



HEALTH NOTES

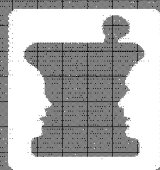


CCSF v Purdue Pharma, et al.
3:18-CV-7591

TE-SF-02798

Admitted:

**CONSUMER
EDUCATION,
INFORMATION AND
COMMUNICATION
COMMITTEE**



Dedicated to building bridges of communication with those Californians whose health depends on proper drug therapy, compliance with a treatment regimen and a healthier lifestyle.

MEMBERS

M. Standifer Shreve, *Chair*

Sandra Bauer

Hope Tamraz, *Staff*

**CALIFORNIA STATE
BOARD OF PHARMACY**

MEMBERS

Darlene Fujimoto, *President*

Holly Strom, *Vice President*

Caleb Zia, *Treasurer*

Sandra Bauer

Gary Dreyfus

Janeen McBride

Thomas Nelson

Raffi Simonian

M. Standifer Shreve

Michael Tilles

Patricia Harris, *Executive Officer*

HEALTH NOTES

VOLUME 1, NUMBER 1

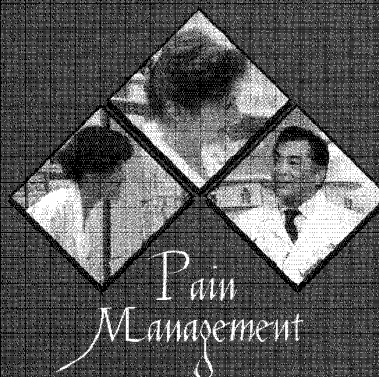


TABLE OF CONTENTS

3 Introduction

Part One - California Board of Pharmacy Advocates for Better Treatment of Patients with Pain

4 Dispensing Controlled Substances for Pain *Pharmacist's Role in Effective Pain Management*

5 Patient's Bill of Rights *A Health Care Ethic that Respects Patients*

Part Two - Role of Pharmacists in Treatment of Patients with Pain

6 Concerns and Facts about Pain Management, by Peter J.S. Koo *Answers to Common Misconceptions about Analgesics*

7 Pain Treatment Guidelines, by Darlene Fujimoto, Holly Strom, Peter J.S. Koo *Assessing a Patient's Pain Therapy Regimen*

10 Selected Tips for Pain Management Counseling in Community Practice, by Marie Belshe *Talking to Patients So They Understand their Therapy*

Part Three - Solving the Problem of Inadequate Pain Management

12 The Impact of Pain on Patients and Families, by Corinne Manetto *Forty-two Percent of Cancer Patients are Undermedicated*

14 What Can Health Professionals and Pharmacists Do to Effect Change in Pain Management in an Institutional Setting? by Lynne M. Rivera *Developing a New Standard of Treatment*

17 Training Programs and Regulatory Changes are Essential for Better Pain Management, by William L. Marcus, Sandra K. Bauer *California Professionals are Taking Action*

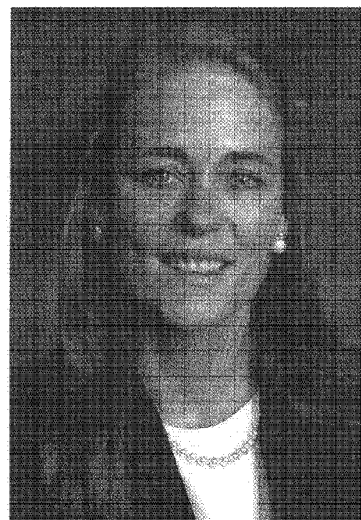
Appendix

18 Continuing Education Questions For Credit by The California Society of Health System Pharmacists

Introduction

HEALTH NOTES is a series of monographs published by the California State Board of Pharmacy's Consumer Education, Information and Communication Committee to help California pharmacists and other healthcare providers become better informed on subjects of importance to their patients.

Today, more than ever in the history of medicine, healthcare professionals are addressing the goals of integrated healthcare. They are providing patient care that focuses on physical wellness, service-satisfaction, and cost effectiveness.



Pharmacists, by virtue of their close relationship with patients, can quickly respond to a patient's medication needs and can satisfy a patient's desire to be informed about their treatment and the medications they are taking.

Access to information is an important component in attaining wellness. Pharmacists who develop programs that assist patients to better manage their medications and to meet their treatment objectives will help Californians reach higher levels of wellness.

As healthcare evolves into a system focused on integrated patient care, one fact becomes very clear: healthcare professionals who provide disease management programs and prescription information that increases medication compliance will help reduce hospital admissions and the need for follow-up care.

HEALTH NOTES is designed to be a reference source for pharmacists and other health care providers to use in helping patients better understand their illness, comply with prescribed treatment regimens and take greater responsibility for their health.

This first HEALTH NOTES monograph addresses the area of pain management. We hope it will be a valuable tool to help health professionals communicate information about the treatment of pain.

A handwritten signature in dark ink, appearing to read 'M. Standifer Shreve'.

M. Standifer Shreve
Editor, *HEALTH NOTES*
Chair, Consumer Education, Information
and Communication Committee
CALIFORNIA STATE BOARD OF PHARMACY

DISPENSING CONTR SUBSTANCES FOR

A STATEMENT OF THE CALIFORNIA STATE BOARD

INTRODUCTION

Healthcare leaders and patient advocates from throughout California met at the *Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing* in Los Angeles in 1994 to discuss the effective management of pain. Summit participants concurred that effective pain management, including the use of controlled substance medications, is essential to the health and welfare of Californians experiencing pain. It was also concluded that inappropriate or undertreatment of pain is serious and wide spread.

In response to these findings, the California State Board of Pharmacy is taking a leadership role in promoting the effective management of pain for the state's citizens. The Board's objectives include educating pharmacists on advances in appropriate pain management and taking active roles in providing this therapy. The Board is working to computerize the triplicate prescription program; is encouraging the timely availability of opioids in different healthcare settings such as hospitals, patient's homes and pharmacies; and is encouraging better knowledge and attitudes of patients, the public and other licensed healthcare professionals in the use of pain medications—all with the goal of positively influencing the care of patients in pain.

The Board of Pharmacy must ensure that laws, regulations, policies, and practices promote the availability and use of controlled substance drugs to patients for legitimate pain management. The Board encourages programs to help educate patients, the public, and licensed healthcare professionals about the effective use of medications in the treatment of various types of pain. The Board also recognizes that, with proper assessment, therapeutic planning, and follow up, medications should be available and used when needed.

The pharmacist's role (as educator and manager) in providing drug therapy for patients in pain is extensive. If pharmacists are to provide complete pain management services, they must fulfill their responsibilities to:

1. Facilitate the dispensing of legitimate prescriptions;
2. Understand and learn about the effective uses of all pain medications, especially opioids and other controlled substances, in the management of pain;
3. Carefully explain dosage regimens, and discuss potential side effects of pain medications;
4. Monitor and assess the patient for effective pain therapy outcomes, evaluate compliance, assess for tolerance to opioids, and ensure subsequent dosage adjustments as needed;
5. Obtain, retain, and update appropriate information documenting the course of, and need for, on-going opioid therapy;

4 HEALTH NOTES Pain Management 1996

6. Encourage patients to talk with their pharmacist about their medications, the benefits and problems;
7. Discuss and allay patients' possible fear of addiction with the use of narcotics where this is a factor;
8. Watch for patients who misuse their prescriptions and be especially aware of a patient or family history of substance abuse that might complicate pain management and act accordingly;
9. Assess the patient for adverse drug reactions from the pain therapy regimen and take action to minimize or eliminate them;
10. Be aware of and recommend non-medication treatments for pain or refer patients for such when appropriate;
11. Evaluate OTC, prescription drugs, and alcohol taken with pain medications for potential drug interactions;
12. Recognize that patients and caregivers are important sources of information in assessing the patient's pain therapy;
13. Act as a liaison between patients and other healthcare providers, ensuring that there is open communication and understanding about the drugs patients are taking to reduce pain; and
14. Optimize pain management so patients can reach their highest level of functioning and quality of life.

ROLE OF OPIOIDS IN PAIN MANAGEMENT

Many patients with cancer or chronic medical conditions experience moderate to severe pain that is often inappropriately treated or undermedicated. Pain can have a negative effect on the patient's health and quality of life resulting in needless suffering, emotional distress, loss of productivity and possibly slower recovery from illness, injury, and disease.

Although there have been significant advances in knowledge about pain and the use of opioids and other medications in pain management, many licensed healthcare professionals prescribe, dispense, or administer these medications suboptimally. There is a misconception by patients, the public, and some licensed healthcare providers that opioids are "bad" drugs because opioids are often associated with drug abuse, addiction, and criminal activity. Studies have shown that opioids used appropriately for pain management have an extremely low potential for abuse.

CONTROLLED PAIN

OF PHARMACY

The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected. In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered "normal" and "to be expected"—they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking."

The Board understands that an important part of effective pain management is ensuring that patients do not have difficulty obtaining adequate medication for pain relief. The Board recognizes that it is the professional responsibility of the pharmacist to recommend that patients in pain receive appropriate, timely, and adequate drug therapy to reduce their pain.

CONCLUSION

Recognition of the utility of opioids and other controlled substance drugs for the treatment of pain resulting from a variety of conditions is well established. The need for regulators and practitioners to understand this use, and to adopt laws, policies, and practices is self-evident if patients are to receive relief from pain which is now medically possible. In addition, pharmacists must understand their role in the on-going monitoring and assessment of patients' pain management. Working cooperatively, the Board of Pharmacy and the profession can ensure that opioids and other controlled substance drugs are used appropriately and effectively. □

Patient's

BILL OF RIGHTS

Introduction

Effective health care requires collaboration between patients, pharmacists, and other health care professionals. Open and honest communication, respect for personal and professional values, and sensitivity to differences are integral to providing patient care. Pharmacists must ensure a health care ethic that respects the role of patients in decision making about treatment choices and other aspects of their care.

The California Board of Pharmacy encourages health care providers to tailor this bill of rights to their patient community by translating and/or simplifying the language of this document as may be necessary to ensure that patients and their families understand their rights and responsibilities.

Bill of Rights

1. *The patient has the right to considerate and respectful care.*
2. *The patient has the right to and is encouraged to obtain from pharmacists and other direct caregivers relevant, current, and understandable information concerning their medication therapy and treatment.*
3. *The patient is entitled to the opportunity to discuss and request information related to their specific drug therapy, the possible adverse side effects and drug interactions.*
4. *The patient has the right to make decisions about the plan of care prior to and during the course of treatment and to refuse a recommended treatment or plan of care.*
5. *The patient has the right to expect that all communication, discussion, and patient counseling will be conducted so as to protect each patient's privacy.*
6. *The patient has the right to expect that all records and discussion pertaining to his/her drug therapy will be treated as confidential by the pharmacist, and the patient has the right to expect that the pharmacist will emphasize the confidentiality of patient information to any other parties entitled to review the patient's information and records.*
7. *Patients have a right to competent counseling from the pharmacist to help them understand their medications and use them correctly.*

Conclusion

The collaborative nature of health care requires that patients, on their families, participate in their care. The effectiveness of patient care and patient satisfaction with the course of drug therapy will depend, in part, on the patient fulfilling certain responsibilities. Patients are responsible for providing information about their medications as well as a history of their drug and food allergies.

To participate effectively in decision making, patients must be encouraged to take responsibility for requesting information or clarification about the drugs they are taking when they do not fully understand information and instructions.

Concerns and Facts About Pain Management

By Peter J.S. Koo, Pharm.D.

Associate Professor, Pharmacist Specialist in Pain Management, Department of

Clinical Pharmacy, University of California San Francisco, School of Pharmacy

If your patient is being treated for chronic pain, you may have concerns about your patient's use of analgesics. The following are some common concerns pharmacists have and the facts regarding them.

Concern: My patient always gets refills of analgesics right on time. The patient must be getting "hooked" or addicted.

Fact: A conclusion a patient is addicted should not be based solely on how frequently a patient is refilling his or her prescriptions. You must first evaluate the patient in light of the overall clinical picture. While the possibility of addiction is a proper concern, it is equally important to determine what the patient is being treated for and whether the current regimen is the best one for the patient's needs.

Too often, patients with pain are given inadequate pain drug therapy. Studies have shown that 20% - 30% of patients with pain are undertreated. Good communication between the prescriber and the pharmacist can significantly improve the patient's pain management outcome. Pharmacists often do not have all the diagnostic or therapeutic information available to them unless they are actively participating in the pharmaceutical care of the patient. Pharmacists who are providing chronic analgesics should at least have a recorded indication for their use in order to provide appropriate pharmaceutical care.

Concern: Patients should take analgesics only when they can no longer tolerate the pain.

Fact: Pain is easier to treat before it becomes severe. Patients should take their pain medication when they first start to feel the pain and on a regularly scheduled basis thereafter.

Frequent clinical assessment of the painful condition is an essential part of chronic pain management, and dosing adjustments must be based on those assessments.

Concern: My patient is taking several medications for pain. Is this polypharmacy necessary?

Fact: Pain has many causes. It can result from direct injury to the bone, muscles, skin, nerves, or other body organs. Pain can sometimes persist even after the initial injury has healed. This pain can be caused by scarring of the nerve or



injured tissue, and it is often maintained by local tissue or sympathetic irritation. Treatment of such pain often requires analgesics that are active locally as well as in the central nervous system. Unfortunately, there is no one drug that is active in all the sites that are responsible for pain sensation and response.

Recent studies have indicated the need for multiple sites of intervention for control of many forms of chronic pain. Therefore, patients with chronic pain often require compound drug therapy. However, multiple fixed dose analgesic combinations should be avoided because of the potential for inadvertent toxicity with acetaminophen or aspirin.

Concern: My patient always requests one particular medication and refuses to change to another analgesic even at equivalent analgesic doses. Does this indicate addiction?

Fact: Rather than addiction, the patient's refusal to change medication may be an indication that an equivalent analgesic does not achieve the same clinical response. Not all patients respond to a particular drug in the same way. All analgesic equivalency studies are based on population statistics or animal studies, but are not absolute, and should only be used as a guide for switching from one analgesic to another. Your patient's drug and dose must be based on his or her clinical response. Therefore, it is to the patient's advantage to stay with one pharmacy and get to know the pharmacist, who functions as the patient's pain management advocate. If the patient is getting an inadequate response from the therapeutic regimen, the pharmacist must then communicate that information to the treating clinician(s).

Concern: Is my patient addicted to opiate analgesics?

Fact: One must not confuse addictive behavior, dependence or tolerance with therapeutic failure. Use of opiates chronically can lead to tolerance and dependence.

Tolerance occurs when the same dose of an analgesic becomes less effective over time and may result in therapeutic failure. The first sign of tolerance is when the given dose of an analgesic is not lasting as long as when it was first introduced. Tolerance can be managed with appropriate dose adjustments or with a change in analgesic.

CONTINUED ON PAGE 9

PAIN TREATMENT GUIDELINES

BY DARLENE FUJIMOTO, PHARM. D., HOLLY STROM, PHARM. D., & PETER J.S. KOO, PHARM. D.

Recent surveys indicate that approximately 34 million adult Americans go to their physicians at least once a year for treatment of pain—pain that is serious enough to have a detrimental effect on their lives. Undertreated pain impedes recovery from surgery, injury or illness. Pain also interferes with physical activity and productivity; increases the use and cost of healthcare services; and decreases the quality of life.

Counseling, educating and discussing pain management with patients, their caregivers and their families, provides pharmacists with a unique opportunity to assist patients in the treatment of pain.

The following PAIN TREATMENT GUIDELINES were developed with the Board of Pharmacy to aid California pharmacists in assessing and evaluating a patient's pain therapy. These Guidelines can help pharmacists—working in cooperation with other healthcare professionals—to provide optimal pain management and minimize the adverse effects associated with many of the drugs used to treat pain.

I EVALUATION OF A PATIENT IN PAIN

When filling prescriptions for chronic pain control medications, pharmacists should assess the following:

1. ASSESSMENT/EVALUATION OF PATIENT'S PAIN CONTROL, e.g., use a pain scale, such as:

0	5	10
.....
No Pain	Moderate Pain	Severe Pain

The pharmacist should ask the patient what is his or her acceptable pain level.

2. ASSESSMENT OF PAIN CONTROL MEDICATIONS. Is the medication being taken in accordance with the indicated directions? If not, the pharmacist should contact the prescriber to update the medication's directions and to evaluate the medication's appropriate use.

3. ASSESSMENT OF SIDE EFFECTS:

- a. Constipation—Is the patient experiencing



constipation from opioid analgesics? If so, the pharmacist should assess the patient and provide recommendations to prevent it. Stimulant laxatives are needed to prevent and treat opioid induced constipation.

- b. Nausea and vomiting—Is the patient about to receive a new opioid analgesic or presently experiencing nausea or vomiting with opioid analgesics? If so, the prescriber should anticipate nausea and prescribe as needed (PRN) anti-nausea medications. The patient should obtain these medications so that they are available for use. The pharmacist may also suggest to the prescriber alternative opioid analgesics that might be better tolerated.

- c. Central nervous system (CNS) side effects—Is the patient experiencing sedation, confusion, stupor, delirium, or hallucinations? These side effects might be anticipated with medications used for pain control. Each patient

may react to these medications differently, therefore the pharmacist should ask the patient early and often about these side effects. Frequently, these side effects will resolve with a change in prescribed pain control medications.

- d. Respiratory depression—Is the patient taking multiple medications that can affect respiration? Patients seldom experience respiratory depression when opioids are taken alone for pain. Most often respiratory depression occurs when opioids are used in combination with other CNS depressants such as benzodiazepines or phenothiazines. Be sure to assess and discuss this complication with the patient so that he or she is aware of this possible side effect.

II RED FLAG SITUATIONS

- 1: A patient is taking a combination of opioid analgesics (i.e., acetaminophen with codeine and acetaminophen with hydrocodone)

ACTION: The pharmacist should contact the prescriber and suggest a stronger opioid analgesic such as morphine or hydromorphone to be taken at appropriately scheduled dosing intervals. The main reason for using a stronger opioid analgesic alone is to avoid an excessive acetaminophen dose.

Alternatively, a longer acting opioid analgesic such as sustained action morphine, levorphanol, or methadone can be used on a schedule in combination with a short acting opioid analgesic as needed (PRN) for breakthrough pain.

- 2: A patient is taking a sustained release (SR) narcotic product on a PRN schedule.

ACTION: The pharmacist should contact the prescriber to recommend changing the product to an immediate acting narcotic (i.e., morphine) that is appropriately dosed if the patient is taking the SR product in shorter than eight hour intervals. The SR product will not work immediately because the onset is delayed.

- 3: A patient is given a prescription for SR opioid analgesics (i.e., SR morphine, or fentanyl patches), and the patient is not on any other short acting analgesics.

ACTION: The pharmacist should ask the patient if he or she is taking any other medications and

having pain between the SR scheduled doses. If the patient is having pain between scheduled SR doses, the pharmacist should educate the patient to talk with the prescriber about getting an immediate acting analgesic for the breakthrough pain. The pharmacist can also talk to the prescriber to discuss the patient's needs.

4: A patient is requesting refills much earlier than scheduled.

ACTION: The pharmacist should consult with the patient because this might be a sign that the patient's pain is not being adequately controlled. After determining the cause, the pharmacist should discuss with the prescriber the patient's uncontrolled pain and the possibility of changing the patient to a better analgesic regimen. If the pain is of a chronic nature, longer acting or sustained action opioids should be preferred for the patient's convenience and comfort. If there are other reasons that the patient is seeking refills, the pharmacist should document the reasons and the amount given per the pharmacist's professional judgment, and notify the prescriber about any loss of medications.

5: A patient is taking more than 4-6 grams per day of acetaminophen from combination analgesic products.

ACTION: The pharmacist should alert the prescriber to the amount of acetaminophen the patient is taking. The pharmacist should also recommend changing the patient to a product that will reduce the total daily amount of acetaminophen intake.

6: A patient is converted from one opioid analgesic to another (i.e., morphine to hydromorphone).

ACTION: The pharmacist should consult with the patient to determine the reason for the change in medication. The pharmacist should estimate the "equianalgesic" dose and verify that the conversion is appropriate to maintain pain control. If the change in medication has decreased the pain coverage or the dose is unreasonably increased, the prescriber should be contacted to recommend an appropriate change in the dosage.

III VERIFICATION AND DOCUMENTATION OF PRESCRIPTIONS

Prescriptions are to be used for legitimate purposes. The pharmacist's responsibility is to make sure that prescribed medications are dispensed to patients in a timely manner and that the pain medication dispensed is the most appropriate one for the patient. Pharmacists also have a responsibility to use professional judgment and their knowledge of medications to ensure all medications are dispensed for a legitimate medical purpose.

8 HEALTH NOTES Pain Management 1996



The pharmacist should be sure that assessment information and medication documentation are readily retrievable — on the prescription hard copy, on the patient's computer medical record profile or in a separate file.

Adequate documentation and verification will allow a pharmacist to answer these questions.

1. Are the directions correct for the medication prescribed; do the directions correspond to the amounts of medication the patient is receiving; and, do the intervals between refills and/or new prescriptions correspond to directions?

2. Is there documentation of the diagnosis?

a. What is the disease state being treated?

b. Is the duration of treatment for:

- Acute pain?
- Chronic pain associated with malignant disease?
- Chronic pain not associated with malignant disease?

3. For chronic pain, does the medication have a long enough half-life for adequate pain control?

Is the patient on routine (around-the-clock) doses? What provision is there for breakthrough pain? Is the patient on medication(s) to prevent constipation?

4. Refer to the directions: are refills requested too soon? (If so, the pharmacist needs to contact the prescriber to recommend alternatives/adjustments to the medication regimen or to update current directions.)

5. Are adjuvant/adjuncts to opioid use needed (e.g., acetaminophen, nonsteroidal anti-inflammatory agents, antidepressants for neurogenic or neuropathic pain or depression, anticonvulsants, antiemetics, and medications for constipation)?

6. If a patient has been on chronic pain medications and the medications are to be discontinued, has the patient had the opportunity to be tapered off the medications to prevent symptoms of withdrawal?

IV. REGULATORY AND LEGAL ISSUES

1. All prescriptions should conform to all legal requirements detailed in the Health and Safety Code §11164 and summarized below:

a. SCHEDULE II prescriptions, among other requirements, must be:

(1) written wholly in ink or indelible pencil in the handwriting of the prescriber;

(2) submitted on a clear and complete triplicate prescription form;

(3) signed and dated by the prescriber; and

(4) filled within 7 days of the date of issuance, with the denoted copy forwarded to the Department of Justice within 30 days after filling.

b. Schedule III-V prescriptions, among other requirements, must:

(1) if written, be signed and dated by the prescriber;

(2) if written, be presented on a prescription document that is not mutilated, forged or altered; and

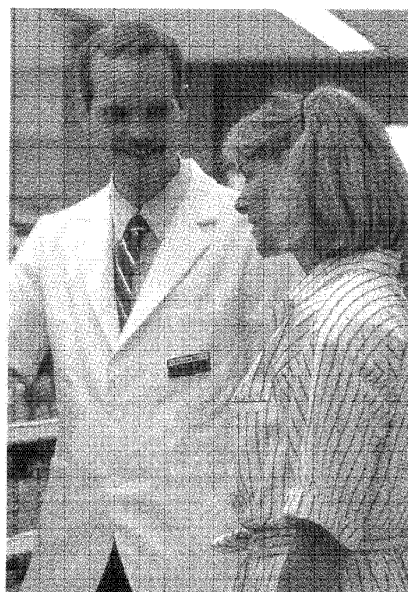
(3) not be refilled more than 5 times or refilled 6 months after the issuance date of the prescription.

2. Prescriptions are to be used only for legitimate medical purposes [21 USC §841.21; 21 CFR §1306.04 (a), Health and Safety Code §11153(a)]

3. Like the prescriber, the pharmacist has a corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances to prevent clearly excessive furnishing of controlled substances or the furnishing of controlled substances for other than a legitimate medical purpose. [Business and Professions Code §4350.5 [4301(d) as of 1/1/1997]; 21C.F.R. section 1306.04(a)]

4. For any controlled substance prescription, the pharmacist's knowledge or lack of knowledge about the prescriber and patient may require additional information before dispensing medications. Factors to consider in evaluating prescription legitimacy include:

a. **PATIENT FACTORS**—Can the patient be identified? What is the distance between the patient's residence and normal trading area of the pharmacy or the distance between patient's residence and office of the prescriber? What is the drug use history of the patient, does the patient submit prescriptions from multiple prescribers for controlled substances?



b. **PRESCRIBER FACTORS**—What is the nature of the prescriber's practice and specialty, prescribing pattern including types of drugs, appropriate frequency and volume, ratio of controlled substance prescriptions written by the physician as compared to the total number of prescriptions filled by the pharmacy?

5. Pursuant to Business and Professions Code §4362(4301(i) as of 1/1/1997), knowingly selling, furnishing, giving away or administering or offering to sell, furnish, give away or administer any Schedule I or II controlled substances to an addict or habitue' constitutes unprofessional conduct. Moreover, except as may be authorized by the Health and Safety Code, a pharmacist may not fill an order for controlled substances for an addict or habitual user of controlled substances (unless in the course of medical treatment) for the purpose of keeping the user comfortable by maintaining customary use. [Health and Safety Code 11153(a)]

Although the legal requirements, verification, and documentation of a prescription are important, a pharmacist's primary responsibility is to make adequate and appropriate pain control medications and adjunctive therapy available in a timely manner.

It is also important to work closely with other healthcare providers to assess medication efficacy, to evaluate and treat side effects, educate patients and their caregivers, and to be an active participant in helping patients receive optimal pain management. □

CONCERNS AND FACTS ABOUT PAIN MANAGEMENT - Continued from Page 6

Dependency is the physiological need for a drug, and without it the body undergoes withdrawal symptoms. Dependencies occur not only with analgesics but with many other medications as well. For example, chronic glucocorticoid use can lead to withdrawal symptoms upon abrupt discontinuation, and this is also true with opiate analgesics. In both cases, the body develops a physiological dependence for the drug.

Addiction is the culmination of drug dependence and drug seeking behavior. A patient is said to be addicted when the drug seeking behavior becomes all-consuming in one's life, and when the patient takes the medication for other than the intended indication(s) or is attempting to achieve euphoria or intoxication.

Criteria for Addiction

1. Taking the drug more often or in larger amounts than intended.
2. Alternates between intake binges and withdrawals.
3. Unsuccessful attempts to quit, persistent desire or craving.
4. Excessive time spent in drug seeking.
5. Feeling intoxicated or withdrawals at inappropriate times.
6. Giving up other things that one enjoys for the drug.
7. Continued use, despite knowledge of harm to oneself and others.

8. Marked tolerance in which the amount needed to achieve the desired effect increases to the point of toxicity.

9. Characteristic withdrawal symptoms for particular drug.

10. Taking the drug to relieve or avoid withdrawal.

These symptoms must have persisted for at least a month or have occurred repeatedly over a longer period. Mild addiction to a drug is determined by meeting four of the ten criteria. Experiencing five of the criteria would indicate moderate addiction and seven would indicate severe addiction.

Concern: What can I do to help my patient who is suffering from pain and is not getting adequate pain relief from the medications?

Fact: Most recent studies indicate that there remains a discrepancy between the patient's report of pain and the clinician's perception of the patient's pain. As healthcare providers who have seen the patient's progress with each medication received, it is our duty to provide the patient with the best information we can about pain management. If the pain is not controlled, recommend that the patient communicate with his or her healthcare provider(s). As an advocate for better pain management, every pharmacist should be part of a team of healthcare providers that is working to improve the quality of life for patients. There are pharmacists now practicing in partnership with other healthcare providers to provide pharmaceutical care in pain management. The pharmacists can serve as a resource and pharmaceutical care liaison for both patients and clinicians. Often, simply understanding your patient's therapeutic goals and providing feedback to other care provider team members can significantly improve your patient's quality of life. □



in Community Practice

BY MARIE BELSHE

Third year student at University of California, San Francisco School of Pharmacy; Winner of the National Patient Counseling Competition, United States Pharmacopeial Convention of 1996.

Pain is one of the most common reasons patients seek medical attention, yet it is frequently undertreated, leaving patients to suffer needlessly and their families with a sense of helplessness. Misperceptions and fears about pain medications, including their respiratory depressive effects, tolerance to the medication, and their addictive potential are common causes of undertreatment and reasons for patient noncompliance. As pharmacists and interns, we must help alleviate these fears by taking active roles in counseling patients about their pain medications so they can receive optimal benefits from the therapy. Counseling is an important component of that therapy, as it improves patient compliance and, consequently, outcomes.

Over-the-counter (OTC) analgesics, including acetaminophen, aspirin, and nonsteroidal anti-inflammatory drugs (NSAIDs), are available in many forms and are often used as first-line therapy for mild to moderate pain. All of these agents are effective analgesics and potential antipyretics; however, acetaminophen and low dose NSAIDs (OTC doses) do not have any significant anti-inflammatory activity. It is important to realize, and inform patients, that even though many medications for pain are available over-the-counter, they are not benign. Patient counseling provides the information that may well prevent drug misadventures.

Narcotics such as codeine, morphine, and oxycodone are usually reserved for severe pain. Although drugs in this class are considered the most effective in relieving nociceptive pain, many patients, unfortunately, are concerned about becoming addicted to this type of medication. The distinctions between tolerance (where more medication is needed to provide the same relief), dependence (the physical need for the drug to control pain), and addiction (the psychological craving and compulsive "seeking" of the drug) should be explained to the patient. This will help patients understand how they may become tolerant and even dependent, yet not addicted to their pain medications.

Narcotics can also be used in combination with NSAIDs, antidepressants, and anxiety agents very effectively for the relief of severe pain.

Counseling Tips for OTC and Prescription Analgesics:

ACETAMINOPHEN

- should be used with caution in patients who are alcoholics or who have liver disease.
- should be used with caution in patients who are fasting.

- should not be taken with alcohol.
- can be found in several OTC agents (e.g., decongestant preparations and cough and cold remedies) which, to minimize the likelihood of liver toxicity, should be avoided when taking acetaminophen for pain.

ASPIRIN

- with concurrent alcohol consumption may worsen gastrointestinal distress and should be avoided.
- may increase bleeding time and should not be used by patients on warfarin.
- should be dosed with caution in patients with diabetes, gout, or poor renal function.
- overdose is indicated by tinnitus (ringing in the ears). This condition is reversible by discontinuing the drug.
- will produce a vinegar-like smell when it has begun to degrade and should not be used. Patients can slow down this process by keeping aspirin in a dry place (i.e., not in the bathroom).

NSAIDS

- can be taken with antacids to decrease gastric irritation, but the liquid form should not be mixed with liquid antacids.
- may be effective in lower doses for the elderly.
- may cause drowsiness.
- have a ceiling effect. When pain relief has been attained, more drug will not provide more analgesia, but analgesia may last slightly longer.

OPIOIDS

- may cause constipation. This can be relieved by an OTC bowel stimulant, not a bulk-forming laxative.
- will cause sedation, and alcohol will intensify this effect.
- may cause dry mouth which can be relieved by sucking on sugarless hard candy or chewing sugarless gum.
- will provide more consistent analgesia for chronic pain patients, if taken around-the-clock rather than as needed.
- are not recommended for long-term use in pregnant women.

Several disease states or medical conditions

require pain management with the previously mentioned analgesics. A select few are discussed here with specific patient counseling tips to help these patients receive better therapy for their pain.

CANCER PAIN

Pain experienced by cancer patients may be caused by either the cancer or the cancer treatment. Often, cancer pain therapy is initiated with NSAIDs, aspirin, or acetaminophen, and may progress to include narcotics or a combination of medications. Many cancer therapy regimens can cause nausea. For these patients, pain medications are available in rectal or transdermal forms.

Counseling Tips

- Patients will get better pain relief if they take the medication as scheduled, rather than as needed.
- Injectable and oral opioids are equally effective. The only difference is that oral opioids take a bit longer to demonstrate their analgesic effect.
- Even though some NSAIDs are OTC, they are effective at higher doses in relieving bone pain associated with cancer.

DENTAL PAIN

Pain due to dental procedures is usually self-limiting, but treatment improves patient comfort and productivity. Short-term, around-the-clock dosing is recommended to prevent the pain rather than trying to stop it. Often, treatment is initiated prior to the dental procedure for this reason. NSAIDs are commonly prescribed for dental pain to provide strong anti-inflammatory relief. Higher than OTC doses of NSAIDs will be required for anti-inflammatory activity.

Counseling Tips

- Patients should expect pain to decrease in three to five days.
- Aspirin should not be used because it may increase the likelihood of bleeding.
- Aspirin should never be applied directly to the gums or oral cavity, as it may cause a burn to these sensitive tissues.

DYSMENORRHEA

Dysmenorrhea may be a primary or secondary syndrome. The primary syndrome is more common and involves menstrual cramping. Though the pain may vary from woman to woman, OTC doses of ibuprofen or naproxen sodium are often successful in improving patient comfort and alleviating the pain.

Counseling Tips

- NSAIDs should be initiated at the onset of menstruation and continued for two to three days.
- Patients on birth control pills may experience a decrease in pain associated with menstruation cramping.

Secondary dysmenorrhea is due to endometriosis, pelvic inflammatory disease (PID), or an intrauterine device. These conditions need to be evaluated by a physician to determine the underlying cause of pain.

SPORTS INJURY PAIN

Sports injuries are generally separated into two types: acute (sprain, dislocation, concussion) and chronic/overuse (joint inflammation). For acute or chronic minor injuries, OTC analgesics or counterirritants are often effective in relieving pain.

Counseling Tips

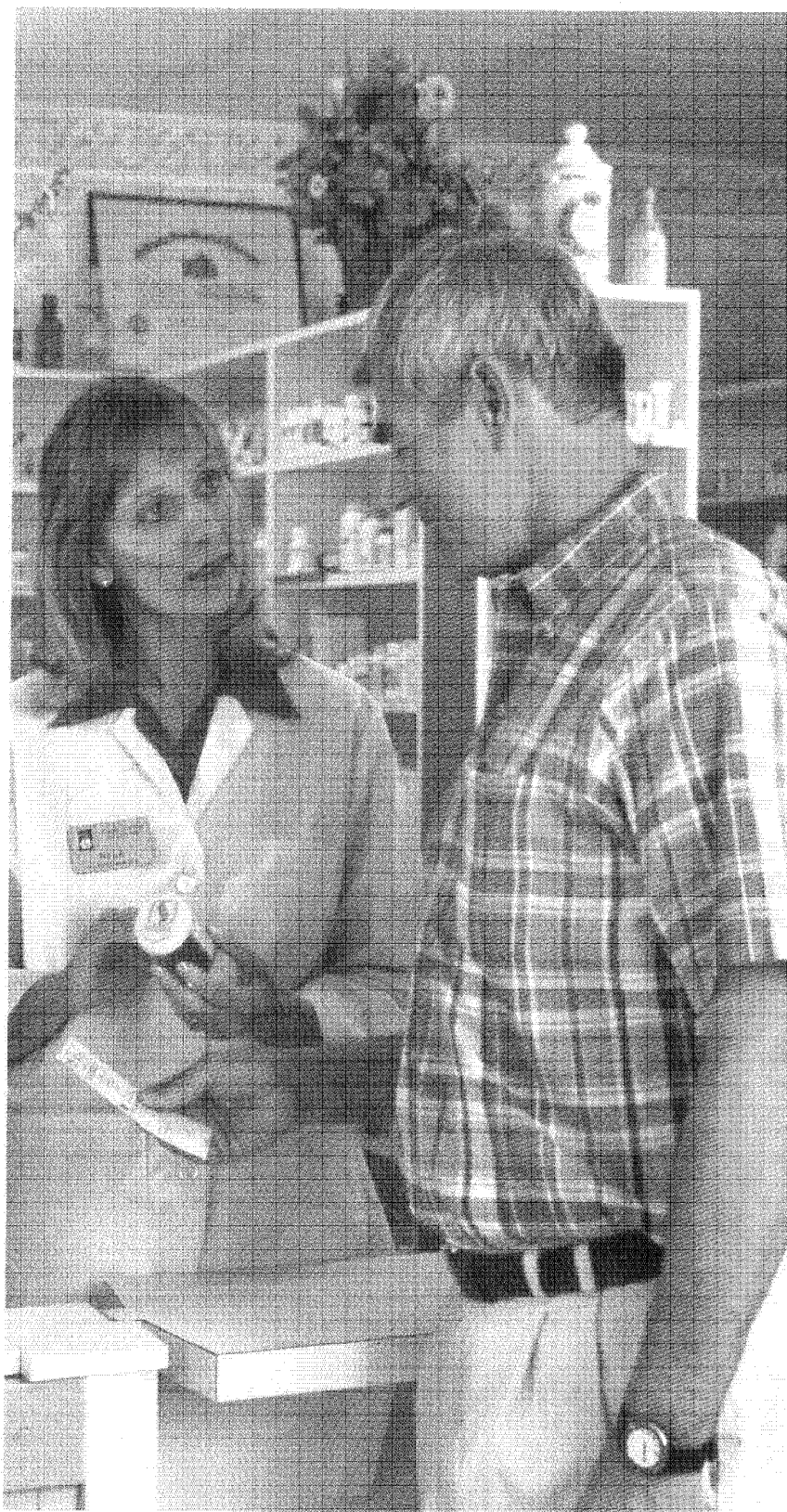
- Acute sports injuries are best treated promptly with a combination of nondrug and drug therapy to help decrease inflammation.
- The R.I.C.E technique (rest, ice, compression, elevation) is recommended.
- An internal analgesic such as ibuprofen may help prevent inflammation due to injury.

Rest and OTC analgesics will often be enough to alleviate the pain of chronic sports injuries.

POST-SURGICAL PAIN

Pain from surgery is often associated with the site of incision and can be treated with nondrug therapy. This may include any combination of massage, hot/cold therapy, rest, relaxation, or transcutaneous electrical stimulation (TENS). Surgical pain may also be alleviated with NSAIDs or opioids, depending on the severity. See "Counseling Tips for OTC and Prescription Analgesics."

Pain is most often treated with OTC analgesics, prescription NSAIDs, or prescription opioids. These medications are effective and fairly well tolerated, but it is important that the patients on these medications be fully informed so that they can be enfranchised as active partners in their care plans. These tips are not meant to be complete, but only a sample of information which should be shared with the patient to improve patient comfort and care. □



The Impact of Pain on Patients & Families

BY CORINNE MANETTO, PH.D.

*Coordinator of Psychological Services
Co-Director, Pain Management Services
Cedars-Sinai Comprehensive Cancer Center, Los Angeles*

Cancer patients and their families must contend with significant changes in many aspects of their lives. These include social, employment, and financial status changes, and alterations in their physical and psychological functioning. Compounding these life changes is the unfortunate reality that as many as 90% of cancer patients with advanced disease experience pain and related symptoms while also facing issues of loss and death. These factors can produce profound distress and despair in patients and their families. In the presence of unmanaged pain, it is quite clear that suffering and psychological disturbances increase significantly both for patients and their caretakers.

The inadequate management of pain may occur in as many as 42% of cancer patients (Cleeland, 1994). This is particularly alarming in light of increasing evidence indicating that unmanaged pain can lead to profound adverse changes in the patients' physiological, psychological, and immunological functionings. While the

factors leading to inappropriately treated pain are many, patient and family barriers can be of particular consequence (Ward, 1993). A careful assessment of patient and family variables is required to fully understand why effective pain relief has not been achieved. Individual reactions to illness and pain include learned responses from their families of origin. If for example, stoicism is a valued family trait, it may make it more likely that a cancer patient will not complain of pain. Additionally, family fears of addiction, tolerance, and side effects of medications can contribute to inadequate analgesia as the family may discourage opioid use.

Although it is recognized that pain is a complex perceptual experience involving the patient and his or her support system, the assessment and management of pain often focuses exclusively on the physiological aspects of pain (Craig, 1994). This occurs despite of the extensive literature suggesting the lack of relationship between the sensory aspects of pain and the ultimate experience of pain (Fordyce, 1988; Romano et al., 1989). The experience of pain is colored by an individual's unique physiology, psychology, sociocultural, and family background. Several studies have suggested that psychosocial factors are better predictors of pain than the extent of pathophysiological damage. For example, Spiegel (1985) has found that fear and meaning of pain tended to be better predictors of the pain experience in cancer patients than the extent or site of metastases. Flor and Turk (1993) have shown that a patient's assessment of hopelessness/helplessness was a better predictor of pain ratings, while physical factors were not predictive of pain severity. Given the likelihood that cancer pain patients will experience changes in cognitive status, motivational, behavioral, and affective capacities, a comprehensive assessment of their pain and related symptoms is required. The inability to manage symptoms that affect pain and its treatment (e.g., sleep disturbance) will severely limit success.

The prevailing current model of pain emphasizes the motivational-emotional, conceptual-judgmental, and sociocultural aspects of pain (Chapman, 1977; 1985). Consideration of these factors is extremely important to the experience of pain. Recent studies have shown that psychological distress and environmental factors are associated with pain and related symptoms (Bradley, et al. 1992). Moreover, Fordyce (1988) underscores the fact that pain and suffering are often confused. Suffering is defined as the emotional or affective response of the nervous system to noxious stimulation or other aversive events such as threat, fear,

The experience of pain
is colored by an
individual's unique
physiology, psychology,
sociocultural, and
family background.

and anticipation. In order to conceptualize the pain experience, distinctions between nociception, pain, suffering and pain behavior must be made (Loeser, 1980). In this model, nociception and pain are the inputs into the system. Suffering and pain behaviors are the culmination of responses of inputs into the nervous system.

Pain behavior is the behavioral manifestation of aversive stimulation and suffering. As such,

prior experiences, expectancies, vulnerability factors, and perceived or anticipated losses should be taken into account. Taken together, these underscore the fact that an evaluation of pain is incomplete without an evaluation that assesses the complex interactions between the patient, their caretakers, and all of the factors that contribute to the pain experience including the idiosyncratic expression of pain and suffering.

Inherent to this model is the notion that in order to adequately manage pain, suffering of the patient and caregivers must also be assessed and treated. Given the frequency and complexity of pain and related symptoms in cancer patients in the face of challenging psychological variables, suffering can be quite severe. Factors such as fear, anxiety, depression, and distress, in addition to contributing to pain, are also predictors of the response to a treatment regimen (Romano et al., 1989). Pain and depression have been shown to be interrelated: Being depressed may cause a person to report higher levels of pain, while higher levels of pain may cause a person to be depressed (Williams & Schultz, 1992). Distress, despair, and hopelessness can result in suicide preoccupation and requests for physician assisted death especially in the presence of unmanaged pain.

In summary, pain is a multidetermined phenomena that affects patients and their families. The consequences of unmanaged pain are significant to the overall psychological, physical, and immunologic status of affected individuals and their loved ones. In addition, the witnessing of a loved one suffering in pain will result in acute and long-term sequelae for caregivers, the effects of which may determine their lifelong reactions to pain and illness. Given today's trend of caring for the terminally ill patient in the home environment, we must more closely attend to relieving unmanaged symptoms in the family unit. By providing patients and families with the necessary resources, education, and support, we can significantly enhance the quality of their lives while going through such a devastating experience. □

REFERENCES

1. L.A. Bradley, J.M. Haile & T.M. Jaworski, "Assessment of Psychological Status Using Interview and Self-Report Instruments," in D.C. Turk & R. Melzack (eds.), *Handbook of Pain Assessment*, Guilford Press, New York, 1992.
2. C.R. Chapman, "Psychological Aspects of Pain Patient Treatment," *Archives of Surgery*, 1977, 112, 767-781.
3. C.R. Chapman, "Pain Measurement and Overview," *Pain*, 1985, 22(1).
4. C.S. Cleeland, R. Gonin, A.K. Hatfield, J.H. Edmondson, R.H. Blum, J.A. Stewart, J. England, & K.J. Pandya, "Pain and Its Treatment in Outpatients with Metastatic Disease," *The New Journal of Medicine*, 1994, 330, 9.
5. K.D. Craig, "Emotional Aspect of Pain," in P.D. Wall & R. Melzack (eds.), *Churchill Livingstone*, London, 1994.
6. H. Flor & D.C. Turk, "Chronic Back Pain and Rheumatoid Arthritis Predicting Pain and Disability from Cognitive Variable," *Journal of Behavioral Medicine*, 1988, 11, 251-265.
7. W.E. Fordyce, "Pain and Suffering: A Reappraisal," *American Psychologist*, 1988, 43 (4) 276-283.
8. J.D. Loeser, "Perspective on Pain," in *Proceedings of the First World Congress on Clinical Pharmacology and Therapeutics*, Macmillan, London, 1980.
9. J.M. Romano, J.A. Turner, J.A. Moore, "Psychological Evaluation," in *Handbook of Chronic Pain Management*, C.D. Tollison (ed.), Williams & Wilkins, Baltimore, 1989.
10. D. Spiegel, "The Use of Hypnosis in Controlling Cancer Pain," *Cancer, A Cancer Journal for Clinicians*, 1985, 35:221-231.
11. S.E. Ward, N. Goldberg, V. Miller-McCauley, C. Mueller, A. Nolan, D. Pawlik-Plank, A. Robbins, D. Stermoen, P.E. Weissman, *Patient-related Barriers to Management of Cancer Pain*, 1993, 52:3, 1993, 319-324.
12. A.K. Williams & B.R. Schultz, "Association of Pain and Physical Dependency with Depression in Physically Ill Middle-Aged Elderly Persons," *Physical Therapy*, 1988, 68:1, 1226-1230.

"You put yourself in neutral. You don't think. You don't plan...(you) just suffer. You live and count to ten often enough (and) hope the pain pill takes effect."

(Ferrell, Grant, Padilla, Vemuri, & Rhiner, 1991)



What Can Health Professionals and Pharmacists Do to Effect Change in Pain Management in an Institutional Setting?

BY LYNNE M. RIVERA, RN, MS.N.

Research Specialist, City of Hope National Medical Center
Department of Nursing Research and Education at Duarte, California
Chair, Public Education Committee, Southern California Cancer Pain Initiative

Pain has been described as an overwhelming experience that consumes all aspects of an individual's life. Unrelieved pain causes unnecessary suffering and burden for the patient. The table below explains the relationship between pain and quality of life (QOL) and demonstrates the enormous impact that pain has on quality of life.

The Impact of Pain on Quality of Life ¹			
PHYSICAL WELL BEING & SYMPTOMS	SOCIAL WELL BEING	SPIRITUAL WELL BEING	PSYCHOLOGICAL WELL BEING
Fatigue / Strength	Family Distress	Religiosity	Anxiety
Appetite	Family Support	Uncertainty	Depression
Sleep	Sexuality / Affection	Positive Changes	Coping
Constipation	Employment	Sense of Purpose	Control
Nausea	Isolation	Hopefulness	Concentration
Function	Financial Burden	Suffering	Sense of Usefulness
	Appearance	Meaning of Pain	Fear
	Roles & Relationships	Transcendence	Enjoyment / Happiness

Over the past two decades, there has been an increased awareness about the impact of pain on a person's QOL. Several professional organizations, (e.g., the American Cancer Society, National Institutes of Health, Joint Commission on Accreditation of Health Care Organizations, and World Health Organization), have identified pain management as a priority in the provision of care. Despite growing awareness of the problem, all types of pain (e.g., acute pain related to injury, disease, procedures, or surgery; and chronic pain related to cancer and other nonmalignant medical conditions such as arthritis or back pain) continue to be undertreated.

Inadequate pain management can lead to costly and unscheduled hospital admissions, and increased length of stay for the patient with pain². Unrelieved acute pain can also cause prolonged postoperative recovery that may lead to other costly sequelae including lost wages and increased length of stay.

BARRIERS TO ADEQUATE PAIN MANAGEMENT

Many barriers to adequate pain management have been identified. Generally, these barriers are attributable to society's viewpoint, both in the health care community and in society at large, that pain relief is not a priority in the delivery of care.

SOLVING THE PROBLEM

Effective pain management can be achieved through institutional commitment—achieving change by means of a top-down approach. Pain management should be an institutional priority that is reflected in the institution's goals, its mission statement, and through strategic planning to develop pain management policies and promote appropriate clinical practice. Several strategies have been identified to achieve institutional commitment to pain management.^{3,4,5,6} Ferrell has identified eight strategies for improving pain management that are discussed below.

DOCUMENTING THE STATUS OF PAIN MANAGEMENT

Strategies for documenting the status of pain management include assessing the knowledge and attitudes of health professionals.^{4,7} These activities are most successful when organized and conducted by a multidisciplinary team.

Chart audits provide information about pain assessment and about documentation and pharmacologic management of pain, inconsistencies between practice and the clinical standards developed by professional organizations. Objective data obtained through audits often identify (a) inadequate assessment

practices, (b) inappropriate prescribing practices, (c) inadequate administration of analgesic doses, (d) use of PRN medication schedules, (e) underuse of pain consultants, and (f) minimal or no use of nonpharmacologic pain relief methods.

Patient interviews supplement the audits. Interviews should include (a) assessment of the patient's current pain intensity, (b) range of pain intensity over the past 24 hours, (c) worst pain, (d) side effects, (e) pain relief, and (f) perceived patient barriers to pain management.⁷ While many institutions are interested in identifying patient satisfaction, this information must be evaluated with caution. Patients often report satisfaction with treatment of their pain, despite being in moderate to severe pain.⁸ Commonly, this occurs because patients have low expectations for receiving pain relief and even minimal pain relief is better than no pain relief at all.

Generally, health professionals perceive themselves as knowledgeable clinicians who provide good pain relief. Thus, it is helpful to obtain objective information related to their pain management knowledge and attitudes. The information is used to identify topics for staff education. These surveys can be simple and easily administered in staff meetings.

ESTABLISHING A STANDARD OF CARE

Standards for the provision of appropriate pain management have been developed by organizations such as the American Pain Society, Committee on Quality Assurance Standards (1991); American Society of Clinical Oncology, Ad Hoc Committee on Cancer Pain (1992); Agency for Health Care Policy and Research (AHCPR), Acute Pain Management Guideline Panel (1992); and AHCPR, Management of Cancer Pain Guideline Panel (1994). However, individual institutions rarely have written policies that reflect these standards. Pain guidelines can serve as a resource and foundation for institutions to develop an institutional standard of care that promotes the institution's commitment to providing appropriate pain relief. An institutional standard of care should include (a) an expectation that pain can be relieved; (b) a uniform standard for the assessment and documentation of pain and its management; (c) and require professional accountability.

EDUCATING THE PATIENTS

Generally, patients have little knowledge about pain related information, have low expectations for receiving effective pain relief, and are unaware of their rights or options. Thus, patient education is a vital step to achieving effective pain relief. The aims of patient education should be to (a) increase knowledge

about the pain control regimen; (b) identify the rationale for the prescribed pain relief regimen; (c) increase the patient's ability to recognize and manage side effects; (d) clarify patient misconceptions related to addiction and tolerance; (e) improve adherence to the pain control regimen; (f) identify the patient's role in managing the pain; and (g) promote effective communication with health professionals. Education provides patients with the knowledge and skills needed to self-advocate for effective pain relief.

While pain information can be provided using one-to-one verbal contact between health professionals and patients, written materials, and audio and video tapes should also be used to reinforce the content and promote retention. Institutions can develop their own patient education materials or use existing materials. The AHCPR has patient education materials on acute pain management and cancer pain management that can be ordered through the National Cancer Institute's toll free number at 1-800-4-CANCER or by writing to the AHCPR Clearinghouse, Cancer Pain Guideline, P.O. Box 8547, Silver Spring, MD 20907. The American Cancer Society has a patient education book that can be ordered through their district offices. Other patient education materials can be ordered through the Mayday Pain Resource Center, located at the City of Hope Medical Center, Duarte, CA, (818) 359-8111, extension 3829.

EDUCATING THE PUBLIC

The general public also lacks accurate and current information about pain management. Therefore, community outreach is an important component to providing effective pain relief. Public education about the problem of pain and its treatment is critical for several reasons including (a) society's unwarranted preoccupation with the risk of drug abuse that is promoted by the media; (b) increased use of home care in which family members are responsible for providing pain management; and (c) the changing health care system.

RECOGNIZING THE COST OF FAILURE TO TREAT PAIN

The current health care system requires health professionals and health care institutions to provide care with fewer resources. While pain relief measures do cost the system, failure to provide effective pain relief is not cost effective. Unscheduled readmissions for uncontrolled pain and increased length of stay are costly.² It is imperative that health care institutions compare cost effectiveness and cost benefits associated with inadequate pain relief and effective pain relief.

SUMMARY

Pain can be effectively relieved for most patients. Health professionals and health care organizations are challenged to accept responsibility for

Patients often report satisfaction with treatment of their pain, despite being in moderate to severe pain.⁹ Commonly, this occurs because patients have low expectations for receiving pain relief and even minimal pain relief is better than no pain relief at all.

providing effective pain relief for their patients in pain. This challenge can be achieved through an organizational commitment that supports acquisition of current pain management knowledge, ongoing pain assessment, patient and public education, and development of an institutional standard of care for the relief of pain. Through these efforts, health care organizations and health professionals will ensure that effective pain relief is provided for all patients and that continuity of care for pain management activities is provided between inpatient units, outpatient units, physicians' offices, hospice, and the home care setting. **E**

References

1. B.R. Ferrell, "The Impact of Pain on Quality of Life: A Decade of Research," *Nursing Clinics of North America*, 1995, 30(4), 609-624.
2. M. Grant, B.R. Ferrell, L.M. Rivera & J. Lee, "Unscheduled Readmissions for Uncontrolled Symptoms: A Health Care Challenge for Nurses," *Nursing Clinics of North America*, 1995, 30(4), 673-682.
3. B.R. Ferrell, "An Institutional Commitment to Pain Management," *APS Bulletin*, April/May 1994, 16-17, 20.
4. B.R. Ferrell, G.E. Dean, M. Grant & P. Coluzzi, "An Institutional Commitment to Pain Management," *Journal of Clinical Oncology*, 1995, 13(9), 2158-2165.
5. B.R. Ferrell & C.J. Leek, "Pain," In J.L. Creasia & B. Barker (Eds.), (pp. 345-362). *Conceptual Foundations of Professional Nursing Practice*, Philadelphia, PA: Mosby.
6. Max, M.B., "Improving Outcomes of Analgesic Treatment: Is Education Enough?", *Annals of Internal Medicine*, 1990, 113:885-889.
7. E.B. Clarke, B. French, M.L. Bilodeau, V.C. Capasso, A. Edwards & J. Empoliti, "Pain Management Knowledge, Attitudes and Clinical practice: The impact of Nurses' Characteristics and Education," *Journal of Pain and Symptom Management*, 1996, 11(1), 18-31.

9. C. Miaskowski, R. Nichols, R. Brody & T. Synold, "Assessment of Patient Satisfaction Utilizing the American Pain Society's Quality Assurance Standards on Acute and Cancer-Related Pain," *Journal of Pain and Symptom Management*, 1994, 9(1), 5-11.

Additional Reading

1. Acute Pain Management Guideline Panel. Clinical practice guideline. Acute pain management: Operative or medical procedures and trauma, U.S. Department of Health and Human Services. Agency for Health Care Policy and Research, AHCPR Publication No. 92-0032, 1992.
2. Ad Hoc Committee on Cancer Pain, American Society of Clinical Oncology. Cancer pain assessment and treatment curriculum guidelines. *Journal of Clinical Oncology*, 1992, 10(12), 1976-1982.
3. Committee on Quality Assurance Standards, American Pain Society. American Pain Society Quality Assurance Standards for Relief of Acute Pain and Cancer Pain. In M.R. Bond, J.E. Charlton & C.J. Woolf (Eds.), (pp. 186-189). *Proceedings of the VI World Congress on Pain*, Amsterdam: Elsevier, 1990.
4. B. R. Ferrell, M. Whedon & B. Rollins, "Pain and Quality Assessment/Improvement," *Journal of Nursing Care Quality*, 1995, 9(3), 69-85.
5. B.R. Ferrell, C. Wisdom, M. Rhiner & J. Alletto, "Pain Management as a Quality of Care Outcome," *Journal of Nursing Quality Assurance*, 1991, 5(2), 50-58.
7. Joint Commission on Accreditation of Health Care Organizations. Accreditation Manual for Hospitals, Oak Brook Terrace, IL: JCAHO, 1993.
8. Management of Cancer Pain Guideline Panel. Clinical Practice Guideline. Management of Cancer Pain, U.S. Department of Health and Human Services. Agency for Health Care Policy and Research, AHCPR Publication No. 94-0592, 1994.
8. Pain Research Group, Department of Neurology, University of Wisconsin-Madison. Available in AHCPR Cancer Pain Management Guideline. May be duplicated and used in clinical practice.
9. S.E. Ward, N. Goldberg, V. Miller-McCauley, C. Meuller, A. Nolan, D. Pawlik-Plank, A. Robbins, D. Stormoen & D.E. Weissman, "Patient-related Barriers to Management of Cancer Pain," *Pain*, 1993, 52, 319-324.
10. World Health Organization. Cancer Pain Relief and Palliative Care. Report of a WHO Expert Committee, Geneva Switzerland: World Health Organization, 1990.

TRAINING PROGRAMS AND REGULATORY CHANGES ARE ESSENTIAL FOR BETTER PAIN MANAGEMENT

By William L. Marcus,
Deputy Attorney General, Department of Justice
Liaison Counsel, California State Board of Pharmacy
Sandra K. Bauer,
Public Member,
California State Board of Pharmacy

One very important aspect of improving pain management involves the education and training of those concerned with or affecting the quality of pain treatment. This includes not only prescribers, pharmacists, and other healthcare professionals, but patients, caregivers, the public, and—of course—those engaged in setting and carrying out regulatory policies.

REFORMING THE TRIPPLICATE PROGRAM

Changes in regulatory policy gained impetus when state Senator Robert Presley gained passage of Senate Current Resolution 74 in 1992. Subsequently, a ten member Council was formed to review the state's triplicate prescription process (which is mandated when Schedule II drugs are prescribed). California's Triplicate Prescription Program has often been cited as a major impediment to patients receiving adequate medication for pain. The Council, chaired by Sandra Bauer, studied the issue, recognized that there was a serious problem of under treatment of pain on the part of the state's medical practitioners, and called for the computerization of the triplicate program in order to facilitate appropriate prescribing.

Reform of the triplicate process continued in 1994 with the Board of Pharmacy funding a computer feasibility study. The Board also supported legislation (AB 3042, Takasugi) in 1996 which makes available over \$1 million to establish an electronic triplicate program as a three year pilot project. The project will be a unique partnership of the Board and the state's Bureau of Narcotic Enforcement.

When implemented, the new Controlled Substances Utilization Review and Evaluation System (CURES) will computerize Schedule II prescription data and revolutionize the current cumbersome triplicate system. It will also for the first time make data available for educational, peer review, statistical, and research purposes. The data could become a very important tool for developing medical policies based on demographic research.

DEVELOPMENT OF EDUCATIONAL PROGRAMS

Regarding training programs, the Department of Consumer Affairs and Board of Pharmacy member Raffi Simonian have developed proactive consumer education programs on pain management and patient rights.

Another equally important facet of pain management training is the presentation of programs for those involved in the investigation and prosecution of pain management disciplinary cases. A half-day program on the nature of pain, methods of pain management, laws and regulations governing pain management, and case examples has been presented by Laura Audell, M.D., the director of the Pain Center at Cedars-Sinai Comprehensive Cancer Center in Los Angeles, John Berger, Pharm.D., J.D., and William Marcus of the Attorney General's Office. The program has been presented for the deputy attorneys general and administrative law judges who handle or hear disciplinary cases for the medical, pharmacy, nursing, dental, and other health profession boards. A similar program, coordinated by Joan Jerzak of the Medical Board of California, was presented at a training conference of state and federal investigators. At least twice separate presentations on pain management have been presented by Board supervising inspector Dora Gonzalez and Mr. Marcus, at Board inspector workshops.

BETTER ENFORCEMENT ACTIVITIES

In addition to providing training, both the Board of Pharmacy and the medical board have aggressively sought out experts in pain management to evaluate potential disciplinary cases and completed investigations. Such evaluations minimize the likelihood of expending time and money on future investigations of legitimate medical practices, while at the same time strengthening cases against those who should have action taken against their licenses.

The effect of training those involved in investigating and prosecuting (and deciding) pain management disciplinary cases, combined with law changes, the boards' statements and guidelines, and some of the other changes cited in this publication, should result in less actual intrusion into appropriate, legitimate medical and pharmaceutical practice. This in turn should lead to lessened fear and tension in professional communities, and more effective (more successful; more cost efficient) investigation and prosecution of the practitioners who should be disciplined and even criminally prosecuted.

Training and education in pain management must be an ongoing process. The state of knowledge about the nature and different kinds of pain and the available and appropriate modalities of treatment is steadily improving. What was accepted 10-15 years ago is often recognized as being in error today. What is believed today may be superseded in another decade or so. The Board understands this and is committed to ensuring it applies appropriate standards to its disciplinary cases and in the development of its laws, regulations, and policies. The Board is helping to communicate current knowledge and standards to its licensees and to the public.

OTHER SIGNIFICANT REGULATORY CHANGES

In 1990, California became the second state to enact an intractable pain treatment act (Business and Professions Code section 2241.5). The act recognized the legitimacy of chronic use of controlled substances to treat pain in appropriate cases.

In 1994, the Governor sponsored the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing. Over 120 regulators, legislators, practitioners, and others met to identify, discuss, and recommend solutions for problems affecting delivery of adequate care of pain patients in California. The Board of Pharmacy co-sponsored the summit. □

HEALTH NOTES Pain Management 1996 17

Continuing Education

By The California Society of Health System Pharmacists

1) Which of the following are considered barriers to effective pain management?

- a) lack of knowledge among consumers about pain management
- b) exaggerated fears of opioid side effects and addiction
- c) fear of legal consequences when controlled substances are used
- d) all of the above

2) When filling prescriptions for chronic pain control medications, the pharmacist should assess whether the patient has:

- a) constipation
- b) nausea and vomiting
- c) central nervous system side effects
- d) all of the above

3) Which of the following statements is not true? If a patient is requesting refills much earlier than scheduled, the pharmacist should:

- a) consult with the patient to determine whether their pain is being adequately controlled
- b) discuss with the prescriber the patient's uncontrolled pain and the possibility of changing the patient to a better analgesic regimen
- c) immediately refuse to fill the prescription and notify the authorities
- d) document the reasons the patient is seeking refills on a more frequent basis and notify the prescriber about any loss of medications

4) Which of the following questions are important for a pharmacist to answer related to the management of a patient's pain?

- a) Are the directions correct for the medication prescribed?
- b) Is there documentation of the diagnosis?
- c) For chronic pain, does the medication have a long enough half-life for adequate pain control?
- d) all of the above

5) Which of the following statements is not true? Schedule III-V prescriptions, among other requirements must:

- a) be signed and dated by the prescriber
- b) be presented on a prescription document that is not mutilated, forged, or altered
- c) be submitted on a clear and complete triplicate prescription form
- d) not be refilled more than 5 times or refilled 6 months after the issuance date of the prescription.

6) According to Cleeland (1994), the inadequate management of pain may occur in as many as % of cancer patients.

- a) 90%
- b) 56%
- c) 42%
- d) 27%

7) With the long term treatment of pain with opioids, patients may develop a tolerance or dependence on the drug. These occurrences are considered "nor-

To receive 3 hours of continuing education credit (0.3 CEUs) for successful completion of this program, you must return the completed answer sheet to the California Board of Pharmacy No later than April 1, 1997.

Please type or print clearly.

Name: _____

Address: _____

City: _____

State: _____

Zip Code: _____

Mail your completed answer sheet to:
Continuing Education Desk
California State Board of Pharmacy
400 R Street
Suite 4070
Sacramento, CA 95814

Please circle one answer for each question.

- | | |
|------------|-------------|
| 1. a b c d | 10. a b |
| 2. a b c d | 11. a b c d |
| 3. a b c d | 12. a b c d |
| 4. a b c d | 13. a b c d |
| 5. a b c d | 14. a b |
| 6. a b | 15. a b |
| 7. a b c d | 16. a b c d |
| 8. a b | 17. a b c |
| 9. a b | |

mal" and "to be expected"—they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking". This statement is:

- a) True
- b) False

8) Several studies have suggested that psychosocial factors are better predictors of pain than the extent of pathophysiological damage. This statement is:

- a) True
- b) False

9) Patients should take analgesics only when they can no longer tolerate the pain. This statement is:

- a) True
- b) False

10) The fact that a patient always requests one particular medication is a sure sign that the patient is addicted to that particular drug. This statement is:

- a) True
- b) False

11) Dependence:

- a) occurs when the same dose of an analgesic becomes less effective over time and may result in therapeutic failure.
- b) is the physiological need for a drug and without which the body undergoes withdrawal symptoms.
- c) is the culmination of drug dependence and drug seeking behavior
- d) none of the above

12) Strategies for documenting the status of pain management include which of the following?

- a) Chart audits
- b) Patient interviews
- c) (a) and (b)
- d) none of the above

13) Patient interviews related to the management of pain should include which of the following?

- a) assessment of the patient's current pain intensity, worst pain, and range of pain intensity over the past 24 hours
- b) side effects
- c) perceived patient barriers to pain management
- d) all of the above

14) The only standards which exist for the provision of appropriate pain management were developed by the AHCP, Management of Cancer Pain Guideline Panel (1994). This statement is:

- a) True
- b) False

15) Generally, patients are well informed about pain related information, have high expectations for receiving effective pain relief, and are aware of their rights and options. This statement is:

- a) True
- b) False

16) Which of the following statements is not true?

- a) Over-the-counter (OTC) analgesics including acetaminophen, aspirin, and non-steroidal anti-inflammatory drugs (NSAIDs) are often used as first-line therapy for mild to moderate pain.
- b) Narcotics such as codeine, morphine, and oxycodone are usually reserved for severe pain.
- c) Narcotics should not be used in combination with NSAIDs, antidepressants, and anxiety agents for the relief of severe pain.
- d) All of the above

17) Which of the following statements is false regarding the management of cancer pain?

- a) Cancer patients will get better pain relief if they take their medication as scheduled, rather than as needed.
- b) Injectable opioids are more effective than oral opioids, since they act faster.
- c) Even though some NSAIDs are OTC, they are effective at higher doses in relieving bone pain associated with cancer.

Making A Difference

KNOLL PHARMACEUTICAL COMPANY

Demonstrating the value of communication, Knoll Pharmaceutical Company provided an educational grant to help fund The Board of Pharmacy's Pain Management Issue of Health Notes.

CALIFORNIA SOCIETY OF HEALTH SYSTEM PHARMACISTS

Advocating that pharmacists provide quality patient care, The California Society of Health System Pharmacists assisted the Board of Pharmacy by facilitating the printing and developing the continuing education section of the first issue of Health Notes.



CALIFORNIA STATE BOARD OF PHARMACY

Bulk Rate
U.S. Postage
PAID
Permit No. 685
Sacramento, CA

State Board of Pharmacy
Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

(916) 445-5014

*Special thanks to the following organizations for providing
photographs of pharmacists counseling patients:*

Long Drug Stores

Safeway Inc.

National Council on Patient Information and Education (NCPPIE)

Walgreen Company

Design: Tim Davis