New Jersey Dental Association

Resources for Safe Prescribing of Opioids and Non-Opiate Alternatives

Including New Jersey Regulatory Updates

June 2017

Contents

Revised June, 2017

A Message to our Members about New Jersey's Opioid Crisis

As the opioid public health crisis in New Jersey continues, we have the opportunity to serve a key role in educating our communities and our patients about the devastation of opioids, both by reducing the number of prescriptions written and by offering non-opiate alternatives for acute dental pain.

As ethical providers of healthcare, we have an obligation to educate ourselves about safe prescribing, about how to have a frank discussion with patients or, in the case of minors, their parents or caregivers, as well as how to identify possible abuse and recommend help.

While these guidelines address alleviation of acute dental pain, they are not intended to supersede an individual practitioner's assessment of their patient's condition or level of pain. The treating of chronic pain is briefly discussed on page 7.

On February 15, 2017, P.L. 2017, c. 28, was signed into law, imposing certain restrictions on how opioids and other Schedule II controlled dangerous substances may be prescribed. A subsequent regulation was imposed, effective May 1st, that clarifies the prescribing requirements of the new law. **State law now makes it unlawful for a prescriber to issue an initial prescription for acute pain for more than a five-day supply.** In addition, the dosage authorized by initial prescriptions for acute pain is to be limited to the lowest effective dose of an immediate–release opioid drug. To better understand how to comply with this limitation and other rule changes, the NJDA offers the following guidance. Please use this resource and share the information with your staff and patients.

Sincerely,

Elisa Velazquez, DMD
Chair, NJDA Council on Governmental and Public Affairs

NJDA Opioid Guideline Subcommittee

Mark A. Vitale, DMD
Mitchell Weiner, DMD
Gregory LaMorte, DDS
Kevin Corry, DDS

Overview

There is a documented epidemic of opioid and heroin abuse in New Jersey. The NJDA has joined with the ***Partnership for a Drug Free NJ*** to advocate for the responsible use and disposal of prescription opiates. The NJDA is committed to informing our members of the latest research. We want to keep you abreast of the latest findings on the efficacy of analgesics and responsible dosing. We share a special rapport with our patients. We are in an excellent position to educate them about the addictive potential of prescribed opiates.

According to the ***Centers for Disease Control & Prevention*** (CDC), *"More people died from drug overdoses in 2014 than in any year on record. The majority of drug overdose deaths (more than six out of ten) involve an opioid. And since 1999, the number of overdose deaths involving opioids (including prescription opioid pain relievers and heroin) nearly quadrupled.From 2000 to 2014 nearly half a million people died from drug overdoses. 78 Americans die every day from an opioid overdose."*

In New Jersey, the numbers are as sobering. While many dentists may believe their patients are not likely to be abusers, the fact is that drug abuse and overdose are on the rise across all demographic groups, regardless of income, ethnicity and age. Abuse among 18 to 25 year olds in the US has jumped dramatically – by 109% -- in the past ten years. Among new heroin users, 80 percent of heroin users reported using prescription opioids prior to heroin abuse. [1]

In the following section, efficacy of opioids and non-opiate alternatives in the treatment of acute pain will be discussed. We respect our members' judgment when prescribing and making health decisions with their patients and offer this information only as guidance. It is with this in mind that NJDA urges its membership to review the data.

[1] *https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use*

Efficacy of Opioids & Non-Opiates in Acute Pain

Dentists have the choice of three different classes of medications when treating pain. We decide based on the perceived effectiveness of each medicine, its side effects, and the physical status of the patient. Acetaminophen can exacerbate pre-existing liver disease. NSAIDs are contraindicated with a history of kidney disease or stomach ulcers. Opioids pose a potential risk to anyone with a personal or family history of addiction.

Many have long believed that opioids are the strongest pain medications and should be used for more severe pain. Scientific literature does not support that belief. Studies have shown NSAIDs are just as efficacious as opioids.

Postoperative pain is most often studied. It is acute pain due to tissue trauma. It also occurs in a controlled environment (hospital or medical office) where rigorous study protocols can be followed.

The Number Needed to Treat (NNT) offers a measurement of the impact of a medicine or therapy by estimating the number of patients that need to be treated in order to have an impact on one person. The concept is statistical, but intuitive, for we know that not everyone is helped by a medicine or intervention — some benefit, some are harmed, and some are unaffected. The NNT tells us how many of each. The data below tell us about the NNT as it relates to the number of patients that are helped. A lower number means a more effective treatment.

- Oxycodone 15 mg: NNT is 4.6. Since it is hard to conceptualize 4.6 people, consider that you would have to treat 46 people for 10 to get 50 percent relief of their pain. Thirty-six of those 46 people would not get adequate pain relief. (Gaskell, Derry, Moore, & McQuay, 2009)
- Oxycodone 10 mg + acetaminophen 650 mg: NNT for this combination treatment (Equivalent to two 5 mg Percocet pills) is 2.7. Clearly this is better than oxycodone alone. Acetaminophen adds a significant benefit. (Gaskell et al., 2009)
- Naproxen 500 mg (or naproxen sodium 550 mg): NNT for this is also 2.7. Naproxen is an NSAID. Naproxen sodium is known to many by the brand name Aleve®. (C Derry & Derry, 2009)
- Ibuprofen 200 mg + acetaminophen 500 mg: The combination of these two OTC medicines provided the best pain relief of all, with an NNT of 1.6. (CJ Derry, Derry, & Moore, 2013)

A review article in the 2013 Journal of the American Dental Association addressed the treatment of dental pain following wisdom tooth extraction. It concluded that 325 mg of acetaminophen (APAP) taken with 200 mg of ibuprofen provides better pain relief than oral opioids. Moore et al. concluded: “The results of the quantitative systematic reviews indicated that the ibuprofen-APAP combination may be a more effective analgesic, with fewer untoward effects, than are many of the currently available opoid-containing formulations.[1]”

In summary, regarding acute pain, many state that NSAIDs and acetaminophen should be used for mild to moderate pain, and opioids should be used for severe pain. There is, however, no scientific evidence to support this recommendation. In fact, the evidence indicates that NSAIDs are more effective for severe pain. The combination of acetaminophen and an NSAID may be the strongest option available for oral treatment of acute pain.

In some situations, limited use of opioids is appropriate. But for many situations in which opioid painkillers are used today, current literature tells us that there are more appropriate alternatives. When there is a treatment that is proven to be both more effective and safer, it is the treatment of choice.

Note: This scientific content has been edited down from a National Safety Council position paper: Evidence for the Efficacy of Pain Medications. (ref. 2)

References

1. Moore PA, Hersh, EV; Combining Ibuprofen and Acetaminophen for Acute Pain Management after third-molar extractions JADA. ***http://jada.ada.org/article/S0002-8177%2814%2960509-2/pdf***. Published August 2013. Accessed October 2016.
2. Teater, D; Evidence for the efficacy of pain medications. ***http://safety.nsc.org/painmedevidence*** *Published October 2014. Accessed October 2016.*

Protocols Required by Law Prior to the Initial Prescription of Schedule II Drugs

- Take a thorough medical history of the patient.
- Conduct a comprehensive dental examination.
- Check the patient against the NJ Prescription Monitoring Program database.
- Develop a treatment plan.
- Prepare a detailed dental record supplied with:
  - Medical history
  - Examination of findings
  - Relevant NJPMP data with notations
  - Name of CDS, dosage, strength, and quantity
  - Instructions on use frequency
- Explain the dangers and risks associated with taking opioids and other Schedule II prescription drugs.
- Explain the proper storage and disposal techniques for opioids or Schedule II prescription drugs as well as hand out the **NJ Safe Disposal Instructions** as required by law.

Dispensing Opioids in the Dental Practice for Acute Pain

Prior to dispensing, the dentist should observe the following protocols including checking the NJPMP/AwaRxe:

- Conduct a thorough medical and dental history, including documentation of current medications taken.
- Consult the NJ Prescription Monitoring Database (see p. 9).
- Provide instructions for safe disposal of unused medications (see p. 8).
- Consideration should be given to local anesthetics, such as Bupivicaine, to assist in pain management, as it provides extended duration of action and analgesia following the return of sensation, decreasing the need for strong analgesics
- Use of NSAIDs as a first-line therapy, unless contraindicated.
    - ❖ Additionally, NSAIDs should be given immediately prior to treatment, with continued dosing as needed following the procedure.
    - ❖ Exercise caution when using NSAIDs in patients taking anti-coagulants as the combination poses a significant increased risk in bleeding.
    - ❖ Adverse reactions to NSAIDs in patients with a history of renal
    - ❖ Refer to the previous section of this guide for scheduled dosing of acetaminophen with NSAIDs.

Prescribing Opioids in the Dental Practice for Acute Pain

- Pain therapy should be coordinated with the patient's other medical providers when possible, especially in cases where there is a history of substance abuse.
- The ***NJ Prescription Monitoring Program***/ **AwaRxe** database must be accessed prior to writing a new Schedule II prescription for a patient of record or a new patient.
- The lowest effective dose for the shortest duration not to exceed a five-day supply, for an initial prescription as specified by NJ State law. ***Note: Your*** initial prescription may not, in fact, be ***the*** first prescription of a CDS or Schedule II for that patient, if one was prescribed by another practitioner. Should that be the case, the regulations that apply when prescribing for *chronic pain* (see p. 7) must be observed.
- Opioid combination medications including acetaminophen should not exceed 3,000 mg/day of acetaminophen for adults.
- In general, it is not appropriate to prescribe via phone request or to patients who are new to the practice without a thorough evaluation.
- Mandated by NJ law, ***safe disposal instructions*** must be given to patients to ensure unused medications are not misused or improperly disposed of.
- The Subcommittee recommends that dentists include in the patient record the signed **informed consent**, (see p. 10) developed by the NJDA, outlining the possible deleterious effects of opiods.

Prescribing for Chronic Pain

Dentists who prescribe for chronic pain must follow the same 5-day maximum for initial opioid or Schedule II prescriptions as well as proceed under the outlined steps on page 5 and 6. In addition, a dentist who wishes to prescribe a second prescription for a patient must consult that patient either on the phone or in person prior to prescribing ***the second prescription.*** Further, prior to prescribing ***a third prescription***, or prior to prescribing any opioid to a minor, the dentist ***must:***

1. Explain the reasons for the medication.
2. Explain possible alternative treatments available.
3. Explain the risks associated with the medications including:
   - Their highly addictive nature
   - Other risks associated with the drugs
   - The danger of consuming alcohol, benzodiazepines and other drugs in combination
4. How to properly store and dispose of the medications.
5. Enter into a pain management agreement with the patient, which includes the following:
   - ❖ Document the understanding of both you and your patient regarding the patient's plan management.
   - ❖ Establish your patient's rights with respect to treatment and his/her obligation concerning responsible use, discontinuation of use, storage and disposal of all controlled substances, refills, and acceptance of similar prescriptions from other prescribers.
   - ❖ Identify the specific medications being prescribed at the time that it is executed, noting that change in medication may occur during the course of treatment and alternative modes of treatment may be part of the treatment plan.
   - ❖ Specify the steps you may take to monitor the patient's compliance, including random specimen screens and pill counts.
   - ❖ Delineate the process for terminating the agreement, including the steps that you can take should the patient fail to comply with the terms of the agreement.

Dentists who need to prescribe for chronic conditions should also become familiar with the **CDC Guidelines for Prescribing Opioids for Chronic Pain.**

Safe Disposal of Unused Medications

NJ law requires prescribers to provide a notice about drug take back programs upon dispensing to each patient a controlled dangerous substance (CDS) prescription medication. Specifically, the new law requires prescribers to furnish to each patient, with any CDS prescription drug or medicine dispensed for that patient a notice prepared by the Division of Consumer Affairs. The NJ Division of Consumer Affairs has developed patient flyers in English and Spanish.

Patient Communication & Informed Consent

Having a open discussion with your patient and parent or guardian is vital to safe prescribing.
When the decision to prescribe an opiate-based medication is determined, dentists should:

1. Discuss the possible side effects, including addiction and misuse, with the patient and parent or guardian. The NJDA has developed an ***informed consent*** **(see p. 10)** that can be used or adapted for use by the clinician.

2. Explain to the patient the dosage and scheduling of the medication.

3. Further explain how you will dispense refills if needed. Refill by phone absent a follow-up examination is discouraged.

4. Refer to the ***NJ Prescription Monitoring Program/AwaRxe*** before prescribing and if/when a refill is requested or needed. Explain the NJPMP to your patient.

5. Provide information on safe disposal of unused medications (see p.7)

6. If you suspect a patient is misusing prescription medications, the ***American College of Preventive Medicine*** (search "drug abuse") offers tips on how to talk to your patients about misuse of prescriptions.

Safeguarding Prescription Pads

All licensees are required to notify the ***Office of Drug Control*** in the New Jersey Division of Consumer Affairs within seventy-two (72) hours of being made aware that any New Jersey Prescription Blank has been stolen or forged. A New Jersey Prescription Blank Incident Report Form must also be completed and filed within seven (7) days after notification.

Continuing Education Requirement

New Jersey state law now requires all prescribers of opioids or Schedule II drugs to take one hour of continuing education on topics relating to opioid prescribing, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. However, this requirement is not effective until the next licensure renewal cycle (11/1/2017 - 10/31/2019).

The State Board of Dentistry, and by extension the NJDA, will inform you of the effective date of this provision of the law.

NJ Prescription Monitoring Program (NJPMP/AwaRxe)

The ***NJPMP*** is a statewide database that collects prescription data on Controlled Dangerous Substances (CDS) dispensed in outpatient settings. The purpose of NJPMP is to help stem the tide of the dangerous practice of "doctor shopping" and the equally dangerous prevalence of "pill mills." **NJPMP also offers a free app for Android and iPhones.**

Doctor shopping - visiting multiple medical and dental practitioners to obtain prescriptions for the same medication. The prescriptions, filled at different pharmacies, are either used by the individual or sold as street drugs.

Pill mills - clinical practices that dispense CDS drugs outside the legitimate scope of practice and in violation of NJ law.

As of November 1, 2015 all prescribers holding CDS registrations need to register to access the NJPMP. Additionally, any practitioner who dispenses or prescribes Schedule II medications must refer to the database for new prescriptions for a patient of record or a new patient.

The database is updated daily. NJPMP is able to generate reports on unusual prescribing patterns related to specific patients. These reports are intended to help practitioners and pharmacists discuss drug misuse and abuse with the patient and refer the individual for help. The NJDA strongly recommends accessing the database prior to every CDS or Schedule II prescription written or dispensed.

Delegation of NJPMP Look Up

Dentists in NJ may, at their discretion, identify licensed dental hygienists or registered dental assistants to review the NJPMP database on their behalf. Dentists must first register these individuals at **https://newjersey.pmpaware.net/identities/new**. Dentists will be responsible for the use or misuse of the NJPMP by the delegated individuals. Visit the Division of Consumer Affairs FAQs at **www.njconsumeraffairs.gov/pmp/Pages/FAQ.aspx** for additional information.

Resources

Centers for Disease Control and Prevention: ***www.cdc.gov***
New Jersey Prescription Monitoring Program (NJPMP): ***www.nj.gov/lps/ca2/pmp/***
Drug Take Back Program: ***www.njconsumeraffairs.gov/meddrop***
Lost or forged prescription blanks:***www.njconsumeraffairs.gov/dcu/Pages/default.aspx***
Disposing of unused medications: ***www.americanmedicinechest.com/***
ADA:***www.ada.org/en/advocacy/advocacy-issues/prescription-drug-abuse***
Partnership for a Drug Free NJ: ***drugfreenj.org/***
Conversations about abuse with patients: ***www.acpm.org/*** (Search drug abuse)

Informed Consent for Opioid Use

I have agreed to use opioids as part of my treatment to manage dental related chronic or post operative pain. I understand that these drugs are useful in managing my pain, but have a high potential for addiction and/or dependency.

I understand that I can discuss possible alternatives for this opioid prescription with my dental prescriber and have furnished a complete and accurate medical history (including pregnancy, if applicable) and list of the medications I currently am taking or have taken in the last 6 months, including information about mental history and drug and/or alcohol use by me and members of my family.

Because my dental provider is prescribing such medication to manage my pain, I acknowledge that I have been made aware of the following information and agree to the following conditions:

1. I am responsible for my pain medications and agree to take the medication not more frequently than as prescribed and only if needed to manage pain. I understand that increasing my dose without my dentist's knowledge could lead to a drug overdose causing severe sedation and respiratory depression and possibly death.

2. Without prior disclosure to my dental provider, I will not request or accept controlled substance medication from any other healthcare provider or individual while I am receiving such medication from my dental provider.

3. There are side effects with opioid medications, which may include, but not be limited to, skin rash, constipation, sexual dysfunction, sleeping abnormalities, sweating, edema, sedation, confusion, depression, increased sensitivity to pain or the possibility of impaired motor ability. As a result, when I take these medications, it may not be safe for me to drive a car, operate machinery, or take care of other people.

4. I have been made aware that I may become addicted to these medications (opioids) and may require addiction treatment. Overuse of this class of medication can lead to physical dependence and the experience of withdrawal sickness if I stop use or cut back too quickly. Withdrawal symptoms feel like having the flu and may include: abdominal pain, nausea, vomiting, diarrhea, sweating, body aches, muscle cramps, runny nose, yawning, anxiety and sleep problems.

5. I understand that the opioid prescription I have been given is for my own use and attest that I will not give or sell any portion of the prescription to another individual.

_____ _____

Patient, Parent or Guardian Signature **Date**