Respective Daily Dose(s) of Opioid Component
Hydrocodone	5 mg, 7.5 mg, 10 mg	325 mg	**12**	3900 mg	60 mg, 90 mg, 120 mg
	2. 5 mg, 5 mg, 7.5 mg, 10 mg	500 mg	**8**	4000 mg	20 mg, 40 mg, 60 mg, 80 mg
	7.5 mg, 10 mg	650 mg	**6**	3900 mg	45 mg, 60 mg
	7.5 mg, 10 mg	750 mg	**5**	3750 mg	37.5 mg, 50 mg
Oxycodone	2.5 mg, 5 mg, 7.5 mg, 10 mg	325 mg	**12**	3900 mg	30 mg, 60 mg, 90 mg, 120 mg
	7.5 mg	500 mg	**8**	4000 mg	60 mg
	10 mg	650 mg	**6**	3900 mg	60 mg
Codeine	15 mg, 30 mg, 60 mg	300 mg	**13**	3900 mg	195 mg, 390 mg, 780 mg
	30 mg, 60 mg	650 mg	**6**	3900 mg	180 mg, 360 mg
Tramadol	37. 5 mg	325 mg	**10**	3250 mg	375 mg (max is 400 mg/day)

Figure 2. Shows maximum tablets/day of a given combination product without exceeding 4000 mg of acetaminophen and the corresponding daily opioid analgesic dose. This assumes the combination opioid product is the only source of acetaminophen.

Standards of Practice

The American Pain Society and the American Academy of Pain Medicine published guidelines for the use of chronic opioid therapy in the management of chronic noncancer pain in 2009.[2] These guidelines cover opioids used to manage all chronic pain conditions outside of cancer pain and end of life pain/palliative care. The American Society of the Interventional Pain Physicians (ASIPP) also updated their guidelines for opioid therapy in the management of chronic noncancer pain in 2008.[1] The benefits of non-opioid and interventional therapy should be considered and weighed against the potential benefits and risks of opioids. Randomized trials that have shown chronic opioid therapy to be beneficial have demonstrated that the benefits are most applicable to patients with moderate or more severe pain who have not responded to non-opioid therapies.[1,2]

Prescribing Principles

Opioid therapy should always be individualized to the specific patient.[1,2,9] Currently, there is insufficient evidence to indicate superiority of any particular opioid agent, or to recommend short-acting versus long-acting opioids or even around-the-clock dosing versus as needed dosing in all situations.[1,2,9] These decisions should be tailored to the patient's pain severity, medical and social history, previous opioid experiences and other individual factors. The available routes of drug administration and elimination may also influence selection, particularly in patients with renal and/or hepatic impairment. In opioid-naïve patients, therapy should be initiated with the lowest dose possible and then titrated based on pain severity and the tolerability of adverse effects.[1,2,9] Short-acting agents may be preferred during the initial opioid trial because they have a shorter half-life and are easier to titrate. Temporal pain patterns may suggest a benefit to around-the-clock dosing versus as needed dosing. Clinicians should also consider if a patient would benefit from a long-acting opioid agent. Most of the assumed advantages of LAOs (e.g., more consistent pain control, improved adherence, lower risk of addiction) are based on clinical experience rather than evidence from randomized controlled clinical trials.[1,2,9]

Risk for Misuse/Abuse

Predicting the risk of opioid misuse is imprecise and can have significant consequences for both the patient and the prescriber if incorrect assumptions are made. Instituting a universal precautions approach (Figure 3) for the assessment of every patient being considered for opioid therapy will help standardize this process. The assumption is that every patient has some degree of risk. The West Virginia Board of Medicine Policy for the Use of Controlled Substances for the Treatment of Pain endorses these practices when evaluating a physician's treatment of pain.[13]

Figure 3: Universal Precautions for Assessment of Chronic Pain[1,2,9,14]
Comprehensive evaluation and differential diagnosis
Psychological assessment (including risk of addictive disorders)
Routine use of informed consent and treatment agreements
Assessment of pain level and function before and after each intervention
Regular assessment of the four "A"s of pain medicine: analgesia, activities of daily living, adverse events, aberrant behaviors
Periodic review of pain diagnosis and comorbid conditions
Regular supervision and monitoring
Routine toxicology screening (for prescribed and non-prescribed drug use)
Careful documentation

Informed consent and opioid treatment agreements are key components of the universal precautions approach to pain management.[1,2,9,14-16] Physicians should discuss the benefits and risks of using a controlled substance with a patient and how to minimize possible adverse effects before starting opioid therapy. The risks of tolerance, opioid dependence, and possible addiction should be included in the discussion. Formalizing the pain management plan with an opioid treatment agreement (OTA) helps to protect both the patient and the provider. These agreements outline the expectations of the patient and the provider and can be tailored to the specific situation. They typically include the purpose of the opioid therapy, responsibilities of the provider in opioid prescribing, and responsibilities of the patient with opioid usage. Additionally, treatment goals to measure failure or success of therapy should be included. Goals are typically to reduce pain and improve function or quality of life. Complete resolution of pain may not be attainable and should not be the patient's expectation. Monitoring parameters such as random urine drug tests and frequency of office visits can be built into the treatment agreement as can behaviors or circumstances that would lead to continuation or cessation of opioid therapy.[1,2,9,14-16]

Patient Monitoring Programs

Many states have implemented controlled substance prescription monitoring programs and these can be an effective tool to prevent and detect prescription drug diversion. These programs are intended to cut down on prescription fraud and doctor shopping by making a patient's controlled substance usage more transparent to both physicians and pharmacists.[15] The West Virginia Board of Pharmacy operates the Controlled Substance Monitoring Program or CSMP. The CSMP was implemented in 2002 and, by law, all pharmacies and dispensers of controlled substances are required to electronically report their dispensing data weekly. The database stores specific information for at least five years (the name, address and birth date for whom the prescription was written; the National Drug Code [NDC], dosage, quantity dispensed and fill date for the Schedule II, III or IV controlled substance; the name and DEA number of the prescriber and dispensing pharmacy). In 2010, the legislature passed a bill that requires all prescribers and dispensers in West Virginia to have access to the CSMP effective July 1, 2011. To obtain additional information about the West Virginia CSMP or to enroll, contact the West Virginia Board of Pharmacy at 304-558-0558 or access their website at http://www.wvbop.com/.

Recently, Governor Earl Ray Tomblin announced that the West Virginia CSMP has entered into an agreement with the National Association of Boards of Pharmacy (NABP) to participate in the NABP Prescription Monitoring Program Interconnect system (PMPi). The NABP PMPi system will facilitate the secure transfer of prescription monitoring program data across state lines and enhance the ability of West Virginia and other participating states to fight prescription drug abuse on a national scale. The goal of the NABP is for all 50 states to enroll in this program and currently six other states besides West Virginia have agreed to participate, including the border states of Virginia and Ohio. Implementation of this pilot project is scheduled for July 31, 2011, with full roll-out in Fall 2011.

For more details regarding pain management and for patient education materials, please visit the following websites:

American Pain Foundation www.painfoundation.org
American Pain Society www.ampainsoc.org
The American Academy of Pain Medicine www.painmed.org
American Academy of Family Physicians www.familydoctor.org

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