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Opioid Therapy for Chronic Low Back Pain: Prescribing Considerations for Advanced Practice Registered Nurses

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ABSTRACT

Chronic low back pain is a common, disabling, and costly condition, and advanced practice registered nurses (APRNs) must carefully evaluate patients before considering long-term opioid therapy as a management strategy. APRNs should refer patients suspected of having a serious condition, or identifiable etiology, for specialist evaluation, as many patients improve with physical therapy, interventional pain management procedures, or surgical intervention. For patients unresponsive to nonopioid treatment, APRNs with an understanding of opioids, and the experience to assess and manage the risks of opioid misuse, abuse, and diversion, may consider long-term opioid therapy as part of a multimodal management plan. Such prescribing necessitates careful patient selection; informed consent; prudent opioid dosing and titration; and monitoring for response to treatment, adverse effects, and aberrant drug-taking behavior. Treatment and regulatory guidelines can assist APRNs in providing safe and effective care to patients with chronic low back pain.

Keywords: chronic low back pain, low back pain, opioid therapy, pain management, prescribing guidelines

ow back pain is a common, disabling, and costly condition, and advanced practice registered nurses (APRNs) must carefully evaluate patients before considering long-term opioid therapy as a management strategy. Low back pain causes suffering for millions of people, is the second most common cause of disability in the United States (U.S.), and costs the national economy more than \$100 billion annually in direct and indirect costs. Furthermore, despite sophisticated diagnostic technologies and therapeutic options, low back pain is often recalcitrant to treatment and progresses to a chronic condition. APRNs caring for patients with chronic low back pain must balance the need for effective pain management with the risks of opioid misuse, abuse, and diversion. Even with careful patient selection, APRNs prescribing opioids for chronic low back pain must monitor patients for adverse treatment effects and the possibility of nonadherence to prescribed therapies. Nevertheless, by practicing in accordance with treatment guidelines and regulatory mandates, APRNs can provide safe and effective care for sufferers of chronic low back pain, while decreasing the risks of opioid

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therapy and avoiding regulatory investigation and discipline. This article will discuss low back pain; benefits and risks of long-term opioid therapy; guidelines for long-term opioid prescribing; and legal requirements, regulatory guidelines, and policy statements addressing the use of opioid therapy for chronic low back pain.

Low Back Pain Etiology

Low back pain is a nonspecific term that describes the symptom of pain in the lumbar region. Some cases of low back pain are caused by a recognizable pathology, such as lumbar disc herniation or lumbar spinal stenosis. Other cases of low back pain are considered nonspecific because they cannot be attributed to a specific disease or abnormality (Chou et al., 2007). Regardless of etiology, all patients with low back pain warrant expert care, as this condition has emerged as one of the most common, disabling, and costly of all health conditions, and a variety of treatment strategies are available, which must be carefully evaluated by APRNs and patients alike.

Epidemiology

Low back pain is common. The global lifetime prevalence of low back pain is 38.9% and is predicted to increase as the population ages (Hoy et al., 2012). In the U.S., more than one quarter of adults report at least 1 day of low back pain in the past 3 months (Centers for Disease Control and Prevention [CDC], 2013). Adults aged 45–64 years

report the highest rates of low back pain, evidencing the frequency with which back pain affects people during a time of maximal family care and work responsibilities (CDC, 2013).

Disability

Low back pain is the second most common cause of disability in U.S. adults (CDC, 2009). Among workplace injuries and illnesses necessitating days away from work, low back injury is the most commonly reported musculoskeletal disorder (U.S. Department of Labor, Bureau of Labor Statistics, 2012). When neck and low back problems are examined together, 28% of affected adults report limitations in physical functioning, 23% describe their physical health as poor or fair, and 12% describe their mental health as poor or fair (Martin et al., 2009). Furthermore, one fifth of adults with neck and low back problems report limitations in work, school, or home functioning (Martin et al., 2009).

Chronicity

Most patients treated for low back pain experience significant improvement in pain and function within 1 month of symptom onset. Some patients, however, do not recover and develop chronic low back pain, typically defined as pain persisting longer than 3 months (Chou & Shekelle, 2010; Martell et al., 2007; Mehling et al., 2012). A recent, prospective, cohort study of 605 patients with low back pain found that 13% of patients had continued pain at 6 months and 19% had continued pain at 2 years (Mehling et al., 2012). Another study of workers with back injuries found that 14% continued to receive work disability compensation at 1 year (Franklin, Stover, Turner, Fulton-Kehoe, & Wickizer, 2008).

Cost of Low Back Pain

The total cost of low back pain in the U.S. exceeds \$100 billion annually (Katz, 2006). One third of costs are direct expenditures for healthcare services, and two thirds are indirect costs because of lost wages and reduced productivity (Katz, 2006). These costs qualify back pain as one of the most expensive conditions in the U.S. adult population. The combined cost of inpatient care, ambulatory care, emergency care, and prescription medication for low back problems ranks alongside the cost of treating diabetes, and positions back problems among the most costly medical conditions affecting the civilian population (Soni, 2011).

In analyzing the costs associated with low back pain, a dramatic increase in prescription medication use becomes evident. Between 1997 and 2006, the number of patients receiving prescription medication for neck and low back problems increased from 7.8 million in 1997 to 10.9 million in 2006, representing an increase of 39.9% (Martin et al., 2009). Meanwhile, the number of prescriptions per patient

increased from 4.12 prescriptions per patient in 1997 to 5.48 prescriptions per patient in 2006, representing an increase of 33.0% (Martin et al., 2009). Opioid therapy accounts for much of this increase. From 1997 to 2004, there was a 108% increase in opioid prescriptions for patients with neck and low back problems. The increase in the number of prescriptions, combined with rising drug prices, resulted in a 423% inflation-adjusted increase in the cost of opioid therapy for neck and low back problems from 1997 to 2004 (Deyo, Mirza, Turner, & Martin, 2009).

Benefits and Risks of Long-Term Opioid Therapy

Benefits and Factors Leading to Increased Use of Opioids

Opioids are broad-spectrum analgesics used to treat nociceptive and neuropathic pain. Their pharmacologic effects derive from interactions with opioid receptors in the brain, spinal cord, and tissues (Freynhagen, Geisslinger, & Schug, 2013). Clinicians have long used opioids to treat acute pain, and their use is included in evidence-based low back pain treatment guidelines (Chou et al., 2007). In contrast, the use of long-term opioid therapy to treat chronic low back pain is a relatively new practice.

During the past 20 years, multiple factors contributed to a dramatic increase in opioid prescribing. In 1996, the American Academy of Pain Medicine and the American Pain Society issued a statement in support of opioid therapy for chronic pain. The organizations reasoned that the needless suffering, lost productivity, and excessive healthcare expenditures associated with undertreated pain justified the consideration of long-term opioid therapy (Haddox et al., 1996). Concurrently, expert opinion maintained that analgesic benefits were possible without intolerable adverse effects or aberrant drug-taking behaviors (Portenoy, 1996). The Joint Commission (2012) and the U.S. Department of Veterans Affairs (2000) launched initiatives emphasizing routine pain assessment, describing pain as the fifth vital sign. Finally, pharmaceutical companies aggressively marketed opioids for chronic noncancer pain (Freynhagen et al., 2013). Thus, in the absence of high-quality evidence about the benefits and risks of long-term opioid therapy, its use increased dramatically (Von Korff, Kolodny, Deyo, & Chou, 2011).

Although rates of opioid prescribing vary by treatment setting, a review of 11 studies identified prescribing rates as high as 66% for chronic low back pain (Martell et al., 2007). Such rates help to explain the quadrupling of opioid sales between 1999 and 2010 (Paulozzi, Jones, Mack, & Rudd, 2011; Von Korff et al., 2011).

Risks of Long-Term Opioid Therapy

There is currently an epidemic of opioid misuse, abuse, and diversion in the U.S. Patients receiving opioids for

chronic pain report high rates of aberrant drug-taking behaviors, including early refills, dose escalations without clinician consent, and the use of opioids to induce feelings of intoxication (Fleming, Davis, & Passik, 2008; Martell et al., 2007). These patients also have high rates of substance abuse disorders, ranging from 5% to 25% among patients taking opioids for chronic low back pain (Martell et al., 2007). Furthermore, large quantities of opioids in homes and communities enable the diversion of these medications to individuals other than the intended recipients (McCabe, West, & Boyd, 2012). Most tragically, increased opioid prescribing has contributed to unprecedented numbers of fatal prescription drug overdoses. Between 1999 and 2010, deaths from opioids increased fivefold for women and 3.6 times for men (Mack, Jones, & Paulozzi, 2013). Every year since 2007, more women have died from prescription drug overdoses than from motor vehicle accidents (Mack et al., 2013). Deaths because of prescription drug overdoses in the U.S. now exceed deaths because of heroin and cocaine combined (Paulozzi et al., 2011).

Guidelines for Long-Term Opioid Prescribing

The U.S. opioid epidemic challenges clinicians and regulators to reduce opioid misuse, abuse, and diversion, while still permitting safe and effective pain management. National organizations now emphasize careful patient selection and monitoring (Chou et al., 2009); chronic pain experts urge caution in prescribing opioids (Freynhagen et al., 2013; Von Korff et al., 2011); and, most recently, the Office of National Drug Control Policy, White House (2013) has called for increased education and legislation to promote safer opioid prescribing.

Safer opioid prescribing depends on informed clinical decisions. APRNs prescribing opioids to treat chronic low back pain require a thorough understanding of opioid prescribing and the experience to assess and manage the risks associated with opioid misuse, abuse, and diversion. Current guidelines for the use of opioid therapy in chronic noncancer pain, including chronic low back pain, emphasize careful patient selection, informed consent, cautious initiation and titration of opioids, and diligent patient monitoring (Chou et al., 2009).

Patient Selection

Before the initiation of opioid therapy, APRNs should conduct a history, physical examination, and diagnostic work-up to identify patients with a potentially serious condition or identifiable etiology. Patients suspected of having cancer, vertebral infection, cauda equina syndrome, or other serious conditions warrant immediate specialist referral (Chou et al., 2007). Patients suspected of having lumbar disc pathology, or lumbar spinal stenosis, also warrant specialist evaluation, as these pathologies are frequently amenable to physical therapy, interventional

pain management procedures, or surgical intervention (Chou et al., 2007). Only when pain is unresponsive to all other treatment options should APRNs consider initiating long-term opioid therapy and, even then, as only one component of a multimodal management strategy.

When initiating opioid therapy, APRNs should document a thorough benefit-to-harm evaluation, weighing the potential benefits of decreased pain and improved function against possible risks. This evaluation may incorporate screening tools, such as the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), a 24-item measure designed to predict aberrant drug-taking behaviors (Butler, Fernandez, Benoit, Budman, & Jamison, 2008). According to the tool's developers, patients scoring 22 or greater on the SOAPP-R are considered at high risk for opioid misuse, patients scoring between 10 and 21 are considered at moderate risk, and patients scoring less than 10 are considered at low risk for opioid misuse (Inflexxion, 2013). This risk stratification helps to identify patients for whom additional precautions or monitoring may be needed and for whom specialist consultation or referral should be considered (Butler et al., 2008; Inflexxion, 2013). The SOAPP-R and scoring instructions are available on the PainEDU.org Web site. In addition, patients with a personal or family history of alcohol or drug abuse and patients with comorbid psychiatric conditions may warrant mental health or addiction specialist consultation or referral (Chou et al., 2009).

Informed Consent and Opioid Management Plans

APRNs should obtain informed consent that clearly communicates the possible benefits and risks of opioid therapy as well as alternatives to opioids (Chou et al., 2009). Written management plans may also be considered; however, the evidence that they are effective in promoting adherence to opioid therapy is limited (Arnold, Han, & Seltzer, 2006; Chou et al., 2009). If used, management plans should stipulate patient and clinician responsibilities, including compliance with prescribed dosing, obtaining opioids from a single clinician, and adherence to the monitoring program. Management plans should also identify indications for tapering or discontinuing therapy. These indications include a failure to progress toward treatment goals or aberrant drug-taking behaviors (Chou et al., 2009).

Initiation and Titration of Opioids

APRNs should dose and titrate opioids based on patients' health status, previous exposure to opioids, and response to treatment. Patients with comorbid health conditions are typically maintained on low opioid doses to minimize adverse effects. For example, patients with sleep apnea and patients taking other central nervous system depressants, such as benzodiazepines, may be at increased risk for

respiratory depression and sedation (Chou et al., 2009; Freynhagen et al., 2013). Patients with renal dysfunction may experience adverse effects because of the accumulation of opioid compounds and their metabolites (Freynhagen et al., 2013). In addition, opioid-naive patients are particularly susceptible to adverse treatment effects and should be started on low opioid doses that are slowly titrated (Chou et al., 2009; Freynhagen et al., 2013).

While monitoring and documenting patient responses to treatment, APRNs should consider the "four As": (a) analgesia, (b) activities of daily living, (c) adverse effects, and (d) aberrant drug-taking behavior (Freynhagen et al., 2013). Documentation of pain intensity is important, as long-term opioid therapy is associated with hyperalgesia, a condition in which patients chronically exposed to opioids experience increased pain sensitivity (Freynhagen et al., 2013). Documentation of activities of daily living is also essential, as functional improvement is typically a prerequisite for continued long-term opioid therapy. APRNs may supplement the assessment of activities of daily living with the use of a functional status instrument, such as the Oswestry Disability Index or the Roland–Morris Disability Questionnaire (Roland & Fairbank, 2000). APRNs must also monitor and document the emergence of adverse effects to opioid therapy. Commonly reported adverse effects include constipation, nausea, vomiting, sedation, and clouded mentation (Chou et al., 2009). Other adverse effects associated with long-term opioid therapy include fractures, respiratory depression, immunosuppression, bowel obstruction, hypogonadism, erectile dysfunction, infertility, osteoporosis, and depression (Chou et al., 2009; Freynhagen et al., 2013; Von Korff et al., 2011). If patients develop intolerable adverse effects, or if they fail to progress toward treatment goals, APRNs should taper or wean them from opioid therapy and consider specialist consultation (Chou et al., 2009). APRNs must also be alert to aberrant drug-taking behaviors. These include repeated requests for replacement of lost or stolen medication, obtaining prescriptions from multiple clinicians, frequent use of emergency care facilities, use of parenteral routes, and opioid diversion (Freynhagen et al., 2013). If patients engage in aberrant drug-taking behaviors and cannot be tapered or weaned from opioid therapy, arrangements should be made for mental health or addiction specialist evaluation (Chou et al., 2009; Freynhagen et al., 2013).

Legal Requirements, Regulatory Guidelines, and Policy Statements

New and revised legal requirements, regulatory guidelines, and policy statements pertaining to opioid prescribing have been forthcoming in recent years. To promote safer prescribing and to avoid possible regulatory investigation or discipline, APRNs prescribing opioid therapy for chronic low back pain should align their practices with these mandates and guidelines (Chou et al., 2009).

APRN prescriptive authority varies from state to state. Some states grant APRNs unrestricted and independent prescribing authority for controlled substances, some states grant limited prescribing authority, and some states prohibit APRNs from prescribing any controlled substance (U.S. Drug Enforcement Administration, 2013b). In addition, some jurisdictions have opioid-specific prescribing regulations that apply to all clinicians. Washington State Department of Health (2011) requires clinicians to refer most patients receiving large quantities of opioids for chronic pain for specialist consultation. New York City limits clinicians in its public emergency rooms to dispensing 3-day supplies of opioids and prohibits clinicians from prescribing long-acting opioids (New York City Department of Health and Mental Hygiene, 2013). Manufacturers of opioid medications are also subject to new requirements. As shown in Table 1, the U.S. Food and Drug Administration (2013) now requires pharmaceutical manufacturers to create a risk evaluation and mitigation strategy (REMS) for extended-release and long-acting opioid medications. The REMS must include an educational program for clinicians and a counseling document and medication guide for patients. Although the development of REMS by pharmaceutical manufacturers is mandatory, clinician participation in the educational programming is voluntary.

Prescription Drug Monitoring Programs have also expanded in recent years. Forty-eight states either have a monitoring program or have passed legislation to implement a program (Alliance of States With Prescription Monitoring Programs, 2013). These databases track the prescribing and dispensing of opioids and help to prevent diversion at the clinician, pharmacy, and patient levels. In

TABLE 1. Extended-Release and Long-Acting Opioid Analgesics Requiring a Risk Evaluation and Mitigation Strategy

Buprenorphine (Butrans)

Fentanyl transdermal system (Duragesic)

Hydromorphone hydrochloride (Exalgo)

Methadone hydrochloride (Dolophine)

Morphine sulfate (Avinza, MS Contin, Kadian)

Morphine sulfate and naltrexone hydrochloride (Embeda)

Oxycodone hydrochloride controlled-release (OxyContin)

Oxymorphone hydrochloride (Opana ER)

Oxymorphone hydrochloride Extended-Release (Opana ER)

Tapentadol (Nucynta ER)

Note. Adapted from U.S. Food and Drug Administration, 2013.

addition, local, state, and federal officials are aggressively targeting illegal Internet pharmacies and "pill mills," the clinical practices renowned for unethical and illegal opioid prescribing (Alliance of States With Prescription Monitoring Programs, 2013; U.S. Drug Enforcement Administration, 2013a).

Many healthcare organizations have released guidelines and statements in support of safer opioid prescribing. These include the American Pain Society and the American Academy of Pain Medicine (Chou et al., 2009), the APRN Healthcare Foundation (Arnstein & St. Marie, 2010), the American Society of Interventional Pain Physicians (Manchikanti et al., 2012), and the Federation of State Medical Boards of the U.S. (2004). APRNs should be familiar with these recommendations, as they provide evidence-based prescribing guidance for opioid therapy and may help them avoid regulatory investigation or discipline through compliance and documentation of best practices.

Conclusion

Low back pain is a complex problem that affects millions of U.S. adults, is often disabling, and consumes billions of dollars annually in direct and indirect costs. Although most patients treated for low back pain experience significant improvement in pain and function within 1 month of symptom onset, some patients develop chronic low back pain, defined as pain that persists for at least 3 months. When evaluating these patients, APRNs must identify patients with a potentially serious condition, such as vertebral infection or cauda equina syndrome, and initiate immediate specialist referral. APRNs must also recognize patients for whom physical therapy, interventional pain management procedures, and surgical intervention are appropriate. Only when low back pain fails to respond to all other treatment options should APRNs consider longterm opioid therapy and, even then, only for carefully selected patients. APRNs should conduct a thorough benefit-to-harm evaluation, obtain informed consent, and consider the use of written management plans. Prescribing decisions must consider patients' health status and prior exposure to opioids. APRNs must regularly evaluate patients on long-term opioid therapy, with particular attention paid to analgesic benefit, functional status, adverse effects, and aberrant drug-taking behaviors. By prescribing long-term opioid therapy in compliance with state and local laws and in accordance with regulatory guidelines and policy statements, APRNs can decrease the risks of long-term opioid therapy, avoid regulatory investigation and discipline, and improve the safety and efficacy of care for patients with chronic low back pain.

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