

Pain Management Issue Brief

Pain affects an individual's personality, ability to function and quality of life. 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 cancer patients, pain can be associated with a tumor, treatment, or not related to either. Increasing evidence suggest that palliative care, which often includes pain management, extends survival of cancer patients.¹

Chronic pain in cancer patients is classified by two categories: persistent pain or breakthrough pain. Persistent pain is continuous and may last all day whereas breakthrough pain is a brief episode of severe pain that occurs even while the patient is regularly taking pain medication. A wide range of pain management therapies are available and most pain associated with cancer can be controlled. Barriers preventing cancer patients from accessing pain medication often prevent achieving optimal pain control. The role of the Hematology/Oncology Pharmacist is to ensure that the cancer patient has a minimal amount of pain and thus improved function, comfort, and quality of life.

Scope of the Problem

According to the National Cancer Institute, an estimated 13.7 million Americans have a history of cancer, and it was anticipated that approximately 1.7 million new cases would be diagnosed by the end of 2014. Pain occurs in approximately one quarter of patients with newly diagnosed cancer, a third of those undergoing treatment, and three quarters of patients with advanced cancer.² Cancer pain can be directly related to the cancer (e.g., tumor progression, nerve damage), the result of surgical interventions and other invasive diagnostic or therapeutic procedures, from the toxicities of chemotherapy and radiation (e.g., ulcerations, nerve damage), from infection or other complications related to the disease.

Management of pain in cancer patients is complex and depends on individual patient factors. Often the management of pain uses several different types of pain treatments, such as:

- Pain medication (over-the-counter and prescription-strength pain relievers, opioids, adjuvant (non-opioid prescription) pain relievers [medications used to complement other pain medications]);
- Removal or reduction of the source of the pain (surgery, radiation, chemotherapy); or,
- Specialized treatment (nerve blocks, physical therapy).

Opioids are the most common drug class used to treat pain in cancer patients. However the misunderstanding about addiction creates unique challenges for healthcare providers when treating cancer pain. Non-opioid therapies, which may be used in conjunction with opioids or alone, may be insufficient, cause unwanted side effects, or interact with cancer therapies. Neither the side effects of opioids nor the fear of addiction should prevent the healthcare team from providing adequate pain control to patients.

Patient and Provider Information and Education

Cancer pain is often undertreated. Understanding the issues surrounding cancer pain and appropriate education of patients and providers will lead to better patient care decisions. Several main issues related to the diagnosis and control of pain includes:

- Reluctance of healthcare providers to ask about pain or offer treatments due to a misunderstanding about cancer pain, fear of misuse, or a fear of legal repercussions;
- Reluctance of patients to speak up about pain because of a fear of an advancing disease, side effects, cost, or addiction; and
- Barriers for patients to access pain medications.

¹ Temel, J.S., Greer, J.A., Muzikansky, A., et al. Early palliative care for patients with metastatic non-small-cell lung cancer. *N Engl J Med.* 2010; 363: 733-742.

² Cohen, M.Z., Easley, M.K., Ellis, C., et al. Cancer pain management and the JCAHO's pain standards: an institutional challenge. *J Pain Symptom Manage.* 2003; 25: 519-27.

Current Regulatory and Legislative Framework

The use of, and access to, medications for cancer pain are regulated through three principle laws: the Federal Controlled Substances Act (CSA), the Federal Food, Drug and Cosmetic Act (FDCA), and the Food and Drug Administration Amendments Act of 2007 (FDAA). Under the FDCA, many drugs have been accepted as safe and effective for human use pursuant to a physician's prescription, including opioids. The CSA classifies substances with the potential for abuse, such as opioids, into 5 Schedules (I-V), with Schedule I having the highest potential for abuse. Only substances in Schedule II-V may be prescribed currently in the US. Schedule II substances must be dispensed by written prescription only and allow no refills, whereas Schedule III-V may be e-prescribed or telephoned in, and refills are allowed. This requires the patient to travel to their physician's office to obtain a hard copy of schedule II prescriptions.

Hydrocodone Rescheduling

There is a significant problem with misuse and abuse of prescription medications in the United States. It is imperative that a proper balance be maintained to keep these medications available to patients while taking steps to minimize inappropriate use and abuse. Combination hydrocodone products (formerly Schedule III drugs and recently changed to Schedule II substances)—used for both acute and chronic pain—are a very important component of the opioid medication arsenal for cancer patients, and continued access to these medications is essential. HOPA does not support changing hydrocodone-containing combination products to Schedule II. Doing so requires cancer patients to visit their oncologist each time a refill is needed, to receive a hard copy prescription, since Schedule II drugs cannot be telephoned or faxed to a pharmacy. Until Schedule II drugs are eligible to be e-prescribed, cancer patients, while battling cancer and the side effects of treatment, will be directly impacted along with the quality of life of their loved ones already suffering from this devastating disease.

REMS

Risk Evaluation and Mitigation Strategies (REMS) are plans designed to manage the known risks and potential harm associated with certain types of drugs. Since 2008, the Food and Drug Administration (FDA) has had the authority to require drug makers to implement REMS for certain categories of drugs to ensure that the benefits of the drug outweigh the risks of the product. Through the REMS process, the FDA is better able to monitor the effectiveness and appropriate use of certain drugs once they are on the market. While the burden for developing REMS falls on the manufacturer, REMS can have a significant impact on healthcare professionals who prescribe and dispense medications with mandated REMS programs.

One provision of the REMS requirement known as “elements to assure safe use” (ETASU) allows the FDA to require a drug maker to: develop education and training certifications for prescribers or dispensers; set limitations on where drugs can be dispensed (e.g. hospital setting only; enroll patients into a registry); or include dispensing restrictions (e.g., require laboratory tests or a consent form acknowledging risks and benefits). These requirements can cause interruptions or delays in care, decrease access to care, or cause a shift in prescribing away from the opioid-based regimen (which may be most effective) to one that is easier and less cumbersome to prescribe and dispense. Such a shift may inadvertently increase the cost of care due to the consequences often seen with suboptimal pain management, such as increased physician and emergency room visits.

Recommendations

HOPA recognizes that steps need to be taken to address misuse and abuse of prescription medications, but a balance should be maintained between prevention and access to critical pain medications. HOPA makes the following recommendations to ensure that patients who need pain medications can adequately receive them and to avoid misuse and abuse of these medications:

- Encourage appropriate patient education about the importance of treating pain and addressing fears of side effects and addiction
- Encourage appropriate training of healthcare professionals to optimally manage pain and to recognize opioid misuse
- Develop systems to monitor patients for adherence, efficacy, and misuse
- Encourage REMS be evaluated in a timely manner to address barriers to access
- Encourage oncologists to include cancer indication on prescription to prevent barriers with filling prescriptions
- Encourage a nation-wide tracking system to view opioid refill records