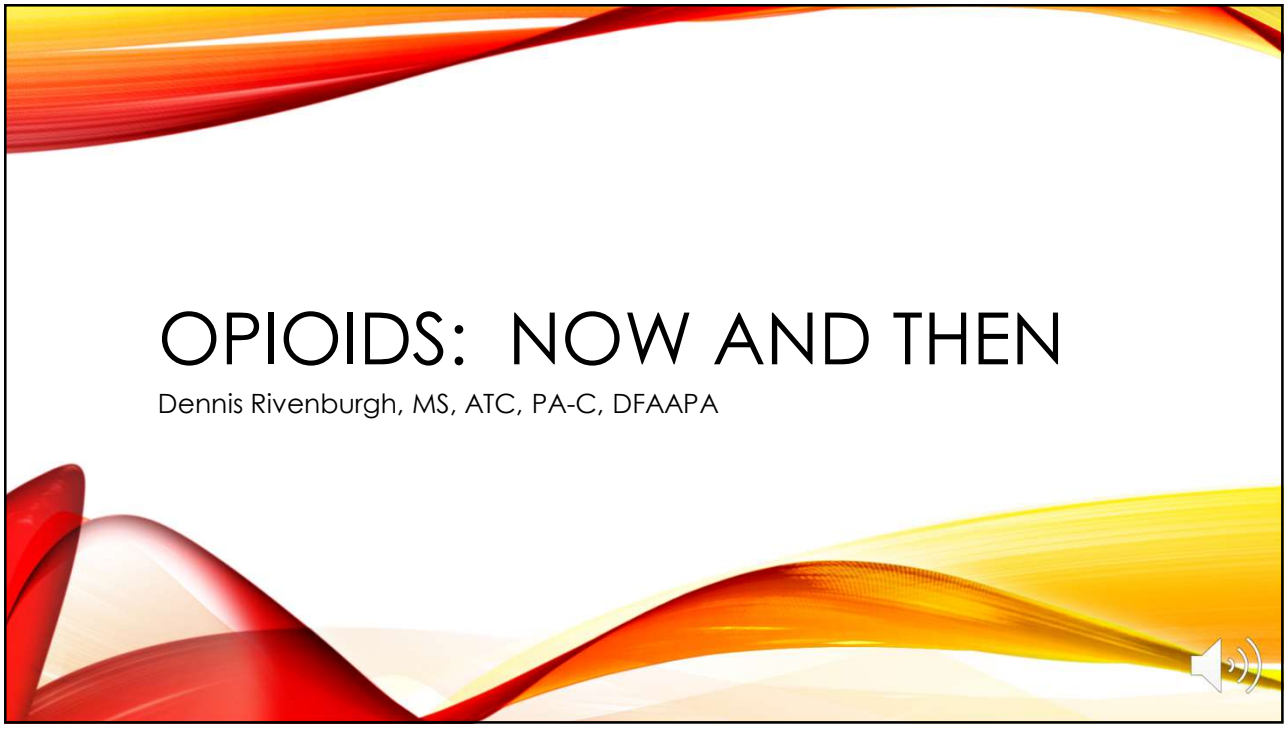


1

FINANCIAL DISCLOSURES

- None

2

OBJECTIVES

- To understand terminology related to use of opioids for acute and chronic non-cancer pain
- To appreciate the prevalence of chronic non-cancer pain, opioid prescribing and adverse events related to opioids
- To review fundamental components of effective management of chronic non-cancer pain
- To understand practical techniques for improving safety and efficacy of opioid prescribing for pain

3

4

B.C – COLONIAL TIMES

- 5000 BC - The earliest reference to probable opium cultivation by the Sumarians
- 3500 BC - The first types of beer, weak alcohols and wines began to emerge in ancient cultures
- 1525 – Paracelsus (1490-1541) introduced laudanum, into the practice of medicine
- 1700s – plant-based medications were used throughout the colonies; abuse substances were tobacco, alcohol, and opium

5

1800S

- Early 1800s – addiction grew with the use of laudanum & the discovery of codeine and morphine
- American Civil War – dramatic increase in opioid based medications, mainly morphine. The addiction was nicknamed the "Soldiers Disease"
- Late 1800s – Opiate abuse rose in the cities. There were no "illegal" drugs. Drug use/abuse/addiction increased with the development of heroin
- 1880's – Cocaine used at Johns Hopkins in experimental surgery by William Halstead, MD one of the founders of JHU. After experimenting on himself, he became addicted.

6

1800S

7

1900 – 1960S

- 1906 The Pure Food and Drug Act (first law) – required labeling of opium contained medications
- 1914 – Harrison Narcotics Act – banned the sale of high dose of opioids or cocaine(Except for doctors and pharmacies)
- These efforts had a significant impact, and drug use and abuse **decreased significantly**
- 1960s – "Drug Culture" – began a new era of illicit drug use/abuse. The 1970 Controlled Substance Act was passed to address the national drug crisis

8

1960S AND 1970S

- 1960s – The main drugs where marijuana, amphetamines, heroin, and LSD/PCP. Myth: "Drugs are everywhere"
  - The truth: It was fairly rare. 1969 Gallup poll – only 4% of US adults said they had tried marijuana
  - The problem: accurate information about the negative effects of illicit drugs was scarce roughly 34% did not know the effects of marijuana in 1969
- 1970s – cocaine reappeared – the "champagne of drugs"
  - Expensive, high-status, "No serious consequences"
  - 10% of Americans used illegal drugs on a regular basis
  - 1973: drug use peak in the US, 24% use marijuana

9

1980S

- 1980s – the highly addictive and dangerous effects of cocaine use emerged and usage decreased
- The price of cocaine dropped steadily
- Drug cartels developed "Crack" cocaine – a very addictive and cheap form of cocaine
- Mid-1980s – 6 million Americans used regularly
- This initiated America's most devastating drug epidemic. Anti-drug abuse act(1986) Set mandatory minimum sentences for drug crimes

10

1990S

- The "War on Drugs" accelerated and several more laws were passed to combat the crisis
- Greater efforts were made to address the source of illegal drugs from foreign countries
- Mid-1990s – Methamphetamine was developed. It was more addictive than "crack" and quickly surpassed cocaine and dominance
- However, the non-medical use and abuse a prescription medications was on the rise

11

2000 - PRESENT

- The same illicit drugs continue to be abused, but the prevalence changed
- Use of marijuana increased 40%, but the use of cocaine decrease by 50%
- Heroin use/abuse held steady until 2007
- Methamphetamine increased, but the percentage of increase was hard to estimate
- in 2002, prescription drug abuse surpassed heroin and cocaine use combined

12

FENTANYL AND FENTANYL ANALOGUES

OD deaths from fentanyl and fentanyl analogues, such as carfentanil, have increased 540% in three years.

Street fentanyl is illegally manufactured; it is generally NOT a diverted pharmaceutical product.

Two causes of fentanyl OD death: opioid-induced **respiratory depression** and **rigid chest wall syndrome**; higher or repeated doses of naloxone are required to reverse a fentanyl overdose.

Fentanyl is also found in heroin, cocaine, and methamphetamine.

Lethal Dose

Photo source: New Hampshire State Police Forensic Laboratory

13

ECONOMIC IMPACT

- 2005 – the total cost of illicit drug use was estimated to be as high as $119 billion. It averaged about $100 billion/year from 2000 – 2010
- 2010 – $109 billion was spent in the US on cocaine, heroin, marijuana, and methamphetamine
  - Most the the money was spent by the minority of heavy users, they used 21 or more days monthly
- The overall cost of the drug abuse crisis to the US economy was $193 billion (2007)

14

US DRUG CONTROL SPENDING 2013-18

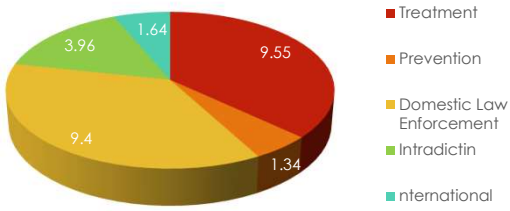
Costs in Millions

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Treatment	7.888.6	9481.8	9553.1	9845.1	10,580.8	10,783.4
Percent	31.3%	36.9%	36.9%	36.6%	38.5%	38.9%
Prevention	1274.9	1316.9	1341.5	1486.4	1507.4	1339.9
Percent	5.1%	5.1%	5.2%	5.5%	5.5%	4.8%
Domestic law-enforcement	8850.0	9348.8	9394.5	9282.8	9298.6	9235.8
Percent	35.1%	36.3%	36.3%	34.5%	33.8%	33.3%
Interdiction	3940.6	3948.8	3960.9	4734.7	4569.0	5022.4
Percent	15.6%	15.3%	15.3%	17.6%	16.6%	18.1%
International	1848.5	1673.1	1643.0	1524.9	1521.0	1375.0
Percent	7.3%	6.4%	6.3%	5.7%	5.5%	5.0%
Total	23,800.4	25724.9	25,893	26,874	27476.8	27756.5

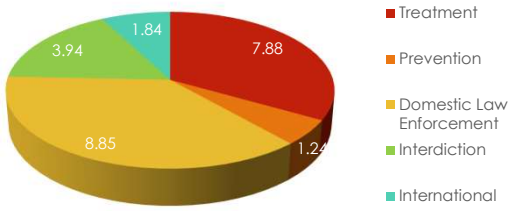
15

SPENDING TRENDS 2015 VS 2018

Costs in Billions of Dollars
2018



Costs in Billions of Dollars
2015



16

PREVALENCE

- 2012 – roughly 24,000,000 Americans aged 12 or older were active illicit drug users, or 9.2% of the US population
- Total chronic drug users from 2000 to 2010:
  - Cocaine – decreased from 3.3 million to 2.5 million
  - Heroin – increased from 1.4 million to 1.5 million
  - Methamphetamine – increased from 0.9 million to 1.6 million
  - Marijuana – increase from 4,000,000 to 8.2 million

17

ADVERSE EFFECTS OF OPIOIDS

DSM-V Substance Use Disorder Opioids:

- ❑ Taking the opioid in larger amounts and for longer than intended
- ❑ Wanting to cut down or quit but not being able to do it
- ❑ Spending a lot of time obtaining the opioid
- ❑ Craving or a strong desire to use opioids
- ❑ Repeatedly unable to carry out major obligations at work, school, or home due to opioid use
- ❑ Continued use despite persistent or recurring social or interpersonal problems caused by or made worse by opioid use
- ❑ Stopping or reducing important social, occupational, or recreational activities due to opioid use
- ❑ Recurrent use of opioids in physically hazardous situations
- ❑ Consistent use of opioids despite acknowledgement of persistent or recurrent physical or psychological difficulties from using opioids
- ❑ Tolerance defined as either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount.
- ❑ Withdrawal, as manifested by either of the following:
- ❑ The characteristic opioid withdrawal syndrome
- ❑ Opioids are taken to relieve or avoid withdrawal symptoms.
- ❑ Severe - > 6 criteria, Moderate – 4-5 criteria, Mild – 2-3 criteria

18

ADVERSE EFFECTS, CONT

- Misuse → Use other than how prescribed:
  - To get high
  - More than prescribed
  - Selling, trading = “diversion”

19

ADVERSE EFFECTS, CONT

- "Drug-seeking Behavior" → requests for opioid medications for the purpose of getting high
- "Aberrant Behaviors" → among patients on opioids for chronic pain, behaviors that may be indicative of misuse or addiction
  - Early refills
  - Frequent phone calls
  - Doctor shopping
  - Prescription forgery

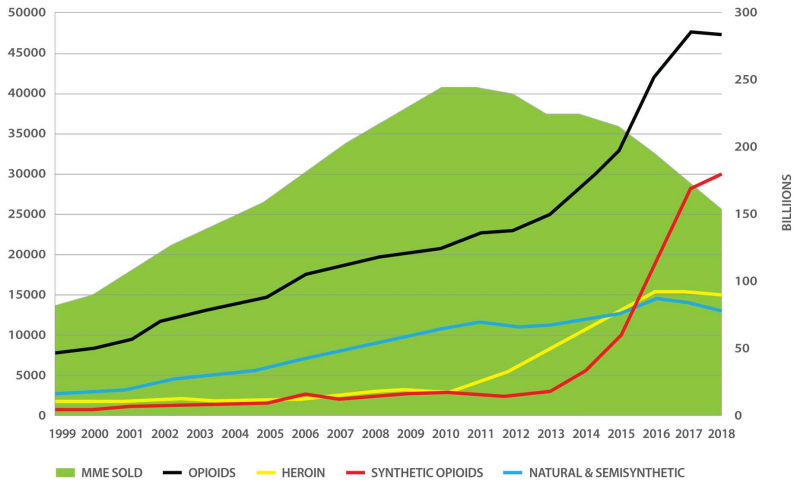
20

ADVERSE EFFECTS, CONT

- Constipation
- Nausea
- Itching
- Dizziness
- Clouded mentation
- Sedation/Respiration Depression
- Falls
- Overdose
- Death

21

PRESCRIBING PATTERNS AND OPIOID-RELATED DEATHS



SOURCE: CDC Opioid Overdose Death data, IQVIA opioid prescribing data, Sullum J
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

22

DEA SCHEDULED DRUGS

SCHEDULE	DESCRIPTION	EXAMPLES
I	High potential for abuse; no currently accepted medical use	Heroin, LSD, cannabis, ecstasy, peyote
II	High potential for abuse, which may lead to severe psychological or physical dependence	Hydromorphone, methadone, meperidine, oxycodone, fentanyl, morphine, opium, codeine, hydrocodone combination products
III	Potential for abuse, which may lead to moderate or low physical dependence or high psychological dependence	Products containing ≤ 90 mg codeine per dose, buprenorphine, benzphetamine, phendimetrazine, ketamine, anabolic steroids
IV	"Low potential" for abuse	Alprazolam, benzodiazepines, carisoprodol, clonazepam, clorazepate, diazepam, lorazepam, midazolam, temazepam, tramadol
V	Low potential for abuse	Cough preparations containing ≤ 200 mg codeine/100 ml

Complete list of products covered under the Opioid Analgesic REMS available at: https://opioidanalgesicrems.com/RpcUI/products.u

23

WORDS MATTER: DEFINITIONS

Misuse	Use of a medication in a way other than the way it is prescribed
Abuse	Use of a substance with the intent of getting high
Tolerance	Increased dosage needed to produce a specific effect
Dependence	State in which an organism only functions normally in the presence of a substance
Diversion	Transfer of a legally controlled substance, prescribed to one person, to another person for illicit (forbidden by law) use
Withdrawal	Occurrence of uncomfortable symptoms or physiological changes caused by an abrupt discontinuation or dosage decrease of a pharmacologic agent
MME	Morphine milligram equivalents; a standard opioid dose value based on morphine and its potency; allows for ease of comparison and risk evaluations
Chronic non-cancer pain (CNCP)	Any painful condition that persists for ≥ 3 months, or past the time of normal tissue healing, that is not associated with a cancer diagnosis

SOURCES: SAMHSHA Resource: https://www.samhsa.gov/capt/sites/default/files/resources/sud-stigma-tool.pdf
World Health Organization, Ensuring Balance in National Policies on Controlled Substances.
https://www.who.int/medicines/areas/quality_safety/GLs_Ens_Balance_NOCP_Col_EN_sanend.pdf

24

HOW DID WE GET HERE?

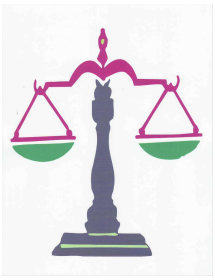
- 1990s
  - Under-treatment of pain
  - Pain as the 5th vital sign
  - Pain as a human rights issue
  - Early data that opioid risks were low, some of which intentionally minimized
  - Intertwined cultural and medical trend towards "a pill for what ails ya'"

25

JUGGLING?

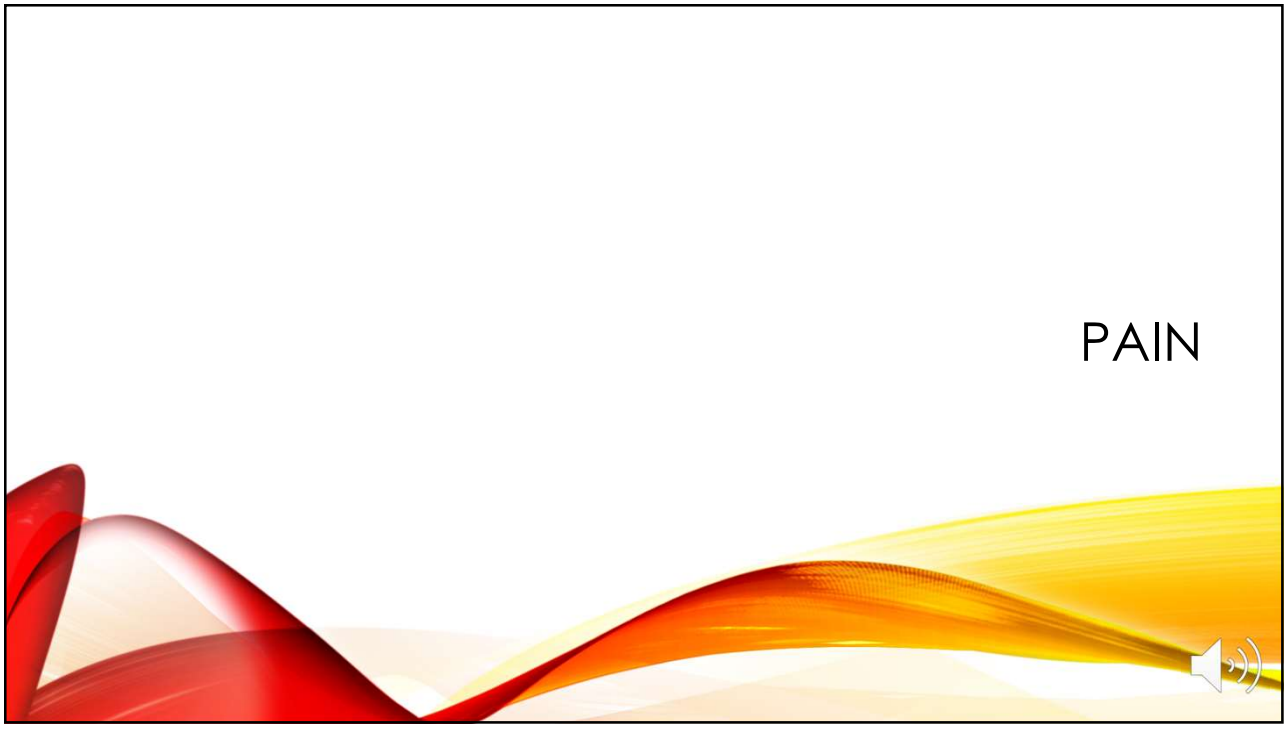
Balancing

BENEFITS

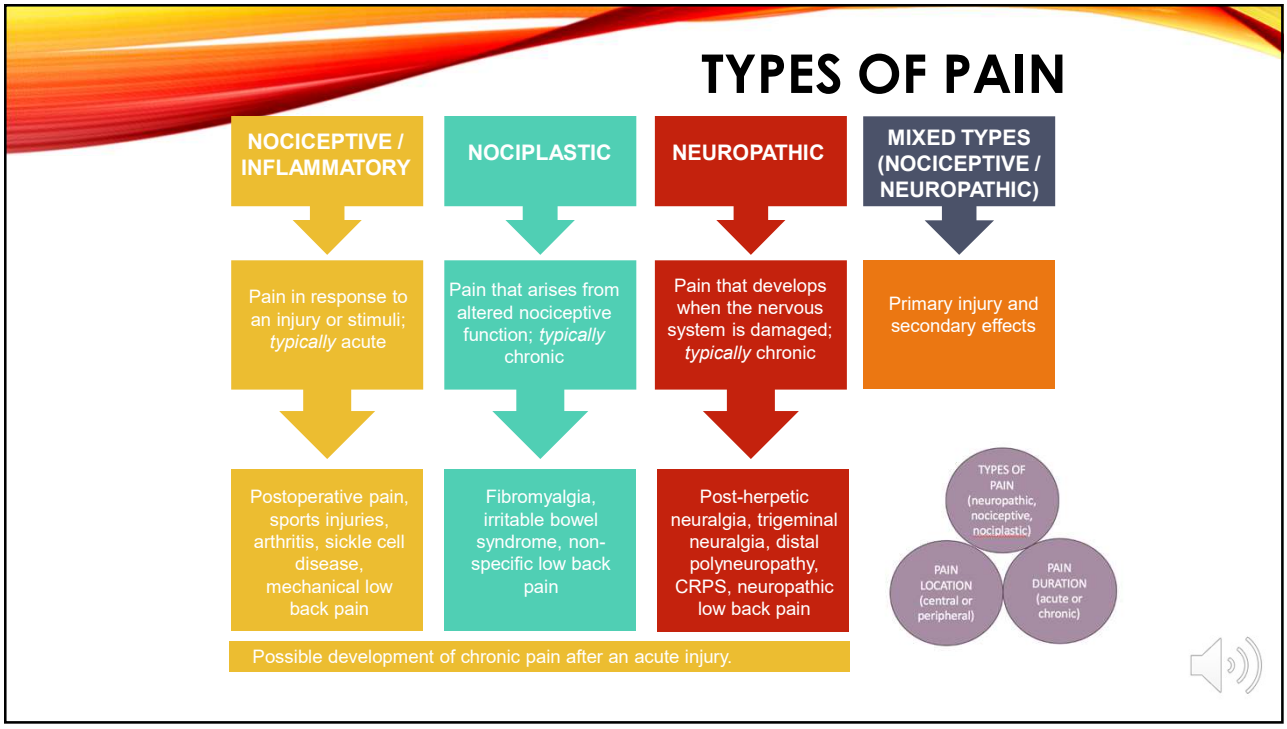


HARMS

26

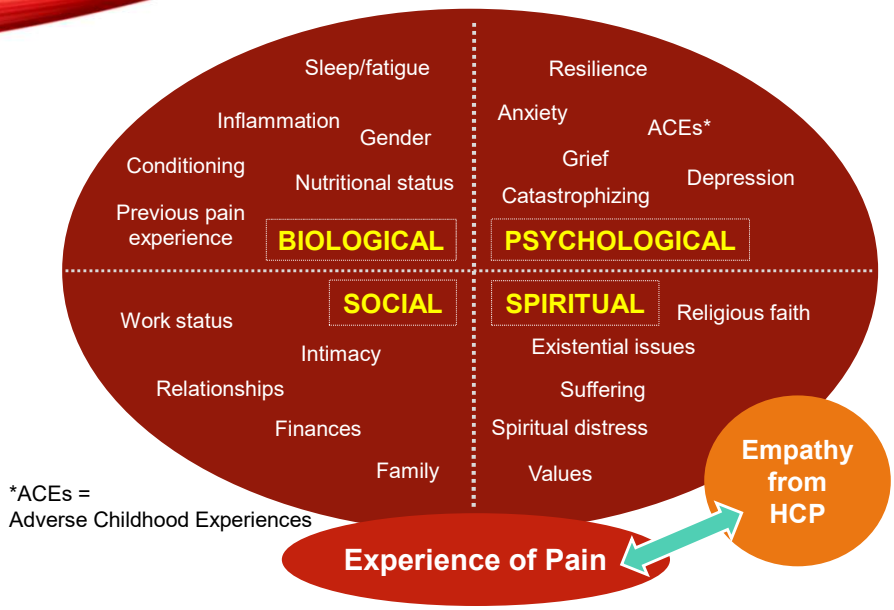


27

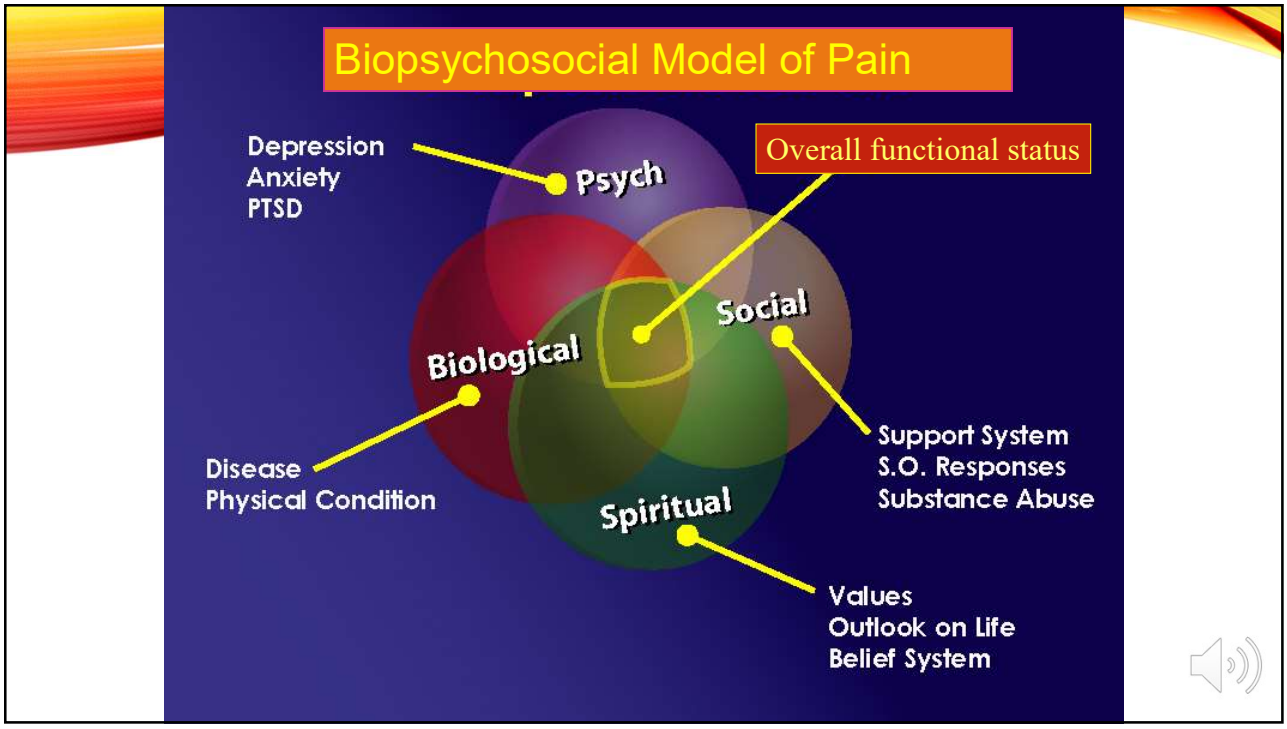

TYPES OF PAIN
NOCICEPTIVE / INFLAMMATORY
NOCIPLASTIC
NEUROPATHIC
MIXED TYPES (NOCICEPTIVE / NEUROPATHIC)
Pain in response to an injury or stimuli; typically acute
Pain that arises from altered nociceptive function; typically chronic
Pain that develops when the nervous system is damaged; typically chronic
Primary injury and secondary effects
Postoperative pain, sports injuries, arthritis, sickle cell disease, mechanical low back pain
Fibromyalgia, irritable bowel syndrome, non-specific low back pain
Post-herpetic neuralgia, trigeminal neuralgia, distal polyneuropathy, CRPS, neuropathic low back pain
Possible development of chronic pain after an acute injury.
TYPES OF PAIN (neuropathic, nociceptive, nociplastic)
PAIN LOCATION (central or peripheral)
PAIN DURATION (acute or chronic)

28

THE BIOPSYCHOSOCIAL SPIRITUAL CONTEXT OF PAIN



29


Biopsychosocial Model of Pain
Depression
Anxiety
PTSD
Psych
Overall functional status
Social
Biological
Disease
Physical Condition
Support System
S.O. Responses
Substance Abuse
Spiritual
Values
Outlook on Life
Belief System

30

CASE

57 M w/ chronic low back pain for 15 years after being thrown out of a jeep

- Worked as officer in BPD until 50
- Lives with wife and 3 daughters, active in community
- Admits to cocaine and speed for 1-2 years 25 years ago
- Pain has been worsening and interferes with functioning
- Dx based on hx/PE/MRI: spinal stenosis
- You prescribe NSAIDS, capsaicin, physical therapy
- After 8 weeks pt still experiencing significant pain that is negatively affecting function; you start opioids (MSContin 15 mg TID titrated to 30 mg TID) to good effect: improved pain and function
- One month later, routine UDT positive for cocaine

31

WHAT DO YOU DO NOW?

We'll get to that discussion but also…

What should you have done in the first place?

32

PRACTICAL TECHNIQUES FOR IMPROVING EFFICACY AND SAFETY OF OPIOID PRESCRIBING

33

OBTAIN A COMPLETE SOCIAL AND PSYCHOLOGICAL HISTORY

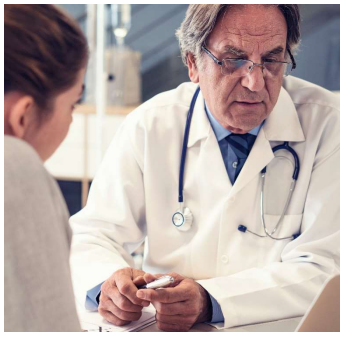
SOCIAL HISTORY

Employment, cultural background, social network, relationship history, legal history, and other behavioral patterns

PSYCHOLOGICAL HISTORY

Screen for:

- Mental health diagnoses, depression, anxiety, PTSD, current treatments
- Alcohol, tobacco, and recreational drug use
- History of adverse childhood experiences
- Family history of substance use disorder and psychiatric disorders
- Depression and anxiety can be predictors of chronic pain



34

CLINICAL INTERVIEW: PAIN & TREATMENT HISTORY

Description of pain


Location


Intensity


Quality


Onset/ Duration


Variations / Patterns / Rhythms

What relieves the pain?

What causes or increases pain?

Effects of pain on physical, emotional, and psychosocial function

Patient's pain & functional goals

Heapy A, Kerns RD. Psychological and Behavioral Assessment. In: Raj's Practical Management of Pain. 4th ed. 2008;279-95. Zacharoff KL, et al. Managing Chronic Pain with Opioids in Primary Care. 2nd ed. Newton, MA: Inflexion, Inc., 2010.

35

CLINICAL INTERVIEW: PAIN & TREATMENT HISTORY, CONT

Pain Medications

Past use

Current use

- Query state **PDMP** where available to confirm patient report
- Contact past providers & obtain prior medical records
- Conduct **UDT**

Dosage

- For opioids currently prescribed: opioid, dose, regimen, & duration
  - Important to determine if patient is **opioid tolerant**

General effectiveness

Nonpharmacologic strategies & effectiveness

36

PAIN ASSESSMENT TOOL BOX

Pain Assessment Tools

BPI or 5 A's

Functional Assessment

SF-36, PPS, Geriatric Assessment

Pain intensity, Enjoyment of life, General activity

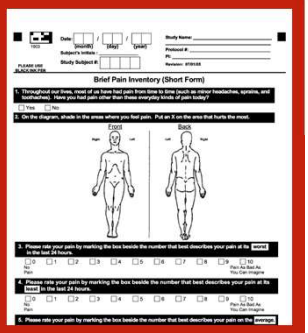
PEG

Adverse Childhood Experience Questionnaire

ACE

Assessment in Advanced Dementia

PAINAD



Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Front Back

3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

Brief Pain Inventory (BPI)

Psychological Measurement Tools (PHQ-9, GAD-7, etc.)

37

RISK ASSESSMENT TOOLS

Tool	# of items	Administered By
Patients considered for long-term opioid therapy:		
ORT Opioid Risk Tool	5	patient
SOAPP® Screener & Opioid Assessment for Patients w/ Pain	24, 14, & 5	patient
DIRE Diagnosis, Intractability, Risk, & Efficacy Score	7	clinician
Characterize misuse once opioid treatments begins:		
PMQ Pain Medication Questionnaire	26	patient
COMM Current Opioid Misuse Measure	17	patient
PDUQ Prescription Drug Use Questionnaire	40	clinician
Not specific to pain populations:		
CAGE-AID Cut Down, Annoyed, Guilty, Eye-Opener Tool, Adjusted to Include Drugs	4	clinician
RAFFT Relax, Alone, Friends, Family, Trouble	5	patient
DAST Drug Abuse Screening Test	28	patient
SBIRT Screening, Brief Intervention, & Referral to Treatment	Varies	clinician

38

DEPRESSION SCREENING

PATIENT HEALTH QUESTIONNAIRE-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING

__0__ + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

- Bill 96127
- ICD 10: Z13.89

- 0-4 No Depression
- 5-9 Mild Depression
- 10-14 Moderate Depression
- 15-19 Moderately Severe Depression
- 20-27 Severe Depression

ASSESS RISK OF ABUSE, INCLUDING SUBSTANCE USE & PSYCHIATRIC HX

Obtain a complete Hx of current & past substance use

- Prescription drugs
- Illegal substances
- Alcohol & tobacco
  - Substance abuse Hx does not prohibit treatment w/ ER/LA opioids but may require additional monitoring & expert consultation/referral
- Family Hx of substance abuse & psychiatric disorders
- Hx of sexual abuse

Social history also relevant

Employment, cultural background, social network, marital history, legal history, & other behavioral patterns

40

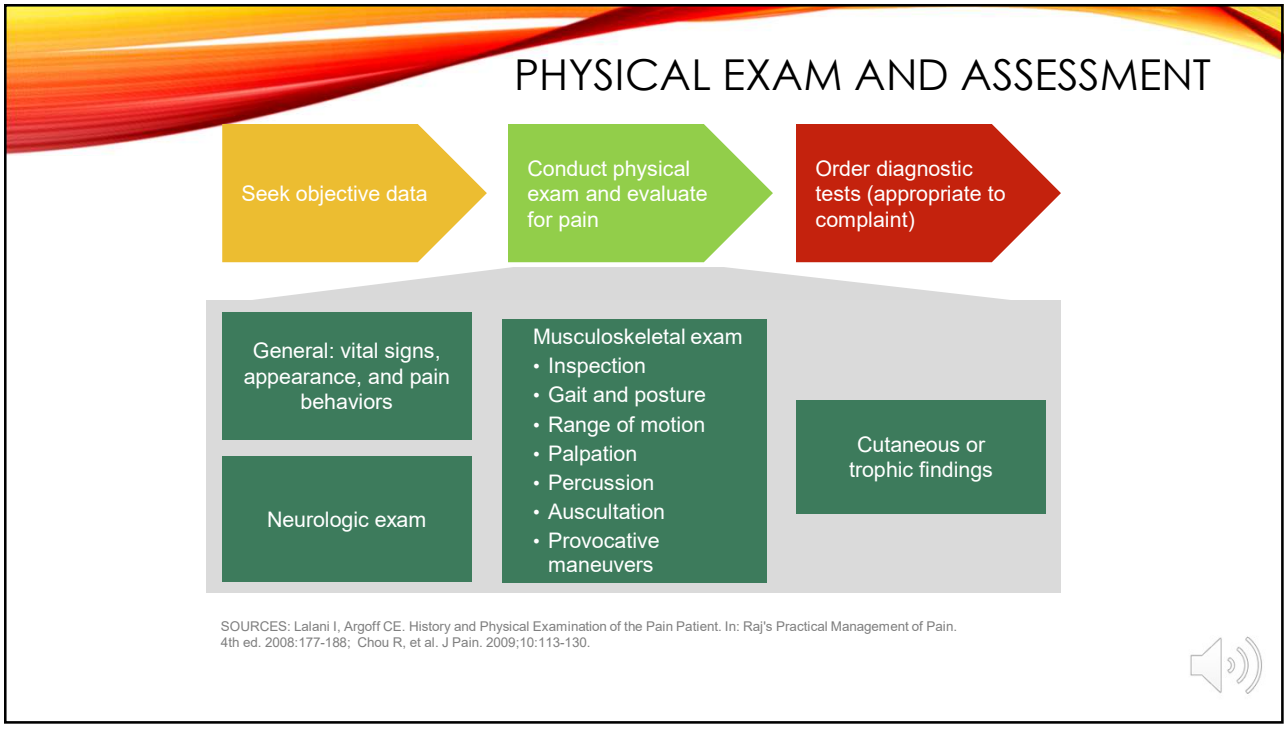
RISK ASSESSMENT, CONT'D

Be knowledgeable about risk factors for opioid abuse	Understand & use addiction or abuse screening tools	Conduct a UDT
• Personal or family Hx of alcohol or drug abuse • Younger age • Presence of psychiatric conditions	• Assess potential risks associated w/ chronic opioid therapy • Manage patients using ER/LA opioids based on risk assessment	• Understand limitations

41


REFERRING HIGH-RISK PATIENTS
Prescribers should
Understand when to appropriately refer high-risk patients to pain management or addiction specialists
Also check your state regulations for requirements
Chou R, et al. J Pain. 2009;10:113-30.

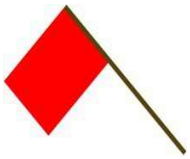
42


PHYSICAL EXAM AND ASSESSMENT
Seek objective data
Conduct physical exam and evaluate for pain
Order diagnostic tests (appropriate to complaint)
General: vital signs, appearance, and pain behaviors
Neurologic exam
Musculoskeletal exam
• Inspection
• Gait and posture
• Range of motion
• Palpation
• Percussion
• Auscultation
• Provocative maneuvers
Cutaneous or trophic findings
SOURCES: Lalani I, Argoff CE. History and Physical Examination of the Pain Patient. In: Raj's Practical Management of Pain. 4th ed. 2008:177-188; Chou R, et al. J Pain. 2009;10:113-130.

43

DON'T MISS THE RED FLAGS

- 'B' symptoms: fever, weight loss, night sweats, malaise
- Sudden focal neurologic symptoms
- Acute worsening of chronic pain
- Failing to thrive

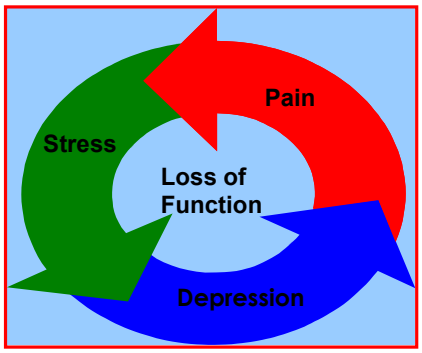


- Suicidal Tendencies

44

EMPATHIZE/PARTNER WITH YOUR PATIENT

"Identification with and understanding of another person's situation or feelings



45

BREAKING THE CYCLE

- "You've been through a lot."
- "My goal is help 'you' manage this better" – EMPOWER the patient to be the locus of control/change
- "Your pain will not go away entirely. Our goal is to get better control of it."
- "Moving, stretching, activity will help you reach your goal."
- "Uncontrolled pain makes mood worse, bad mood makes pain worse – have to work on both."

46

SET FUNCTIONAL GOALS

Functional Status:

- What's a typical day like?
- What's the most active thing you do?
- Do you ever stay in bed all day?
- Do you get any exercise?
- How have these things changed over the past weeks/months/years?

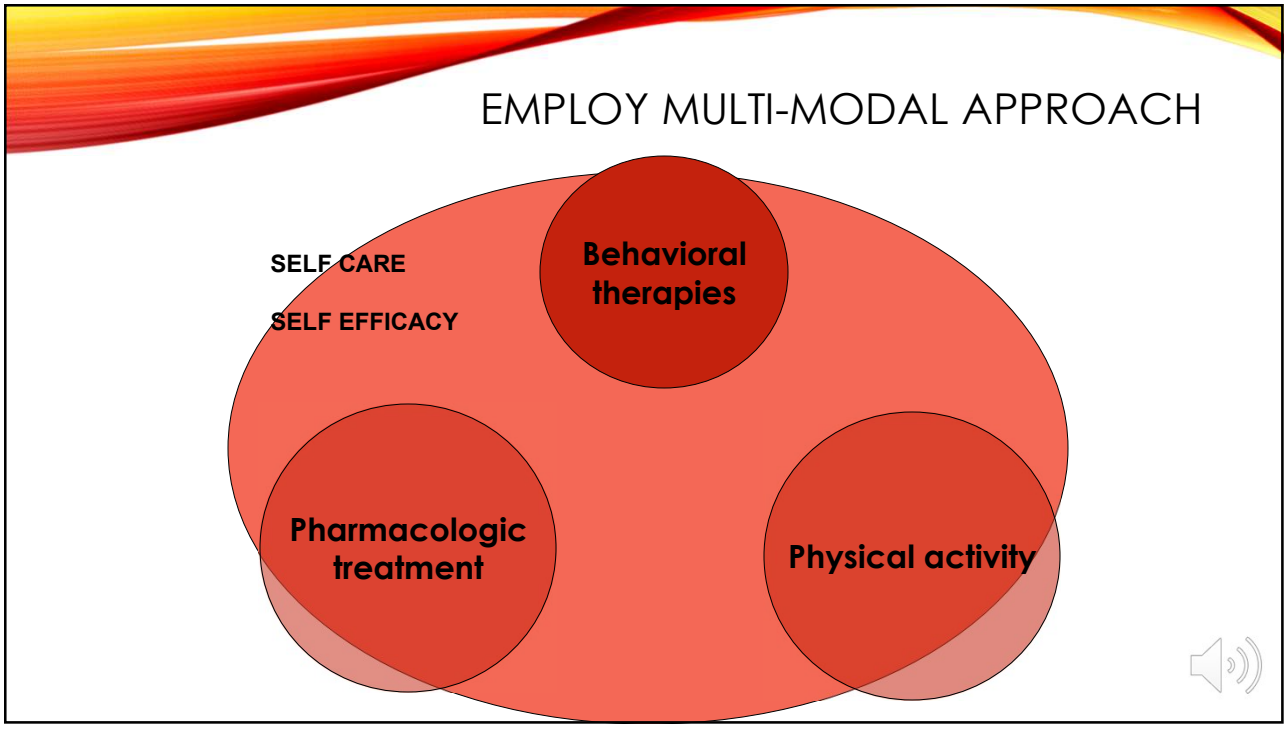
What would you (realistically) like to be able to do?

47

UTILIZE SHARED-DECISION MAKING

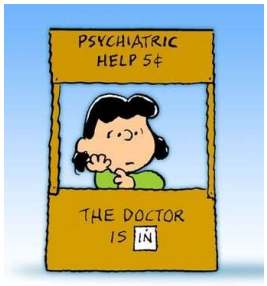
- Uncontrolled chronic pain is found more often in patients who
  - Are passive
  - Catastrophize
  - Perceive an external locus of control
- Counteract these by requiring the patient to make decisions and set goals with you.

48


EMPLOY MULTI-MODAL APPROACH
SELF CARE
SELF EFFICACY
Behavioral therapies
Pharmacologic treatment
Physical activity

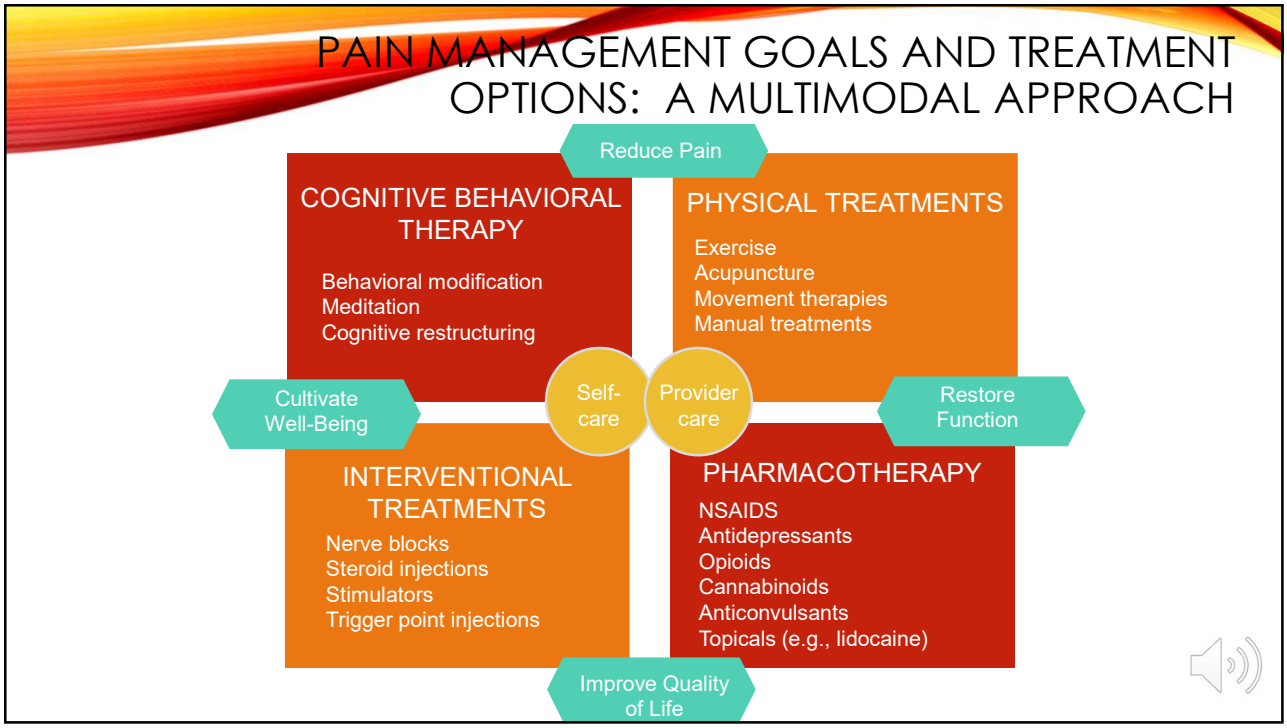
49

COMPONENTS OF A MULTIMODAL TREATMENT PLAN FOR PAIN



50

PAIN MANAGEMENT GOALS AND TREATMENT OPTIONS: A MULTIMODAL APPROACH



51

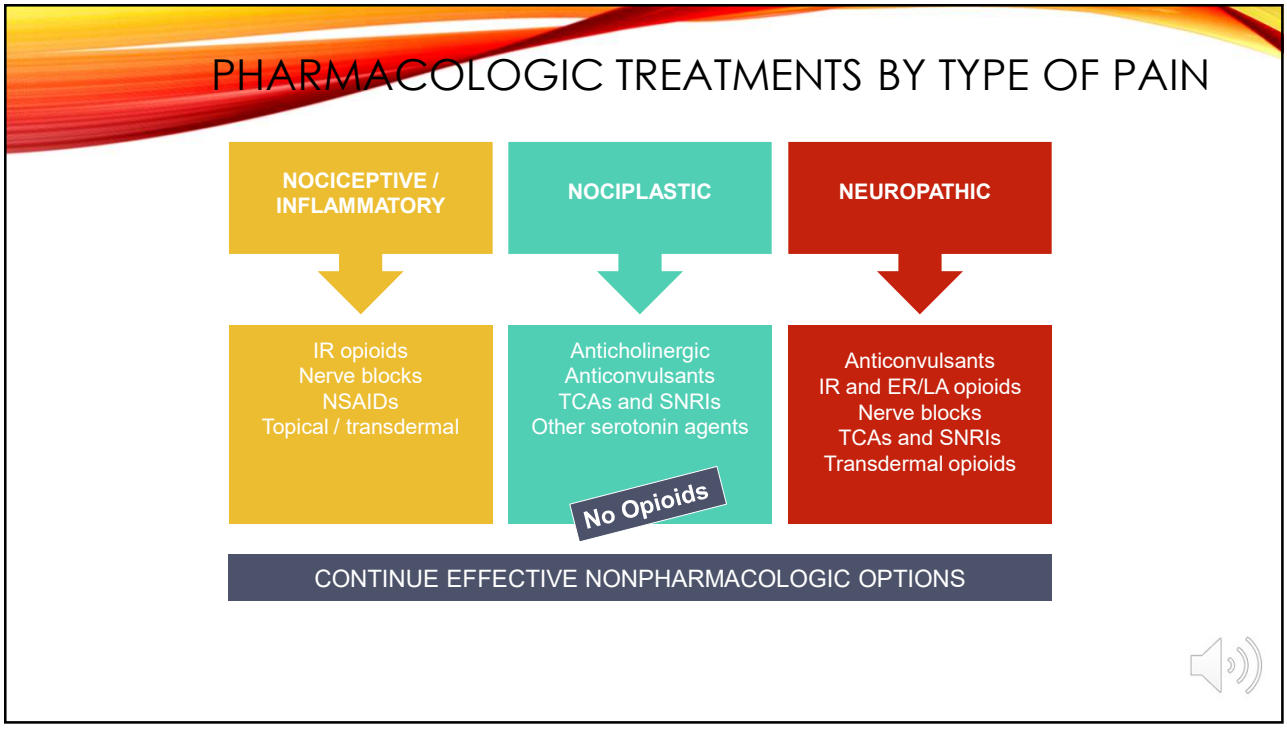
EVIDENCE-BASED NONPHARMACOLOGIC TREATMENTS

What is appropriate for your patient?

- Tai Chi
- Yoga
- CBT and ACT
- Acupuncture
- PT/OT/aquatic
- Mindfulness meditation
- OMT
- Massage therapy
- Chiropractic
- Neuromodulation or surgical approaches (in some situations)

CBT = cognitive behavioral therapy; ACT = acceptance commitment therapy; OMT = osteopathic manipulative therapy

52


PHARMACOLOGIC TREATMENTS BY TYPE OF PAIN
NOCICEPTIVE / INFLAMMATORY
NOCIPLASTIC
NEUROPATHIC
IR opioids
Nerve blocks
NSAIDs
Topical / transdermal
Anticholinergic
Anticonvulsants
TCAs and SNRIs
Other serotonin agents
No Opioids
Anticonvulsants
IR and ER/LA opioids
Nerve blocks
TCAs and SNRIs
Transdermal opioids
CONTINUE EFFECTIVE NONPHARMACOLOGIC OPTIONS

53

PRESCRIBERS OF SA VS LA

Opioids Should Balance:

The benefits of prescribing SA opioids to treat pain

The risks of serious adverse outcomes

Opioid analgesics should be prescribed only by health care professionals who are knowledgeable in the use of potent opioids for the management of pain

54

WHEN USING OPIOIDS, FOLLOW THE HARM/BENEFIT PARADIGM

CONTINUE IF BENEFIT OUTWEIGHS HARM.

DISCONTINUE IF HARM OUTWEIGHS BENEFIT.

Perform frequent monitoring, re-assessment and DOCUMENTATION

55

INITIATING OPIOID TREATMENT: WHEN?

- When functional goals have not been achieved with non-opioid therapies (acetaminophen, ibuprofen, lidocaine, capsaicin, TCAs, gabapentin, physical therapy)
- New patient already on opioids

56

INITIATING OPIOID TREATMENT: WHO?

- Active addiction (alcohol, illicit drugs, prescription medications) is a contraindication
- Risk factors for misuse that should prompt closer follow up but do not necessarily preclude opioid therapy
  - Younger age
  - Personal history of substance abuse
    - Illicit, prescription, alcohol, smoking
  - Family history of substance abuse
  - Legal history (DUI, time in jail)
  - Mental health disorders
- Patient who is showing engagement with process

57

INITIATING OPIOID TREATMENT: HOW?

- Therapeutic trial in the harm/benefit paradigm
  - Set specific, functional goals
  - Refer back to those goals to assess benefit
- Which medication?
  - Long/short acting
  - Strength
  - Formulation
  - Abuse potential

58

SPECIAL CONSIDERATIONS: ELDERLY PATIENTS

Does patient have medical problems that increase risk of opioid-related AEs?

Respiratory depression more likely in elderly, cachectic, or debilitated patients

- Altered PK due to poor fat stores, muscle wasting, or altered clearance
- Monitor closely, particularly when
  - Initiating & titrating ER/LA opioids
  - Given concomitantly w/ other drugs that depress respiration
- Reduce starting dose to 1/3 to 1/2 the usual dosage in debilitated, non-opioid-tolerant patients
- Titrate dose cautiously

Older adults more likely to develop constipation

- Routinely initiate a bowel regimen before it develops

Is patient/caregiver likely to manage opioid therapy responsibly?

American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons. *J Am Geriatr Soc.* 2009;57:1331-46. Chou R, et al. *J Pain.* 2009;10:113-30.

59

SPECIAL CONSIDERATIONS: PREGNANT WOMEN

Managing chronic pain in pregnant women is challenging, & affects both mother and fetus

Potential risks of opioid therapy to the newborn include:

- Low birth weight
- Premature birth
- Hypoxic-ischemic brain injury
- Neonatal death
- Prolonged QT syndrome
- Neonatal opioid withdrawal syndrome

Given these potential risks, clinicians should:

- Counsel women of childbearing potential about risks & benefits of opioid therapy during pregnancy & after delivery
- Encourage minimal/no opioid use during pregnancy, unless potential benefits outweigh risks

If chronic opioid therapy is used during pregnancy, anticipate & manage risks to the patient and newborns

Chou R, et al. *J Pain*. 2009;10:113-30.

60

SPECIAL CONSIDERATIONS: CHILDREN (<18 YEARS)

Safety & effectiveness of most ER/LA opioids unestablished

Pediatric analgesic trials pose challenges
Transdermal fentanyl approved in children aged ≥2 yrs
Oxycodone ER dosing changes for children ≥ 11 yrs (see Unit 6)

Most opioid studies focus on inpatient safety

Opioids are common sources of drug error

Opioid indications are primarily life-limiting conditions

Few children with chronic pain due to non-life-limiting conditions should receive opioids

When prescribing opioids to children:

Consult pediatric palliative care team or pediatric pain specialist or refer to a specialized multidisciplinary pain clinic

Berde CB, et al. *Pediatrics*. 2012;129:354-64. Gregoire MC, et al. *Pain Res Manag* 2013;18:47-50.
Mc Donnell C. *Pain Res Manag*. 2011;16:93-8. Slater ME, et al. *Pain Med*. 2010;11:207-14.

61

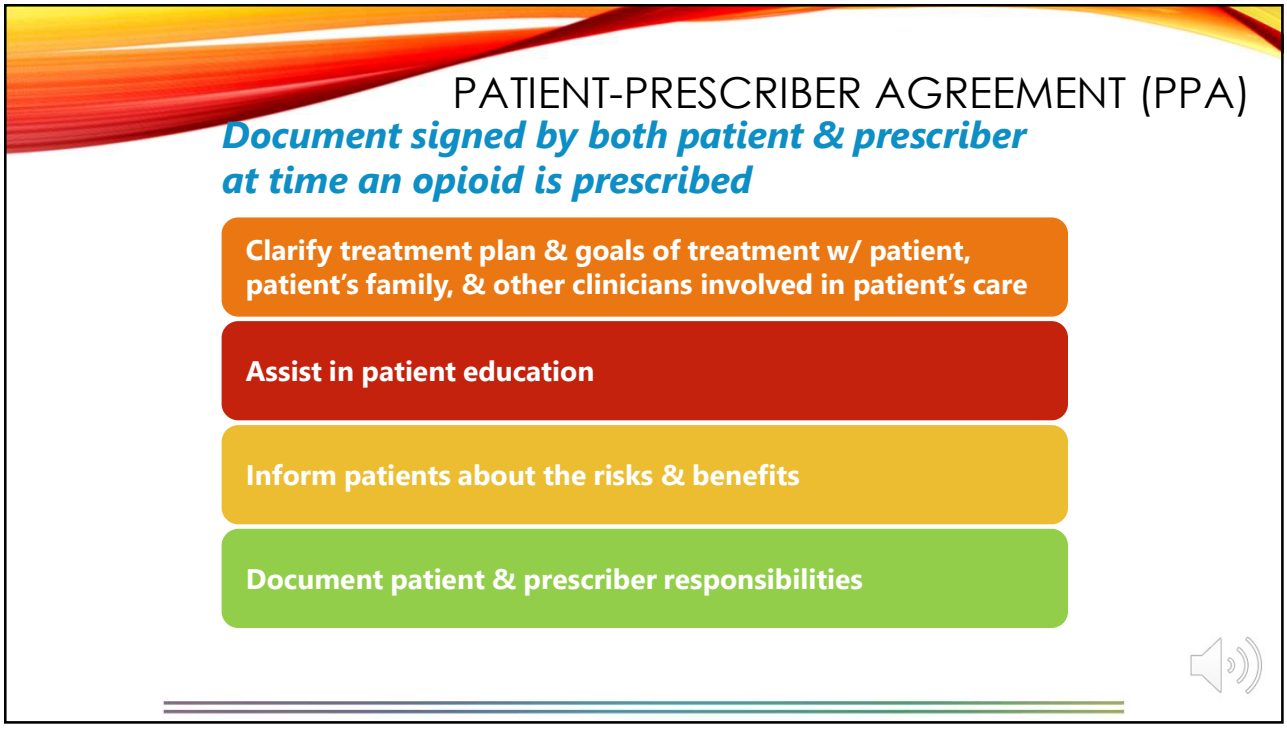
CONSIDER A PPA

Reinforce expectations for appropriate & safe opioid use

- Obtain opioids from a single prescriber
- Fill opioid prescriptions at a designated pharmacy
- Safeguard opioids
  - Safe Storeage
  - Keep locked (e.g., use a medication safe)
  - Do not share or sell medication
- Instructions for disposal when no longer needed

- Commitments to return for follow-up visits
- Comply w/ appropriate monitoring
  - E.g., random UDT & pill counts
- Frequency of prescriptions
- Enumerate behaviors that may lead to opioid discontinuation
- An exit strategy

62


PATIENT-PRESCRIBER AGREEMENT (PPA)
Document signed by both patient & prescriber at time an opioid is prescribed
Clarify treatment plan & goals of treatment w/ patient, patient's family, & other clinicians involved in patient's care
Assist in patient education
Inform patients about the risks & benefits
Document patient & prescriber responsibilities

63

MONITOR PATIENTS DURING OPIOID THERAPY

Therapeutic risks & benefits do not remain static	Identify patients	Periodically assess continued need for opioid analgesic
Affected by change in underlying pain condition, coexisting disease, or psychologic/ social circumstances	• Who are benefiting from opioid therapy • Who might benefit more w/ restructuring of treatment or receiving additional services (e.g., addiction treatment) • Whose benefits from treatment are outweighed by risks	Re-evaluate underlying medical condition if clinical presentation changes

64

MONITOR PATIENTS DURING OPIOID THERAPY, CONT

Periodically evaluate:

- Pain control
  - Document pain intensity, pattern, & effects
- Functional outcomes
  - Document level of functioning
  - Assess progress toward achieving therapeutic goals
- Health-related QOL
- AE frequency & intensity
- Adherence to prescribed therapies

Patients requiring more frequent monitoring include:

- High-risk patients
- Patients taking high opioid doses

65

ANTICIPATE & TREAT COMMON AE

Constipation — most common AE; does not resolve with time

- Initiate a bowel regimen before constipation develops
- Increase fluid & fiber intake, stool softeners, & laxatives
- Opioid antagonists may help prevent/treat opioid-induced bowel dysfunction

Nausea & vomiting — tend to diminish over days or weeks

Oral & rectal antiemetic therapies as needed

Drowsiness & sedation — tend to wane over time

Counsel patients about driving, work & home safety as well as risks of concomitant exposure to other drugs & substances w/ sedating effects

Pruritus & myoclonus — tend to diminish over days or weeks

Treatment strategies for either condition largely anecdotal

Chou R, et al. J Pain. 2009;10:113–30

66

MONITOR ADHERENCE AND ABERRANT BEHAVIOR

Routinely monitor patient adherence to treatment plan

- Recognize & document aberrant drug-related behavior
  - In addition to patient self-report also use:
    - State PDMPs, where available
    - UDT
      - Positive for nonprescribed drugs
      - Positive for illicit substance
      - Negative for prescribed opioid
- Family member or caregiver interviews
- Monitoring tools such as the COMM, PADT, PMQ, or PDUQ
- Medication reconciliation (e.g., pill counts)

PADT=Pain Assessment & Documentation Tool

67

ADDRESS ABERRANT DRUG-RELATED BEHAVIOR

Behavior outside the boundaries of agreed-on treatment plan:

Behaviors that are **less** indicative of aberrancy	Behaviors that are **more** indicative of aberrancy
Unsanctioned dose escalations or other noncompliance w/ therapy on 1 or 2 occasions	**Multiple dose escalations or other noncompliance w/ therapy despite warnings**
Unapproved use of the drug to treat another symptom	**Prescription forgery**
Openly acquiring similar drugs from other medical sources	**Obtaining prescription drugs from nonmedical sources**

68

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS)

49 states have an operational PDMP
DC has enacted PDMP legislation, not yet operational
1 state **Missouri** ***has no legislation***

Individual state laws determine

- Who has access to PDMP information
- Which drug schedules are monitored
- Which agency administers the PDMP
- Whether prescribers are required to register w/ the PDMP
- Whether prescribers are required to access PDMP information in certain circumstances
- Whether unsolicited PDMP reports are sent to prescribers

69

PDMP BENEFITS

Record of a patient's controlled substance prescriptions	Provide warnings of potential misuse/abuse
• Some are available online 24/7 • Opportunity to discuss w/ patient	• Existing prescriptions not reported by patient • Multiple prescribers/pharmacies • Drugs that increase overdose risk when taken together • Patient pays for drugs of abuse w/ cash

Prescribers can check their own prescribing Hx

70

PDMP UNSOLICITED PATIENT THRESHOLD REPORTS

Reports automatically generated on patients who cross certain thresholds when filling prescriptions. Available in some states.

E-mailed to prescribers to whom prescriptions were attributed

Prescribers review records to confirm it is your patient & you wrote the prescription(s) attributed to you

If inaccurate, contact PDMP

If you wrote the prescription(s), patient safety may dictate need to discuss the patient w/ other prescribers listed on report

- Decide who will continue to prescribe for the patient & who might address drug abuse concerns.

71

FEDERAL & STATE REGULATIONS

Comply w/ federal & state laws & regulations
that govern the use of opioid therapy for pain

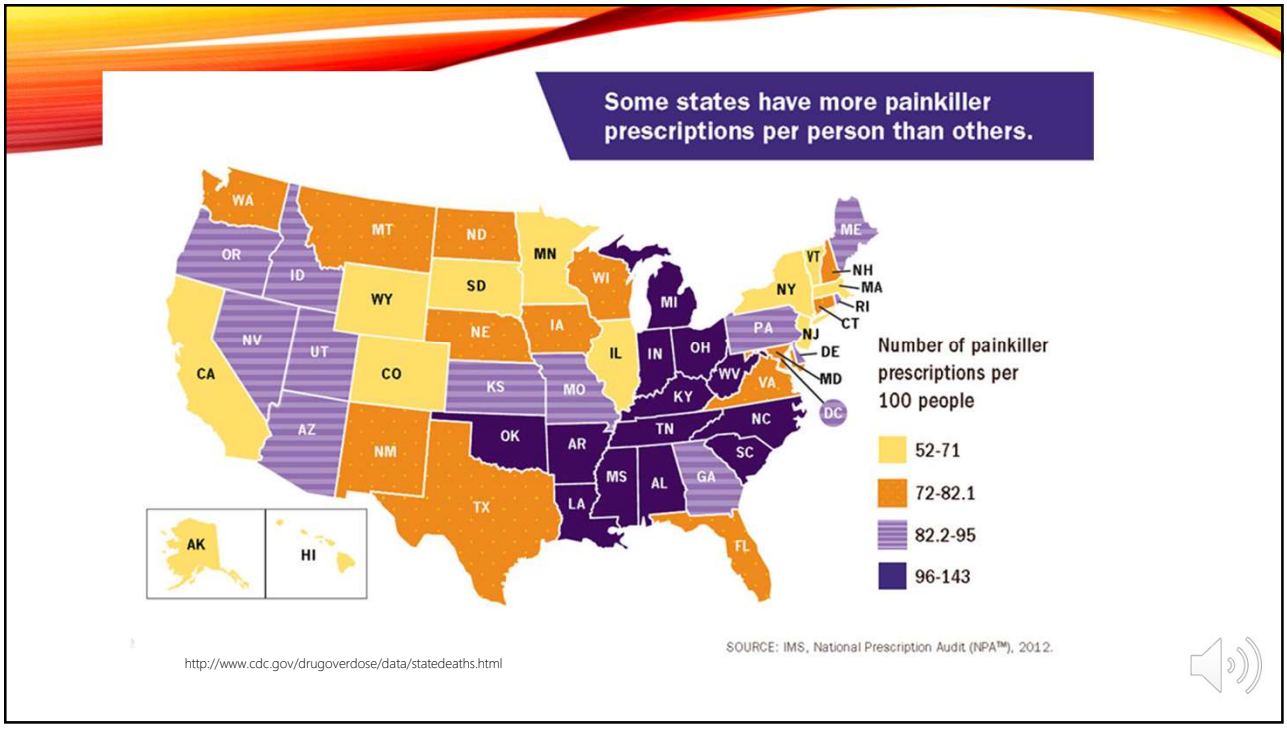
Federal

- Code of Federal Regulations, Title 21 Section 1306: rules governing the issuance & filling of prescriptions pursuant to section 309 of the Act (21 USC 829)
  - www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm
- United States Code (USC) - Controlled Substances Act, Title 21, Section 829: prescriptions
  - www.deadiversion.usdoj.gov/21cfr/21usc/829.htm

State

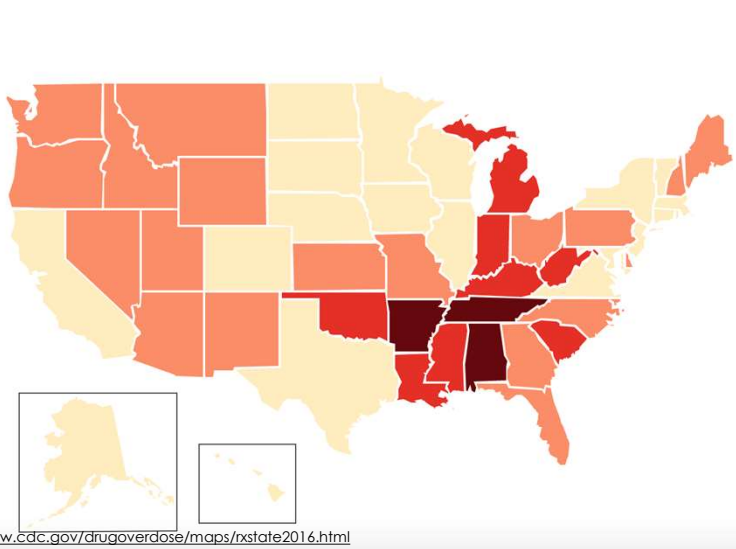
- Database of state statutes, regulations, & policies for pain management
  - www.medscape.com/resource/pain/opioid-policies
  - www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management

72


Some states have more painkiller prescriptions per person than others.
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MS
MI
IN
KY
TN
AL
OH
WV
GA
FL
SC
NC
VA
PA
NY
ME
VT
NH
MA
RI
CT
NJ
DE
MD
DC
AK
HI
Number of painkiller prescriptions per 100 people
52-71
72-82.1
82.2-95
96-143
SOURCE: IMS, National Prescription Audit (NPA™), 2012.
http://www.cdc.gov/drugoverdose/data/statedeaths.html

73

U.S. STATE PRESCRIBING RATES, 2016



74

CO-PRESCRIBING NALOXONE

Naloxone:

- An opioid antagonist
- Reverses acute opioid-induced respiratory depression but will also cause withdrawal and reverse analgesia
- Administered intramuscularly and subcutaneously
- Intranasal formulation currently under consideration with the FDA

Available as:

- Naloxone kit (w/ syringes, needles)
- EVZIO™ (naloxone HCl) auto-injector
- NARCAN nasal spray

What to do:

- Encourage patients to create an 'overdose plan'
- Involve and train family, friends, partners and/or caregivers
- Check expiration dates and keep a viable dose on hand
- In the event of known or suspected overdose, administer Naloxone and **call 911.**

75

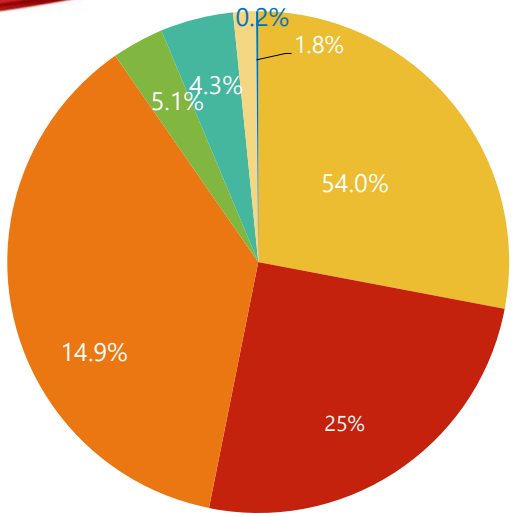
PROTECTING THE COMMUNITY

Caution Patients

- **Sharing ER/LA opioids w/ others may cause them to have serious AEs**
  - Including death
- **Selling or giving away ER/LA opioids is against the law**
- **Store medication safely and securely**
- **Protect ER/LA opioids from theft**
- **Dispose of any ER/LA opioids when no longer needed**
  - Read product-specific disposal information included w/ ER/LA opioid

76

(2011-2012)

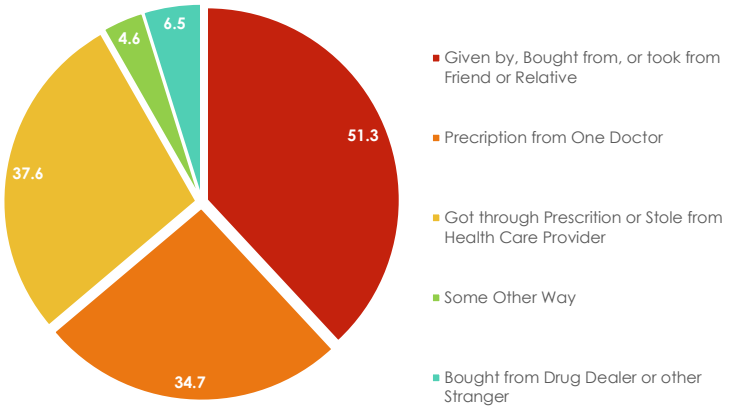


Free: friend/relative
1 doctor
Bought/took: friend/relative
Other
Drug dealer/stranger
>1 doctor
Bought on Internet

SAMHSA. (2013). *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings.* NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD.

77

SOURCE OF MOST RECENT RX OPIOIDS AMONG PAST-YEAR USERS 2018



Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health. August 2019

78

RX OPIOID DISPOSAL

New "Disposal Act" expands ways for patients to dispose of unwanted/expired opioids

Decreases amount of opioids introduced into the environment, particularly into water

Collection receptacles
Call DEA Registration Call Center at **1-800-882-9539** to find a local collection receptacle

Mail-back packages
Obtained from authorized collectors

Local take-back events
- Conducted by Federal, State, tribal, or local law enforcement
- Partnering w/ community groups

Voluntarily maintained by:
- Law enforcement
- Authorized collectors, including:
  - Manufacturer
  - Distributer
  - Reverse distributer
  - Retail or hospital/clinic pharmacy
    - Including long-term care facilities

DEA National Prescription Drug Take-Back Day on Twice yearly fall and spring

DEA. *Federal Register*. 2014; 79(174):53520-70. Final Rule. Disposal of Controlled Substances. [Docket No. DEA-316] www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf
DEA. Disposal Act: General Public Fact Sheet. www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public.pdf

79

OTHER METHODS OF OPIOID DISPOSAL

If collection receptacle, mail-back program, or take-back event unavailable, throw out in household trash

- Take drugs out of original containers
- Mix w/ undesirable substance, e.g., used coffee grounds or kitty litter
  - Less appealing to children/pets, & unrecognizable to people who intentionally go through your trash
- Place in sealable bag, can, or other container
  - Prevent leaking or breaking out of garbage bag
- Before throwing out a medicine container
  - Scratch out identifying info on label

80

PRESCRIPTION DRUG DISPOSAL

FDA lists especially harmful medicines –
in some cases fatal w/ just 1 dose –
if taken by someone other than the patient
- Instruct patients to check medication guide

Flush down sink/toilet if no collection receptacle, mail-back program, or take-back event available

- **As soon as they are no longer needed**
  - So cannot be accidentally taken by children, pets, or others
- **Includes transdermal adhesive skin patches**
  - Used patch worn for 3d still contains enough opioid to harm/kill a child
  - Dispose of used patches immediately after removing from skin
- **Fold patch in half so sticky sides meet, then flush down toilet**
- **Do NOT place used or unneeded patches in household trash**
  - Exception is Butrans: can seal in Patch-Disposal Unit provided & dispose of in the trash

81

INCREASING OPIOID MISUSE, MORBIDITY, MORTALITY

- ↑incidence misuse[1,2]
- ↑admissions for addiction treatment[3]
- ↑ED visits[4]
- ↑overdose deaths[5]

1. MTF; 2. NSDUH; 3. TEDS; 4. DAWN; 5. CDC

82

STAY IN THE HARM/BENEFIT PARADIGM

- Explain how patient's behavior or the outcome of the treatment is not in line with the treatment agreement.
- Firm but empathic -- you will still work with pt on pain treatment and primary care
- Pt is not bad; treatment is not effective, not safe, not appropriate.
- Benefits no longer outweighing harms. "Cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good."

83

CASE

57 M w/ chronic low back pain for 15 years after being thrown out of a jeep

- After 8 weeks pt still experiencing significant pain that is negatively affecting function; you start opioids (MSContin 15 mg TID titrated to 30 mg TID) to good effect: improved pain and function
- One month later, routine UDT positive for cocaine

84

WHAT WAS DONE/SHOULD HAVE BEEN DONE IN ADVANCE

- Comprehensive approach to high-quality management of chronic pain
- Treatment agreement: discussion with pt about risk and benefits
- "Fair warning" that UDTs would be done
- "Fair warning" that + UDT might mean discontinuing opioids
- Practice-wide decision about how treatment agreement violations handled

85

WHAT TO DO NOW?

- Get GC/MS confirmation of any unexpected result
- (if confirmed) Talk to patient, reveal result of test, ask him why he used
- Show empathy but do not allow patient to dispute results
- Show empathy but do not allow patient to shift blame: ‘I did it because my pain was out of control/you are not treating my pain’
- Based on practice policy, either begin opioid taper or ‘second chance’ with close monitoring (1-2 week follow up with UDT)
- Consider addiction referral based on your assessment

86

OPIOID MANAGEMENT: SUMMARY

- If prescribed, opioids for chronic pain must be part of a comprehensive pain management plan
- Treatment agreements are useful to keep everyone on the same page
- Patients must be monitored for the 5 As
- Know the tools available to you for monitoring and how to use them
- Opioids should be continued when effective and safe, discontinued if ineffective or unsafe
- Use this harm/benefit paradigm to help you communicate with patient
- Document

87

For questions please feel free to contact me at:
drivenb1@jhmi.edu

88