Safe Opioid Prescribing: Maximizing Benefits and Minimizing Risks

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Southeastern Consortium on Substance Abuse Training
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J. Paul Seale, MD, Disclosures

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Target Audience

- The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.

- Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.
Educational Objectives

At the conclusion of this activity participants should be able to:

• Describe negative consequences that may occur in patients who receive prescriptions for opioid medication

• Construct an initial assessment and baseline measurement of a patient requesting opioid therapy

• Use a monitoring framework to protect the safety of patients receiving ongoing opioid therapy

• Treat concerning behaviors of patients on chronic opioid therapy
Scope of the Problem of Prescription Drug Misuse and Abuse

• In 2006, an estimated 7.0 million persons were current users of prescription drugs taken nonmedically (2.8 percent of the U.S. population). This class of drugs is broadly described as those targeting the central nervous system, including drugs used to treat psychiatric disorders (NSDUH, 2007).

• Prevalence of prescription opioid abuse requiring substance abuse treatment is highest (80 percent) with persons 30 years and younger (SAMHSA/TEDS, 2007).
Most Commonly Abused Classes of Prescription Drugs

- Opioids, such as OxyContin and Vicodin, which are most often prescribed to treat pain

- Central nervous system (CNS) depressants, such as Valium and Xanax, which are used to treat anxiety and sleep disorders

- Stimulants, which are prescribed to treat certain sleep disorders and attention deficit hyperactivity disorder (ADHD), and include drugs such as Ritalin and Adderall
Consequences

• Increased prescribing of opioid pain relievers (OPR) is concomitant with increasing rates of drug overdose death, and chronic, nonmedical use of OPR.

• Deaths from opioid pain relievers (OPRs) increased fivefold between 1999 and 2010 for women; OPR deaths among men increased 3.6 times.

• Women are more likely than men to be prescribed OPR, to use them chronically, and to receive prescriptions for higher doses of OPR (6,7).
Opioid User’s Pyramid

Addiction (4 Cs: Loss of control, compulsive use, craving, continued use despite harm)

Prescription Drug Misuse (recurrent harms related to use)

Concerning (Aberrant) Medication Taking Behaviors &/or Multiple Risk Factors

Low Risk Patient with No Concerning Behaviors
Level 1: Low Risk Patient with No Concerning Behaviors

- Initial risk assessment identifies patient as low risk
- No requests for early refills or dose escalation
- Keeps regularly scheduled appointments
- Brings medication container
- Medication counts always correct
- UDS results are as expected
  - “right drug” is present
  - “wrong drugs” are absent
Level 2: Concerning (Aberrant) Medication Taking Behaviors—*The Spectrum of Severity*

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple “lost” or “stolen” opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
- Resistance to change therapy despite adverse effects (e.g. over-sedation)
- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, “brand name only”
- Requests for increased opioid dose
- Non-adherence with other recommended therapies (e.g., physical therapy, behavioral therapy, etc.)

Butler et al. Pain. 2007

Note: for most of these, need to track pattern & severity over time
Level 3: Prescription Drug Misuse/Abuse

- **Recurrent problems** related to prescription drug use
  - Failure to fulfill major role obligations at work, school, or home
  - Use in physically hazardous situations
  - Substance-related legal problems
  - Continued use despite persistent or recurrent substance-related social or interpersonal problems (for example, arguments with spouse, physical fights, etc.).
Level 4: Addiction

- A clinical syndrome presenting as...
  - Loss of Control
  - Compulsive use
  - Continued use despite harm
  - Craving

- Not equal to physical dependence, which develops in most patients on chronic opioids
SBIRT Approach

- **Screening**
  - **Initial Assessment**: before prescribing, check PMP & medical records, assess for risk factors & obtain baseline measures using the PEG/6 A's
  - **Implement Universal Precautions**: agreement, UDS, pill counts
  - **Monitor for benefit & concerning/aberrant behaviors**

- **Brief Intervention**:  
  - **Address concerning/aberrant behaviors**: express concern, ask pt to explain  
  - **Increase monitoring**  
  - **Taper** if there’s no benefit or behaviors continue

- **Referral to Treatment**: if abuse/addiction, refer for formal treatment, buprenorphine or methadone
Part 1: Initial Assessment & Baseline Measurement
Screening

- **Initial Assessment**: before prescribing, assess for risk factors & obtain baseline measures using the PEG/ACA (6 A’s)

- **Implement Universal Precautions**: agreement, UDS, pill counts

- **Monitor for benefit & concerning (aberrant) behaviors** using PEG/ACA (6A’s) & compliance with agreement
Initial Assessment

Starts before the office visit:

- Obtain records from previous MDs
- Check state Prescription Monitoring Program
- Scan available hospital &/or clinic records
- Defer prescribing if data are unavailable
Prescription Monitoring Programs

- Now exist in 49 states; rules vary by state
- Rhode Island:
  - Opioid prescribers are required to register w PMP
  - For pain > 90 days & opioid Rx, RI requires
    - H&P, pain assessment
    - Document changes in pain relief
    - Document changes in functional status
    - Note other diagnostic & treatment interventions planned
PMP (RI) continued

• Provide patient education re risks, interaction w alcohol & sedatives

• Safekeeping, destruction of unused med

• Written agreement in medical record if 90 days or more of opioid Rx

• Periodic re-assessment

• Taper/change/DC if no benefit or suspicion of misuse
Ask about Risk Factors

• **Known risk factors** for all types of addiction are **good predictors** for problematic prescription opioid use
  - Past alcohol, cannabis and/or cocaine use
  - Lifetime history of alcohol or substance use disorder
  - Family history of alcohol or substance abuse
  - History of legal problems
  - Tobacco dependence
  - History of severe depression or anxiety

Ives et al., 2006; Reid et al., 2002; Michna et al., 2004; Akbik et al., 2006; Liebschutz et al., 2010
Risk Assessment Screening Tools

- **ORT: Opioid Risk Tool** (Passik et al. 2008; Webster & Webster 2005; Chou et al., 2009)

- **DIRE: Diagnosis, Intractability, Risk, Efficacy** (Passick et al., 2008; Belgrade et al., 2006)

- **SOAPP/SOAPP-R: Screener & Opioid Assessment for Patients with Pain**, revised (Passick et al., 2008; Chou et al., 2009; Butler et al., 2008)

- **SISAP: Screening Instrument for Substance Abuse Potential** (Coambs et al., 1996)

www.opioidrisk.com/
# OPIOID RISK TOOL

<table>
<thead>
<tr>
<th>Item</th>
<th>Mark each box that applies</th>
<th>Item Score If Female</th>
<th>Item Score If Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Family History of Substance Abuse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>[ ]</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Illegal Drugs</td>
<td>[ ]</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>[ ]</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>2. Personal History of Substance Abuse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>[ ]</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Illegal Drugs</td>
<td>[ ]</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>[ ]</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>3. Age (Mark box if 16 – 45)</td>
<td>[ ]</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4. History of Preadolescent Sexual Abuse</td>
<td>[ ]</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>5. Psychological Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia</td>
<td>[ ]</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>[ ]</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Score Risk Category: Low Risk 0-3, Moderate Risk 4-7, Hi Risk ≥ 8

Reprinted by Permission: Lynn Webster, MD

TOTAL _______ _______
Ongoing Assessment Screening Tools

- **COMM**: Current Opioid Misuse Measure (Butler et al., 2007; Chou et al., 2009)
- **ABC**: Addictions Behavior Checklist (Wu et al., 2006)
- **Chabal 5-point Prescription Opioid Abuse Checklist** (Chabal et al., 1997)
- **PMQ**: Pain Medication Questionnaire (Adams et al., 2004; Dowling et al., 2007; Holmes et al., 2006; Passik et al., 2008)
- **PDUQ**: Prescription Drug Use Questionnaire (Compton et al., 1998; Compton et al, 2008)
- **PADT**: Pain Assessment & Documentation Tool (Chou et al., 2009; Passik et al., 2004)
- **Six A’s** (Jackman & Mallet, 2008)

[www.opioidrisk.com/](http://www.opioidrisk.com/)
Assessment: The PEG/ACA (6 A’s)

- Analgesia
- Affect
- Activity
- Adverse effects
- Concerning (Aberrant) behaviors
- Adjuncts

Jackman RP & Mallett BS, AFP 2008; 78: 1155-1162
1. What number best describes your **Pain** on average in the past week? (0=No pain – 10=Pain as bad as you can imagine)

2. What number best describes how, during the past week, pain has interfered with your **Enjoyment of life**? (0=Does not interfere – 10=Completely interferes)

3. What number best describes how, during the past week, pain has interfered with your **General activity**? (0=Does not interfere – 10=Completely interferes)

*Add these 3 numbers to generate a validated measure you can follow over time*
## Consider Using a Pain Scale with More Objective Descriptors

<table>
<thead>
<tr>
<th>Pain Scale</th>
<th>Level of Pain</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
<td>No pain and no physical impairment.</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td><strong>Functional pain</strong>&lt;br&gt;(Pain definitely present and may even require regular medication but does not interfere with daily activities.)</td>
</tr>
<tr>
<td>2</td>
<td>Mild</td>
<td>Having a very difficult time functioning with existing responsibilities and pleasurable activities are rare and concentration is impaired.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Missing work, canceling social activities, staying in bed because of inability to function.</td>
</tr>
<tr>
<td>4</td>
<td>Discomfort</td>
<td>Hospitalization</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Distressing</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Horrible</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Excruciating</td>
<td></td>
</tr>
</tbody>
</table>
Adverse Effects of Opioids

• CONSTIPATION
• Nausea
• Sedation
• Decreased cognition
• Loss of control
• Hyperalgesia
• Hypogonadism
• Urinary retention
Concerning (Aberrant) Medication Taking Behaviors

*The spectrum of Severity*

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple “lost” or “stolen” opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
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- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, “brand name only”
- Requests for increase opioid dose
- Non-adherence with other recommended therapies (e.g., physical therapy, behavioral therapy)

**Butler et al. Pain. 2007**

Note: for most of these, need to track pattern & severity over time
Adjuncts

• “What else have you done to try to reduce or manage your pain?”
  ▪ Non-opioid drugs (NSAIDs, anticonvulsants, etc.)
  ▪ Exercise with flexibility training
  ▪ Nondrug treatments
    – Physical therapy
    – Complimentary therapies
    – Cognitive behavioral therapy
  ▪ Injections
  ▪ Pumps
Heads Up!

• You will have opportunity to see a series of videos which demonstrate approaches which are taught in this module

• In the skills practice sessions which follow each video, you will have a chance to practice these approaches
View Video 1—Pain Management: Assessment with the PEG/ACA (6 A’s)

Observe this physician-patient assessment encounter with a 46 year-old new patient whose records from her previous physician showed occasional escalation of dose due to complaints of increased pain and no urine drug screening. The Prescription Monitoring Program showed prescriptions only from her gastroenterologist. Her score on the Opioid Risk Tool (ORT) is 3 (low risk).

https://www.youtube.com/watch?v=VFKGEqSMZzc
Practice Session #1 Instructions

• Pt: 58 yo disabled man moved to town with 20 yrs LBP, multiple surgeries, did PT and acupuncture, Fam Hx unknown, did marijuana in his 20s, no cocaine/other drugs, no legal/psych problems, pain is 9, PMP record: Norco 10 mg tid, 1 MD, ORT score=3

• Clinician: Assess with PEG/ACA—Pain score, how does pain interfere w enjoyment of life/general activity; any adverse effects, concerning behaviors, adjuncts tried?
Part 2: Implementing a Monitoring Framework—Why Use One?

Increasing evidence that structured care programs can assist patients in reducing or resolving concerning/aberrant behaviors
Outcomes of Structured Care

• 171 pts with concerning/aberrant behaviors received structured opioid care (agreement, UDS, etc.)

  ▪ 45% adhered to the agreement and resolved concerning/aberrant behaviors
  ▪ 38% self-discharged
  ▪ 13% referred for addiction treatment
  ▪ 4% with consistently negative UDT were weaned from opioids

Weidemer, Harden, Arndt & Gallagher, Pain Medicine, 2007
Outcomes of Structured Care

- 61 patients followed over 6 months
  - 21 high risk pts received standard care
  - 21 high risk pts received structured care – monthly UDS, compliance checklists, motivational counseling
  - 20 low risk pts – standard care

- Findings: Positive Drug Misuse Index (PDUQ, ABC, urine screens)
  - High-Risk control patients – 73.7%
  - High risk structured care - 26.3%
  - Low risk controls - 25%

Jamison et al, Substance Misuse Treatment for High Risk Patients on Opioid Therapy: A Randomized Clinical Trial, Pain 2010
Steps for Implementing a Monitoring Framework

1. Have a risk/benefit discussion about opioids (include in your agreement)

2. Explore non-opioid treatment options

3. If appropriate, talk about an opioid “test/trial”

4. Define treatment goals

5. Encourage patient responsibility

6. Explain opioid monitoring measures, emphasizing patient safety issues
Step 1: Have a Benefit/Risk Discussion About Opioids

<table>
<thead>
<tr>
<th>Potential Benefits</th>
<th>Potential Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Analgesia</td>
<td>- Toxicity/side effects</td>
</tr>
<tr>
<td>- Function</td>
<td>- Functional impairment</td>
</tr>
<tr>
<td>- Quality of life</td>
<td>- Physical dependence</td>
</tr>
<tr>
<td></td>
<td>- Abuse/addiction</td>
</tr>
<tr>
<td></td>
<td>- Overdose</td>
</tr>
<tr>
<td></td>
<td>- Increased pain sensitivity</td>
</tr>
</tbody>
</table>
Clarify Side Effects & Risks

- Include these in your patient agreement
- Side effects (short and long term)
  - sedation, constipation, impaired driving
  - physical dependence, addiction
- Risk of drug interactions or combinations
- Risk of unintentional or intentional misuse
  - abuse, addiction, death (abuse &/or addiction rates in chronic pain patients are 3-19%)

Serious Opioid-Related Consequences

- Addiction: SAMHSA estimates 980,000 opioid addicts in 2010
- Opioid-related visits to Emergency Rooms—305,885 visits in 2008
- Opioid-related fatalities (accidental or intentional overdoses)—16,651 deaths in 2010
- Costs healthcare insurers up to $72.5 billion annually in direct healthcare costs
Dose-Related Risk: How much opioid is too much?

- Compared with patients receiving 1-20 mg/d of oral morphine equivalents, patients receiving 50-99 mg/d had a 3.7-fold increase in overdose risk.

- Patients receiving 100 mg/d or more had an 8.9-fold increase in overdose risk with a 1.8% annual overdose rate.

- Morphine equivalent doses over 120 mg/d doubled the risk of substance-related health services utilization encounters (withdrawal, intoxication, overdoses).

Braden JB et al. Arch Intern Med 2010
Consider pain consultation at 120 mg morphine equivalent/day

- RI now requires “considering” such a consultation

- If no consultation is obtained, document it was considered and why it was deferred

- Use online tools to calculate morphine equivalent dose, such as:
  - [http://agencymeddirectors.wa.gov/mobile.html](http://agencymeddirectors.wa.gov/mobile.html)
Step 2: Explore Non-Opioid Treatment Options

- Nonopioid drugs (NSAIDs, anticonvulsants, etc.)
- Exercise with flexibility training
- Nondrug treatments
  - Physical therapy
  - Complimentary therapies (yoga, meditation, guided imagery, etc.)
    - Guided imagery: online resources such as:
      - http://mydoctor.kaiserpermanente.org/ncal/mdo/presentation/healthtools/healthtoolspecialties.jsp#media_group=Podcasts
  - Cognitive behavioral therapy
- Injections
- Pumps
Exploit Synergism

Morphine, Gabapentin, or Their Combination for Neuropathic Pain

Ian Gilron, M.D., Joan M. Bailey, R.N., M.Ed., Dongsheng Tu, Ph.D., Ronald R. Holden, Ph.D., Donald F. Weaver, M.D., Ph.D., and Robyn L. Houlden, M.D.

[Graphs showing pain intensity and dose for baseline, placebo, gabapentin, morphine, and combination treatment]

NEJM 2005; 352:1324-34
Step 3: If Appropriate, Offer an Opioid “Test/Trial”

- We lack strong accurate predictors:
  - Who will experience lasting benefit from chronic opioid analgesics
  - Who will be harmed by chronic opioid analgesia
- Current evidence suggests that a 3-6 month trial may be appropriate
  - In patients with no contraindications
  - If not continued past the point of obvious failure
- Offer opioid prescriptions/changes as a “test” of the medication
Opioid Efficacy in Chronic Pain

- Most literature surveys & uncontrolled case series
- RCTs are short duration <4 months with small sample sizes <300 pts
- Mostly pharmaceutical company sponsored
- Pain relief modest
- Modest to no functional improvement
- **Not all chronic pain is opioid responsive**

Balantyne JC, Mao J. NEJM 2003
Eisenberg E et al. JAMA. 2005
Variability in Response to Opioids

Mu Receptor

- >100 polymorphisms in the human mu opioid receptor gene
- Mu receptor subtypes
  - Not all patients respond to same opioid in same way
  - Not all pain responds to same opioid in the same way
  - Incomplete cross-tolerance between opioids

Mu receptor genome

Smith H, Pain Physician, 2008
Long-Term Opioids Can Increase Pain Sensitivity (in some patients)

- Some patients obtain pain relief when tapered off opioids
- Animal studies chronic opioids increased pain sensitivity
- Methadone maintenance pts w/ increased pain sensitivity
- ? neuroadaptation to chronic opioids
- Opioid withdrawal mediated pain
- Opioid-induced hyperalgesia

www.sbirtonline.org

Li X et al. Brain Res Mol Brain Res 2001
Doverty M et al. Pain 2001
Angst MS, Clark JD. Anesthesiology 2006
Withdrawal-Mediated Pain

![Graph showing the relationship between withdrawal, opioid concentration, and comfort. Peaks represent pain periods, and arrows indicate opioid administration.](image-url)
Step 4: Define Treatment Goals

- Work with patient to identify **specific measurable realistic** functional goals

- Use these goals jointly to measure benefit

- Remind patient that pain is unlikely to go away completely
Step 5: Encourage Patient Responsibility & Safety

- Explain legal responsibilities
  - Safeguarding (lock box), disposing, not sharing or selling

- Encourage the patient to look out for early signs of harm
  - Am I safe to drive or operate heavy machinery?
  - Am I having trouble controlling the use of my medication?

- Give Rx for naloxone for OD reversal
## Naloxone Prescription Instructions

### Intramuscular
- **Rx:** Naloxone 0.4 mg/mL
- **Quantity:** 2-4 single-use 1 mL vials or 1 X 10 mL multi-use vial
- **Sig:** For suspected opioid overdose, inject 1 mL in shoulder or thigh. Repeat after 3 minutes if no or minimal response
- **Refills:** prescriber preference

### Intra-Nasal
- **Rx:** Naloxone 1mg/1mL
- **Quantity:** 2-4 x 2 mL prefilled Luer-Jet™ Luer-Lock needleless syringe
- **Sig:** For suspected opioid overdose, spray 1 mL (half of the syringe) into each nostril. Repeat after 3 minutes if no or minimal response
- **Refills:** prescriber preference

### Auto-Injector
- **Rx:** Naloxone 0.4 mg/mL
- **Quantity:** 1 kit containing 2 auto-injectors
- **Sig:** View instructional video. For suspected opioid overdose, inject 1 mL in thigh. Repeat after 3 minutes if no or minimal response
- **Refills:** prescriber preference
Step 6: Explain Opioid Monitoring & Why We Do It

• Focus on patient safety

• Designed to help protect patient from getting harmed by medications.
  ▪ Statin-LFT monitoring analogy.

• A standard policy used with all patients
  ▪ Note: set level of monitoring to match risk (more frequent visits & monitoring in higher risk patients)
“Universal Precautions”
Protect Patients & Help Detect Concerning (Aberrant) Behaviors

- Agreements ("contracts")
- Urine Drug Testing
- Pill Counts
- Prescription Monitoring Programs
- Phone Follow up
Agreements (Contracts)

• Educational and informational, articulating rationale and risks of treatment

• Spell out monitoring (pill counts, etc.) and action plans for concerning/aberrant medication taking behavior

• Universal use takes “pressure” off provider to make individual decisions (Our clinic policy is...)

Arnold RM et al. Am J of Medicine 2006
Monitoring: Prescription Monitoring Programs

- “better than a urine drug screen”
- Identify patients using multiple providers
- Share information with patient in a non-judgmental fashion and ask them to explain discrepancies
- Beware limitations: time lag, often will not include information from neighboring states
Monitoring: Urine Drug Tests

- Evidence of therapeutic adherence
- Evidence of non-use of illicit drugs
- Know limitations of test and your lab
- Know a toxicologist/clinical pathologist
- Consider Medical Review Officer (MRO) training
- Efficacy not well established
- Helpful strategies…
  - What, if anything, do you think we might find today…
  - Your urine was positive, what can you tell me about it?

Heit HA, Gourlay DL. J Pain Symptom Manage 2004
Standridge JB et al. Am Fam Physician 2010
Monitoring: Pill Counts

• Confirm medication adherence
• Minimize diversion
• Important: know what the pills look like
• Helpful strategies…
  ▪ Bring patient back 3-7 days early
  ▪ “Forgot pills”, schedule return visit with in a week
  ▪ Unsanctioned dose escalation is unacceptable
Consultation with a Friend or Family Member

- Consider including a section in your Controlled Substance Agreement granting permission for you to contact a specific friend or family member if you become concerned about the patient’s safety while on opioids

- Consider including this person in overdose prevention education and use of naloxone
View Video 2—Pain Management: Opioid Agreement

Observe this physician-patient encounter between a physician whose office uses “universal precautions” including a controlled substance agreement that establish safeguards to increase patient safety when prescribing chronic opioids.

https://www.youtube.com/watch?v=So7rGNUmQqQ
Practice Session #2 Instructions

- Clinician: Discuss med agreement—risks & benefits of opioids esp addiction, OD & death; legal responsibilities, universal precautions: 1 prescriber/pharmacy, no early refills, urine drug tests, pill counts, take only as prescribed, try 1 non-opioid adjunct (same dose of Norco for now)

- Patient: limited knowledge—risks=can be habit forming or affect driving, benefit=pain relief (I need more! I’m not addicted; I’m in pain, need more!), concerned re risk of dying, shocked: I would never sell my meds
Part 3: Addressing Concerning (Aberrant) Behaviors
Concerning (Aberrant) Medication Taking Behaviors

*The spectrum of Severity*

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple “lost” or “stolen” opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
- Resistance to change therapy despite adverse effects (e.g. over-sedation)
- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, “brand name only”
- Requests for increase opioid dose
- Non-adherence with other recommended therapies (e.g., PT, behavioral therapy)

Butler et al. Pain. 2007

Note: for most of these, need to track pattern & severity over time
Concerning/Aberrant Medication Taking Behaviors: Differential Diagnosis

- **Inadequate analgesia** – “Pseudoaddiction”\(^1\)
  - Disease progression
  - Opioid resistant pain (or pseudo-resistance)\(^2\)
  - Withdrawal mediated pain
  - Opioid-induced hyperalgesia\(^3\)

- **Addiction**
- **Opioid analgesic tolerance**\(^3\)
- **Self-medication of psychiatric and physical symptoms other than pain**
- **Criminal intent** - diversion

\(^1\) Weissman DE, Haddox JD. 1989; \(^2\) Evers GC. 1997; \(^3\) Chang C et al 2007
Screening: Assess for Opioid Benefit

- PEG scores—lack of improvement may indicate a failure of therapy

- Changes in function: Is opioid therapy achieving the patient’s goals?

- Use these findings in your “risk-benefit” decision making
Brief Intervention: Discuss Concerning (Aberrant) Medication-Taking Behavior

- Non-judgmental stance
- Use open-ended questions
- State your concerns about the behavior
- Examine the patient for signs of flexibility
  - Is the patient focused more on the opioid or pain relief?
- Discuss the need for increased monitoring

Passik SD, Kirsh KL. J Supportive Oncology 2005
Continuation of Opioids

• Assess and document benefits and harms

• To continue opioids:
  ▪ Does the PEG show evidence of benefit?
  ▪ Does the benefit outweigh observed or potential harms?

• Note: you do not have to prove addiction or diversion to justify tapering opioids—lack of benefit and/or high level of risk is enough
Options for Addressing Concerning (Aberrant) Behaviors & Continuing Pain

1. Increase monitoring—more frequent visits, return for pill counts, call in for UDS
2. Consider non-opioid options to address continuing pain
   • Re-attempt to treat underlying disease & co-morbidities
   • Re-explore possible adjuncts
3. If concerning/aberrant behaviors decrease or disappear, consider escalating dose as a “test.”
4. If simply no benefit after several months, begin opioid taper
5. If concerning/aberrant behaviors continue, consider a discontinuation strategy
   • Begin opioid taper
   • If signs of addiction: switch to buprenorphine/methadone or refer to treatment
View Video 3: Follow-up Interview

Observe this clinician-patient encounter between a patient who is requesting increased medication and a clinician who discovers behaviors that concern him.

https://www.youtube.com/watch?v=ur_PxJ8QPCM
Practice #3 Address Concerning Behaviors: requesting early refill (1 wk), did not leave urine last visit, forgot pill bottle, missed PT appt, UDS today positive for benzos

- Clinician: Assess PEG/ACA, express concerns: no UDS last visit, now ran out of pills, no pill bottle, missed PT, now using BZD (not revealed). You’re concerned she may be losing control. State since agreement was not met, more monitoring will be necessary: 2 wk RX, come in at 1 wk for pill ct, UDT today, no more BZDs

- Patient: UDS is expensive, problem is pain (9), tried taking 4/day & ran out, took partner’s lorazepam to get to sleep, it reduced pain & helped you sleep. Respond to new limits in a way your patients might respond.
Discontinuing Opioids

Opioids may be discontinued when the physician’s assessment indicates:

1. Lack of benefit (monitor using PEG scores)
2. Risk outweighs benefit
Discontinuation of Opioids: Discussing Lack of Benefit

- Stress how much you believe / empathize with patient’s pain severity and impact.
- Express frustration re: lack of good pill to fix it.
- Focus on patient’s strengths.
- Encourage therapies for “coping with” pain.
- Show commitment to continue caring about patient and pain but without opioids
Discontinuation of Opioids: Discussing Lack of Benefit

• Stress that some patients experience improvement in function and pain control when chronic opioids are stopped

• Make it clear that you are not discharging the patient but discontinuing an ineffective treatment

• Taper patient slowly to prevent opioid withdrawal
How to Taper Opioids

• Decrease by 10-20% each week
  ▪ Pill formulations may dictate amount of drop in dose
  ▪ Rate of decrease determined by circumstances of withdrawal

• Allow supply of short acting medications to treat “breakthrough” symptoms
  ▪ Build up alternative pain treatment modalities
  ▪ Comfort medications

• Schedule close follow-ups
# Treatment: Clonidine

## Oral Dosing
- Initial dosing: 0.1 mg po
  - Watch BP carefully
- Titrate up to 0.1 to 0.3 mg po q4-6 hours, then taper
- Risk: HYPOTENSION
- Effective adjuvant to other meds listed

## Transdermal (Patch)
- More steady levels of med; avoid cyclic hypotension and rebound.
- Dosed one patch per week ($10/patch).
- Dose range: 0.1-0.4 mg
- 24-48 hours to start to work -- can use oral clonidine initially while waiting for effect.
“Comfort” Meds

- **Ibuprofen** 600 QID
- **Dicyclomine** 20 mg QID for stomach cramping
- **Antiemetics:** Trimethobenzamide 250 mg po/ 200 mg IM q6-8 hours or promethazine
- **Muscle relaxants:** Methocarbamol 500-750 mg up to QID

- **Antidiarrheals:**
  - Kaolin with Pectin
  - Bismuth subsalicylate
  - Loperamide (less effective)

**Sleep aids**
- Trazodone 50-100 mg
- Doxepin 25-50 mg
- Amitriptyline 50mg
Scenario B: Possible Addiction: Talking Points

- **Give specific feedback** on what previous behaviors raise your concern for possible addiction/loss of control
  - You may have to agree to disagree on your diagnosis

- **Explain that benefits no longer outweigh risks.**
  - “I cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good.”

- **Offer a menu of treatment options**: detox & opioid free treatment, buprenorphine, or methadone.
  - Stay 100% in “Benefit/Risk of Med” mindset.
Buprenorphine—Advantages

- Moderate pain relief
- Stops craving & withdrawal symptoms
- Low addiction risk (doesn’t give a high)
- Low risk of overdose or respiratory depression (ceiling effect)
- Can be prescribed in primary care
- Covered by many insurance plans
- Typically involves counseling/other addiction treatment
Buprenorphine—Disadvantages

- Expensive
- Risk of respiratory depression if used with benzodiazepines
- Less effective for pain management than other opioids
- Makes pain management more difficult in case of surgery or a severe accident
- Requires regular office visits with monitoring (UDS, pill counts, etc.)
Methadone Treatment: Advantages

- Also treats both addiction and pain (typically involves counseling/addiction treatment)
- Prescribed by physicians/staff with expertise in both
- Provides a highly structured environment
- Inexpensive
Methadone: Disadvantages

- For patients with opioid dependence methadone can only be prescribed in specialized treatment centers
- Requires daily visits (except weekends)
- Can cause respiratory depression at high doses, especially if mixed with other sedatives (alcohol, benzodiazepines, etc.)
Advantages:

• A good option for becoming drug-free for those who desire it
• Consistent with the philosophy of many traditional treatment programs and 12 step programs
• Tx of withdrawal is medically safe and often relatively brief (except for patients on long-acting opioids)
• May be used in conjunction with naltrexone p.o. or IM

Disadvantages:

• Risk of relapse is very high
Observe this physician-patient encounter between a physician and a patient who is documented in his state’s Prescription Monitoring Database to be receiving opioids from multiple prescribers.
https://www.youtube.com/watch?v=GhPoWgLAvfU
Practice #4 DC Opioids: 38 yo, chronic neck pain, Percocet 10 QID, dog ate meds, Rx stolen 2 mos. ago, PMP: Percocet from other MD, PEG scores unchanged, UDS: cocaine in EC

- Clinician: Ask PEG questions (score 29/30)—Norco not helping, signs of poss. loss of control/addiction, risks outweigh benefits, offer menu: referral for addiction tx, buprenorphine or methadone. Stay in mindset of benefit/risk of med, addiction as a disease

- Patient: PEG scores 10/10/9, pain=severe, refused surgery--uncle paralyzed post surgery, you are disabled now, feel desperate, use THC & extra pills but no better, sometimes see other MD when out of pills, friend thinks you have drug problem (no! pain!), dismissed by MD in other state. If offered help, choose your response
SBIRT Approach

• **Screening**
  - **Initial Assessment**: before prescribing, check PMP & medical records, assess for risk factors & obtain baseline measures using the PEG/ACA
  - **Implement Universal Precautions**: agreement, UDS, pill counts
  - **Monitor for benefit & concerning/aberrant behaviors**
  - **Document!**

• **Brief Intervention**:
  - **Address concerning/aberrant behaviors**: express concern, ask pt to explain
  - **Increase monitoring**
  - **Taper** if there’s no benefit or behaviors continue

• **Referral to Treatment**: if abuse/addiction, refer for formal treatment, buprenorphine or methadone
General Principles

- Not all chronic pain responds to opioids.
- Opioids will not provide complete pain relief and may not improve function.
- A trial period of 3-6 months with close monitoring to assess efficacy, adverse effects is usually adequate to establish opioid responsiveness.
- Be cautious not to dose-escalate in patients who may not respond.
- Misuse of opioids can be minimized by making expectations and goals explicit and by careful monitoring and documentation.
General Principles

- Maintain risk-benefit model, not a police-offender model
- Reassure patient that you understand pain severity
- Reflect on patient strengths (self-efficacy)
- Success needs to be defined on a case-by-case basis
- Opioids are only one part of the treatment plan
- Exploit synergism with NSAIDs, adjuvants
- Know and adhere to your state’s PMP and prescribing guidelines
Additional Materials

- Visit [PCSS-O.org](http://PCSS-O.org) & [sbirtonline.org](http://sbirtonline.org) for additional materials including:
  - CME & mentoring opportunities
  - Videos demonstrating interview techniques
  - Model Controlled Substances Agreement
  - Model Pain Assessment Form
  - Practice Role Plays (scripts for patient, clinician and observer scripts)
  - Pocket Card on Pain and Addiction
Thanks!

• Questions? Comments? Suggestions?

• Contact info: seale.paul@navicenthealth.org
PCSS-O Colleague Support Program

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.

- PCSS-O Mentors comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.

- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.

- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit: www.pcss-o.org/colleague-support

- Listserv: A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
For questions email: pcss-o@aaap.org

Twitter: @PCSSProjects

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