



Managing the Risks of Prescribing Controlled Medications

PAINWeek

Las Vegas, Nevada

September 9, 2016

Michael C. Barnes, J.D., M.I.E.P.

@mcbtweets

Disclosure

DCBA Law & Policy provides professional services to health care companies and professionals. To avoid conflicts of interest, DCBA adheres to the District of Columbia Rules of Professional Conduct §§ 1.7-1.9.

Objectives

- ★ Discuss why it is advisable to attempt alternative treatments prior to prescribing opioids and other controlled medications.
- ★ Detail a question a prescriber should always ask and document the answer to before re-issuing a prescription for a controlled medication.
- ★ Identify three sets of facts that must be documented in a medical record when a controlled medication is prescribed.

Preview

- ★ Controlled medications
- ★ Legal standard for prescribing
 - Legitimate medical need
 - Ordinary course of professional practice
 - Reasonable steps to prevent harm
 - Thorough documentation
- ★ CDC guideline
- ★ Adjusting the treatment plan
- ★ Urine drug testing
- ★ Questions and discussion

Controlled Medications

- ★ High potential for abuse
- ★ Federal Controlled Substances Act (schedules II through V)
- ★ State controlled substances acts
- ★ Greater risks yield greater duties
 - Federal registration to prescribe
 - Reasonable steps to prevent harm

Prescription Opioid Abuse

- ★ 4.3 million Americans abuse Rx opioids each year¹
- ★ Decrease in prescription opioid-related deaths
 - CDC: 5% nationwide in 2012 (1st time in over a decade)²
 - 27% in FL between 2010 and 2012³
 - 27 % in WA between 2008 and 2012⁴
 - 29% in Staten Island between 2011 to 2013⁵
- ★ Shortsightedness of approaches exposed
 - Focusing solely on opioids for pain
 - Supply reduction w/o corresponding demand reduction

Stimulant Abuse

- ★ 17% of college students abuse Rx ADHD medications⁶
- ★ 62% of college students diverted their Rx ADHD medications⁷
- ★ 74% received from friend with prescription⁸
- ★ Linked to high stress levels and exam prep⁹
- ★ 20% of middle & high school students with Rx are asked by friends for medications¹⁰
- ★ 50% give medications to friends; bullying a factor¹¹

Benzodiazepine Abuse

- ★ Overdose deaths involving benzodiazepines increased five-fold between 2001 and 2014¹²
- ★ Benzodiazepine involvement in opioid related overdose deaths increased from 18% in 2004 to 31% in 2011¹³
- ★ PA: Present in 50% of drug-related overdose deaths (40% involved alprazolam)¹⁴
- ★ GA: Misuse of alprazolam leading cause of drug-related death (35%, 231 out of 644)¹⁵
- ★ Increasingly used as date rape drug¹⁶
- ★ AL: 33 arrests; 10,000 pills/liquid forms confiscated in 2015 (e.g., lorazepam and diazepam)¹⁷

Counterfeits and Analogs

★ Counterfeit/analog fentanyl

- Synthetic opioid-related overdose death nearly doubled between 2013 and 2014.¹⁸
 - Data combines Rx and illicit fentanyl
 - Most cases of fentanyl-related deaths linked to illicit fentanyl
- August 2013 – December 2015, law enforcement seized at least 239 kilograms of illicitly produced fentanyl.¹⁹
- January – March 2016, 9 people died from counterfeit alprazolam pills containing fentanyl in Florida.²⁰
- March – April 2016, 52 overdoses and 10 deaths in Sacramento, California from counterfeit hydrocodone/acetaminophen pills containing fentanyl.²¹

★ Heroin price, purity, and availability (FDA/CDC/NIDA)²²

Standard for Prescribing Controlled Medications

1. Legitimate medical need
2. Ordinary course of professional practice
3. Reasonable steps to prevent harm (as part of 1 and 2)
4. Thorough documentation in medical record

★ *Active Verification & Vigilance: A Method To Avoid Civil and Criminal Liability When Prescribing Controlled Substances*

- Federal and state controlled substances acts
- Criminal liability (homicide)
- Civil liability (wrongful death, malpractice)
- Not a guarantee against need to defend

CDC Guideline

- ★ Recommended for primary care²³
- ★ Recommends consulting a pain specialist as needed to provide optimal pain management
- ★ CMS and insurer adoption is occurring²⁴
- ★ Licensing boards may consider voluntary guidelines when making determinations at hearings²⁵
- ★ Health care must be individualized and unique medical needs and decisions documented

CDC Recommendations 1-6

1. Try non-pharmacologic and non-opioid pharmacologic treatments before opioids.
2. Document intended and actual clinical improvements.
3. Counsel patients on risks and benefits.
4. Try IR (vs. ER) opioids first.
5. Start with lowest effective dose.
6. Prescribe in low quantities for acute pain.

CDC Recommendations 7-12

7. Re-evaluate benefits and harms often.
8. Assess risk factors and mitigate risks.
9. Check PDMP before prescribing and periodically thereafter.
10. Conduct UDT before prescribing and periodically thereafter.
11. Avoid concurrent benzodiazepine use.
12. Refer patients with opioid-use disorder to addiction treatment.

Legitimate Medical Need

- ★ Medical history
- ★ Physical exam
- ★ Verify diagnosis
- ★ Consider special populations (e.g., older adults, pregnant women) and special risks (e.g., history of substance use)
- ★ Tried non-pharmacologic or non-controlled pharmacologic option (lower risk)

Ordinary Course of Professional Practice

- ★ Informed consent
- ★ Counseling on risks and benefits
- ★ Written treatment plan
- ★ Monitoring to ensure treatment remains suitable (“How has this treatment improved your life?”)
- ★ Adjustments to treatment plan

Reasonable Steps To Prevent Harm+

+These steps are part of verifying legitimate medical need and the ordinary course of professional practice

- ★ Screening for substance use
 - PMP data check
 - Urine drug testing
- ★ Mental health exam
- ★ Pregnancy test
- ★ Follow label or document reasons for deviation
- ★ REMS compliance

Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics
Patient Name:
The DOs and DON'Ts of Extended-Release / Long - Acting Opioid Analgesics
DO: <ul style="list-style-type: none"> Read the Medication Guide Take your medicine exactly as prescribed Store your medicine away from children and in a safe place Flush unused medicine down the toilet Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
Call 911 or your local emergency service right away if: <ul style="list-style-type: none"> You take too much medicine You have trouble breathing, or shortness of breath A child has taken this medicine by accident
Talk to your healthcare provider: <ul style="list-style-type: none"> If the dose you are taking does not control your pain About any side effects you may be having About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements
DON'T: <ul style="list-style-type: none"> Do not give your medicine to others Do not take medicine unless it was prescribed for you Do not stop taking your medicine without talking to your healthcare provider Do not cut, break, chew, crush, dissolve, snort, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider. Do not drink alcohol while taking this medicine
For additional information on your medicine go to: dailymed.nlm.nih.gov

Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics
Patient Name:
Patient Specific Information
Take this card with you every time you see your healthcare provider and tell him/her: <ul style="list-style-type: none"> Your complete medical and family history, including any history of substance abuse or mental illness If you are pregnant or are planning to become pregnant The cause, severity, and nature of your pain Your treatment goals All the medicines you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements Any side effects you may be having
Take your opioid pain medicine exactly as prescribed by your healthcare provider.

TAKING OPIOIDS RESPONSIBLY

for Your Safety
and the Safety of Others

Patient Information Guide
on Opioids
for Chronic Pain



VA
HEALTH
CARE | Defining
EXCELLENCE
in the 21st Century

VA National Pain Management Program
VA National Center for Ethics in Health Care

Thorough Documentation

- ★ Physical exam
- ★ Medical need/diagnosis
- ★ Tried non-pharmacologic/non-controlled pharmacologic
- ★ Informed consent
- ★ Patient responsibilities form, including risks
- ★ Written treatment plan
- ★ PMP data
- ★ UDT results and actions taken
- ★ Benefits and detriments of treatment
- ★ Discussions (“How has this treatment improved your life?”)
- ★ Adjustments to treatment plan

Adjusting the Treatment Plan

★ Kick up, not out (increase the level of care and supervision)

- Abandonment under civil law or professional rules
- Illicit substance use, overdose, or death

★ Jane C. Ballantyne, M.D., F.R.C.A., University of Washington, *Practical Aspects To Following Opioid Guidelines*, June 6, 2016

- Forced taper is only indicated for gross non-compliance and issues of safety
- Taper slowly (e.g., 10% per month) or use buprenorphine-assisted taper
- Consider opioid “maintenance” if taper is unsuccessful

Urine Drug Testing

★ Written policy

- Compliance with standard of care and best practices
- Objective reasons for testing (vs. profiling and suspicion)
- Optimal use of limited health care resources

★ Principles that can be adapted to meet individual needs

★ Frequency of testing

★ Test selections

- Analytes and metabolites
- Method (preliminary vs. definitive)

★ Document results, counseling, and treatment plan adjustments

References

1. <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.htm>
2. http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning.htm
3. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm>
4. <http://www.doh.wa.gov/Newsroom/2014NewsReleases/14012PrescriptionOpioidOverdoseDeathsDrop>
5. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6418a3.htm>
6. <http://www.drugfree.org/join-together/study-finds-17-percent-college-students-misuse-adhd-drugs/>
7. <http://medicineabuseproject.org/assets/documents/NPSFactSheet.pdf>
8. <http://www.fsunews.com/story/news/2015/10/28/one-college-students-misuse-adhd-drugs/74766356/>
9. <http://nj1015.com/some-college-students-are-turning-to-stimulants-to-help-them-study/>
10. <http://www.latinoshealth.com/articles/12515/20151123/children-who-take-adhd-medication-more-susceptible-bullying-find-out.htm>
11. Id.
12. <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>
13. <http://www.ncbi.nlm.nih.gov/pubmed/26143953>

References

14. <http://www.delcotimes.com/general-news/20151118/heroin-deaths-in-delco-at-record-high-fed-study-ranks-county-fourth-in-state-for-fatal-overdoses>
15. <http://www.popehoward.com/prescription-drug-overdoses-drop-but-xanax-tops-list/>
16. <http://globalnews.ca/news/2096655/what-you-need-to-know-about-date-rape-drugs/>
17. http://www.al.com/news/birmingham/index.ssf/2015/11/tuscaloosa_gang_rape_illustrat.html
18. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>
19. <https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf>
20. Id.
21. Id.
22. <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/heroin-use-driven-by-its-low-cost-high-availability>
23. <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1>
24. <http://www.businesswire.com/news/home/20160519005703/en/Cigna-Outlines-Steps-Curb-National-Drug-Epidemic>
25. <http://www.oregon.gov/oha/news/Pages/State%20standard%20for%20opioid%20prescribing%20will%20follow%20CDC%20guideline.aspx>; <https://www.flrules.org/gateway/RuleNo.asp?ID=64B8-9.013>

Conclusion

- ★ Thanks to PainWeek staff and conference sponsors
- ★ Thank you
- ★ Questions and discussion

Michael C. Barnes, J.D., M.I.E.P.
DCBA Law & Policy
202-644-8525
[LinkedIn.com/in/MichaelCBarnes](https://www.linkedin.com/in/MichaelCBarnes)
[@mcbtweets](https://twitter.com/mcbtweets)