SAFER PRESCRIBING OF OPIOIDS & CONTROLLED SUBSTANCES

L.A. Care Opioid Use Disorder Conference
In Collaboration with Los Angeles County Department of Public Health
Saturday, May 18, 2024, Almansor Court, Alhambra, CA

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DISCLOSURES

The following CME planners and faculty do not have relevant financial relationships with ineligible companies in the past 24 months:

- Leilanie Mercurio, L.A. Care PCE Program Manager, CME Planner.
- Kevin Burns, MD, MPH, L.A. Care CalAIM Medical Director, CME Planner.
- Brian Hurley, MD, MBA, FAPA, DFASAM, Medical Director, Substance Abuse Prevention and Control, County of Los Angeles, Department of Public Health, CME Planner.
- José Luis González, MD, VP & Medical Director Clinical Services, Healthcare in Action, CME Faculty.

An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Commercial support was not received for this CME/CE activity.

LEARNING OBJECTIVES

1. Name three (3) key components of chronic pain.
2. Identify three (3) factors associated with chronic pain.
3. List five (5) evidence-based non-opioid treatments for chronic pain.
4. Specify four (4) benefits of buprenorphine transdermal patch over traditional opioids.

OUTLINE

- Definitions & Epidemiology
- General Approach to Managing Pain
- Non-pharmacotherapy Interventions
- Non-opioid Pharmacotherapy
  - Alternative & adjunct therapies
- Opioids
  - Full opioid agonists
  - Methadone
  - Buprenorphine
  - Peri-operative

DEFINITIONS, TYPES OF PAIN, & GENERAL APPROACH

PAIN TYPES & DEFINITIONS

Nociceptive

- Structural / Mechanical – compression by cancer, DJD, OA, disc herniation
- Inflammatory – RA, UC, SLE
- Other - vaso-occlusive

Neuropathic

- carpal tunnel, trigeminal neuralgia, disc herniation
- post-herpetic neuralgia, HIV, DM-associated PN, sciatica

Nociplastic

- arises from altered nociception / modulation of pain, i.e. no clear e/o tissue damage
- E.g. fibromyalgia, CRPS, tension headache

Hyperalgesia – heightened sense to noxious stimuli

Allodynia – pain resulting from normally painless stimuli (i.e. post-sunburn)

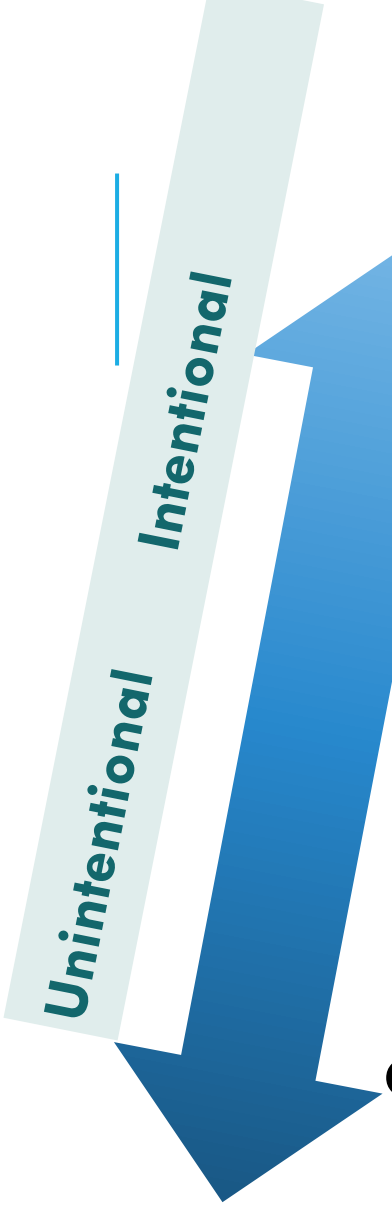
KEY COMPONENTS OF CHRONIC PAIN

- > 3 months (sometimes 6)
- Lasts beyond time required for normal healing
- In the absence of ongoing tissue injury
- Non-cancer
- Involves a dysregulation of descending pain modulation

EPIDEMIOLOGY – CHRONIC PAIN

- 21% population experienced pain in 2021 w/ a higher prevalence in:
  - Non-Hispanic American Indian & Alaskan Native adults
  - Bisexual adults
  - Divorced or separated adults
- **Associated w/ depression, dementia, suicide risk, substance use**
- 7% high-impact chronic pain w/ disparities – higher prevalence in:
  - Older adults
  - Females
  - Currently unemployed who previously worked
  - Veterans
  - Adults living in poverty
  - Adults living in non-metropolitan areas

MORE DEFINITIONS



- **Malingering** – symptoms motivated by external incentives

  feigning illness to stay home from school

- **Factitious disorder** – symptoms motivated by internal incentives

  pretending to be sick to seek attention

- **Somatization** – psychologic distress expressed in the form of physical symptoms

  tension headache, stomach ache due to stress

Conversion disorder – somatization involving neurologic symptoms

pseudo seizures, weakness or paralysis

How does the management of each differ?

STUDIES SUPPORTING PSYCHOLOGICAL CONTRIBUTION TO PAIN

Cross-sectional cohort study of 611 post-mastectomy cancer patients.

Survey of persistent post-mastectomy pain (>6 months post-surgery)

Demographic Factors: age, sex, edu, SSI, red hair, other pain, marital status, BMI, etoh, exercise, work

Surgical Factors: POD#, bil/total mastectomy, node dissection, reconstruction, complication

Medical Tx & Disease: radiation, chemo, hormone therapy, stage, tumor size, recurrence

Psychosocial Factors: anxiety, depression, sleep, catastrophizing, stress, positive affect

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Psychosocial Factors: **anxiety, depression, sleep, catastrophizing, stress,** positive affect

Limitation: study did not establish temporal (thereby causal) relationship

2021 meta-analysis, 47 studies (N=15,987), weak but significant predictors of pain 12-months post-op: anxiety, depression, pain catastrophizing, and distress

FACTORS ASSOCIATED WITH DEVELOPMENT OF CHRONIC PAIN

- Genetic: females > males, bell shaped curve
- Psychological: Depression, Anxiety, Catastrophizing
- Biologic: age, inflammation, central sensitization

THE ANALGESIC EFFECTS OF GOOD BEDSIDE MANNER

Can it be fixed? If so, fix it.

- nerve compression, sickling, RA, OA, gallstones

Would you tell a patient "it's all in your head?"

Be upset about your patient's pain

Don't Reassure; Validate

Expectations about level of control

Perception of pain: normal or abnormal

~~Is it real?~~ → How do I address it?

"IT'S ALL IN YOUR HEAD"

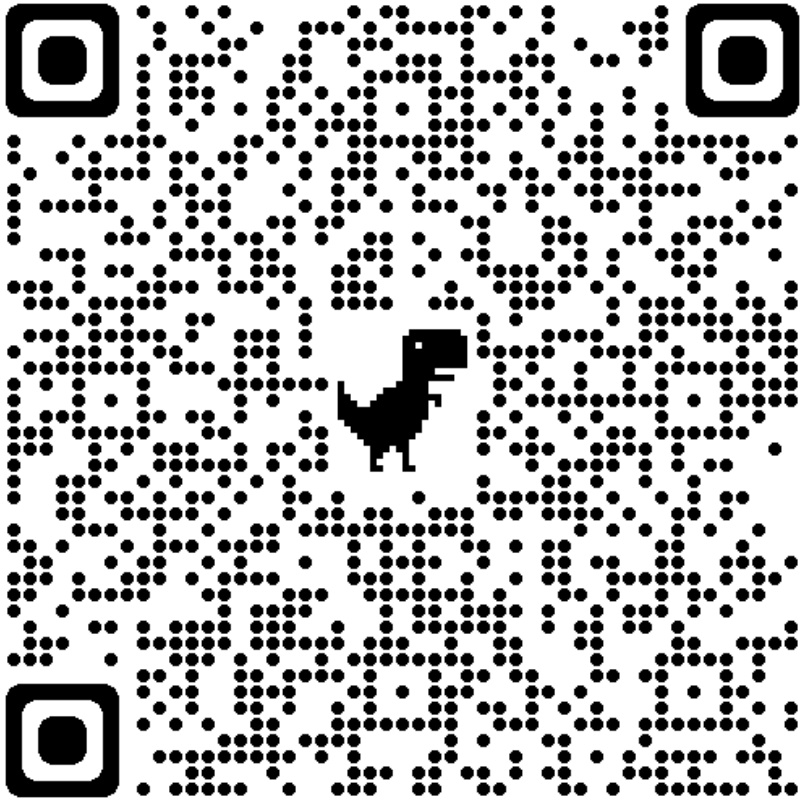
Bidirectional link between pain & **mood disorders**

Bidirectional link between pain & **sleep quality**

Strongest predictors of chronic pain development: **depression, anxiety, distress**

~~Pain is pathologic~~ → pain is **normal** & it's okay to experience it

"It's not in all your head", but probably some of it is.



CHRONIC REGIONAL PAIN SYNDROME

Chronic pain condition w/ **autonomic** & **inflammatory** features

May be associated **hyperalgesia & allodynia**

Skin color, temp changes, altered hair pattern, muscle atrophy

Usually associated w/ *serious impairments in ADLs & function*

Usually occurs after trauma or surgery: limb fxs, surgery, or other injury

Most resolve within a year

Multiple mechanisms involving **central & peripheral sensitization**

Diagnosis of exclusion

Substance Use Disorder DSM-V

+ Withdrawal symptoms

+ Tolerance symptoms

Use in ↑ amounts or for longer than intended

Wanting to cut down, but unable to

↑ time spent getting, using or recovering from use

+ Cravings and urges

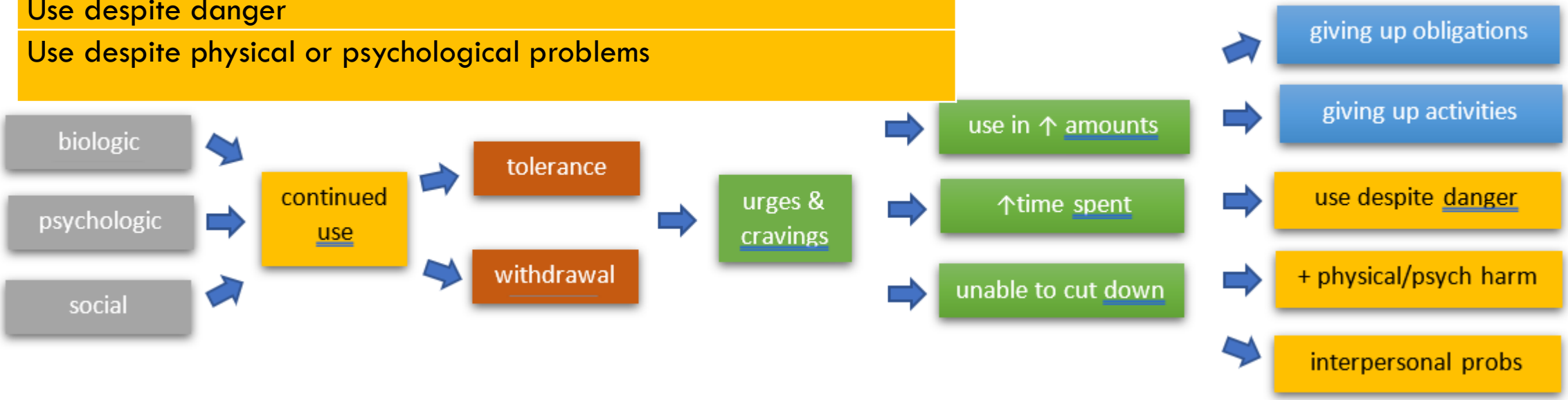
Not meeting obligations at home, work, school

Giving up social, occupational & recreational activities

Use despite interpersonal problems

Use despite danger

Use despite physical or psychological problems



NON-PHARMACOLOGIC THERAPIES

NON-PHARMACOLOGIC THERAPIES

Acupuncture

Compression / Brace

Massage

Heat/Cold therapy

CBT

Meditation, Mindfulness

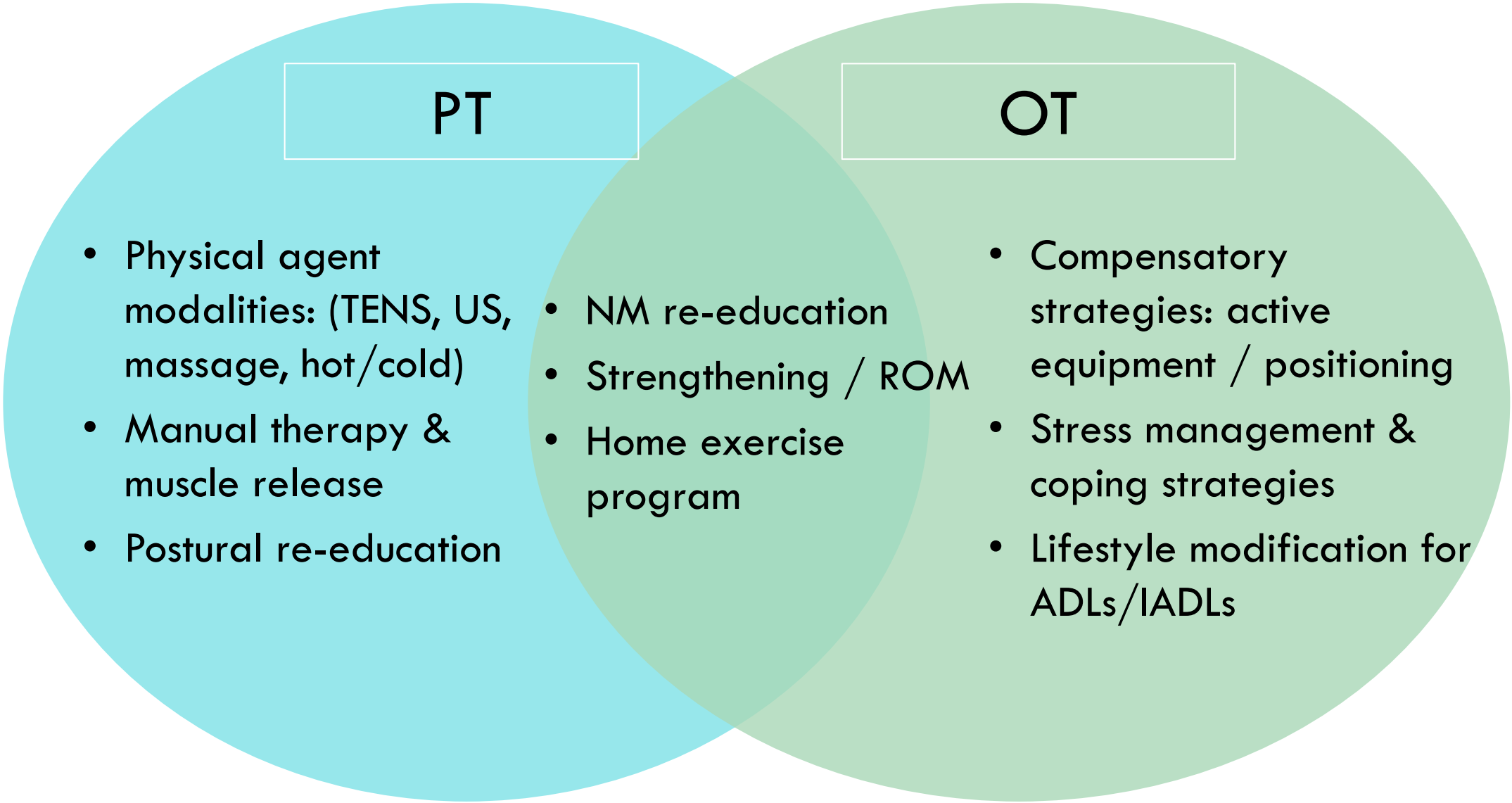
Yoga

TENS therapy

Exercise

PT/OT

PHYSICAL & OCCUPATIONAL THERAPY



EXERCISE

Meta-analysis 118 trials (N=9k):

Best exercises for reducing low back pain & disability:

Pilates, core-based, & mind-body exercise

Cochrane database review for chronic pain (general):

small-modest benefit but low-quality evidence 2/2
small sample size, underpowered studies

<u>Other benefits of exercise:</u>

Improves mood
Increases energy
Improves sleep
Promotes weight loss
Improves cardiovascular health
Improves cognition / reduces dementia
Improves sexual performance
Low risk
Free

NON-OPIOID PHARMACOTHERAPY

BECOME WELL VERSED IN THE NSAIDS

COX inhibitors → ↓ thromboxanes → ↓ inflammation

Inflammation sensitizes pain receptors

Side Effects:

- GI: COX-1 inhibition → ↓ prostaglandins: protect gastric mucosa
- Renal: afferent arteriole vasoconstriction → AKI
- CV: MI, thromboembolic events, Afib.
- Heme: ↓ platelet adhesion → ↑ bleeding.
- Gyne: Contra-indicated in third trimester of pregnancy

Non-Selective

Ibuprofen (Advil, Motrin)

Naproxen (Aleve)

Aspirin

Indomethacin (Indocin)

Ketorolac

Diclofenac (Voltaren Gel)

Selective

Celecoxib (Celebrex)

Meloxicam (Mobic)

ANTIDEPRESSANTS

SSRIs – weak evidence for neuropathic pain, none for MSK pain

TCAs – more effective than SSRIs (**NNT ~3**) recommended by AAFP

- Alpha-1 adrenergic, H1-blockade, Muscarinic blockade
- Careful w/ anticholinergic SEs, anxiety, agitation, psychosis, seizures, cardiac
- Require BID to TID dosing
- Amitriptyline (Elavil) 25mg, Nortriptyline 25-50mg, Imipramine 250-50mg
- Doxepin 25-75mg - insomnia, depression, anxiety, but most sedating

SNRIs – NNT = **3.6-6.4** for >50% pain relief – noradrenergic medication enhances centralized inhibitory pain modulators

- **Duloxetine** – the only FDA approved antidepressant for pain
  - Cochrane review of **25** different antidepressants – **duloxetine** is the only effective AD
  - Avoid in **renal and hepatic insufficiency**
- Venlafaxine similar efficacy to TCAs (**NNT = 3**) for neuropathic pain (Cochrane)

Remember: If patients have depression – treat the depression!

ANTISEIZURE MEDICATION FOR NEUROPATHIC PAIN

Gabapentin – 300-1200mg TID.

- FDA approved for post-herpetic neuralgia.
- Off Label for: AUD, fibromyalgia, neuropathic pain, diabetic neuropathy
- Renally cleared, increased risk of OD

Pregabalin (Lyrica) 50-100mg TID

- FDA approved for neuropathic pain from spinal cord injury, post-herpetic neuralgia, fibromyalgia, diabetic neuropathy
- Renally cleared, increased risk of OD

Carbamazepine

- FDA approved for trigeminal neuralgia

TOPICALS

Lidocaine crm / gel vs patch (3-5%)

Methyl Salicylate (Icy-Hot, Bengay)

- Risk of subsalicylate toxicity w/ overuse

Capsaicin Cream / Gel

- Post-herpetic neuralgia

Diclofenac Gel (5%)

TRAMADOL

Opioid w/ weak affinity for **μ-opioid receptor**

Class IV drug since 2014

Dose = 50-100mg q6hours

CYP2D6 enzyme = ↑ **drug-drug interactions** (MAOi, TCAs)

↑ risk 5-HT syndrome & seizures

Resp depression

MUSCLE RELAXANTS & BENZOS

Benzodiazepines

- **No evidence** for use in treatment of pain
- Beware of "shifting" indications
- Remember: unlike opioids it is dangerous to stop benzos abruptly
- Don't neglect treatment of anxiety

Muscle relaxants:

- Limited evidence of effectiveness
- Sedating
- May help with spasticity in acute pain

Ketamine

N-methyl-D-aspartate (NMDA) antagonist

FDA approved for unipolar depression & suicidality, but ***not for pain***

Despite this, several promising studies showing ***good*** efficacy

High prevalence of NMDA receptors in CNS & PNS → **+++ Side Effects**

- **Dissociative side effects** require monitoring
- May be considered in a monitored setting

Marijuana

- 2018 meta-analysis of 47 randomized trials of cannabis for chronic pain = moderate evidence of 30% reduction in pain, but high adverse events
- NNT = 24 & NNH = 6

SUMMARY: NON-OPIOID TREATMENT FOR CHRONIC PAIN

- Acupuncture
- Yoga
- PT/OT
- Exercise
- NSAIDS
- Tricyclic Antidepressants
- Duloxetine
- Topicals
- Gabapentinoids

OPIOID THERAPY

THREE CLASSES OF OPIOIDS

1. Short-acting full-opioid agonists
2. Long-acting full-opioid agonists
3. Partial agonists

SHORT-ACTING OPIOIDS

Opioids target **μ-opioid receptors** in the brain = ↑ **analgesia,** ↑ **resp depression**

Side Effects: *Immunosuppression*, pruritus, constipation, cognitive dysfunction, *hypogonadism*, sarcopenia, respiratory depression → overdose

Tolerance: your body's attempt to maintain homeostasis = → ↑ **dose**

- Counter-regulatory neurotransmitters
- Downregulation of receptors
- Upregulation of drug metabolism
- Desensitization of receptor signaling

- Occurs at different rates for different SEs: Lower rate of tolerance to constipation & respiratory depression
- *Anyone* on opioids will have rebound pain upon stopping an opioid → not evidence of continued need

Opioid Induced Hyperalgesia: hypersensitivity to painful stimuli → ↑ **pain** → ↑ **dose**

- *More* likely to occur at *higher* doses of opioids
- Temporal Summation Test

OPIOIDS: USING A CSA AKA PAIN CONTRACT

2- way agreement, , conversation piece, not a punitive document

CURES, CURES, CURES (PDMP)

Urine drug screen

Set goals for pain and function

Treat with multiple modalities

Treat depression & anxiety

Evaluate frequently

Short Acting > Long Acting

NSAIDS and other drugs act synergistically with opioids

Beware of “shifting” indications

LONG-ACTING FULL OPIOID AGONISTS

Sustained release (Contins)

- Safer than short-acting, but start w/ short-acting
- Steadier serum levels

Fentanyl patch

- 24-hours to reach steady state; Half-life = 6-17 hours
- Hepatic metabolism – dose accordingly
- Ok in renal disease

Methadone

WHAT ABOUT CANCER PAIN?

Methadone (be excessively careful)
- May also need to be adjusted slowly

Consider buprenorphine

If pt is taking large doses: LA > SA
- 50:50 distribution LA vs IR
- Consolidate all LAs and SAs to one each

Fentanyl patch q72°
- Don't adjust before 24°

Calculate MMEs
- Adjust for incomplete cross-tolerance

Opioid (doses in mg/day, except where noted)	Conversion factor
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥ 61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

EXAMPLE: CALCULATING MMES

62 yo M w/ end-stage lung disease and severe pain taking MSContin 30 BID and Percocet 5/325 1 tab q8 hours and Tylenol 3s (30mg) twice daily. You want to convert him to a fentanyl patch? What dose would you use?

+MSContin 30 (2x daily) = 60mg morphine x 1 CF = 60MMEs

+Percocet 5 (3x daily) = 15 mg oxycodone x 1.5 CF = 22.5 MMEs

+Codeine 30 (2x daily) = 60mg codeine x 0.15 CF = 9MMEs

= 91.5 MMEs

91.5MMEs x 0.75 adjustment for incomplete cross tolerance = 68.6 MMEs

68.6MMEs / 2.4 (ucg/hr) = 28.3 ucg/hr

Patches available in: 12, **25**, 37.5, 50, 62.5, 75, 87.5, 100 (ucgs/hr)

2nd line opioid treatment option

METHADONE

Benefits:

- May help reduce OIH
- Lower development of tolerance
- Long half-life
- Good pain management achieved in multiple studies

Risks:

- High risk of 5-HT syndrome (avoid SSRI coadministration)
- **QT prolongation** → torsades
- Higher risk of overdose compared to other opioids: starts to increase > 20 mg
- Unique pharmacokinetics
  - **Alpha-half-life ~ 3°** → 2/2 drug redistribution to peripheral compartments (correlates w/ short duration of analgesia)
  - **Beta-half-life ~9-47°** → 2/2 drug metabolism (actual clearance is delayed compared to action)
  - Dose titrate *no sooner* than 5-7 days
  - +++ drug interactions: Hep C, HIV meds

OVERDOSE TREATMENT & PREVENTION: NALOXONE (NARCAN)

- IV, IM, SC & intranasal formulations available
- Onset of action is 1-2 minutes
- *Duration* of action 30-120 mins: may require multiple doses
- *Very strong affinity* for μ-opioid receptor: displaces all else
- IN formulation absorbed via mucosa: no resp drive necessary
- ***Not*** a controlled substance, ***no*** potential for abuse or diversion, prescribed by any licensed physician or pharmacist
- Used in ICU, ERs, ambulances and at home. Used by physicians, EMTs or family/friends.

BUPRENORPHINE

Discovered in 1966, FDA approved in 1989, for OUD in 2002

Pharmacokinetics:

- 25-100x more potent than morphine
- Slow dissociation from receptor (1/2 life = 20-73°) → ↓ withdrawal
- Poor oral bioavailability when swallowed (<5%)
- SL, buccal, TD formulations bypass 1st pass metabolism → bioavailability ~ 30%

Compared to full opioid agonists:

- Antagonist at **μ-opioid** receptor = ↓ **likelihood OIH, depression, stress**
- Blocks ORL-1 → ↓ **tolerance**
- Little immunosuppressive effect & *reduced* gonadal axis suppression
- *Less* constipating than morphine
- Does **not** block monoamine receptors & not associated with 5-HT syndrome

Analgesia & Resp Depression

- Fentanyl, morphine target **μ-opioid receptors** in **brain** = ↑ **resp depression, ↑ analgesia**
- Buprenorphine activity @ **spine** = ↑ **analgesia, ↓ resp depression**
- Analgesic effect is dose-dependent *w/o a ceiling effect*
- Buprenorphine exhibits effective analgesia at **5-10%** receptor occupancy rates
- 2mg dose naltrexone will reverse buprenorphine effects

Side effects (all formulations):

- GI: Abd pain (12%), nausea (14%), vomiting (8%), constipation (3-13%)
- Neuro: Headache (29%), insomnia (21%), dizziness (2-15%), drowsiness (10%)
- TD patch: pruritus (10%)

BUPRENORPHINE CONTINUED

BUTRANS PATCH

Evidence:

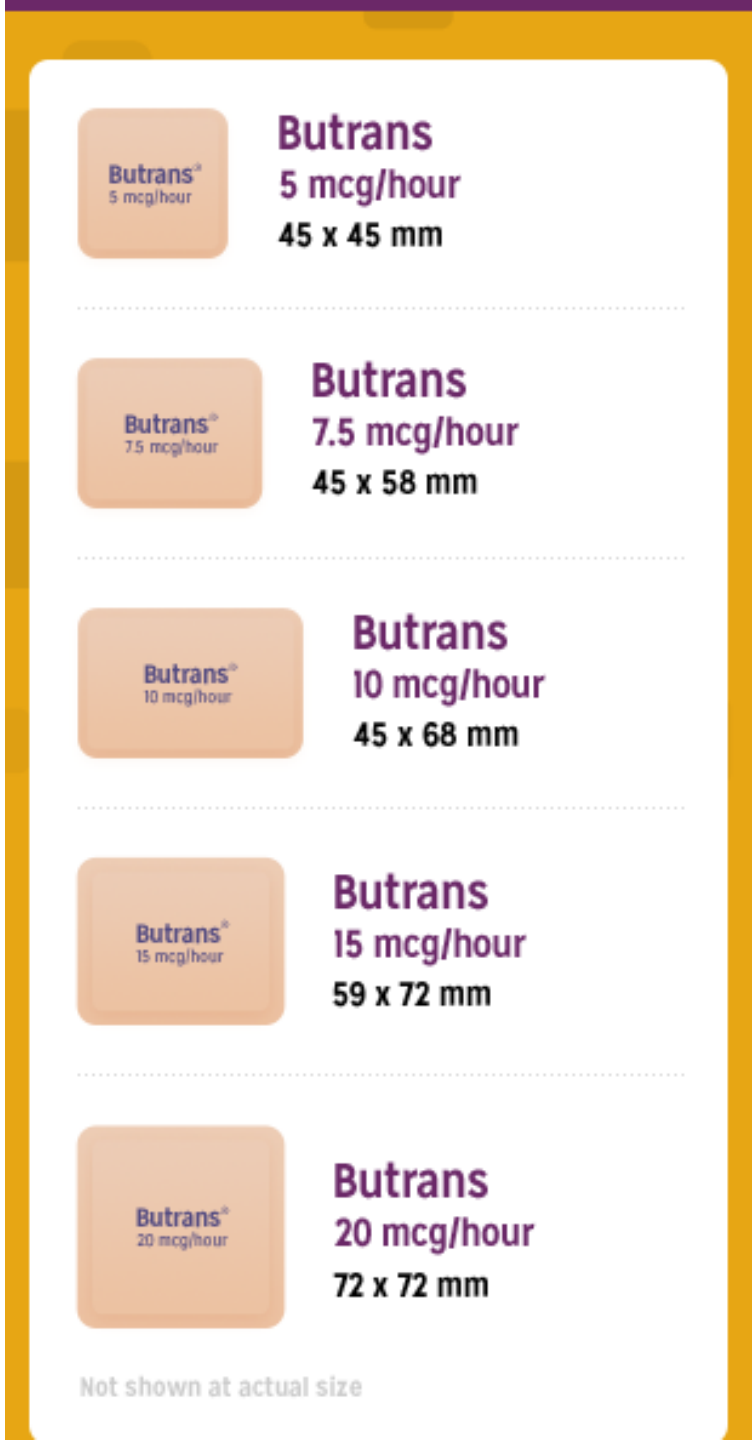
- TD formulations showed 90% efficacy in chronic pain patients > 3 years
- German study of 9k chronic, non-ca pain = 80% good or v. good control
- Lit review of 29 studies TD patch + 4 buccal film = 100% found it effective

BUTRANS PATCH

- 1st FDA approved formulation for chronic pain in 2010
- **Q7 Days**
- Adjust dosing *no more frequently* than **q72°**
- Dosing: calculate MME of current opioid 1st

Full-Opioid Agonist Dose	Patch Dose
Opioid naïve or < 30 MME	**5 ucg/hr**
30-80 MME	**10 ucg/hr**
Max dose in US	**20 ucg/hr**
Max dose in UK	**140 ucg/hr**

(140 ucg/hr patch = 3.36mg/d)



BUTRANS PATCH CONTINUED

- Pts can be started on TD patch directly from potent ***opioids w/o inducing withdrawal*** 2/2 low rise in buprenorphine levels.
- In Europe **35-70ucg** patch are used w/o precipitating withdrawal
- Full opioid agonist can be prescribed *in addition* to butrans patch for breakthrough pain
- Remember: No efficacy in those taking **naltrexone or vivitrol**
- Covered by Medi-Cal!

BENEFITS OF BUTRANS PATCH

- reduced OIH / sensitization compared to full-agonist opioids
- long duration (7 days)
- less risk of overdose compared to full-agonist opioids
- less tolerance compared to full-agonist opioids
- reduced side effects profile compared to full-agonist opioids
- low risk of precipitated withdrawal compared to OUD tx dose (suboxone)
- fewer drug-drug interactions compared to methadone
- simple pharmacokinetics compared to methadone

BULBECA (TRANSMUCOSAL)

FDA approved in 2015

Doses: 70, 150, 300, 450, 600, 750, 900 ucg

Q 12-hour dosing

- Expected analgesic effects of buprenorphine are shorter than it's half-life
- Thus, may be dosed BID to QID

Adjust *no more frequently* than every **4 days**

PERIOPERATIVE PAIN MANAGEMENT

Three Options for patients on buprenorphine:

1. **Stop buprenorphine**, start opioid, re-start buprenorphine after recovery
   - If pt has comorbid OUD, risk of relapse
2. **Continue buprenorphine**, add full dose opioid agonist
3. **Reduce buprenorphine** by ~25% to free up receptors, add full opioid agonist
   - Multiple studies show that buprenorphine use + full opioid is safe and effective for analgesia

SUMMARY: TOP 3 PEARLS FOR MANAGING PAIN

1. Cycle through the **NSAIDS** (if no contra-indications)
   - Selective vs non-selective
   - Remember topical diclofenac!
2. Mood is ***strongly*** correlated with pain, so assess for depression & anxiety & treat.
   - Good pain control will be difficult with severe depression or anxiety
3. If considering opioids, use buprenorphine
   - Consider Butrans patch (5, 7.5, 10, 15, 20ucg patches available)
   - Less likely to be stolen
   - Lasts 7 days
   - Easy bridging
   - On LA Care's formulary!

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FAQS

1. How do you manage chronic pain in the setting of addiction?
2. How do you approach patients unwilling to try alternatives to opioids?
3. How do you manage patients already on high doses of opioids?
4. How do you handle patients whose pain may be at least partly somaticized?

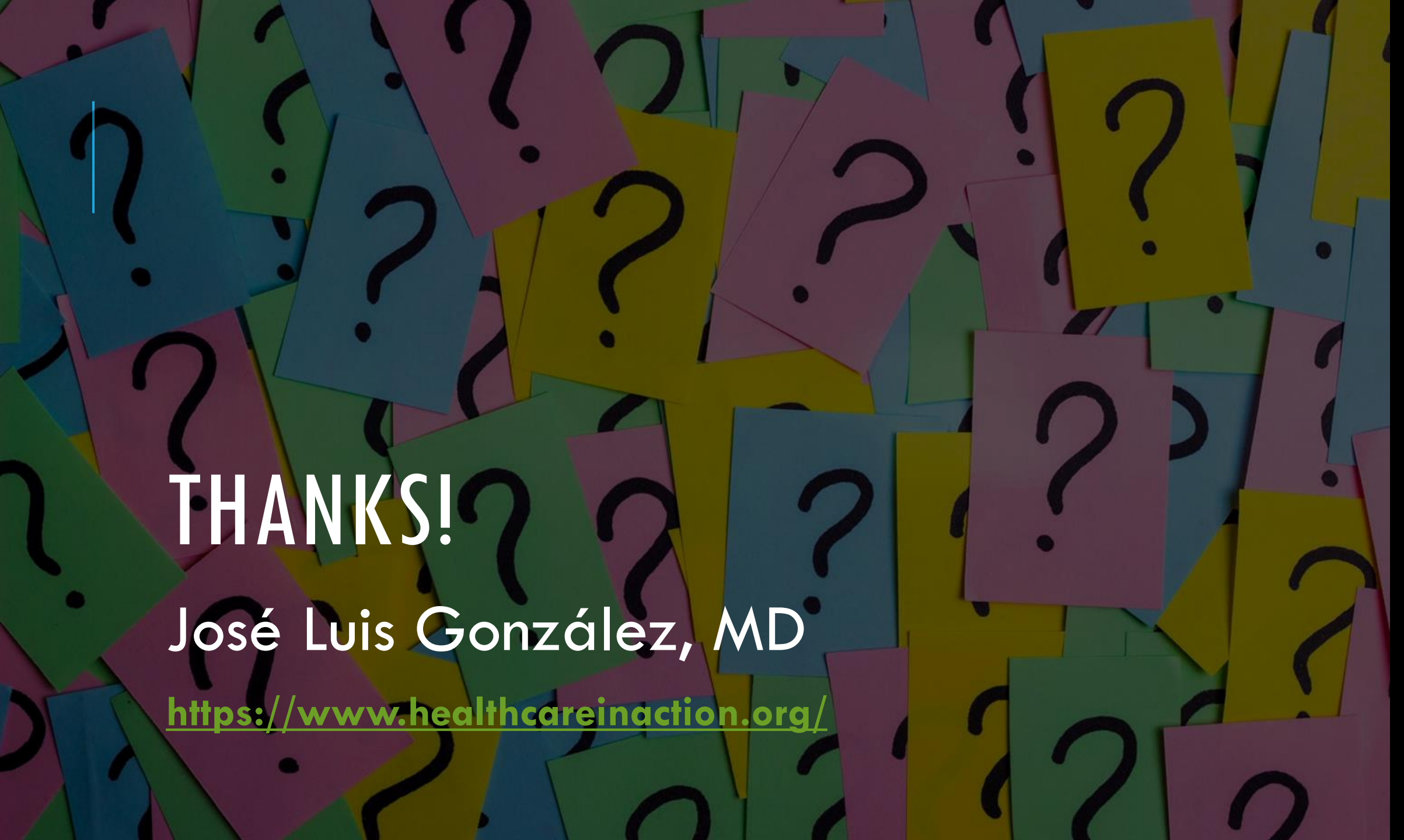
ANSWERS TO FAQS

1. Discuss your concerns with the patient. Use a multimodal approach to pain management. Explain principles of tolerance and withdrawal (at their level). Consider OUD doses of buprenorphine. Remember that methadone is better at pain control than buprenorphine.

2. Set limits. Negotiate. Establish policies you can point to. (i.e. our office doesn't prescribe opioids in isolation – only in conjunction with other meds).

3. Establish ground rules for continuing safe prescribing. Educate on tolerance, hyperalgesia. Go slow if downtitrating. Consider cross-transitioning with microdoses or butrans patches.

4. Treat comorbid psychiatric conditions. Validate. Use a multimodality approach.



THANKS!

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