Chronic opioid therapy in dentistry: Creating Control for Controlled Substances

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After attending this presentation, participants should:

- understand that chronic pain, including a sub-specialty of dentistry that deals with chronic orofacial pain, sometimes requires long-term pain management with the use of opioid medications.
- recognize the complexities of treating chronic pain patients with long-term use of opioid medications.
- identify those clinical tools that can help reduce risk factors, insure patient compliance, and improve outcomes with long-term opioid therapy.
This presentation focuses on:

- **Who** to prescribe opioids to:
  (patient selection)
- **How** to safely prescribe opioids:
  (therapeutic and management tools)

Although important, the following topics cannot be addressed in this presentation due to time constraints:

- **What** opioids to prescribe
- **When** it is appropriate to prescribe opioids
- **Where** it is appropriate to prescribe opioids
- **Why** it is or is not appropriate to prescribe opioids
Dentistry and Orofacial Pain

- Dentistry has taken a leading role in all of health care to address a major patient problem by developing the field of Orofacial Pain.
- In the past 30 years, there have been many developments in the field of chronic pain and specifically Orofacial Pain that have lead to the need for formal advanced education programs.
In the United States
- 3 million people annually require treatment for chronic orofacial pain
- Universities have established orofacial pain clinics in nearly every dental school and created 2 year advanced programs in 14
  - Numerous Orofacial Pain dentists graduate annually
- Major dental organizations recognize orofacial pain
  - Commission on Dental Accreditation of the American Dental Association
  - The American Association of Dental Schools
  - The United States Armed Forces has established Orofacial Pain as an advanced field of Dentistry
- Certification examinations are available
Impact and Burden of Chronic Pain

- Performance of ADLs
  - Sleep disturbance
  - Work, household chores
  - Leisure activities
  - Energy

- Functional activities

- Socioeconomic consequences
  - Healthcare costs
  - Disability
  - Low productivity

- Social consequences

- Emotional Functional
  - Irritable
  - Angry
  - Anxious
  - Depressed

- Intimacy
  - Social isolation
  - Marital & family relations

- Work, household chores
- Leisure activities
- Energy

- Sleep disturbance
Healthcare Costs of Chronic Pain

- Chronic Pain
- Heart Disease
- Hypertension
- Respiratory Disease
- Diabetes
- GI Disease
- Arthritis
- Cancer
- Depression
- Stroke
- Pregnancy
- Dementia
- Anxiety
- HIV Infection
- Sclerosis
- Multiple
- Panic Disorder

Cost in Billions
Barriers to treatment

- Inadequate assessment/missed diagnoses
- Co-morbid conditions (such as diabetes, stroke, cancer etc)
- Substance abuse
- Lack of available resources
- Poor continuity of care
- Inappropriate medication dosing/titrating
- Lack of behavioral health treatment providers in rural areas
Understanding Pain Mechanisms

- Know the difference between acute and chronic pain
  - Dental emergency, etc. vs. chronic neuropathic, musculoskeletal or vascular orofacial pain disorders
- Target the mechanism with the appropriate medication: an opioid may be the appropriate medication in some cases
- The provider must demonstrate that he understands the diagnoses, or lack thereof, and has explored non opioid possibilities
Annual drug related deaths for pain medications in the US

- Rx Opioid abuse, 2006: 13,800
  (Tripled in the past 7 years)

- Rx & OTC NSAIDs, 1998: 16,500
  (Considered and under-estimate)
  [http://www.phend.co.za/health/Nsaid.htm](http://www.phend.co.za/health/Nsaid.htm)

- Rx & OTC Acetamenaphen: 450

- Approximately 30,750 people in the US die each year due to medications used for the management of pain!!!
Health insurers lose up to $72.5 billion every year because of prescription drug diversion of opioids alone.


2009 National Prescription Drug Abuse Prevention Strategy
Center for Lawful Access and Abuse Deterrence
**Important Questions to consider:**

- Is the dentist familiar with the Controlled Substance Act of 1970 and state laws and regulations regarding the prescription of these medications? [http://www.justice.gov/dea/pubs/abuse/1-csa.htm](http://www.justice.gov/dea/pubs/abuse/1-csa.htm)

- Does the dentist want to prescribe long-term opioids for *chronic* (non-malignant) pain patients?

- Does the dentist want to prescribe long-term opioids for this particular *chronic* pain patient?

- How does the dentist prescribe long-term opioids safely for this particular *chronic* pain patient?
“The Massachusetts Board of Registration in Medicine does not wish to discourage physicians from prescribing strong analgesics to relieve the suffering of patients who are in severe pain, both acute and chronic. **Opiates and opioids have legitimate clinical usefulness, and physicians should not hesitate to prescribe them when they are indicated** for the comfort and well-being of patients who require relief that cannot be provided by non-opiate analgesics and alternative forms of therapy.”

“…the Board has specifically endorsed the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* that were developed and adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, in May 2004.”

For purposes of this Advisory, the inappropriate management of pain includes non-treatment, under-treatment, over-treatment and the continued use of ineffective treatment. The Board encourages dentists to view pain management as a part of quality dentistry practice for all patients experiencing pain within the maxillofacial area. All dentists should become knowledgeable about assessing and diagnosing patients’ pain and effective methods of pain management.

Adapted from the Preamble, Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004), Federation of State Medical Boards of the United States, Inc.
Managing Abuse Potential: Recruit Community Involvement and Support

- Medical Community
  1. Primary Care
  2. Pain Management Services
  3. Emergency Department
  4. Medical specialists
  5. Pharmacists
  6. Psychiatry
  7. Bio-psycho-social
  8. Addiction

- Law Enforcement
  1. Local Police Department
  2. DEA

- Pain Care Organizations
  1. SAMHSA
  2. APF
  3. IASP
  4. AAOP
  5. Etc.
Patient selection

- Documentation of a treatable chronic pain condition.
- Documentation of current medications and prescribers.
- Documentation of the patient’s current or past pharmacy or pharmacies.
- Substance use and/or abuse history:
  1. Smoking
  2. Alcohol
  3. Eating disorders and food addictions
  4. Illicit and/or recreational drug use
  5. Interaction with other users of illicit/recreational drugs
Monitoring progress and efficacy

The Pain Assessment and Documentation Tool (PADT) Janssen Pharmaceutica Products, L.P. 2003

On a regular basis (weekly, monthly, bimonthly, etc.) evaluate the patient for:

- Benefits of Analgesic Effect
- Review of Activities of Daily Living (ADL)
- Review of Adverse Effects and/or Events (AE)
- Review of Potential Aberrant Drug-Related Behavior
- Assessment of overall patient progress and possible opioid induced hyperalgesia (OIH)
- A plan for continued use of opioids:
  1. Continue present regimen
  2. Adjust dose
  3. Change analgesics
  4. Add/Adjust concomitant medications or therapy
  5. Taper or withdraw opioid therapy
**Aberrant Behavior and drug abuse:**

from: “Avoiding Opioid Abuse While Managing Pain”
Lynn R. Webster, MD, and Beth Dove
Sunrise River Press, North Branch, MN, 2007

### More predictive
- Frequent lost or stolen Rx
- Frequent cancelled or missed appointments
- Use of other drugs of abuse, alcohol, etc.
- Seeking drugs from multiple providers
- Using Rx for euphoria or relief of anxiety
- Rx forgery
- Selling or sharing Rx drugs
- Unauthorized & repeated increase of dosage
- Overdose
- Aggressive demands to increased dose
- Altering route of administration (i.e. injecting oral formulations)
- Stealing or borrowing another patient’s Rx
- Arrest for DUI or drug-related activities
- Interacting with street drug culture

### Less predictive
- Hoarding drugs during periods of decreased pain
- Early refill requests
- Minor accidents (mva, falls, etc.)
- Abusive relationships
- Oversedation or appearing intoxicated
- Requesting a specific medication
- Unkempt appearance
- Obtaining drugs from other medical sources
- Discharge from another practice due to non-compliance
- Anonymous calls from “concerned friends” regarding alleged aberrant behaviors
- Addiction to the “drama”
Addiction!

A chronic neurobiological disorder that has genetic, psychosocial, and environmental dimensions and is characterized by one of the following: the continued use of a substance despite its detrimental effects, impaired control over the use of a drug (compulsive behavior), and preoccupation with a drug's use for non-therapeutic purposes.


- Multiple aberrant behaviors
- One or more egregious behaviors
- Defy efforts to limit aberrant behavior
- Uncooperative with efforts to improve pain management techniques
- Loss of quality of life and function
- Persistent craving for opioids to create psychogenic effects
- Escalated substance dosage for prolonged periods without authorization
- Overwhelming focus on medications such as opioids, sedatives, etc.
- Compulsive search for opioids, etc.
- Reduced social interaction and work effort
- Continued use of substances of abuse in spite of harm to health, family, finances, etc.
- Return to substance abuse after successful withdrawal
Standardized Provider Tools For Chronic Orofacial Pain Include:

1. **Notice of Privacy Practices (HIPAA)**
2. **General Medical Intake Form and Consent for Treatment**
3. **Pain Assessment Tool**
4. **Risk Assessment Tools**
5. **Informed Consent and Controlled Substance Agreement**
6. **Quantitative Urine screening**
7. **Prescription Monitoring Systems**
8. **Prescription Writing Software**
9. **Follow-up Pain Assessment Tool**
10. **Aberrant Behavior Documentation**
11. **Termination of Controlled Substance Agreement**
4. Risk Assessment Tools

- **Alcohol Use Disorders Identification Test (AUDIT):** developed by the World Health Organization
  (http://whqlibdoc.who.int/hq/2001/WHO_MSD_MSB_01.6a.pdf)

- **Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST):** developed by the World Health Organization

- **Drug Abuse Screening Test**
  (http://counsellingresource.com/quizzes/drug-abuse/index.html)

- **Substance Abuse and Mental Health Services Administration: Screening, Brief Intervention, and Referral to Treatment**
  (www.sbirt.samhsa.gov)
5. Informed Consent and Controlled Substance Agreement

I, _________________________________, understand and agree to follow the policies regarding the use of opioids, narcotics, or other controlled substances for management of chronic conditions. I understand that (Provider’s name) is under no obligation to prescribe these medications for me. I also understand that breaking the terms within this agreement may lead to its termination or my dismissal from treatment.

I have tried other medical treatments which have not worked to control my condition. (Provider) has recommended that I be placed on a course of medications to help manage my symptoms, and to improve my ability to participate in my activities of daily living (work, family, etc.). I also understand that these medications are not expected to entirely eliminate all my symptoms, but are intended to help me to improve my quality of life. This is a decision that I have made after fully discussing the risks, benefits, as well as alternatives to this treatment, with (Provider).

_______ (initials)
Risks of Medications

I understand that treatment of my condition with medications does have risks including, but not limited to:

- Constipation and/or nausea.
- Sleepiness or drowsiness.
- Problems with coordination or balance that may make it unsafe to operate dangerous equipment or vehicles, or to cook and perform various tasks at work.
- Agitation, confusion or other change in mental state or thinking abilities.
- Physical dependence—meaning that abrupt discontinuation of the drug may lead to withdrawal symptoms including: runny nose, diarrhea, abdominal cramping, “goose flesh” and/or anxiety, etc. I understand that this may be uncomfortable but not life threatening, and the worst symptoms typically resolve after 72 hours.
- Psychological dependence - meaning it is possible that discontinuation of the drug may cause me to miss it or crave it.
Risks of Medications (cont.)

- Decreased appetite.
- Problems urinating.
- Sexual difficulties
- Breathing too slowly—meaning that overdose can lead to respiratory arrest and potentially to death without the intervention of emergency personnel. I understand that it is recommended that I wear an emergency alert bracelet or necklace with information regarding the use of this medication.
- Known and unknown risks to unborn and nursing children which includes narcotic dependence. Contraception is highly recommended.
- Other less common risks and side effects are possible.

________ (initials)
Your Responsibilities and Conditions of the Agreement:

- I recognize that other acceptable forms of medical treatment have not been effective or have produced undesirable side effects. ________ (initials)

- I will inform (Provider) of any history of problems with substance abuse, illegal drugs, or drug dependence. ________ (initials)

- I am currently not involved in the sale, illegal possession, diversion or transport of controlled substances (narcotics, sleeping pills, nerve pills, stimulants, or painkillers), nor do I live or associate with individuals who do. I will disclose to (Provider) any past involvement in the sale, illegal possession, diversion or transport of controlled substances. ________ (initials)

- I will inform (Provider) of any severe depression, or having thoughts of suicide or harming others, and will disclose to (Provider) any prior drug overdose or dependency. ________ (initials)

- I agree to obtain controlled medications only from (Provider). I agree to notify (Provider) in advance of any upcoming acute needs or procedures (dental work, surgery, etc) that may necessitate a change in my medication dosing. ________ (initials)

- I will use only _______________________________ Pharmacy for filling my prescriptions for controlled medications. ________ (initials)
Your Responsibilities and Conditions of the Agreement: (cont)

- I will take medicines only as prescribed by (Provider), and under no circumstances allow other individuals to take my medications. I will not change the amount or frequency of these medications without prior approval of (Provider). ________ (initials)

- I will inform (Provider) of any and all controlled drugs (pain medications, sleeping pills, nerve pills, sedatives, etc.) prescribed for me by other medical providers. ________ (initials)

- I will inform (Provider) of any alcohol consumption because it may interact with the medications that I am currently taking. ________ (initials)

- I give permission to (Provider) to communicate with the Emergency Department, and any other physicians, dentists, health care providers, and pharmacist that may be involved in my care regarding my treatment and the use of controlled substances. ________ (initials)

- These prescriptions will be continued as long as I show evidence of improvement of my symptoms and function. I will follow the advice of (Provider) in regard to stopping controlled substances, should they feel it advisable. ________ (initials)
Your Responsibilities and Conditions of the Agreement: (cont)

- I understand and consent to have unannounced blood screen, urine tests, or pill counts in order to assess my compliance with my medical regimen, and identify any other medications or substances that I am taking.

  ________ (initials)

- I understand that my main treatment goal is to improve my quality of life. This includes alternative treatment modalities and better health habits such as exercise, weight control and withdrawal from caffeine and nicotine.

  ________ (initials)

- If recommended by (Provider), I agree to participate in health care consultations with, and evaluations by, the following services:
  
  A psychiatrist for evaluation of psychotropic medications and treatment.
  A psychologist or other health care provider for behavioral or other mental healthcare therapies which may include behavioral pain management.
  An acupuncturist for acupuncture pain control
  A physiatrist or physical therapist for physical and rehabilitation medicine
  A physician or other health care provider for other medical conditions
  Other alternative treatment modalities recommended by (Provider).

  ________ (initials)

- Due to known and unknown risks to unborn children, which include narcotic addiction, I will notify (Provider) if I am or if I become pregnant. I will also notify (Provider) if I am breastfeeding or if I intend to breastfeed.

  ________ (initials)
Your Responsibilities and Conditions of the Agreement: (cont)

- I will keep all scheduled appointments and understand that this agreement may be in jeopardy if I miss any appointments. ____ (initials)

- At any time that I may need to discontinue these medications, (Provider) will usually reduce the dosage slowly over several days or weeks. If (Provider) determines that I have a drug dependence problem, I may be referred to another healthcare provider for management of that dependency. ____ (initials)

- I understand that, in general, allowances will not be made for lost, stolen or damaged drugs or prescriptions. ____ (initials)

- The following is a list of all current (prescription and non-prescription) medications that I am currently taking:

  - ___________________________ Medication ___________________________ Dose ___________________________
  - ___________________________ ___________________________ ___________________________
  - ___________________________ ___________________________ ___________________________
  - ___________________________ ___________________________ ___________________________
  - ___________________________ ___________________________ ___________________________

( include additional page or attach list if necessary )

______ (initials)
Confirmation of Understanding

- I understand that, in general, my controlled medications may be discontinued if any of the following occur:
  - (Provider) finds that the medications are not effective for my symptoms or that my condition is not improved.
  - I give, sell or misuse drugs.
  - I develop rapid tolerance or loss of effect from this treatment.
  - I develop side effects that (Provider) believes are significant and detrimental to me.
  - I obtain controlled medications from sources other than (Provider).
  - Test results indicate the improper use of my prescribed medications or the use of illicit drugs.
  - I violate any of the terms of this consent agreement.

    ________ (initials)

- I agree that a copy of this document will be given to my primary care physician, the Emergency Department, my pharmacist, and other healthcare providers involved with my treatment. I will inform (Provider), my pharmacist and other medical providers in my care of all medications I am receiving at all times.

    ________ (initials)

- I agree that (Provider) may contact law enforcement if there is suspicion of my committing illegal activities including but not limited to selling drugs and sharing my medications.

    ________ (initials)
My current medical providers are:

- Primary Care Physician: __________________________
  Phone Number# __________________________
  Address: __________________________

- Other Providers: __________________________
  Phone Number# __________________________
  Address: __________________________

- Other Providers: __________________________
  Phone Number# __________________________
  Address: __________________________

  _____(initials)

I have read this document, understand it, and have answered all questions truthfully. I consent to the use of medications to help control my symptoms, and I understand that my treatment with these medications will be carried out in accordance with the conditions stated above.

/ __________________________ /  __________________________ /  __________________________
patient’s signature    date    renewal date    renewal date

/ __________________________ /  __________________________ /  __________________________
witness    date    renewal date    renewal date
Doctor’s Certification

I certify that the above named patient or responsible individual has received a careful explanation of the treatment to be provided including the risks and benefits to be expected. I have disclosed alternative methods of treatment that might be appropriate for this patient. I have offered to answer any questions by this patient and/or responsible individual regarding this treatment.

_________________________________________  ________________________
Doctor                                        date

In an effort to assure that your prescription will be filled in a timely manner, our office is requiring that all requests for refills be made at least ____ business days in advance of the refill date. Please leave your first and last name, your phone number, and your date of birth. Also provide the name of the medication, the dose and the quantity needed, as well as the name and phone number of your pharmacy.
Vermont Statutes, Title 18: Health
Chapter 84: Possession and Control of Regulated Drugs
4223. Fraud or deceit

(a) No person shall obtain or attempt to obtain a regulated drug, or procure or attempt to procure the administration of a regulated drug, (1) by fraud, deceit, misrepresentation, or subterfuge; (2) by the forgery or alteration of a prescription or of any written order; (3) by the concealment of a material fact; or (4) by the use of a false name or the giving of a false address.

(b) Information communicated to a physician in an effort unlawfully to procure a regulated drug or unlawfully to procure the administration of any such drug shall not be deemed a privileged communication.

(c) No person shall willfully make a false statement in, or fail to prepare or obtain or keep, or refuse the inspection or copying under this chapter of, any prescription, order, report or record required by this chapter.

(d) No person shall, for the purpose of obtaining a regulated drug, falsely assume the title of, or represent himself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian or other authorized person.

(e) No person shall make or utter any false or forged prescription or false or forged written order.

(f) No person shall affix any false or forged label to a package or receptacle containing regulated drugs.

(g) The provisions of this section shall apply to all transactions relating to amounts or types of drugs excepted from the provisions of this chapter by regulation of the board of health under section 4204 of this title, in the same way as they apply to transactions relating to any other regulated drug.

(h) Any person who in the course of treatment, is supplied with regulated drugs or a prescription therefore by one physician and who, without disclosing the fact, is knowingly supplied during such treatment with regulated drugs or a prescription therefore by another physician, shall be guilty of a violation of this section.

(i) A person who violates this section shall be imprisoned not more than two years and one day or fined not more than $5,000.00, or both. (1967, No. 343 (Adj. Sess.), § 23, eff. March 23, 1968; amended 1989, No. 100, § 12.)
When All Is Said and Done, Ask yourself:

Is this patient well enough informed to take this medication as prescribed and expected? If not, who is at fault?
6. Urine screening

- “Qualitative” testing: Immunoassay
  (Note that this technique does not distinguish between opioids and may miss oxycodone, methadone and fentanyl. Ingestion of poppy seeds or quinolone antibiotics may produce false-positive results.)

- “Quantitative testing: Gas Chromatography/ Mass Spectrometry (GC/MS) and Liquid Chromatography/ Tandem Mass Spectrometry (LC/MS-MS)
  (Note that this technique can produce false-negative or positive results but is generally more accurate than immunoassay)

Indicators of a Non-compliant Patient

1. Presence of illicit drugs (cocaine, heroin, THC, methamphetamine, etc.).
2. Unexplained presence of other controlled substances in combination with the prescribed Rx.
3. Absence of the prescribed controlled substance.
4. Presence of an un-prescribed controlled substance in the absence of the prescribed Rx.
5. Failure in validity testing suggesting tampering of the sample (pH, specific gravity, etc.).
Indicators of a Non-compliant Patient

6. Variable finding of metabolites from the intended controlled substance.

7. Controlled substances present that are metabolites from another controlled substance or other sources (i.e. morphine presence as a metabolite of codeine, poppy seeds & heroin).

8. Above normal range for dose prescribed

9. Below normal range for dose prescribed

(Modified from the Ameritox overview: “Caring for a Non-Compliant Patient: A Pain Practitioner’s Guide.”)
Management of the non-compliant patient (conflict management):

- Review of the non-compliant circumstances and aberrant behavior
- Re-education of the patient regarding the obligations of the opioid agreement
- Assessment of possible pseudo-addiction
- Resolution of doctor-patient conflicts
- Confirmation of understanding (verbal or written)
- Termination of opioid prescribing with or without dismissal
The general assembly recognizes the important public health benefits of the legal medical use of controlled substances and also the significant risk to public health that can arise due to the abuse of those substances. It is the intent of this chapter to create the Vermont prescription monitoring system, which will provide an electronic database and reporting system for electronic monitoring of prescriptions for Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances. (Added 2005, No. 205 (Adj. Sess.), § 1.)

Is the issue of prescription drug abuse a health care or law enforcement problem…… or Both?

Do prescribers in Massachusetts have access to the information available from their prescription monitoring system?
Comparable to the VPMS: would allow pharmacists, physicians, and other prescribers to access an electronic drug dispensing database that would include the name of each drug prescribed; the date it was filled; the patient's name, birth date, and social security number; and the name of the prescribing physician.

The bill was unanimously passed by the House and Senate and signed into law by President George W. Bush in 2005.

To date, the organization has received only $2 million in funding to begin implementation of the program.

Only 33 states had operational prescription drug monitoring programs as of June 2009.

The program is a patient information tool, not a law enforcement tool.
VPMS monitoring of a 32 y.o. male from 04/09 to 10/09: (a former patient)

- 4 .......... number of different addresses
- 13 ........ number of different pharmacies
- 17 ........ number of different controlled drugs
- 21 ........ number of different prescribers
- 76 ........ number of individual written Rx

Would you prescribe for this patient if you knew this information?

Can we consider this “keeping control over controlled substances?”

Will he become opioid abuse death number 13,801?
10. Termination of Controlled Substance Agreement

In an effort to better coordinate and monitor care of our patients who required chronic pain management with controlled substances, we are sending you this notification that our controlled substance agreement with the following patient has been terminated.

Patient Name: ___________________________________________ DOB: __________

- We will no longer be prescribing controlled substances, however the patient will continue to be in our practice.
- We will no longer be prescribing controlled substances and this patient is in the process of leaving our practice.
- This patient has discontinued care in our practice.
- Other comments/recommendations: ___________________________________________
In Conclusion

The dental practitioner must be able to diagnose and treat OFP. It is our responsibility to manage pain in this region. Statistics have shown that these OFP patients often go years and incur great expense and disability when untreated. The dentist is the health care provider who is best trained to administer treatment for these patients and the proper use of opioid therapy can be a safe and effective therapeutic tool.
“Responsible Opioid Prescribing”: a Physician’s Guide
Scott Fishman, MD
Waterford Life Sciences, Washington, DC, 2007
(As commissioned by the Federation of State Medical Boards)

“Avoiding Opioid Abuse While Managing Pain”
Lynn R. Webster, MD, and Beth Dove
Sunrise River Press, North Branch, MN, 2007

“Managing Chronic Pain While Keeping the ‘Control’ in Controlled Substances”
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services, 2009