PAINWEEK®

Winning the Game of Groans

Jennifer Bolen, JD

Disclosures from Last 12 Months

- Nothing to disclose

Learning Objectives

- Name common allegations made by the federal government in criminal prescribing cases.
- Explain the usefulness of reviewing state licensing board rules and guidelines, as well as the CDC Opioid Prescribing Guidelines.
- State why documentation of prescribing rationale is critical to demonstrating that a controlled substance prescription is issued for a legitimate medical purpose, by an individual practitioner acting in the usual course of professional practice.

Common Allegations

- Drug Trafficking
  - Prescribed High Doses
  - Prescribed Same Drugs to Most Patients
  - Prescribed for Cash
  - Prescribed to Patients Outside Your State of Licensure
  - Failed to Taper When No Pain Relief
  - Failed to Attempt Any Taper
  - Failed to Address Aberrant Behavior, Including Patient Use of THC

Utility of Reviewing Rules and Guidelines

- State Licensing Board
    1. Rules
    2. Guidelines
    3. What's the Difference?

- CDC Opioid Prescribing Guidelines
    1. Do they apply to me?
    2. Should I pay attention to them?
    3. al course of professional practice.

Document. Document. Document.

- Documentation is critical, but it must also be helpful to you and your patients:
  - 1. Comprehensive Evaluation
  - 2. Rationale for Prescribing (Diagnosis, Reasons for Use of Opioids, including other treatments tried and failed, and rationale for not revisiting).
  - 3. Treatment Plan – Starting opioids, Trial period, Exit Strategy.

Document. Document. Document.

- 4. Informed Consent and Treatment Agreement – Follow your state's language.
- 5. Periodic Review – Frequency of Visit. Special Conditions. Risk Monitoring. Addressing Problem Behaviors. Reevaluation Goals of Treatment.
- 6. Coordination of Care and Consultations/Referrals
- 7. Compliance with Federal and State Drug Laws and Other Applicable Laws

Legal Standard – Valid Controlled Substance Prescription

Valid Rx only if . . .

Legitimate Medical Purpose	Usual Course of Professional Practice	Reasonable Steps to Prevent Abuse and Diversion

PAINWEEK®

Winning the Game of Groans: Bare Bones of Pain Assessment and Treatment

Darren McCoy, FNP-BC, CPE

Disclosure

- Nothing to disclose

Learning Objectives

- Explain the importance of establishing a clear diagnosis prior to prescribing opioids for chronic pain
- Describe how to apply an "upside down pyramid" approach to documentation of chronic pain
- Evaluate the quality of examples of chronic pain-management documentation

What's the Big Deal?

- Pain of some sort is THE MAIN REASON patients will come to see you
- Acute pain = protective
- Chronic pain?
  Not so much

St Stauver J, Warner D, Yawn B, et al. Why patients visit their doctors: assessing the most prevalent conditions in a defined American population. Mayo Clin Proc. 2013;88(1):56-57

Acute Pain

- If all the pain was acute, treatment would be much easier
- Sprained ankle
- Sore throats
- UNDERSTANDABLE
- Frequently changing treatments, but little controversy

Chronic Pain

- Unfortunately, pain may lose its utility as a "sentinel" of injury
- Larger-diameter, slower-conducting C fibers
- Over time, changes within CNS →self-perpetuating neurological impulses which an be interpreted as being painful
- Chronic pain may be of a different sensation to initial injury, or may simply be a prolongation of that sensation after acute injury heals
- "Burning, gnawing" is common descriptor of centralized pain

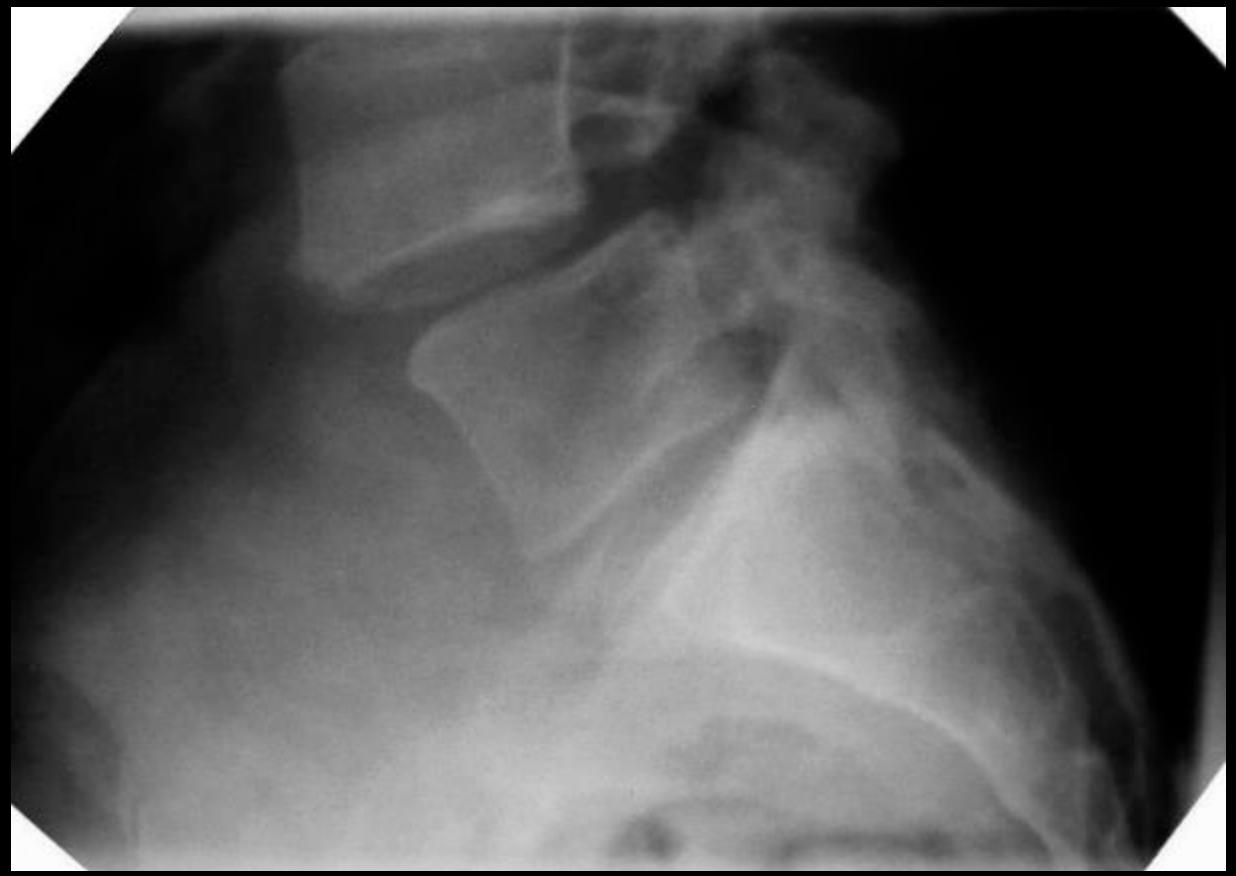
Woolf, C. Central sensitization: implications for the diagnosis and treatment of pain. Pain. 2011; 152(3 Suppl):S2-15

Central Sensitization

- Some painful signals are transmitted "straight line" with increased amplitude +/- frequency of signal → increased perception of pain
- Some pain complaints, though, seems out of proportion to what can be seen or detected on exam or testing
- "Central sensitization" offers an explanation for how chronic pain exists separate from continuous external input (e.g. back pain after postop healing is a central pain syndrome, not continued tissue damage)

Woolf, C. Central sensitization: implications for the diagnosis and treatment of pain. Pain. 2011; 152(3 Suppl):S2-15

You Will Meet a Lot of People with Pain!



- OA/RA
- Spondylosis/listhesis
- Spinal stenosis
- Peripheral neuropathy
- Vascular insufficiency
- PHN
- Phantom limb pain
- Fibromyalgia
- Post-stroke pain

Establishing the Diagnosis

Universal Precautions for Pain: Step 1

- *Establish diagnosis*
- Conduct assessment of risk of substance abuse disorders
- Discuss plan, obtain informed consent to plan
- Written agreement with patient (not "contract")
- Initiate TRIAL of opioids, with or without adjuvants
- Perform regular assessments
- Assess pain AND function
- Evaluate in terms of the "5 As"
- Periodically review diagnoses and treatment plan, and update as needed
- Document carefully and completely the initial eval and followup visits

Gourlay D, Heit H, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain Pain Med. 2005;6(2):107-113

FSMB Revised Model Policy, July 2013

"The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following. …"

- *Inadequate attention to initial assessment* to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain
- Inadequate monitoring during the use of potentially abusable medications
- Inadequate attention to patient education and informed consent
- Unjustified dose escalation without adequate attention to risks or alternative treatments
- Excessive reliance on opioids, particularly high dose opioids for chronic pain management
- Not making use of available tools for risk mitigations (e.g. CSMD/PMP, risk evals)

Federation of State Medical Boards. Model policy on the use of opioid analgesics in the treatment of chronic pain www.fsmb.org/policy/advocacy-policy/policy-documents Accessed 17 July 2016

First Things, First

First step in good pain care is to ESTABLISH THE DIAGNOSIS

EASY: chronic knee pain (either before or following TKA), chest wall pain following CABG or mastectomy, back pain post-laminectomy; clear signs/symptoms of radiculopathy

MORE CHALLENGING: polyarthralgia when a patient has no joint deformity or autoimmune/inflammatory marker abnormalities, myofascial pain without a clear underlying skeletal abnormality, vague visceral pain, or even low back pain in an otherwise healthy person

The Interview

- Essentially, medical journalism:
  Who, What, Where, When, Why, How?
- Not simply "what hurts," but the story of how it started, changed, and responded to treatments. (Fell down stairs v. pushed down stairs, delays in care and reason why, etc.)
- The readers (e.g. insurer, state board, ALJ, etc.) are human, too. Their interest may lag or they may miss important info if you don't lead with it

http://historyofjournalism.onmason.com/2009/12/02/importance-of-the-inverted-pyramid/ Accessed 17 July 2016

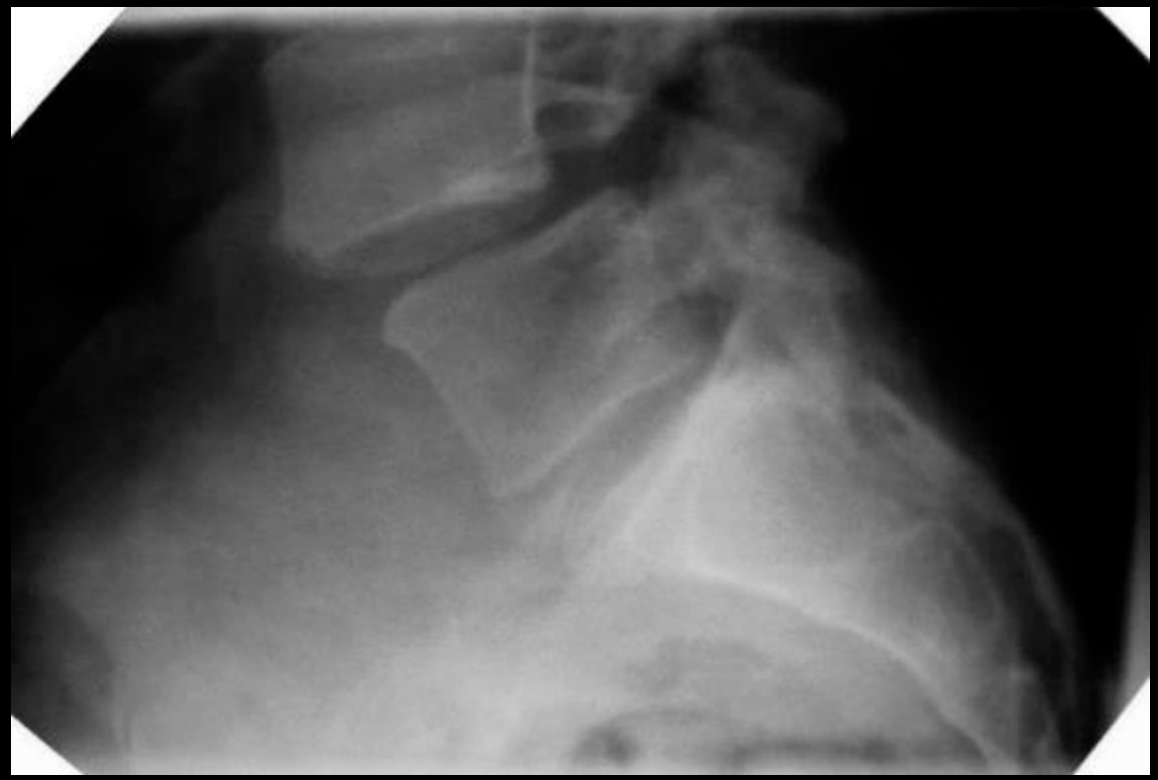
Pain Focused Examination

- Get them into a gown for initial pain exam
- Comment on ROM, muscular tension/tenderness/atrophy, coordination (e.g., how "smoothly" they get up, if they can)
- Sensory testing for light touch, sharp/dull, vibration, cold sensitivity (may help differentiate presence of central sensitization)
- Also, important to document overall posture (Slouched? Shifted to one side? The "look of radiculopathy?" Most importantly, is it consistent with complaint?)
- Comment on grooming/hygiene. If patient can't get in and out of tub easily, or can't reach for toileting, poor hygiene may be real validator of reported chronic pain issue

University of Wisconsin School of Public Health and Medicine. Pain management table 3: components of a sensory examination http://projects.hsl.wisc.edu/GME/PainManagement/tables.html?panel=1. Accessed 17 July 2016

Assessment/Diagnosis

- Feel free to order an image if you have none, or request prior images
- "Dynamic" views show body in motion (e.g., unstable listhesis = almost certain mechanical, if not discogenic, back pain)
- Avoid MRI/CT if no true radiculopathy
- Don't get hung up on "DDD"
- Consider attending basic radiology CME review



Jensen M, Brant-Zawadzki M, Obuchoski N, et al. Magnetic resonance imaging of the lumbar spine in people without back pain. N Engl J Med. 1994;331(2):69-73

Now, Whaddya Do?

Non-Opioids Options/Risks

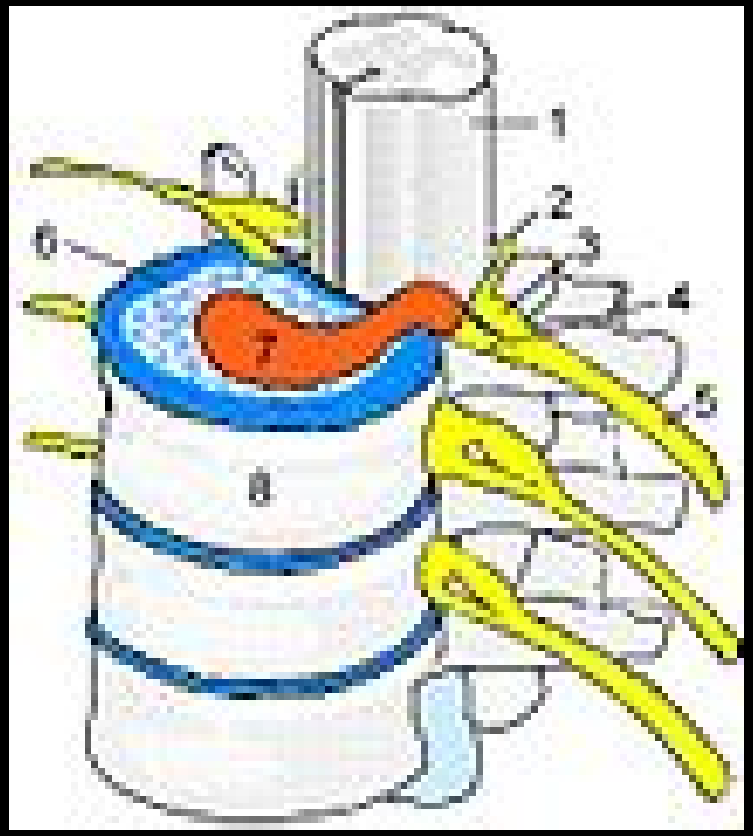
- All we do in treating pain has the potential for benefit, but also the potential for harm
- Nonopioids: NSAIDs (GI bleeds, renal toxicity), APAP (hepatotoxicity), TCAs (arrythymias/lethality), tizanidine (hypotension)
- PT: destabilization of listhesis if not previously identified; MU can break stuff!
- DME: burns from heating pads, sores from poorly-fitted braces (especially in diabetics or vascular disease patients)

Non-Opioids Options/Risks

- Document reasonable procedures recommended (or considered/to be avoided)
- Knee joint/shoulder joint and/or bursae injections are well within scope of primary practice, with proper training
- TPIs for myofascial pain can facilitate motion and PT/rehab for tight, painful muscles
- Anticoagulant use may complicate these treatments

Wong, C and Wong, S. 2012. A new look at trigger point injections. Anesthesiol Res Prac. 2012;2012:492452 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3182370/ Accessed 18 July 2016

Non-Opioids Options/Risks



- Spinal injection therapies for blockade of nerves may help clarify the diagnosis
- Some injections purely diagnostic (medial branch blocks for facet pain)
- Others are therapeutic (ESI/TFE for radicular pain or canal/foraminal stenosis)

Risk Management: It's in All We DO

- Opioids require honest, holistic approach to prescribing; there is no "one size fits all"
- 65 y.o. man with no substance abuse history has OA knee pain. Failed to get relief from NSAID and PT. Just wants to be able to take something PRN to play golf. Probably, reasonable candidate for a trial of tramadol (but find out who else is in the home!)
- 20 y.o. man with history of ETOH and THC use, on meds for schizophrenia, with complaint of low back pain, requests pain meds around the clock. Even if failed NSAID and PT, not necessarily good candidate for even something as mild as tramadol

Sample Documentation for EMR

Assessment: chronic pain, long term medical management with opioids, lumbar spondylolisthesis, peripheral neuropathy

Comorbidities affecting pain management: hypertension, GERD, seizure disorder, CAD, sleep apnea

Plan:
DME: (Y/N) DIAG: (Y/N) PT/OT: (Y/N) PROCEDURES: (Y/N)
NONOPIOID MEDS (Y/N) OPIOIDS: (Y/N, and other state-specific documentation as required such as ">72")
REFERRALS: (Y/N) CSMD: last checked? Appropriate?
PSYCH EVAL: Date? Findings?
DRUG TEST: Date/Type (EIA v GC/LCMS)/Findings; needed now, or not?
RISK/ABERRANT BEHAVIORS: (Y/N)

Short Acting vs Long Acting

- Same chemicals, so one is not "better" than the other
- Recent study reveals no pain-relieving advantage to LA vs SA
- BUT: LA cut down the number of individual doses "out there"
- LA are all C-II (except for buprenorphine patch), so cuts down on fraudulent prescriptions called to pharmacies
- LA manufacturers developing better tamper resistance (enough that it's turning some abusers to resort to heroin)

Pedersen L, Borchgrevink P, Breivik H, Fredheim O. A randomized, double-blind, double-dummy comparison of short- and long-acting dihydrocodeine in chronic non-malignant pain. Pain. 2014;155(5);843-844

Argoff C, Kahan M, Sellers E. Preventing and managing aberrant drug-related behavior in primary care: systematic review of outcomes evidence

SAO vs LAO

- If it's *available*, it's *abusable*
- Negative press led many prescribers to quit prescribing a particular LAO several years ago. Unfortunately, many just switched to multiple doses per day of same chemical as a SAO
- At least twice as many dose units, plus rapid onset = problem was worse than ever
- SAMHSA: In 2011-2012, 54% of those aged 12 and older who used opioids nonmedically got them from friend/relative for free, 10.9% bought from friend or relative → 65% who abused opioids NEVER HAD A PRESCRIPTION

US Department of Health and Human Services Substance Abuse and Mental Health Services Administration Center for Behavioral Health Statistics and Quality
Results from the 2012 national survey on drug use and health: summary of national findings
http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm Accessed April 24, 2014

Opting Out? Not So Fast

- YOU HOLD THE PEN
- If you are not comfortable with a given situation, don't prescribe
- No need for 3rd party excuse (Practice site, State/Feds, etc.)
- If not comfortable with situation, EXPLAIN WHY

Pearls of Pain Management

- Counsel patients: this is like baseball. Few "home runs."
- Assess/document risks of aberrant behavior before prescribing (Brief Risk Interview, SOAPP-R, etc.)
- Identify realistic goals up front. If not reaching ANY of the functional goals, need to modify treatment
- Have boundary, and stick to it

Jones T, Moore T. Preliminary data on a new opioid risk assessment measure: the Brief Risk Interview. J Opioid Manag. 2013;9(1):19-27

PAINWEEK®

Initial Assessment Basics: Risk Assessment and Education

Ted Jones, PhD, CPE

Disclosures

- Contract with Ethos Laboratories regarding an electronic version of the Brief Risk Questionnaire (BRQ)

Learning Objectives

- Name at least two validated risk assessment tools.
- Explain the usefulness of obtaining information from a UDT and the PDMP at the initial evaluation.
- State why a treatment agreement is important and helpful when prescribing opioids

Psychosocial Aspects of the Initial Evaluation

- In addition to the PE and Dx, psychosocial and behavioral aspects of the patient need to be assessed, particularly if opioids are to be considered/prescribed.
- There are several tools to use in this assessment.
- These gather data on the patient's behavior with opioids and the estimated likelihood of a negative outcome.

"Risk Assessment"

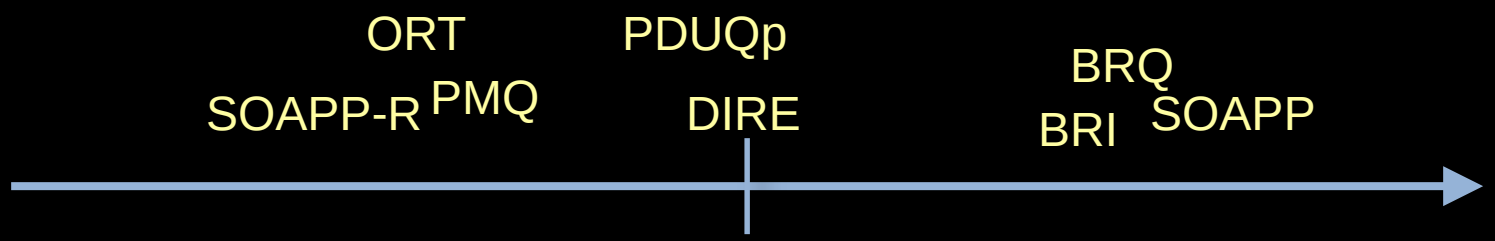
- It's more than one questionnaire or tool.
- You should use several sources of information to get at "risk."
- The tools:
  - Risk assessment tools (medication aberrant behavior)
  - PDMP
  - UDT
  - Past records
  - Overdose risk estimation

Validated Risk Assessment Tools

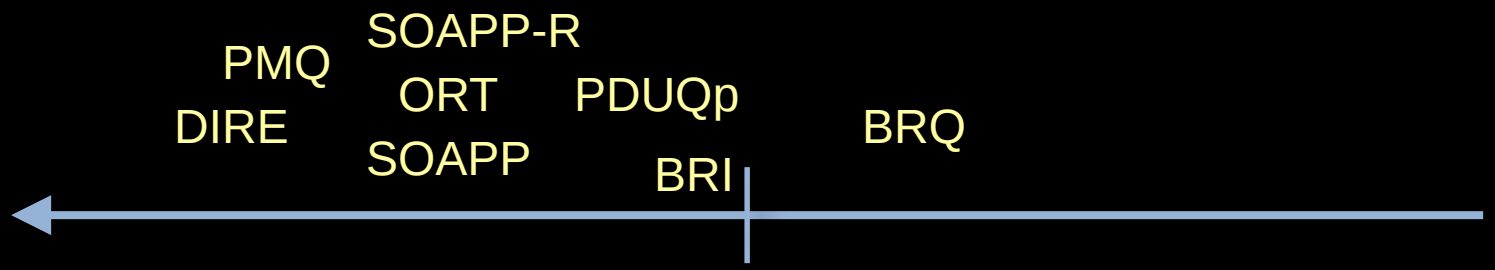
- Screener and Opioid Assessment for Patients with Pain (SOAPP). (Butler, 2004)
- Pain Medication Questionnaire (PMQ). (Adams, 2004)
- Opioid Risk Tool (ORT). (Webster, 2005)
- Diagnosis, Intractability, Risk, Efficacy (DIRE). (Belgrade, 2006)
- Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP-R). (Butler, 2008)
- Prescription Drug Use Questionnaire Self-report (PDUQp). (Compton, 2008)
- Brief Risk Interview (BRI). (Jones, 2013)
- Narcotic Risk Manager (NRM). (Gostine, 2014)
- Brief Risk Questionnaire (BRQ). (Jones, 2015)
- Screen for Opioid-Associated Aberrant Behavior Risk (SOABR) (Ehrentraut, 2014)

Study Averages

Sensitivity (Identifying risk)



Specificity (Identifying no risk)



Which Tool?

- Each has advantages and disadvantages
  - Patient time required
  - Staff time required
  - Paper vs. tablet
  - Reimbursement options
  - Sensitivity (identifying riskier patients)
  - Specificity (not over-estimating risk)

Risk Score vs Risk Assessment

- The score on one of the above risk tools is not necessarily the patient's risk.
- A risk score is like a lab test and is not diagnostic by itself.
- Use the score + PMP + UDT + records to come up with an overall risk rating.
- Other pieces of data may increase risk - but likely won't reduce it.

PDMP

- Hopefully you have a functioning PDMP in your state.
- Even if it's not required in your state, it is a generally expected standard of care to get this information.
- Run it as far back as you can?
- Compare it vs what the patient says as a check on the patient's honesty / ability to give you important information.

UDT

- Even if your state does not require it, it is a generally accepted standard of care that a UDT is obtained before opioids are prescribed.
- Look for
  - —The presence of opioid medications reported taking
  - —The presence of any other opioids not reported
  - —Any illicit drugs, reported or not.

UDT

- IMHO, you should confirm the initial UDT. It's important. Some states require confirmation.
- Yes, you should test for THC, no matter what you think the CDC said.
- That's because you should act on a finding of THC, no matter what you think the CDC said.
- The CDC did not issue you your license and won't be the one taking it away.

Another Risk

- Usually “risk assessment” means predicting medication aberrant behavior.
- There is ANOTHER RISK: the risk of overdose.
- The predictors of this are different.
- Overdose is correlated with such factors such as being elderly, hepatic sx, pulmonary sx, sleep apnea, bz use, alcohol use and higher dose opioids

We Are Not There Yet

- There is no validated tool to assess the risk of overdose.
- The RIOSORD (Zedler et al, 2015) is one proposed tool but it is not yet validated.
- Despite this, you should document in some way that you have evaluated risk of overdose, and have considered this risk as well.

Overdose Risk

- At the very least, if a patient has more than one risk factor for overdose and you are about to prescribe opioids, you should
  - —document that you have noted these risk factors,
  - —[aka, you were not negligent in ignoring or not assessing these factors]
  - —and for reason A you are choosing to prescribe opioids anyway.

Now You Have

- Complaint, Hx, PE, diagnostics and a working dx
- Risk assessment score
- PDMP information
- UDT information
- Overdose risk factor list

- Now what?

Create & Decide

- Overall risk assessment rating (Low, Medium, High).
- Note presence of overdose risk factors
- Decide on whether to rx opioids
  - If opioids are being prescribed, choose which one and why.
  - Insurance coverage, SA vs. LA, likeability to addicts, doses per month, strength of dose all are considerations.

Monitoring Plan

- Based on risk level, create monitoring plan.
- Monitoring: frequency of the "Four P's
  - Patient (report and behavior)
  - PDMP (checking the report)
  - Pills (pill counts)
  - Pee (UDS/UDT/OFT)
- How often will you do each of these?
- Be aware of your state's expectations.

That's it?

- NO.
- If you handing a patient a rx for opioids, you need to go over with him/her your expectations for proper use.
- They need to be educated.
- A "patient REMS" interaction/session.
- The treatment agreement. (not a contract).

Medication Agreement

- It is not just about getting a signature.
- Just like informed consent is not just about getting a signature.
- It is about educating your patient about what you expect, and what to do and not do.
- They don't know al of what they need to know. Don't assume that they do.

Education

- Can be a 1:1 interaction
  - By administrative staff
  - By med-level clinician
  - By lead clinician
- Can be a group education session
- Should include:
  - a patient signature that it happened
  - a handout to reinforce what was said
  - documentation by you that it happened and what was covered

Include

- Review such topics as:
  - Prn vs non-prn medication use
  - What to do if you get hurt or have surgery
  - How to carry opioid medications around legally
  - Storage of medication
  - THC use
  - Alcohol use
  - Visit expectations (what to bring to visits)
  - When and how to call the practice
  - The primary goal of treatment: improved function, not pain elimination

Patient education

- The better job you do on the front end:
  - The less work you have to do later
  - The more you are showing that you really care about your patient
  - The more you are meeting legal and regulatory guidelines
  - The more you are being a responsible pain practice

PAINWEEK®

Pitfalls and Pearls around Documenting Periodic Review, Consultations and Referrals, Ongoing Risk Monitoring and Changes to the Treatment Plan

Douglas Gourlay MD, MSc, FRCPC, FASAM

Disclosure

- Nothing to disclose

Learning Objectives

- Describe the role of documentation
- Explain the requirement of periodic review
- Describe ongoing risk monitoring
- Discuss the use of consultations and referrals
- Describe potential documentation traps with electronic medical records

A perspective on the Medical Record

Documentation Requirements

The Medical Record

- The medical record is a memory aid to the busy practitioner –but it's more
  - –it is an ongoing record of patient care from which a peer / expert should be able to follow the thought process behind the actions you took (and elected NOT to take) over the course of clinical care
  - –It should contain relevant information in a logical and easily accessible form
    - The current use of EMR (electronic medical records) has simplified this… but also created some challenges

The Electronic Medical Record

- In some ways, this has been a great advance toward optimum medical care but…
  - In the efforts to improve efficiency, some software short cuts have been taken
    - "boilerplate entries"
      - Blocks of generic text that may/may not be personalized while making the entry
    - "Normative defaults"
    - Generally not as useful in multidisciplinary settings where medical and psychological care is rendered – lack of data integration and accessibility

Hybrid Charts

- Most older practices that enter into EMR have a combination of paper records AND electronic records
  - Electronic records may be incomplete without detailed examination of the paper chart
    - The harder the auditor has to work – the more likely the outcome will be bad
    - Certain information from the paper charts need to be duplicated and entered into the EMR
      - It's not sufficient to say "it's all there somewhere"
      - The clearer is the story – the better the record looks

The EMR

- "If you didn't document it – it never happened"
  - The detail with which you record this information can be critical in defending your practice
    - Be cautious around documenting information to support your clinical decisions
      - Better to record the information accurately and arrive at appropriate conclusions/treatment decisions BASED on that documentation

Periodic Review

- Goal of Periodic Review
  - —The Five A's
  - —Universal Precautions and Follow-up Evaluations
- Key Areas of Documentation (what an expert looks for)
- Typical Weaknesses in the Physician's Documentation of Rationale for changing or continuing the treatment plan

Consultations and Referrals

- Should be made "as necessary" for the individual patient
  - Scope of practice concerns
  - Coordination of care concerns
- Documenting physician decision-making relating to the use of consultations/referrals
- Documenting the "waiting game" (it can take a while to accomplish the consultation or referral)
- Unintended consequences associated with the failure to consider consultations and referrals

Ongoing Risk Monitoring

Universal Precautions

Risk Levels and Monitoring

Common Risk Monitoring Tools (PDMP, UDT, Medication Counts, Patient Questionnaires, and Dialogue with the Patient)

Documenting Clinical Rationale for Changes or Continuation of the Treatment Plan

- What should be documented
- Challenges in documentation
- "Continue medication management" does not constitute a proper update to a treatment plan

The value in reviewing your documentation efforts

Self-Audit/Chart Review

Chart Reviews

- The purpose behind a chart review is to insure that your documentation meets current standards
  - It's also an opportunity to review more complex patients in a different light
  - Can be useful to see what conclusions a colleague might come to as a result of reading your chart
  - Help you evaluate what is *really* there rather than what you *think* is there wrt the EMR

Chart Assessments

- The ultimate goal is to assess all your charts but this process needs to be ongoing
  - The initial aim is to bring your medical records up to an acceptable stand
    - But you are also evaluating ongoing “blind spots” that might exist in your practice
  - The long term benefits of this process are significant
    - Most jurisdictions allow for CME credit for this process

Peer Assessments

- When you read your notes, you tend to see information differently than an independent evaluator would
  - In multi practitioner practices, this is relatively easy
    - Have a colleague do either a brief or more detailed review of the records using a simple check list you develop for your own practice
  - In solo practices, this can be more difficult
    - But a mid level practitioner can follow a check list and record what is/isn't there
      - The order of priority is Expert; Peer; Midlevel; Self assessment

Chart Assessments

- First, establish a relevant check list for your practice type
  - A general family practice will be different than a specialist practice
  - Keep it simple – the more complex it is, the more difficult it will be to use
    - You want to find the "low hanging fruit" ie the charts with no clear diagnosis; the charts with excessive doses (>90MME/day opioids)
      - You particularly need to identify the "exceptions" in your practice
        - » One or two cases – reasonable
        - » Most of your practice – "defiant doctor?"

Chart Assessment

- Confidentiality
  - All staff in your practice should have signed non-disclosure agreements
    - Consider redacted charts in cases where an external auditor is used
- Standard Operating Practices
  - In your office binder of "SOP", the audit/review process should be listed
    - Frequency?
    - "if it's in your SOP, you better use it"

EMR traps

- Older EMR's tended to "default" to normative entries
  - "No Voiced Complaints"; "CNS Normal"; "Physical exam within normal limits"
    - This implies certain things were done – but as a default entry, that may or may not be the case
- Some EMR's offer the clinician "boilerplate" entries
  - Often the text is general with little evidence that it applies to this patient or this encounter
    - In some cases, the author "personalizes" the text– sometimes with contradictory information

Conclusions

- Chart Audits can be valuable tools to improve patient care
  - They are also valuable sources of CME
- In the context of an external review – regulatory/judicial
  - They provide strong evidence of your efforts to provide optimum medical care for your patients