



# SCOPE of Pain

**Safe and Competent** Opioid Prescribing Education

Part 2 of 3





## ***Module 1 Case Summary: Mary Williams***

- 42 yo woman
- Diabetic, hypertensive, obese, smoker, with remote history of alcohol dependence
- Chronic neuropathic and back pain
- Regimen of gabapentin and oxycodone/acetaminophen for pain



## ***Module 1 Case Summary: Mary Williams***

New primary care provider:

- Initial history and physical exam
- Assessments:
  - Pain and function
  - Mental health
  - Substance use
  - Opioid misuse risk
- Findings:
  - Pain moderate to severe
  - Impact on function and quality of life
  - Some risk factors for opioid misuse

## Mary Williams Case Study

### ***In the interim...***

- Her medical records confirmed her history and medication lists
- Her urine drug test last time was positive for oxycodone only
- State prescription drug monitoring program data showed for the past 12 months she had one prescriber and went to one pharmacy

### ***Office Visit 2***

- Pain score is unchanged from previous week
- Has run out of opioid prescription



# ***Initiating Opioid Therapy Safely***



# Learning Objectives: Presentation 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

# Universal Precautions in Pain Medicine

## *Part of a Controlled Substance Policy for your Office*

- Opioid misuse risk prediction is imprecise
  - Protects all patients
  - Protects the public and community health
- Consistent application of precautions
  - Takes pressure off provider during time of stress
  - 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
  - Canadian National Pain Centre

# 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
- Patient Prescriber Agreements (PPA) with informed consent and plan of care
- Regular face-to-face visits
- Monitoring for adherence, misuse, and diversion
  - Urine drug testing
  - Pill counts
  - Prescription drug monitoring program data (when available)
- Clear documentation

# Patient Prescriber Agreements (PPA)

## *Two Components*

### Informed Consent

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

### Plan of Care

- Documents mutual understanding of clinical care plan
- Takes pressure off providers to make individual decisions
- Articulates monitoring procedures and responses to unexpected findings

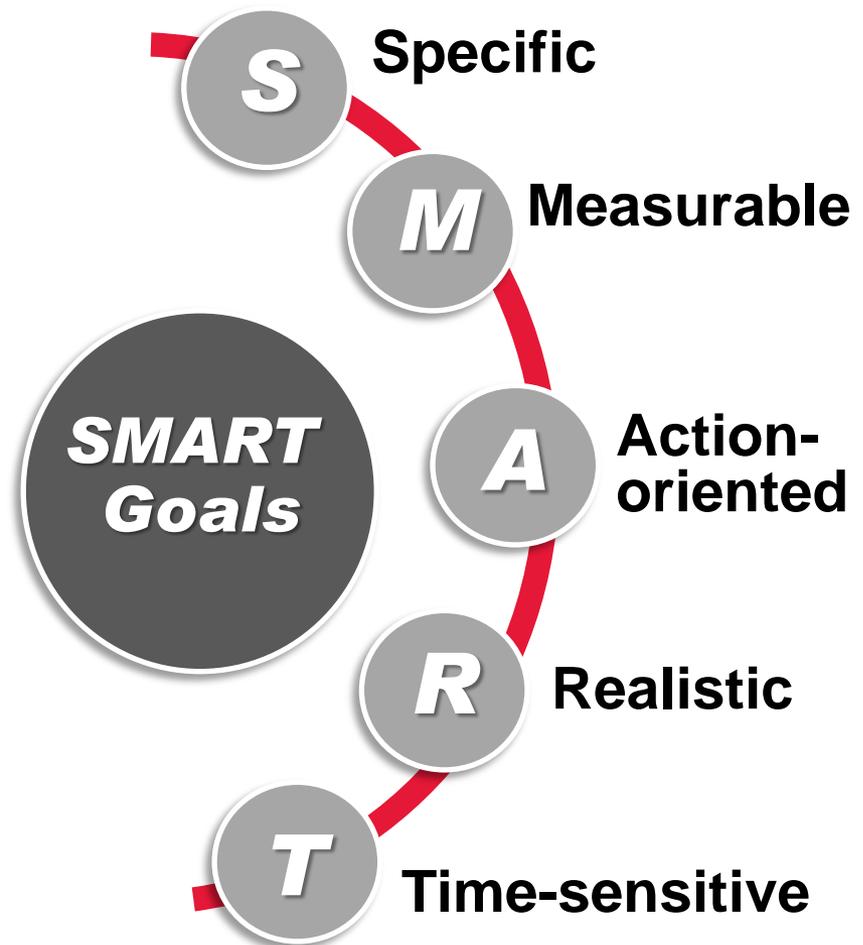
- Efficacy not well established
- No standard or validated form
- Printed copy, signed by both patient and prescriber, given to the patient may serve as a **Patient Counseling Document**

# PPA Informed Consent

## Common Components - Benefits

Targeted benefits/  
goals of opioids:

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



# PPA Informed Consent

## *Common Components - Risk*

### Risks of opioids

- Side effects (short and long term) – call provider
- 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 Abstinence Syndrome
- Possible hyperalgesia (increased pain)
- Victimization by others seeking opioids

# PPA Plan of Care

## *Common Components*

- Engagement in other recommended pain care and other treatment activities
- Follow up visit and appointment policies
- Monitoring polices - 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

# PPA Plan of Care

## *Common Components*

### Medication Management

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

# Use a Health-Oriented, Risk-Benefit Framework

***Judge the opioid treatment –  
not the patient***

## **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)?**

# ***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
  - Mu polymorphisms – differences in opioid responsiveness
  - Genomic differences in metabolism
  - Resulting in differing effects and side effects
- Patient's level of opioid tolerance (always assess before starting ER/LA formulations)
- Route of administration
- Cost and insurance issues

# Immediate Release (IR) Opioids

## *When to Consider*

- No opioid tolerance/opioid naive
- Intermittent or occasional pain
- Incident or breakthrough pain with ER/LA opioids
  - May be manageable with non-opioid modalities, behavioral interventions or r



# ER/LA Opioids

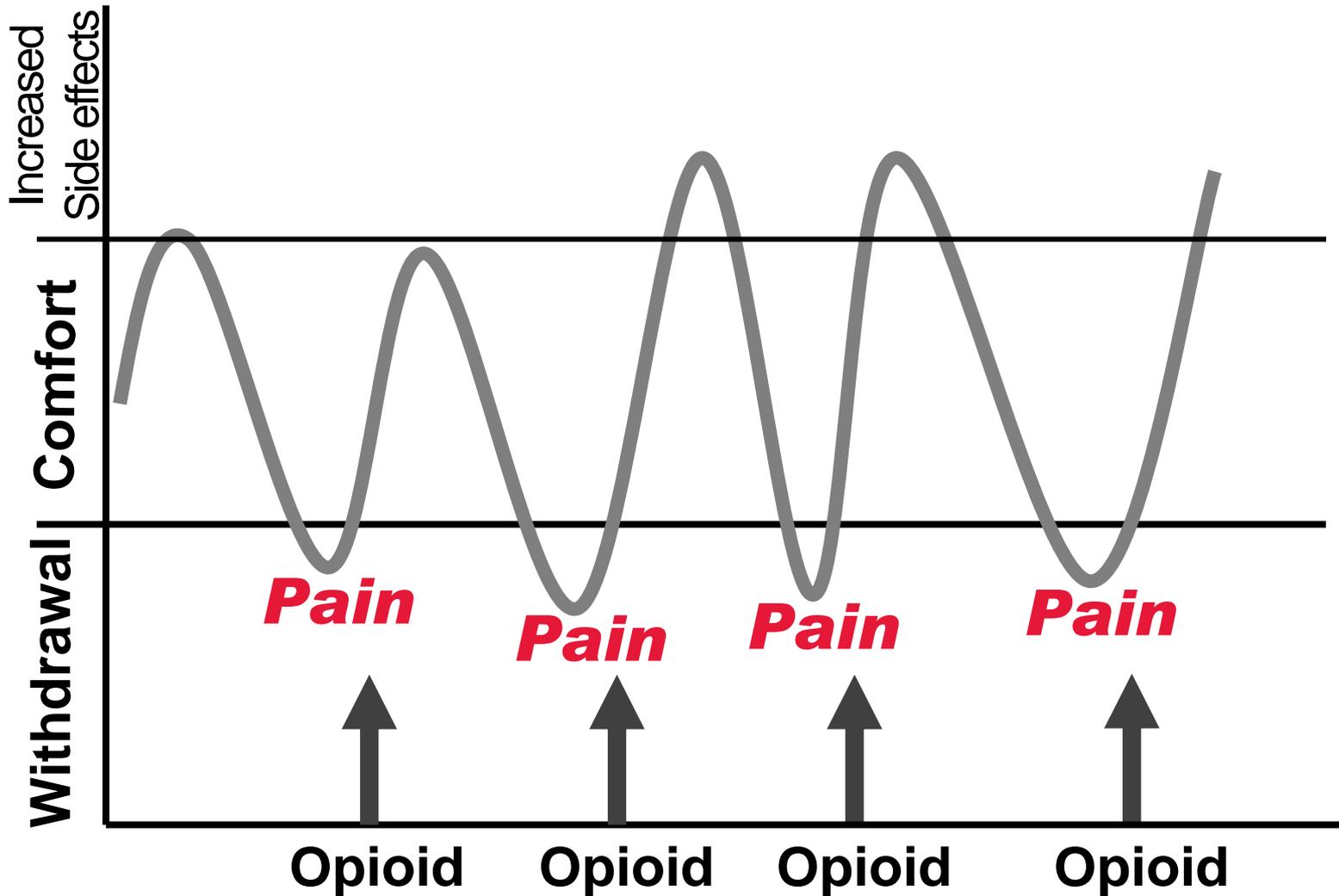
## *When to Consider*

- Opioid tolerance exists
- Constant significant pain is present
  - Round the clock
  - Protracted pain for hours
- To stabilize pain relief when patient using multiple doses IR opioids

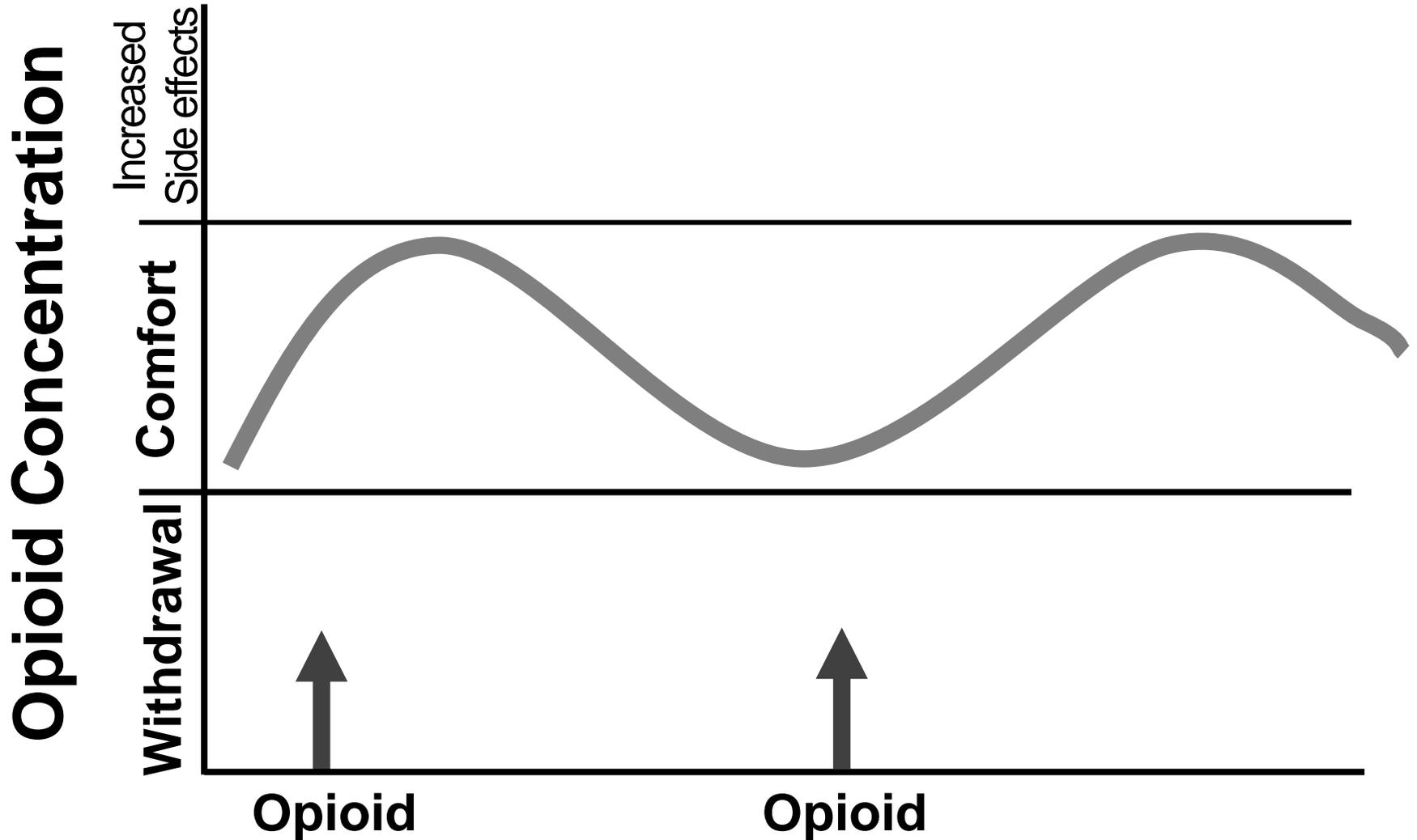


# Theoretical Concern with IR Opioids

Opioid Concentration



# Theoretical Benefit of ER/LA Opioids



# IR vs ER/LA Uncertainties

- Insufficient evidence to determine whether ER/LA opioids are more effective or safer than short-acting opioids
- Debate whether bolus dosing (IR) or continuous exposure (ER/LA) are more likely to drive challenges such as tolerance, hyperalgesia or addiction
- Choose options that best meet patient needs – individualize treatment

# ***Opioid Dosing***

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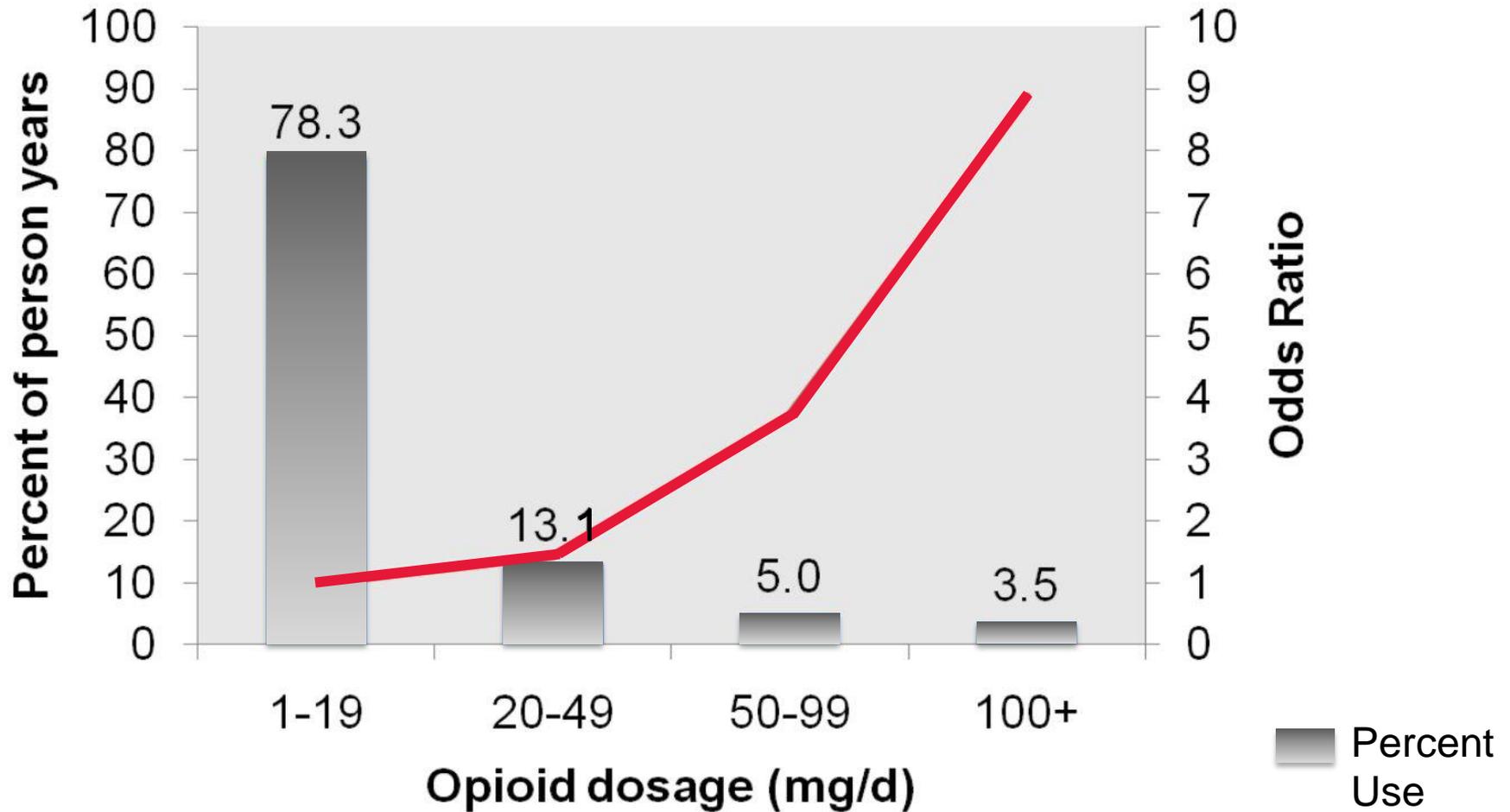
# Opioid Dosing



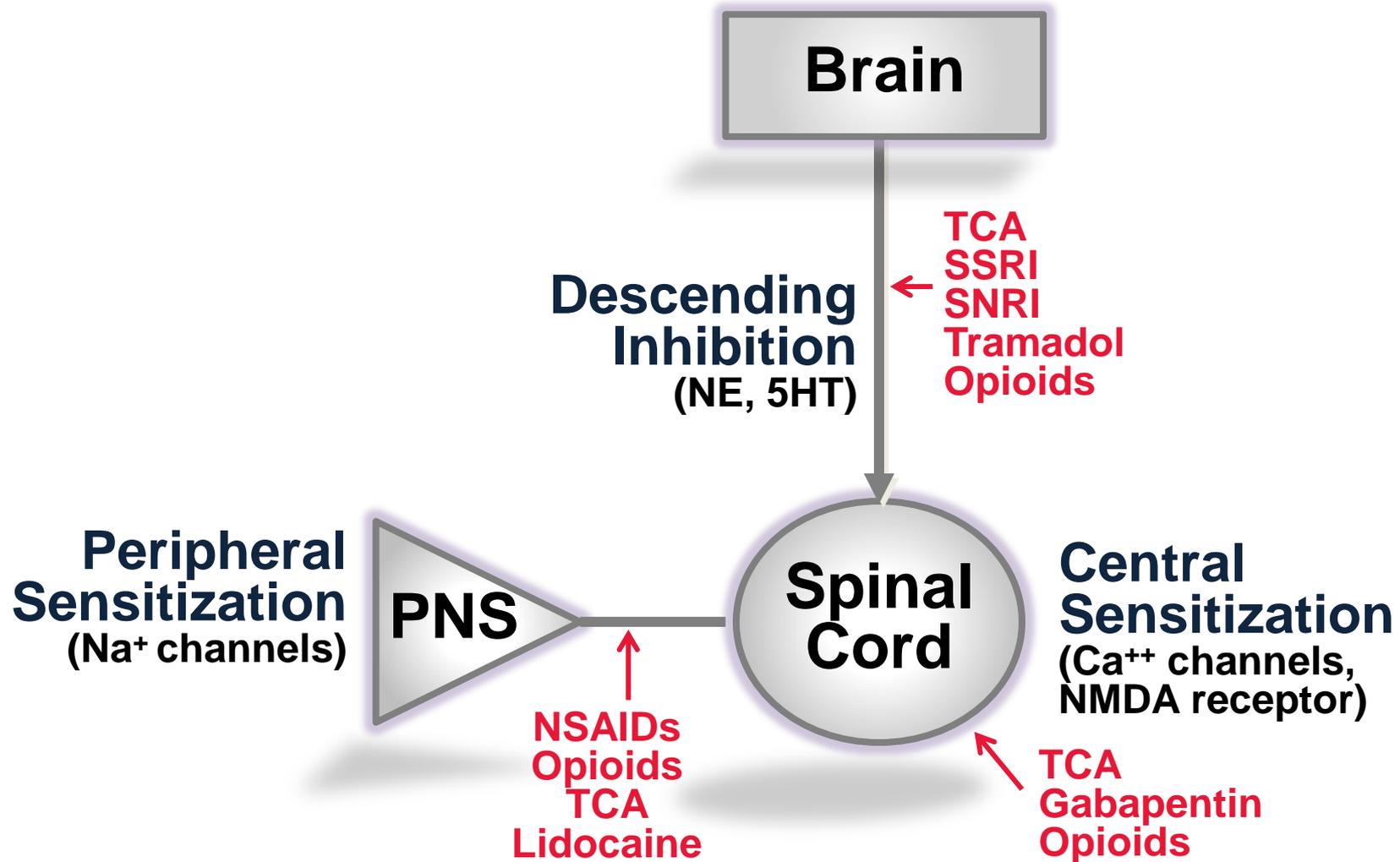
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# Risk of Opioid Misuse



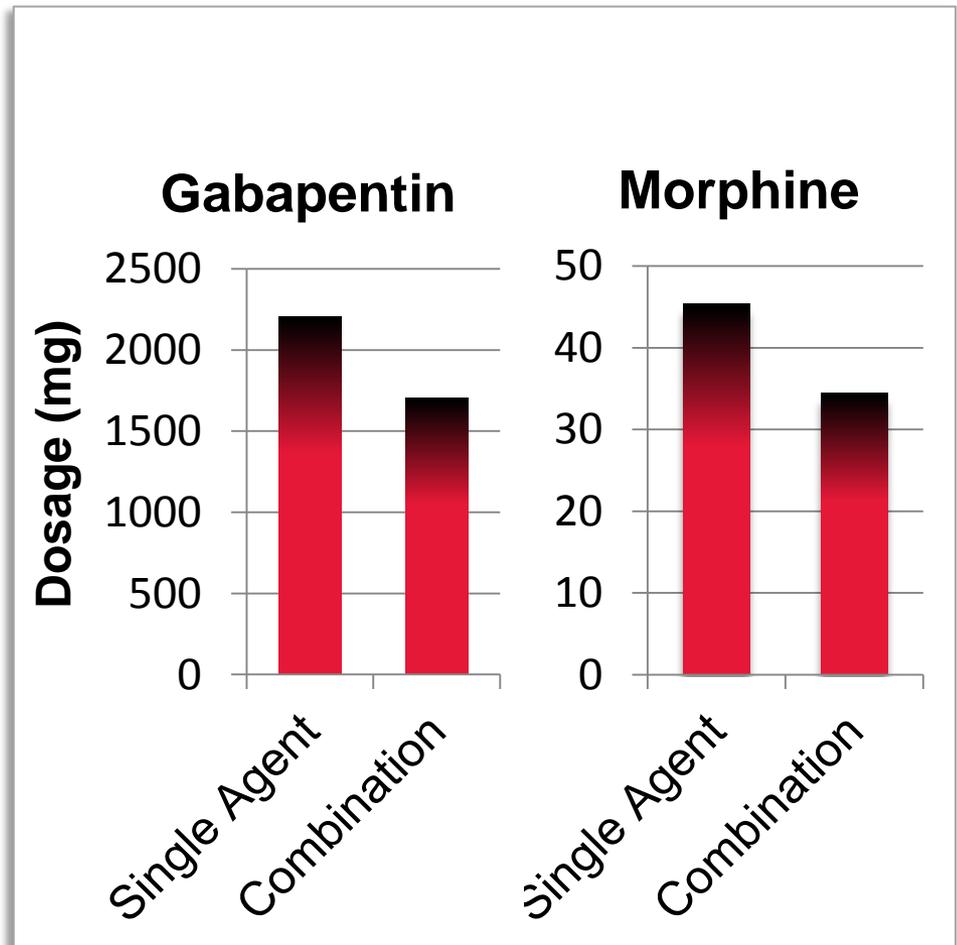
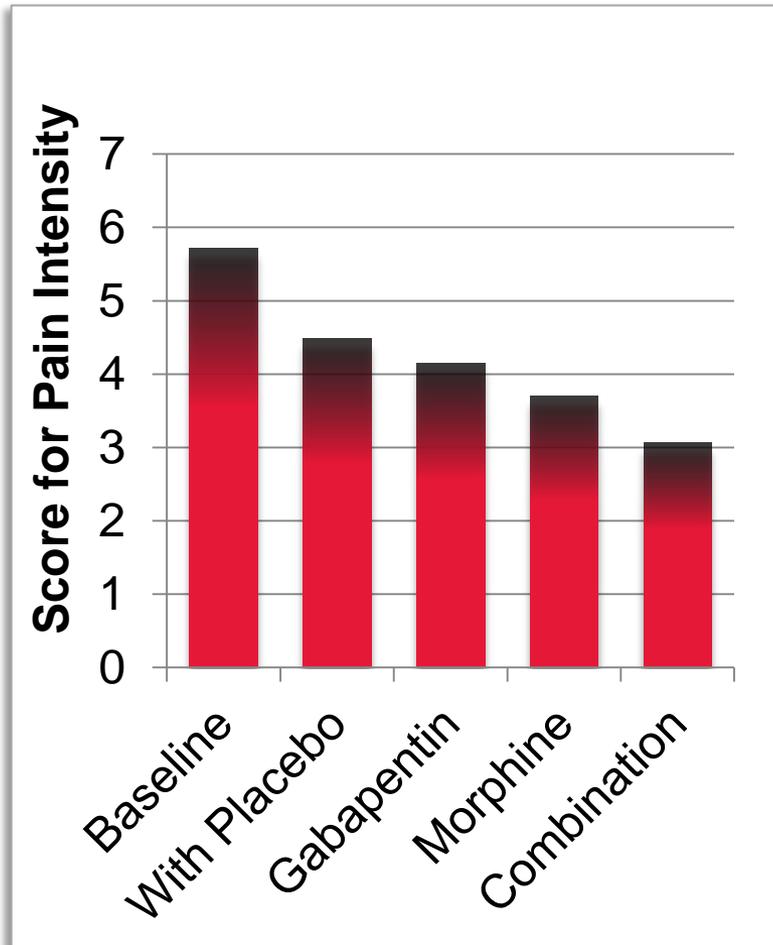
# Rational Polypharmacy



# Exploit Synergism

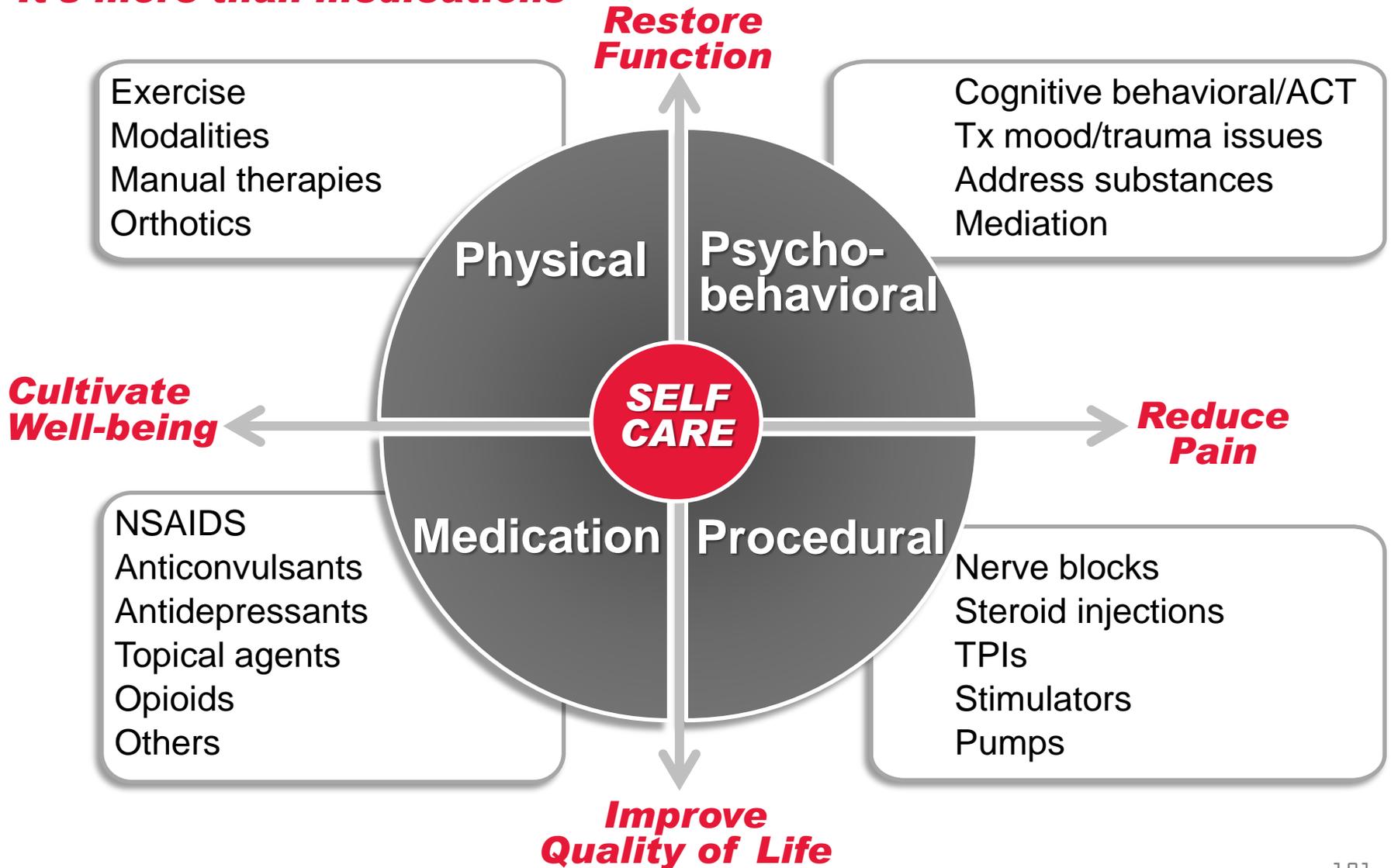
## **Rational Polypharmacy**

Morphine, Gabapentin, or Their Combination for Neuropathic Pain



# Multidimensional Care

*It's more than medications*



## ***Prescription Rationale***



- Patient known to tolerate oxycodone
- Reported good analgesia on 8 tablets a day (40mg)
- Periodicity of effects (off-on) (i.e., withdrawal mediated pain) may drive pain
- Analgesia may be improved with more stable blood levels, perhaps at slightly lower dose (30mg/day) (Titrate somewhat if needed)
- If poor analgesia or significantly higher doses required, consider rotation to alternative opioid
- Follow closely, continue or discontinue based on response

# 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

# 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 medication or substance misuse
  - Check PDMP (if available)
  - Urine drug tests
  - Pill counts
- Revise treatment as indicated

# ***Monitoring Strategies***

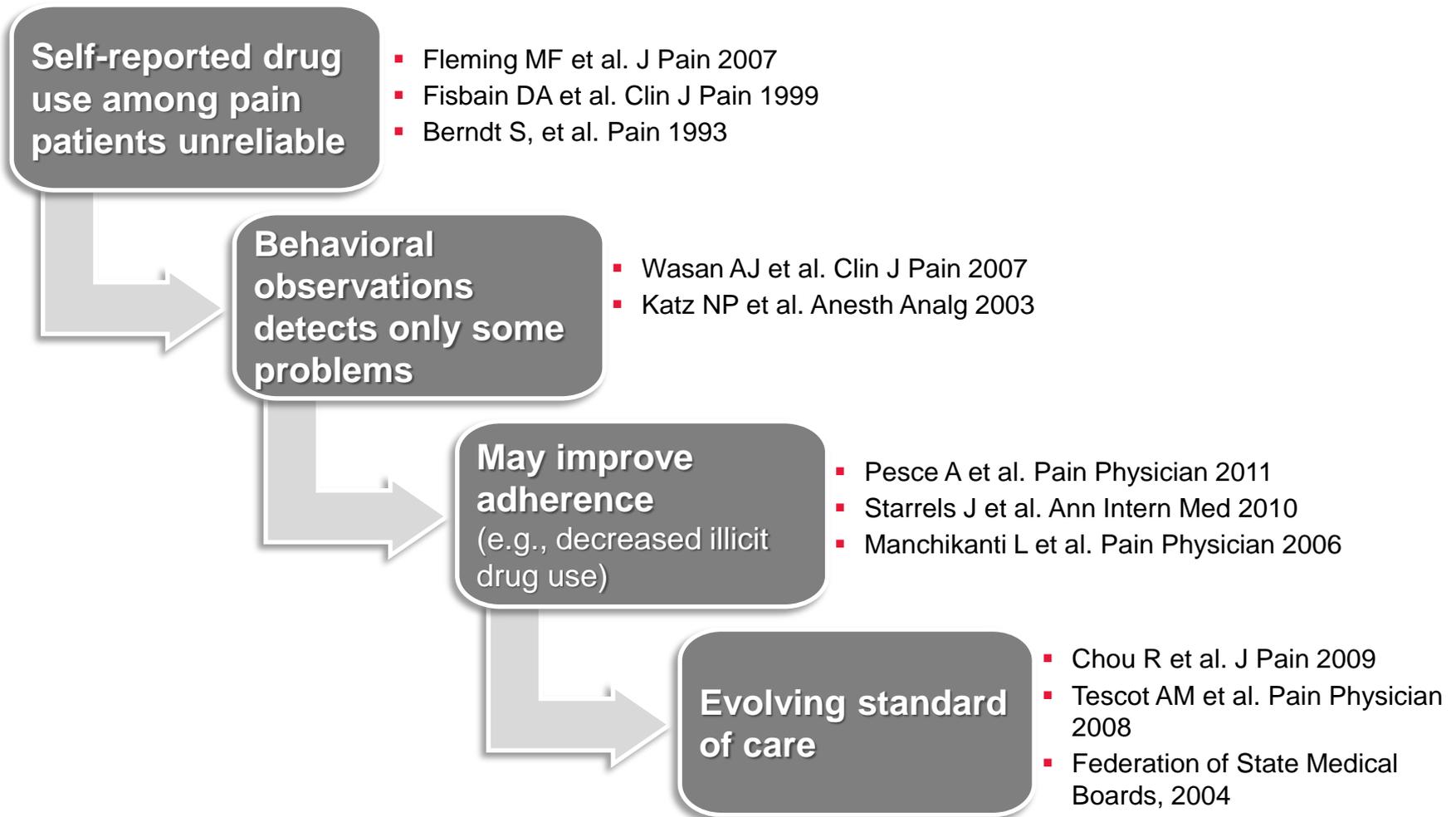
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# Monitoring: Urine Drug Tests

- 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
  - Or is purposely diverting
- Natural medical discussion if framed as a personal and public health issue
- Random, scheduled and/or when concerns arise

# Why Drug Test?

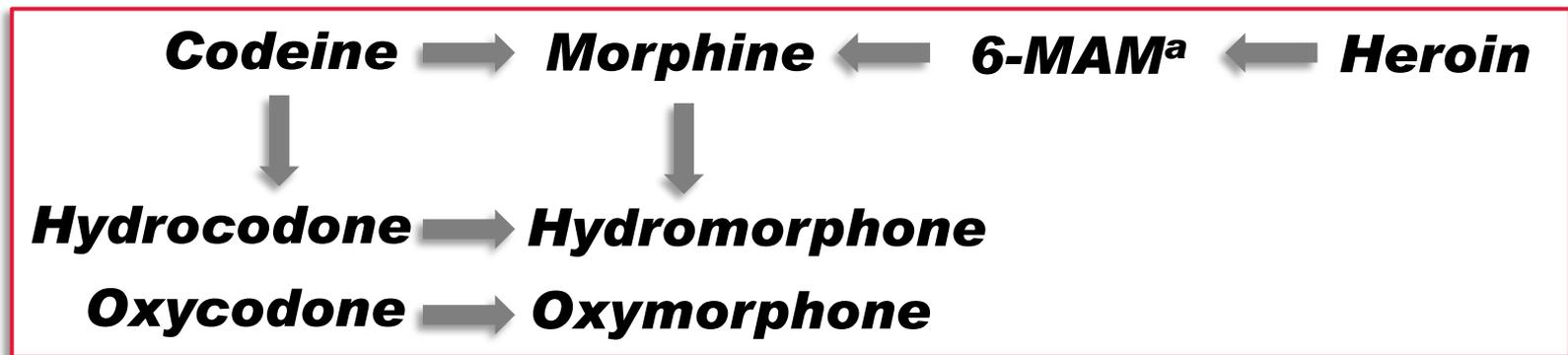


# Urine Drug Testing

- 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 GC/MS

# Urine Drug Testing

- **Gas Chromatography/Mass Spectroscopy confirmation**
  - Identifies specific molecules
  - Sensitive and specific
  - More expensive
  - Must be aware of opioid metabolism to interpret



Not comprehensive pathways, but may explain the presence of apparently unprescribed drugs  
6-MAM: 6-monoacetylmorphine; an intermediate metabolite

# 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

# Monitoring: 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

# ***Discussing Monitoring with Patients***



# Discussing Monitoring

- Review the personal and public health (community health) risks of opioid medications
- Note medical 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

## ***Past Medical History***



- **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 yrs)
- **Obesity**

# Patients with Past Addiction History

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

# Patients with Past Addiction History

## *Tighten 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)

# ***Office Systems***

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# Optimize Office Systems

## *Save Time and Stress*

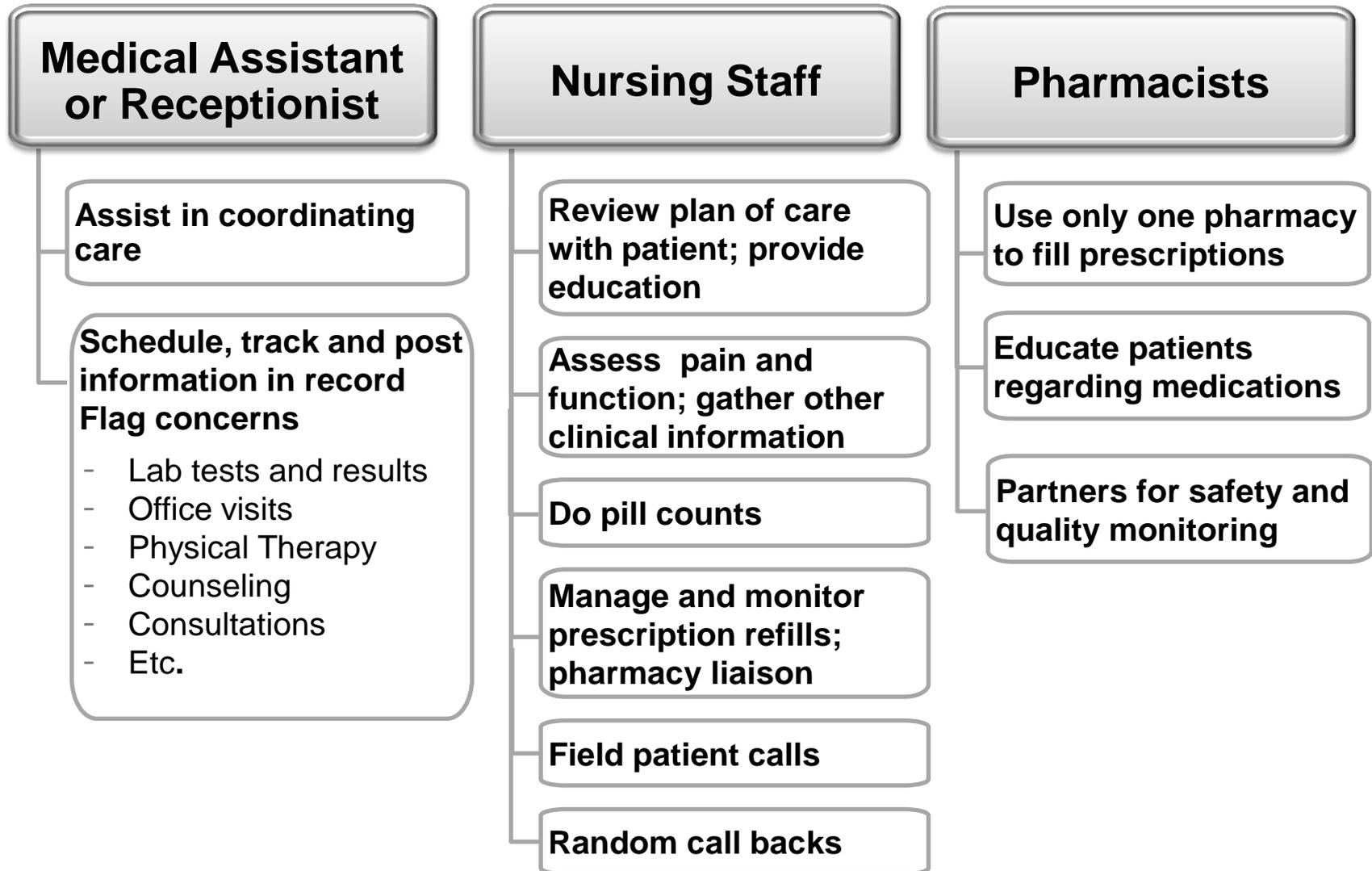
Develop and implement

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



# Optimize Office Systems

## Save Time and Stress



## ***Follow-up***



- 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

**Mary Williams**  
Case Study

***Visit 2, cont.***



- 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

# ***Documentation***

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# 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 resource section this program

# 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*

### STATES



- 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)

# Summary Points: Presentation 2

- Opioids are one tool in a multidimensional approach that includes
  - An active patient role in self-care
  - Synergistic treatment
- Initiate as a trial aimed at clear goals
- Employ universal precautions with all patients
- Tailor plan of care to the individual
- Employ monitoring strategies to improve outcomes
- Continue or discontinue treatment based on response
- Document, document, document

## Mary Williams

### Case Study



- 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 an 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 oxycodone to last until her next primary care provider appointment

# Questions for Ongoing Monitoring

## *Assessing and Managing Aberrant Medication Taking Behavior*

### Provider Concerns:

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

