ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

Agenda

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For attendance, purposes please text the following code: MEDPOP to 608-260-7097

Session Date: Friday May 15th, 2020

Didactic Topic and Presenter:
Opioid Antagonist TX
Alyssa Tilhou, MD – UW Madison Addiction Medicine Fellow

Content Experts:
Ritu Bhatnagar, MD and Susan Mindock, CSAC; and Sheila Weix, MSN, RN, CARN

- 12:30 PM: Attendance text-in – Introductions
- 12:45 PM: Case Presentation
  - Presenter: Rebecca Kellum MD, SSM Health
- 1:10 PM: Didactic Presentation
  - Presenter: Alyssa Tilhou, MD – UW Madison Addiction Medicine Fellow
- 1:30 PM End of Session

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ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2018-2020

Opioid Antagonist TX
Friday May 15th, 2020
Alyssa Tilhou MD, UW Madison Addiction Medicine Fellow
Rebecca Kellum MD, SSM Health

Provided by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP)

Intended Audience:
Physicians, Physician Assistants, Nurses, Social Workers, Pharmacists and Counselors.

Objectives:
As a result of this educational regularly scheduled series, learners will be able to:

1. Review appropriate opioid prescribing and monitoring practices.
2. Participate in office-based management of substance use disorders.
3. Seek, with greater frequency, overdose prevention education.
4. Identify the role of medication-assisted therapies, such as methadone, naltrexone, and buprenorphine in the management of substance use disorders.

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Name/Role	Financial Relationship Disclosures	Discussion of Unlabeled/Unapproved uses of drugs/devices in presentation?
Rebecca Kellum MD, Presenter	No relevant financial relationships to disclose	No
Alyssa Tilhou, MD, Presenter, Planner,	No relevant financial relationships to disclose	No
Kathleen Maher, RSS Coordinator	No relevant financial relationships to disclose	N/A
Briana Kleinfeldt, RSS Coordinator	No relevant financial relationships to disclose	N/A
Randy Brown, RSS Chair	No relevant financial relationships to disclose	Yes
Paul Hutson, Planner, Pharmacy	Consultant for Projections Research Inc.	Yes
Ritu Bhatnagar, Planner, Psychiatrist	No relevant financial relationships to disclose	Yes
Melissa Ngo, Planner, Pharmacist	No relevant financial relationships to disclose	N/A
Susan Mindock, Planner, AODA Counselor	No relevant financial relationships to disclose	No
Sheila Weix, Planner, Nurse	No relevant financial relationships to disclose	No
Lindsey Peterson, MS, CRC, Planner	No relevant financial relationships to disclose	No
Kim Sprecker, OCPD Staff	No relevant financial relationships to disclose	No

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Antagonist Therapy for Opioid Use Disorder

Alyssa Tilhou, MD, PhD

ECHO Presentation, May 15

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Overview

- OUD definition
- OUD treatment
- Antagonist therapy
  - Evidence
  - Mechanism of action
  - Side effects and contraindications
  - Logistics of administration
  - Special populations
- Conclusions

DSM-5 Definition of OUD

In past 12 months:

- Tolerance
- Withdrawal

} **Physical Dependence ≠ Use Disorder**

- Larger amts/longer periods than intended
- Persistent desire/failed attempts to quit/control use
- Much time obtaining/using/recovering
- Important activities sacrificed
- Continued use despite known adverse effects
- Failure to fulfill major obligations
- Recurrent hazardous use
- Craving
- Ongoing use despite interpersonal problems

Sum: 2–3 = mild
4–5 = moderate
≥ 6 = severe

Opioid Use Disorder: Treatment

- Medications
  - Full agonist: methadone (Scheduled II)
  - Partial agonist: buprenorphine (mono/combo) (Sched III)
  - Antagonists: naltrexone and XR-naltrexone (unscheduled)

- Behavioral health (as adjunct)
  - Prescriber led
  - Individual AODA counseling
  - IOP/PHP/inpatient/residential
  - Court mandated

OUD: Antagonist therapy

Evidence for oral naltrexone

- Compared to XR-naltrexone and other OUD Rx options
  - Higher rates of mortality[1]
  - Lower rates of retention[2]
  - Best if pt highly motivated/observed/legally mandated

- Behavioral health can help modestly: Nunes et al, AJDAA 2006
  - RCT naltrexone + intensive BH vs naltrexone alone
  - BH: Addition of CM, CBT, MI, and network therapy
  - BH improved retention, but still fell to 22% (vs 9%) at 6mo

[1]Kelty and Hulse, Addiction, 2012, 107:1817

[2]Degenhardt et al, Drug and Alcohol Review 2015, 34:90.

OUD: Antagonist therapy

Evidence for XR-Naltrexone

- **Krupitsky et al, Lancet 2011:** RCT XR-naltrexone v placebo
  - Longer retention, time to use, less use overall, ↓ cravings
- **Lee et al, NEJM 2016:** RCT XR-Naltrexone vs usual care
  - Subjects: OUD + ongoing supervision or <12m since release
  - 10 vs 5 wks to relapse (HR 0.49); relapse rate OR 0.43
- **Tanum et al, JAMA Psych 2017:** RCT XR NT vs bupe-naloxone
  - Noninferior retention and reported/objective opioid use
- **Lee et al, Lancet 2018:** RCT XR NT vs bupe-naloxone
  - Inpatient induction at 8 sites f/b transition to outpt care
  - 72% vs 95% initiated and 65% vs 57% relapse rate
  - BUT, relapse explained the lower initiation rate

OUD: Antagonist therapy

Naltrexone: Mechanism of Action

- A long-acting synthetic opioid antagonist
- Binds central mu-opioid receptors to block euphoria
- Extremely high affinity – difficult to overdose
- Oral: Naltrexone 50mg tablet taken once daily or 3x/wk
- Injectable soln: Vivitrol (XR Naltrexone) 380mg IM q28-30d

OUD: Antagonist therapy

Side effects

- Precipitated withdrawal
- Mild transaminitis; rarely hepatitis (oral naltrexone only)
- GI – nausea (33%), anorexia, vomiting, diarrhea (<15%)
- Insomnia, depression, anxiety (~10%)
- Injection site rxn (pain, induration, erythema, pruritis: 69%)
  - *Use longer needle*
- Headache, dizziness (~20%)
- Reduced tolerance to opioids

OUD: Antagonist therapy

Contraindications

- Chronic opioid use (+/- physical dependence)
- Anticipated need for opioid therapy
- Increased risk of precipitated withdrawal
  - Acute opioid withdrawal
  - Positive urine drug testing for opioids
  - Precipitated withdrawal following naloxone challenge
- Hypersensitivity

OUD: Antagonist therapy

Logistics

- Order prior to dosing
- Keep refrigerated; warm 30-60min prior to injection
- LFTs: baseline and in 4-8 wks (oral naltrexone only?)
  - Do not withhold treatment while waiting for labs[1]
  - Contraindicated if >5x ULN
  - Monitoring q3mo likely sufficient, (unless clinically indicated); No change with comorbid HCV, HIV.[2]
- UDS: Baseline and if >28 since last injection

[1] 2015 ASAM Practice Guidelines
[2] PCSS 2014 "Monitoring of LFTs"

OUD: Antagonist therapy

Logistics

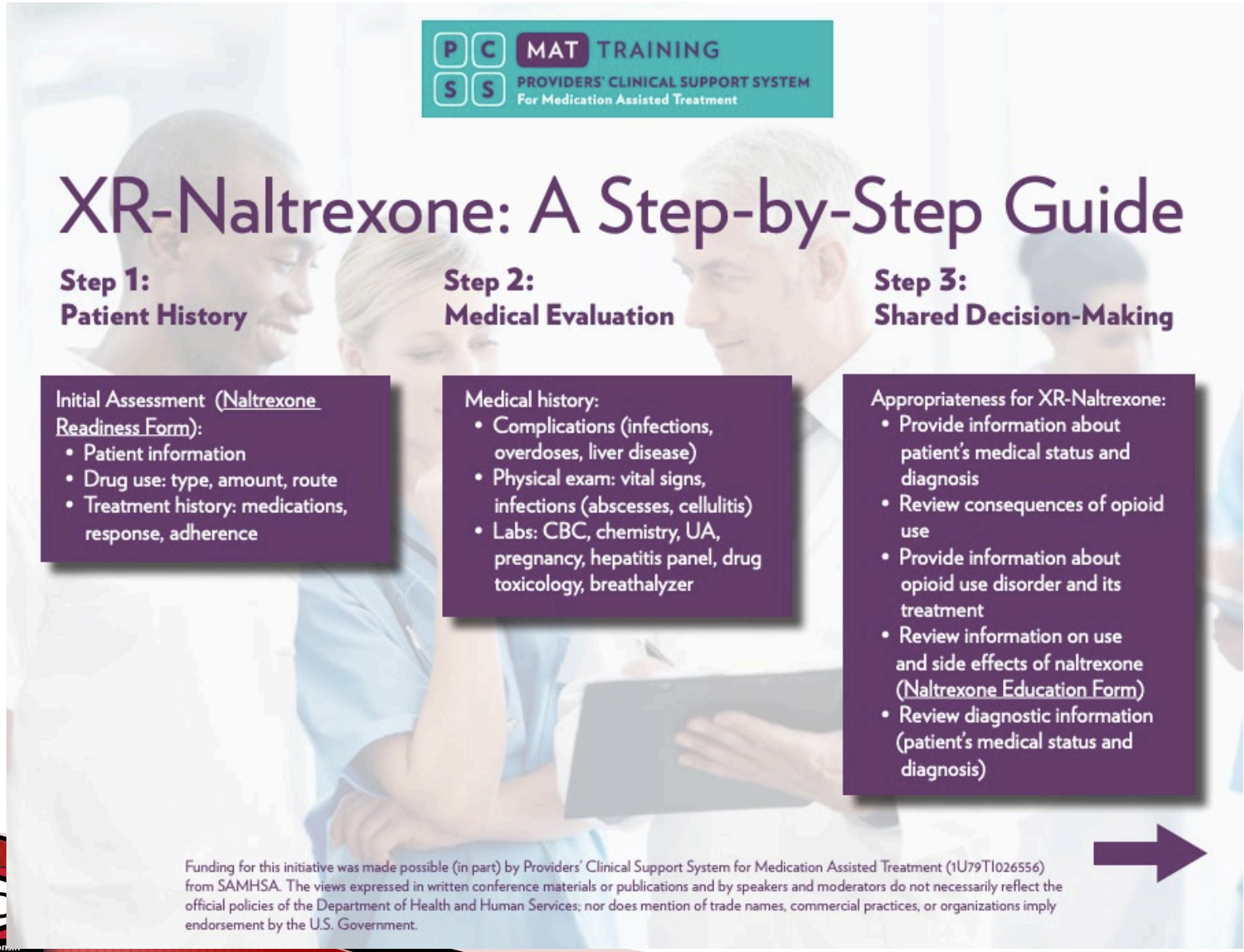
- Initiating XR-Naltrexone
- After buprenorphine
- After methadone
- Onto buprenorphine
- Onto methadone

OUD: Antagonist therapy

Logistics

- **Initiating XR-Naltrexone**
- After buprenorphine
- After methadone
- Onto buprenorphine
- Onto methadone

Provider's Clinical Support System
http://pcssnow.org/wp-content/uploads/2017/02/Naltrexone_Step-by-Step_Virtual_Brochure-1.pdf



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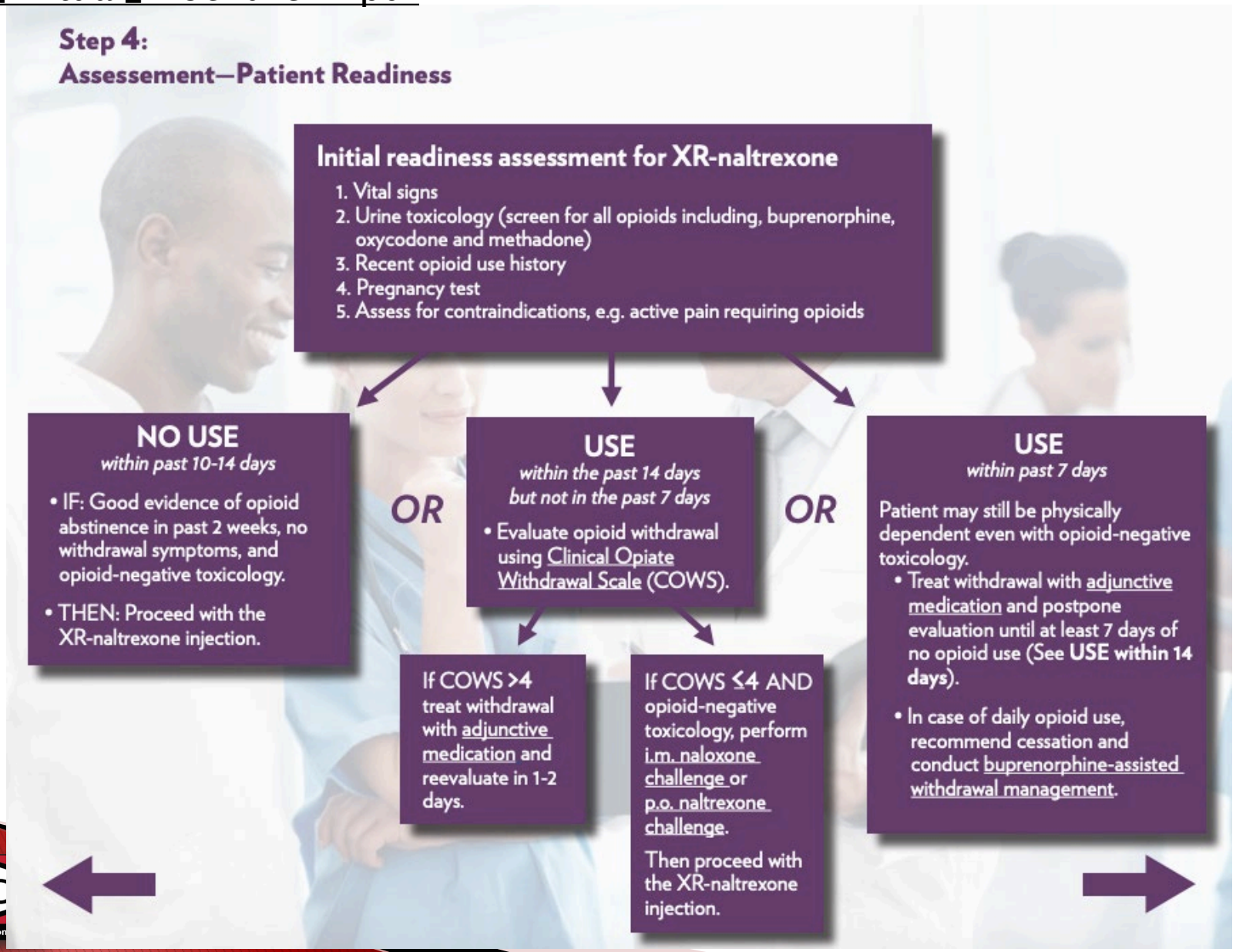
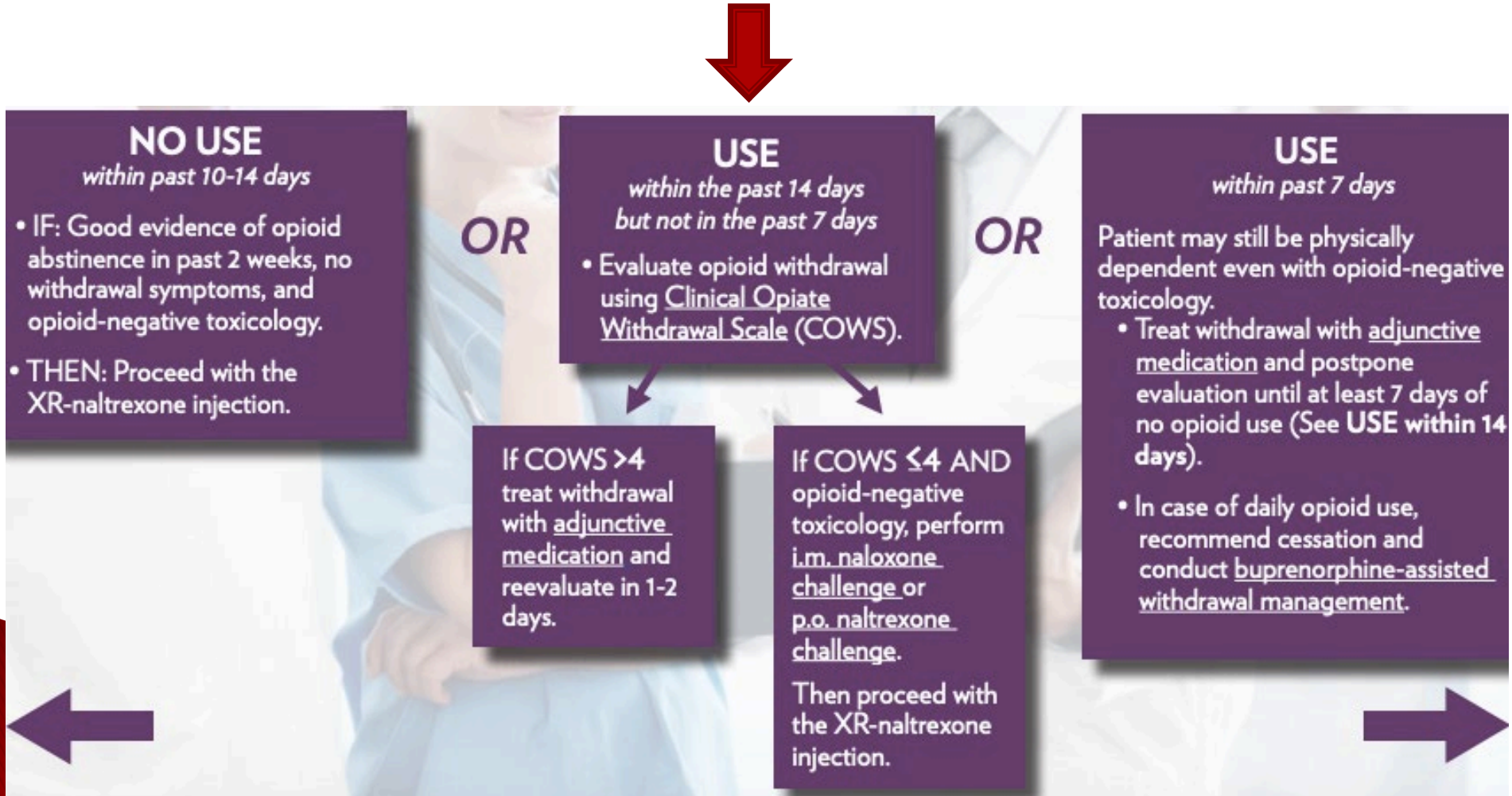


Provider's Clinical Support System

http://pcssnow.org/wp-content/uploads/2017/02/Naltrexone_Step-by-Step_Virtual_Brochure-1.pdf

1. Gather recent opioid use history (past 1-2 wks)
2. Urine drug screen and pregnancy test



Provider's Clinical Support System
http://pcssnow.org/wp-content/uploads/2017/02/Naltrexone_Step-by-Step_Virtual_Brochure-1.pdf

Step 5: Materials

- Refrigeration — Keep XR-naltrexone refrigerated at all times (36° to 46° F). Remove from refrigeration at least 30 minutes before administration. If not used, it can be returned to the refrigerator.
- IM injection setup (gloves, alcohol and/or betadine swab, sterile gauze pads, adhesive bandage, and sharps container)

Step 6: Drug/Patient Preparation

- Assess body habitus of patient – layer of fat over muscle not greater than length of injection needle (2"/usually BMI <40)
- Review medication preparation and injection via instructional video and/or package insert.

Step 7: Injection

- Proceed with dorsogluteal injection (upper outer quadrant, aspirate for blood)
- Alternate buttocks with subsequent injections
- Avoid injecting subcutaneously or into adipose
- If unable to inject because of clogged needle, withdraw, replace the needle and repeat procedure

Step 8: Observation

- Observe patient for 10 minutes for any immediate adverse reactions.
- Perform Medical Management Support for Opioid Dependence: Initial Medical Management Form (10 minutes)
- Remind patient to contact doctor/health care facility in case of any side effects.
- Patient should be given a medication safety card or bracelet to carry and present to caregiver to show in an emergency.

Step 9: Follow-up Visit

- Conduct active outreach to have patient return to the office for monthly injections (appointment reminders, family involvement)
- Unless contraindicated, administer injection of XR-Naltrexone every 4 weeks.
- Perform Follow Up Medical Management session
- If patient misses injection, administer injection only if no use or perform naloxone/naltrexone challenge (see Step 4)

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OUD: Antagonist therapy

Administration

- IM gluteal injection: needle length longer than depth of adipose/subq (usually 1.5 - 2”)
- Alternate injection sites
- Observe 10 minutes after injection for adverse effects
- Provide medication safety card and bracelet

OUD: Antagonist therapy

Logistics

- Initiating XR-NTX
- After buprenorphine
  - Precipitated withdrawal possible up to 10d after cessation
- After methadone
  - Precipitated withdrawal possible up to 14d after cessation
- Onto buprenorphine/methadone
  - Wait at least 1 day (oral) or 30 days (XR-NTX)
  - Start low
    - Decreased opioid tolerance will require lower agonist dose
    - Agonist effect will evolve as antagonist effect wanes

OUD: Antagonist therapy

Special situations

- >28d after last injection
  - Consider naloxone/naltrexone challenge
- Chronic pain
  - Consider agonist therapy if opioid tx anticipated
- Pregnancy
  - If already stable on naltrexone: continue, discontinue, or transition to buprenorphine
- Pre-operative
  - Oral naltrexone – stop 1-3d prior to surgery
  - XR-N – stop 30d prior to surgery

Conclusions

- XR-Naltrexone is as effective as agonist therapy for OUD
- XR-Naltrexone is well-tolerated
- Biggest risks of XR-NTX
  - Relapse prior to dose #1
  - Overdose with treatment cessation
- Particularly useful in populations with:
  - Contraindication to agonist therapy
  - Inadequate response to agonist therapy
  - Restricted living situation (prison, certain recovery settings)

    especially prior to re-entry
  - Those who desire to avoid agonist therapy
  - Co-occurring opioid and alcohol use disorders

Conclusions

Questions?

Thank you!

ACCEPT

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Patient Case Presentation

***Please do not attach any patient-specific files or include any Protected Health Information.**

1. Date: May 15, 2020
2. Presenter Name: Rebecca Kellum MD
3. Presenter Organization: SSM Health, Dean Clinic East, Madison
4. ECHO ID: 4395
5. Have you presented this patient during this teleECHO clinic before? no
6. PLEASE STATE YOUR MAIN QUESTION FOR THIS PATIENT CASE: best management of patient with long-standing high dose opioid Rx for pain, now with worsened anxiety and repeated medication over-use when attempting taper to taper (x 14 years).

Patient Demographic Information:

7. Age: 53
8. Sex: female
9. Education/Literacy: BA
10. Income source: dog trainer; limited with anxiety and now, with COVI-19
11. Social Factors/History:
    - Reports marital stress at prior visits. Currently, husband is unemployed and helps to manage her

12. **Substance Use History:**
    - **In Summary: pt wants to taper down from high doses of prescribed oxycontin/oxyIR. She is admittedly no longer taking it for pain but to limit withdrawal and anxiety. Tapering is difficult because pt will frequently call for early refills and dose increases. Recently admitted to having been taking extra doses in order to avoid withdrawal.**

    - Prescribed benzodiazepines at age 19 for anxiety and panic. Has history of using extra clonazepam.
    - Was started on opioids around 2002 after a fall and back pain. Opioids made her feel better emotionally. She enjoyed the euphoria and the sense of well-being. Continuously used them after her pain was subsiding. Was overusing them at a point – was in outpatient treatment as well as Hazelden.
    - Has been attempting an opioid taper since 2006 when she was on max daily dose ~ 290 mg oxycodone per day. Was initially able to lower to 160mg/d but then pain and withdrawal affected her ability to work. Has had various flares of pain and/or surgeries requiring dose increases. 11/2018 UW pain consult with assessment of

opioid dependence with tolerance and withdrawal. No clear OUD, but does have aberrant medication behavior. Buprenorphine discussed. Plan for slow opioid taper every 4-12 weeks.

- 11/2019 transferred primary care from UW to SSM because her PCP had changed and new PCP was tapering her too abruptly. Pt reports that original MD told her it was normal to be on 300 MME. She stated she wanted to continue tapering her opioids, though she emphasized at that time that they were needed for pain flares. She was told by an addiction specialist that she was not addicted, just dependent. At that time, on oxycontin 35mg bid and oxyIR 10mg six times daily: 95mg/d total. She was to continue with her pain psychologist at UW. She specifically asked for 5-10mg daily dose decrease every 4 weeks.
- Since 11/2019, our office received 45 phone and mychart encounters detailing how we might be able to coordinate prior authorizations or to explain why she has used extra pills or needs early refills (eg travel for work, vomiting, tooth pain, neck pain, cat knocked bottle of OxyIR into acetone). Husband frequently sends multiple-paged documents about refills strategies. She also frequently requests that we increase her daily dose temporarily and then resume the taper. Several times, when I offer to slow her taper to every 8-12 weeks, she insisted she wanted to come off the oxycodone and requested to be tapered every 4 weeks. She then calls later requesting that we slow the taper.
- 5/1/20 video visit: pt states that she needs to go back to 130mg/d because that is the only dose at which she doesn't feel withdrawal. She admitted that it is usual for her to take enough oxycodone on any given day in order to avoid withdrawal. This was her first admission of overuse.

13. <u>Consequences of Substance Use:</u>

- Social/occupational/educational:
    - Stressor in her marriage. Her husband is not working. He is very actively engaged in her oxycodone dosing. Again, writing 5 page letters (scanned into mychart) for options for how to manage prior authorizations with various dose regimens.
    - Initially reported that pain made it difficult for her to work as a dog training (including travel). Later admitted that anxiety was the primary barrier.
- Pain psychology: most recent visit: frustrated with providers. Identifies early relational trauma regarding her mother and how feeling misunderstood by her providers is invalidating. Felt that she was identified as having an addiction vs poor adjustment in the context of chronic pain and existing mental health symptoms.
    - I did receive a call from her psychologist several months ago where he mentioned that she has a history of difficulty tapering, often having various reasons for not continuing with the taper.
    - Has not followed through with specific AODA treatment
- Complicated my ability to manage her pain medications:
    - every prior dose change has led to complicated, time-intensive Rx changes (requires more nursing and MD time than we have available) as well as fluctuating doses (pattern of requesting higher doses then subsequently requesting a faster taper).
    - I have given her the benefit of the doubt on multiple occasions and allowed for a "temporary" dose increase or slowed taper. Unclear how to proceed with a taper now that she has admitted she has been intentionally using extra oxycodone in order to avoid w/d.

- Physical (including evidence of tolerance/withdrawal):
    - Pt reports anxiety and withdrawal with doses less than 130mg/d of oxycodone

14. <u>Interventions that have been tried:</u>

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Gabapentin gave bad s/e (drunk, tired, non-functional)
Nortriptyline 10mg q 8r prn: s/e, couldn't urinate
Flexeril: didn't work
Tizanidine 2mg q8rhprn (very bad s/e)
Venlafaxine: seizure
Clonidine: triggered migraines
Suboxone 2008: was a complete zombie (lower MME prior: 80mg hydrocodone/d)

15.

Current Addiction and Mental Health-related Medications:	Medical/Behavioral Health Diagnosis:
• Oxycontin 15mg bid, 20mg bid • oxyIR 10mg 4.5 per day • clonazepam 0.5mg tid • escitalopram 20mg/d • propranolol 40mg bid	• anxiety, depression, panic with agoraphobia • opioid dependence • OUD (6-8 criteria) • Chronic pain syndrome • insomnia • Migraines • IBS • Hypothyroidism • SI arthritis • fibromyalgia

16.

Patient Strengths/protective factors:	Risk factors:
• Strong desire to cut back on opioids • Has ongoing counseling with pain psychologist • Engaged in her career – animal trainer • Support from husband • Has insurance • Has housing, food	• Lack of insight into the degree to which her behavior represents opioid misuse. • Support from husband (he appears to spend a great deal of time interacting with providers and pharmacy regarding oxycodone) • Reports history of trauma • Shame around feeling that she is perceived as an addict. • Frequently over-estimates how quickly she can taper • History of overusing medications when in anxious and/or in withdrawal instead of being honest with care team about concerns • Has been unable to re-establish with psychiatry for clarification of diagnoses and optimization of medications for anxiety, depression, panic

17. <u>Labs (as indicated), include summary of urine testing or last urine drug screen results</u>

11/2019 UDS with opioids

Hasn't come in for TSH since 3/2018

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18. Patient Goals/Motivations for Treatment:

- Wants to be off the oxycodone. Doesn't like how it makes her feel, how she has to go through withdrawal.
- Wants to go back to work.
- I recently unequivocally declined her latest request to increase her daily dose and/or slow the taper.

19. Proposed Diagnoses:

Anxiety with panic

Benzodiazepine dependence

Opioid use disorder mod-severe

20. Proposed Treatment Plan:

Slower opioid taper (every 12 weeks) -- if so, can this be done in my care?
vs MAT?

By initialing here ___RK___ you have acknowledged that Project ECHO case consultations do not create or otherwise establish a provider-patient relationship between any ECHO clinician and any patient whose case is being presented in a teleECHO clinic.

DSM 5 Criteria for Substance Use Disorder

A use disorder is characterized by maladaptive use resulting in repetitive consequences over the previous 12 months. A minimum of 2-3 criteria is required for a mild substance use disorder diagnosis, while 4-5 is moderate, and 6-7 is severe (American Psychiatric Association 2013)

1. **Taking the substance in larger amounts and for longer than intended**
2. **Wanting to cut down or quit but not being able to do it**
3. **Spending a lot of time obtaining the substance**
4. Craving or a strong desire to use **?**
5. Repeatedly unable to carry out major obligations at work, school, or home due to use **?**
6. **Continued use despite persistent or recurring social or interpersonal problems caused or made worse by use**
7. Stopping or reducing important social, occupational, or recreational activities due to opioid use
8. Recurrent use in physically hazardous situations
9. **Consistent use despite acknowledgment of persistent or recurrent physical or psychological difficulties from using**
10. ***Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount. (Does not apply for diminished effect when used appropriately under medical supervision)**

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11. ***Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal (Does not apply when used appropriately under medical supervision)**

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