Risk Reduction Strategies in Pain Management

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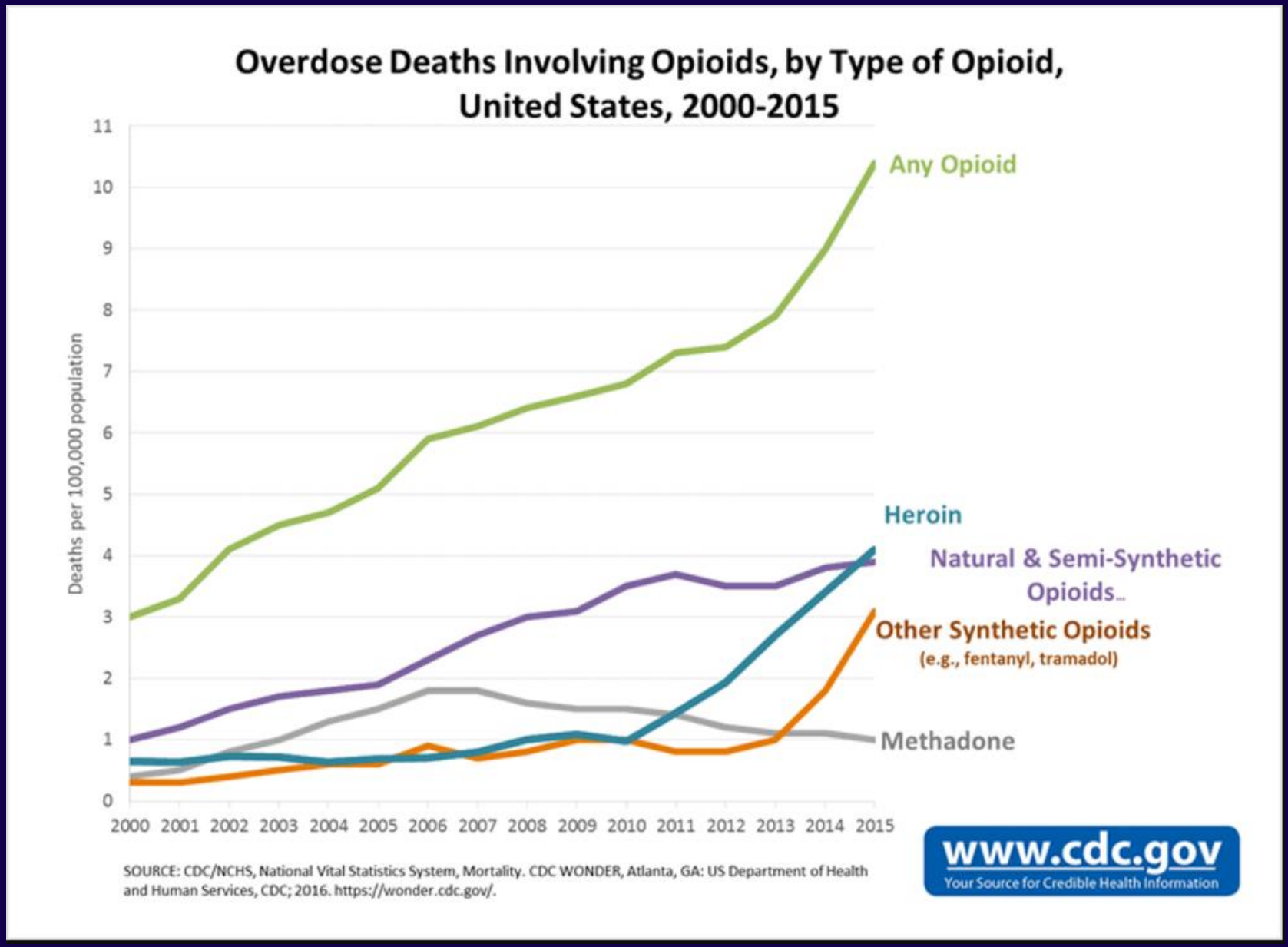
Learning Objectives

- By the end of this session, attendees will be able to:
  - Describe current issues and trends related to prescription drug abuse and misuse
  - Describe methods to assist in recognizing patients who are at risk for, or currently abusing opioids
  - Discuss potential methods for reducing risk on the part of dispensers and prescribers when managing patients with pain







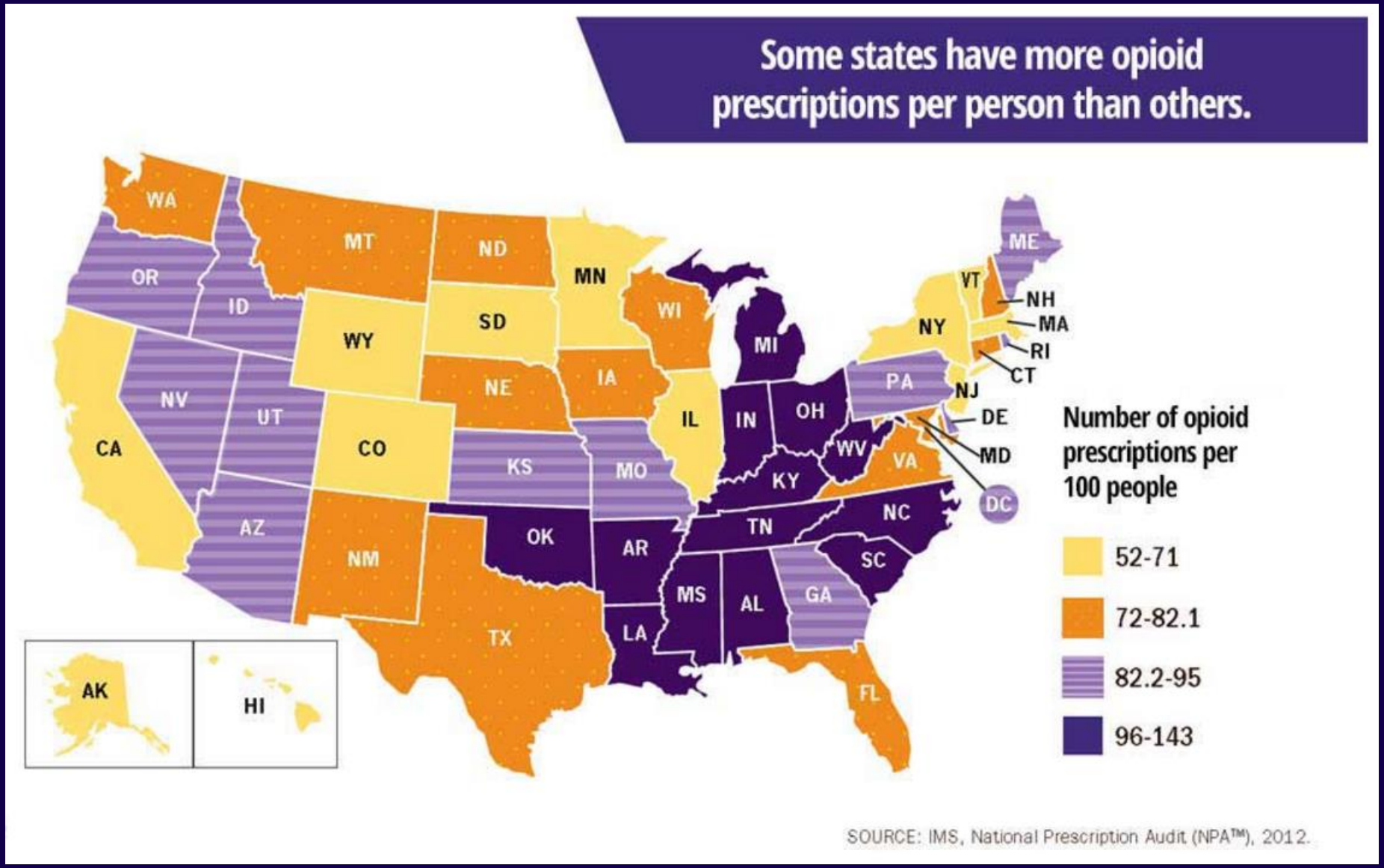
91 people die each day in the U.S. from an opioid overdose

https://www.cdc.gov/drugoverdose/epidemic/

The Opioid Epidemic

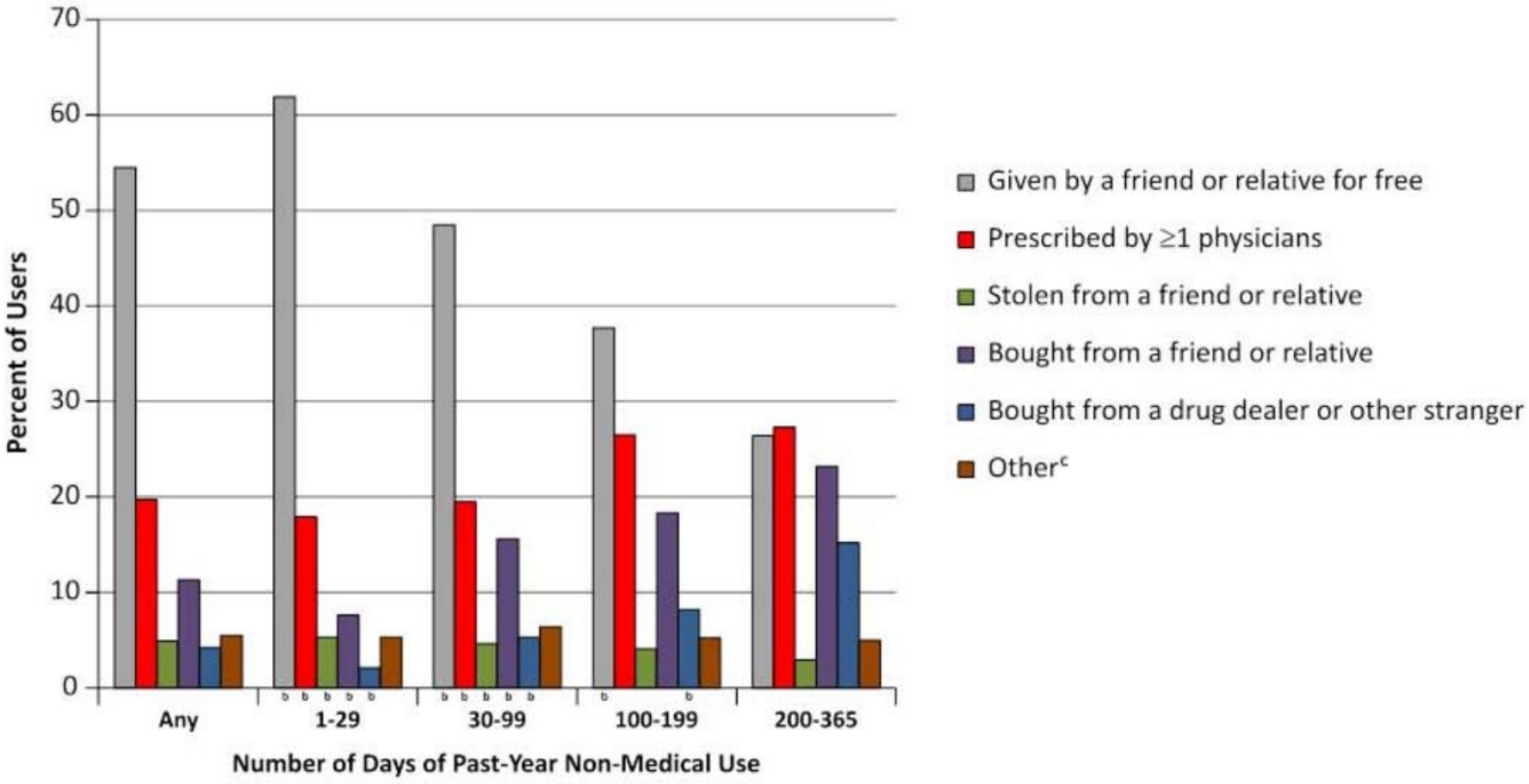
- Nearly half of all opioid overdose deaths involve an Rx opioid
- In 2015, nearly 15,000 people died from overdoses involving Rx opioids
- Most common Rxs involved
  - Methadone, oxycodone, hydrocodone
- In 2014 almost 2 million Americans abused or were dependent on Rx opioids

https://www.cdc.gov/drugoverdose/epidemic/



https://www.cdc.gov/drugoverdose/data/prescribing.html

Sources of Prescription Opioids Among Past-Year Non-Medical Users[a]



[a] Obtained from the US National Survey on Drug Use and Health, 2008 through 2011.[5]
[b] Estimate is statistically significantly different from that for highest-frequency users (200-365 days) ($P < .05$).
[c] Includes written fake prescriptions and those opioids stolen from a physician's office, clinic, hospital, or pharmacy; purchases on the Internet; and obtained some other way.

SOURCE: Jones C, Paulozzi L, Mack K. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008–2011. JAMA Int Med 2014; 174(5):802-803.

https://www.cdc.gov/drugoverdose/data/prescribing.html

Predictors of Abuse

- Past substance abuse[1, 3] or family Hx[3]
- Psychopathology[2, 3, 4]
- Age (16-45 years)[3]
- Hx of preadolescent sexual abuse[3]
- Predictors for continued use after treatment[4]
  - High level of use pre-treatment
  - Depression, high stress
  - Employment problems
  - Substance abusing peers

1) Ives, et al. BMC Health Services Research 2006, 6:46
2) Manchikanti L, et al. J Opioid Manag. 2007 Mar-Apr;3(2):89-100.
3) Webster LR, Webster RM. Pain Med. 2005 Nov-Dec;6(6):432-42
4) Brewer D, et al. Addiction, Volume 93, Number 1, 1 January 1998, pp. 73-92(20)

Tolerance and Physical Dependence

- Tolerance
  - Repeated administration of therapeutic doses results in gradual loss of effectiveness
  - Larger dose must be administered to produce original response
    - Analgesia, sedation, respiratory depression
    - Not constipation, not miosis
- Physical dependence
  - Develops along with tolerance
  - Withdrawal symptoms upon abrupt discontinuation
- Dependence vs. Addiction vs. Pseudo-Addiction

Major Aberrant Drug-Taking Behaviors

- Selling Rx drugs
- Prescription forgery
- Stealing or borrowing drugs
- Injecting oral formulations
- Obtaining prescription drugs from nonmedical sources
- Concurrent abuse of related illicit drugs
- Multiple unsanctioned dose escalations
- Recurrent prescription losses

Minor Aberrant Drug-Taking Behaviors

- Aggressive complaining about need for higher doses
- Drug hoarding during periods of reduced symptoms
- Requesting specific drugs
- Acquisition of similar drugs from other medical sources
- Unsanctioned dose escalation 1-2 times
- Unapproved use of the drug to treat another symptom

CA Board of Pharmacy "Red Flags"

- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medications)
- Multiple patients at the same address(es)
- Cash payments
- Requests for early refills of prescriptions
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for potentially duplicative drugs
- The same combinations of drugs prescribed for multiple patients

Dichotomous Roles

- Caring clinician
  - Moral/ethical responsibility to relieve pain and suffering
- Policing investigator
  - Legal/regulatory obligation to control abuse-prone medications
- Both prescribers and dispensers share responsibility

What Can Be Done?

- Improve opioid prescribing
- Expand access to substance abuse treatment
- Expand access and use of naloxone
- Promote the use of state PDMPs
- Implement and strengthen state strategies

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Good Clinical Processes to Minimize Abuse Risk

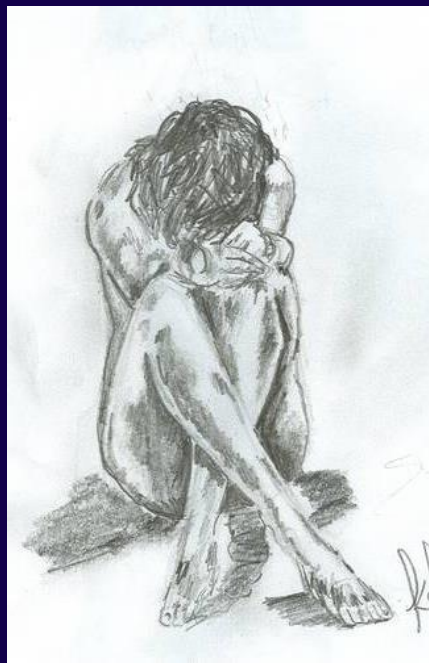
- Thorough history
  - Personal or family drug issues, past or present
- Patient informed consent
- Controlled substance agreement
- Risk Assessment Tools
  - Opioid Risk Tool (ORT)
  - Current Opioid Misuse Measure (COMM)™
  - Screener and Opioid Assessment for Patients with Pain (SOAPP)®

Good Clinical Processes to Minimize Abuse Risk

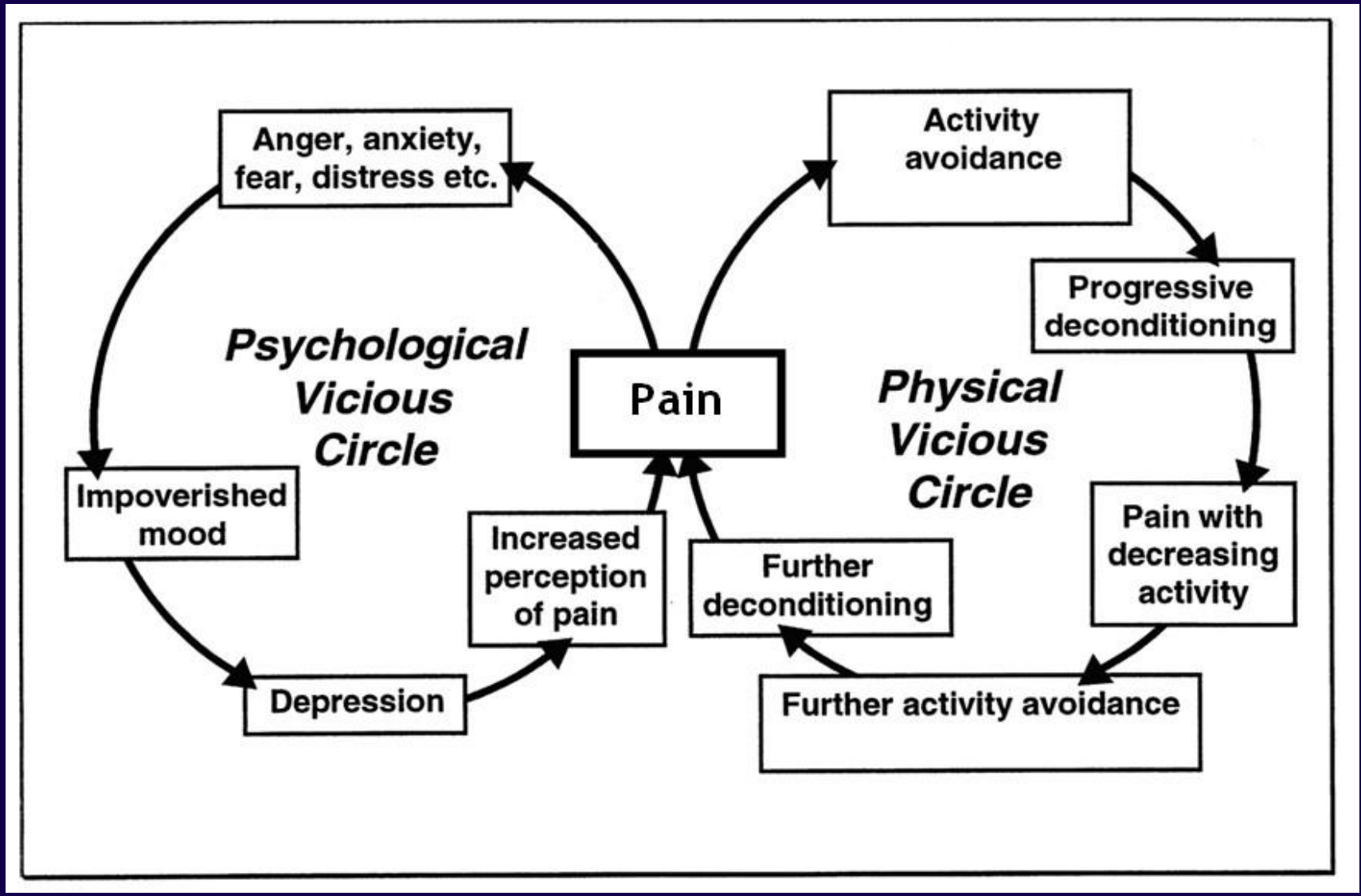
- Rational Controls
  - Small quantities
  - Frequent visits
  - One prescriber/group
  - One pharmacy
  - Tamper-deterrent formulations
- Monitoring
  - Pain diary
  - Urine testing
  - Prescription Drug Monitoring Programs
  - The 4 A's of Pain
    - Analgesia
    - ADLs
    - Adverse Effects
    - Aberrant Drug Behaviors

Importance of Identifying Psychopathology

- Interferes with successful rehabilitation
- Increases pain intensity and disability
- Anxiety decreases pain thresholds and tolerances
- Depression is linked to poor treatment outcomes with traditional medical approaches
  - Significantly higher rates in patients with chronic pain
- 3X more likely to be non-adherent



Clin J Pain 1996;12:118-125
Pain 1998;35:105-113
J Clin Consult Psychiatry 1998;05:434-439


Anger, anxiety, fear, distress etc.
Activity avoidance
Progressive deconditioning
Psychological Vicious Circle
Pain
Physical Vicious Circle
Impoverished mood
Increased perception of pain
Further deconditioning
Pain with decreasing activity
Depression
Further activity avoidance

Genetic Testing

- Opioid risk
- Drug metabolism
- Pain perception
- NSAID risk
- Addiction risk
- Opioid-induced side effects

CDC Guidelines for Opioids

Determining when to initiate or continue opioids for chronic pain outside end-of-life care

- Preference for non-pharm and non-opioid pharm therapy
- Providers need to establish treatment goals for pain and function
- Providers need to discuss patients' risks and realistic benefits

CDC Guidelines for Opioids

Opioid selection, dosage, duration, follow-up, and discontinuation

- Long-term opioid use often begins with treatment of acute pain
- At start of opioid therapy providers should:
  - Prescribe short-acting opioids instead of ER/LA opioids
  - Prescribe the lowest possible effective dosage and be cautious of increasing dose to ≥50 MME/day

CDC Guidelines for Opioids

Opioid selection, dosage, duration, follow-up, and discontinuation

- Re-evaluation of patients within 1 to 4 weeks of starting long-term opioid therapy or dose escalation
- Re-evaluation of long-term opioid therapy every 3 months

CDC Guidelines for Opioids

Assessing risk and addressing harms of opioid use

- Before starting and periodically during continuation of opioid therapy, evaluate risk factors for opioid-related harms
- Offer naloxone when factors increase risk of opioid-related harms
- Review of patient's hx of controlled substance prescriptions using state PDMP data

CDC Guidelines for Opioids

Assessing risk and addressing harms of opioid use

- Urine drug testing before starting and at least annually in long-term opioid therapy
- Avoid prescribing opioid pain meds and benzodiazepines concurrently
- Offer or arrange evidence-based treatment (opioid agonist in combination with behavioral therapies) for patients with opioid use d/o

Tamper-Deterrent Formulations

- Hydrocodone (Hysingla ER)
- Hydrocodone (Zohydro ER)
- Oxycodone/Naloxone (Targiniq ER)*
- Oxycodone (Oxycontin)*
- Tapentadol (Nucynta ER)
- Morphine/Naltrexone (Embeda)*
- Oxymorphone (Opana ER)

* = “Abuse Deterrent” per FDA

Risk Evaluation and Mitigation Strategies (REMS)

- Required by the FDA of manufacturers of certain medications
- Ensure that the benefits of a drug or biological product outweigh its risks
  - Provide training for HCPs
  - Distribute educational materials to prescribers and patients
- Buprenorphine transmucosal, fentanyl transmucosal, extended release/ long-acting opioids
- No REMS for short-acting opioids

Case #1 - Dispensers

- RJ comes to the pharmacy with a prescription for hydrocodone/APAP 10/325mg PO Q4h #240
- Gets the same prescription every month from the same rheumatologist
- Every patient of this particular prescriber receives the exact same prescription each month
- You decide to contact the prescriber to discuss her prescribing habits and the appropriateness of opioid therapy for her patients.

- How would you approach the prescriber?

The Tough Conversation with Prescribers – 3 steps

1) Approach as a colleague
   - Use your title and your last name
   - Discussion regarding the care of a mutual patient
   - Two-way conversation
   - Gather missing information
   - Don’t be the “Drug Police”
     - Be non-threatening and non-accusatory

The Tough Conversation with Prescribers – 3 steps

2) Be prepared
   - Speak to the patient first and assess
   - Have specific recommendations ready to go

3) Hold your ground
   - Be prepared to say so when something is not appropriate
   - Be prepared to refuse to fill
   - Have confidence in your education and training. (If not, get more!)

Simple Ways to Start the Conversation with Patients

- What medications are you taking?
- What medications have you taken to manage pain and how did you respond?
- Describe how you normally take your medications.
- How well is your medication controlling your pain?

https://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf

Simple Ways to Start the Conversation with Patients

- Are you experiencing any side effects from your pain medications?
- In addition to medications, what other ways are you managing your pain?
- Do you know which medications you should avoid while taking opioids?
- What questions do you have about your medications?

https://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf

Case #1 - Prescribers

- RJ comes to the clinic for a pain management follow up. This is your first visit with her since you have taken over another provider's patient panel. She seems nervous during the visit and even expresses concern that you are going to "take her meds away."
- She previously received a prescription for hydrocodone/APAP 10/325mg PO Q4h #240 every month for the past 5 years
- You do not feel that regimen is appropriate for her and want to begin a taper.

- How would you approach the patient?

The Tough Conversation with Patients – 3 steps

1) Be clear on the rules of the game
   - Review the patient-provider agreement intermittently
   - Hold your ground

2) Present the evidence
   - Decisions based on scientific evidence, not on fear of regulatory scrutiny
   - In the interest of patient health and safety

3) Be reassuring yet firm
   - Slow changes, adjunctive therapy, frequent follow up

What Can Be Done?

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The Comprehensive Addiction and Recovery Act of 2016 (CARA)

- Improves access to MAT
- Expands availability of naloxone
- Improves PDMPs
- Shifts resources to identify and treat people incarcerated for drug use
- State grants for response
- Expands prescribing privileges for MAT to NPs and PAs

https://www.govtrack.us/congress/bills/114/s524/summary

Case #2 - Dispensers

- KW walks into your pharmacy with a prescription for hydrocodone/APAP 10/325 mg every 4 hr (quantity: 180 tablets).
- You have seen this patient come into your pharmacy before on numerous occasions. However, this prescription seems to be under a different name.
- KW claims that he is indeed the name printed on the prescription, and has an elaborate story regarding a lost ID.
- Numerous calls to the prescriber have been unsuccessful and you suspect this to be a fake prescription.
- Deciding not to fill this prescription, how would you consult KW on the validity of the prescription and direct him to resources if he needs help?

Case #2 - Prescribers

- You have received a call from a pharmacy conveying concerns about opioid misuse with one of your patients, KW.
- He has a clinic appointment scheduled with you tomorrow morning.

- How would talk to KW regarding his medication use, and direct him to resources if he needs help?

A Refusal or an Opportunity?

- Passive response of dispensers
  - "We don't have it."
    - Could be a missed opportunity
    - When used?
      - Fear of/discomfort with confrontation?
      - Safety concerns?
      - Other repercussions?

A Refusal or an Opportunity?

- Proactive response
  - Provide a truthful explanation to the patient
    - "I will not fill/write for this because _____ ."
    - "I am not comfortable filling this/writing for this because _____.
  - Respond without judgement
  - Express caring/concern
    - "I am concerned that this medication could be harmful to your health."
    - "I would like to provide you with assistance/resources if you wish."
  - Be ready with available resources

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CA PDMP
Controlled Substance Utilization and Evaluation System (CURES)

- Pharmacies transmit data electronically on a weekly basis
- Schedules II-IV
- Supposed to be “real-time” but there is some lag
- All providers that prescribe or dispense controlled substances must register for online access
  - Prescribers must review CURES before prescribing schedule II or III for the first time
  - At least annually with ongoing care
  - No requirement for pharmacists to check

CURES pdmp

Patient Activity Report (PAR)

Department of Justice - Bureau of Narcotic Enforcement
Controlled Substance Utilization Review & Evaluation System

PATIENT/CLIENT ACTIVITY: CONSOLIDATED REPORT

01/17/2013 11:19

CONFIDENTIAL DOCUMENT

Prescription Drug Transaction Details:

Number of Hits: 9 **Start Date: 01/17/2012** **End Date: 01/17/2013**

Date Filled	First Name	Last Name	DOB	Address	Drug Name	Form	Str	Qty	PHY Name	PHY#	Dr.'s DEA #	Dr.'s Name	RX#	Refill#
01/20/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	VICODIN	TAB	1000 MG-5 MG	10	WALGREENS #610	PHY12345	AB5678909	SMITH, JOHN	02345678	3
1/23/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	APAP/HYDROCODONE BITARTRATE	TAB	500 MG-5 MG	40	CVS/PHARMACY #110	PHY12345	AB5678909	SMITH, JOHN	02375678	1
02/01/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	XANAX	TAB	100 MG-5 MG	60	WAL-MART #926	PHY12345	AB5678909	SMITH, JOHN	00284920	1
02/04/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	VICODIN	TAB	200 MG-5 MG	60	TARGET #261	PHY12345	AB5678909	SMITH, JOHN	09244920	2
03/01/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	APAP/HYDROCODONE BITARTRATE	TAB	5000 MG-5 MG	60	WALGREENS #100	PHY12345	AB5678909	SMITH, JOHN	04247940	4
03/08/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	XANAX	TAB	500 MG-5 MG	80	CVS/PHARMACY	PHY12345	AB5678909	SMITH, JOHN	02434960	1
03/07/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	APAP/HYDROCODONE BITARTRATE	TAB	500 MG-5 MG	60	WALGREENS	PHY12345	AB5678909	SMITH, JOHN	02795765	1
03/10/2012	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	APAP/HYDROCODONE BITARTRATE	TAB	500 MG-5 MG	90	CVS/PHARMACY #934	PHY12345	AB5678909	SMITH, JOHN	02549607	2
01/01/2013	JOHN	DOE	05/23/1960	2560 COLLEGE WAY, SACRAMENTO, CA, 95821	VICODIN	TAB	1000 MG-5 MG	30	TARGET #234	PHY12345	AB5678909	SMITH, JOHN	02649603	3

Disclaimer: The Patient Activity Report (PAR) is compiled from information maintained in the Department of Justice's Controlled Substance Utilization Review and Evaluation System (CURES). The CURES maintains Schedule II, Schedule III and Schedule IV prescription information that is received from California Pharmacies and is therefore only as accurate as the information provided by the Pharmacies. If data was submitted with errors or have unknowns within a field, it will not be displayed within this report.

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Thank You