

Pain Management, Prescription Drug Abuse, and Risk Evaluation and Mitigation Strategies (REMS):

What Clinicians Need to Know (A 3-Part Case-Based Series)

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Newsletter 1 of 3

New Patient Requests Opioid Refills: How to Protect Your Practice and Provide Effective Patient Care

A 48-YEAR-OLD WOMAN with low back pain presents to your office for her first visit late on a Friday afternoon. She says that she has recently moved to your geographic area because of her husband's employment. She currently experiences low back pain at 6/10 at rest. The pain is aggravated by ambulation or bending. She demonstrates depressed affect. She tells you that she receives Social Security Disability because of her pain. The purpose of this visit is to request refills of the following prescriptions:

- Oxycodone ER 80 mg 3 times a day #90
- Hydrocodone/acetaminophen 10/325 12 daily #360 for breakthrough pain
- Oxycodone/acetaminophen 5/325, four times a day, as needed, #60 for severe breakthrough pain

CE INFORMATION

This 3-part continuing education (CE) series of newsletters has been designed to meet the educational needs of nurse practitioners (NPs) involved in women's health.

Newsletter 1:

New Patient Requests Opioid Refills: How to Protect Your Practice and Provide Effective Patient Care

CE APPROVAL PERIOD:

September 1, 2013 through August 31, 2014

Newsletter 2:

Long-Term Patient Demonstrates Increasing Pain and Potential for Risk: Can You Manage a Patient Who Exhibits Troubling Behavior Patterns?

CE APPROVAL PERIOD:

September 15, 2013 through September 14, 2014

Newsletter 3:

Elderly Patient With Established Pain and Potential for Diversion of Opioids: How to Address Patient and Family Issues

CE APPROVAL PERIOD:

October 1, 2013 through September 30, 2014

Estimated Time to Complete This Activity: 0.5 hour

■ NEEDS ASSESSMENT

This CE program will present practical strategies to meet the needs of nurse practitioners (NPs) who provide primary care for women. It will help clinicians provide quality care for patients who have chronic pain, help prevent diversion or misuse of opioids, and increase responsible prescribing.

This program will address needs uncovered as a result of a 2010 preconference activity of the National Association of Nurse Practitioners in Women's Health (NPWH) and through additional surveys of the NPWH e-mail database. One survey revealed that many clinicians (42.8% out of 992 responders) were not at all confident in managing patients with chronic pain. In a separate

survey, clinicians were again queried regarding their level of comfort in diagnosing and managing patients with chronic pain. Only 14% expressed a high level of self-confidence. This program has been designed to overcome these knowledge gaps.

■ EDUCATIONAL OBJECTIVES

At the conclusion of this activity, clinicians should be better able to:

- Identify patient and clinician goals for pain management
- Monitor and review pain diagnosis and comorbid conditions
- Document care plans
- Understand legal issues associated with prescribing in independent or physician-led practices

■ ACCREDITATION STATEMENT

This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH), and each e-newsletter has been approved for 0.5 contact hour of CE credit, including 0.25 contact hour of pharmacology content.

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Dr McCarberg reports the following:

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■ SUCCESSFUL COMPLETION OF THE ACTIVITY

Successful completion of this activity requires the participant to: (a) read the learning objectives, disclosures, and disclaimers; (b) study the material in the learning activity; (c) during the approval period: 1. log on to the NPWH Online Continuing Education Center (<https://npwh.globalclassroom.us/portal/>); 2. click on CE Education link; 3. click on link to all the case studies and review; 4. complete the post test and evaluation online before printing out the CE certificate; 5. to receive CE credit, a score of 70% or better on the post test is required.

■ COMMERCIAL SUPPORT

This e-newsletter is sponsored in part by an unrestricted educational grant from Purdue Pharma, LP to NPWH.

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What constitutes safe prescribing?

To prescribe opioids in a safe manner, the healthcare provider should:

- Be aware of all requirements for a legal prescription in his/her licensing state(s)
- Use national guideline information and recommendations to guide practice
- Perform a complete and thorough history and physical examination to establish a diagnosis and treatment plan
- Screen patients for risk of opioid misuse/diversion and implement treatment strategies that mitigate this risk and assist in adherence to appropriate treatment regimens¹

She reports that she is allergic to gabapentin, pregabalin, and duloxetine.

When you ask about her medical history, she says that she was diagnosed with an L4-L5 disc rupture proven by MRI. For several years, she received treatment from a pain specialist in another state. During this time, she failed treatment with physical therapy, epidural steroid injections, nonsteroidal anti-inflammatories, and tricyclic antidepressants. She attempted a functional rehabilitation program; however, she discontinued it when the pain worsened. Surgery was suggested; she declined that approach.

Physical examination is positive for tenderness at the paraspinal area bilaterally from L3 to S1. She demonstrates numbness between the first and second toes on the right, without other neurologic deficits, and a negative straight leg raise.

You do not have the patient's medical records. She has just run out of medication. What do you do?

This is not an unusual presentation for a patient who has just relocated from another state. The patient is clearly experiencing pain and distress, despite her current treatment regimen. You have no ability to quickly verify her history, and the time you have spent gathering information has taken more time than you allocated for this visit. You are already 15 minutes late for your next appointment.

Should You Provide Refills of Current Prescriptions?

We should always be wary of the patient who presents without records late on a Friday, particularly in situations in which the

office may be short-staffed, your partners may be taking a long weekend, and you are already behind schedule and stressed. All of us have had patients who fit this profile, and undoubtedly, we do not forget them.

There are serious issues about which we need to be mindful. National statistics regarding the use and misuse of opioids underscore the necessity of caution. Data from the 2010 National Survey on Drug Use and Health suggest that more than 35 million Americans age 12 and older used an opioid analgesic for nonmedical use some time in their life—an increase from about 30 million in 2002. In 2009, there were nearly 343,000 emergency department visits involving nonmedical use of opioid analgesics. In 2008, nearly 36,500 Americans died from drug poisonings, and of these, nearly 14,800 deaths involved opioid analgesics. Improper use of any opioid can result in serious side effects, including overdose and death, and this risk can be greater with extended-release/long-acting (ER/LA) opioid analgesics.²

Current Risk Evaluation and Mitigation Strategies (REMS) guidelines mandate that safe use, storage, and disposal of ER/LA opioid analgesics be discussed with patients every time clinicians prescribe these medications. In light of your schedule, is this feasible?²

Recommended Next Steps

Rather than simply fill this patient's prescriptions, your next steps should include:

- **Assess risk factors associated with opioid use.** Available tools include the Opioid Risk Tool (ORT), Screener and Opioid Assessment for Patients with Pain (SOAPP), and similar instruments.
- **Access your state's prescription drug monitoring program (PDMP).** Although the patient reports that she has recently relocated from another state, she may have been obtaining medication from other physicians in your state. You can use this resource to quickly ascertain whether these elements of her verbal history are accurate.
- **Obtain permission to access her previous records.** You will need to verify her stated history in order to assess the potential for misuse or diversion of opioids.
- **Perform urine drug testing (UDT).** Her urine should show oxycodone, oxymorphone, hydrocodone, hydromorphone, and no other compounds. This is another strategy to verify the patient's reported history, although you will not have the results immediately.
- **Make a differential diagnosis.** The patient demonstrates numbness between the first and second toes, an appropriate manifestation of an L5 nerve root injury. The examination also suggests myofascial pain with

widespread bilateral tenderness in the back. She is also depressed and likely deconditioned. Her symptoms suggest muscular pain (central sensitization), neuropathic pain, and, possibly, ongoing inflammation (nociceptive pain). Each of these pain types requires a different treatment strategy (Table 1).

By the time you complete your assessment, you have taken still more time with this patient, are now further behind schedule, have other patients waiting, and are feeling increasingly exhausted. It would be easiest to provide her with the three prescriptions that she requests and schedule a follow-up appointment. However, because you have only the patient's verbal account of her history, this would be a mistake. Remember, you are not obligated to prescribe any medication at this visit. Although her history sounds reasonable and her examination is consistent with her reports of her initial injury, you have insufficient information. And there are too many unanswered questions:

- Why was she prescribed 2 short-acting opioids?
- Why is she taking 12 hydrocodone daily for breakthrough pain?
- Why is she taking oxycodone ER 80 mg, which has a high street value?

Is the Patient's Current Pharmacologic Treatment Appropriate?

The literature notes that patients prescribed ongoing opioid therapy frequently experience breakthrough pain, which should be assessed separately from the baseline condition. It may—or may not—be related to the primary pain condition. Evaluation may require additional testing and follow-up. Management of breakthrough pain should be directed at causative factors. Limited evidence suggests that short-acting or rapid-onset agents may be effective. Therefore, you clearly have insufficient information to prescribe agents for breakthrough pain at this time.³

Further, her current dose of 495 mg morphine equivalents may indicate opioid tolerance. Recent data suggest that this dose may no longer be providing analgesia and may actually be increasing pain, a condition referred to as *opioid-induced hyperalge-*

sia (OIH). It is characterized by increased sensitivity to painful stimuli for patients receiving opioids for pain management. It appears to be a distinct, definable, and characteristic phenomenon that may explain loss of opioid efficacy in some patients^{4,5} (Table 2). Numerous mechanisms have been implicated in the development of OIH, which seems to be associated with increased transmission of nociceptive signals and antiopioid neuropeptide proinflammatory cytokine activity, among others.⁵

Although OIH is dose-related and may occur with both short- and long-acting agents, the use of long-acting opioids generally is preferred for patient management because they offer a more gradual onset and decline of action and provide relatively constant coverage of analgesic effects. Intermittent opioid dosing or repeated episodes of opioid withdrawal worsen OIH.⁴

Again, you note that too much information is missing to feel sufficiently confident in providing her with prescription refills. In general, it is best to refuse to give such a patient any medication until you have a prior medical chart.

We are compassionate in primary care and do not want our patients to suffer, but this is a situation in which medication can be abused. And, if you continue prescribing the current medication regimen, it will be difficult for you to stop. Not giving medication at this time may precipitate withdrawal, but it is more important to protect yourself and your practice. You may, however, decide to provide a small amount of medication until you can gather more information.

You tell the patient you will provide care but are uncomfortable with providing a large dose of medication, especially in the absence of her medical records. You spend precious time negotiating with the patient (you are now even further behind schedule). She agrees to discontinue the oxycodone ER and hydrocodone/acetaminophen. After shared decision making and active patient input, she accepts a prescription for

Table 1. Mechanistic Characteristics of Pain

Peripheral (nociceptive)	Neuropathic	Central (non-nociceptive)
Primarily due to inflammation or mechanical damage in periphery	Damage or entrapment of peripheral nerves	Primarily due to a central disturbance in pain processing
NSAID-, opioid-responsive	Responds to both peripheral and central pharmacologic therapy	Tricyclic, neuroactive compounds most effective
Responds to procedures		Behavioral factors more prominent
Behavioral factors minor		Examples
Examples		– Fibromyalgia
– Osteoarthritis		– Irritable bowel syndrome
– Rheumatoid arthritis		– Tension headache
– Cancer pain		– Idiopathic low back pain

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Table 2. Differentiating OIH From Other Pain Conditions

Condition	Characteristics of Pain	Presentation of Pain	Response to Opioids
Opioid-induced hyperalgesia (OIH)	Increased sensitivity to pain; diffuse pain beyond initial site; allodynia may occur	Abrupt onset with high-dose or rapidly increased opioid administration	Pain worsens
Worsening pain pathology	Localized to site of preexisting pain or new site	Variable, depends on pain source	Pain improves
Opioid tolerance	Localized to preexisting site	Gradual onset	Pain improves
Opioid withdrawal	Increased sensitivity to pain; diffuse pain beyond initial site	Abrupt: use of short-acting opioids or antagonist administration Gradual: use of long-acting opioids	Pain improves
Opioid addictive disease	Increased sensitivity to pain; diffuse pain beyond initial site	Gradual onset	Pain may improve; functionality may worsen
Pseudoaddiction	Localized to preexisting site	Variable, depends on pain source	Pain improves

Adapted from Compton P, Leavitt SB. The OIH paradox: can opioids make pain worse? *Pain Treatment Topics*. 2008. Available at: <http://pain-topics.org/pdf/Compton-OIH-Paradox.pdf>. Accessed July 28, 2013.

Table 3. Morphine Equivalents (mg)

Opioid	Oral	Parenteral
Hydrocodone	30	N/A
Hydromorphone	7.5	1.5
Methodone (conversion rates are not provided because rates are highly variable)		
Morphine	30	10
Oxycodone	20	N/A
Oxymorphone	10	1

Adapted from Darcy Y, Bruckenthal P. Safe opioid prescribing for nurse practitioners. *Oxford American Pocket Notes*. New York, NY: Oxford University Press; 2011:35-42.

a 7-day supply of oxycodone/acetaminophen 10/325 8 daily #56 (converts to 120 mg morphine equivalents).

Her previous regimen was 80 mg × 3 oxycodone ER (converts to 360 mg morphine equivalents) plus 10 mg × 12 hydrocodone (converts to 120 mg morphine equivalents) and 5/325 × 2 (average monthly dose of 60 pills divided by 30) oxycodone/acetaminophen (converts to 15 mg morphine equivalents). Her total usage was the equivalent of 495 mg

morphine equivalents daily. **Table 3** provides basic information on morphine equivalents.

She leaves a urine sample for a drug test, and signs a form for the release of records from her prior provider and a medication agreement. You verify that she shows no activity on your PDMP.

You discuss with her that the lower daily dosage—decreased from 495 mg to 120 mg—of morphine equivalents will likely precipitate withdrawal but that this represents a necessary trade-off. You tell her that, although you do not want her to suffer, you must be cautious in providing opioids to a new patient without access to her records, as there is always a potential for misuse or diversion of drugs. You must protect yourself, your practice, and your staff.

If you are very uncomfortable, you can—rather than treat her—provide her with names of other providers and pain specialists. The standard practice of pain clinics, however, is not to provide any scheduled medication on the first visit and to prescribe none without records. Pain specialists do not give opioids without knowing the patient better; therefore, you are not obligated to do so. In this case, you have already agreed to give some medication—and this is more than many experts would prescribe. You provide the patient with information about withdrawal. The office staff is instructed to follow up with the patient in 48 hours by telephone. A follow-up visit is scheduled in 1 week.

Follow-Up

The 48-hour follow-up call was uneventful and indicated that the patient, although experiencing withdrawal symptoms, was coping well.

At the follow-up office visit, the patient indicates that she appreciates your treatment and says that she understands your concerns. She says she did not see another provider. She relates symptoms of nausea, vomiting, diarrhea, low-grade fever, and tremors. She says that these symptoms are improving. She is surprised by changes in her levels of pain: after an initial worsening, she reports that she feels better pain control on the lower dose.

The records from her previous healthcare provider have not arrived; however, you were able to have a telephone conversation with that clinician, who reported a patient history consistent with myofascial pain, disc injury, and treatment as described by the patient.

The urine drug test results are appropriate.

The patient reports that, on the lower dose, she feels that her “brain seems to be working better.” She is experiencing less fatigue. This is fairly typical. When questioned, patients will frequently describe constipation—but not other side effects—as being related to opioid administration. As the dose is lowered, analgesia improves and unexpected changes (improved cognition, sleep, energy, etc) occur, underscoring the extent of previously unrecognized side effects.

Because of these improvements, she asks if it might be possible to further reduce her dose of oxycodone/acetaminophen. She tells you that, initially, she was angry with you for not simply filling her prescription as she requested. She did,

however, appreciate that you invited her to participate in the decision making at her initial visit. She feels that you respected her opinion.

Over time, she is able to discontinue routine opioid use, using oxycodone/acetaminophen occasionally during times of pain flare. She also becomes one of your most vocal supporters, telling everyone how you “saved her life.”

Conclusion

Pain patients often are desperate, rejected from our practice, accused of abuse and diversion, and do not know where to get care. The compassionate yet cautious provider described above—open and honest with the patient yet not bending to the easy answer of giving medication—resulted in a lifelong advocate for the practice. Thanks to our caring nature and our training to stand up for the patient, chronic pain management can lead to patient/provider interactions that are as strong and rewarding as with any other chronic illness. ■

References

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