Bree Collaborative | Treatment for OUD Revision April 16th 2024| 3-4:30PM Hybrid

MEMBERS PRESENT VIRTUAL

Charissa Fotinos, MD, WA HCA	Cris DuVall, PharmD, SUDP, Compass Health,
John Olson, MD, MHA, Sound Health	Island Drug
Maureen Oscadal, RN, CARN, Harborview/UW	Tina Seery, RN, MHA, CPHQ, CPPS, CLSSBB,
ADAI	WSHA
Tawnya Christiansen, MD, CHPW	Nikki Jones, LICSW, SUDP, CMHS, DDMHS,
Kelly Youngberg, MHA, UW ADAI	GMGS, United Health Community
Mark Murphy, MD, Multicare	Ryan Caldeiro, MD, Kaiser Permanente
Sue Petersohn, RN, CARN, Multicare,	Jason Fodeman, MD, L&I
Libby Hein, LMHC, Molina Heatlhcare	Brad Finegood, MA, LMHC, King County
Tom Hutch, MD, We Care Daily	Amanda McPeak, PharmD, Harborview
Liz Wolkin, MSN, RN, NPD-BC CEN, WA HCA	Everett Maroon, MPH, Blue Mountain H2H
	Bob Lutz, MD, MPH, CHAS Health

STAFF AND MEMBERS OF THE PUBLIC

Beth Bojkov, MPH, RN, Bree Collaborative Emily Nudelman, DNP, RN, Bree Collaborative Karie Nicholas, MA, GC, Bree Collaborative Fan Xiong, WA DOH Michael Duong, Jillian Jetson, WA DOH Audrey Hu Alissa T

WELCOME

Beth Bojkov, Bree Collaborative Staff welcomed the group to the April meeting and reviewed the agenda for the day. Once quorum was reached Beth transitioned the group to approve the April meeting minutes.

Comment:

- Maureen commented that the minutes stated that the Eat Sleep Console model is not recommended.
- Charissa clarified she did not say it was not recommended, but it's not appropriate for people not using at time of delivery.
- Beth updated minutes to state: "Eat sleep console model is appropriate for those not actively in withdrawal. It is not the model for people actively using or not stable on MOUD at time of delivery. Swedish hospital and SAMHSA working on compassion model of care, potentially looking at longer postpartum stays at time of delivery."

Action: Unanimously approved March meeting minutes with amendment.

PRESENT & DISCUSS: SHARED DECISION MAKING FOR MEDICATION FOR OPIOID USE DISORDER

Maureen Oscadal, RN, CARN, presented the ADAI's tools for shared decision-making for MOUD. Maureen began by reviewing that SUD treatment is siloed and people are not usually given a choice in treatment, so shared decision-making is not traditionally part of SUD treatment. The goal of shared decision-making is to keep patients engaged in whatever treatment pathway they want to take. The SDM tools shared came out of conversations with providers in the field and after development of an initial treatment decision making guide. Study in 2020 found that the tool was shown to increase initiation of MOUD after release from jail. Maureen then transitioned the group to reviewing the online shared decision-making tools with the group:

Format	Location	
Brochure	Medications for Opioid Use Disorder. <u>https://www.learnabouttreatment.org/wp-</u> content/uploads/2023/01/MOUD-Brochure-2023-11-web.pdf	
Website	Talking to Clients about OUD. https://www.learnabouttreatment.org/for-professionals/client-engagement/	
Web guide	Talking to Someone About Medications for Opioid Use Disorder. https://www.learnabouttreatment.org/guide/#/	
Handout	Medications for Opioid Use Disorder: Guide to Using the Brochure. <u>https://www.learnabouttreatment.org/wp-</u> <u>content/uploads/2020/09/medicationbrochureguide.pdf</u>	
More at: Le	earnAboutTreatment.org	

Maureen stated the most recent brochure was updated to reflect the fact that long acting buprenorphine is available for people now, and the group is working on getting the shared decision making tool approved by the healthcare authority.

Questions:

• Question from the chat: is this relevant to SB 6228

• Charissa: yes

- SB 6228 directs HCA to have BHA use shared decision-making tool when admitted, and when they are not using one they may not get funding. There are still issues with people being asked to reduce their doses of methadone when admitted.
- When the HCA certifies the tool, it allows it to be used as informed consent can be used in any setting.
- ADAI has a mechanism for sending this tool out to different programs. There is a printable version, and the email to order the brochures:
- Are long acting injectables their own column?
 - o No they are included in the column for buprenorphine
 - Comment: this is a wonderful tool, this tool has been shared in national meetings, it's such a great informative tool. One thing to know for the Bree is how people can get these different medications varies a lot by setting one of the nuances is if you're in residential treatment how are you going to get methadone? Depending on the setting there is contextual issues that influence how it will be used in different settings.
- Is there also an AUD brochure?
 - Kelly: believe we are in process of this, not sure if those are openly shareable or not yet.

- Why is there 'risk for dying' on the brochure itself.
 - Maureen: as a nurse, talk about risks and benefits of all medications so they can make a decision based on the evidence.
 - Charissa: the decision was made, there was a lot of controversy around the treatment, and now it's clear that MOUD is the treatment of choice. We need to make it clear that we are talking about staying alive and not just feeling good. There is a higher risk of stroke and death with Vivitrol, so that's why the decision was made to put it in there.

Charissa informed the group that the HCA will be reviewing this decision aid for approval or steps to approval as certified.

PRESENT: EVALUATION DATA COLLECTION TOOL

Karie Nicholas, MA, GDip, reviewed the OUD Data Collection tool and shared with the group that the tool will be reviewed with the subcommittee on Thursday April 18th in the morning. Questions

- Who would see metrics and would this overlap or complement SCALA NW?
 - Karie: not sure if they overlap or complement SCALA NW, but will look that up. These metrics are ones that we recommend different stakeholders track and measure. At the Bree we will look for data sources to see how much impact these guidelines have.

PRESENT & DISCUSS: MOUD UPDATES IN FENTANYL ERA

Beth then turned the meeting over to Dr. McPeak to share some updates to MOUD since 2017. Dr. McPeak reviewed the history of MOUD including the medications available, :

- Methadone has shown to be more effective than counseling at reducing heroin use and in retaining patients in treatment (when compared to medically supervised withdrawal alone and to buprenorphine naloxone)
 - Mechanism: fill opioid agonist, eliminates opioid withdrawal
 - Methadone limitations: can only be dispensed under supervision of a clinician at an OTP that has been accredited by a SAMHSA-approved accrediting body
 - Formulations: Oral tablet, oral solution, IV/IM/SQ, oral concentrate, soluble oral tablet, etc
- Buprenorphine
 - Formulations
 - Sublingual tablet was added just a few years ago
 - o Buprenorphine/Naloxone
 - Efficacy is similar to buprenorphine
 - Having naloxone means that it's not often diverted for misuse, will not get euphoric effects
 - Charissa: most providers are having conversations that the risk of using buprenorphine/naloxone during breastfeeding is theoretical risk, and there are studies that support that. Pregnancy providers are using combination form.
- Naltrexone
 - Formulation: oral tablet since the 80s, IM suspension of Vivitrol is newer most often used in correctional facilities instead of Sublocade
- Naloxone
 - Narcan generic nasal spray
 - Considerations: recent shortages, will not cause harm if used on someone who is not suffering from overdose

- Mark: good to separate Rx for MOUD treatment from the Rx for opioid OD
- **Fan**: is this group considering a review or making recommendations for pain treatment among individuals on MOUD, esp sublocade?
 - That is outside the scope of this group.
- **Mark**: many of my patients don't understand why Narcan appears on their med list-"remove it please" which prompts discussion with patient. EHRs pop alerts if Narcan removed from Med list every time Bup or any other opioid is prescribed, depending on how EHR alert is configured.
- New to 2024 Existing Medications with Increased Access
 - Suboxone, prescribing limitations lifted
 - Sublocade entered the market in 2017
 - Narcan now over the counter
 - Methadone 72-hour rule
- New Medications for MOUD
 - o Brixadi
 - Kloxxado
 - o Opvee
- In 2022 Mainstreaming Addiction Treatment (MAT) eliminated the waiver for prescribers of buprenorphine for MOUD
- **Brad**: let's pull apart meds for treatment and meds for overdose reversal, we don't want people to get the wrong idea of what some of these meds do
- Sublocade:
 - Pharmacies are required to go through a REMS certification process and develop extensive policies and procedures to make sure meds never go to the patient and only go to the provider
 - Currently only 19 REMS certified pharmacies in Washington 6 only dispense to correctional facilities
 - Prescribers who store non-patient specific Sublocade must also go through this process
 - Around 1900 per dose can cause high copays and insurance limitations.
 - **Charissa**: we continue to work with WSHA to figure out REMS certification process, trying to put together toolkit for REMS certification. We are trying to make it more widespread, distribution plan to small providers funded right now.
 - Amanda: Sublocade dispensing has doubled in last calendar year we are able to deliver Sublocade to providers embedded in supportive housing
 - Have seen commercial insurance prior authorizations increase barriers to getting Sublocade.
- Narcan
 - Not all plans cover generic or OTC Narcan
 - Modeling distribution methods including regularly delivering to permanent supportive housing, working with providers to have already filled Narcan at the appointment
- Brixadi
 - Similar to Sublocade
 - Fatal if injected IV and must never be dispensed to a patient
 - Can cause occlusion, tissue damage, including life threatening pulmonary embolism if injected IV
 - Case reports of Brixadi 8mg being administered in ED post overdose with no precipitated withdrawal
 - No washout period when switching from PO buprenorphine

- **Kelly**: most sites not doing 7 day leadin with bupe anymore, now seeing about an hour lead in time
- **Mark**: brixadi and PI call for a single test dose, only reason for sublocade and 7 day lead in is that's the way the trial was done – the manufacturer is trying to get that changed so it will resemble their competitor
- Charissa: a lot of folks are trying various versions of transitioning people quickly from fentanyl to buprenorphine and sometimes that's massive amounts bupe along with sublocade, there's not a best answer out there but providers are trying all different things with hopes on getting some more focused recommendations on how to transition people. For some providers it's hard to tell people keep using fentanyl until you
- Tom: we're one of the sites for Mark Duncan's survey for patients that take no lead-in sublocade or a cold-start, long-acting injectable without sublingual first. It's because people come to us in situations difficulty getting on sublingual from HPSO in the past. Even getting a single dose of 300mg sublocade can almost guarantee no overdose for the next week. There's lots of ways to measure effectiveness, and for our patients that are coming in having used HPSO recently and take a Sublocade shot are well counseled that they will get sick, asking them if they want to have buprenorphine, but they come back. Colleague of mine has had 19 of first 20 patients come back for the second month shot, and it's worked better than any on-label use of another med.
- Around \$2000 per monthly dose, \$500 per weekly dose
- Only 11 listed REMS certified in Washington state
- **Mark**: Brixadi highest dose (128) does not match Sublocade 300 mg for serum drug levels.
- Mark: For patients deemed to be at highest risk of relapse, especially fentanyl,
 Sublocade 300mg is best choice, in my opinion (due to highest serum levels of bup)
- In this arena there's a lot of off-label use, Sublocade is designed to keep 2 nanogram/mL plasma concentration, not usually high enough for people coming off HPSO
- Kloxxado
 - Double strength of Narcan
 - Community case reports of overdoses require 24-34mg of naloxone to revive patients
 - Same nasal spray design as existing naloxone nasal sprays
 - **Fan**: The higher dosage has a higher prevalence of precipitated withdrawal: https://www.cdc.gov/mmwr/volumes/73/wr/mm7305a4.htm
 - Brad: a lot fo concern about higher dose naloxone with the impact it has on precipirated withdrawal. I think what happens is that someone shorts naloxone up someone's nose and when they don't get up immediately they continue to give them Narcan until they pop. Recommendations from the field is that that might be unnecessary, Fan put a great article around higher dose naloxone. There is a fair amount of research saying that higher doses of naloxone doesn't provide more benefit, and can lead to precipitated withdrawal
 - Charissa: I think the issue is more one of education on how to use Narcan appropriately rather than needing higher doses. The effective dose of naloxone is when the person is breathing not getting up and walking away. And watching someone overdose is frightening.
 - Brad: This is the compassionate overdose summit. <u>https://www.healthmanagement.com/insights/webinars/compassionate-overdose-response-summit-and-naloxone-dosing-meeting/</u>

- Liz: The discomfort associated with naloxone precipitated withdrawal can also be addressed by buprenorphine if the naloxone was administered by a health care provider or if a health care provider responds to the scene of overdose reversal, which could be another tool (in addition to titrating dose to the goal response mentioned by Dr. Fotinos) towards compassionate overdose reversal.
- Opvee
 - Mu-receptor antagonist
 - Nalmefene 2.7mg nasal spray
 - Half-life of 11 hours vs naloxone 2 hour half-life
 - o Stronger affinity to mu-receptors than naloxone
 - Precipirate severe and drawn out withdrawal
 - Twice the cost of OTC Narcan,
- How fentanyl changed the landscape
 - o 2020 fentanyl became the #1 cause of opioid related death in Washington
 - o In 2021, it rose to be the primary cause of all overdose death statewide
 - There has been over 280% increase in fatal fentanyl overdoses from 2021 to 2023
 - If that pace continues in 2024 here will be over 3,000 fentanyl related fatalities by the end of the year
 - Fentanyl is the only opioid most people can access, use of prescription opioids and heroin is downtrending
 - Fentanyl is 50 times stronger than heroin
 - Fentanyl has a half-life of 2-4 hours, heroin has half-life of 3-4 minutes
 - Many street drugs are cut with fentanyl resulting in unintentional and unaware overdose
 - 96.9% of all opioid deaths in King County 2023 were unintentional
 - **Brad**: most of the fentanyl we're seeing in King County is coming in either 1) counterfeit pills, or 2) white powders or rock form. Only time there might be mistaken understanding of fentanyl is if someone thinks they are buying cocaine and it's fentanyl
 - Little lacing of other meds right now, people know what they are buying
- Impacts to practice in fentanyl era:
 - Older guidelines: stop induction if withdrawal symptoms with first dose of phonenorphine
 - Currect practices: at first withdrawal symptoms, take 24mg buprenohpine and supporting medications take 8mg bup in an hour PRN
 - o Dosing
 - Oral: target dose 16 mg QD, actual doses 24-32mg
 - LAI: target use 300 mg x 2 months, 100mg maintenance can increase to 300mg if subtherapeutic and well tolerated
 - Actual use: 300 mg day one, 100 mg during days 14-21, 300mg day 28, continue until therapeutic stop 100mg
 - Goal plasma 2ng/mL
 - Combo: start LAI, and use PO PRN until plasma concentration of LAI sufficiently therapeutic
 - Treatment goals are harm reduction, safe use, less emphasis on abstinence
- **Kelly**: hearing that 300mg shot, there is significant overdose prevention. If a patient misses some doses, they are still seeing overdose protection.
- Mark: will you be addressing option of LAI bup as "exit strategy" from chronic transmucosal bup therapy?

- **John**: sublocade works great as an exit strategy! Even in people who are highly intolerant of withdrawal symptoms. It's my taper plan of choice now.
- Mark: exit strategy study 6 monthly injections sets up an auto-taper, and found trace amounts of buprenorphine in 24 months, and it's a nicer way to land and easier than people trying to get off the sublingual products. There are some populations that want to get off chronic buprenorphine, and usually talk to them about why they want to get off the medication and how they want to. If we are not including LAIs in the initial shared decision-making discussion, and in the discussion for people that want to transition off long-term buprenohrpine, we're missing out.
 - Sue: will you update on the refrigeration of sublocade
 - Mark" there is a reformulation coming out soon not requiring refrigeration.
 - Version currently available can be room temperature is 7 days, but risk of wasting that dose is high once it reaches room temp. We can maintain cold chain in the field, but there's some
- Impacts to practice
 - Sublocade injection is a game changer, since the window of opportunity is so small to start people on these medications
 - DATA waiver removal means there is increased access MOUD can now be provided by PCPs and others
 - Fentanyl potentcy has resulted in need for higher doses of MOUD
 - Brixadi could expand LAI to individuals as it doesn't require refrigeration or cold chain
 - Charissa: Maintaining a cold chain in the field is doable. Is it annoying but manageable. There is also a time off the shelf Sublocade has without the need for refrigeration
 - **John**: I did not realize there were so few pharmacies REMS certified for LA buprenorphine. I imagine this is really slowing the adoption of Sublocade.
 - **Fan**: I thought the 72-hour rule includes all drugs approved for treating opioid withdrawal and not limited to just methadone (even though it may be the one most affected by it)?
 - That's correct, but the challenge with using other drugs is there's nothing to transition them to. We can't prescribe Dilaudid like they do in Canada. It just makes it a bit more complex.
- **Charissa**: we asked what our Medicaid utilization of Sublocade was 7920 doses in 2023, 29 in 2018.
- John: I would really encourage "casual" buprenorphine prescribers to really incorporate LA buprenorphine as a useful tool. Not better than SL, but addresses a lot of problems I deal with SL.
- **Brad**: Is there room to discuss what settings to prioritize long acting injectables to those who are most at risk and most likely to benefit from getting them.
 - Charissa: cost is most likely going to drive access, so HCA is trying to negotiate some different options to purchase long-acting buprenorphine. We know 30-40,000 people on Medicaid have OUD, so we cannot afford to put everyone on that. Unless and until the cost is the same as sublingual, how do we think about prioritizing this useful tool to those at highest risk of immediate harm.
 - Mark: DSM5 has mild-moderate-severe labels now, LAIs are indicated for just moderatesevere (may be true for submucosal as well) but throwing ideas on the table, if we wanted to restrict to severe OUD that is one way to risk stratify

- Brad: one of the complications is that people who have mild SUD or OUD may have even higher risk of overdose because of lower tolerance, we see the young and old having lower tolerance to opioids; people transitioning from acute to community settings seem to be at higher risk because of loss to follow up
 - Mark: we have to prescribe based on diagnostic criteria
- **Everett**: there is a lot of volatility in the drug supply, so it's difficult to predict the amount of fentanyl someone is getting which increases risk of overdose. There's not an easy way to understand that except for doing more drug checking across the state. One other thing we do know raises overdose risk and fatality risk is drug busts themselves, when people move to another dealer.
- Liz: may be worthwhile to consider proximity to an OTP as well as a qualifying factor for LAIs
- Ryan: It seems like another way to approach managing the cost of this treatment is encouraging transition to SL after a period of time - say 6 months. You could allow some UR for continuing beyond that point. If you limit initial use to check for a priority population then you are going to slow how quickly it can be started which is probably most important with the population

PUBLIC COMMENT AND GOOD OF THE ORDER

Beth invited final comments or public comments, then thanked all for attending. At the next workgroup, we'll continue the discussion on prioritization of LAIs for those at most immediate harm and begin discussing potential guidelines for transitions in care. The workgroup's next meeting will be on May 21st, 2024.