The Practical Aspects of Prescribing Opioids for Chronic Pain - 2018

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Disclosure Information

Dr. Saberski has indicated that he has no financial relationships to disclose.

Prescribing Opioid Medications

- Use of chronic controlled substances in chronic pain management is acceptable in appropriate clinical situations.
- However, there are a number of risks associated with these medications, which have been well documented and include addiction, overdose, and death.
- Careful monitoring is required to maximize safety when prescribing opioid medications

This is not a lecture on how to pick the right opioid

- This is a liability discussion for providers that write prescription for controlled substance
 - What needs to be in the medical record
 - An understanding of your medical decision making and judgment

New Connecticut Laws

- New Connecticut (CT) laws limit initial prescriptions to a 7 day supply for adults. Exceptions are allowed for patients with chronic pain or acute pain that will last beyond 7 days with appropriate chart and prescription (Rx) documentation.
- The law also requires that the associated risks of addiction and overdose be explained to the patient before prescribing controlled substances for the first time.

Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage



Types of Pain

- Acute pain there is always tissue damage (nociceptive model of pain)
- Chronic pain there may not be any tissue damage
- Psychogenic pain there is no tissue damage

The Sub-Types of Pain

- Acute Pain
 - Normal protective
 - Nociceptive model
 - Somatic
 - Superficial & deep
 - Visceral
- Chronic Pain
 - Maladaptive
 - Biopsychosocial model
- Psychogenic Pain
 - Maladaptive
 - Biopsychosocial model



Acute Pain is Different Than Chronic Pain

It is important to remember that the <u>management of chronic pain</u> is very different than the management of acute pain.



Biopsychosocial Model of Pain



Source: Yale School of Medicine pain management seminars

Establishing Legitimacy for Opioids: Document Legitimacy

Managing Chronic Intractable Pain

When You Prescribe Opioids

- Legitimate medical diagnoses
 - Acute
 - Malignant
 - Chronic benign
- Addiction cannot be in the differential diagnosis



Now That You Have Your Legitimate Diagnosis, What Must You Do?

- Document history & physical examination
 - Sets the foundation for controlled substance use

History & Physical Examinations are Important Tools Because:

- There is no routine clinical test that measures pain or determines source of pain
- There is no radiological or laboratory test that shows job dissatisfaction, marital discord, financial distress, alcoholism, drug addiction, etc.



Location of Pain







Quantifying Pain

- Numerical Rating Scale (NRS)
- Visual Analogue Scale (VAS)
 - Quantify pain with a Visual Scale
 - Use the same scale
 - Ask the same way





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Quantifying Function:

Functional Status:

- What's a typical day like?
- Do you work?
- What's the most active thing you do?
- Do you ever stay in bed all day?
- Do you get any exercise?
- How have these things changed over the past weeks/months/years?
- What would you like to be able to do?



Chronic Pain History Should Include:

Does pain interfere with anything?

- Walking?
- Mood?
- Sleep?
- Quality of life?
- Relationships
- Sex life?



Chronic Pain History

 Goals need to be clear and written into the medical record and periodically need to be reviewed

Opioid Risk Assessment

 Each patient must be screened to assess his or her risk status

- A full medical and personal Hx.
- Administration of a risk questionnaire or interview
- Review of any documented evidence that may exist of any type of aberrant behavior known
- To indicate a potentially increased risk to the patient, if chronic opioid management is utilized as part of that patient's treatment plan

Opioid Risk Assessment and Informed Consent

 Opioid medications can interact with many medications, including:

- Other prescribed controlled substances (i.e., benzodiazepines)
- Anti-depressants
- Medical marijuana
- Other common medications

Opioid Risk Assessment

- If you think opioids would be beneficial for your patient for the management of their pain you must do an assessment and determine risk:
 - Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)
 - Opioid Risk Tool (ORT)
 - Sleep Apnea

MARK EACH BOX THAT APPLIES	FEMALE	MALE
FAMILY HISTORY OF SUBSTANC	E ABUSE	
Alcohol	1	□ 3
Illegal drugs	□ 2	3
Rx drugs	□ 4	□ 4
PERSONAL HISTORY OF SUBST	ANCE ABUSE	
Alcohol	□ 3	□ 3
Illegal drugs	□ 4	□ 4
Rx drugs	□ 5	□ 5
AGE BETWEEN 16-45 YEARS	1	1
HISTORY OF PREADOLESCENT SEXUAL ABUSE	□ 3	0
PSYCHOLOGIC DISEASE		
ADD, OCD, bipolar, schizophrenia	□ 2	□ 2
Depression	1	1
SCORING TOTALS		

ADMINISTRATION

- On initial visit
- Prior to opioid therapy

SCORING (RISK)

- 0-3: low 4–7: moderate
- ≥8: high

Risk Should Be Stratified by ORT or SOAPP-R and Morphine Milliequivalents/day (MEQ/day)

- Low risk < 50 mg. MEQ, ORT = 0-3
- Mod. Risk 50-90 mg. MEQ, ORT = 4-7
- High risk >90 mg. MEQ, ORT >8

RISK GROUP	ORT Score / SOAPP Score	MEQ / MED*	ABERRANT BEHAVIOR
Low	0-3 / <7	≤ 60	No
Moderate	4-7 / ≥7	60 – 120	No
High	≥7 / ≥7	> 120	Yes
			 Suspicious behaviors, including: self-escalation of dose doctor-shopping, with documentation on Connecticut's Prescription Drug Monitoring Program (CT PDMP) indications / symptoms of illegal drug use evidence of diversion other documented misuse or abuse a notable change in affect or behavior pattern

New CT Law - PMP

- By CT state law the <u>Prescription</u> <u>Monitoring</u> <u>Program</u> must be checked prior to the first prescription if the Rx. is for more than 3 days of meds.
- CT laws also require that the PMP must be checked every 3 months for patients on chronic meds.

Prescription Monitoring Programs:

- In Massachusetts you must check the PMP every time an opioid script is written
- In Connecticut, every 90 days



Before Writing for Opioids

- Make it clear, only the prescribing doctor can increase or change Rx
 - There can only be one prescribing doctor
 - You will check urine drug screens
 - You will check the state data base
 - You may do pill counts



Routine Urine Drug Testing (UDT)

It is "best practice" when providing pain management and opiate therapy – such testing can help to identify:

- Drugs of abuse
- Prescribed medication, compliance
- Absence of prescribed medication
- Detect substances that could result in adverse events; drug-drug interactions
- Illicit or unsanctioned medicines

Frequency for UDT Testing

- Frequency for UDT testing should be stratified by individual patient risk profile.
- All patients should be tested with the initiation of controlled substance treatment (i.e. - with first practice visit) and then:

 Low risk – 2x/12 mo.
 Moderate risk – 1-2x/6 months
 High risk – 1-3x/3months

MARK EACH BOX THAT APPLIES	FEMALE	MALE
AMILY HISTORY OF SUBSTANC	E ABUSE	
llcohol	□ 1	3
legal drugs	□ 2	3
x drugs	□ 4	□ 4
PERSONAL HISTORY OF SUBST	ANCE ABUSE	
lcohol	3	3
legal drugs	□ 4	□ 4
x drugs	D 5	5
GE BETWEEN 16-45 YEARS	1	• 1
ISTORY OF PREADOLESCENT EXUAL ABUSE	3	0
SYCHOLOGIC DISEASE		
DD, OCD, bipolar, schizophrenia	□ 2	2
epression	1	• 1
CORING TOTALS		

RATION

pioid therap (RISK) rate

Point of Care Testing

- Point-of-Care (POC) or "in-office" that which is done in the office using any number of types of immunoassay testing.
- Oral swabbing
 - when cannot void



Point of Care Testing

- Initial tests are generally done with immunoassays.
 - RISKS:
 - False negatives due to cut-offs for test sensitivity
 - False positive due to cross re-activity with other drugs.

Confirmatory Testing

- Unexpected findings
 - Analysis using gas chromatography/mass spectroscopy (highly sensitive and specific) to identify specific compounds.

Confirmatory Testing

When confirmatory testing requested, the clinician must document the rationale supporting the definitive UDT, and all tests ordered must be documented in the patient's medical record as well.
Confirmatory Testing

- UDT should be sent for confirmation for all new patients (first-time visit) and when:
 - There are inconsistencies in UDT with prescribed meds
 - To confirm patient is taking the medications on their list
 - To check for illicit medications all patients with moderate or high risk should be periodically tested for illicit medications
 - A prescribed medication is not included in standard POC

Protecting the Public and Your Patient

- Dangerous to mix opioid with illicit substance
 - Zero tolerance for illicit substance
 - Marijuana is potentially dangerous
 - Alcohol is potentially dangerous



Abnormal Urine Drug Screen

- Must be documented in the medical record
- Documentation should also include what action is being taken
- Losing medical legitimacy for opioids

If Non-Compliant...What Do You Do?

- You must stop prescribing opioid
 - Don't abandon the patient
 - Develop an alternate care plan
 - Manage the patient with non-opioids
 - Physical Therapy / Occupational Therapy
 - Refer to pain management
 - Refer for detoxification



Writing an Opioid Script... Secrets

- Full name
- Address
- Birth date
- Date script written
 - Date script can be filled
 - Date the script should last

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Phone: (203) Fax: (203) 62					
Patient:	XXXXXXX			XXXXX	
Home Phone Address	XXXXXX XXXXXXX	Merid	Work Pho	CT	06450
Dispense	: ONE PO qAM fo on or after 03-25- til: 04-25-13		с рай		
Refill	NONE				
Signatur	e:Val	id if sign	ed in B	LUE ink	and EMBOSSED

Opioid Dose

- Adjust dose up and down based on response
- High doses of opioid
 - > 100 mg MEQ/day
- Low doses of opioid
 - < 100 mg MEQ/day</p>



Morphine Equivalents

- Add up the potency of all the opioids and convert to MEQ/day
 - Use a table
 - Use an application
 - Calculate the total MME per day for all opioids using an opioid dose calculator. Webbased opioid dose calculators are widely available for both PC and mobile devices.

Goals for Effective Chronic Pain Care

- Reducing reliance on the health care system (less ER and emergency doctors visits) increased function and/or return to work; maintaining Activities of Daily Living (ADLs); 50% or more reduction in pain
- Taking the edge off, 10% improvement, good pain relief for 1 hour are never sufficient reasons to continue opioid

Opioids for Chronic Pain



- Not curative care
- Symptomatic care
 - May be managing for years to come
 - Always ask if such treatment safe for decades
 - Never provide a treatment that cannot be used long term

Life Stage Appropriate Therapy

- Young
- Old
- Active addiction
- Hx of addiction
- Working
- Child bearing
- Heavy machinery
- Driving



Guidelines: Chronic Benign Pain Management

- Use medications known to be safe for decades?
 - Limited options
 - Opioids
 - Anticonvulsants
 - Some antidepressants
 - Behavioral care
 - Physical modalities





How to Prescribe Opioids for Benign Pain

Time contingent use

- Do not let pain dictate use of pain med
- Take on a set schedule
 - Minimize or no use of breakthrough Rx for pain



PRN for Function (not pain)

Preservation of activity

- Predictable
- Minimal use
 - Examples:
 - Physical Therapy
 - Getting out of bed in the morning
 - Dancing at a wedding



When Opioids Work Great for ~1 Hour

- Never a reason to continue Rx
 - Euphoric effect
 - Energy effect
 - Hyperalgesic effect
 - Consider opioid induced hyperalgesia



How to Gauge Success

- 50% or greater reduction in pain
- Increased function
- Compliance
- Not impaired
- Using as directed
- Not using alcohol or other illicit substance including marijuana



Summary: Treatment (Tx) Chronic Benign Pain

- The riddle of chronic benign pain cannot be solved with the nociceptive model alone; must consider the biopsychosocial model.
- Before you treat chronic benign pain realize that the course you choose may be for a lifetime of care; choose wisely.
- When you treat, be sure you can measure success or failure: pain scales, diagrams, sketches, digital photography, function.

- If you choose to manage with long-term use of pharmaceuticals make sure your choices are safe for decades to come; do a risk assessment.
- For all medication the patient and doctor should be clear on the rules of engagement, especially for opioids; have a written agreement that spells out the Dos & Don'ts.
- Be sure what you prescribe is life stage appropriate; sensitive to age, sex, and activity.
- Consider the benefits of a time-contingent prescribing when choosing to use opioids for chronic benign pain.

- Write scripts with good until dates...helps you easily know if there is request for early refills...and saves lots of time.
- Titrate dose upward to achieve clinical effect, but recognize that opioids alone are unlikely to improve clinical function; engage following the biopsychosocial profile.
- Avoid "pro re nata" (PRN) for pain...but can use extra doses specifically for a particular function

- The principle goal of chronic pain management for benign disease is functional.
- Most guidelines suggest that the total MEQ dose for benign disease be kept at 100 mg or less as long as goals achieved.

- Zero tolerance for mixing opioid with alcohol and marijuana...a liability to any opioid prescriber.
- Urine drug screens, checking the state data base and pill counts
- Instead of discharge from your practice for misuse of opioids you change management...to a safer management.



Long Term Opioid Therapy in Management of Chronic Pain

- Use of chronic controlled substances in chronic pain management is acceptable in appropriate clinical situations
- Risks associated with these medications have been well-documented and include addiction, overdose and death
- Careful monitoring is required to maximize safety
- Refer to the CDC Checklist for Prescribing Opioids



When CONSIDERING long-term opioid therapy

- Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- □ Check that non-opioid therapies tried and optimized.
- □ Discuss benefits and risks (eg, addiction, overdose) with patient.
- □ Evaluate risk of harm or misuse.
 - Discuss risk factors with patient.
 - Check prescription drug monitoring program (PDMP) data.
 - Check urine drug screen.
- □ Set criteria for stopping or continuing opioids.
- \Box Assess baseline pain and function (eg, PEG scale).
- \Box Schedule initial reassessment within 1–4 weeks.
- Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

Assess Risk of Harm or Misuse

MARK EACH BOX THAT APPLIES	FEMALE	MALE
FAMILY HISTORY OF SUBSTANC	E ABUSE	
Alcohol	□ 1	3
Illegal drugs	□ 2	□ 3
Rx drugs	□ 4	□ 4
PERSONAL HISTORY OF SUBST	ANCE ABUSE	
Alcohol	3	3
Illegal drugs	□ 4	□ 4
Rx drugs	□ 5	5
AGE BETWEEN 16-45 YEARS	1	1
HISTORY OF PREADOLESCENT SEXUAL ABUSE	3	0
PSYCHOLOGIC DISEASE		
ADD, OCD, bipolar, schizophrenia	□ 2	□ 2
Depression	1	1
SCORING TOTALS		

ISTRATION

tial visit

o opioid therapy

IG (RISK)

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CT Prescription Monitoring and Reporting System (CPMRS)

- All prescribers in CT who prescribe opioids must register
- <u>https://connecticut.pmpaware.net/identities/new</u>

Assess Baseline Pain and Function PEG Scale (Pain, Enjoyment, General Activity)

- What number from 0-10 best describes your pain in the past week?
- What number from 0-10 describes how, during the past week, pain has interfered with your enjoyment of life?
- What number from 0-10 describes how, during the past week, pain has interfered with your general activity?



Follow-Up Visit

- Monthly follow-ups preferred
- Check the CTPMP database every 3 months
- Urine Drug Screen
- Opioid Risk Assessment

- Low risk: 2 visits/12 months
- Moderate risk: 1-2 visits/6 months
- High risk: 1-3 visits/3 months

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- □ Assess pain and function (eg, PEG); compare results to baseline.
- □ Evaluate risk of harm or misuse:
 - Observe patient for signs of over-sedation or overdose risk.
 - If yes: Taper dose.
 - Check PDMP.
 - Check for opioid use disorder if indicated (eg, difficulty controlling use).
 - If yes: Refer for treatment.
- \Box Check that non-opioid therapies optimized.
- □ Determine whether to continue, adjust, taper, or stop opioids.
- □ Calculate opioid dosage morphine milligram equivalent (MME).
 - If ≥ 50 MME/day total (≥ 50 mg hydrocodone; ≥ 33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
 - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- \Box Schedule reassessment at regular intervals (\leq 3 months).

Electronic Prescribing of Controlled Substances

- Public Act No. 17-131, Section 3
- Requires Electronic Prescribing of Controlled Substances (EPCS) starting on January 1, 2018 for all controlled substances
- Improved efficiency
- Reduction in prescription fraud as fewer opportunities to duplicate or modify paper prescriptions
- http://www.portal.ct.gov/DCP/Drug-Control-Division/Drug-Control/EPCS-Information-Page

Electronic Prescribing of Controlled Substances (EPCS)

• What is EPCS?

EPCS allows prescribers to use a software system to electronically transmit Schedule II-V prescriptions to a pharmacy

What is required for a prescriber to transmit an electronic Schedule II-V prescription?

Software used to transmit must meet the requirements set for by the DEA

Which medications must be electronically prescribed?

All Schedule II, III, IV, and V controlled substance medications

More information may be found on the DEA's website

https://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

Verification of Electronic Prescriptions

- Two stage verification
- Requires a personal cell phone (not a practice/shared phone)
- Need to download an application to your phone specific to the software you are using to e-prescribe (ask your vendor)
- After submission of e-script to pharmacy, the software on your phone will request a confirmation
- After confirming on your phone, you will be asked to type in a code that is sent to you or your network login

If you do not have the capacity to prescribe electronically you can apply for a waiver

http://www.portal.ct.gov/DCP/Drug-Control-Division/Drug-Control/EPCS-Information-Page

Procedure for Filing EPCS Exemption

- Department of Consumer Protection will send a brief questionnaire to each prescriber with an active controlled substance registration. The questionnaire serves as the exemption. Only need to complete if seeking an exemption
- At this time, any prescriber that completes the exemption questionnaire and answers "<u>Yes</u>" to question #4 has successfully completed exemption
- The prescriber is encouraged to document that they have completed the exemption with the Department of Consumer Protection

EPCS Exceptions

- Temporary technological and/or electrical failure
- Adverse impact on the patient's medical condition or care (e.g., complicated prescriptions, complicated directions for use)
- Pharmacy is not located in the State of Connecticut
- Lack of technological capacity (waiver required)

Technological or Electrical Failure

- A temporary failure of a computer system, application, or device or the loss of electrical power to such system, application, or device, or any other reasonable service interruption to such system, application, or device that reasonably prevents the prescriber from utilizing their EPCS system
- Failure for a pharmacy to accept an electronic prescription could also constitute a technological failure. Prescriber should notify pharmacy of issue so that they may attempt to correct it

Technological or Electrical Failure – Prescriber Procedure

- Prescribers should attempt to correct any and all causes within one's control
- Prescribers must document in the patient's medical record the reason why a paper, facsimile (fax), or telephone prescription was authorized during a technological or electrical failure. This must be done as soon as practicable, but no later than 72 hours following the end of the temporary technological or electrical failure that prevented the electronic transmission of prescriptions
- Prescribers are encouraged to document the reason for a paper prescription on the paper, fax, or telephone prescription provided to the patient

Oral Prescriptions for Schedule II Medications

- Schedule II prescriptions can be communicated by a prescribing practitioner known or confirmed by a pharmacist orally in an emergency
- The filling pharmacist shall promptly reproduce the oral order to writing on a prescription blank. The oral order shall be confirmed by the proper completion and mailing or delivery of the prescription prepared by the prescribing registrant to the pharmacist filling the oral order within 72 hours
- The pharmacist shall affix the temporary prescription to the properly completed prescription
- The properly completed prescription can either be hand written or electronically transmitted but should indicate that it is part of the telephoned in prescription

Frequently Asked Questions

Do we need to check into the CTPMP database with each prescription once we are fully electronic?

What level of improvement in function and pain do you yourself judge as enough to continue opioids?

THE END



Further Reading

- 1. Baldini A, Von Korff M, Lin EHB. A review of potential adverse effects of long-term opioid therapy: A practitioner's guide. Prim Care Companion CHS Disord 2012; 14(3):PCC.11m01326. Available at http://tinyurl.com/ajpl3op
- 2. Centers for Disease Control and Prevention. CDC Guideline for Prescribing Opioids for Chronic Pain. 2016. Available at: https://www.cdc.gov/drugoverdose/prescribing/guideline.html
- 3. Chou C, et al. Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain. J Pain 2009; 10(2):113-130. Available at http://tinyurl.com/csrz8f
- Federation of State Medical Boards of the United States, Inc. Model policy for the use of controlled substances for the treatment of pain. Available at <u>http://tinyurl.com/as5f5am</u>
- 5. Jackman RP, Purvis JM, Mallett BS. Chronic nonmalignant pain in primary care. Am Fam Physician 2008; 78(10):1155-1162. Available at <u>http://tinyurl.com/b7ce3oo</u>
- 6. Kahan M, Mailis-Gagnon A, Wilson L, Srivastava A. A Canadian guideline for safe and effective use of opioids for chronic noncancer pain. Clinical summary for family physicians. Part 1: general population. Can Fam Physician 2011; 57(11):1257-1266. Available at <u>http://tinyurl.com/arsrsx7</u>
- Kahan M, Mailis-Gagnon A, Wilson L, Srivastava A. A Canadian guideline for safe and effective use of opioids for chronic noncancer pain. Clinical summary for family physicians. Part 2: special populations. Can Fam Physician 2011; 57(11):1269-1276. Available at <u>http://tinyurl.com/auqt5yq</u>
- 8. Manchikanti L, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain. Part 2 guidance. Pain Physician 2012; 15:S67-S116. Available at http://tinyurl.com/a5dgagp

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