The Use of Risk-Management Approaches to Protect Patients With Cancer-Related Pain and Their Healthcare Providers

Christine Miaskowski, RN, PhD, FAAN

Purpose/Objectives: To describe the factors that contribute to the risk for undertreatment of cancer pain, as well as the risk factors associated with misuse or abuse of opioid analgesics, and to describe approaches to identify and manage the risks.

Data Sources: Published research, articles from a literature review, and U.S. statistics.

Data Synthesis: Oncology nurses should perform systematic assessments to determine whether patients are at risk for undertreatment of cancer pain or whether they are at risk for abuse or addiction to opioid analgesics. Oncology nurses must develop effective approaches to manage both types of risk. Patient education is a critical component to help patients who are at risk for undertreatment to adhere to analgesic regimens and to experience optimal benefit from medications. For patients who are at risk for abuse or addiction, oncology nurses should perform ongoing screening for behaviors that are predictive of addiction and implement appropriate interventions to reduce risks of abuse.

Conclusions: Oncology clinicians should have a balanced perspective of risk management within the context of cancer pain management.

Implications for Nursing: Clinicians must be cognizant of the fact that a significant risk exists for undertreatment of cancer pain. In addition, oncology nurses should recognize patients who are at risk for abuse or addiction or who are actively abusing opioid analgesics and establish appropriate safeguards for patients with cancer and oncology clinicians.

Key Points . . .

- ➤ As more patients survive cancer, more patients will require management of chronic pain.
- ➤ A need exists to balance the effective management of cancer pain with the identification of individual patient risk for abuse of prescription medications.
- ➤ Oncology nurses play a significant role in the assessment of patients who are at risk for undertreatment of cancer pain, as well as those who are at risk for misuse or abuse of opioid analgesics.

Since the 1970s, oncology clinicians have provided leadership to improve the assessment and management of cancer pain. The efforts have led to the development of clinical practice guidelines for cancer pain management (Miaskowski et al., 2005). In addition, the efforts have fostered an examination of the undertreatment of chronic noncancer pain and have led to efforts to improve the assessment and management of the chronic medical condition. As a result of the efforts, the use of prescription opioids has increased substantially (Caudill-Slosberg, Schwartz, & Woloshin, 2004; Gilson, Ryan, Joranson, & Dahl, 2004; Joranson, Ryan, Gilson, & Dahl, 2000; Zacny et al., 2003). Although opioids are appropriate to treat cancer and noncancer pain, concerns have arisen about the potential for misuse and abuse of prescription opioids (Birnbaum et al., 2006; Edlund, Sullivan, Steffick, Harris, & Wells, 2007; Hughes, Bogdan, & Dart, 2007; Morasco & Dobscha, 2008).

Concerns about misuse and abuse of opioids have not been discussed in most presentations and publications about cancer pain management. However, as more patients survive cancer and require management of chronic cancer and noncancer pain, healthcare professionals must balance effective pain management with the identification of individual patient risk for substance abuse. In 2006, a case study highlighted the important issue (Kushel & Miaskowski, 2006). The case involved Mr. K, a 66-year-old African American man who was homeless for 50 years and sold drugs to support his daily heroin and cocaine use. In 2002, he presented to the emergency room with flank pain and was diagnosed with renal cell carcinoma localized to one kidney. At that time, his cancer was highly curable with surgery. However, the stipulation was made that the surgery would be performed only if Mr. K ceased using drugs. The patient refused and was lost to follow-up for one year. In 2003, the patient presented to the emergency room with abdominal pain and heroin withdrawal. By that time, he was suffering from severe hypertension and bone metastases and was referred for palliative care.

Christine Miaskowski, RN, PhD, FAAN, is a professor and associate dean for academic affairs in the Department of Physiological Nursing at the University of California at San Francisco. Miaskowski has received honoraria from Endo Pharmaceuticals. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.* *(Submitted February 2008. Accepted for publication June 14, 2008.)*

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The goal for patients like Mr. K is managing cancer pain effectively while being mindful of the potential risks for misuse of, abuse of, or addiction to opioid analgesics. Within the context of effective cancer pain management, a balanced perspective is required. A balanced perspective entails the need to recognize that significant barriers to effective cancer pain management exist, including the fact that patients, family caregivers, and clinicians have concerns about the development of tolerance to, physical dependence on, and addiction to opioids.

On the other hand, clinicians should identify patients who are at increased risk for abuse or addiction and those who are actively abusing opioid analgesics. Both groups of patients need to be identified so that appropriate interventions can be initiated to achieve optimal pain management. Therefore, the purpose of this article is to describe the factors that contribute to the risk for undertreatment of cancer pain, as well as the risks for misuse or abuse of opioid analgesics, and potential approaches to identify and manage the risks.

Most of the research in cancer pain management has focused on the problem of undertreatment of pain and barriers to effective pain management, as well as on the appropriate use of opioids. The chronic use of opioids has been advocated for the management of noncancer pain (Hojsted & Sjogren, 2007; Rowbotham & Lindsey, 2007). Pain experts and regulatory agencies have suggested that risk management approaches should be implemented to ensure effective treatment of chronic noncancer pain (Gourlay & Heit, 2006). Although clinicians involved in management of cancer pain have not been involved in the discussions, three important reasons exist for increased attention to risk management issues in patients with cancer pain.

First, the number of cancer survivors and the percentage of oncology patients with cancer-related and noncancer-related pain have increased (Deimling, Bowman, & Wagner, 2007; Janz et al., 2007; Phipps, Braitman, Stites, & Leighton, 2008; Rannestad & Skjeldestad, 2007). Second, the population of older patients who are at increased risk for the development of cancer and chronic, noncancer-related pain problems is growing exponentially (Lunenfeld, 2008; Lutz, Sanderson, & Scherbov, 2008). Older patients are at a particularly high risk for undertreatment of pain. Third, concern is growing about abuse of prescription opioids in the United States. Estimates suggest that approximately 1% of the population meet the criteria for abuse of or addiction to prescription opioids (Katz, 2007).

Oncology nurses play a significant role in the assessment of patients who are at risk for undertreatment of cancer pain, as well as those who are at risk for misuse or abuse of opioid analgesics within the context of cancer pain management. To achieve the goal of effective pain management, healthcare professionals must make comprehensive assessments of both types of risk and initiate appropriate interventions to reduce both types of risk.

Defining Terms

Any assessment of the risk of misuse or abuse of opioid analgesics requires uniform definitions. A consensus document published by the American Academy of Pain Medicine, American Pain Society, and the American Society of Addiction Medicine (2008) defined the terms tolerance, physical dependence, and addiction. **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. **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, or administration of an antagonist. **Addiction** is defined as 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.

Patients with cancer should understand that tolerance and dependence are physiologic effects of opioid analgesics and that the effects occur in all patients who take opioids. In contrast, addiction is a neurobiologic disease that has multiple concomitant factors that influence its development and manifestations.

Other important terms include pseudoaddiction, misuse, and abuse (Katz, 2007). **Pseudoaddiction** describes patient behaviors that may occur when pain is undertreated. Patients may focus on obtaining medications and "clock watching." Such behaviors may be interpreted by clinicians as "drug seeking" when patients are trying to ensure adequate pain treatment. **Misuse** is the use of a substance in a manner not consistent with legal or medical guidelines, such as altering a dose or sharing medicines, which has harmful or potentially harmful consequences. Misuse can be intentional or unintentional. **Abuse**, by definition, is the use of illegal substances, the use of any substance for nontherapeutic purposes, or the use of medications for purposes other than those for which they were prescribed. Opioid abuse may occur when a person attempts to produce pleasure, alleviate stress, or avoid reality. From a risk management perspective, clinicians must assess all patients to identify those who may be at higher risk for misuse or abuse (Katz).

Assessment of Risk of Undertreatment of Cancer Pain

One approach to overcoming barriers to optimal pain relief is to provide patients with education about the myths and realities of cancer pain management. However, work suggests that educational interventions are not effective for some patients (Schumacher, Koresawa, et al., 2002; Schumacher, West, et al., 2002). In addition, some patients with cancer who had severe pain reported low levels of adherence with a prescribed analgesic regimen (Schumacher, West, et al.).

To explore the reasons for that apparent paradox, a study among adult patients with cancer asked, "Why were certain patients, who had an intense psychoeducational intervention, reluctant to use opioids despite significant pain?" (Schumacher, West, et al., 2002). Findings from the study suggested that previous personal experience plays a powerful role in the genesis of many barriers to opioid use. Patients often spontaneously provided detailed explanations about why they were reluctant or unwilling to take analgesics in general, or opioids in particular. The explanatory accounts were termed "pain management autobiographies" because of their narrative character and multilayered, richly detailed quality. The autobiographies included stories that ranged from stigmatizing interactions with clinicians and family members; to intractable side effects associated with analgesic use, including severe constipation; to strongly held convictions about medication use (e.g., all

medications are toxins that should be avoided). Based on the interviews with patients with cancer, the researchers developed a series of questions to evaluate patients who might be at risk for undertreatment of cancer pain (see Figure 1). The questions can be used to ascertain fears, concerns, and barriers that may cause patients to reduce their levels of adherence with their prescribed analgesic regimens.

Patient education is a critical component to help patients adhere to analgesic regimens and experience optimal benefit from medications. The American Pain Society's *Guideline for the Management of Cancer Pain in Adults and Children*, published in 2005, explicitly emphasized the need for patient education regarding cancer pain management (Miaskowski et al., 2005). The main recommendation in the guideline is that all patients should receive a written pain management plan. The pain management plan should enumerate the cause(s) of a patient's pain; the type of, and rationale for, the analgesic medications; specific instructions for filling prescriptions; specific instructions on how to dose and titrate analgesic medications; instructions on storage and safekeeping of medications; whom to call if pain is not relieved, if pain intensity increases, or if side effects occur; and when and how to use nonpharmacologic approaches for pain management.

To improve patients' and family caregivers' level of understanding, education should include clarification of any myths and misconceptions about cancer pain and its management. In addition, patients and family caregivers should be reassured that cancer pain can be relieved effectively and that addiction and tolerance are not generally associated with effective cancer pain management (Miaskowski et al., 2005).

Responsible Use of Opioid Analgesics

The responsible use of opioid analgesics requires the ability to identify high-risk patients who might misuse or abuse opioids. Federal and state laws stipulate that clinicians must be responsible for the use and prescription of analgesic medications. Clinicians have the right to prescribe opioid analgesics, and the risk of regulatory censure is low if simple procedures are followed and documented. Documentation must outline a patient's history and physical examination, confirm that the patient is seen with appropriate frequency, ensure that an outcome evaluation is performed, and ensure that procedures are in place to allow for the detection of aberrant drug-taking behavior. A good resource for clinicians to follow is *The Model Guidelines From the Federation of State Medical Boards* (Federation of State Medical Boards of the United States, Inc., 2004).

The accurate assessment of the risk for misuse or abuse of prescription drugs in general, and opioid analgesics in particular, is an extremely challenging endeavor. Katz (2007) proposed a risk-stratification hierarchy that identifies patients as low, medium, or high risk for misuse or abuse of prescription analgesics. Low-risk patients have no history of substance abuse and minimal, if any, risk factors. Medium-risk patients have a history of substance abuse, no prescription abuse, and significant risk factors. High-risk patients are those with an active substance-abuse problem or a history of prescription opioid abuse. Proponents of the assessment of risk for misuse or abuse of prescription drugs suggest that clinicians adopt a universal screening approach for risk of abuse (Gourlay & Heit, 2006).

Passik and Kirsh (2004, 2005); Passik, Kirsh, Donaghy, and Portenoy (2006); and Passik and Portenoy (1997) developed a loose hierarchy of behaviors (see Figure 2) that are more predictive versus behaviors that are less predictive of addiction. Among the behaviors that are more predictive of addiction are buying pain medications from a street dealer, seeing two doctors at once without them knowing, and forging prescriptions. Behaviors that are less predictive of addiction include hoarding medications, drinking alcohol with analgesic medications when in pain, and increasing opioid doses without consulting a clinician. Clinicians need to assess for such behaviors and then interpret them appropriately to yield clinically meaningful understanding of the factors that contribute to their appearance. Once an assessment is done, strategies should be implemented to reduce high-risk behaviors and regain control over the pain management plan (Passik et al., 2006).

A number of screening tools have been developed to assess the risk for misuse or abuse of prescription opioids. One tool that was developed by expert consensus and has undergone some level of validation is the Screener and Opioid Assessment for Patients in Pain (SOAPP®) (Akbik et al., 2006; Butler, Budman, Fernandez, & Jamison, 2004; Butler, Fernandez, Benoit, Budman, & Jamison, 2008; Wasan et al., 2007). The SOAPP tool assists clinicians in determining how much monitoring is required for patients being considered for long-term opioid therapy. The tool is not intended to be a "lie detector test" but rather should be used in conjunction with other clinical information to assess an individual patient's relative risk level. Two versions of the SOAPP tool exist: a 24-item form of which 14 items are scored and a 5-item short form. Various statements are rated on a Likert scale that ranges from 0 (never) to 4 (very often). Cutoff scores have been established for risk. On the long form, a score of 7 or higher indicates high risk; on the short form, a score of 4 or more indicates high risk. The SOAPP tool is better at identifying high-risk compared with low-risk patients. The questions on the short form are as follows.

- How often do you have mood swings?
- How often do you smoke a cigarette within an hour after you wake up?
- How often have you taken medication other than the way it was prescribed?
- How often have you used illegal drugs (e.g., marijuana, cocaine) in the past five years?

- Have you ever experienced chronic or severe pain in the past?
- If so, how was it managed? What medications did you take? How did the medications work for you?
- People respond to pain and pain management in uniquely individual ways. Through your past experience, what did you learn about your unique response to pain and pain management?
- Has a member of your family suffered from chronic or severe pain? If so, how was his or her pain managed?
- How similar are your beliefs about pain and pain management to the beliefs of other members of your family?
- What have physicians and nurses told you about pain and pain management in the past? What are your feelings about what they told you?
- Do you have a preference about how you would like your pain to be managed?
- Are there particular medications that you know work better for you than others?
- Do you have any concerns about taking pain medications?

Figure 1. Assessment of Past Experiences With Pain

Note. Based on information from Schumacher, West, et al., 2002.

Behaviors More Indicative of Addiction

- Bought pain medication from a street dealer
- Stole money to obtain drugs
- Tried to get opioids from more than one source
- Performed sex for drugs
- Saw two doctors at once without them knowing
- Stole drugs from others
- Performed sex for money to obtain drugs
- Sold prescription drugs
- Prostituted others for money to obtain drugs
- Prostituted others for drugs
- Forged prescriptions

Behaviors Less Indicative of Addiction

- Expressed anxiety or desperation over recurrent symptoms
- Hoarded medications
- Took someone else's medications
- Aggressively complained to doctor for more drugs
- Requested a specific drug or medication
- Used more opioids than physician recommended
- Drank more alcohol when in pain
- Expressed worry over changing to a new drug, even if it would have fewer side effects
- Took someone else's opioids
- Raised dose of opioids on own
- Expressed concern to family, saying that pain may lead to use of street drugs
- Expressed concern to doctor, saying that pain may lead to use of street drugs
- Asked for a second opinion about pain medications
- Smoked cigarettes to relieve pain
- Used opioids to treat other symptoms

Figure 2. Aberrant Behaviors More and Less Likely to Be Indicative of Addiction

Note. Based on information from Passik et al., 2006.

- How often, in your lifetime, have you had legal problems or been arrested?

More information about the SOAPP tool is available at www.painedu.org/soap-tutorial_04.asp.

The Pain Assessment and Documentation Tool (PADT) is a follow-up tool recommended to guide the evaluation of several important outcomes during opioid therapy. In addition, it provides a simple approach to document patient care (Passik et al., 2004). The PADT focuses on the four "A's": analgesia—a patient's average pain intensity, activities—a patient's level of functioning, adverse events—side effects, and aberrant behaviors—evidence of abuse, misuse, or addiction. Using the tool, clinicians can gain a sense of the effectiveness of cancer pain management plans.

Management of High-Risk Patients

Oncology clinicians must develop management plans for high-risk patients. Based on the recommendations in the American Pain Society's *Guideline for the Management of Cancer Pain in Adults and Children*, six strategies should be considered if a patient is assessed to be at high risk (Miaskowski et al., 2005). The most important strategy is to establish and maintain a therapeutic relationship with the patient that is based on empathetic listening and acceptance. If possible, nonopioid and behavioral interventions should be used to enhance the effectiveness of pain management. However, clinicians should not use such strategies as substitutes for the use of opioids.

When opioids are prescribed for high-risk patients, clinicians must consider tolerance, route of administration, and duration of action. Importantly, preexisting tolerance must be taken into account, because patients with cancer who have misused or abused opioid analgesics may require higher doses to achieve optimal pain relief.

Clinicians should consider using long-acting opioid analgesics for cancer pain management because the longer duration and slower onset of analgesia may reduce some aberrant behavior in high-risk patients. Lastly, clinicians should use the four "A's" on an ongoing basis to assess the adequacy of pain management and other symptom control, as well as any increased use of aberrant behaviors.

Strategies to promote adherence with the analgesic regimen in patients who are at high risk for misuse or abuse include the following principles (Miaskowski et al., 2005).

- Establish clear expectations for the roles played by clinicians and patients and the consequences of aberrant drug taking.
- Consider the use of spot urine toxicology screens.
- Establish clear expectations about the parameters of responsible drug taking.
- Consider having the patient attend a 12-step program.
- Involve family members and friends in the treatment to bolster social support.
- Consider the need for comanagement with a substance-abuse specialist.

Summary

Oncology clinicians must have a balanced perspective of risk management within the context of cancer pain management. Clinicians should be cognizant that a significant risk for undertreatment exists, often associated with patients', family caregivers', and clinicians' fears of tolerance, physical dependence, and psychological addiction. Appropriate and individualized education may remove such barriers. Lastly, oncology clinicians should recognize patients who are at risk for abuse or addiction, as well as those who are actively abusing opioid analgesics, and institute appropriate safeguards for patients and clinicians.

Author Contact: Christine Miaskowski, RN, PhD, FAAN, can be reached at chris.miaskowski@nursing.ucsf.edu, with copy to editor at ONFEditor@ons.org.

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