



# SCOPE of Pain

Safe and Competent Opioid Prescribing Education



Boston University School of Medicine  
Continuing Medical Education

## Case Study Mary Williams

### In the interim...

- Medical records confirmed history
- Unable to contact previous PCP who moved out of state
- UDT positive for oxycodone only
- PDMP showed one prescriber, one pharmacy

42 yo woman

T2DM

Chronic, painful, diabetic neuropathy and back pain

Remote h/o alcohol dependence

Gabapentin and oxycodone/acetaminophen

### Office Visit 2

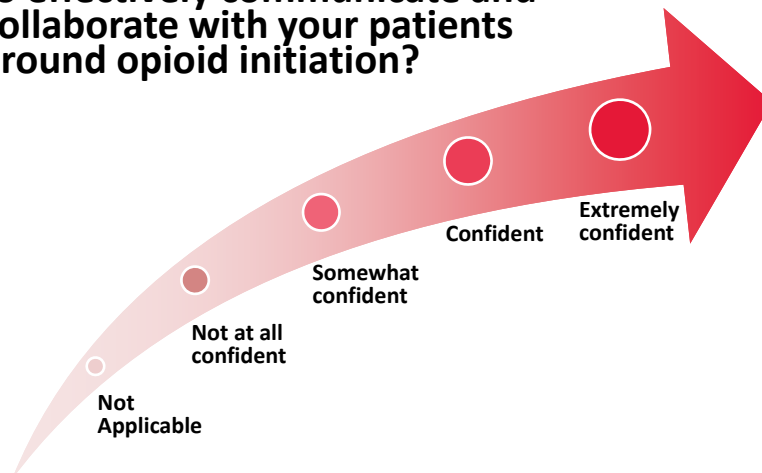
- Pain and function scores unchanged
- Completed her previous Rx for IR/SA oxycodone/APAP on schedule

## Initiating Opioid Therapy Safely



### POLLING QUESTION

How confident are you in your ability to effectively communicate and collaborate with your patients around opioid initiation?



## Learning Objectives: Essential Content 2

- Describe universal precautions and their role in chronic opioid therapy
- Describe monitoring and documentation strategies for chronic opioid therapy
- Describe initiating opioid therapy
- Apply counseling and communication strategies to ensure appropriate and safe use of opioid medications

5

## Universal Precautions in Pain Medicine

### Part of an Office Controlled Substance Policy

- **Predicting opioid misuse is imprecise**
  - Protects all patients
  - Protects the public and community health
- **Consistent application of precautions**
  - Takes pressure off provider
  - Reduces stigmatization of individual patients
  - Standardizes system of care
- **Resonant with expert guidelines**
  - American Pain Society/American Academy of Pain Medicine
  - American Society of Interventional Pain Physicians
  - Federation of State Medical Boards
  - Canadian National Pain Centre

Gourlay DL, Heit HA, Almahrezi A. Pain Med. 2005 Mar-Apr;6(2):107-12.

6

## Common Universal Precautions

- Comprehensive pain assessment including opioid misuse risk assessment
- Formulation of pain diagnosis/es
- Opioid prescriptions should be considered a test or trial; continued based on assessment and reassessment of risks and benefits
- Regular face-to-face visits
- Clear documentation

Federation of State Medical Boards Model Policy 2013. [www.fsmb.org/grpol\\_policydocs.html](http://www.fsmb.org/grpol_policydocs.html)  
Gourlay DL, Heit HA, Almahrezi A. Pain Med. 2005 Mar-Apr;6(2):107-12.  
Chou R, et al. J Pain. 2009 Feb;10(2):147-59.

7

## Common Universal Precautions

- Patient Prescriber Agreements (PPA)
  - Informed consent
  - Plan of care
- Monitoring for adherence, misuse, and diversion
  - Urine drug testing
  - Pill counts
  - Prescription drug monitoring program data (when available)

Federation of State Medical Boards Model Policy 2013. [www.fsmb.org/grpol\\_policydocs.html](http://www.fsmb.org/grpol_policydocs.html)  
Gourlay DL, Heit HA, Almahrezi A. Pain Med. 2005 Mar-Apr;6(2):107-12.  
Chou R, et al. J Pain. 2009 Feb;10(2):147-59.

8

## Patient Prescriber Agreements (PPA)

### Two Components

#### Informed Consent

- Establishes targeted benefits or goals of care
- Educational re: potential risks

#### Plan of Care

- Documents mutual understanding of clinical care plan
- Articulates monitoring procedures and responses to unexpected findings

- Efficacy not well established
- No standard or validated form
- Printed copy, signed by both patient and prescriber, given to the patient may serve as a **Patient Counseling Document**

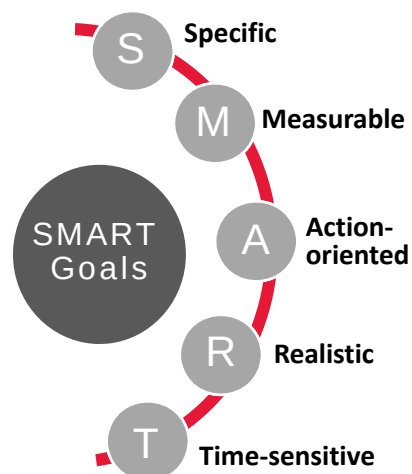
Cheatle MD, Savage SR. J Pain Symptom Manage. 2012 Jul;44(1):105-16.

9

## PPA Informed Consent: Benefits

Targeted benefits/  
goals of opioids:

- Reduce pain, not eliminate
- Increase function (individualized and SMART goals)



Nicolaidis C. Pain Med. 2011 June;12(6):890-7.  
Cheatle MD, Savage SR. J Pain Symptom Manage. 2012 Jul;44(1):105-16.

10

## PPA Informed Consent: **Risks**

- Side effects (short and long term)
- Physical dependence, tolerance
- Drug interactions/over-sedation
- Potential for impairment e.g., risk of falls, working with heavy machinery and driving
- Abuse, addiction, overdose with misuse
- Pregnancy and risk of Neonatal Opioid Withdrawal Syndrome
- Possible hyperalgesia (increased pain)
- Victimization by others seeking opioids

Paterick TJ, et al. Mayo Clin Proc. 2008 Mar;83(3):313-19.  
Cheatle MD, Savage SR. J Pain Symptom Manage. 2012 Jul;44(1):105-16.

11

## PPA Plan of Care

- Engagement in other recommended pain care and other treatment activities
- Follow up visit and appointment policies
- Monitoring policies - urine drug testing and pill counts
- Permission to communicate with key others - providers, family members
- No illegal drug use, avoid sedative use
- Notifying provider of all other medications and drugs including OTC and herbal preparations

Fishman SM, Kreis PG. Clin J Pain. 2002 Jul-Aug;18(4 Suppl):S70-5.  
Arnold RM, Han PK, Seltzer D. Am J Med. 2006 Apr;119(4):292-6.

12

## PPA Plan of Care

### Medication Management

- One prescriber, one pharmacy
- Use as directed (*dose, schedule, guidance on missed doses*)
  - No adulteration of pills or patches
  - ER/LA opioid tablets must be swallowed whole
- Don't abruptly discontinue opioids
- Refill, renewal policies
- Safe storage (*away from family, visitors, pets*), protect from theft
- Safe disposal (*read product specific information for guidance*)
- No diversion, sharing or selling (*illegal; can cause death in others*)

Fishman SM, Kreis PG. Clin J Pain. 2002 Jul-Aug;18(4 Suppl):S70-5.  
Arnold RM, Han PK, Seltzer D. Am J Med. 2006 Apr;119(4):292-6.

13

## Use a Health-Oriented, Risk-Benefit Framework

### NOT...

- Is the patient good or bad?
- Does the patient deserve opioids?
- Should this patient be punished or rewarded?
- Should I trust the patient?

### RATHER...

Do the benefits of opioid treatment outweigh the untoward effects and risks for this patient (or society)?

**Judge the opioid *treatment* –  
NOT the patient**

Nicolaidis C. Pain Med. 2011 Jun;12(6):890-7.

14

# Principles of Choosing Opioids



## Opioid Choice

### Considerations

- Duration and onset of action
  - Consider pattern of pain – incident, constant
  - Fast on, fast off – most rewarding/addicting
- Patient's prior experience  
*(differing effects and side effects)*
  - Mu-opioid receptor polymorphisms
  - Differences in opioid metabolism
- Patient's level of opioid tolerance  
*(always assess before starting ER/LA formulations)*
- Route of administration
- Cost and insurance issues

16

## IR/SA Opioids

### When to Consider

- No opioid tolerance/opioid naïve
- Intermittent or occasional pain
- Incident or breakthrough pain with ER/LA opioids
  - May be manageable with non-opioid and non-pharmacologic modalities



17

## ER/LA Opioids

### When to Consider

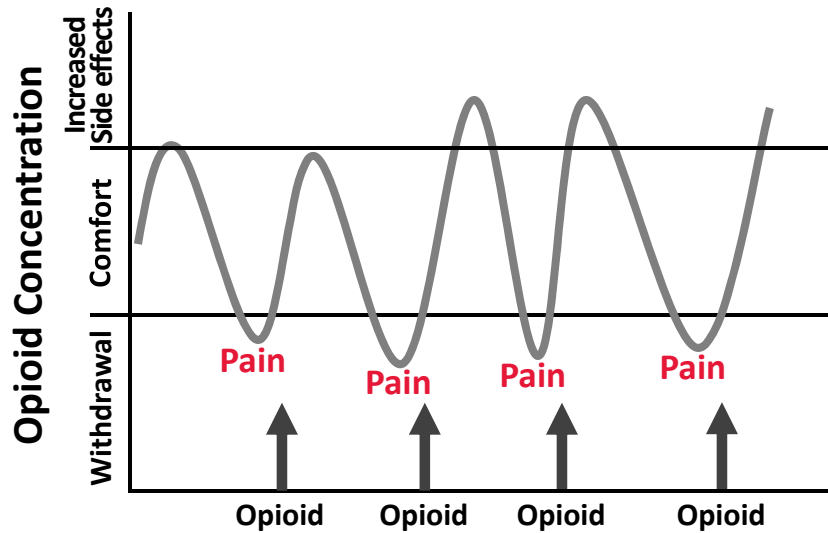
- Opioid tolerance exists
- Constant, severe, around-the-clock pain is present
- To stabilize pain relief when patient using multiple doses IR/SA opioids



18

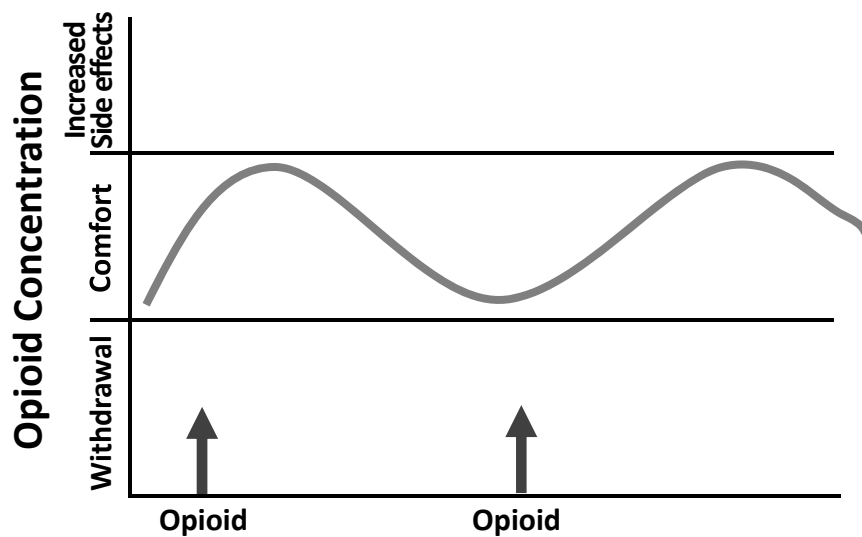
## Theoretical Concern with IR/SA Opioids

### Opioid Withdrawal-Mediated Pain



19

## Theoretical Benefit of ER/LA Opioids



20

## IR/SA vs ER/LA Uncertainties

- Insufficient evidence to determine whether ER/LA opioids are more effective or safer than IR/SA opioids
- Debate whether bolus dosing (IR/SA) or continuous exposure (ER/LA) is more likely to result in tolerance, hyperalgesia or addiction
- **Choose options that best meet patient needs**
  - **individualize treatment**

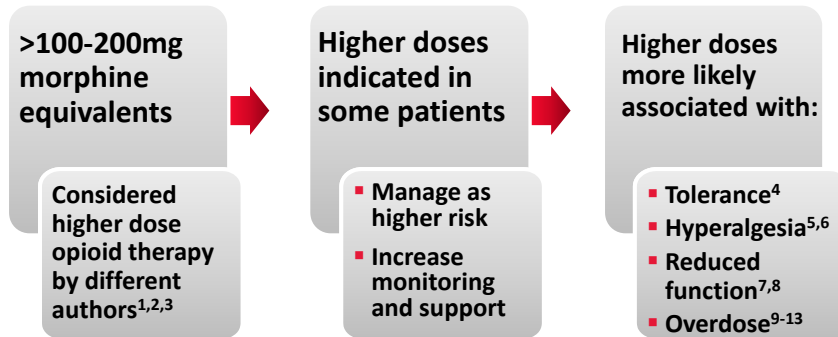
Chou R, Clark E, Helfand M. J Pain Symptom Manage. 2003 Nov;26(5):1026-48.  
Argoff CE, Silvershein DI. Mayo Clin Proc. 2009 Jul;84(7):602-12.

21

## Opioid Dosing



## Opioid Dosing



1. Chou R, et al. J Pain. 2009 Feb;10(2):147-59.

2. Ballantyne JC, Mao J. N Engl J Med. 2003 Nov 13;349(20):1943-53.

3. Kobus AM, et al. J Pain. 2012 Nov;13(11):1131-8.

4. Huxtable CA, et al. Anaesth Intensive Care. 2011 Sep;39(5):804-23.

5. Brush DE. J Med Toxicol. 2012 Dec;8(4):387-92.

6. Lee M, et al. Pain Physician. 2011 Mar-Apr;14(2):145-61.

7. Kidner CL, et al. J Bone Joint Surg Am. 2009 Apr;91(4):919-27.

8. Townsend CO, et al. Pain. 2008 Nov 15;140(1):177-89.

9. Dunn KM, et al. Ann Intern Med. 2010 Jan 19;152(2):85-92.

10. Braden JB. Arch Intern Med. 2010 Sep 13;170(16):1425-32.

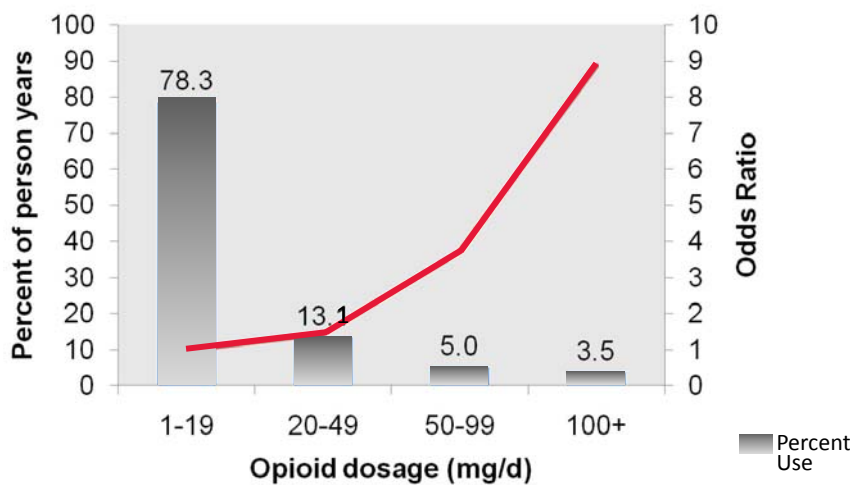
11. Bohnert AS, et al. JAMA. 2011 Apr 6;305(13):1315-21.

12. Gomes T, et al. Open Med. 2011;5(1):e13-22.

13. Paulozzi LJ. Pain Med. 2012 Jan;13(1):87-95.

23

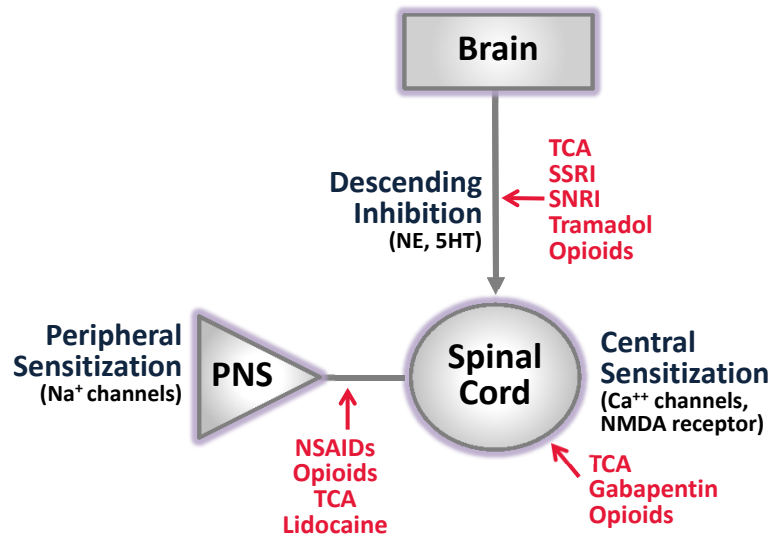
## Risk of Opioid Overdose



Dunn KM, et al. Ann Intern Med. 2010 Jan 19;152(2):85-92.

24

## Rational Polypharmacy

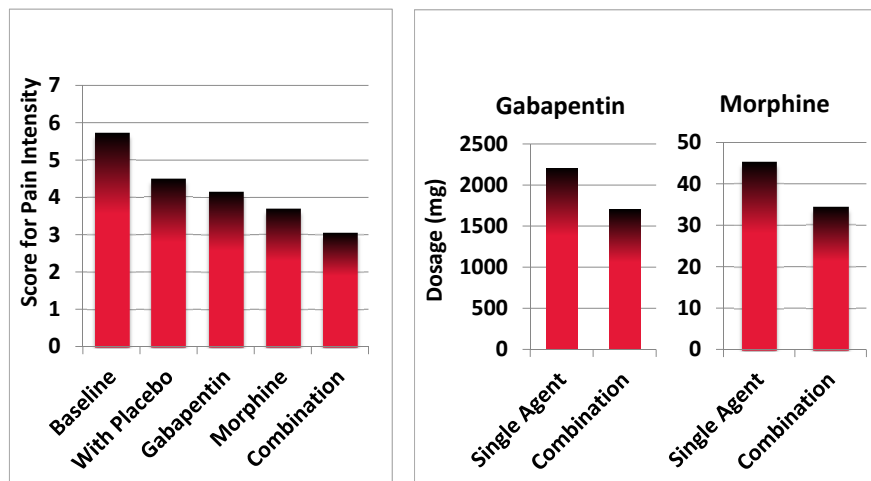


Woolf CJ. Ann Intern Med. Mar 2004;140(6):441-51.

25

## Exploit Synergism

**Morphine, Gabapentin, or their Combination**  
for Neuropathic Pain

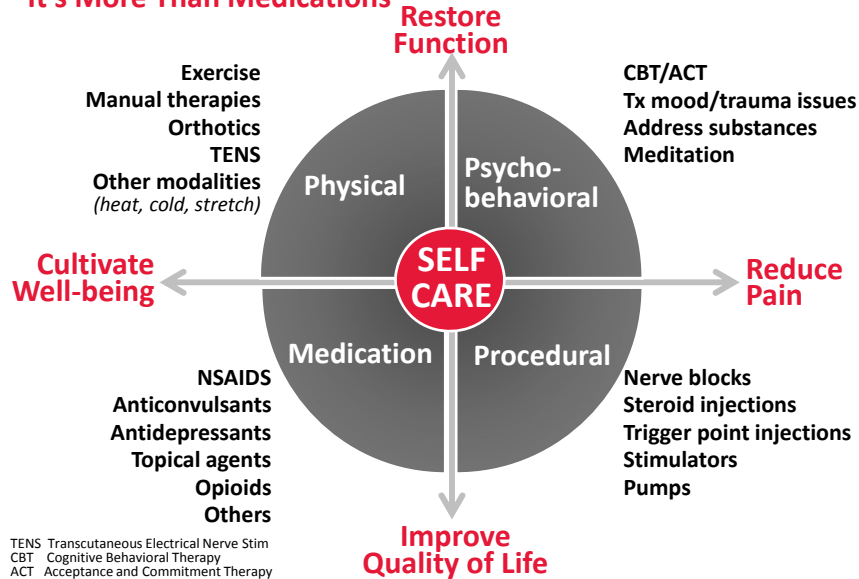


Gilron I, et al. N Engl J Med. 2005 Mar 31;352(13):1324-34.

26

## Multidimensional Care

It's More Than Medications



27

## Case Study Mary Williams

### Rationale for Change in Opioid Prescription

42 yo woman

T2DM

Chronic, painful, diabetic neuropathy and back pain

Remote h/o alcohol dependence

Gabapentin and oxycodone/acetaminophen

- Patient known to tolerate IR/SA oxycodone with good analgesia on 8 tablets/day (40mg)
- Periodicity of effects (off-on) (i.e., withdrawal mediated pain) may drive pain
- Analgesia may be improved with more stable blood levels using ER/LA oxycodone perhaps at slightly lower dose (15mg bid)

28

## Case Study Mary Williams

### Rationale for Change in Opioid Prescription

42 yo woman

T2DM

Chronic, painful, diabetic neuropathy and back pain

Remote h/o alcohol dependence

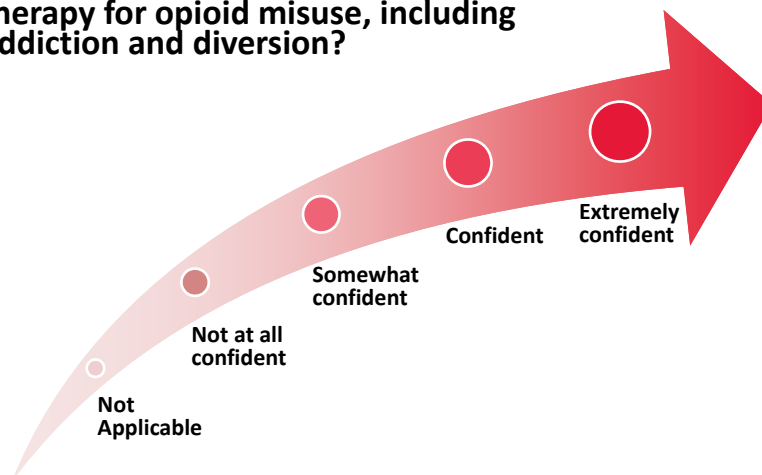
Gabapentin and oxycodone/acetaminophen

- If inadequate benefits, would consider dose titration or opioid rotation to alternative opioid and/or use of adjuvant medications and nonpharmacological treatments
- Follow closely, continue or discontinue based on response

29

### POLLING QUESTION

**How confident are you in your ability to monitor patients on chronic opioid therapy for opioid misuse, including addiction and diversion?**



30

## Monitoring Strategies



### Office Visits

#### Pain Management Review

- Assess progress towards goals
  - Function
  - Pain
- Review engagement in self care
  - Exercise, stress reduction, use of modalities (*e.g., cold, heat, stretch*)
  - Recovery activities if indicated
- Review non-opioid pain treatment
  - Behavioral counseling
  - Physical therapy
  - Interventionalist treatment

32

## Office Visits

### Opioid Risk Review

- How is patient actually using prescribed opioids?
  - Take 24-hour inventory
- Review emotional, psychiatric and social issues
- Health care use patterns
- Objective information
  - Observe for signs of medication or substance misuse
  - Check PDMP (*if available*)
  - Urine drug tests
  - Pill counts
- Revise treatment as indicated

33

## Urine Drug Tests

- Objective information that can provide
  - Evidence of therapeutic adherence
  - Evidence of use or non-use of illicit drugs
- Subjective reports may not be accurate if patient is:
  - Challenged by substance use or mental health disorders
  - Purposely diverting
- Discuss urine drug testing openly with patient
- Random, scheduled and/or when concerns arise

Heit HA and Gourlay DL. J Pain Symptom Manage Mar;27(3):260-7.  
Christo PJ et al. Pain Physician. 2011 Mar-Apr;14(2):123-43.

34

## Why Drug Test?

Self-reported drug use among pain patients unreliable

- Fleming MF, et al. J Pain 2007.
- Fisbain DA, et al. Clin J Pain 1999.
- Berndt S, et al. Pain 1993.

Behavioral observations detects only some problems

- Wasan AJ, et al. Clin J Pain 2007.
- Katz NP, et al. Anesth Analg 2003.

May improve adherence (e.g., decreased illicit drug use)

- Pesce A, et al. Pain Physician 2011.
- Starrels J, et al. Ann Intern Med 2010.
- Manchikanti L, et al. Pain Physician 2006.

Evolving standard of care

- Chou R, et al. J Pain 2009.
- Tescot AM, et al. Pain Physician 2008.
- FSMB 2013

35

## Urine Drug Testing

- Urine drug **screens** are usually immunoassays
  - Can be done at point of care or in a lab
  - Quick and relatively inexpensive
  - Need to know what is included in testing panel
  - Risk of false negatives due to cut offs
  - Risk of false positives due to cross reactions
  - All unexpected findings should be sent for confirmation by Gas Chromatography/Mass Spectroscopy (GC/MS)

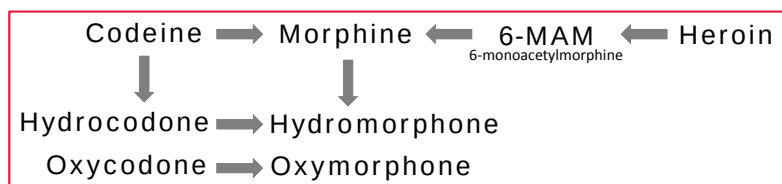
Reisfield GM et al. Bioanalysis 2009 Aug;1(5):937-52.

36

## Urine Drug Testing

### ■ GC/MS confirmation

- Identifies specific molecules
- Sensitive and specific
- More expensive
- Must be aware of opioid metabolism to interpret



Peppin JF et al. Pain Medicine 2012 Jul;13:886-96.  
Heit HA, Gourlay DL. J Pain Symptom Manage. 2004 Mar;27(3):260-7.  
Heit HA, Gourlay DL, Caplan YH. Urine Drug Testing in Clinical Practice; Pharmacom Group Inc., May 2010.

37

## Urine Drug Testing

### Caveats

- One medical data point to integrate with others
- Cannot discriminate elective use, addictive use and diversion
- Small risk for mislabeling, adulteration, other error
- Consult toxicologist/clinical pathologist before acting if patient disputes findings
- Dedicated deceivers can beat the system

Heit HA, Gourlay DL, Caplan YH. Urine Drug Testing in Clinical Practice; Pharmacom Group Inc., May 2010.

38

## Pill Counts

- Intended to:
  - Confirm medication adherence
  - Minimize diversion

| Strategy                                                                             |
|--------------------------------------------------------------------------------------|
| 28 day supply (rather than 30 days)                                                  |
| Prescribe so that patient should have residual medication at appointments            |
| Ask patient to bring in medications at each visit                                    |
| For identified risks or concerns, can request random call-backs for immediate counts |

39

## Discussing Monitoring

- Review the personal and public health (community health) risks of opioid medications
- Discuss your responsibility to look for early signs of harm
- Discuss agreements, pill counts, drug tests, etc. as ways that you are helping to protect patient from getting harmed by medications
- Use consistent approach, but set *level* of monitoring to match risk

40

## Case Study Mary Williams

### Past Medical History

42 yo woman

T2DM

Chronic, painful, diabetic neuropathy and back pain

Remote h/o alcohol dependence

Gabapentin and oxycodone/acetaminophen

- Type 2 diabetes mellitus x 8 years
- Painful diabetic neuropathy x 2 years
- Hypertension
- Chronic low back pain
- Tobacco dependence
- **Alcohol dependence (in recovery 10 years)**
- Obesity

41

## Patients with Past Addiction History

- Frame addiction as a challenging health issue
- Express admiration for patient's recovery
- Acknowledge patient's desire to "never go there" again
- Encourage active recovery engagement
- Discuss higher risk
- Partner with patient to reduce risk

42

## Patients with Past Addiction History

### Increase Structure of Care as Indicated

- **Setting** of care (*care coordination and expertise*)
- **Supports** for substance/mental health recovery
- **Selection** of treatments (*less rewarding*)
- **Supply** of medications
- **Supervision** intensity (*frequency of visits, UDT, pill counts, other monitoring and support*)

Savage SR, Kirsch KL, Passik SD. Addict Sci Clin Pract. 2008 June; 4(2): 4–25.

43

## Office Systems



## Optimize Office Systems

### Saves Time and Stress

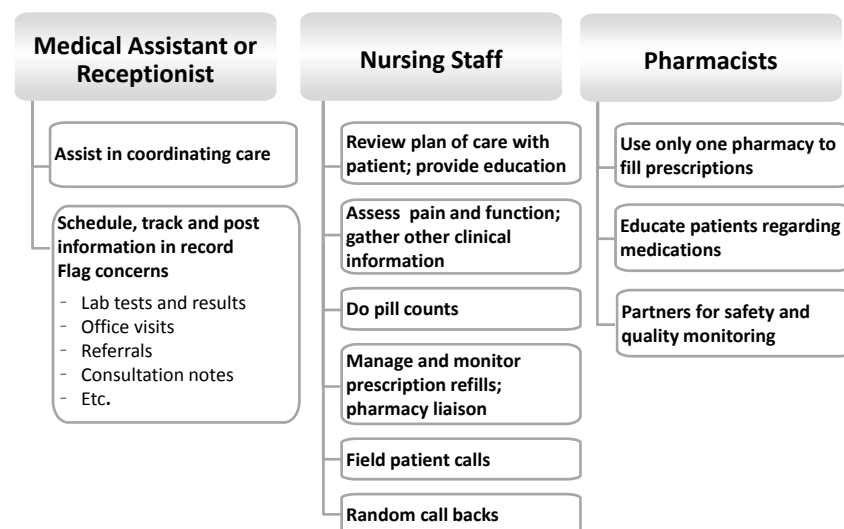
Develop and implement:

- Office controlled substance policies, reflected in Patient Prescriber Agreement
- Management flow sheet
- Patient registry
- Lists of referral and support resources (*pain, mental health, addiction*)

45

## Optimize Office Systems

### Saves Time and Stress



46

## Case Study Mary Williams

### In the Ensuing Months...

42 yo woman

T2DM

Chronic, painful, diabetic  
neuropathy and back pain

Remote h/o alcohol  
dependence

Gabapentin and  
oxycodone/acetaminophen

- Patient reports somewhat more consistent pain relief and denies sedation
- But about 9 hours after her dose, pain increases and interferes with concentration
- Provider increases ER/LA oxycodone to 20mg every 12 hours to reduce end of dose failure
- In one week the nurse contacts her and confirms that this has been effective in improving pain relief; patient reports she is more active and able to concentrate on work

47

## Documentation



## Documentation

- Detailed record can better inform care
- Protects prescriber when concerns arise
- Inclusions
  - Subjective reports (*pt, family, co-care providers*)
  - Standardized screens and assessments
  - Objective info (*exams, labs, UDTs, pill counts, PDMP*)
  - Clinical and diagnostic impressions
  - Rationale for all decision-making
    - Special care: off-label, outside of guidelines, high risk pts
- Templates in Resources at [www.scopeofpain.com](http://www.scopeofpain.com)

Passik SD, et al. Clin Ther. 2004 Apr;26(4):552-61.

49

## Federal and State Regulations

### Federal

#### PAIN

- **May prescribe any opioid for pain**
  - Sublingual buprenorphine is off-label for pain
  - Limits based on controlled substance class
  - Refer to the DEA Practitioners' Manual  
[www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html)

### Federal

#### ADDICTION

- **Buprenorphine** - must have 8 hours of training and CSAT waiver/DEA X-number
- **Methadone** - must be part of licensed Opioid Treatment Program

### States

#### PAIN and ADDICTION



- May have stricter regulations than Federal
- Useful state-specific information compiled by the FSMB and available at:  
[www.fsmb.org/PDF/grpol\\_pain\\_management.pdf](http://www.fsmb.org/PDF/grpol_pain_management.pdf)

50

## Summary Points: Essential Content 2

- Employ universal precautions
- Individualize plan of care
- Initiate opioid treatment as a trial/test aimed at clear functional goals
- Opioids are just one tool in a multimodal approach that includes self-care and synergistic treatments
- Continue or discontinue opioid treatment based on response and clinical indication
- Document benefits and risks/harms

51

## Case Study Mary Williams

42 yo woman

T2DM

Chronic, painful, diabetic neuropathy and back pain

Remote h/o alcohol dependence

Gabapentin and oxycodone/acetaminophen

- Did well on regimen of ER/LA oxycodone 20 mg bid with gabapentin 300 mg tid for the next 11 months
- She then went to the ER of her local hospital, requesting early refill of her oxycodone because she ran out early
- ER physician noted that she was in moderate to severe opioid withdrawal and gave her enough ER/LA oxycodone to last until her next PCP appointment in one week

52

## Questions for Next Visit

### Assessing and Managing Aberrant Medication Taking Behavior

#### Provider Concerns:

- How to address recent aberrant behavior?
- Is she addicted?
- Has she developed tolerance to the opioid?
- How do I accurately assess and manage this new behavior?



53