Pain Management and End-of-Life Care CME Program

Module 6

Registration: The registration page and test questions are at the end of this article. The 12 questions must be answered and submitted to the CSA in order to receive the CME credit. The full text of each module of this CME program, along with references, also will be accessible through the CSA Web Site, **www.csahq.org**, in the Online CME section and as part of the online *CSA Bulletin*.

Fees: This is a free service for CSA members. Non-members will be charged $25 per CME credit hour. Your CME certificate will be mailed from the CSA office.

Availability: This module is available from June 30, 2005, until June 30, 2008.

Target Audience: California law now requires that every licensed physician complete 12 credit hours in pain management and end-of-life care by the end of 2006. This module fulfills one credit hour of CME toward that requirement. This program is intended for all licensed physicians, including anesthesiologists, residents, and physicians with an interest in pain management.

Faculty and Disclosures for Module 6:

Steven Richeimer, M.D.
Associate Professor of Anesthesiology and Psychiatry
Chief of the Division of Pain Medicine, and
Director of Palliative Medicine for the USC/Norris Cancer Center
at the University of Southern California, Keck School of Medicine

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In addition, speakers must disclose when a product is not labeled for the use under discussion, or when a product is still investigational.

Dr. Richeimer has received honoraria for speaking from these companies: Janssen, Pfizer,

and Merck. None of these affiliations represents a conflict with regard to the content of this article.

CME Sponsor/Accreditation: The California Society of Anesthesiologists is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.
The California Society of Anesthesiologists Educational Programs Division designates this educational activity for a maximum of 1 credit hour toward the AMA Physician's Recognition Award.

Evaluation: An evaluation of Module 6 of this series is offered after the test questions. Please fill in your responses and return them to the CSA office.

Objectives: At the conclusion of this course, participants should be able to:

1. Describe the legal risks of under- or over-prescribing opioid analgesics;
2. Discuss the legal requirements for assessment and documentation regarding the treatment of pain;
3. Apply preventive measures in the treatment of pain that reduce medical-legal risk;
4. Identify factors that can be used to assess the trustworthiness of pain patients; and
5. Describe the risk of addiction in pain patients.

Resources: These materials, including questions, are offered online at the CSA Web Site at **www.csahq.org**. Instructions for the *Bulletin* version are on the registration page.

Opioids for Pain: Risk Management

By Steven Richeimer, M.D., Associate Professor of Anesthesiology and Psychiatry, Chief of the Division of Pain Medicine, and Director of Palliative Medicine for the USC/Norris Cancer Center at the University of Southern California, Keck School of Medicine

Dr. Richeimer is board certified in pain medicine, anesthesiology, and psychiatry. He has lectured extensively on medical-legal issues in pain medicine and is a Forensic Pain Management sub-section editor for the Journal of Pain Medicine.

The treatment of our patients' pain has become a medical-legal minefield. Rightly or wrongly, we are being held to a very high standard. As physicians, we are being asked to assess accurately whose pain is real and whose is not. We are getting sued for over-prescribing pain medications as well as for under-prescribing. On the one hand, patients are claiming that we turn them into addicts, and on the other hand they claim that we leave them suffering

unnecessarily. Furthermore, the regulatory agencies are watching over our shoulders, ever vigilant for mis- prescribing. To a much lesser degree, some state medical boards (including California) are also taking an interest in the under-treatment of pain.

There are several preventative measures that can help to reduce the practitioner's risk of suffering a medical-legal action:

1. Prescribe only to your patients
2. Assess pain thoroughly
3. Educate and provide informed consent
4. Document
5. Don't hesitate to get help
6. Know how to manage addiction risk in patients with pain
7. Have a reliable emergency call system
8. Don't fail to treat pain

Most physicians already incorporate most of these principles into their practices, but it is likely that there are one or two of these that need to be added or further developed.

1. Prescribe only to your patients

First and foremost: never prescribe, certainly not a controlled substance, to anybody who is not your patient. As soon as you prescribe to somebody that is not your patient, in the eyes of the DEA and the Medical Board you just moved out of the "doctor box" and into the "dealer box." How do you prove that someone is your patient? Billing records will not suffice. The only way to prove it is with a documented history, physical and treatment plan.[1] Without this documentation, they are not your patient.

There is an exception-when you are on call for another physician. California law[2] allows for a designated physician to maintain and dispense drug treatment "only as necessary to maintain the patient until the return of his or her practitioner, but in any case, no longer than 72 hours." So if you are on call on a three-day weekend, you may exercise your medical judgment and prescribe a three-day supply of medication, but if you are covering your colleague for a two-week vacation, then before prescribing a controlled substance, it is best for you to see the patient for a history, physical, and documentation of a treatment plan.

Imagine you have a friend visiting from out-of-state who tells you that he forgot to pack his back pain medication (hydrocodone), and he wants you to prescribe enough to cover him for his trip. You have two choices: "no," or "perhaps, but first I have to make you my patient, so I need to do a history, physical, and establish a treatment plan."

2. Assess pain thoroughly

Assessment is a key issue. The history and physical examination (H&P) provides the information that allows the physician to judge if the patient is legitimately in pain, or if the patient is improperly seeking drugs. Physicians are not trained to be lie detectors, but a good faith assessment can reinforce the initial impression of a need for analgesics, uncover warning signs that might trigger the physician to delve more deeply, or prompt the physician to request assistance via consultation.

I would like to highlight a few critical issues in the assessment. (A more detailed review of the pain assessment is covered elsewhere.[3]) It is important to recognize that in the H&P, there are no objective markers for pain. The H&P may provide important clues-inconsistencies should be carefully examined. Not all inconsistencies imply malingering, instead they may be an indication of the patient's level of emotional turmoil. The history should cover the patient's prior and current history of analgesic use, as well as their history of substance abuse. Prior medical records and/or contact with prior providers can help to verify the history.

The physician must use the information from the H&P to assess for the presence of risk factors for addiction. A history of prior substance abuse or addiction is the primary risk factor. Other issues to consider include the presence of untreated depression or anxiety, or a history of rapidly escalating opioid dosing without a rapidly progressive disease. Without the presence of risk factors, it appears to be rare for pain patients to develop addiction.[4]

It is important to realize that the initial H&P does not allow the clinician to assess a critical variable: the trustworthiness of the patient. This can only be assessed by monitoring the patient over time. Is the patient fully compliant with prescription instructions and other treatments? Does the patient make an effort to get better by pursuing recommended treatment (e.g., physical therapy)? Is the patient consistent with coming to appointments and with the use of medications? The patient should be instructed always to call you before changing the dose of any prescribed medication-do they comply? Because pain is subjective, we rely on the patients to report accurately their symptoms. Assessing the

trustworthiness of the patient allows the physician to determine if they can rely on the patient's self-reports.[5]

In addition to assessing trustworthiness, follow-up visits should be used to assess the patient's response to treatment. Opioids should only be used when it is clear that they are helpful. The alert physician should look for a deterioration of the patient's overall psychosocial functioning; this may herald the development of addiction. The assessment of trustworthiness and treatment response will often enable the physician to distinguish between addiction and pseudoaddiction-the latter is a description for the drug seeking behavior that can result from the under- treatment of pain.[6]

3. Educate and provide informed consent

Physicians must provide their patients with information about the risks of all proposed treatments, including the risks of using and not using opioids.[7] This can be done together with a process of educating the patient about the risks of addiction and the steps that your practice takes to minimize the risk. This should be done as a discussion with the patient. According to California law, a document is not necessary, but is valuable as a way to memorialize the discussion.[8] Various combinations of informed consent documents[9] and treatment agreements[10] can and should be used, but the key is the discussion with the patient. The consent and education process also provides an opportunity to discuss issues of driving while taking analgesic medications.[9]

4. Document

Good record keeping is part of good medicine, and it is also your best protection from frivolous lawsuits. Documenting the H&P and the treatment plan is more than good medicine, it is a requirement of the Medical Board of California.[1] Furthermore, it is necessary to document your assessment and new treatment plan for follow-up visits. Include some indication of your rationale for changes to the treatment plan. These follow-up evaluations should be done at least semi-annually, and the documentation should include your assessment of the patient's symptoms and functioning.

In addition to your assessment and treatment plan, you need to have a flow sheet. Imagine the following scenario: It is January 1; you prescribe oxycodone 5 mg, one po tid, # 90. Two weeks later you are on the phone, your nurse rushes in and hands you a piece of paper from the pharmacy asking for a refill, you sign off. This happens periodically, so that after a year the DEA comes knocking on

your door and says, “Doctor, we have a question. Why are you prescribing 30 days of medication every two weeks to patient X?”

At this point you have two bad answers. Bad answer number 1 is, “Oh, I didn’t know I was doing that.” The solution: maintain a flow sheet for all controlled substance prescriptions. For each prescription this sheet should document the date, drug, instructions, and the amount and refills. This allows the physician to easily check if a refill is due before writing for a refill. Alternatively, some physicians keep ordered copies of all their prescriptions in the chart.

Bad answer number 2 is, “That is what the patient needed.” On the surface this seems to be a good answer, but nothing in your chart reflects why you are giving enough medicine for two tablets po tid. The prescription shows one po tid, and your notes don’t indicate differently. Your notes have to reflect any change in treatment plan and should briefly state your rationale. You also need to update the instructions on the prescriptions from one TID to two TID. Everything in your chart should be clear and consistent.

5. Don’t hesitate to get help

If you are prescribing opioids on a long-term basis for a patient with intractable pain, then you should get a consultation.[1] This consultation can help to determine that no other treatment is needed and can provide a chart record from an expert that says, “I agree that chronic opioid therapy is appropriate.”

Consider obtaining a consultation for any pain patient that is at high risk for addiction, is not responding to treatment, requires rapidly escalating dosing, is non-compliant with treatment protocols, or is known to be abusing drugs. The clinician should also be alert for co-existing diagnoses of mood or anxiety disorders-here too, consultation may be helpful.

6. Know how to manage addiction risk in patients with pain

What happens if you have a patient who has a history of prior addiction, but who also has legitimate pain? These are some of our most difficult cases. I would like to convey a basic overall viewpoint that I think will help keep this problem in perspective. The viewpoint is that this scenario is not inherently different from any other case where you have a patient that has two diagnoses and where the treatments conflict.

If you have a patient with steroid dependent asthma and brittle diabetes, the steroids help with one problem and hurt the other problem. We are all very familiar with treating patients that have two conflicting illnesses. We have to carefully balance, titrate, and monitor our treatments-that is the same here. Our patient has two problems-they may need opioids for their pain, but the opioids may trigger their addiction. Therefore, carefully titrated, time limited doses should be provided together with close monitoring of response. Don't give the patient a month's worth of medication, give him a few days' or at the most a week's worth. Carefully monitor the outcome-family members may be helpful with this assessment.

It is also important to note that if the patient is actively abusing opioids, then you cannot prescribe for them outside of a controlled (inpatient) setting, where you can be assured that the patient is not using the medications for "non-therapeutic purposes."[1] Similarly, without special licensure, physicians may not prescribe opioids for the treatment of addiction. The non-expert physician should not manage these kinds of complex situations on their own. Get help. Get an addictionologist, a psychologist, a psychiatrist, or a pain doctor to work with you.

7. Have a reliable emergency call system

The following scenario is derived from an actual medical malpractice case. A 51-year-old, obese female, with intractable neck pain and headaches went to a new pain doctor. The doctor makes several medication changes. The changes result in an aggressive increase of the patient's analgesic dosing, but the changes are not below the standard of care. After two days, the patient complains the pain is worse. This time the doctor is even more aggressive in his dose increases. Thirty hours after this last dose increase, at five in the afternoon, the patient calls the physician with an urgent message that she is feeling light-headed, has a new kind of headache, and is very groggy. The call is not returned. At 5:00 a.m. the husband finds the patient unresponsive and 24 hours later, she dies in the hospital. This tragedy may have been averted had the physician responded in time.

The jury agreed with the plaintiff's attorney that if you prescribe any kind of potentially dangerous treatment, you have to have a bulletproof call system. Whether it is antibiotics, whether it is narcotics, whether it is surgery, if it puts the patient at any risk, you have to have a 100 percent effective call system. This particular doctor gave several reasons why he did not get this message, but the jury did not care. They considered it his responsibility to have a bulletproof emergency call system.

8. Don’t fail to treat pain

There are many situations where nothing can be done to improve the underlying painful condition that a patient has. Nevertheless, we can and should treat their pain and suffering-often this is best done by prescribing opioids. Opioid dosing has no fixed upper limit-treatment should be carefully titrated to the patient’s clinical requirements. After reviewing all of the precautions discussed earlier, we might be tempted to simply avoid treating with opioids or to minimally treat the pain. But we are accountable for treating pain and suffering. Failure to do so is both a moral and a legal problem.

In North Carolina, $15 million in damages were awarded to the family of Henry James, a patient who suffered at the end of his life because of the withholding of pain medications. In this case, the physician prescribed pain medications, but the nursing home nurse withheld the medications because she assessed the patient as being “addicted to morphine.”[11]
In California, the famous *Bergman vs. Chin and Eden Medical Center* is a similar case of a dying patient with under-treatment of his pain. In this case, the physician did not provide adequate treatment of the pain, and he was found liable for elder abuse and reckless negligence. The jury awarded 1.5 million dollars, which was subsequently reduced to a quarter million dollars.[12]

Physicians are well advised to listen to a medical-legal commentator’s observation that the “continued professional and public recognition of the importance of pain control likely will broaden liability exposure of health care providers who inappropriately manage pain.”[11]

Physicians must treat their patients’ pain, but this should be done in combination with thorough assessments, patient education, informed consents, complete documentation, use of consultants, carefully managed risk of addiction, and back-up emergency call systems. These preventative measures are nothing less and nothing more than good medicine.

References

1 Guidelines for Prescribing Controlled Substances for Pain, Medical Board of California: <http://www.medbd.ca.gov/Controlled_Substances.htm>

2 California Business and Professions Code, Section 2242: <http://www.leginfo.ca. gov/cgi-bin/displaycode?section=bpc&group=02001-03000&file=2220-2319>

3 Richeimer SH: Evaluation of the Patient with Pain; in, Gershwin ME, Hamilton M (Eds): *The Pain Management Handbook: A Comprehensive Guide to Diagnosis & Treatment*. Humana Press, 1998.

[4] The Risk of Opioids for the Treatment of Chronic Pain, A consensus statement from the American Academy of Pain Medicine and the American Pain Society. <http://www.painmed.org/productpub/statements/pdfs/opioids.pdf>

[5] Richeimer SH, Case GA. Ethical Issues and Problems of Trust in the Management of Chronic Pain; in, Warfield CA, Bajwa ZH (Eds): *Principles and Practice of Pain Management*, 2nd edition. McGraw Hill, 2004.

[6] Weissman DE, Haddox JD. Opioid pseudoaddiction-an iatrogenic syndrome. *Pain*. 1989 Mar;36(3):363-6.

[7] Informed Consent. Pain and the Law. <http://www.painandthelaw.org/mal practice/ informed_consent.php>

[8] Brushwood DB. *The Pain Treatment Agreement.* University of Florida. June 2002. <http://www.painandthelaw.org/mayday/brushwood_060302.php>

[9] Consent for Chronic Opioid Therapy. American Academy of Pain Medicine. <http:// www.painmed.org/productpub/statements/pdfs/opioid_consent_form .pdf>

[10] Long-term Controlled Substances Therapy for Chronic Pain: Sample Agreement. American Academy of Pain Medicine. <http://www.painmed.org/productpub/state ments/pdfs/controlled_substances_sample_agrmt.pdf>

[11] Shapiro RS: Health Care Providers' Liability Exposure for Inappropriate Pain Management. *Journal of Law, Medicine & Ethics*, 24, no. 4 (1996): 360-64. <http://www. painandthelaw.org/aslme_content/24-4c/24.4j.html>

[12] Undermedicating Cases. Pain and the Law: <http://www.painandthelaw.org/malprac tice/undermedicating_cases.php>

Additional Reading

Federation of State Medical Boards of the United States, Inc.: Model Guidelines for the Use of Controlled Substances for the Treatment of Pain: <http://www.fsmb.org/Policy %20Documents%20and%20White%20Papers/model_pain_guidelines.htm>

California Health and Safety Code, Section 11150-80: <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=01483116629+0+0+0&WAISaction=retrieve>

Registration

To register for the CSA CME Course in Pain Management and End-of-Life Care, Module 6, fill out this form. Then complete the test and the evaluation. Then **mail or fax** the form, the test answers and the evaluation to the CSA office at:

951 Mariner's Island Boulevard #270
San Mateo, CA 94404 FAX: (650) 345-3269

Pain Management and End-of-Life Care CME Course, Module 6
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Questions

1. Physicians should prescribe controlled substances only to their patients. California law allows which of the following exceptions?

    a. While covering for another physician, you may prescribe for up to 30 days, until their doctor returns.
    b. While covering for another physician, you may prescribe for up to 3 days, until their doctor returns.
    c. Regarding individuals that are well-known to you, you may exercise judgment regarding prescribing Schedule III drugs (but not Schedule II drugs).
    d. As long as you know that another doctor has done a history and physical, you may prescribe scheduled drugs.
    e. Physicians may never prescribe Schedule II drugs to an individual that is not their patient.

2. Which of the following factors can help you to assess the trustworthiness of your patient?

    a. Does the patient seek early refills of their pain medicine?
    b. Is the patient reliable about appointments and follow through with instructions?
    c. Does the patient pursue all suggested treatments in an effort to get better?
    d. Does the patient follow your instructions not to increase the analgesics without talking to you?
    e. All of the above

3. Regarding documentation, which of the following are true?

    a. The chart must contain an H&P and a treatment plan.
    b. A formal, written consent is necessary before prescribing opioids.
    c. It is wise to include a notation of opioid treatment consent discussions.
    d. If you fail to document an H&P, your billing records can serve as backup proof that you evaluated the patient.
    e. A and C
    f. B and D

4. Regarding treatment with opioid medications:

    e. Any knowledgeable, DEA certified physician may prescribe them for the treatment of pain.
    f. Any knowledgeable, DEA certified physician may prescribe them for the prevention of addiction-related withdrawal symptoms.
    g. Analgesic doses should never exceed the morphine equivalence of 100 mg per day.
    h. Patients with a prior history of substance abuse should never be treated with opioids.

i. Patients with an active history of substance abuse should only be prescribed long-acting opioids-short-acting opioids should be avoided.

5. If you are treating pain in a patient with a prior history of addiction:

   a. Ethical principles require that you treat the patient identically to pain patients without such a history.
   b. It is important to recognize that you are treating a patient that has two conflicting diagnoses.
   c. You should never prescribe opioids-the risk of addiction is just too great.
   d. You should seek consultation with a clinician experienced with treating patients with addiction risk.
   e. B and D are true

6. Which of the following strategies help physicians reduce the medical-legal risks associated with the treatment of pain?

   a. Have a 100 percent effective, emergency call system.
   b. Tell your patients that you "don't treat pain with narcotics," and that you will only prescribe anti-inflammatory medications.
   c. Document a thorough assessment, a treatment plan, and your rationale for your treatment plan.
   d. Pain is what the patient says it is; therefore, provide opioid analgesics to any patient that requests them.
   e. A and C are true

7. The public is becoming more aware of the importance of pain control, and is demanding better treatment.

   a. True
   b. False

8. Surgeons are trained to cure-they should leave pain control to their non-surgical colleagues.

   a. True
   b. False

9. Physicians have been sued for over-prescribing to their patients, but they have never been sued for under-prescribing.

   a. True
   b. False

10. Prior addiction is the biggest risk factor for patients developing addiction to opioid analgesics.

a. True

b. False

11. Any inconsistencies found in the history and physical examination imply that the patient is malingering.

    a. True
    b. False

12. Trustworthiness is a clinical variable that is best measured over time-it is difficult to assess on a single, initial visit.

    a. True
    b. False

Evaluation of Module 6

As part of the CSA Educational Programs Division's ongoing efforts to offer continuing medical education, the following evaluation of this program is requested. This is a useful tool for the EPD in preparing future CME programs.

1. How well were the learning objectives of this program met?

Very Well	5	Above Average	4
Average	3	Below Average	2
Not Well at All	1		

2. How relevant was the information in this program to your clinical practice?

Very Well	5	Above Average	4
Average	3	Below Average	2
Not Well at All	1		

3. How would you rate this program overall?

Very Well	5	Above Average	4
Average	3	Below Average	2
Not Well at All	1		

4. Did you detect any commercial bias in this module? Yes No