Proper Prescribing of Controlled Substances in Tennessee

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DeBusk College *of* Osteopathic Medicine

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Disclosures

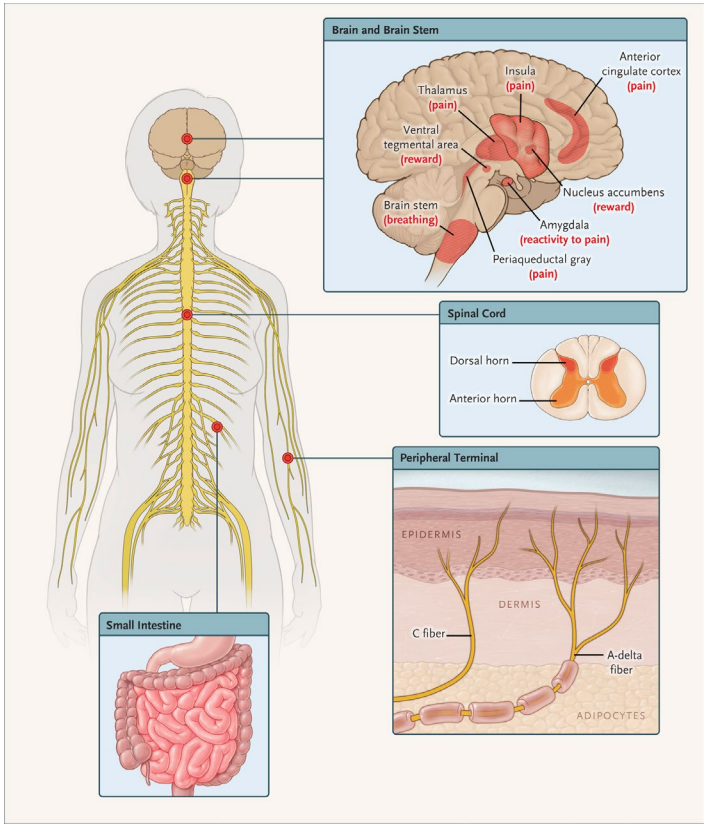
- Consultant - NEVRO medical device company
- No commercial support for this presentation
- No off label use presented
- No conflicts of interest for the purposes of this presentation

Objectives

- Present the scope of opiate crisis
- Compare and contrast addiction, physical dependence, tolerance, pseudoaddiction
- Documentation requirements regarding controlled substances
- Review TN requirements regarding controlled substances
- Understand how medical prescriptions have impacted the opiate crisis

Opiates and the rise of the pandemic[1]

- Mechanism of action
  - Agonist at the mu receptor
    - Augmenting pain perception
      - Periaqueductal gray
      - Thalamus
      - Cingulate cortex
      - Insula
    - Emotional responses
      - Amygdala
    - Reward centers
      - Ventral tegmental area
      - Nucleus accumbent



History of Pain Treatment in the US[2]

- 1900-1920
  - Governmental reductions in the use of analgesics
    - Increased use in injured Civil War veterans
    - Morphine
    - Heroin
- 1940-1960
  - Disabled veterans rise in the US
    - 0.5 million to 3 million
  - 1960-70's
    - Gate control theory of pain
    - Pain multifaceted
    - Controlled Substances Act moved drugs to schedule 1
      - Heroin
      - LSD
      - Marijuana

History of Pain Treatment in the US[2]

- 1980's
  - Subjective evaluation of pain moved to objective
  - 500K people removed from disability
- 1990's
  - Move from chronic pain use to acute
  - APS '95, VA '99, Joint commission '01
    - Pain is the fifth vital sign
  - Institute of Medicine
    - Pt satisfaction is a proxy for experience
    - Satisfaction required relief of pain even if experience was rated as acceptable
  - HCAHPS
    - Pt satisfaction as a proxy for quality
    - 3 questions related to pain in inpatients

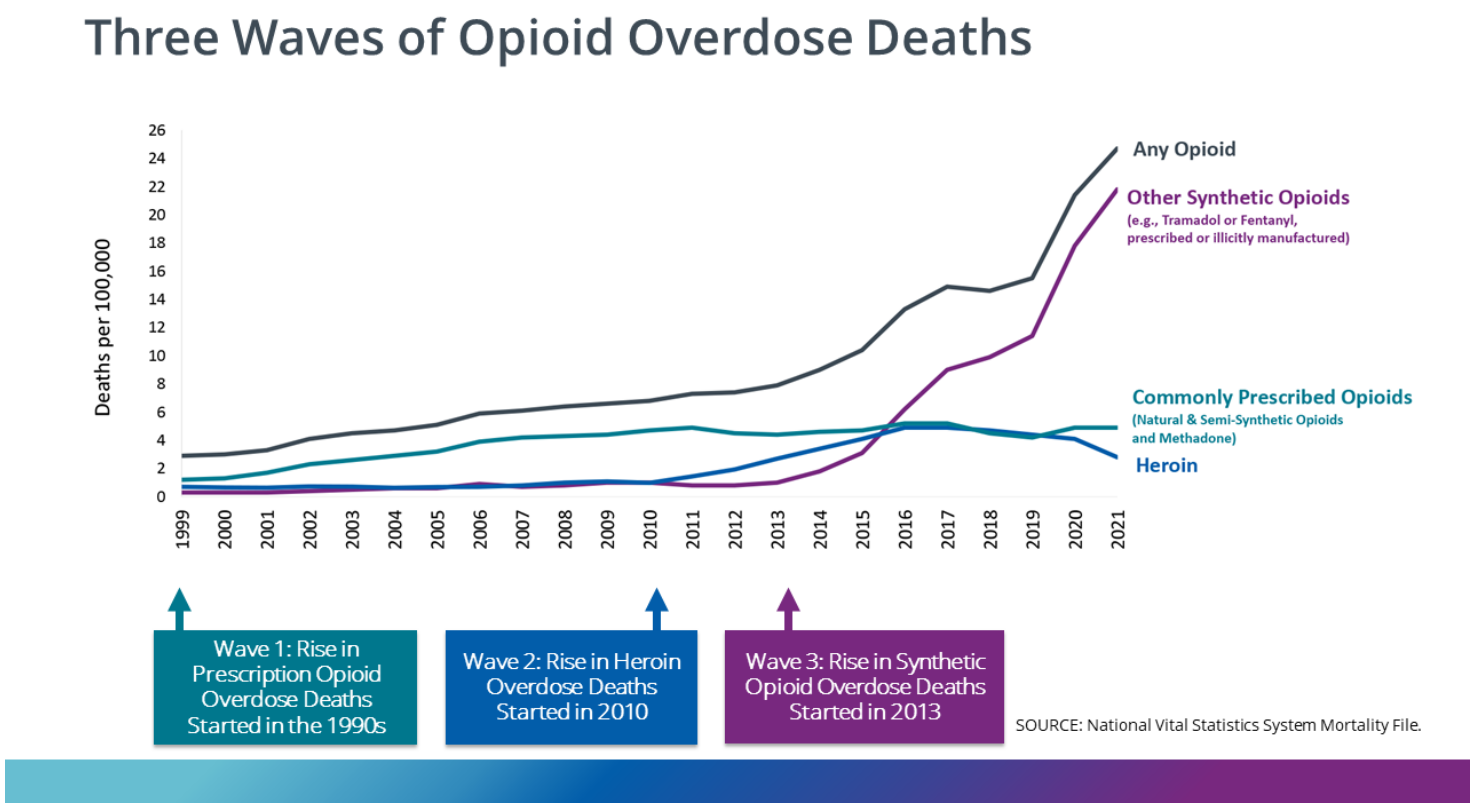
History of Pain Treatment in the US[2]

- 1995 Purdue Pharma approval for Oxycontin
- 1991-2011
  - Prescription opiates tripled
  - 2010 Abuse deterrent Oxycontin release
    - Precipitous rise in the use of Heroin

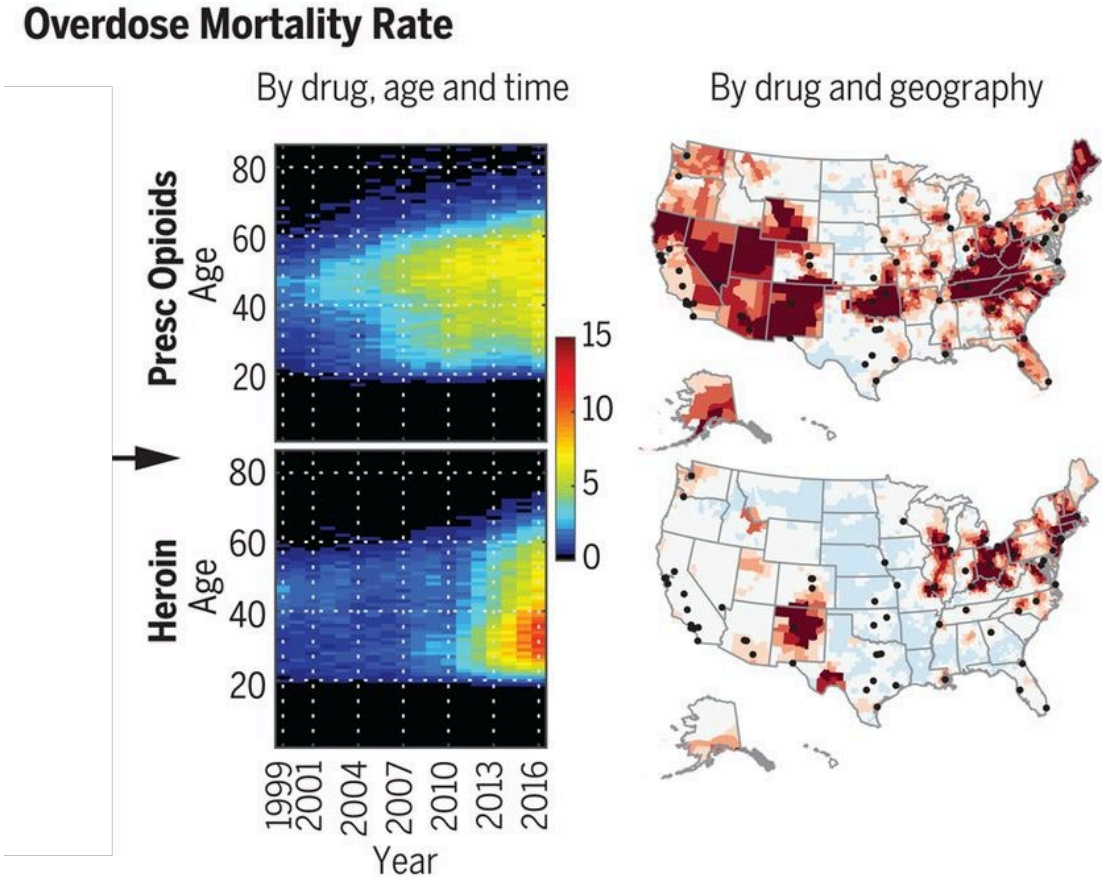
Escalating Problem[3]

- Mortality rate from drug overdose in ’21 was over 6 times the rate in ’99
- Drug overdose deaths increased 16% from ’20 to ’21
- Over 75% of the 107k overdose deaths in ’21 involved an opioid
- ’20-’21
  - Opioid-involved death rates increased 15%
  - Rx opioid-involved death rates remained the same
  - Heroin-involved death rates decreased 32%
  - Synthetic opioid-involved death rates increased 22%

Escalating Problem[3]



Tennessee at the epicenter



Tolerance vs Physical Dependence[1]

- Tolerance
  - Decrease in opioid potency with repeated administration
  - Can lead to 10 times dose to maintain analgesia
  - Analgesic and euphoric tolerance develops more quickly than respiratory depression
  - Rate not similar among opioids and no objective way to determine

Tolerance vs Physical Dependence[1]

- Physical Dependence
  - Physiologic response to the abrupt discontinuation of opioids
    - piloerection (quitting cold turkey)
    - chills
    - insomnia
    - N/V/D
    - muscle aches
    - lower extremity myoclonus (kicking the habit)
    - lasts 1-14 days

Addiction vs Pseudoaddiction[4,5]

- Addiction
  - A chronic, relapsing psychological disorder characterized by
    - compulsive drug seeking
    - use despite adverse consequences
      - physical
      - psychological
      - financial
      - legal
      - social

Addiction vs Pseudoaddiction[4,5]

- Addiction cont
  - changes to brain circuitry involved in
    - Reward
    - Stress
    - Self control
  - Changes persist long after a person has stopped taking drugs
  - preoccupation with taking drugs persists despite adequate analgesia

Addiction vs Pseudoaddiction[4,5]

- Psdudoaddiction
  - Iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management
    - Many of the features of addiction
    - Use of multiple providers
    - preoccupation with use
    - frequent ER visits
    - use despite negative consequences
  - All features of addiction disappear once adequate analgesia achieved

Clinical Example

- 76 yo with chronic osteoarthritic knee pain. Presents to ER in Arizona while on vacation. States that he forgot his pain medications at home.
  - States the only thing that has worked for him is percocet
  - Demanding of staff for his medications
  - HR 110, diarrhea, insomnia

Clinical Example

- 47 yo with chronic radicular LBP treated with ER and IR oxycodone for years.
  - Poor performance reviews at work
  - Spouse % being more aloof and not there during family time
  - Last UDT was positive for norfentanyl and hydrocodone

Clinical Example

- 36 yo with fibromyalgia and Interstitial cystitis
  - Calls daily for increases in pain medications
  - hostile with clinic staff
  - poor work performance
  - poor relationships at home being rude and short with family
  - Previous month seen in ER for overdose on methamphetamine
  - s/p bladder stim one week and all behavior has stopped

Clinical Example

- 67 yo with chronic LBP secondary to spinal stenosis. 75mcg/hr fentanyl patch with 10mg percocet for BTP four times per day for years.
  - s/p laminectomy day 2 on the general floor
  - fentanyl patch continued during hospital stay
  - getting 2mg hydromorphone IV PCA q 30min
  - Respiratory code on the floor with RR 2
  - Nursing notes show VAS scores 9/10 and having to wake for assessments

Opioid Management Documentation in the Outpatient Setting

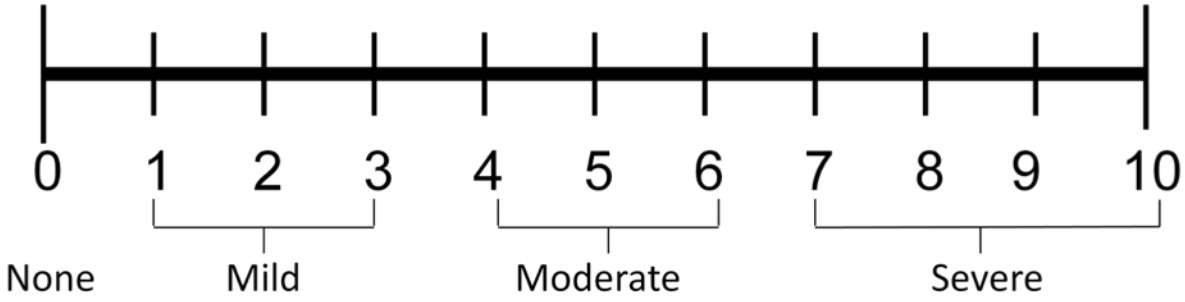
- Specifics in TN code to follow
- Acute setting fairly simple
  - Dx appropriate for narcotic rx
  - short term course
  - No contraindications
    - morphine/codeine in kidney failure pts
    - able to take pills

Chronic Setting

- Becomes important when pain persists beyond the acute phase
  - Documentation of the 4/5 A's
    - Analgesia
    - Activity
    - Adverse Events
    - Aberrant Behavior
    - Affect*

Analgesia

- Some measure of relief of the pain from your treatment
  - NRS 1-10



Analgesia

- Adult Non Verbal Pain Scale

Categories	0	1	2
Face	No particular expression or smile.	Occasional grimace, tearing, frowning, wrinkled forehead.	Frequent grimace, tearing, frowning, wrinkled forehead.
Activity (movement)	Lying quietly, normal position.	Seeking attention through movement or slow, cautious movement.	Restless, excessive activity and/or withdrawal reflexes.
Guarding	Lying quietly, no positioning of hands over areas of body.	Splinting areas of the body, tense.	Rigid, stiff.
Physiology (vital signs)	Stable vital signs	Change in any of the following: * SBP > 20 mm Hg. * HR > 20/minute.	Change in any of the following: * SBP > 30 mm Hg. * HR > 25/minute.
Respiratory	Baseline RR/SpO_2 Compliant with ventilator	RR > 10 above baseline, or 5% ↓SpO_2 mild asynchrony with ventilator	RR > 20 above baseline, or 10% ↓SpO_2 severe asynchrony with ventilator

Odhner, M., Wegman, D., Freeland, N., Steinmetz, A., & Ingersoll, G. L. (2003). Assessing Pain Control in Nonverbal Critically Ill Adults. *Dimensions of Critical Care Nursing*, *22*(6), 260–267. https://doi.org/10.1097/00003465-200311000-00010

Analgesia

- Behavioral Pain Scale

Table 1. Behavioral pain scale

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing but tolerating ventilation for most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4

Payen JF, Bru O, Bosson JL, Lagrasta A, Novel E, et al. Assessing pain in critically ill sedated patients by using a behavioral pain scale. Crit Care Med. 2001; 29:2258-2263.

Analgesia Pediatrics

- Faces scale

https://wongbakerfaces.org/

Activity

- Some measure of the functional gains or loses during treatment
- Helpful to have the pt state their goals
  - Gets provider and pt on the same page
  - Helpful for setting expectations
  - Adds other dimension of treatment effects

Table 2.

Indiana Polyclinic Combined Function Scale

How is your overall daily function impacted by your pain?

0	**No Interference with Activity (Completely Independent)** - Can complete daily activities; work/volunteer daily; active participant in family/social life; active on weekends, normal quality of life, complete household & yard work
1	**Slightly Modified Activity** - Can take part in family and social life; can work/volunteer 8+hours daily; some weekend activity, complete household & yard work with increased fatigue but independent
2	**Minimal Limitations** - Can work/volunteer a few hours daily; active 5+ hours/day; can plan & keep 1-2 social events during evenings/weekends; can complete household/yard work with some strain, may need help w/ select activities
3	**Mild Limitations** - Can work in or out of home for few hours a week; active for 3-5 hours daily; can complete ADL's and household chores with help needed 15-25% of the time
4	**Mild to Moderate Limitations** - Can complete some more complex household tasks with help needed 30-45% of the time; Occasional missed work/volunteer; limited social activities
5	**Moderate Limitations** - Can leave the house only 1-2 times a week (unrelated to work or important appointments); can complete daily hygiene; can complete some daily household tasks with help needed half (50%) of the time
6	**Moderate to Severe Limitations** - Can complete only simple household tasks with help needed 60% of the time, unable to grocery shop; can talk to others on phone; can only leave house for important appointments/emergencies
7	**Severe Limitations** - In bed half the day almost every day; can get dressed, shower, watch TV, make phone calls & do minimal household tasks (needs help 70% of the time); leaves home only for emergencies, usually with assistance
8	**Severe to Maximal Limitations** - In bed more than half the day every day, some contact with others in the home; limited self-care activity (needs help 80% of the time); leaves home only for emergencies and only with assistance
9	**Maximal Limitations** - In bed most of the day every day; limited contact with others; minimal to no self-care activity (help needed 90% of the time), completely home bound
10	**Totally Dependent** - Unable to get out of bed all day every day; no self-care; no function possible without assistance

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Global Pain Scale

Global Pain Scale

Instructions: For each question, please indicate your level of pain by circling a number from 0 to 10.

YOUR PAIN:

My **current** pain is	**No pain:**	0	1	2	3	4	5	6	7	8	9	10 **:Extreme pain**
During the *past week*, the **best** my pain has been is	**No pain:**	0	1	2	3	4	5	6	7	8	9	10 **:Extreme pain**
During the *past week*, the **worst** my pain has been is	**No pain:**	0	1	2	3	4	5	6	7	8	9	10 **:Extreme pain**
During the *past week*, my **average** pain has been	**No pain:**	0	1	2	3	4	5	6	7	8	9	10 **:Extreme pain**
During the *past 3 months*, my **average** pain has been	**No pain:**	0	1	2	3	4	5	6	7	8	9	10 **:Extreme pain**

YOUR FEELINGS: During the past week I have felt:

Afraid	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Depressed	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Tired	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Anxious	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Stressed	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**

YOUR CLINICAL OUTCOMES: During the past week:

I had trouble sleeping	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
I had trouble feeling comfortable	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
I was less independent	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
I was unable to work (or perform normal tasks)	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
I needed to take more medication….	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**

YOUR ACTIVITIES: During the past week I was **NOT** able to:

Go to the store	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Do chores in my home	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Enjoy my friends and family	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Exercise (including walking)	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**
Participate in my favorite hobbies	**Strongly Disagree:**	0	1	2	3	4	5	6	7	8	9	10 **:Strongly Agree**

Scoring: Add up the total score and divide by 2. Each subset is worth 25 points. The maximum total score is 100.

PAIN DOCTOR
WE CHANGE LIVES HERE

paindoctor.com

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ODI

OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE

Instructions: this questionnaire has been designed to give us information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only the ONE box which applies to you at this time. We realize you may consider 2 of the statements in any section may relate to you, but please mark the box which most closely describes your current condition.

1. PAIN INTENSITY
- ☐ I can tolerate the pain I have without having to use pain killers
- ☐ The pain is bad but I manage without taking pain killers
- ☐ Pain killers give complete relief from pain
- ☐ Pain killers give moderate relief from pain
- ☐ Pain killers give very little relief from pain
- ☐ Pain killers have no effect on the pain and I do not use them

2. PERSONAL CARE (e.g. Washing, Dressing)
- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self care
- ☐ I don't get dressed, I was with difficulty and stay in bed

3. LIFTING
- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, i.e. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

4. WALKING
- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me walking more than one mile
- ☐ Pain prevents me walking more than ½ mile
- ☐ Pain prevents me walking more than ¼ mile
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time and have to crawl to the toilet

5. SITTING
- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favorite chair as long as I like
- ☐ Pain prevents me from sitting more than one hour
- ☐ Pain prevents me from sitting more than ½ hour
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

6. STANDING
- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than one hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

7. SLEEPING
- ☐ Pain does not prevent me from sleeping well
- ☐ I can sleep well only by using medication
- ☐ Even when I take medication, I have less than 6 hrs sleep
- ☐ Even when I take medication, I have less than 4 hrs sleep
- ☐ Even when I take medication, I have less than 2 hrs sleep
- ☐ Pain prevents me from sleeping at all

8. SOCIAL LIFE
- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, i.e. dancing, etc.
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

9. TRAVELLING
- ☐ I can travel anywhere without extra pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad, but I manage journeys over 2 hours
- ☐ Pain restricts me to journeys of less than 1 hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from traveling except to the doctor or hospital

10. EMPLOYMENT/ HOMEMAKING
- ☐ My normal homemaking/ job activities do not cause pain.
- ☐ My normal homemaking/ job activities increase my pain, but I can still perform all that is required of me.
- ☐ I can perform most of my homemaking/ job duties, but pain prevents me from performing more physically stressful activities (e.g. lifting, vacuuming)
- ☐ Pain prevents me from doing anything but light duties.
- ☐ Pain prevents me from doing even light duties.
- ☐ Pain prevents me from performing any job or homemaking chores.

Adverse Effects

- Side effects of narcotics
  - NVD
  - Somnolence
  - decreased appetite
  - blurred vision
  - confusion
  - fainting

Aberrant Behavior

- Assessment of compliance to therapy
  - Check the Prescription Drug Monitoring Program (PDMP)
  - Check the Urine Drug Screen and Urine Drug Test
  - Assessment of opiate risk

PDMP

- Able to check for multiple prescriptions and providers
  - Do the prescriptions overlap
  - Using other controlled substances
  - Does the pt's story and urine match the refill dates

UDS/UDT

- UDS
  - quick assessment
  - High negative predictive value
- UDT
  - qualitative assessment
  - takes time
  - gold standard
  - High positive predictive value
  - Assesses for parent and metabolites of molecule

Opiate Risk Assessments

- Opiate Risk Tool
  - Easy and quick
- Screener and Opioid Assessment for Patients with Pain SOAPP
  - longer
  - greater sensitivity/specificity
- Diagnosis, Intractability, Risk, and Efficacy Score
  - clinician administered

Clinical Examples

- Pt prescribed hydrocodone 10mg QID
  - PDMP filling every month on the month
  - Pill counts correct
  - UDS pos for opiates
  - UDT pos for hydrocodone no metabolites
  - previous UDT pos for both parent and metabolites

Clinical Example

- Pt prescribed hydrocodone 10mg TID
  - PDMP filling every 8 weeks
  - Pill counts correct
  - UDS pos for opiates
  - UDT pos for metabolites no parent hydrocodone
  - previous UDT pos for both parent and metabolites

Clinical Example

- Pt prescribed hydrocodone 10mg QID
  - PDMP filling every month on the month except comes in 3 days after refill due
  - no pills to count
  - UDS negative
  - UDT negative for parent and metabolites
  - previous UDT pos for both parent and metabolites

Affect

- Not universally accepted 5th A
- Pt being evasive with their history
- Pt acting defensive
- Pt argumentative
- Reaping praise on the practitioner

Tennessee Prescription Safety Act of 2016
T.C.A. 53-10-310

- Acute Pain Sect. 63-1-164
  - A provider shall not treat a patient with more than a 3-day supply of an opioid AND
  - Shall not treat a patient with an opioid dosage exceeding 180 MME
  - Not required to include an ICD-10 code on rx

T.C.A. Sect. 63-1-164
Acute pain

- A patient shall not be treated with an opioid more frequently than every 10 days
- What if a patient has an adverse reaction to an opioid?
- The provider may treat a patient with a different opioid within a 10 day period if:
  - The provider is employed by the same practice that initially treated the patient with the opioid that caused the adverse reaction
  - The provider personally evaluates the patient, assesses the adverse reaction, and determines a different course of treatment appropriate
  - The provider confirms with the dispenser that the remainder of the initial rx has been cancelled by the dispenser
  - The provider counsels the patient to appropriately destroy any remaining opioids that were previously dispensed to the pt
  - The providers treatment of the pt conforms to TN's prescribing requirements

Moderate Pain Treatment (4-10 days)
T.C.A. Sect. 63-1-164

- You can treat a pt with more than a 3 day supply of an opioid if you treat the pt with no more than 1 rx for an opioid per encounter and you:
  - Personally conduct a thorough evaluation of the pt
  - Document consideration of non-opioid and non-pharmacologic pain management strategies and why the strategies failed or were not attempted
  - Include the ICD-10 code for the primary disease in the pt's chart and on the rx when one is issued
  - Obtain informed consent (subject to exceptions) and document the reason for treating with an opioid in the chart

Informed consent Exception
T.C.A. Sect. 63-1-164(d)(1)©

- If provider complied with law in issuing an initial opioid rx, then not required to obtain and document informed consent if:
  - Subsequent rx is for the same opioid, and
  - Same episode of treatment
  - Must update informed consent “periodically” during course of treatment

Moderate Pain Treatment (4-10 days)
T.C.A. Sect. 63-1-164

- If provider treats with more than a 3 day supply of an opioid:
  - no more than a 10 day supply and with a dosage that does not exceed a total of 500 MME dose
  - for women of childbearing age (15-44): Prior to prescribing more than a 3 day supply of an opioid or an opioid dosage that exceeds a total of 180 MME, a provider shall:
    - Advise the pt of the risks associated with opioid use during pregnancy
    - Counsel the pt on appropriate and effective forms of birth control
    - Offer information about the availability of free or reduced cost birth control to the pt TCA Sect. 53-11-308

Moderate Pain Treatment (4-10 days)
T.C.A. Sect. 63-1-164

- Women of childbearing age requirement does not apply if:
  - The prescriber has previously taken all actions required with respect to the pt within the past 3 months or
  - The prescriber reasonably believes that the pt is not capable of becoming pregnant
- If the pt is under 18 years of age
  - The physician may satisfy these requirements by advising, counseling, and providing information to the parent or guardian instead of the pt, but the provider is not prohibited from advising, counseling, and providing information directly to the pt if not otherwise prohibited by law TCA Sect. 53-11-308

Treatment of upper respiratory symptoms or cough

- Opioid prescribing restrictions in TCA 63-1-164 are N/A to opioids approved by the FDA to treat URI/cough
- But, provider shall not treat with more than a 14 day supply

Naloxone Prescribing Law
Effective 7/1/22 TCA Sect. 53-11-308(i)

- Requires healthcare prescriber to offer an opioid antagonist (or other FDA approved drug for complete or partial reversal of an opioid overdose event) to patients when certain conditions are met:
  - The provider prescribes more than a 3 day supply of an opioid medication and
    - The provider prescribes an opioid concurrently with a prescription by the same provider for benzodiazepine, or
    - The pt presents with an increased risk for overdose, including a hx of overdose, hx of substance abuse disorder, or being at risk for returning to a high dose of opioid medication to which the pt is no longer tolerant
  - Does not apply to an opioid rx that is written as part of a pt's palliative care treatment

Post-op Pain 1-30 days
TCA Sect. 63-1-164

- In rare cases where the procedure is more than minimally invasive and sound medical judgement determines the risk of adverse effects from pain exceeds the risk of developing a substance use disorder or overdose:
  - 30 day max of 1 opioid, not to exceed 1200 MME
  - In person exam
  - Document non-opioid and other treatments discussed or tried or reasons not tried
  - Document reasons for opioid
  - ICD-10 code in chart and on rx
  - Signed informed consent (if childbearing age, include additional information)

Prolonged Pain up to 30 days

- In rare cases after trial and failure of reasonable, appropriate, and available non-opioid treatments for the pain condition or documenting the contraindication, inefficacy, or intolerance of non-opioid treatments, where medical necessity and sound medical judgment would determine the risk of adverse effects from the pain exceeds the risk of developing substance use disorder, or overdose event:
  - 30 day max of 1 opioid, not to exceed 1200 MME
  - In person exam
  - Document non-opioid and other treatments discussed or tried or reasons not tried
  - Document reasons for opioid
  - ICD-10 code in chart and on rx
  - Signed informed consent (if childbearing age, include additional information)
  - Write “medical necessity” on rx

Exceptions to Opioid Prescribing Restrictions

- Patient undergoing active cancer treatment/recent cancer treatment/undergoing palliative care treatment/or are receiving hospice care
- Pts being treated for sickle cell disease
- Pts receiving certain inpatient treatment
- Prescriptions issued by pain management specialists, or by practitioners who are collaborating with a pain management specialist
- Rx's for treating pts in an outpatient setting of a hospital that holds itself out as a pain management clinic

Exceptions to Opioid Prescribing Restrictions

- Treatment of pts who have been treated with an opioid daily for 90 days or more during the 365 days prior to 4/15/2018 or those who are subsequently treated for 90 days or more under statutory exceptions
- Direct administration of/dispensing of methadone to treat opioid use disorder by a practitioner registered for research under 21 USCA Sect. 823(g)(1)
- Treatment of a pt for opioid use disorder with products approved by the US FDA for opioid use disorder by a provider under 21 USCA Sect. 823(g)(2)
- Treatment of a pt who suffered a severe burn or major physical trauma and where the risk of adverse effects from pain exceeds the risk of developing a substance use disorder or overdose

Prescribing for Exempt Conditions

- Include the ICD-10 code for the primary disease on the rx
- Include the word “EXEMPT” on rx
- For a woman of childbearing age, informed consent must be signed, and include additional information

Electronic Prescriptions
TCA 63-1-160©

- Beginning 1/1/21
- Any rx for a schedule II, III, IV, or V controlled substance issued by a prescriber must be issued as an electronic prescription from the person issuing the rx to a pharmacy
- The name, address, and telephone number of the collaborating physician of an advanced practice RN or PA must be included on electronic rx's issued by an NP or PA

Exceptions to Electronic Prescription Requirement

- Does not apply to rx's:
  - Issued by veterinarians
  - Issued in circumstances where electronic prescribing is not available due to technological or electrical failure, as set forth in rule
  - Issued by a health care prescriber to be dispensed by a pharmacy located outside the state
  - Issued when the health care prescriber and dispenser are the same entity
  - Issued while including elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist interface SCRIPT Standard

Tennessee Chronic Pain Guidelines
Tennessee Department of Health
Version: January 2020

- Applicable to chronic (greater than 90 days) non-malignant pain (n/a to hospice, palliative, emergency room, hospital, or acute pain management care)
- Available on TN DOH website www.tn.gov/health/hcf/pain-management-guidelines.html

Prior to Initiating Opioid Therapy for Chronic Non-malignant Pain
Summary of Section I

- Try non-opioid therapy first, don't initiate opioid therapy just because previous provider did
- Administer a UDS to the newly pregnant woman, before administering opioids, or renewing rx's to childbearing woman, discuss a birth control plan and evaluate for a possible pregnancy
- A full medical workup including hx, physical, ROS, prior opioid use, co-morbid conditions, mental health disorder screening, review of medical records should be documented prior to initiating opioids
- In person exam, do not rx through telemedicine
- A current diagnosis should justify the need for opioids
- Assess for risks of abuse using risks assessment tools, obtain a UDT, and check CSMD
- Establish and follow goals for treatment with the 3 item PEG assessment scale (Pain average, interference with enjoyment of life, and interference with general activity), the goal to increase the function and reduce pain (document discussion in medical record)

Prior to Initiating Opioid Therapy for Chronic Non-malignant Pain
Summary of Section II

- Prescribe the lowest effective dose for the shortest time period required
- Start with immediate release opioids
- Avoid benzodiazepines or naloxone combinations with an opioid for chronic pain
- Methadone should only be used for addiction or by a pain specialist
- Document any reasons for deviations from guidelines
- Obtain informed consent discussing and documenting risks and benefits
- Obtain written treatment agreement - reasons to discontinue, refill policy, lost rx policy, safe storage, periodic drug testing, and pregnancy issues
- Ongoing monitoring for abuse, misuse, or diversion
- If potentially childbearing, obtain pregnancy test and discuss methods to avoid unintended pregnancy, with documented an signed discussion of risks and benefits

Prior to Initiating Opioid Therapy for Chronic Non-malignant Pain
Summary of Section III

- All opioid therapy by a single provider and single pharmacy
- Only one short acting opioid at a time
- Document five A's (Analgesia, activities of daily living, adverse side effects, aberrant drug-taking behavior, affect)
- Review the pts hx of controlled substance rx's using the Controlled Substance Monitoring Database (CSMD) data to determine whether the pts receiving opioid dosages or potentially dangerous combinations
- Continually monitor for signs of abuse, misuse, or diversion, including UDS at least twice per year
- Ongoing risks assessment of behavior, the CSMD results, and UDS
- Emergency physicians should inform providers of any incidents or conditions
- Opioids are to be discontinued when the risks, side effects, lack of efficacy or presence of medication, or aberrant behavior outweigh the benefits
- Document CSMD queries
- Discuss a method to prevent unintended pregnancy with every woman of childbearing age who has reproductive capacity when opioids are initiated
- If pt plans to become preganant, refer to an obstetrician
- Document the UDS results

CSMD

- Electronic access required
  - Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a healthcare practitioner provides healthcare services to a human patient potentially receiving a controlled substance
- When to check CSMD
  - Before prescribing a controlled substance at the beginning of a new episode of treatment (meaning a rx for a controlled substance that you have not prescribed within the previous 6 months)
  - Before each new rx for the controlled substance for the first 90 days of a new episode of treatment
  - At least every 6 months when that prescribed controlled substance remains part of the treatment
  - Before prescribing anytime abuse/fraud/illegal/medically inappropriate use is suspected
- Who may check the CSMD
  - An authorized healthcare practitioner's delegate may check the CSMD on behalf of the practitioner

CSMD

- You or your delegate must check the database for the following:
  - Opioids
  - Benzodiazepines
  - Schedule II-V substances identified by Commissioner of Health/Controlled substance database committee as demonstrating a potential for abuse
- All non-exempted healthcare practitioners to check the CSMD prior to issuing a schedule II amphetamine (TN ADC 1145-01-04 drugs of abuse) rules amended 1/26/22

CSMD

- Exceptions
  - You are not required to check the database if:
    - The pt is currently receiving hospice care
    - The rx does not exceed an amount adequate for a single 3 day treatment period and does not allow a refill, or
    - The rx is for administration to pt during inpatient or residential treatment in hospital or nursing home

The Opiate Crisis a Broader Picture

- Ryan W. Bearer, DO, MPH, MS
- Specialists in Pain Management
- Chattanooga, Ooltewah, Cleveland

Definition

- "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." -
  International Association for the Study of Pain

Sensory AND Emotions

- Pain is always subjective
- Based on past experiences at the individual level
- The sensations and emotions are linked:
  - Not all unpleasant sensations have emotional responses ie pricking
  - Not all emotional experiences have abnormal sensations i.e. loss of loved one
  - Noxious stimulation of nociceptors under general anesthesia does not have emotional response


DURING LABOR, THE PAIN IS SO GREAT THAT A WOMAN...
CAN ALMOST IMAGINE WHAT A MAN FEELS WHEN HE HAS A FEVER

Tissue Damage

- Many people report abnormal sensory experiences without evidence of identifiable tissue damage:
  - Fibromyalgia
  - Phantom limb pain
  - Post herpetic neuralgia
  - Somatic Symptom Disorder
- If we take the subjective report as indistinguishable from that of actual tissue damage, then there is pain
- Under this definition pain and stimulus are not tied

Clinical examples

- Paraplegic has fallen in nursing home sustaining compound fracture to right tibia. Increased HR and BP. Reports no abnormal sensations in the affected limb?
- Masochist?
- Wife stubs her toe states, “I'm fine!”

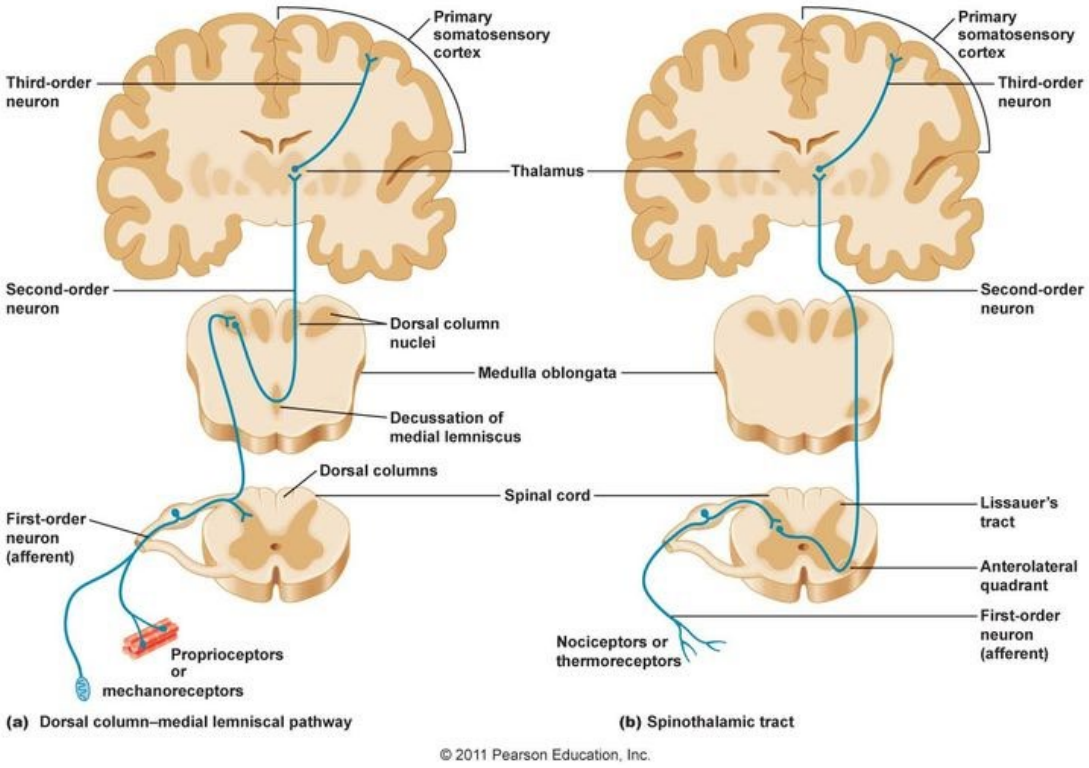
ACUTE VS CHRONIC

- "pain that extends beyond the period of healing, with levels of identified pathology that often are low and insufficient to explain the presence and/or extent of the pain." - Jacobsen L, Mariano A. General considerations of chronic pain. In: Loeser JD, Butler SH, Chapman CR, et al, eds. Bonica's Management of Pain. 3rd ed. Baltimore, MD: Lippincott Williams & Wilkins; 2001:241-54.
  - serves no adaptive purpose
  - disrupts sleep and normal living
  - degrades health and functional capacity
  - ANS hyperactivity less common

Analgesic vs Pain Reliever

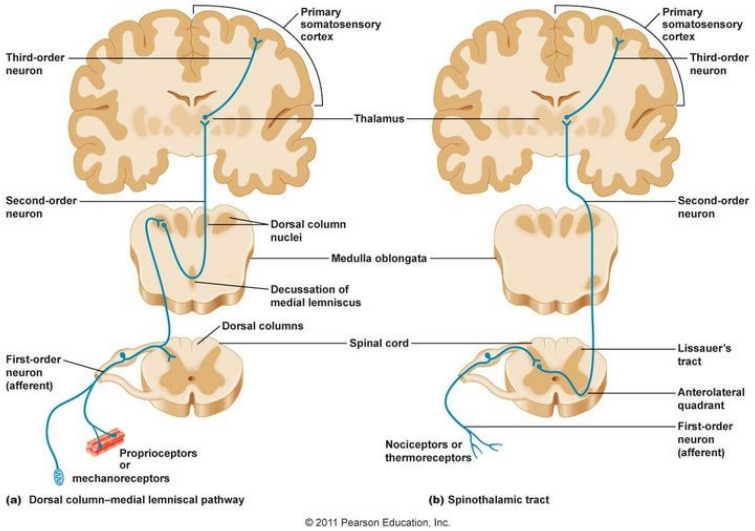
- Analgesic:
  - A compound capable of producing analgesia, that is, one that relieves pain by altering the perception of nociceptive stimuli without producing anesthesia or loss of consciousness.
    - https://medical-dictionary.thefreedictionary.com/analgesic

Spinothalamic Tract



Common Analgesics

- NSAIDs
- Opiates
- Local anesthetics
- Norepinephrine Reuptake Inhibitors
- Calcium channel blockers



Pain Reliever

- Any agent, maneuver, or experience which palliates the pain on an individual level – Ryan Bearer
  - Spinal Stenosis
    - Williams flexion exercises
  - Fibromyalgia
    - Massage
  - Somatic Symptom Disorder
    - Meditation
    - Biofeedback

Clinical Examples

- 42 yo with burning dysesthesia left L5 distribution, worse with forward flexion, and left paracentral disc herniation L4-5. Failed PT, Ibuprofen, tramadol
- Norco
  - Analgesic? YES
  - Pain Reliever? UNLIKELY
- Duloxetine
  - Analgesic? YES
  - Pain Reliever? MAYBE

Clinical Examples

- 35 yo with chronic widespread pain secondary to fibromyalgia. Failed PT, NSAIDs, norco
- Cardiovascular Exercise
  - Analgesic? NO
  - Pain Reliever? VERY LIKELY
- Naltrexone
  - Analgesic? NO
  - Pain Reliever? LIKELY

Clinical Examples

- 46 yo female with chronic abdominal pain. Hx of childhood sexual abuse by a family member. 20 year history of seeking medical care without clear diagnosis. Lost two jobs due to missed work because of pain. Frequent ER visits due to pain. Has been on fentanyl patch last six months and ER visits down 80% and has not missed work.

- Fentanyl
  - Analgesic? YES
  - Pain Reliever? YES

LACK OF DESCRIPTION OF TISSUE DAMAGE

So if pain is personal, subjective, does not require an objective causal factor, and can be treated by agents that are not known analgesics, how are we to know how to treat patients?

DRUGS OF CHOICE

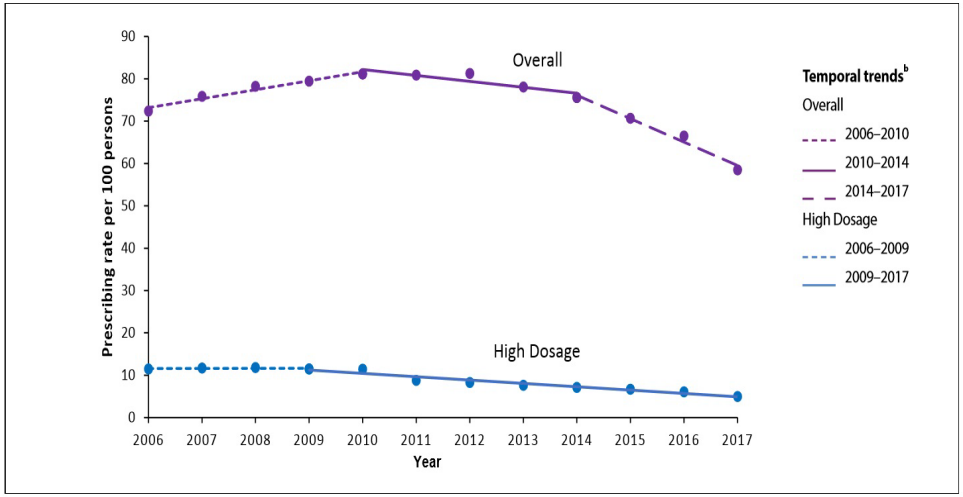
- Drugs of choice can help the clinician determine underlying etiology
  - NSAIDs and narcotics more helpful for arthritic LBP than neuropathic LBP
  - Is the patient using drugs to mask underlying psychological angst?
  - Is the use social?

PROHIBITION

- Assumption #1
  - Decreasing the amount of narcotic prescriptions will have beneficial impact on opiate deaths
- High dose opioid prescriptions fell 58% from '08-'17
- Total volume of opioid dispensed fell 29% from '10-'17

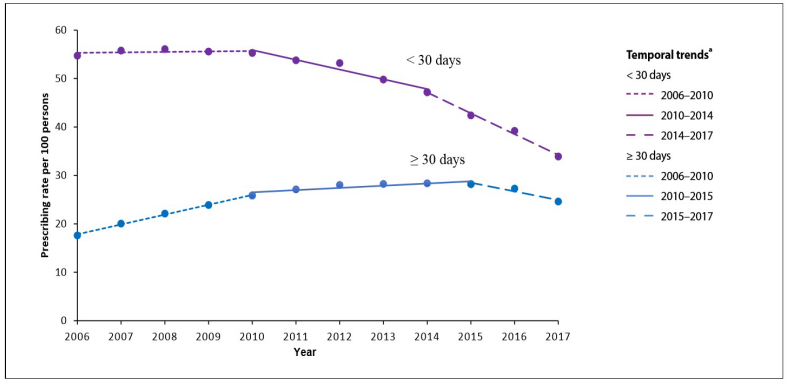
Trends in Opioid Prescribing

FIGURE 1A **Annual opioid prescribing rates overall and for high-dosage prescriptions[a] (≥ 90 MME/day)[b] — United States, 2006–2017**



Source: IQVIA™ Transactional Data Warehouse.
[a] High-dosage prescriptions were defined as opioid prescriptions resulting in a daily dosage of ≥ 90 morphine milligram equivalents.
[b] Temporal trends from 2006 to 2017 were evaluated by applying joinpoint regression methodology. This modeling approach simultaneously identified statistically significant trends as well as shifts in trends that occurred within a time series. A maximum of two joinpoints was allowed, and the permutation method was used for model selection. Different line dashes correspond to year groupings as determined by joinpoint regression.

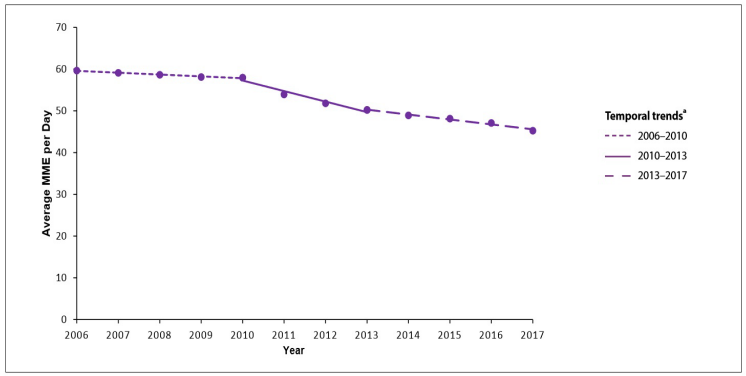
FIGURE 1B **Annual opioid prescribing rates by days of supply per prescription[a] — United States, 2006–2017**



Source: IQVIA™ Transactional Data Warehouse.
a Temporal trends from 2006 to 2017 were evaluated by applying joinpoint regression methodology. This modeling approach simultaneously identified statistically significant trends as well as shifts in trends that occurred within a time series. A maximum of two joinpoints was allowed, and the permutation method was used for model selection. Different line dashes correspond to year groupings as determined by joinpoint regression.

Annual Surveillance Report of Drug-Related Risks and Outcomes | United States CDC National Center for Injury Prevention and Control | 2018

FIGURE 1C **Average daily morphine milligram equivalents (MME) per opioid prescription[a] — United States, 2006–2017**



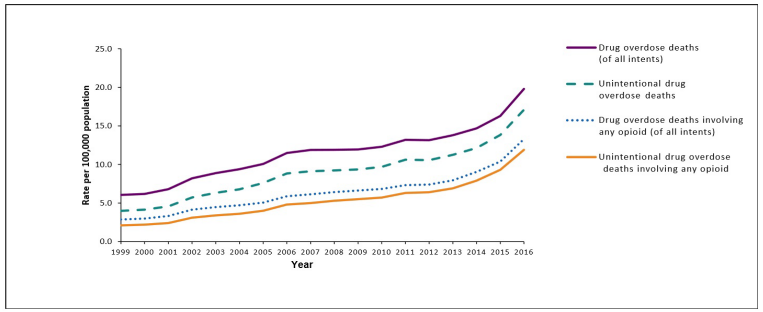
Source: IQVIA™ Transactional Data Warehouse.
Abbreviation: MME, morphine milligram equivalents.
[a] Temporal trends from 2006 to 2017 were evaluated by applying joinpoint regression methodology. This modeling approach simultaneously identified statistically significant trends as well as shifts in trends that occurred within a time series. A maximum of two joinpoints was allowed, and the permutation method was used for model selection. Different line dashes correspond to year groupings as determined by joinpoint regression.

- Days of supply per prescription is falling
- Average MME's per prescription has been falling for over 10 years

RESULTS

Trends in Drug Overdose Deaths

FIGURE 2A **Age-adjusted rates[a] of drug overdose deaths[b] and drug overdose deaths involving any opioid[c] for all intents and for unintentional intent by year — United States, 1999–2016**

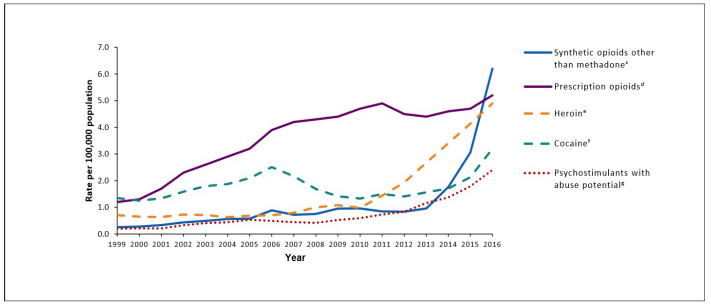


Source: National Vital Statistics System, Mortality File, CDC WONDER.
[a] Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage year population of the data year.
[b] Deaths are classified using the International Classification of Diseases, Tenth Revision (ICD–10). All drug overdose deaths are identified using underlying cause-of-death codes X40–X44 (unintentional), X60–X64 (suicide), X85 (homicide), and Y10–Y14 (undetermined). Unintentional drug overdose deaths are identified using underlying cause-of-death codes X40–X44. Note that overall drug overdose deaths and opioid overdose deaths include deaths of any intent. In 2016, 5.7% of drug overdose deaths had undetermined intent; this is a decrease from 14.7% of drug overdose deaths that had an undetermined intent in 1999. Some of these deaths may be unintentional drug overdose deaths.
[c] Drug overdose deaths, as defined, that involve opium (T40.0), heroin (T40.1), natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids excluding methadone (T40.4), and other and unspecified narcotics (T40.6). Specification on death certificates of drugs involved with deaths varies over time. In 2016, approximately 15% of drug overdose deaths did not include information on the specific type of drug(s) involved. Some of these deaths may have involved opioids.

- Intentional and unintentional opioid deaths have been increasing by all opiate type

Annual Surveillance Report of Drug-Related Risks and Outcomes | United States CDC National Center for Injury Prevention and Control | 2018

FIGURE 2B **Age-adjusted rates[a] of drug overdose deaths[b] by drug or drug class and year — United States, 1999–2016**



Source: National Vital Statistics System, Mortality File, CDC WONDER.
[a] Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage year population of the data year. Because deaths might involve more than one drug, some deaths are included in more than one category. Specification on death certificates of drugs involved with deaths varies over time. In 2016, 15% of drug overdose deaths did not include information on the specific type of drug(s) involved. Some of these deaths may have involved opioids or stimulants.
[b] Deaths are classified using the International Classification of Diseases, Tenth Revision (ICD–10). Drug overdose deaths are identified using underlying cause-of-death codes X40–X44 (unintentional), X60–X64 (suicide), X85 (homicide), and Y10–Y14 (undetermined).
[c] Drug overdose deaths, as defined, that involve synthetic opioids other than methadone (T40.4).
[d] Drug overdose deaths, as defined, that involve natural and semi-synthetic opioids (T40.2) or methadone (T40.3).
[e] Drug overdose deaths, as defined, that involve heroin (T40.1).
[f] Drug overdose deaths, as defined, that involve cocaine (T40.5).
[g] Drug overdose deaths, as defined, that involve psychostimulants with abuse potential (T43.6).

- Prescription opioid deaths seem to be plateauing but dramatic increases in illegal fentanyl, heroin, cocaine, and psychoactives

PROHIBITION

- Assumption #2
  - Prescription opiates are the leading cause of death in “opiate deaths”
  - In order for this assumption to be true, opioid deaths should be the common thread while controlling for all other covariates

2016. NYC Health. Epi Data Brief. June 2017, No. 89

- 75% of opiate deaths had heroin or fentanyl
- 97% of overdoses involved MULTIPLE DRUGS
- Heroin was involved in 771 (54%) of all overdose deaths in NYC in 2016, making it the most common substance involved in overdose deaths.
- In 2015, 10% (n=17) of cocaine-involved overdose deaths that did not involve heroin involved fentanyl. Fentanyl was increasingly present in cocaine-involved overdose deaths that did not involve heroin, increasing to 38% (n=122) in 2016

Case Fatality vs Infection Fatality

	2013			2014			2015			2016		
	Number	Percent	Rate	Number	Percent	Rate	Number	Percent	Rate	Number	Percent	Rate
Total Unintentional Drug Poisoning Deaths	**788**	**100%**	**11.6**	**800**	**100%**	**11.7**	**942**	**100%**	**13.7**	**1425**	**100%**	**20.7**
Drug type**												
Alcohol	342	43%	5.0	359	45%	5.3	373	40%	5.5	551	39%	8.0
Benzodiazepines	298	38%	4.4	301	38%	4.4	374	40%	5.4	470	33%	6.9
Cocaine	364	46%	5.4	326	41%	4.8	403	43%	5.8	655	46%	9.5
Heroin	424	54%	6.2	460	58%	6.7	561	60%	8.1	771	54%	11.1
Methadone	169	21%	2.5	127	16%	1.8	154	16%	2.3	205	14%	2.9
Opioid Analgesics[††]	213	27%	3.1	200	25%	3.0	232	25%	3.4	279	20%	4.0

2,931 206%

- Manner vs cause of death impacts data
- Typically reported as manner vs cause
- Cause of death supports the counterfactual concept and manner may or may not

Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study

- BMJ 2018;360:j5790
- Study evaluating misuse rate in acute pain setting
- 1,015,116 opioid naive patients undergoing surgery
- 568,612 patients received opioids postoperatively
- Misuse rate of 0.6%

Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality.

- Pain Med. 2016 Jan;17(1):85-98
- Study evaluating the mortality rate among chronic opiate users
- 2,182,374 prescribed opioids
- Death rate of 0.022% per year
- Death rate among those taking benzodiazepine 10 fold higher
- No evidence of a dose dependent risk threshold

PROHIBITION

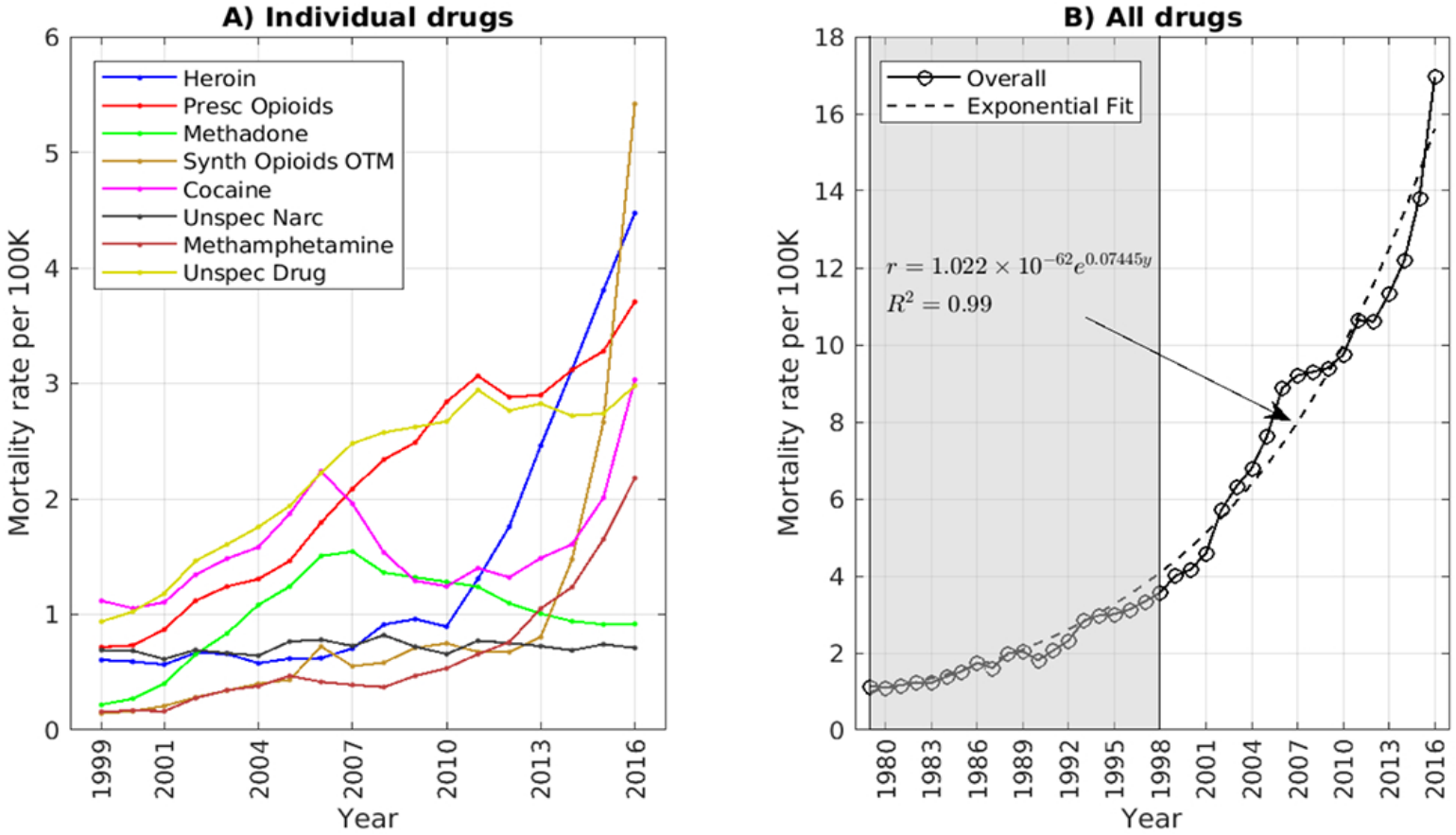
- Assumption #3
  - Opiate addiction starts when a person is given a prescription opiate
  - 27,000 oxycontin addicts who entered rehab bt 01-04
    - 78% said the drug was never prescribed to them
  - Opiate volume bt 02-14 doubled but rates of non medical use stayed flat

- J Singer, et al. today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder. Journal of Pain Research 2019:12 617–620

PROHIBITION

- ASSUPTION #4
  - Overdose death rates increased in step with increased opiate prescriptions in the 90's
  - “Death rates from drug overdoses in the US have been on an exponential growth curve that began at least 15 years before the mid-1990s surge in opioid prescribing, suggesting that overdose death rates may continue along this same historical growth trajectory for years to come. These findings suggest that, to be successful, prevention efforts must extend beyond control of specific drugs to address deeper factors driving the epidemic. “
  - University of Pittsburgh Schools of the Health Sciences. "Drug overdose epidemic has been growing exponentially for decades." ScienceDaily. ScienceDaily, 20 September 2018. <www.sciencedaily.com/releases/2018/09/180920161028.htm>.

Individual and all cause mortality from unintentional drug overdoses



Jalal H, Buchanich JM, Roberts MS, Balmert LC, Zhang K, Burke DS. Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016. Science. 2018 Sep 21;361(6408):eaau1184. doi: 10.1126/science.aau1184. PMID: 30237320; PMCID: PMC8025225.

UNINTENDED CONSEQUENCES

- Alcohol Prohibition
  - 1926 government required the addition of methanol, benzene, pyridine bases to denatured alcohol
  - Bootleggers redistilled alcohol and the supply wound up causing blindness
  - New York City medical examiner Charles Norris exclaimed, “The government knows it is not stopping drinking by putting poison in alcohol, yet it continues the poisoning process... the harmful effects of this abuse deterrence fell disproportionately on the poor because they could not afford better whiskey and “deal in low grade stuff.”
  - Deborah Blum, “The Chemist’s War,” Slate, February 19, 2010, http://www.slate.com/articles/health_and_science/medical_examiner/2010/02/the_chemists_war.html.

UNINTENDED CONSEQUENCES

- 2015 Article about the use of Abuse Deterrent Formulations
  - Heroin deaths increased steeply after introduction of tamper resistant oxycontin in 2010
  - The quality and expense of ADF's causes shifting of use to street drugs which have adulterants such as fentanyl/carfentanyl
  - Tamper-resistant drugs cannot solve the opioid crisis. Pamela Leece, Aaron M. Orkin and Meldon Kahan. CMAJ July 14, 2015 187 (10) 717-718

UNINTENDED CONSEQUENCES

- 2018 article How The Reformulation of OxyContin Ignited the Heroin Epidemic
  - we find that opioid consumption stops rising in August, 2010, heroin deaths begin climbing the following month, and growth in heroin deaths was greater in areas with greater pre-reformulation access to heroin and opioids. The reformulation did not generate a reduction in combined heroin and opioid mortality—each prevented opioid death was replaced with a heroin death.
  - William N. Evans et al., "How the Reformulation of OxyContin Ignited the Heroin Epidemic," working paper, June 2017, p. 5, https://www3.nd.edu/~elieber/research/ELP.pdf.

UNINTENDED CONSEQUENCES

- 2012 Endo reformulated Opana ER so that it could not be crushed or snorted
  - 2015 190 people in Scott County Indiana tested positive for HIV
  - Biggest outbreak in Indiana history
  - Health officials tied the outbreak to the sharing of dirty needles from attempting to inject Opana
  - Tom Dreisbach, “How a Painkiller Designed to Deter Abuse Helped Spark an HIV Outbreak,” NPR, April 1, 2016, https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak; and Mike Riggs, “Opana ER and the Failure of the Tamper-Proof Drug Model,” Reason, Hit and Run Blog, June 9, 2017,

    http://reason.com/blog/2017/06/09/opana-er-and-the-failure-of-the-tamper-p.

CDC Recommendations

- Guideline https://doi.org/10.1016/j.jcf.2014.06.012
  - a public statement on a particular aspect of medical knowledge that is generally agreed upon as an evidence-based, state-of-the-art knowledge by a representative group of experts in that area [1]. Its main objective is to counsel physicians on the best possible and acceptable way to address a particular decision-making area for diagnosis, management or treatment.
- Recommendation
  - Consensus statements synthesize new information, largely from recent or ongoing medical research that may have implications for re-evaluation of routine medical practices. Consensus statements however do not provide specific algorithms or guidelines for practice because these depend on cost, available expertise and technology, and local practice circumstances.

Practicing of Pain under the current culture

- Stigmatizing and criminalizing opioid use makes patients less likely to be honest during a history and physical exam
- Restricting access to medical use does not get to the root of the problem and supported by literature
- Restricting the use has unintended consequences that have direct and indirect negative effects

Practicing of Pain under the current culture

- Direct effects
  - People shift to black market supply increasing the chance of death
  - Decreases the efficacy of medically treated pain
  - Legitimate pain patients cannot pursue the treatment plan
- Indirect effects
  - Increasing costs through increased ER visits, medical visits for non medical use, encouraging expensive lab tests and TRFs,
  - Shifting behavior to more dangerous use

Take aways

- Pain behaviors are complex interplay that involves multiple factors
  - patient experience
  - psychological
  - societal
- Narrowed focusing on opiates may miss the underlying culprit
  - Use sedative inventories to avoid poly pharmacy
  - Careful of stigmatization
  - Understand the underlying need and use resources appropriately

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- 2. Bernard SA, Chelminski PR, Ives TJ, Ranapurwala SI. Management of Pain in the United States—A Brief History and Implications for the Opioid Epidemic. Health Services Insights. 2018;11. doi:10.1177/1178632918819440
- 3. Understanding the Opioid Overdose Epidemic. CDC. https://www.cdc.gov/opioids/basics/epidemic.html
- 4. Juurlink DN, Dhalla IA. Dependence and Addiction During Chronic Opioid Therapy. J. Med. Toxicol. (2012) 8:393–399
- 5. Drugs, Brains, and Behavior: The Science of Addiction. Drug Misuse and Addiction. National Institute on Drug Abuse. https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction