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Prescribing opioids, relieving patient suffering and staying out of personal trouble with regulators

Reprising Old Ideas and Offering New Suggestions

In 1998 The Pain Practitioner had a one page article about prescribing opioids and staying out of trouble. The world was simpler then! The US Federation of State Medical Boards had taken a pro-opioid position and illicit diversion and inappropriate use of OxyContin had not yet been reported by the media. Most importantly for me, Richard Weiner, PhD, cofounder and Executive Director of this Academy had not been diagnosed with the pancreatic cancer that would take his life. It is his death that brings me to re-examine our commitment to patient care and the relief of pain through the use of opioid analgesics. If the Executive Director of the largest pain management organization in the USA must suffer with pain due to the fear within physicians to prescribe opioids then what is the average citizen having to endure?

What about the "OxyContin Fiasco" anyway? Virtually no patients receiving licit prescriptions have actually died as a consequence of the medication. Yes, a few patients have committed suicide and used their prescription medications to do so. The truth is that this fiasco has nothing to do with patients suffering from intractable pain, but rather is directly due to the illicit diversion of lawfully prescribed medications and the subsequent use by opioid naive individuals or by desperate addicts who will do anything to get as high as they can. Why are millions of pain sufferers being punished by withholding their needed medications because of a small population of careless drug abusers? Should terminal patients have to go to their death taking handfuls of over-the-counter analgesics because no one felt comfortable prescribing opioids? Perspective has been lost.

I am aware that there are "bad apples" in the world and I do know "script clinics" exist that have done less than was required under both federal and state laws regarding controlled substances while clearly making their operators very wealthy. I have come to know too many physicians who have gotten into trouble in the past three years because of weaknesses in their prescribing habits. I have reviewed many boxes of medical records trying to help these individuals who were not profit minded, greedy crooks, but were caring clinicians trying to do what they thought was the right thing for their patients. Most were just trying to help patients, but got "caught" prescribing controlled substances without adequate documentation.

The 10 Tips I wrote about in 1998 are still true and should keep most prescribing practitioners out of serious trouble with regulators. I want to add some new considerations to these 10 tips without frightening readers today. First, understand that all prescribers can be "trended" because every controlled substance prescription written or telephoned to a pharmacy is linked to the prescriber's unique DEA registration number. Yes, they are looking over your shoulder. Know that if you are

practicing pain management as a true pain practitioner with proper documentation then you are perfectly safe prescribing opioids for your patients.

What Can Get You Into Trouble?

During the past few years, I have found several common practices that have gotten physicians into trouble regarding opioid prescribing:

1. Failure to evaluate patients (i.e. no history or physical examination)
2. Failure to make any diagnosis prior to the initiation of treatment
3. Failure to obtain outside medical records or to talk with previous practitioners (any verification at all)
4. Failure to establish goals for treatment (i.e. reduction in pain, improvement in function)
5. Failure to suspect misbehavior or substance abuse (i.e. no screen for addictive potential and no monitoring through treatment)
6. Failure to document the diagnosis, treatment plan, goals for treatment, continuing need for medication and lab results
7. Failure to understand what drug testing can and cannot tell you
8. Deviation from the "contract" (i.e. misbehavior is never addressed either verbally or written)
9. Blind acceptance of whatever is said by patients
10. Trying to bully law enforcement or regulatory agents or assuming an arrogant "I-know-best" attitude when confronted by them

This is not an all inclusive list, but is a fair representation of what I have seen in the records that have been submitted to the Academy for review through the Second Opinion Utilization Review program.

Ten Tips for Staying Out of Trouble

I will now examine each tip that was written in 1998 and offer some updated comments:

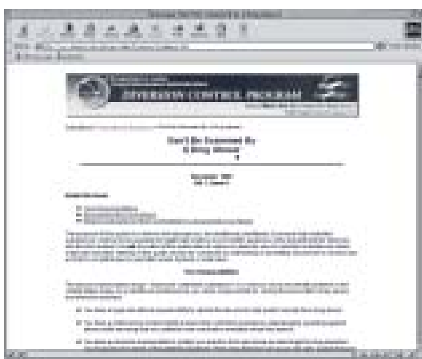
1. Obtain a thorough history and perform a first rate physical examination on your patients to accurately determine what causes their pain. Do not call their pain a headache or backache, but try to find a specific pathological process to explain why your patients hurt. Make certain you have screened your patients for substance abuse and other forms of psychological dependency prior to prescribing controlled substances. Consider using the CAGE questionnaire (Buchsbaum & Buchanan, 1991) or other methodology for detecting substance abuse.
2. Chart everything you see, think, feel and hear about your patients. Leave nothing to the imagination of the future reader. Have every chart entry sufficiently detailed so that it stands alone if separated from the rest of the chart. Have a progress note for every prescription written or telephoned to a pharmacy. Explain what you are doing, why you believe opioid analgesics will be helpful or continue to be helpful, what alternatives have been considered, that your patient agrees to the treatment and how you intend to follow your patient over time. Don't put "off-the-cuff" comments in your chart notes (Amazingly, this statement was found in an actual doctor's chart: "Ms. J. my little Demerol addict, returns for her monthly prescription " and the doctor was still prescribing Demerol!).
3. Obtain informed consent from your patients so there is no doubt about the treatment proposed. All

treatments contain elements of risk. The benefits must outweigh the risks. Your patients must agree that only you will prescribe controlled substances for their painful conditions, and there will be no going to the emergency room or other practitioners without your permission except for non-pain related life threatening problems. Consider using written opioid agreements to document this process. If patients breach their agreements or fail to agree initially to the terms of treatment (i.e. won't sign such an agreement), do not continue to maintain the status quo and continue writing for any or more medication. Without a practitioner-patient relationship there is no legal basis for prescribing any controlled substances.

4. Get your patients to agree to use only one pharmacy. Call the pharmacist with the patient's permission (perhaps in the patient's presence) and explain why you intend to prescribe long term opioids. Ask the pharmacist to tell you if there are any concerns or issues about your patients receiving opioids. Make certain that the pharmacy stocks the medications you expect to prescribe. Ask if the pharmacist needs prior notification before each prescription is written and whether fax copies are required before the written prescription is received.
5. If you are seeing your patients in the capacity of a primary care practitioner who is not trained as a pain specialist, get a second opinion from a pain management specialist, a specialist in the involved organ system or a specialist in the overall disease process. Share the responsibility to prescribe opioid analgesics with another practitioner. Have the other practitioner give you a written statement for your medical records.
6. Prescribe long acting opioid analgesics on a time contingent basis so that stable levels are achieved. Avoid "as needed" medications and only use immediate release medications to cover periods of breakthrough pain. Continue to adjust the sustained release medications until the use of immediate release breakthrough medication is no more than three times daily. Expect pain to possibly fluctuate over time and have contingencies established prospectively with patients.
7. See your patients who are receiving opioid analgesics on a regular basis. Do not just see patients in crises (4:45 pm on the Friday afternoon before the three day weekend when they are down to a single pain pill and don't know what they are to do). Always document why your patients continue to need opioid medications. Do not give open ended prescriptions with refills (refills are not allowed on Schedule II agents). See your patients when new prescriptions are written. Don't just leave written prescriptions with the office staff for patients to pick up when you are not in the office. Avoid telephone prescriptions if at all possible. If it is clinically necessary for you to continue prescribing controlled substances over time, it is clinically necessary for you to see these patients.
8. Determine the minimum dose necessary to maintain function and useful activities of daily living by potentially trying to decrease the dosage (25-35%). See if your patients can maintain their level of activities and stay out of bed with less medication. Discuss this with your patients before you decrease their dosages and agree together about the outcome criteria and future course of action should they do just as well with less medication.
9. Order urine drug screens for your patients of concern to document that you are able to recover their prescribed medications (to rule out significant diversion) and that you are thinking about their potential use of illicit substances (things you do not prescribe). Understand that not all screens used clinically can recover all medications prescribed, and that lower doses of some medications will not always give a positive result. Inexpensive dip sticks often miss fentanyl and oxycodone at lower levels. More expensive comprehensive drug screens (GLC/MS) can detect up to 700 different medications and differentiate between members of the same class, but cost around $100 or more per test. Will your patients pay for the tests personally if their insurance won't cover them? Consider ordering urine drug screens on two consecutive appointments if the clinical circumstances do not make sense to you, or if no improvement has occurred with your patients after multiple dosage adjustments (few patients would expect consecutive appointment testing so might use something not prescribed and not expect to be caught). Don't document continuing treatment failure and then continue to do the same thing! That is a red flag for reviewers and regulators alike.
10. Continue to receive opioid analgesic education by attending recognized meetings and conferences, like the Annual Clinical Meeting of the American Academy of Pain Management. Stay abreast of changes in state laws governing the prescribing of controlled substances for the management of chronic, intractable pain. These laws have been changing rapidly over the past 5

years throughout the USA. Educate yourself about the controversies that still exist regarding long term opioid prescribing and the concerns that regulators must have about creating addicts or opportunities for medication diversion to criminals. Be willing to explain what you know, how you know it, how you make treatment decisions, how you monitor patients over time, and most importantly try to politely listen to their concerns. Like it or not, there are drug seeking people in the world and they do actually try to scam good prescribers. The practitioners and regulators have to work together, or we practitioners will be saddled with severe draconian measures.

I recommend that you visit the DEA web site designed to help curb medication diversion *(www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm)* and try to understand what you should and should not do when confronted by a drug abuser or diverter in your practice. Here are some recommendations that they make:



Do

- perform a thorough examination appropriate to the condition;
- document examination results and questions you asked the patient;
- request picture I.D., or other I.D. and Social Security number. Photocopy these documents and include them in the patient's record;
- call a previous practitioner, pharmacist or hospital to confirm patient's story;
- confirm a telephone number, if provided by the patient;
- confirm the current address at each visit;
- write prescriptions for limited quantities.

Do Not

- "take their word for it" when you are suspicious;
- dispense drugs just to get rid of drug-seeking patients.
- prescribe, dispense or administer controlled substances outside the scope of your professional practice or in the absence of a formal practitioner-patient relationship.

We have good tools for the treatment of pain and new rules have been enacted to protect us, but old beliefs, fears and misconceptions are still present. Having said this and having put all of this in context, let me clearly say that not everyone needs opioid analgesics for pain relief. There are some patients who should never receive opioid analgesics. Proper patient selection for opioid or any other therapy remains the most critical action prescribers and interventionalists must do every single day. Opioids should provide improvement in activities of daily living if pain impairs these activities. Failure to improve despite dose adjustments to the point of toxicity is clear evidence of treatment failure and good reason to reassess patients thoroughly. Used appropriately, opioid analgesics will reduce the desperate desire that leads patients to seek relief through repeated surgical interventions despite diminished efficacy or by committing suicide. Opioids have been used for more than 3,500 years with outstanding efficacy and safety. Following the common sense prescribing guidelines above, you may expect to stay out of trouble for years to come.

The American Academy of Pain Management has an information packet that includes a sample "opioid agreement." If you would like a copy of this information or other risk reducing strategies please contact the Academy at (209) 533-9744.

CAGE

Ask your patients these four questions:

C Have you ever thought you should **CUT DOWN** on your drinking or substance use?

A Have you ever felt **ANNOYED** by others' criticism of your drinking or substance use?

G Have you ever felt **GUILTY** about your drinking or substance use?

E Do you have a morning **EYE OPENER** (start your day with alcohol or other substances?)

Implications from CAGE screening:

2 positive responses suggest a 50 % probability of substance abuse

3 positive responses suggest a 75 % probability of substance abuse

4 positive responses suggest a 90 % probability of substance abuse

References

Buchsbaum, D.G., Buchanan, R.G., et al. (1991). Screening for alcohol abuse using CAGE scores and likelihood ratios. Ann Internal Medicine 115(10), 774-7.

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US Department of Transportation. (2002). Sample alcohol screening tools. Available FTP: *www.nhtsa.dot.gov/people/injury/alcohol/EmergCare/appendix_d.htm.*