Advanced Concepts: Pain/Risk Evaluation and Mitigation Strategy

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Report: Tiger Woods had marijuana, painkillers in system at arrest

Terry Spencer  Aug 15, 2017  Comments
FORT LAUDERDALE, Fla. — Tiger Woods had the active ingredient for marijuana, two painkillers and two sleep drugs in his system when he was arrested on a DUI charge earlier this year, a report released Tuesday by prosecutors said.

Police in Jupiter, Florida, released the report less than a week after the golf superstar agreed to enter a diversion program to settle his driving while intoxicated charges. The report’s contents were first reported Monday by ESPN.

The report, prepared by the Palm Beach County Sheriff’s Office, says Woods, 41, had THC, the active ingredient for marijuana, as well as the painkillers Vicodin and Dilaudid; the anxiety and sleep drug Xanax; and the anti-insomnia drug Ambien in his system when he was arrested at 2 a.m. May 29 about 15 miles from his home in Jupiter. Officers had found him unconscious in his Mercedes-Benz, which was parked awkwardly on the side of the road and had damage to the driver’s side. It’s not clear how he damaged the car. Officers checked the area but didn’t find that he had hit anything.

Spencer 2017
Learning Objectives

1. Explain key elements of the CDC guidelines for managing patients on chronic opioids

2. Identify and appropriately triage patients on chronic opioids who have an opioid use disorder or who are at increased risk

3. Develop compassionate yet objective, evidence-based treatment plans for patients with chronic pain

Risk Evaluation and Mitigation Strategy (REMS) Program

• “A drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication”
But You’re Not Here to Learn a Document!

• Chronic pain
  – Among the most common complaints family physicians face
• For many patients
  – No clear etiology
  – Non-opioid interventions recommended by experts may be too costly, not feasible or frankly ineffective
• Conflict
  – Provide relief/satisfy the patient, yet limit opioids/control costs?

What is the frontline family physician to do?

What Affects Pain?

• Transduction
• Transmission
• Modulation
• Perception
• Interpretation
• Behavior

“Pain is inevitable; suffering is optional.”

Buddhist proverb
What Does Pain Affect?

- Physical Functioning
  - Activities of daily living (ADL's), sleep issues

- Social Consequences
  - Relationships with family and friends (social isolation), intimacy/sexual activity

- Mood/mental health
  - Depression, anxiety, anger, loss of self-esteem
  - Self-medication

- Societal Consequences
  - Healthcare costs, disability

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Goals (Metrics/Outcomes) of Treatment

- Reduce “pain” level (very subjective!)
- Improve physical function
- Improve functional status
  - Activities of daily living, social/recreational activities, domestic activities
- Increase self-management of pain
- Improve vocational ability and status
- Reduce health care utilization
  - Medical procedures, emergency department visits, outpatient office visits, phone calls
- Eliminate, minimize or even stabilize the use of opioids
Realistic, *Individualized* Goals

- **Example comparisons**
  - Back to work vs. visiting with grandkids
  - Eliminating opioids vs. not increasing opioids
  - Improving function vs. decreasing ED visits

- **Factors influence treatments**
  - Baseline physical and mental health
  - Support system – people, financial
  - System factors – transportation, locations
  - Patient insight and capacity

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**Opioids For CNCP?**
*(Choosing Wisely Campaign)*

- Don’t prescribe opioid analgesics as long-term therapy to treat chronic non-cancer pain until the risks are considered and discussed with the patient

American Society of Anesthesiologists, 2014

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*AMERICAN ACADEMY OF FAMILY PHYSICIANS*
1. Nonpharmacologic & nonopioid pharmacologic therapy are preferred

**Guideline for Prescribing Opioids for Chronic Pain**

Improving Practice Through Recommendations

The American Academy of Family Physicians (AAFP) has developed guidelines for the use of opioids in the treatment of chronic pain. These guidelines recommend the use of nonpharmacologic and nonopioid pharmacologic therapy as preferred options for the treatment of acute pain from non–low back, musculoskeletal injuries with topical nonsteroidal anti-inflammatory drugs. ACP and AAFP recommend that clinicians treat patients with acute pain from non–low back, musculoskeletal injuries with topical nonsteroidal anti-inflammatory drugs.
2. Establish treatment goals, including realistic goals for pain and function: how/when to d/c opioids if benefits < risks

3. Discuss known risks and realistic benefits, and patient and clinician responsibilities
4. When starting, prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA)

5. Prescribe lowest effective dosage; reassess benefits/risks when considering ≥50 morphine milligram equivalents (MME)/day; avoid increasing to ≥90 MME/day (or carefully justify a decision to titrate dosage to ≥90 MME/day)
6. For acute pain, prescribe lowest effective dose of immediate-release opioids; three days or less - often sufficient; more than seven days rarely needed

7. Evaluate benefits and harms with patients within 1 to 4 weeks (when starting opioids or dose escalation)
8. Mitigate risk; consider offering naloxone when factors increase risk for overdose such as h/o OD, h/o SUD, OSA, higher dosages (≥50 MME/day), concurrent benzodiazepines

Naloxone: Not just for opioid use disorder!

9. Use state prescription drug monitoring program (PDMP) data
10. Drug testing before starting opioids and at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs

11. Avoid prescribing opioids and benzodiazepines concurrently whenever possible
12. Offer/arrange evidence-based treatment (usually medication assisted treatment in combination with behavioral therapies) for patients with opioid use disorder

Sample Tools to Identify OUD

- Opioid Risk Tool (ORT)
  - Available for free, online at MDCalc
- Screener and Opioid Assessment for Patients in Pain (SOAPP)
- Current Opioid Misuse Measure (COMM)

- Which to use?
  - Based on EMR/local standards, goals, availability of tool, etc.
The Golden Question

“What does ___ do for you?”

Suspecting OUD – Tips

More Obvious

• H/o overdose
• H/o OUD or other use disorder
• Erratic behavior, poor follow-up, conflicting stories
• Obvious drug test results
  − Ex: Positive opiates in someone not on any Rx pain meds
• Positive screen using standardized screening
  − Ex: SBIRT, DAST (during CPE’s, adolescent WCC’s)

More Subtle

• Avoidance/not returning calls when asked for pill counts, follow-ups
• Subtle drug test results
  − Ex: negative opiates in someone with opiate w/d or intoxication symptoms (Fentanyl?)
• When asking “what does your opioid do for you?”, getting answers such as:
  − “It helps me sleep”
  − “It relaxes me”
  − “It energizes me”
OUD vs. Physiologic Dependence/
“Pseudo-addiction”

• I’m usually ok if:
  – I follow opioid Rx guidelines (CDC), and
  – Patient has good/improved function/QOL (the goal), and
  – Use is not adversely affecting life (ex, arguments at home/relationships), and
  – Patient open/honest (ex, needing more d/t tolerance), and
  – Monitoring is as expected (drug testing, pill counts, etc.)

• I’m concerned if:
  – Tolerance/hyperalgesia develops and patient is not open/honest
  – Tolerance/hyperalgesia develops and life adversely affected (arguments at home, isolates, too
tired to go out, mood swings, etc.)
  – Despite Rx, function/QOL stagnant or worsens
  – Patient using for other (subconscious) reasons – sleep, anxiety, energy
  – Missed follow-ups, avoids drug tests/pill counts, etc.

Useful Stems (To Bring Up Concerns)

• “Given [objective findings/concerning behavior], I’m worried that the opioids may be causing some problems . . . I’d like to get a second opinion with someone [pain management, addiction medicine] who has expertise with these medications.”

• “We have talked about risks of dependence and what is called hyperalgesia; I’m worried that these opioids may be causing more pain especially in the long run than they are helping . . . I’d like to get a second opinion . . .”

• “We had talked about the risks of addiction; almost everyone on these meds will have their body become physically dependent - that’s different from addiction but hard to tease out . . . I’d like to get a second opinion . . .”
Diagnosing Suspecting OUD

• Your job:
  − Suspect
  − Be curious
  − Investigate
  − Bring up
  − Motivate
  − Refer/get help

• NOT your job:
  − Formally diagnose (unless you want to!)

• Diagnosis is made by DSM-V criteria
  − Slightly subjective
  − Varies by interviewer, how questions asked/interpreted
  − Varies by time/when assessed

• Criteria applies to any/all substances
  − Alcohol, opioids, stimulants, etc.

• Presence/severity of a use disorder based on how many criteria are met

Use Disorder Diagnostic Criteria

• Using larger amounts/for longer time than intended
• Desire/unable to ↓/control use
• Lot of time spent to obtain/use/recover
• Craving
• Failure to fulfill major life roles
• Use despite social problems
• Giving up important activities/isolation
• Use in hazardous situations

• Use despite causing/exacerbating physical or psychological problem(s)
• Tolerance
• Withdrawal

2-3 criteria → mild
4-5 criteria → moderate
>=6 criteria → severe

American Psychiatric Association, 2013
Increasing Evidence: Buprenorphine for Chronic Pain

- OUD vs. dependence: semantics?
- Less hyperalgesia, tolerance?
- Most buprenorphine products NOT labeled for pain, but for OUD

“Doc, I wish I had done this years ago”

- “The overall consensus of the panel was that buprenorphine is a unique Schedule III opioid with favorable pharmacologic properties and a safety profile that may be desirable for chronic pain management.” (Webster)
- “On the basis of these clinical data and individual patient risk/benefit assessments, clinicians should consider utilizing buprenorphine buccal film as a first-line opioid treatment for chronic pain over other buprenorphine formulations or other opioids.” (Hale)
- “The meta-analysis revealed that buprenorphine has a beneficial effect on pain intensity overall, with a small mean effect size in patients with comorbid chronic pain and OUD and a moderate- to large-sized effect in chronic pain patients without OUD.” (Lazaridou)

Webster, 2020
Hale, 2020
Lazaridou, 2020

Mrs. Smith called for a refill of her Percocet . . .

- What are you feeling right now? Why do we feel that way?
  - Feelings vs. facts
  - Biases?
- Put the patient first
  - What is best for the patient?
  - Avoid adversarial relationships
- It’s not about you

AMERICAN ACADEMY OF FAMILY PHYSICIANS
Steps to Peace and Prosperity

1. Deep breath: “The patient is the one with the disease”
2. Collect information; decide agenda & your goals
   - Difference between “recommended” and “required” – what’s your line in the sand?
   - It’s about the patient, not you
3. Take emotional inventory; what biases make you feel that way?
   - “The last patient like this put me way behind in my schedule”
   - “He always has some excuse for not going to PT”
   - “My partners will think I’m (good/bad) for (prescribing/not prescribing) this”
   - “I hate feeling manipulated”
   - “I don’t think he needs it, but, what’s the alternative?”
   - “I inherited this mess, it’s just not fair”
4. Recognize a Feeling is . . . Just a Feeling
   - Feelings and biases are real . . . But maybe irrational and not fair to the patient (or you)

Steps to Peace and Prosperity (con’t)

5. Hit Your Reset Button
6. Listen, Process, and Proceed
7. Validate the patient’s feelings, needs, requests
   - Validate ≠ agree
8. Develop a plan
   - Based on guidelines and individualized
   - Fair and clear
   - Hint: I dictate patient instructions in the room into my EMR
9. Adhere to the plan
   - Politely stand your ground
If You Must Wean . . .

- Happens on occasion
  - Discharging from a practice? Should be rare!
- Clarity on the reason
  - “Because” is not a reason!
  - Should have a better alternative
- No sudden stoppages
  - Rare exceptions
  - “Opioid refugees”

Delicate Balance

- Complete elimination of chronic pain: usually unrealistic
- Give hope, yet be realistic?
  - They’ve already been told ‘It’s all in your head’
  - How to address their mental health?
- Some helpful phrases to get people to counseling:
  - “My patients with pain usually have two things going on - the terrible, ongoing physical pain, for which we are doing XYZ, but in addition, they tell me they get angry and/or anxious about the pain. Do you ever notice that?”
  - “While we treat your physical pain, maybe we can address the [anxiety, insomnia, anger] surrounding the pain – there is so much science to tell us the two are different but related.”
  - “The pain is severe and real, but while we are taking care of that, can we have you talk to someone about the pain’s impact on your life?”
  - “You’ve said ‘of course I’m angry and anxious, get rid of the pain and my mood will improve’ – and I get that, but – here we are; how about we do something to help improve the mood?”

Davis, 2019
Final Thoughts

- If you’re looking for a reason to kick the patient out of the practice...
  - Find another business!
- Unexpected drug test results are the start – NOT END – of a conversation

Opioid Guideline Summary:
If I Open the Chart, Can I Find:

- Why are they on opioids?
- Discussion – risks/benefits/alternatives
- Assessment of risks, and mitigation (naloxone, PDMP)
- MEDD, concurrent benzo’s, use of screening tools, OUD assessment
- Assessment of function
- Drug screens
- Controlled substance agreements
Case: Disclaimers

• Hypothetical
• Due to time, will go fairly quickly
• There are MANY reasonable options every step!
  − These are just some possibilities

Case: Introduction

• Your partner retires
  − You “inherit” one of many patients
• 47 y.o. male with:
  − Hypertension
  − Hyperlipidemia
  − Smoking
  − Lower back pain
  − Erectile dysfunction

• Medications:
  − Atorvastatin
  − Enalapril
  − Oxycodone/acetaminophen (Percocet)
  − Oxycodone ER (OxyContin)

• Reason for follow-up visit
  − “I’m due for my Percocet”
  − 15 minute visit and you’re behind schedule
Case: Brief Chart Review

- **Opioids**
  - #90 oxycodone/acetaminophen (Percocet) 5/325mg monthly X 3 years
  - #60 oxycodone ER (OxyContin) 15 mg monthly X 1 year
- **3 office visits in the last year**
- **Last chem 8 & lipids 2 years ago**
  - Ordered by partner, never gotten
- **Last UDS 1.5 years ago**
  - "Pos for opiates, o/w neg"

- **LBP**
  - Etiology?
  - MRI 4 years ago essentially unremarkable ("spinal osteoarthritis")
- **Referred to pain management two years ago but never went**

Next Steps?
Gather Information!

• Dive deeper in the records – look for:
  – Previous consults, imaging, PT records
  – Previous medications tried
  – Medical problems/co-morbidities

• Start with the basics! Focused assessment reveals:
  – Pain is non-specific, central LS area
  – Some R-sided sciatica but no objective findings

• Regarding his oxycodone use:
  – Uses the ER (long-acting) bid regularly
  – Short-acting helps him sleep; uses every night & some days
  – Denies constipation, drowsiness, dizziness

• ROS
  – No CP, SOB, constipation
  – Trouble sleeping d/t racing thoughts
  – Some fatigue, low libido & erectile dysfunction

Initial Thoughts & Agenda Setting

• LBP etiology?
  – Repeat MRI to delineate etiology given sciatica and 4-year lapse?
  – Referral to orthopedics, neurosurgery, physiatry?

• Oxycodone
  – #90 each month but uses average of 1.5 per day . . . that's 45/month . . . hmm . . .
  – Limited previous monitoring; anything concerning about the UDS results 1.5 years ago?
    • Hint: positive for opiates . . . is oxycodone an opiate or opioid?

• Potential interventions
  – Work-up for LBP etiology
  – What does the oxycodone do?
    • Give relief for ADL's or "relax" him/help sleep?
  – Check testosterone given ROS & chronic opioids
    • Not necessarily to Rx if low . . .
  – Evaluate for depression, anxiety
  – Physical therapy for "good" evaluation
  – Check PDMP, recheck UDS, pill count
  – Non-opioid medications - NSAID's (watch BP), topical lidocaine or NSAID
  – 1 week oxycodone Rx?
    • Not 1 month, not zero . . . Why?
    • "I'll be a sucker once"
1 Week Later

• PDMP as expected, UDS sent
  − You forgot to send UDS last visit . . That’s ok! This is a journey, not a race
• Updated “opioid contract”
  − For mutual understanding, not to be used as a ‘gotcha
• MEDD
  − 15mg short-acting daily (his “max”) + 30mg long-acting = 67.5 MEDD – pretty high!
• Naloxone Rx’d
  − His safety, your safety (medico-legal), and to highlight the dangers of his regimen
• PHQ-9 = 9 (mild depression), GAD-7 = 12 (moderate anxiety)
• Testosterone 180 (low); TSH, CBC, LFT’s WNL
• STOP Bang high risk for OSA → sleep study
  − Work-up fatigue, and mitigate opioid risks by identifying/treating OSA

So You . .

• Refer for cognitive behavioral therapy (CBT)
  − Underlying MH issues, anxiety surrounding the pain/pain management, CBT-I (insomnia)
• Start SNRI
  − Neuropathic pain help? Treat anxiety
• Consider med to help sleep (for now)
  − Low-dose TCA (help neuropathy as well)? Mirtazapine? Trazodone (but priapism risk)
  − You choose melatonin for now
• Send for CPAP
• Send for physiatry evaluation (thorough back assessment, maybe EMG/NCS?)
• Start planting the seeds
  − “I’m worried this medicine may be causing more pain in the long run . . I think it’s a major cause of many symptoms and your low testosterone . . . I think we’ll explore all options for your pain; in the meantime, here’s a refill, I’ll see you back in two weeks”
Two Days Later

• UDS comes back positive for oxycodone and THC (marijuana)
• You decide to do pill count
  − Nurse visit next day
    • “I didn’t get a chance to fill the new prescription.”
    • Nurse notes the oxycodone Rx’s were filled yesterday, and appropriately, one day’s worth of each is missing

Two Week Follow-up Since Last Visit

• You ask about THC: helps him sleep
  − He: “It’s legal anyway, what’s the big deal?”
  − You: “If you don’t stop, we may have to stop your opioids”
  − Review risks on employment, of laced THC
• He “forgot” to make the appointments for counseling and physiatry
• Your thoughts: concerned and curious, NOT angry
Subsequent Discussion

• You:
  – “Help me understand:
  – You told me about the anxiety and poor sleep, yet you did not fill the new medication even though you were at the pharmacy to get the oxycodone
  – We talked about how CBT would be great for your insomnia, but you didn’t make the appointment.
  – We don’t exactly know what’s causing your back pain, but you didn’t call the other doctor.
  – I’m confused; maybe it’s me, but if I had as much pain as you did, I would do anything to stop it.”
    • Editorial: I am legitimately confused – aren’t you in these situations?

• Then you zip it and listen

Patient Perspective

• Patient’s thoughts:
  – Wow . . When the doctor says it like that, hmm, it doesn’t make sense
  – Why didn’t I do those things?

• Patient: “I guess I just didn’t think of it; the oxy seems to help so I don’t want to change; I’ve had other doctors who think this is all in my head so when you talked about counseling it got me mad.”

• You: “That’s understandable; here you are suffering and feel like we don’t take you seriously. That must be hard.”
  – [validation; not adversarial]

• Patient’s thoughts:
  – This doctor nailed it – I trust them
  – Also, I guess if this doctor thought it was all in my head, they wouldn’t have prescribed me the oxycodone in the first place
And THEN . . .

- CLEAR instructions reviewed with the patient
  - “By next visit, let me know the names, dates and times of appointments with . . .”
  - “Fill the other medication . . .”
  - “Discontinue the marijuana – I am worried that you may be self-medicating anxiety . . .”
- Regarding oxycodone
  - “Some patients tell me that oxycodone helps them feel better in general, even relax – is it possible that applies here somewhat?”
  - “For most causes of back pain, opioids actually makes it worse in the long run . . .”
  - “Let’s keep you on them [for now . . . Build trust] but tweak the dose that you’ll barely notice the difference, especially with the other things we’re doing.”
  - “Instead of 15mg bid long-acting, let’s do 15mg in AM and 10mg in PM, but keep the #90 of the short-acting for now”

Potential Paths

- If LBP etiology identified, Tx appropriately
- Increase/augment non-opioid treatments
- Assess impact of anxiety on his pain
- Continue super slow opioid wean
  - Maybe d/c long-acting over months, then short-acting by 4 pills/month?
  - Maybe wean until off completely?
  - Maybe he’ll be on PRN bid short-acting for a long-time – if guidelines are followed and function is good, so what?
- If he’s insistent on high-dose opioids, pain management referral?
  - Not to manage opioids, but 2nd opinion on the need for opioids for his specific condition
- If continued “yellow” flags/THC, maybe addiction medicine referral?
  - To help screen for OUD/misuse, consider alternatives (buprenorphine), etc.
- If anxiety becomes more prominent, psychiatry referral?
Objectives: At the End Of This Presentation, An Attendee Will Be Able To . . .

- Explain key elements of the CDC guidelines for managing patients on chronic opioids
- Identify and appropriately triage patients on chronic opioids who have an opioid use disorder or who are at increased risk
- Develop compassionate yet objective, evidence-based treatment plans for patients with chronic pain

AES Question
A healthy 37 y.o. female is on oxycodone for chronic hip pain. She has no medical problems, is only on ibuprofen and an oral contraceptive, and has no history of drug or alcohol problems. You calculate her MEDD.

Per most guidelines, at what MEDD should you consider prescribing naloxone?

A. It doesn’t matter the dose; everyone on chronic opioids should have naloxone
B. 50
C. 90
D. She is low-risk and thus does not qualify for naloxone
AES Question

You ask her how the oxycodone is helping. Which of the following responses would most make you concerned to evaluate further for opioid use disorder and/or monitor closer for potential problems/complications?

A. “My hip is so painful; the oxycodone helps me sleep”
B. “If I miss a dose, I can’t get out of bed and get my kids ready for school”
C. “We went to the park this weekend; I actually took two extra doses above my usual prescribed, because we did so much walking”
D. “The oxycodone has been great; I feel so much better and have more energy”
AES Question 2

You ask her how the oxycodone is helping. Which of the following responses would most make you concerned to evaluate further for opioid use disorder and/or monitor closer for potential problems/complications?

A. “My hip is so painful; the oxycodone helps me sleep”
B. “If I miss a dose, I can’t get out of bed and get my kids ready for school”
C. “We went to the park this weekend; I actually took two extra doses above my usual prescribed, because we did so much walking”
D. “The oxycodone has been great; I feel so much better and have more energy”
AES Question 3

In follow-up, despite the opioid contract describing that she should not use illicit drugs, and though she seems to be doing well clinically, her in-house rapid UDS is positive for amphetamines (stimulants). Two previous tests have been negative.
Which of the following is NOT a reasonable next step?

A. Tell her “Given the amphetamines on the test, you broke our contract; I can no longer in good conscience prescribe you the opioids”
B. Call the lab and/or send the urine out for confirmatory testing before addressing
C. Tell her “Help me understand; your urine was positive for amphetamines – is anything going on?”
D. Ignore the results, but repeat the test in the very near future (1-2 months)
“Family Physicians Continue to Combat Opioid Crisis”

• Links there to AAFP Resources
  − AAFP Pain Management and Opioid Abuse
  − AAFP Policy: Substance Abuse and Addiction
  − AAFP Position Paper: Chronic Pain Management and Opioid Misuse: A Public Health Concern
  − AAFP Chronic Pain Management Toolkit
  − AAFP Pain Management and Opioid Abuse Resources

REFERENCES A-D

REFERENCES E-N


REFERENCES P-Z

27. Screener and Opioid Assessment for Patients with Pain (SOAP). Available at: https://www.nhms.org/sites/default/files/Pdfs/SOAP-14.pdf
Answer Key

1. B
2. D
3. A