DEPARTMENT OF HEALTH

Tackling Opioid Use with Networks (TOWN) Project

MEDICATION FOR OPIOID USE DISORDER (MOUD) PROGRAM

Third Edition

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Executive Summary

Tackling Overdose with Networks (TOWN) is a clinic-based model promoting an approach that includes multiple strategies to reduce opioid overdose within communities. This manual highlights strategies and tactics to help clinics implement a similar program in their community. The primary goals of the program are: Reduce the number of chronic opioid prescriptions, increase access to Medication for Opioid Use Disorder (MOUD), and increase community care coordination and prevention efforts.

TOWN clinics are preventing opioid overdoses within their communities by:

- Developing controlled substance care teams
- Having a case coordinator to manage the relationship between the health care system and patients
- Giving clinicians the credentials, procedures and skills needed to provide MOUD/MAT for treatment in rural settings
- Providing and distributing Naloxone and drop boxes for safe ways to dispose of expired or unused prescriptions
- Creating or joining community task forces that are already active and focused on preventing substance use. The task forces may include mental and behavioral health experts, law enforcement, emergency medical teams, public health, non-profits, and for-profit organizations.

The TOWN model works to put in place strategies focused on 1) clinic and 2) community level changes to support overdose prevention.

The nurse coordinator works with clinicians and staff in the clinic and broader community to:

Monitor Chronic Opioid Usage (taper patients to safe levels)

- Incorporate Prescription Monitoring Program
- Implement Controlled Substance Care Teams

Increase Access to MOUD amongst patients with substance use disorder (SUD)

- Increase the number of providers who have credentials to provide MOUD
- Integrate MOUD into Emergency Departments

Increase Care Coordination and Prevention Efforts in the Community

- Join or start community task forces
- Expand relationships between social service and behavioral health referral programs
- Support naloxone distribution

For these strategies to be successful, they must be used together. Staff and clinics are supported to expand their ability to provide services through individual technical assistance.

This manual shares best practices and procedures for successful implementation of the TOWN model.

Introduction

We hope you find this information helpful, as this manual is a product of our learning and experiences over the past five years in doing this work. The opioid epidemic, along with the equally devastating stimulant crisis, continues to be a public emergency. In communities, correctional institutions and healthcare organizations need to work together to implement programs to decrease the staggering morbidity and mortality our country is experiencing. It is time to take action by creating comprehensive plans that address the prevention and treatment of opioid use disorder and other substance use disorders.

We have spent many years partnering with Tackling Overdose with Networks (TOWN) communities to refine and streamline a comprehensive program that addresses all facets contributing to this epidemic in hopes that others would consider implementing it in their communities. The need for this work has also been identified and supported by the Minnesota Opioid Prescribing Workgroup. Throughout this, we have created protocols and clinical forms to help facilitate implementation; however, we appreciate that customization to fit the needs of individual healthcare systems and communities may need to be made. We have also documented a narrative that allows for a greater understanding of the intricacies leading to use disorders and how they should and can be addressed. This narrative focuses on the most significant hurdle we need to overcome as a society: the prevailing individual bias against people with addiction and the stigma that fuels it.

Acknowledgement

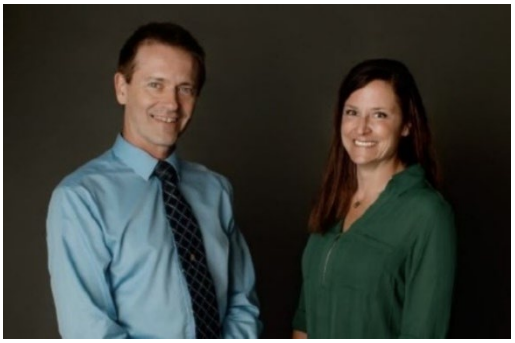
Thank you to the many individuals who played a part in developing this manual and the previous two editions. Special thanks to Katie Stangl (our Program Coordinator) and Erin Foss (our Controlled Substance Care Team Nurse (CSCT RN), who have been with us since the beginning and who helped develop and streamline the program. Additional thanks to the Minnesota Department of Health (MDH), who took a chance on two rural primary care physicians who have stood by and supported us ever since; and to Stratis Health for partnering with us as we expand our reach. Finally, for every patient who suffers from the disease of addiction, who has trusted us to join in their recovery journey, and for those who have lost the fight - we see you, we are here for you, and we will continue to advocate and fight for you.

Also, we would like to express gratitude to the thirteen TOWN sites across that indeed have tackled overdose with networks and provided exceptional patient care. This is nothing short of amazing, and we want to thank you for joining us on this journey. These thirteen TOWN sites include:

- Riverwood Healthcare, Aitkin/McGregor
- Centracare Clinic, Redwood Falls
- Altru Clinic, Warroad
- Fairview Range Medical Center, Hibbing
- Welia Health, Mora
- CCM Health, Montevideo
- Ortonville Area Health Services, Ortonville
- Lake Region Healthcare, Fergus Falls
- Mille Lacs Health System, Onamia
- Olmsted Medical Center, Rochester
- Alomere Health, Alexandria
- Tri-County Healthcare, Wadena
- Cuyuna Regional Medical Center, Crosby

This publication was supported by Cooperative Agreement Number NU17CE924985 from the Centers for Disease Control and Prevention and funds from the U.S Department of Justice (DOJ), Office of Justice Programs (OJP) and Bureau of Justice Assistance (BJA), specifically Grant Award number 2019-AR-BX-K050. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the U.S Department of Justice (DOJ), Office of Justice Programs (OJP) and Bureau of Justice Assistance (BJA).

Authors' biographies



Drs. Heather Bell and Kurt DeVine began their careers as rural primary care physicians. With the surge in opioid prescribing and the mounting opioid epidemic, in 2015, they started an opioid stewardship program through state funding that has since led to pilot programs in 13 other Minnesota communities. Funding through the Minnesota Department of Health (MDH) enabled these communities to focus efforts on appropriate opioid prescribing and medications for opioid use disorder (MOUD) treatment with technical assistance provided by Drs. Bel, DeVine and their team.

After notable success in their local programs, The Department of Human Services (DHS) provided funding for Drs. Bell and DeVine to facilitate a ProjectECHO®, telehealth weekly teaching program focused on all topics relating to addiction, now into its 5th year. The ECHO program, over time, grew to include programs for medical students, physician assistant students, and even COVID! With their partners at Stratis Health, their programs continue to expand to include advocating for, and implementing, addiction treatment within corrections. Their passion for this field led them both to pursue an additional board certification in Addiction Medicine. Their work has led to recognition, most notably, the American Hospital Association (AHA) Nova Award, the 2020 Minnesota Medical Association (MMA) President's Award, as well as being named Family Physicians of the year for 2021 by the Minnesota Academy for Family Physicians (MAFP). For fun, they also co-host a popular podcast on 'all things addiction" called "The Addiction Connection."

Dr. Kurt Devine and Dr. Heather Bell.

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History

Although it does not help solve the problem, understanding the history of events leading to the current opioid epidemic is vitally important. In 1986, Dr. Russell Portenoy co-wrote a paragraph letter to the editor discussing opioids in the treatment of 38 patients with chronic non-malignant pain. From this study, in which six patients were maintained longer than seven years, he stated, "We conclude that opioid maintenance therapy can be safe, salutary and a more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse" (Portenoy & Foley, 1986). The reality was the paper looked at few patients, very low doses (usually <20mEq of morphine), and, as such, "Few substantial gains in employment or social function could be attributed to the institution of opioid therapy" (Portenoy & Foley, 1986).

It would not be until 10 years later that Dr. James Campbell, president of the American Pain Society, gave a speech that labeled pain as the fifth vital sign, stating: "If pain were accessed with the same zeal as other vital signs, it would have a much better chance of being treated properly" (Neilson, 2016). Coincidentally, it was the same year (1996) that Purdue Pharma released OxyContin. Several medical organizations, including the Joint Commission for Accreditation of Healthcare Organizations (JCAHO or now The Joint Commission, referred to in this document as TJC), American Pain Foundation, and the Veterans Health Administration, all followed suit by adopting pain as the fifth vital sign. Drug representatives suggested that a mere 1% of patients had the potential to become addicted to opioid pain medications. They quoted the *New England Journal of Medicine* article by Porter and Jick (Porter & Jick, 1980) and another article by Perry and Heidrich in *Pain* (Perry & Heidrich, 1982). The cited studies, however, were based on patients in the hospital receiving the medications for acute pain, not daily long-term chronic use. Purdue Pharma then used this 1% statistic in its marketing of OxyContin. Aside from Purdue Pharma using this information to sell OxyContin, pain specialists and teaching seminars exploited this information as "evidence" of the low risk of addiction. What they chose to ignore, however, were the numerous studies, summarized in a paper by VanZee entitled *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,* that showed addiction rates from 3-43% in patients using opioid pain medications chronically (VanZee, 2009).

The push for prescribers to treat pain increased in the following years. By 1998, the Federation of State Medical Boards "recommended" a policy stating doctors would not face disciplinary action for prescribing even large amounts of opioids for chronic pain. TJC published a prescribing guide for providers, paid for by Purdue Pharma, that stated, "some clinicians have inaccurate and exaggerated concerns" about addiction, tolerance, and risk of death. "This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control" (JCAHO, 2001). Prescribing opioids accelerated in 2004 when the Federation of State Medical Boards began to hold physicians accountable for under-treating a patient's pain. Ironically, the Federation of State Medical Boards received nearly $2 million in funding from Purdue Pharma and other opioid manufacturers. Minnesota followed suit, releasing the following statement by the Controlled Substance Work Group on November 10, 2007: "Untreated pain or under-treated pain is as serious a departure from the standard of care, and as serious a violation of the Minnesota Medical Practice Act as is excessive prescribing of controlled substances or prescribing of controlled substances for non-therapeutic purposes" (Group, 2007). This statement is in stark contrast to a publication by the Centers for Disease Control and Prevention (CDC) released in March 2016:

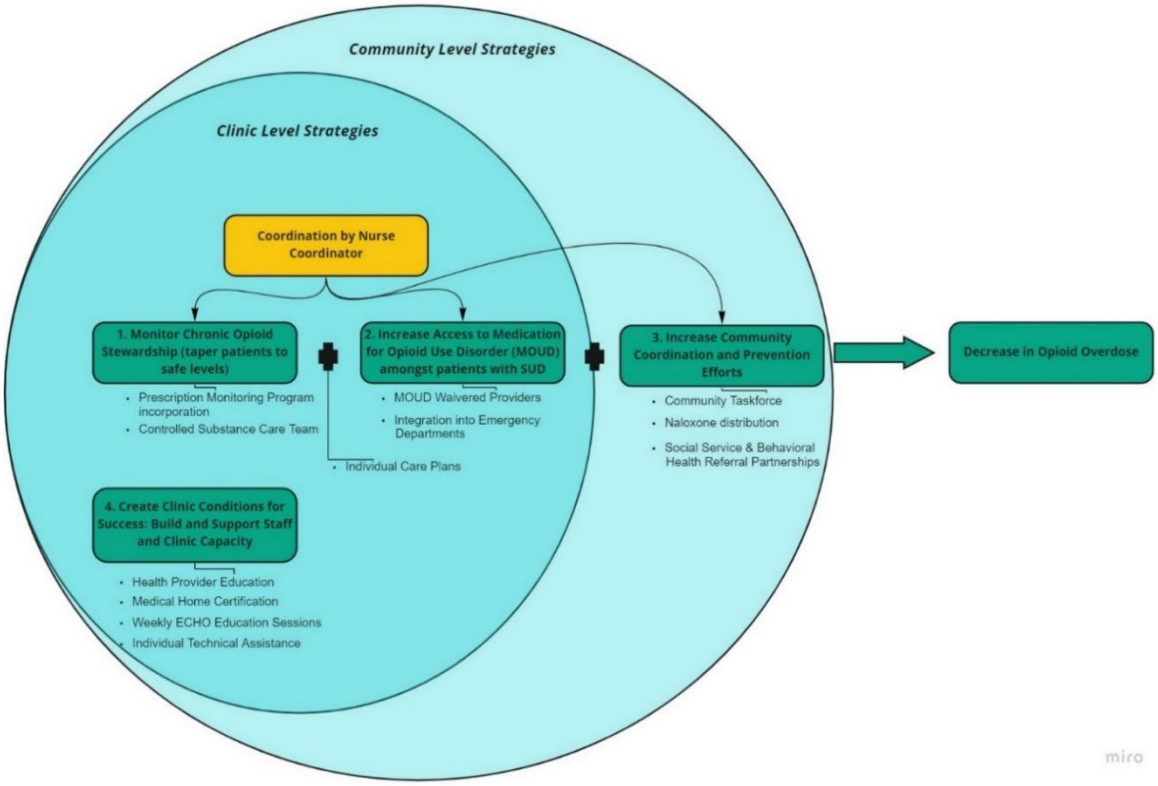
> *No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least one year; extensive evidence shows the possible*

harms of opioids (including opioid use disorder, overdose, and motor-vehicle injury); and extensive evidence suggests some benefits of non-pharmacologic and non-opioid pharmacologic treatments compared with long-term opioid therapy, with less harm (CDC, 2016).

In just 10 years, the consensus and guidelines changed thanks to staggering and overwhelming statistics. According to the *Pain Physicians Journal,* in 2010, the U.S. had 4.6% of the world's population, yet had 80% of the world's opioid consumption and 99% of the world's hydrocodone consumption (Fellows, Ailinani, Manchikanti, & Pampati, 2010). In Minnesota (MN Department of Health statistics) alone, in 2000, there were 23 opioid deaths compared to 317 in 2014. In 2013, national opioid overdose deaths surpassed car accidents as the leading cause of accidental deaths, with an average of one person in the U.S. dying every 20 minutes. Now, nine years later, as we update this publication, the statistics are even more devastating, with an average of one person in the U.S. dying every 10.5 minutes, nearly twice as many.

It became the perfect storm illustrated by physicians and other providers being strongly encouraged to aggressively treat pain and heavy marketing by profit-seeking opioid producers targeting providers with less-than-accurate statistics regarding addiction and other risks. Like virtually every other community, our community was negatively affected by overprescribing opioids, diverting medications, and an increasing number of patients developing opioid use disorders, including heroin and, more recently, fentanyl and other synthetically derived opioids. Inadequate and misinterpreted studies, along with questionable data, ushered us into an opioid epidemic that has continued to take the lives of tens of thousands of U.S. citizens each year with no 'end-in-site.'

The current situation requires us to not only quickly but efficiently improve physicians' prescribing practices for patients' safety and to care for those who have developed the disease of addiction. Using this manual, we hope to accomplish three objectives: 1) show the process of how to implement a clinic-based program which includes monitoring and educating on appropriate patient-safety-focused prescribing of opioids (and other controlled substances), 2) illustrate a basic method for treating those with opioid use disorder(s), and 3) how to leverage community collaboration to support and identify patients that need assistance and treatment.


Community Level Strategies
Clinic Level Strategies
Coordination by Nurse Coordinator
1. Monitor Chronic Opioid Stewardship (taper patients to safe levels)
Prescription Monitoring Program incorporation
Controlled Substance Care Team
2. Increase Access to Medication for Opioid Use Disorder (MOUD) amongst patients with SUD
MOUD Waivered Providers
Integration into Emergency Departments
Individual Care Plans
3. Increase Community Coordination and Prevention Efforts
Community Taskforce
Naloxone distribution
Social Service & Behavioral Health Referral Partnerships
Decrease in Opioid Overdose
4. Create Clinic Conditions for Success: Build and Support Staff and Clinic Capacity
Health Provider Education
Medical Home Certification
Weekly ECHO Education Sessions
Individual Technical Assistance
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Program Model Description

The key strategies recommended in this model can be organized by their primary objectives:

1. Monitor chronic opioid stewardship by tapering those who have a diagnosis inappropriate for chronic opioid prescriptions slowly and gently to ensure patient comfort and most importantly, safety.
2. Increase access to Medication for Opioid Use Disorder (MOUD).
3. Increase community prevention efforts and coordination to respond to people experiencing substance use disorder and/or those who have experienced an overdose.
4. Build and support staff and clinic capacity.

The strategies related to each objective are described in more detail below.

Model strategies

To decrease chronic opioid prescriptions, this model advocates for creating a controlled substance care team and regularly utilizing the prescription monitoring program (PMP). To increase access to MOUD, the model recommends increasing MOUD-waivered providers and integrating MOUD into emergency departments (ED) and education for surgical services should MOUD patients require a surgical procedure. Individual care plans are an integral component of both key objectives. To increase community coordination and prevention efforts, sites implement community taskforces and establish partnerships with social service and behavioral health providers. Additional intentional efforts build and sustain clinic and staff capacity through individual technical assistance and cross-site Extension for Community Healthcare Outcomes (ECHOs) led by Drs. Bell and Devine, alongside encouragement to obtain medical home certification.

In practice, nurse coordinators and ‘physician champions’ - MOUD-waivered physicians/prescribers within each clinic who are seen as local experts and advocate internally for adoption of best practices - are crucial to the implementation of all objectives and ensure continuity of efforts. Many core strategies could not be successfully implemented without a nurse coordinator or similar role to lead the work. While sites had some variation in the job title and background requirements for this position, a dedicated position is necessary to coordinate the components, provide non-judgmental client-centered care, and build community partnerships.

Physician Culture

Most facilities are made up of physicians from multiple generations, which often makes implementing change more difficult. Providers practicing when the State Boards emphasized pain as the fifth vital sign were encouraged to treat pain aggressively with opioids. They have often continued to be more generous in their prescribing. In contrast, providers who went through training after 2010 appear to be more judicious in prescribing and tend to be more receptive to new information regarding appropriate prescribing and monitoring. Continuing education, newsletters, and presentations at provider meetings, emphasizing current recommendations, may continue to help us shift provider beliefs and attitudes regarding high-risk prescribing. We must be careful to provide consistent information about guidelines regarding quantities and strengths of opioids, indications for opioids, as well as dangers of co-prescribing with benzodiazepines. Considerations regarding patients' medical co-morbidities should also be a part of the educational process.

Providers are often concerned with additional work and the time constraints that monitoring and educating patients may cause. When prescribers utilize a care coordinator, usually a registered nurse (RN), much of the work will fall to the care team resulting in more appropriate and safe treatment of patients with less work needing to be performed by the provider. As patients enter the program, the nurse or social worker can assist with care plans and other forms, ensuring that all are kept up to date. The care team can also access the Prescription Drug Monitoring Program (PDMP) at the initiation of the care plan and subsequent office visits. This workflow enables the provider to have the information at hand and allows for more time with the patient for education and discussion. Care Coordinators can also take work from providers by placing orders for urine drug screens, pill counts, and confirmatory testing as indicated by screening tests and/or protocols.

However, there may still be delays before uniform provider buy-in regarding opioid stewardship. Changes in provider attitudes and confidence in the program often come with unexpected urine test results and concerning patient behaviors. Some of these behaviors may involve patients with long-standing relationships with their providers, who feel that additional monitoring is unnecessary for these trusted individuals. As there is no single identifying profile to determine which patients are at high-risk for diverting or using non-prescribed or illicit substances, uniform patient monitoring is imperative. It is unethical to have screening practices built around discrimination and bias.

It may be more effective to avoid prescriber mandates but instead focus on education and support, encouraging compliance with accepted guidelines. An emphasis on appropriate documentation at each visit is also essential. This includes a qualifying diagnosis for long-term opioids, the patient's functional status in relation to their opioid medications, discussion of risks and benefits of the medications noting their co-morbidities, other modalities trialed, justification for dose increases, and an appropriate physical exam in relation to their opioid diagnosis. Documenting the above not only allows for the completeness of records but will often give the provider insight into the appropriateness of opioids for each patient. If changes in the treatment plan, both acutely and to achieve long-term goals, must occur, shared decision-making between the provider and the patient should be emphasized.

The overall goal of the education and focus on opioid stewardship is improved patient safety and better patient outcomes. It should be mentioned that forced tapers or cutting patients off their medications should not be a part of an effective program and may be considered patient abandonment. Taper initiation is a situation where the medical team's support surrounds the patient. This situation produces anxiety for most, and it is imperative that patients feel heard. Immediate cessation of opioids is inhumane and highly uncomfortable for the patient as life-

threatening acute opioid withdrawal symptoms could likely be experienced. Slow and gradual tapers are highly recommended, with a heavy presence of care coordination. Often, it is helpful for two taper plans to be drafted by pharmacy, so the patient can choose the plan of care that suits them best. In addition to patient safety and potential overdose conversation that occurs with patients, it is also imperative to provide education regarding opioid hyperalgesia. This diagnosis is classified as an enhanced pain response resulting from either injury to part of the body or chronic opioid use. When a person becomes more sensitive to pain due to opioid medication, it's called opioid-induced hyperalgesia.

Staff from participating clinics recommended the following strategies to build buy-in for MOUD:

- Encourage formal adoption of OUD screening and showcase MOUD as a best practice to support existing patients.
  - Staff commonly reported that providers who did not want to become MOUD-waivered expressed concerns that they did not want to start serving an OUD patient population, framing patients with OUD as distinctly different than their current patient population. However, upon implementing MOUD, many of the first patients were not new patients but rather existing patients identified as having OUD. Seeing this helped resistant clinicians recognize the need for MOUD as part of care for their current patients.
- Encourage getting a waiver as additional education, not as a commitment to regular prescribing.
  - Some sites found success in encouraging clinicians to pursue getting waivered as a form of additional education without the expectation that they would have to prescribe MOUD actively. Of course, not all waivered physicians/prescribers at each site are actively prescribing; however, this approach successfully convinced some physicians/prescribers who were hesitant to eventually prescribe after they understood the science and medicine behind MOUD through the education process.
- Demonstrate the impact of MOUD on patient and clinician interactions.
  - Highlighting preliminary data on early patient successes (i.e., ongoing participation in MOUD, reduced recidivism, family reunification, or gaining employment), as well as sharing experiences of how patient/clinician interactions became more productive, favorable, and less time-consuming were identified as keyways to build greater physician buy-in. In this way, clinicians see how MOUD adds value to the practice.
- Frame MOUD as a proactive option to prevent overdose and highlight similarities to other diseases.
  - Staff reported that encouraging the mindset that MOUD was something to offer versus providing nothing and contributing to a potential death was a compelling argument for many providers to at least make a referral to a MAT-waivered physician, if not get waivered themselves.
- Articulate administrative or leadership support of this effort.
  - In the limited cases where physician champions reported not gaining any traction on encouraging participation in MOUD, staff advocated for more significant administrative or leadership pressure to support full clinic participation in the TOWN model.

Community Collaboration

Partnerships in the community should be developed as each member can bring different assets, skills, knowledge, and resources to the table. For example, periodic task force meetings where all community stakeholders come together to discuss the patterns, trends, and issues in your community will enable the prioritization of next steps your community may take to address local substance use.

Many task force members may not work directly with patients. They are critical to the health and safety of the community. It is essential to understand that HIPAA laws limit what patient-specific information providers can discuss with task force members. However, trends and patterns within the healthcare facility can be disclosed. If a crime is committed or there are issues surrounding vulnerable patients, HIPAA may not apply. Any clarification on what is or is not allowed should be first discussed with your clinic administration or hospital legal team. Community Taskforce

In the TOWN model, monthly community taskforce meetings are recommended to build community partnerships, increase community education, and leverage collective assets, skills, knowledge, and resources. In addition, task forces provide an avenue for community stakeholders to discuss the patterns, trends, and issues observed in the community and identify opportunities to address substance use issues.

Most sites were not previously involved in a community taskforce and began their taskforce from scratch, although less frequently, sites joined onto existing taskforces already established in their communities. Nurse coordinators took the lead in recruiting and facilitating meetings. Cross-sector participants most often included representatives from local schools, pharmacists, law enforcement, criminal justice entities (jails, drug court if present, probation), and treatment providers (county mental health providers, inpatient treatment, mental health providers).

Sites identified the following primary purposes of their taskforces:

- Basic education of substance use disorder and harm reduction; sharing of available resources and identifying community issues or trends in substance use.
- Raising awareness specifically of clinic MOUD offerings and processes for getting patients started. Coordinated referral process between taskforce members.
- Coordination of naloxone distribution.
- Coordination of prevention efforts, most commonly community education or awareness-raising strategies; in some cases, coordinated policy or system changes to promote prevention (i.e., changing employment policies to encourage hiring someone with prior substance-related charges; strategizing to address community transportation and barriers to treatment access).
- Active community outreach (i.e., creating and disseminating business cards to promote treatment access).

While more challenging to start, sites reported that community partners were excited to learn about expanded MOUD clinic offerings and for the opportunity to work collectively to address opioid misuse.

> *"Up to this point, I didn't have the time to do this. Having the nurse coordinator here who can foster relationships with people who I haven't had time, so it's taken a while to get that going. So the first meeting will be who we are, what we do, what we treat. Asking what are you seeing in the community and how can we help? Moving towards how do we coordinate*

referrals and particularly the connections between police and the clinic, so the more folks know what we do they can better refer people to us. That's the goal. I'm very excited it's finally coming to life. I think the community has been waiting for this." - Physician

Best practices and lessons learned for implementing community taskforces

Many sites reported that getting their task force up and running **relied on the prior personal and professional networks staff had created**. Without existing relationships, staff devoted time to doing individual outreach to explain the MOUD program and how people could access MOUD services.

Like initial resistance from physicians/prescribers to becoming MOUD waivered, law enforcement, criminal justice, and abstinence-based treatment facilities all had initial resistance to MOUD, seeing it as the further introduction of suboxone onto the streets and replacing one drug with another. Clinics addressed this by **demonstrating initial patient successes of MOUD and explaining the science behind MOUD**.

Some taskforces were successful by prioritizing efforts to **identify opportunities for policy, system, and environmental change.** Multiple clinics reported being surprised by the impact of the taskforce and the ability to implement coordinated cross-system referral pathways, policy changes, or pilot entirely new interventions to address community-identified issues.

Potential members of your task force, including their possible roles and contributions, may include:

- Law Enforcement: Local Police Department and Sheriff and State Patrol:
  - Updates on local drug trends
  - Discussions on current diversion trends
  - Organize and participate in drug take-back days
  - Potentially house medication disposal receptacles
  - Community education projects
- School Officials:
  - Education for students, staff members, and families
  - Collaborate with other members of the task force for community education efforts on:
    - Local drug trends
    - Substances of concern being found in the school buildings
  - Follow the Minnesota State High School League policies surrounding substance use in student-athletes
  - Encourage student groups such as "Drug-Free Schools" to empower student involvement and guidance
  - Nursing, and potentially other staff, to assist in setting up naloxone (Narcan) availability
  - Referral processes for students, creating a safe place to seek assistance
- Community Pharmacy/Pharmacies:
  - Ensure immediate access to medications for opioid use disorder (MOUD)

        - Physicians prescribing Naloxone with controlled substances
        - For prescriptions coming in
        - Appropriate stock
    - Provide ease of access to naloxone and encourage patients (whether a patient with substance use disorder (SUD) or other patients with any controlled substances) to have naloxone at home
        - Educate on the importance of this for safety
        - Minimize the stigma associated with having naloxone accessible.
        - Enroll with Steve Rummler Hope Network to become a Narcan Access Point Site
        - Understand stigma and aid in educating this at patient face-to-face interactions
    - Become aware of [other] methods of harm reduction:
        - Sterile syringes and needles (consider offering these)
        - Fentanyl test strips
        - Standing order for Narcan with all opioid prescriptions
        - Participation in National Drug Take Back events at the local level
    - Partner specifically with providers and care teams to aid in the quick resolution of prior authorization issues
    - If not an available service within the clinic, assist in creating taper plans for controlled substances (opioids and benzodiazepines specifically) as needed
- County Attorney's Office/Drug Court:
    - Provide education and insight into the intricacies of drug court and legal processes
    - Advocate for patients utilizing personal relationships with county staff
    - Be open to education on addiction as a disease to support clients more thoroughly
- Child Protection:
    - Advocate for children impacted by SUD under the lens of the understanding of addiction as a disease
- Be open to understanding childhood trauma from the parenting person's perspective and how supporting the family unit may Minimize the stigma associated with having naloxone accessible. Local Foundations/Community Non-Profit Organizations
    - Offer ideas of fundraising opportunities to help offset:
        - Costs of medications (specifically MOUD, naloxone, etc.)
        - Gas cards to aid in transportation barriers
        - Collaborate with potential short-term, low-income housing outlets in your community
        - Food cards to aid in social determinants risks
    - Assist in grant writing for the community and clinical/hospital teams

- Local Clinic(s)/Hospital:
  - Specifically:
    - Emergency Departments
    - Obstetrics
    - Clinic physicians
    - Surgical departments
    - Clinical/hospital pharmacist
    - Administration/Leadership
  - Coordinate between all areas in facilities, ensuring patients with SUD are maintained on their MOUD (if applicable) and cared for in a non-stigmatized manner
  - Gain education on and become aware of the recognition of SUD and become comfortable with that conversation to offer support to patients
- Public Health/Social Services:
  - Provide information to the task force on locally available services to which patients can be referred
  - Share information on county resources, funding, and prevention strategies being developed and utilized
  - Present the results of the Community Health Needs Assessment
  - Perform Chemical Use Assessments (previously Rule 25 Assessments) and aid in treatment facility coordination, if needed
- Home Care/Hospice:
  - Monitor active medications for their patients, including quantities
  - Understand the high risk of diversion in this group:
    - Personal Care Assistants (PCAs) in the home
    - Other support service individuals in the home
    - Family members in the home
  - Brainstorm drug disposal/acquisition plans as, upon death, the medications 'belong' to the patient and, therefore, the family. Offer drug disposal bags, take the medications to be disposed of, etc. Many times hospice patients have many classes of controlled substances and/or high doses, making any medications remaining upon death high risk for diversion
- Mental Health/Therapy Providers:
  - Communication, with frequent release of information (ROIs), for collaboration between providers (the clinical provider and the mental health provider) as many times SUD and mental health diagnosis co-occur
  - Assist in coordinating additional services, if needed, for a higher level of mental health care
- Local In-Patient and/or Out-Patient Treatment Facilities:

- Update on bed access availability
- Understand the importance of MOUD and maintaining MOUD while in treatment
- Work with the clinical care team on transitions of care to ensure patients/clients are not lost to follow up

Care Team and Roles

- Physician Champion(s):
  - Review patient charts, ensuring a thorough work up of the diagnosis [for the controlled substance(s)] has been done.
  - Review notes from consultations obtained, including specialty clinic evaluations (i.e., orthopedic or surgery clinic notes).
  - Review appropriateness of prescribed medications and identify high-risk combinations and co-morbid conditions that may increase a patient's risk for respiratory depression and death.
  - Appraise urine drug screens and confirmatory testing to ensure proper interpretation.
  - Encourage providers to gain additional information, such as old records and other past workup(s) in outside facilities.
  - Offer recommendations for further workup or referral, if appropriate.
  - Serve as liaison for law enforcement; document any information they would like to share.
  - Educate clinic physicians on the Centers for Disease Control (CDC) guidelines, state guidelines as well as standards of care put forth by the American Society of Addiction Medicine (ASAM) and/or Substance Abuse Mental Health Services Administration (SAMHSA).
  - 1:1 physician conference, if necessary, to discuss recommendations or concerning findings during chart reviews.
  - Invite primary providers to the Controlled Substance Care Team (CSCT) meetings to gain further insight into their workup and treatment goals for their patients; then, create a patient safety-focused plan of care.
  - Develop and discuss chronic opioid medication recommendations, including tapering and/or discontinuation, offering justification.
  - Oversee the overall and daily activities of the other team members.
  - Review referrals for buprenorphine (Medication for Opioid Use Disorder-MOUD).
- Care Coordinator:
  - Nurse coordinators are essential to the initial implementation and ongoing sustainability of the TOWN model. They are the key touchpoint between patients and the clinic, providing patient-centered care and adapting clinic processes to best meet the needs of patients. Clinics unable to fill this position or a parallel role struggled with implementing the model. Many core strategies cannot be successfully implemented without a nurse coordinator or parallel role to lead the work. While sites have some variation in the exact job title and background requirements for this position, a dedicated role is necessary to coordinate the components, provide non-judgmental client-centered care, and build community partnerships.

The nurse coordinator implements protocols for MOUD patient visits. This includes the more intensive first visit to induce MOUD, which takes approximately three hours (time varies based on intensity of withdraw) and utilizes the individual care plan as described below in more detail, as well as determining and implementing the process for coordinating ongoing visits within the clinic including onsite drug testing, scheduling, and follow-up. Nurse coordinators are part of most follow-up visits

with the patient before or after the doctor to maintain care coordination and reinforce trust in the relationship with patients. In addition, nurse coordinators remain connected to patients in between visits through follow-up phone calls and are responsive to patient-initiated requests.

- Review care plans, expectations, and goals with patients, as well as obtain signatures and ROI. Renew care plans yearly or as needs change. *Consult with your facility regarding release of information (ROI) requirements.*
- Complete a personal interview with patients to build a patient history, preferably when the care plan is signed and before the initial CSCT chart review.
- Develop a personal plan of care with each patient, one that is patient-centered. Assess for patient's:
  - Strengths and needs
  - Functionality and goals
- Identify, plan, arrange, coordinate, implement services per clinic protocols, and assist with referrals to mental health or other services identified.
- Provide education and support to Emergency Department, OB and Surgical Services staff to ensure continuity, smooth care transitions, and expedient follow-up care with addiction provider to directly prevent relapse or overdose
- Support and guide standing order to prescribe Narcan for clinic patients prescribed opioids
- If care coordination services are billable, maintain annual contact with patients to renew care plans, meet face-to-face, and maintain phone contact at least quarterly. (This is still recommended even if services are not billable in the organization).
- Assist, as needed, with collection of urine drug screens, per the facility's Urine Drug Screen (UDAS) policy.
- Attend and/or facilitate training with the team to promote cohesion and continued program development.
- Develop and present education to the public, schools, and other interested partners.
- Provide support to clinic providers and patients on as needed basis.
- Request random pill counts and urine drug screens. If needed, administer the urine drug screen. Arrange as needed. (See appendix on UDAS and Pill Counts).
- Attend weekly CSCT meetings and [ideally] monthly drug task force meetings. Depending on the task force workflow, direct and run the monthly task force meetings. Complete chart reviews (see CSCT Chart Review Form) and bring this information to weekly CSCT meetings.
- Provide staff training regarding UDAS, care plan completion, and CSCT protocols.
- Support providers and nurses with patient concerns regarding their individual care plan or taper plan.
- For MOUD Patients:
  - Complete intake, including the forms for:
    - Intake assessment

        - Substance Use Assessment
    - Assist in scheduling buprenorphine patients' initial visit, preferably as immediately as possible. Consider the timing of their withdrawal.
    - Case manage buprenorphine patients and develop a treatment plan.
    - When and if indicated, support patients through chemical use assessment (formerly Rule 25).
    - Obtain releases, as able, for all providers to coordinate care for buprenorphine patients.
    - Review and sign the care plan form with the patient and consent for treatment with the buprenorphine form (see appendix).
    - Meet with patients during their scheduled appointments, as able.
    - If induction is indicated, perform Clinical Opioid Withdrawal Score (COWS- see forms)- if this is the facility's workflow.
- Be a direct point of contact for patients, ideally with a direct line.
- Enroll patients in care coordination, if possible, at the organization, maintaining, at minimum, monthly phone contact and document all contact in the patient's chart.
- Help coordinate services and resources as patients need, including mental health and social services
- Identify and re-engage patients who have been lost to contact.
- Provide patient education about common mental and substance use disorders and available treatment options.
- Coordinate patient care, as needed, between various service providers.
- Coordinate and assist in coordination of transfer of patients to and from incarceration.
- Social Worker, if available:
    - Assist, or provide services like the Care Coordinator, as needed.
    - Coordinate and arrange for diagnostic assessments or neuropsychological evaluations.
    - Arrange referrals to WIC, County public assistance programs, medical assistance programs, housing programs, food programs, in-home services, support groups, transportation resources, utility programs, renter's assistance, and refunds.
    - Provide and coordinate referrals to mental health supports (ARMHS, MHBA, CBT, DBT, EDMR, CMH, DD/Rule 185, and AMH), Crisis Teams, free cell phones, school/childcare supports, and education.
    - Maintain contact with the patient, meet face-to-face at least once to twice a year, and have phone contact quarterly.
    - Assist with program development, writing policies and best practices.
    - Attend training with the team to promote cohesion and continued program development.
    - Develop and present educational material for the public and other interested partners.
    - As needed, provide social work interventions and support to other clinic providers and patients.

- Attend weekly CSCT meetings and monthly drug task force meetings.
- If needed, complete chart reviews.
- Obtain releases for all providers to coordinate care for buprenorphine patients throughout their treatment process.
- If possible, provide Rule 25 assessments for buprenorphine patients.

- Pharmacist, if available on the CSCT or an as-needed basis:
  - May be able to provide a direct link between a community pharmacy and the Controlled Substance Care Team (CSCT).
  - Design opioid taper plans for providers to review with patients. Multiple options are often more ideal, allowing for shared decision-making with the patient and involving the patient in the process.
    - Taper no faster than 25% every three days to avoid withdrawal symptoms
    - Normal taper goal is a decrease of ~10% every two weeks
    - Tapers can be as slow as 5% every month
    - If on high opioid doses, the first half of milligram morphine equivalent (MME) may go faster than the second half
  - Meet with patients, if needed, to educate them on the risk of opioid dosing, stressing safety.
  - Suggest alternative medications for chronic pain or other diagnoses not consistent with chronic opioids.
  - Review patient charts and evaluate for drug interactions.

Role of the Controlled Substance Care Team

Controlled Substance Care Teams

The Controlled Substance Care Team (CSCT) is the mechanism to determine if current clinic opioid prescription practices are safe and appropriate. The CSCT is intended to review the chart of each patient prescribed a controlled substance. The review includes evaluating the reason for the initial prescription of opioids or controlled substances, the amount of medication prescribed, including morphine milligram equivalents (MME), and other health conditions or prescribed medications that put the patient at higher risk for adverse health outcomes or death related to their opioid prescription. The physician champion's role on the CSCT is to determine the appropriateness of the prescriptions by evaluating previous steps taken to address the underlying health issue, assessing for alternative solutions, reviewing dosages, and making recommendations for next steps for patient treatment, including a tapering plan, if needed. The role of the nurse coordinator on the CSCT is to gather all necessary information to complete this review and support the creation of a tapering plan if necessary.

In practice, all sites described implementing some version of a CSCT, naming the CSCT as the main mechanism for identifying and responding to patients at higher risk for adverse outcomes due to chronic opioid prescription. However, how often the team met, and participating roles varied across sites and mainly depended on staffing capacity and organizational buy-in. At a minimum, waivered physicians/prescribers and nurse coordinators constituted the CSCT; where available, pharmacists, clinic social workers, physical therapists, and practitioners of alternative pain management techniques were also present. Most commonly, teams met weekly or monthly. However, multiple sites reported that while the CSCT was prioritized in the beginning to launch tapering efforts, over time, the ongoing meetings were substituted with ad-hoc convenings in response to specific requestions or issues. This was especially true if the CSCT team was small and only consisted of the nurse coordinator and waivered physicians/prescribers.

One site reported already having a pain management team within their clinic, who then took on the role of the CSCT. While this was reported as effective at supporting tapering and alternative pain management techniques within the clinic, it siloed tapering efforts from the MOUD work. Therefore, additional efforts had to be made to integrate MOUD-waivered physicians/prescribers into the pain management team or situate MOUD as a resource to clinic providers working on tapering. Other beneficial modality considerations are social work and pharmacy staff attendance of CSCT meetings to ensure a patient-centered approach in multimodal care strategies.

Best practices and lessons learned for implementing CSCT

While the CSCT was described as effective at identifying patients at risk and creating alternative treatment or tapering plans, those plans will not be implemented without the buy-in from the primary care doctor. **Physician champions identified the need to provide follow-up with individual clinicians to encourage the adoption of tapering plans and pre-emptively build buy-in for tapering.** Physician champions were described as best suited to follow-up with primary care physicians/prescribers after a patient was identified as benefiting from tapering. In addition to priming the entire clinic through general education around the role and benefits of MOUD, at some sites, physician champions met individually with each provider to explain program expectations, how the CSCT could be a resource for clinic providers and asked how each physician would want to receive information about their patients.

Framing as a resource and coming from the angle of sharing experiences was described as more successful than authoritarian approaches to suggesting alternative care plans. Additionally, multiple physician champions reported using the opioid report cards (https://mn.gov/dhs/opip/reports/) and communal sharing of other data to encourage healthy competition between providers and facilitate self-reflection to lower their opioid prescriptions. This groundwork for building physician buy-in and individual follow-up with providers to present tapering plans took significant time for physician champions.

A few sites indicated they knew their CSCT was successful when providers across their medical clinic and, in some cases, their organization began reaching out and explicitly requesting the team to review patients. This was more commonly reported among clinics with a CSCT comprised of colleagues from a wide array of fields (e.g., social work, pharmacy, physician therapy) who had established respect within the clinic before the formation of the CSCT. **Presenting the CSCT as a resource for clinic providers as opposed to a requirement, audit, or other authoritarian role encouraged the adoption of tapering plans.** Similarly, early in TOWN model implementation efforts, including administrative staff, medical, or clinic director, helped ensure leadership support and participation in clinic policy recommendations.

Highlighted challenge

In most cases, physician champions reported that once they reviewed the data on prescribing rates with their colleagues and discussed the dangers of high MME in combination with certain other prescriptions, most colleagues were on-board with tapering efforts. However, **some resistance was continually encountered, particularly as physicians/prescribers, while theoretically in favor of tapering, struggled with implementing it in practice with their patients.** One clinic described having more success with physician commitment to lessen opioid prescriptions for new patients but little success with tapering of current patients. For sites with limited CSCT participation, the key challenge identified was a lack of staff resources (i.e., no social worker on the team) and a lack of organizational leadership support reinforcing the effort. In many cases, the ongoing convening of the CSCT lost emphasis or support when competing priorities emerged in response to the COVID-19 pandemic.

- Controlled Substance Care Team (CSCT) Members:
  - Registered Nurse (RN) Care Coordinator
  - Administrator or Member of Leadership
  - Social Worker, if available. (If not available, a relationship with a county social worker is important/recommended.)
  - 1-2 physician champions
  - Pharmacist, if available in the clinic setting.
- Controlled Substance Care Plan (previously 'Pain Contract') (See Care Plan Form):
  - Lists the members involved in the CSCT. These members, per the care plan, are permitted to access the patient's medical chart and perform chart reviews
  - Explains expectations for patients:
    - Appropriate provider follow-ups
    - Communication with care team on changes in care and health status

        - Understanding urine drug screening as a required component
        - (See CSCT Plan form)
    - Describes provider/prescriber expectations:
        - Timely refills
        - Appropriate follow-ups with patient
        - Discussion on other modalities for pain management
        - (See CSCT Plan form)
- Chart Reviews (See CSCT Chart Review Form):
    - Refer to Appendix Pieces for Workflow Diagrams:
        - Controlled Substance Care Team (CSCT) Workflow
        - CSCT Work-Flow Form for Expected Urine Drugs Analysis System (UDAS),
    - Ensure up-to-date Controlled Substance Care Plan
    - RN Care Coordinator reviews the patient's chart before the CSCT meeting and fills out the form with a focus on the following:
        - Diagnosis for controlled substance
        - Co-morbid medical conditions
        - Medication list, including milligram morphine equivalents (MME)
        - Previous work ups of diagnosis
        - Findings from the prescription drug monitoring program (PDMP)
        - Results of a urine drug screen (UDAS) previously done
        - In select situations where diversion is a concern, may consider a review of Department of Corrections (DOC) records for diversion/sales of controlled substance charges
            - Charges related to possession should not necessarily prohibit chronic controlled substance medications if indicated
            - Other non-drug related charges also should not prohibit chronic controlled substance medications, if indicated
    - Provider Champion(s) during CSCT meetings:
        - Review CSCT Review Form
        - Review medications:
            - MMEs of opioid therapies
            - Potential co-prescribed medication interactions
            - Poly-pharmacy situations
        - Discuss and recommend further work-up of the diagnosis for controlled substances
        - Give recommendation(s) for non-opioid medications/treatments to address pain symptom(s)

    - Summarize the next steps and recommendation
    - Follow-up with the primary provider, if needed, to explain and answer questions about the recommendations and help moving forward
- CSCT Goals:
    - Ensure patient safety by encouraging close monitoring for adverse effects, and if the patient requires controlled substances, patient safety is the focus
    - Evaluate for, and be aware of, aberrant behaviors (including diversion)
    - Utilize monitoring, including urine drug screens (UDAS) and pill counts
    - Monitor, and screen for, substance use disorders and then refer to, or offer, treatment
- CSCT as Prevention:
    - One purpose of the CSCT is to decrease patient exposure to medications (especially controlled substances) that have significant risk of adverse events, including co-morbid complications, addiction, death, etc.

Metrics

Having metrics can help direct the focus of your Controlled Substance Care Team (CSCT) and help direct Care Plans (formerly known as 'Pain Contracts') aimed at patient safety, minimizing diversion, and strengthening the patient-provider relationship. (See Controlled Substance Care Plan sample form). Consider monitoring [some of] the following metrics to show progress, or lack thereof, in your opioid stewardship program:

- Visits to the Emergency Department for opioid-related issues such as:
    - Needs for refills
    - Accidental overdoses
- Number of patients on chronic opioid therapy
    - In the clinic total
    - Per each provider
- Milligram Morphine Equivalent (MME) for patients on chronic opioid therapy
- Number of patients who have had opioids discontinued (consider also tracking the total MME of what was discontinued)
- Number of patients co-prescribed benzodiazepines

Following all or some of these metrics and results can further guide educational needs in the organization. They can also direct where the specific focus may be aimed if concerning trends are identified. Ultimately, the focus is always on maintaining patient safety and appropriate treatment of patients and their diagnosis-directed needs. The goal is not to taper every patient off their controlled substances but rather to allow patients to be prioritized based on findings associated with higher risk(s). Higher-risk patients may include:

- Patients on the highest doses/MME of their chronically prescribed opioid(s)

- Patients of advanced age
- Patients with co-prescribed benzodiazepines
- Patients with co-morbid chronic health conditions
- Patients with a significant co-morbid mental health diagnosis

Baseline data can be obtained from several sources, including:

- Electronic Health Record (EHR):
  - Many EHRs can generate reports that identify patients who are currently on, and who have been on, controlled substances for >3 months (or any other timeframe of interest).
  - EHRs can also [typically] pull data based on specific providers, departments, and other cohorts requested. This creates 'lists' to guide quality improvement (QI) projects or other focused efforts.
- Pharmacy:
  - Most pharmacies can quantify the total number (quantity) of controlled substances filled in their location. This data isn't as specific as MME measurements but can be surprising and impactful.

Getting Started

1. Controlled Substance Care Team (CSCT) initial steps: First goal is getting active care plans for all patients on controlled substances, outlining guidelines and recommendations. (See Appendix: Care Plans)
2. General Care Plan Workflow:
    a. Obtaining care plans is, initially, best achieved as patients are presenting to the clinic for a provider visit. These can be presented to the patient for review by the provider's clinic nurse, medical assistant, or the RN Care Coordinator on the CSCT.
    b. Each clinic provider will fill out the specific medication(s) and the section stating the goal of the controlled substance for the following year.
    c. The patient, provider, and another witness (medical assistant, RN Care Coordinator) all sign and date the care plan.
    d. Care plans are renewed annually.
3. High-Risk Patient [Behavior] Workflow:
    e. Some patients are at an increased risk of complications and may warrant obtaining a care plan sooner than during an already scheduled visit:
        i. History of overdose: accidental and/or intentional
        ii. Verbal/physical confrontations with staff regarding refills (pharmacy/clinic)
        iii. Law enforcement contact/arrest for selling, sharing, or over-using controlled substances
        iv. Frequent ER visits: for early refills, new pain complaints, or other situations involving controlled substances
    f. Although the above situations do not [immediately or imminently] result in the discontinuation of controlled substances, they warrant the close evaluation, monitoring and review that ensures the patient receives the safest and best care for their diagnosis. This may include ongoing use of controlled substances.
4. High-Risk Patient [Medical/Medication] Workflow:
    g. Patients with co-morbid medical conditions/diagnosis or who are co-prescribed medications that may interact with their current controlled substances also need more prioritized care plans and evaluation:
        i. Patients on methadone [for pain] may need an electrocardiogram (EKG) as well as a thorough review of other medications assessing for medication interactions
        ii. Patients on benzodiazepines, especially if co-prescribed with opioids
        iii. Patients with: COPD, Asthma, Obesity, Renal Insufficiency, Liver Disease, and other chronic health diagnoses:
            1. Sleep study for central sleep apnea, or co-occurring central and obstructive sleep apnea
            2. Lab monitoring for:
                a. Metabolic dysfunction leading to slowed, or altered, clearance of controlled substances

b. Hormonal changes, primarily testosterone, leading to bone, heart, and other complications

3. Balance and fall risk assessment

Working the List

Once you have identified patients on controlled substances, each patient must be treated in a patient-centered manner. Therefore, each patient on your 'list' will need to be reviewed individually. There are several 'Opioid Risk Calculators/Tools' that can be used to risk stratify patients. However, none of the tools are without error and can inadvertently stereotype patients or overlook other high-risk situations. Therefore, patient-centered review and care should be the program's focus, although potentially more time-consuming. In an effort to minimize additional time to the provider visit, the RN Care Coordinator and/or Social Worker (depending on your CSCT structure) may obtain the history and pertinent information necessary (CSCT Review Form).

Pertinent information may include:

1. Diagnosis requiring controlled substances
2. Medications:
    a. Previously trialed medications, including all controlled substances (licit) and non-opioid pain medications, past and current.
    b. Mental health medications, including all previous and current
    c. If a pharmacist is on your CSCT or available, it is helpful to have them review medication interactions, side effects, and other alternative non-opioid medication options.
3. Mental health diagnosis, including previous hospitalizations and/or treatments
4. Substance use disorder history
5. PDMP review
6. Family history of substance use disorders
7. Emergency Department visit history
8. Other pertinent comorbidities, such as sleep apnea

Understanding the complexity of co-morbid health diagnosis, including the overlap of mental health with substance use disorders and other chronic health conditions, will also lead to a more comprehensive overview of each patient. Obtaining an ACE Score (Adverse Childhood Experiences- see ACEs form) can help tailor other treatment modalities and may guide other recommendations for improved patient safety and treatment outcomes.

During, ideally, weekly meetings, the care team reviews the CSCT Review Form with the physician champion(s). Additional chart review will evaluate previous workups, initiated treatments and/or procedures, and subsequent outcomes. In your review, you may occasionally discover patients on chronic opioid therapy despite no obvious previous work-up or evaluation. This may include patients prescribed opioids for diagnosis where opioids are not indicated or recommended (such as fibromyalgia, chronic daily headache, etc.). In these circumstances, recommendations may include education, further work- up and/or evaluation to confirm their diagnosis (or discover an alternative diagnosis), and other non-opioid treatment modalities. The patient must feel that you are genuinely

listening to them and understanding that they have pain. It must be conveyed to them that your approach to treating their pain will be based on the best available evidence on effective treatments for their diagnosis.

Another situation that may be discovered during the chart review is patients on opioids chronically for a previous acute diagnosis. For example, it is not unusual to find a patient that was started on a controlled substance for an acute injury/trauma/surgery/etc. that inadvertently was not discontinued in a timely fashion leading to years of exposure to high-risk medication(s).

During the review process, previous urine drug screens (UDAS) and/or pill counts should also be looked at, as interpretation can be difficult due to the complexity of medication metabolism. There are also situations where medications may cause false positive results and conditions where false negative results may arise (See Common False Positive/False Negative Form). Medication management should not and cannot be based on preliminary urine testing alone, and if there are any concerning or unexpected findings, a confirmatory test should be performed. (See Urine Drug Screen Review/Analysis Forms). The interpretation of urine drug screens and confirmatory testing, including metabolites, can be challenging even for experienced clinicians. Information and resources should be available to ensure the process is consistent and accurate. Patients should be offered additional services or treatment if a urine drug screen reveals an unexpected illicit or licit substance(s) confirmed on the confirmatory test. An unexpected urine drug screen should not result in discharging a patient from your practice but rather lead to further information gathering and support. The RN Care Coordinator and/or Social Worker can also help connect patients with services they may qualify for, suggest referrals to mental health treatments, or assess for and refer to chemical dependency treatment. A 'non-punitive' approach is essential. Caring for the whole patient involves discovering, assessing, and meeting each individual patient's needs.

Preliminary urine testing is often done in the clinic or in a situation where the results are available within minutes or a day or so. Confirmatory testing typically takes several days, and each test must be ordered for a specific medication or drug. Confirmatory testing is not 'reflexively' done as the cost can be high, and there are situations where a confirmatory test is not clinically necessary. Especially when caring for patients with known use disorders that the care team is monitoring (typically a buprenorphine-naloxone patient in primary care), the necessity of confirmatory UDAS should be considered. A patient in a MOUD program who struggles with other use disorders (such as methamphetamines, marijuana, etc.) or one having a lapse or relapse that discloses their use of an illicit or other substance often does not need a confirmatory test for their unexpected result(s), unless it will impact the care plan. Relationship building in an MOUD program is essential and if/when a patient discloses their use, adding the additional cost of a confirmatory test is unnecessary. Confirmatory testing can also give the 'level' of a substance in the urine. For many substances, the 'level' is not clinically significant as many other factors can affect it, such as urine concentration, infection, the individual's metabolism, adulterants, and others. The presence of 'adulterants,' when present, are often added to the urine specimen cup, should prompt additional discussion with the patient and may not always result in requesting a repeated UDAS or witnessed UDAS. Many different adulterants will alert lab personnel on a screening UDAS, and they can often offer more insight into significance. Lab, and occasionally the nursing staff who obtained the urine, will also note if the urine isn't at an expected temperature. Anything unexpected on a UDAS, including results, adulterants, and temperature, should be addressed in a non-confrontational and non-punitive approach. Patient-centered care is the goal, and conversations about additional support and care should follow.

Important Calculations and Utility

Milligram Morphine Equivalent (MME) (See Appendix)

MME is a unit of measurement used to compare opioids of varying potencies. When all opioids are converted to a standard value, the equivalent of one milligram of morphine, providers are more able to assess a patient's potential risk for adverse events. To calculate a patient's total MME, consider the following steps:

1. Strength per unit x number of units/day = total daily dose
    a. Example: hydrocodone/acetaminophen 5mg/325mg three times daily = 5mg x 3/day = 15mg/day of hydrocodone
2. Convert total daily dose to MME by multiplying by respective MME conversion factor: (see Appendix for MME Opioid Conversion Factors)
    a. Total daily dose x MME conversion factor = daily MME
        i. Example: 15mg/day hydrocodone x 1 = 15 MME/day
    b. 20mg/day oxycodone x 1.5 = 30 MME/day
3. Calculate MEDD (morphine equivalent daily dose)
4. Add each MME [for each opioid a patient is on] = MEDD
    a. Opioid A daily MME + Opioid B daily MME = MEDD
        i. Example: 15 MME/day + 30 MME/day = 45 MEDD

Calculating MME of opioids allows for the following:

1. Knowing the total MME of different opioids given to each patient
2. Assessment of safety risk based on MME per day
3. Switching between different opioids safely.
    a. Equianalgesic dosages (doses that are comparable in MME between two different opioids) are approximations and may not account for the following:
        i. Genetic factors
        ii. Incomplete cross-tolerance between opioids
        iii. Variable pharmacokinetics and pharmacodynamics
    b. It should be considered, when converting from one form of opioid to another, to decrease the dose by 25-50% initially until the patient response is evaluated.

Adverse Childhood Experiences (ACE Score)
(See Appendix for ACE questionnaire)

Calculating a patient's Adverse Childhood Experience (ACE) score can also be helpful and/or add insight. A patient answers 10 yes/no questions, with a 'point' given for each "yes" response. The questions represent an individual's, before age 18, history of suffering from or dealing with abuse [physical, emotional, sexual], neglect [physical, emotional] and household dysfunction [mother-figure violence, substance use disorder (SUD), mental health, separation/loss of a parent, household member incarcerated]. The higher the patient score, the greater the risk of experiencing poor physical and mental health conditions and significant negative social consequences. This includes an increased risk of substance use disorders. For example, an individual with 4+ ACEs concerning mental health and SUD has a: 4.5x risk for depression, 2-4x risk for alcohol use disorder (AUD), 7x risk for drug use, and 12x risk for suicide.

As they accumulate ACEs, patients have resultant alterations in their "stress pathways, " resulting in over-expression and responsiveness of the sympathetic nervous system, heightening the 'Fight, Flight, Freeze (FFF)' response. ACEs also affect brain development and function, specifically the nucleus accumbens, the amygdala, and the hippocampus, and delay the development of the prefrontal cortex (the 'adulting'). The FFF response overlaps and parallels the cycle of addiction. To best care for patients with ACEs, providers must first be aware of a patient's trauma history but then also utilize the trauma-informed care approach (TIC). TIC realizes the prevalence of trauma, recognizes how trauma impacts neurobiology and physiological response(s), and then responds to individuals' needs, focusing on strengths and adaptation rather than re-traumatizing an individual.

Finally, ACEs are linked to attachment and attachment styles. Oxytocin is related to social-pair bonding, with increases in oxytocin enhancing trust between individuals. Endogenous opioids also regulate the maintenance of social attachment. Individuals with many ACEs have decreased levels of endogenous opioids (aka β-endorphin), leading to seeking social connections from outside sources rather than in their family unit. Exogenous morphine/opioids also inhibit β-endorphin, further leading to 'seeking social connections.'

On the other hand, socialization and touch increase β-endorphin; therefore, social support and patient-centered care can moderate the adverse effects and oxytocin levels. In clinical practice, this translates to: for each ACE, the odds of relapse increase by 17%, whereas when a patient is cared for in a trauma-informed clinic, there is a 2% reduction in the odds of relapsing. When patients understand that their ACEs are not their fault but rather things that happened to them, they can understand the resultant responses they have favored and can autonomously be empowered to seek healthy responses and connections. Whole-person care is imperative when caring for patients with SUD and when ACEs are evaluated and asked about, patients start to feel heard and understood, and trust bonds between provider and patient can be built.

Treating Use Disorders in a Family Practice Setting

Family practice providers are uniquely positioned to care for the "whole patient," and use disorder(s) treatment should also be a service that family physicians offer to their patients. In rural communities, patients with use disorders often travel significant distances from their homes to receive medications for opioid use disorder (MOUD). This not only marginalizes this patient population but also creates additional barriers, especially with employment and childcare. Traveling long distances to receive care is also very challenging for patients as many patients have barriers in finding transportation and must rely on insurance-paid medical rides, creating additional societal costs.

Much like diabetes, opioid use disorder (OUD) is a chronic disease with treatment and follow-up potentially lasting a lifetime. Patients with the disease of addiction should have the same access to treatment and follow-up as other chronic health diagnoses. Family physicians, and other primary care providers, are also in a unique position to uncover use disorders during office visits for different needs. Primary providers, who typically provide comprehensive health care, should be especially astute with recognizing signs and symptoms related to substance use disorders; much like they provide screening for diabetes, thyroid dysfunction, and hyperlipidemia, they are well placed to provide screening for use disorders, especially in high-risk patients. As many other chronic health diagnoses are genetic, addiction is no different, as ~50% of addiction is heritable.

Although there is an overall decrease in opioid prescribing, there continues to be an increasing number of overdose deaths. Primary care, especially in underserved areas without access to specialists, is essential in adding additional access to care, especially MOUD. Family practice residency programs in Minnesota have shifted towards adding MOUD training, and as these providers enter the workforce, access to these services is increasing. However, there is still a great need for established providers to expand their practice to include care for patients with the disease of addiction, as it impacts the patients' lives and the entire community.

Buprenorphine

Buprenorphine was developed in the 1970s by Rickitt and Coleman and was initially studied as an analgesic. The FDA approval to treat opioid use disorder (OUD) occurred in 2002 as a sublingual (SL) preparation. Since then, a subcutaneous formulation (Sublocade®) has received FDA approval, and other formulations are in development. Buprenorphine (Subutex®) and buprenorphine-naloxone (Suboxone®) are the recommended sublingual formulations for medication for opioid use disorder (MOUD). They have the same dosages of the buprenorphine component, with the difference being the presence of the naloxone [which is not active when the medication is taken correctly, but if injected or taken in an alternative way, will become active and precipitate severe withdrawal.] Buprenorphine and buprenorphine-naloxone come in sublingual tablets or strips. Although the dose of buprenorphine between the formulations is the same, it is important to understand that factors may impact dosing, especially with changing between tablet/film formulations. (Absorption speed, non-active ingredients in the preparations, etc.) There also may be variations in absorption between patients, and, along with the above, it is always essential to prescribe in a patient-centered and individualized manner.

Buprenorphine is a mu-opioid receptor partial agonist; it has some binding at the delta-opioid receptor and appears to be an antagonist at the kappa-opioid receptor. The delta and kappa receptor activity may positively affect depression, and buprenorphine is currently being investigated as a possible treatment. However, Kappa antagonism may also be associated with a lack of tolerance development

associated with buprenorphine treatment. (This is not pertinent when treating OUD and should not dictate dosing.)

Buprenorphine has many properties that make it unique compared to full opioid agonists such as oxycodone, morphine, or methadone. The affinity of buprenorphine for the mu-receptor is often stronger than full opioid agonists (varying degrees depending on the opioid), which has implications when patients are induced (started on buprenorphine). [This will be further explained below as it pertains to precipitated withdrawal.] The high affinity for the mu-receptor also helps protect patients who, while on buprenorphine maintenance therapy, take or use a full-opioid agonist, as full-opioid agonists cannot displace buprenorphine completely from the mu-opioid receptors. This, therefore, prevents or blunts the adverse effects of opioids. (As explained in the Peri-Operative section, it is possible to override this affinity with much higher doses of full-opioid agonists.) Buprenorphine also dissociates slowly from the mu-receptor contributing to its long duration of action. This allows for once-daily dosing if necessary and if the patient chooses. Once-daily dosing, however, may be difficult for patients, especially early on in treatment, as they are often accustomed to using their drug multiple times a day.

Precipitated withdrawal is an important concept to understand with [buprenorphine] MOUD treatment. Induction protocol examples are included in the appendix section, but even if followed, precipitated withdrawal may, at times, occur. The presumed mechanism involves tolerance to a highly activating full-opioid agonist such as fentanyl or a very long-acting full-opioid agonist such as methadone. For example, suppose a large dose of buprenorphine, with higher affinity yet lower activation to the mu-opioid receptor, is given to a patient. In that case, it, in essence, “pushes” the fentanyl off the mu-receptor [high-affinity reaction]. Because of buprenorphine’s lower activation, the patient will quickly feel withdrawal symptoms. The severity of the symptoms will vary depending on the full-agonist opioid the patient was taking, their tolerance, and the dose of buprenorphine given. There are different strategies for induction to avoid precipitated withdrawal, although there are no general ‘recommendations or specific guidelines.’ One approach, macro-dosing, involves giving very high doses of buprenorphine to over-ride withdrawal. Another strategy, low-dosing or micro-dosing, involves starting with lower dosing of buprenorphine (lower than the typical dosing) and slowly increasing the dose as the more activating opioid dissipates from the system. (This is the dosing strategy we prefer.)

Finally, the ceiling effect of buprenorphine is an important topic to understand. As an analgesic, it does not appear to have a ceiling effect, meaning that increasing dosages does increase the analgesic response. The effects of buprenorphine on respiratory depression, however, are impacted beneficially by the ‘ceiling effect.’ Therefore, as the dose of buprenorphine is increased, the risk of respiratory depression does not. Full-opioid agonists, on the other hand, do not have a ceiling effect, thus why increasing dosages of these opioids increases the chances of respiratory depression as well as other complications.

In summary, this general overview is not meant to be an exhaustive review of buprenorphine but rather a brief and high-level description of the unique properties of buprenorphine. Reviewing additional information or consulting an appropriate specialist is always recommended if questions arise; however, these topics hopefully will help guide your comfort level in prescribing this life-saving medication.

Buprenorphine in the emergency department

The emergency department is a significant point of contact for patients in your community with opioid use disorder (OUD) and a critical place to address early on in your program. Patients with OUD will often present to the emergency department following an overdose, asking for treatment, or, at other times, in withdrawal. It is important to recognize and acknowledge all forms of presentation, as this may be the patient's only contact with the medical community. Unfortunately, until recently, few emergency departments have addressed this gap in care and treatment for these patients. Identifying and treating OUD and withdrawal in emergency departments cannot only change the trajectory of OUD, but it will also save lives.

Typically, when patients are brought to the emergency department after receiving naloxone (Narcan) for an overdose, they are often in acute severe withdrawal as the naloxone reverses the effects of the opioid. Understandably, patients then are often irritable and uncomfortable and know the way to feel better is to use more opioids. When patients are prematurely discharged from the emergency department or leave against medical advice (AMA), they are at a very high risk of overdose. Not only does the naloxone leave the system quickly, allowing the remaining opioid in the patient's system to re-bind to the receptors, patients will often also use more opioids. Historically, only symptomatic medications were given to alleviate patients' symptoms while in the emergency department. Unfortunately, these treatments do not treat the underlying disease or engage the patient in treatment.

Starting a patient on buprenorphine when they present in withdrawal will alleviate many of the withdrawal symptoms and begin the process toward recovery. Even if emergency department providers are not waivered to prescribe buprenorphine, they are, by law, able to dose it while the patient is in the department. Therefore, immediate follow-up care with a buprenorphine provider after the emergency department visit is critical and should be arranged before discharge, if possible. Suppose it is impossible to decide for the patient to have an immediate same-day or next-day follow-up. In that case, the patient can return to the emergency department for two additional subsequent days for dosing even if the provider, again, is not waivered. (See Title 21 CFR Part 1306.07(b)).

It is vital that OUD treatment in emergency departments becomes supported and, much like other treatments in the department, an enforced, measured, and expected policy. This life-saving treatment is not, and should not, be seen as an elective treatment based on stigma and discrimination but rather as the standard of care that it is for the disease of addiction.

Emergency department providers are often reluctant to provide buprenorphine as many are not DATA 2000 waivered. Although it would be ideal for all emergency room providers to become waivered to provide the best possible care for all patients, according to Title 21 CFR Part 1306.07(b), providers can administer, but not prescribe, buprenorphine for up to three days (Three Day Rule) for a patient with opioid use disorder. This would require the patient to return to the ED daily for dosing while waiting to get into a clinic program. We are concerned that ER providers are required to have Advanced Trauma Life Support (ATLS) to care for patients involved in motor vehicle accidents. Still, they are not generally required to be waivered and prescribe buprenorphine even though more people die from overdose than in car accidents. We feel treatment with buprenorphine by ER providers should be the standard of care. In addition to the benefits of DATA 2000 waivered Emergency Department providers, it is also crucial that ED providers identify the need and provide Narcan before patient discharge to prevent subsequent overdose and mortality. Discharge planning and referral methods tailored to facility workflow need to be discussed and implemented to ensure a smooth transition of care from ED to clinic addiction services.

Best practices and lessons learned for integration of MOUD into ED

Nurse coordinators and physician champions worked to provide simple, clear induction protocols and continuous education opportunities with ED staff through individual meetings and group presentations to highlight the impact of ED inductions on patients, explain protocols, and build familiarity. While not a requirement for starting buprenorphine in the ED, a few sites reported success in identifying waivered physicians/prescribers who worked in both the clinic and the ED who became ED-specific champions and promoted MOUD in the ED context. In addition, clinics reported success coordinating with the pharmacy associated with the ED to ensure medications are stocked and available and clarifying the handoff process to connect ED patients with clinic based MOUD. At one site, the nurse coordinator encouraged new patients wanting weekend access to MOUD to utilize the ED for induction which eased MOUD scheduling tensions while supporting continued clinic-based follow-up after a patient is induced in the ED. Lastly, one clinic observed that having the nurse coordinator position housed within the social work team eased coordination with ED as social workers are accustomed to navigating across the medical system.

Highlighted challenge

Most sites had not yet consistently implemented buprenorphine into EDs. This was primarily described as a workflow issue in that other components of the TOWN model had been prioritized for implementation thus far, with ED described as a priority for the following year. Additional challenges sites faced in implementing ED use of buprenorphine were general unfamiliarity with the process, concern about fentanyl-precipitated withdrawal, insufficient ED space for lengthy inductions, and the need for clinician education.

We have developed a protocol for our Emergency Department (Appendix BB). Feel free to use it or modify it to fit your institution.

Peri operative

Invariably MOUD patients, like all other patients, will need surgical procedures. There is no set recommendation or protocol for managing patients on buprenorphine or buprenorphine-naloxone; however, more recently, there is now an expert consensus for management.

It is essential to understand the pharmacology of buprenorphine and how it interacts with the mu-opioid receptor. As a partial agonist (see the section on Comparison of MOUD) with high-affinity, buprenorphine binds to the mu-receptor differently than full agonists. Still, it does so very ‘tightly’ and will displace full mu-opioid agonists. The strength of buprenorphine on the mu-opioid receptor compared to full agonists shows:

1. 1.7 times stronger affinity than hydromorphone
2. 5.4 times stronger affinity than morphine
3. 6.2 times stronger affinity than fentanyl
4. 120 times stronger affinity than oxycodone

It is important to note, however, that this can be overridden with higher doses of the stronger full agonist opioids such as Dilaudid or Hydromorphone, which are commonly used post-operatively. Depending on the buprenorphine dose, there is still receptor availability for other opioids to bind.

For each dose of buprenorphine, the following percentages of mu-opioids are available:

1. 1mg: 71-85%
2. 2mg: 53-72%
3. 4mg: 36-55%
4. 8mg: 11-22%
5. 12mg: 13-24%
6. 16mg: 9-20%
7. 24mg: 4-15%
8. 32mg: 2-12%

Historically it was recommended to taper buprenorphine to a lower dose for this reason. However, that is no longer recommended as other strategies can be utilized that allow the patient to stay on the appropriate level of buprenorphine needed for their OUD.

Many recent studies have led to the expert's consensus on maintaining buprenorphine. Continuing buprenorphine is not associated with an increased risk of respiratory depression but with a lower incidence of respiratory complications. Patients maintained on their medications also were found to have lower opioid analgesic requirements as buprenorphine may produce similar clinical analgesic efficacy as full mu-agonists. In contrast, many complications can arise if buprenorphine is discontinued or tapered before surgery. Most striking, patients whose buprenorphine was discontinued, in a study by Bentzley et al. 2015, had a >50% (range 50-90%) chance of OUD recurrence/relapse or death. The highest risk patients for tapering or discontinuation are those who had their buprenorphine tapered before surgery and replaced with a full mu agonist, those who have been in a buprenorphine treatment program for <20 months, those who had an unexpected UDAS in the previous 20 months and those who were discharged from the hospital without communication and follow-up plan in place with their buprenorphine provider.

According to the expert consensus, there is a general strategy when caring for surgical patients on buprenorphine. First, communication with the surgeon is critical. Buprenorphine instructions on a pre-operative History & Physical form are very helpful as all members of the surgical care team will see it (this is often even more recognized when the instructions can be put on the top of the patient's surgical History and Physical). Many non-opioid pain strategies can be discussed and can, in many situations, be even more effective and better tolerated than opioids. Including the patient in the conversation(s) and setting expectations should also be done. Patients should feel heard, supported, and understood, as many feel their pain will be undertreated and/or their pain concerns will not be respected when they ask for additional support.

Procedures can be classified into different categories to help guide options and additional modalities to address pain. (Remember, however, that each patient has their own pain experience.):

1. Mild: sprains, dental issues, small lacerations
5. Moderate: minor bone fractures/breaks, minor surgical procedures (ex., Carpal tunnel release)
6. Severe: large bone breaks/fractures, abdominal procedures (appendectomy, cholecystectomy, cesarean section, etc.), large lacerations or trauma, joint replacements

Intra-operative approaches, when a patient is on buprenorphine, typically do not alter from 'standard' management. As previously stated, patients on buprenorphine typically have fewer respiratory complications. Anesthesia personnel can also utilize strategies that may influence postoperative pain severity. Use of IV Ketamine, lidocaine, or other forms of local anesthetic agents, if not contraindicated, is recommended along with continuous regional anesthesia techniques such as epidurals, peripheral nerve catheters, Exparel, etc.). Caution should be exercised when benzodiazepines are used or needed as, together with any opioid, the risk of respiratory depression is greater. When stronger medications for pain are needed, IV Fentanyl is preferred. For more severe procedures where it is expected that the pain will last longer, consideration should also be given to other non-opioid analgesic options such as gabapentin, pregabalin, and NSAIDs (if not contra-indicated).

Although buprenorphine is a partial opioid agonist, it still has analgesic properties. Typically, buprenorphine will offer analgesia for around 4 hours; therefore, more frequent dosing of a patient's total daily dose (TDD) may provide adequate pain relief. Additionally, post-operatively, a patient's buprenorphine dose can be increased to achieve more pain relief while maintaining a partial mu-receptor agonist medication. This can benefit patients at high risk for relapse if exposed to oral opioids, especially if their drug of choice is an oral opioid (such as hydrocodone or oxycodone). This can also be a strategy for patients who are adamant about avoiding opioids at all costs. Examples:

1. A patient taking buprenorphine-naloxone 8/2mg twice daily (16/4mg TDD) may obtain adequate pain relief if their TDD is taken as 4/1mg (1/2 of a tablet or film) 4 times daily (16/4mg TDD).
2. A patient taking buprenorphine-naloxone (or buprenorphine mono-product) 8/2mg three times daily (TID, TDD 24/6mg) may obtain adequate pain relief if they, instead, take 4/1mg (1/2 of a tablet or film) every 4 hours (6 times daily rather than TID).
3. A patient taking buprenorphine-naloxone 8/2mg twice daily (16/4mg TDD) may obtain pain relief if their TDD is raised to 24/6mg and then, as above, divided into 4/1mg (1/2 of a tablet or film) every 4 hours (6 times daily), or simply 8/2mg TID.

There are situations in which a patient may, however, need/require a full agonist opioid. Importantly and primarily, the patient should be supported and reassured, as often this can not only be a trigger for patients but can also make a patient feel shame. Patients in recovery from opioid use disorder on MOUD are often treated with judgment and stigma by healthcare professionals who are unfamiliar with or do not understand addiction as a disease and treatment with MOUD. If a patient feels this way, they will often not ask for pain medications for fear of being seen as a "seeker" or "addict," etc., and therefore will often suffer. When patients on MOUD require full-agonist opioid medications, it is also essential to understand the dosing necessary to achieve relief. Usually, patients, while on buprenorphine, will need about two times the average dose [of a full agonist] to penetrate the mu receptor. Long-acting opioids should be avoided, and benzodiazepines should be used cautiously and with close respiratory status monitoring.

- For a bullet point of the levels of procedures and recommended management of pain, including options for buprenorphine management through the perioperative period, see the form:
    - Perioperative Pain Management
- For sample letters of recommendation for surgeons from the buprenorphine prescriber, see the forms:
    - Simple Procedure Sample Letter
    - Moderate Procedure Sample Letter
    - Severe Procedure Sample Letter

Obstetrics

Since 2008, opioid overdose deaths in women have nearly tripled, and, in turn, the prevalence of opioid use disorders (OUD) in delivering women has also increased, nearly 7-fold, resulting in not only overdose deaths but also maternal injury and death. In addition, there are several additional pregnancy complications when an active OUD is present. One common complication is infectious disease complications which may include: sexually transmitted infections (syphilis), Hepatitis C, HIV, endocarditis, osteomyelitis, cellulitis, and sepsis. Additional obstetrical complications include preterm labor and placental abruption. Aside from maternal complications, there are many fetal/neonatal complications, having and resulting in:

1. Fetal growth restriction:
    a. Pre-term birth
    b. Stillbirth
    c. Small for gestational age
    d. Intra-uterine growth restriction
2. Preterm delivery:
    a. Neurological complications
    b. Physical complications
    c. Death
3. Trans-placental/peripartum infections:
    a. Syphilis
    b. HIV
    c. Hepatitis B/C
4. Neonatal opioid withdrawal syndrome (NOWS)

Pregnant persons who are treated with MOUD during pregnancy have many benefits and positive outcomes. Depending on the specific opioid and frequency of self-dosing of illicit substances, frequent withdrawal episodes put patients at risk of suffering from miscarriage or pre-term labor. However, treating a patient with MOUD prevents withdrawal symptoms and cravings resulting in decreased relapse risk. The primary benefit, however, of treatment with MOUD in pregnancy is improved adherence to prenatal care. Both the American College of Obstetricians and Gynecologists (ACOG) and the Substance Abuse and Mental Health Services Association (SAMHSA) endorse and recommend MOUD during pregnancy. However, there are differences in preference for available MOUD forms, and it is important to understand the benefits and risks. (See chart below.)

Mandated reporting laws vary by state and are very important to discuss with pregnant patients. Many patients avoid prenatal care for fear of being reported to social services/child protection. Recently, Minnesota reporting laws have removed the mandate, allowing for patients suffering from the disease of addiction to receive prenatal and substance use disorder care which, in turn, reduces substance use and improves maternal and fetal outcomes. Universal screening for substance use disorder(s) facilitates treatment conversations and retention by utilizing validated screening tools and not simply urine drug screens (UDAS). In addition, pregnant patients should be informed of the services available

in the community to aid in their recovery journey and, if the patient chooses to parent, parenting resources.

Addressing post-delivery plans during the pregnancy should begin and continue throughout the pregnancy and post-partum time. Parenting support groups, lactation support [if desired], and peer recovery support can empower the transition from pregnancy to parenthood. Breastfeeding should be encouraged and supported for the known health benefits but also to aid in parent/infant bonding which can minimize infant withdrawal. In addition to patient choice on whether to breastfeed, several other factors must be considered. When a patient is on MOUD, they should be aware that there is minimal transfer of [their MOUD] medication, which should not be a deterrent. Hepatitis C is not a contraindication to breastfeeding but should be avoided if there are bleeding nipples. HIV infection and ongoing illicit substance use are contraindications for breastfeeding. Finally, contraception and further pregnancy plans should be discussed. All forms of contraception should be discussed, and access should be immediate and easily accessible. These conversations should continue with patients after discharge as well. The post-partum period can be a time of exacerbation of mental health diagnoses and substance use disorders. All post-partum persons, including those choosing to parent, those unable to parent, and those who choose to adopt their infant out, should be followed closely and frequently.

Throughout labor and delivery, patients should be supported similarly to other delivering patients. It is important to manage expectations concerning labor as well as pain. MOUD should be maintained throughout the antepartum and postpartum periods. MOUD itself can provide additional analgesia for patients. If a patient has a cesarean section, TAP blocks and ketorolac can minimize opioid requirements, but if needed, a PCA [with fentanyl] is preferred. Staff education is important, so patients feel safe and comfortable and not discriminated against.

MOUD pregnancy comparison charts

Consideration/ Medication	Methadone	Buprenorphine	Buprenorphine/ Naloxone	Naltrexone	Medically-Assisted Withdrawal	Methadone	Buprenorphine
Mechanism	Full opioid agonist	Partial opioid agonist	Partial opioid agonist with naloxone combo product	Opioid antagonists	Using an agonist to assist in tapering off of illicit opioid	Full opioid agonist	Partial opioid agonist
Advantages	Established pregnancy/ breastfeeding safety	Established pregnancy/ breastfeeding safety	Decreased diversion/misuse	Reduces cravings, reduces overdoses	Current data: no association with fetal death or preterm delivery	Established pregnancy/ breastfeeding safety	Established pregnancy/ breastfeeding safety
	Reduced cravings	Lower overdose risk	Improved insurance coverage	IM formulation (Vivitrol) has no diversion	Minimizes neonatal withdrawal	Reduced cravings	Lower overdose risk
	Long duration of action	Fewer drug interactions	Lower overdose risk	Office-based delivery	Decreases neonatal care costs	Long duration of action	Fewer drug interactions
	Higher treatment retention	Office based treatment	Fewer drug interactions			Higher treatment retention	Office-based treatment
	Reduced obstetric and fetal complications	Shorter NOWS	• Office based treatment • Shorter NOWS • Block other opioids			Reduced obstetric and fetal complications	Shorter NOWS
		Blocks other opioids					Blocks other opioids
Disadvantages	Prolonged time to stable dose	Limited long-term data	Limited data in pregnancy/ breastfeeding (compared to mono product)	- Limited safety data	Requires close medical supervision	Prolonged time to stable dose	Limited long-term data

Consideration/ Medication	Methadone	Buprenorphine	Buprenorphine/ Naloxone	Naltrexone	Medically-Assisted Withdrawal	Methadone	Buprenorphine
	Significant overdose risk	Maternal clinical withdrawal (although minimal) needed before starting (induction)	Current training recommends change to monotherapy	Problematic pain management at delivery	No long-term outcome noted	Significant overdose risk	Maternal clinical withdrawal (although minimal) needed before starting (induction)
	Daily treatment at opioid treatment program (OTP)	Less success (historically) with polysubstance use disorders		Unknown breastfeeding safety	High relapse rates: up to 90%	Daily treatment at opioid treatment program (OTP)	Less success (historically) with polysubstance use disorders
	Longer, more significant NOWS	Lower treatment retention		Cannot start directly off of opioids, must be off other opioids ~10 days (risk of withdrawal complication)	Overdose risk with relapse	Longer, more significant NOWS	Lower treatment retention
	Pure agonist, will not block other opioids	Less structured environment			Low compliance rates (~56% success rates)	Pure agonist, will not block other opioids	Less structured environment
					No long-term maternal outcomes		
Dosing/ Clinical Pearls	Increased metabolism and volume of distribution necessitate dosage increase	May need increase in dosing	Decision to continue combo product vs. mono-product on a case-by-case basis (shared decision making)	No agreement on continued use in pregnancy	Not ideal in pregnancy	Increased metabolism and volume of distribution necessitate dosage increase	May need increase in dosing
	May need split (BID) dosing	Diversion is real: can be injected/snorted. Patients may feel pressured to share/sell	May need increase in dosing	Not a first-line treatment due to complete detoxification, relapse risk	Used only if MOUD is unavailable	May need split (BID) dosing	Diversion is real: can be injected/snorted. Patients may feel pressured to share/sell
				If continued, need delivery anesthesia plan			

	Methadone	Buprenorphine	Buprenorphine/ Naloxone	Naltrexone	Medically-Assisted Withdrawal
Mechanism	Full opioid agonist	Partial opioid agonist	Partial opioid agonist with naloxone combo product	Opioid antagonist	Using an agonist to assist in tapering off of illicit opioid
Advantages	- Established pregnancy/ breastfeeding safety - Reduced cravings - Long duration of action - Higher treatment retention - Reduced obstetric and fetal complications	- Established pregnancy/ breastfeeding safety - Lower overdose risk - Fewer drug interactions - Office-based treatment - Shorter NOWS - Blocks other opioids	- Decreased diversion/misuse - Improved insurance coverage - Lower overdose risk - Fewer drug interactions - Office-based treatment - Shorter NOWS - Blocks other opioids	- Reduces cravings, reduces overdoses - IM formulation (Vivitrol) has no diversion - Office-based delivery	- Current data: no association with fetal death or preterm delivery - Minimizes neonatal withdrawal - Decreases neonatal care costs
Disadvantages	- Prolonged time to stable dose - Significant overdose risk - Daily treatment at opioid treatment program (OTP) - Longer, more significant NOWS - Pure agonist, will not block other opioids	- Limited long-term data - Maternal clinical withdrawal (although minimal) needed before starting (induction) - Less success (historically) with polysubstance use disorders - Lower treatment retention - Less structured environment	- Limited data in pregnancy/ breastfeeding (compared to mono product) - Current training recommends change to monotherapy	- Limited safety data - Problematic pain management at delivery - Unknown breastfeeding safety - Cannot start direct off of opioids, must be off other opioids ~10 days (risk of withdrawal complication)	- Requires close medical supervision - No long-term outcome noted - High relapse rates: up to 90% - Overdose risk with relapse - Low compliance rates (~56% success rates) - No long-term maternal outcomes
Dosing/ Clinical Pearls	- Increased metabolism and volume of distribution necessitate dosage increase - May need split (BID) dosing	- May need increase in dosing - Diversion is real: can be injected/snorted. Patients may feel pressured to share/sell	- Decision to continue combo product vs. mono-product on a case-by-case basis (shared decision making) - May need increase in dosing	- No agreement on continued use in pregnancy - Not a first-line treatment due to complete detoxification, relapse risk - If continued, need delivery anesthesia plan	- Not ideal in pregnancy - Used only if MOUD is unavailable

Neonatal Opioid Withdrawal Syndrome (NOWS)

Neonates exposed to substances during pregnancy must be observed and monitored for signs of neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS). This applies to many substances, licit and illicit, as well as infants exposed to medications for opioid use disorder (MOUD). NAS is a physiologic/neurobehavioral withdrawal in newborns with in-utero exposure to any psychotropic substance. It includes tobacco, alcohol, prescription medications, and illicit substances. NOWS, however, relates only to prenatal opioid exposure, including MOUD. From 2010-2017, the incidence of NOWS increased by 82%, or one baby diagnosed every 19 minutes in the United States.

It is also crucial to be aware of the timeline for NAS and NOWS and to understand the signs related to different exposures, the typical onset of symptoms, and the duration of neonate withdrawal. Examples include:

Drug	Signs	Onset of Signs	Duration
Alcohol	– Hyperactivity – Crying – Poor suck – Tremors – Seizures – Diaphoresis – Hyperphagia	3-12 hours	Up to 18 months
Amphetamines	– Premature birth – Low birth weight – Intracranial bleeding – Cleft palate – Malformed ribs – Placental abruption – Small head circumference	Within 24 hours	Up to 7-10 days
Caffeine	– Jitteriness – Vomiting – Bradycardia – Tachypnea	At birth	1-7 days
Cannabis	– Low blood sugar – Low blood calcium – Poor feeding	Varies: 12-48 hours	6 days-6 weeks

Drug	Signs	Onset of Signs	Duration
	– Tachypnea		
Cocaine	– Increased startle reflex – Jitteriness – Excessive sucking	2-4 days	5-7 days
Nicotine	– Low birth weight – Stillbirth – Increased startle/jitteriness/tremor	12-24 hours	Within 36 hours
Opioids	– Tremors – Irritability – High-pitched cry – Hypertonia – Hyperreflexia – Yawning – Sneezing – Constant sucking – Poor feeding – Increased sweating – Vomiting	**Heroin:** within 24 hrs. **Methadone:** 24-72 hrs. **Buprenorphine:** 24-72 hrs.	**Heroin:** Varies- may be up to 7 days **Methadone:** Up to 7 days (if not needing to be treated) **Buprenorphine:** 3-5 days (Peak: 70 hours)
Selective Serotonin Reuptake Inhibitors (SSRIs)	– Crying – Irritability – Tremors – Poor suck – Feeding difficulty – Hypertonia – Tachypnea – Sleep disturbances – Hypoglycemia – Seizures	Hours-Days	1-4 weeks

It is important to understand how opioids differ in their properties and, in turn, vary in treatment needs and monitoring. Notably, for providers, the maternal dose of buprenorphine does not correlate with infant withdrawal severity or pharmacologic treatment needs. With buprenorphine products, the peak withdrawal is ~70 hours of life. Depending on your institution and resources, a typical observation time is 4-5 days, often longer than the maternal stay. Most hospital systems allow the parenting person to stay with the infant as a discharged patient, continuing to care for the newborn. Compared to maternal methadone maintenance, buprenorphine-exposed neonates have shorter lengths of stay, and if pharmacological treatment is needed, they also have fewer days of treatment. Buprenorphine-exposed neonates average ~5.8 days fewer days of stay and ~6.1 fewer days of pharmacological treatment. Buprenorphine-exposed infants also have improved birthweight and gestational age.

Historically, neonates were monitored using Finnegan Scoring. The Finnegan Scoring system protocol begins at ~2 hours of life and is rescored every 3-4 hours, often before feedings. An infant without any intrauterine exposure to substances, if scored, typically would receive a median score of 2.5. A clinically significant score is 8. It is recommended to begin an opioid agonist withdrawal protocol when, during serial scores, the sum hits 24 (three consecutive scores of 8 or two consecutive scores of 12). Using the Finnegan Scoring system, many neonates require an opioid agonist resulting in NICU placement, separation from the parenting person, and an average hospital stay of 16-20 days.

More recently developed and utilized, the Eat, Sleep, Console (ESC) Model is also a scoring tool to monitor infants for NOWS. It uses three simple screening points and has led to a decrease in opioid agonist treatment requirements and a decreased length of hospital stay without any adverse complications or readmissions. The three measurements include: the infant's ability to eat ≥ 1oz or breastfeed well, sleep undisturbed for≥ 1 hours, and be consoled. If not met, environmental and nonpharmacologic approaches are addressed first, saving pharmacotherapy if these adjustments are unsuccessful. The original study evaluating ESC showed significant differences in neonatal treatment needs and hospital stays: 12% of infants scored with ESC compared to 62% of infants scored with Finnegan needed morphine treatment, and the average length of stay was eight days [utilizing ESC] vs. 76 days [using Finnegan]. (This study has been repeated with more significant numbers and has shown even more impressive results.)

Rooming-In strategies have also led to decreased neonatal distress and pharmacotherapy needs due to minimizing the often-over-stimulating NICU environment and reducing the separation of the infant-parenting person dyad. Alone, rooming-in is associated with lower rates of pharmacotherapy and shorter lengths of hospital stay.

Non-pharmacological approaches, and rooming-in strategies, to care for opioid-exposed infants facilitate parent-infant bonding and help the family interpret infant-specific signs of NOWS and other infant-specific cues. Strategies include:

1. Breastfeeding, if not contraindicated (it should, however, never be forced upon a mother)
2. Frequent, small amounts of feedings
3. Provide a quiet, dim room with low activity
4. Rooming-In
5. Limit visitors
6. Avoid overheating
7. Skin-to-skin (occasionally referred to as Kangaroo Care)
8. Swaddling
9. Gentle rocking/swaying

If the neonate continues to have significant symptoms after utilizing non-pharmacologic techniques, full opioid agonists are used to help the neonate withdrawal safely. There are several approaches concerning the specific opioid agonists used to treat the neonate, including morphine, methadone, or buprenorphine. Smaller hospitals without a NICU or that do not treat NOWS frequently transfer to a higher level of care should be strongly considered. As always, it is essential to use patient-centered and appropriate language when discussing NOWS, as newborns are not [born] “addicted” to opioids [or other substances]. Instead, they are physiologically dependent on them.

Corrections: Jail and Criminal Justice

Clinics identified the need to prioritize building relationships **and coordination of MOUD before and after incarceration and inpatient treatment** as transition points where coordinated referrals and continuation of care are critical to prevent overdose and relapse. Multiple sites focused on streamlining care coordination at transition points for patients entering or leaving jail and inpatient treatment. The use of MOUD as part of jail or inpatient treatment varies by facility. In both cases, if inpatient treatment or jail requires abstinence and does not offer MOUD services, clinic based MOUD can play an integral role in tapering patients in a safe way to prepare for entering into facilities or strongly advocate for the continuation of MOUD for optimal patient outcomes. Likewise, exiting from jail or inpatient facilities is a crucial time of risk for many patients to resume substance use as there may be lapses in medical coverage, discontinuation of MOUD if started in-facility, or other conditions to instigate use. Some sites could coordinate with facility-based nursing staff to offer continuation of MOUD if started while in the facility or offer it to patients immediately upon transition. Staff reported these partnerships were established through persistence, prior relational trust, and active education about MOUD on the part of nurse coordinators. In one case, willingness to coordinate with clinic based MOUD programs only occurred after a patient experienced an overdose after leaving a facility. Grant-funded technical assistance helped to facilitate collaboration across TOWN sites.

Your county jail can and should be a place to engage and retain patients with opioid use disorder (OUD). This includes patients who have not yet entered treatment for their OUD and those already in your program. Communication and collaboration between your clinic program, typically through the Care Coordinator, and the jail, typically through the contracted medical provider in your local county jail, is the most critical first step for capturing and treating incarcerated patients with the standard of care, medications for opioid use disorder (MOUD):

Possible barriers to treatment for incarcerated persons:

- Stigma:
  - Against:
    - Mental Health (MH)
    - Substance Use Disorder(s) (SUD)
- By (not an exhaustive list):
  - Medical staff
  - Correctional staff
  - Jail administrators
  - County boards
  - Society
- Medical limitations imposed by non-clinicians:
  - Jail administration
  - Agencies (see below)
  - County boards/commissioners
- Medication Availability:
  - Certain medications 'not allowed' in corrections:
    - Abuse potential of MH and OUD medications
    - Costs of medications
  - Examples:
    - Bupropion (Wellbutrin®)
    - Gabapentin
    - Quetiapine (Seroquel®)
    - Trazodone
    - Buprenorphine products (Subutex®/Suboxone®)
    - And many more
  - Lack of Knowledge on Harm-Reduction:
    - Medications with abuse potential discontinued without reason
    - Unexpected urine drug screens (UDAS) result in the complete discontinuation of high-risk medications (see above) and MOUD
  - Mental Health (MH)
    - Inadequate services:
    - Disproportionately high levels of severe MH diagnosis +/- SUD in the incarcerated population ('locking-up' rather than hospitalized)

- No, or limited access to higher levels of care
- MH providers' knowledge:
  - Not adequately trained in severe MH diagnosis and treatment(s)
  - Not adequately trained in co-occurring MH and SUD
- Not timely:
  - Rationing of treatment hours per contract with MH providers
  - Prioritizing patients [many do not get care timely] due to limited hours in the contract
- Different correctional agencies have different standards for care, authorizations needed for care, financial availability, and oversight, resulting, potentially, in refusal or delay of treatment:
  - Immigration (ICE)
  - US Marshalls (USM)
  - Department of Corrections (DOC)
  - County inmates
- Cost:
  - Insurance [especially for state programs] discontinued upon incarceration
  - County [of incarceration] responsible for costs: (see above in medical decision making)

Data surrounding corrections and treatment for MH and SUD:

- Risk of death from overdose (OD) is >12x's higher in the first 2 weeks after release from incarceration:
  - Loss of tolerance for opioids with the resumption of use
  - Services and support systems were not established for inmates, and they had nowhere to go except where they were
- National prison data from January 2022:
  - 45.3% of all inmates are incarcerated for drug offenses
  - Compared to:
    - 11.6% for sex offenses
    - 3.1% for homicide, aggravated assault, and kidnapping [combined]
    - 5% for burglary, larceny, and property offenses [combined]
  - Minnesota prison statistics:
    - Length of drug sentences: 39-97 months
    - Almost half of women incarcerated on drug charges
    - Race and ethnicity:
      - Black: 15% jail population, 6% state population

        - Native American: 7% jail population, 1% state population
        - Latinx: 7% jail population, 5% state population
        - Asian/Pacific Islander: 1% jail population, 5% state population
        - White: 44% jail population, 83% state population
- Costs: 2007 data:
    - Total ~$193 billion annually, ~$113 billion annually, alone, linked to drug-related crimes and criminal justice system expenditures
    - Treating SUD: ~$14.6 million annually
    - MOUD treatment in the community: ~$5000/year/person
    - Incarcerating a person: ~$24,000-$28,000/year/person
    - Residential drug treatment program (not all patients require this, however): ~$6,800/year/person

Reality of treating OUD in jails/prisons:

- Humane treatment of the individual with the disease of addiction
  - Less OD risk upon release
  - Reduced recidivism
  - Decrease in hospitalizations
  - Efficient use of staffing resources
  - Reduced medication cost for treatment of acute withdrawal symptoms
  - Improved public safety:
  - Lower crime
  - Higher employment
  - Less child protection
- Harm reduction:
  - Less Hepatitis C
  - Less HIV
  - Less endocarditis
  - Lower death rates
- MOUD is the standard of care

Legal considerations/human rights

- Memorandum from Massachusetts 11/26/2018: (MOUD was discontinued on a patient incarcerated):
  - 8th Amendment violation: cruel and unusual punishment
  - "Deliberate indifference to a medical condition"
  - Violation of the American Disability Act (ADA)
- Does not mean legalization but instead focuses on treatment and rehabilitation rather than criminalizing and incarcerating those with [non-violent] drug crimes.
- Benefits:
  - Reduced prison/jail populations (cost)
  - Increased treatment
  - Reduction in arrests
  - Reduction in stigma with recognition of addiction as a disease
  - Reduced societal violence
  - Better MH treatment
- Cons (Currently):

- Treatment infrastructure is still lacking
- Logistics of what is/should be decriminalized- level of charges
- Up-front costs with delayed recognition of financial benefit

It is our responsibility to give the same access to care to incarcerated individuals recognizing, again, that addiction is a chronic medical condition. As a community and a health care system, we would have better MH and SUD outcomes if patients received appropriate treatment before release from prison or, with decriminalization efforts, instead of incarceration. This, in turn, would ease the societal financial burden not only for the incarceration costs but also costs associated with employment deficits, child protection, infectious diseases, and other secondary cost burdens.

In April 2022, the U.S. Department of Justice (DOJ), Civil Rights Division, responded to the Opioid Crisis concerning the criminal justice system and released a guidance document for prioritizing prevention, enforcement, and treatment of those with OUD. It includes enforcing the ADA as well as information on how the ADA can protect individuals with OUD (and other SUD) from discrimination. Although the primary focus of the document is on protecting those in recovery and not engaging in illegal drug use and those on MOUD, it provokes hope that those with active OUD will also be able to access treatment when incarcerated in the near future. The current document does, unfortunately, not protect individuals engaging in the current illegal use of drugs. Still, it does state that these individuals cannot be denied health services or services in connection with drug rehabilitation. The document, again, is not fully inclusive of patients actively suffering from the disease of addiction as it also states that patients may be denied drug rehabilitation or treatment who engage in the illegal use of drugs while in a program, thus allowing for release and dismissal from a treatment program in a non-harm reduction, non-patient centered approach. Recognizing, capturing, and treating incarcerated individuals with OUD/SUD reduces discrimination and stigma, leading to positive downstream societal effects. Inmates with the disease of addiction are being penalized for their chronic health diagnosis; however, recognizing this lack of care allows us to extend treatment lowering active rates of SUD and saving lives.

Child Protection

Strong communication and collaboration with your County's Child Protection Services (CPS) are beneficial in providing continuity of care for parenting patients. Learning how CPS functions in your county can alleviate many misconceptions surrounding its services, goals, and purpose, allowing for improved patient education and alleviating fears. Communication also benefits CPS, allowing for an increased understanding of addiction as a disease rather than a choice. To a parenting patient with substance use/opioid use disorder (SUD/OUD), CPS typically seems threatening and punitive. They often comment that CPS is expecting failure, hoping even, and at no point wants parent/child reunification. When SUD/OUD providers and CPS communicate and collaborate, patients often feel more supported, empowered and, in some cases, motivated to discuss their progress, triggers, fears, and struggles.

Reporting guidelines in each state vary, and it is vital to understand the statutes that apply to your patients and practice. Every state is different regarding who is a mandated reporter and being aware of your requirements is essential. Mandated reporters, in general, are required to report information obtained while performing professional duties, which leads them to believe a child may have been maltreated. An oral report of alleged maltreatment should be followed up with a written report within 72 hours, excluding holidays and weekends. An appropriate law enforcement agency should evaluate reports, or questions, on what should be reported, an agency responsible for assessing or investigating a report, or the local welfare agency.

The State of Minnesota recently passed new legislation on mandated reporting for healthcare and social service professionals allowing for more patient-focused care where trust is encouraged, resulting in improved prenatal care.

The summary of the Minnesota Statue, 260E.31 [Reporting of Prenatal Exposure to Controlled Substances] is as follows:

> *Subdivision 1. Reports required.*
>
> *(a) Except as provided in paragraph (b), a person mandated to report under this chapter shall immediately report to the local welfare agency if the person knows or has reason to believe that a woman is pregnant and has used a controlled substance for a nonmedical purpose during the pregnancy, including but not limited to tetrahydrocannabinol, or has consumed alcoholic beverages during the pregnancy in any way that is habitual or excessive.*
>
> *(b) A health care professional or a social service professional who is mandated to report under this chapter is exempt from reporting under paragraph (a) if the professional is providing or collaborating with other professionals to provide the woman prenatal care, postpartum care, or other health care services, including care of the woman's infant. However, suppose the woman does not continue to receive regular prenatal or postpartum care after the woman's health care professional has attempted to contact the woman. In that case, the professional is required to report under paragraph (a).*

If you want more information about child maltreatment statutes, visit the Minnesota Department of Human Services website, or review your state's child maltreatment laws: Child protection, foster care, adoption: Program overviews (https://mn.gov/dhs/partners-and-providers/program-overviews/child-protection-foster-care-adoption/)

Frequently Asked Questions

How many patients can a DATA 2000 waivered provider manage at a time?

Newly waivered providers typically only have 30 active patients during the first year. The following year, physicians and prescribers may apply to SAMHSA to increase their active patient limit to 100 patients. In certain situations, providers can apply early to increase their limit sooner, up to a maximum of, at this time, 275 patients. For more information, visit the Substance Abuse and Mental Health Services Administration (SAMHSA) website.

Can un-waivered providers order and administer buprenorphine?

Yes. Providers working as hospitalists or emergency room providers may administer buprenorphine [for opioid use disorder (OUD)] but cannot prescribe it. Title 21 CFR 1307.06(b) defines the "three-day rule" to relieve acute withdrawal symptoms while arranging for the patient's referral to treatment under the following conditions:

1. Not more than one day's medication may be administered or given to a patient at one time.
2. This treatment may not be carried out for more than 72 hours.
3. The 72-hour period cannot be renewed or extended.

For more information, visit The National Alliance of Advocates for Buprenorphine Treatment website at The National Alliance of Advocates (www.naabt.org)

If the patient is admitted to the hospital or placed on observation, the attending provider, even if not waivered, can prescribe buprenorphine during the inpatient stay. However, the patient's primary diagnosis or chief complaint cannot be addiction/withdrawal related. For example: If a patient is admitted for monitoring after an opioid overdose, the diagnosis must be respiratory failure, not substance use or opioid overdose. Unfortunately, many insurance companies will not reimburse hospitals for inpatient stays related to overdose and/or withdrawal. Using an alternative, although not incorrect, primary diagnosis also allows the attending provider to order buprenorphine for the patient without being waivered throughout the patient's stay in the hospital. It is good practice for the attending care team to consult a clinic-based buprenorphine provider for management guidance and to arrange close follow-up upon discharge.

Can I disclose substance use disorder records in a primary care setting?

We refer you to CFR Part 2 Confidentiality of Substance Use Disorder Patient Records. In addition, please visit SAMHSA's website and consult your clinic's attorneys.

Summary

This manual is our third attempt to bring together information and protocols that allow community clinics to implement programs without having to “reinvent the wheel.” Not long ago, it seemed as though the opioid epidemic was showing improvement. However, data from 2020-2021 shows a sharp increase in overdose deaths. Many question the ‘why’ of the sharp increase again. Has it been driven by more readily accessible and potent synthetic fentanyl? Did the COVID-19 pandemic drive the surge due to social isolation and even more significant barriers to care? Is it an unfortunate combination of these coupled with many other factors? Regardless, as a society and as a medical community, we must increase our efforts to implement MOUD programs and increase access to care and treatment. Aside from the downstream detrimental effects, upstream prevention efforts must also be increased.

We are hopeful that this manual plays a small part in these efforts by giving some direction on appropriate opioid prescribing, guidance for the identification of opioid use [and other substance use] disorders, and support and encouragement for the treatment of opioid use disorder in clinical practice. The disease of addiction will take an entire community and comprehensive strategies to assist those who wish to start and maintain their recovery journey.

Every one of us plays a part in our patient’s successful recovery journey. Together we can disseminate knowledge, reduce stigma, provide exceptional addiction care, and prevent overdose deaths.

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28 C.F.R. §§ 35.108(b)(2), 36.105(b)(2). Regulations implementing Title I of the ADA define the term “physical or mental impairment” as including “any physiological disorder or condition.” 29 C.F.R. § 1630.2(h)

1 42 U.S.C. §§ 12111-12117. The Equal Employment Opportunity Commission (EEOC) and the Department of Justice jointly enforce the ADA’s ban on employment discrimination. For more information or to file a complaint of employment discrimination, visit eeoc.gov

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Appendix

Controlled Substance Care Plan

The purpose of this agreement is to prevent misperceptions about any controlled medications you will be prescribed as part of the care plan for your diagnosis. This agreement will help you, your Clinical Provider, and members of your care team (RN's, social workers, pharmacists, clinical nurses, CMA's etc.) to comply with the law and best practice guidelines regarding controlled medications, including those used to treat substance use disorders (SUD).

I,_____ (patient name), _____ (DOB), have agreed to use my medication(s) as part of my treatment plan for my diagnosis.

Diagnosis (es): _____

_____

Plan:_____

_____

Terms of Agreement

- I have been made aware of the risks associated with my prescribed medications.
- I will not take medications prescribed for others nor will I share my medications with others.
- I will keep all my medications away from children.
- Additional referrals (physical therapy, other providers etc.) or programs (in/out-patient treatment, mental health services etc.) may be recommended by my Clinical Provider or care team.
- I will actively participate in any program(s) designed to improve function including social, physical, psychological, and daily/work activities.
- I agree to allow my care team to communicate with other health care professionals regarding my diagnosis as they deem necessary. I understand that I may need to sign a consent form for this first.
- I understand this mode of treatment may be stopped and/or I may be referred for additional and/or higher level of care if any of the following occur:
- I give away, sell, or misuse my medications or use medications prescribed for others.
- I am non-adherent with any of the terms of this contract.
- I disrespect or harass any members of my care team.
- I have read and understand these terms and have asked all relevant questions.
- I consent to the agreed upon treatment in my care plan under the terms of this agreement.

This agreement will remain in effect for duration of therapy and updated as appropriate, and/or annually.

Patient Signature: _____ Date: _____

Provider Signature: _____ Date: _____

Witness Signature: _____ Date: _____

NOTICE TO PATIENTS REGARDING PRESCRIBED CONTROLLED SUBSTANCES

At our facility, we are committed to providing our patients with the best care possible, focusing on the patient as a whole person. We understand the importance of caring for each patient individually while maintaining standards of appropriate and responsible care. To ensure safety and achieve positive health outcomes, we have developed a process of care for all patients who are prescribed controlled substances for chronic, or daily, use.

What is a controlled substance?

Controlled substances are medications that have significant risk(s) associated with them. These risks include addiction, dependence, overdose, and others. A controlled substance includes medications such as:

- Stimulants (i.e., Adderall®, Ritalin®)
- Benzodiazepines (i.e., Xanax® (alprazolam), Ativan® (lorazepam), Klonopin® (clonazepam))
- Opioids (i.e., oxycodone, morphine, hydrocodone, fentanyl, Percocet®, Norco®)

What to expect

Focusing on the best possible health outcomes for all of our patients, our clinic closely monitors patients on chronic use of controlled substances.

This may include:

- Signing a controlled substance care plan.
- Urine drug screening.
- Pill counts.
- Meeting with members of our controlled substance care team (RN Care Coordinator, social worker, or a pharmacist) in addition to your primary care provider and their nurse.
    - Additionally, further work-up of the diagnosis for your controlled substances may be recommended, and additional or alternative treatments may also be recommended.
    - Patient safety remains our primary goal. In some situations, this may include tapering or discontinuing controlled substances. Our goal is NOT to take all patients off of their medications, but rather, treat each with the most effective, and safe, means possible.

Following your care plan is very important.

Monitoring medication use is important for the safety of all of our patients and our community. Each patient will be treated with respect and dignity. Do not hesitate to ask your provider or their nurse if you have any questions or concerns.

Controlled Substance Care Team (CSCT) Review

Patient Name: _____ DOB: _____

Age: _____

Provider:_____

Patient MRN: _____

Active Signed Care Plan (Within the last year): Yes ☐ No ☐ (If No- Chart Cannot Be Reviewed)

Current Controlled Substances with Dose: _____

_____

_____

Is the Patient on Opioids and Benzodiazepines Together: Yes ☐ No ☐

Pain Generator/Diagnosis for Controlled Substances: _____

Treatment(s) Tried for Diagnosis (i.e., Physical Therapy, Surgery, Injections, Procedures etc.):

_____

Images Reviewed: Yes ☐ No ☐ Date of Most Recent Images: _____

Pertinent Findings: _____

Mental Health (MH) Diagnosis: _____

Provider/Clinic That Manages MH: _____

Mental Health Medications and Dose: _____

_____

Adverse Childhood Experience (ACE) Score (Last Page): _____

History of Any Substance Use Disorder (SUD): Yes ☐ No ☐ Substance(s): _____

History of:

- Nicotine use: Active ☐Past History ☐ Never ☐
- Suicide Attempt: Yes ☐No ☐ Unknown ☐
- Overdose: Yes ☐ No ☐ Unknown ☐
- MH/SUD Treatment/Hospitalization: Yes ☐ No ☐ Unknown ☐

PDMP Reviewed: Yes ☐ No ☐

- Early Refills: Yes ☐ No ☐
- Multiple Pharmacies: Yes ☐ No ☐
- Multiple Prescribers: Yes ☐ No ☐

Other Important Co-Morbidities:

- Obesity: Yes ☐ No ☐ Unknown ☐

Sleep Apnea: Yes ☐ No ☐ Unknown ☐

Osteopenia/Osteoporosis: Yes ☐ No ☐ Unknown ☐

If Male, Recent Testosterone Test: Yes ☐ No ☐ Unknown ☐

Result:

_____

Social Needs (Including: Housing, Transportation, Insurance, Food etc.):

_____

_____

Recent Urine Drug Screen and Confirmatory Results (If Applicable):

Date: _____ Results: _____

Date: _____ Results: _____

CSCT Recommendations: _____

_____

_____

CSCT Lead Signature: _____Date: _____

Sent/Given to Primary Provider: Yes ☐ No ☐

Response From Primary Provider: Yes ☐ No ☐

Next Steps Discussed with Primary Provider: (Taper, Pharmacist Referral, Imaging, Other Referrals, Pill Counts, Random UDAS, Substance Use Disorder Evaluation, Record Request, Nothing Further etc.)

1. _____

2. _____

3. _____

4. _____

5. _____

Secondary (Re-)Review Date: _____

Further Recommendations/Next Sets/Plan: _____

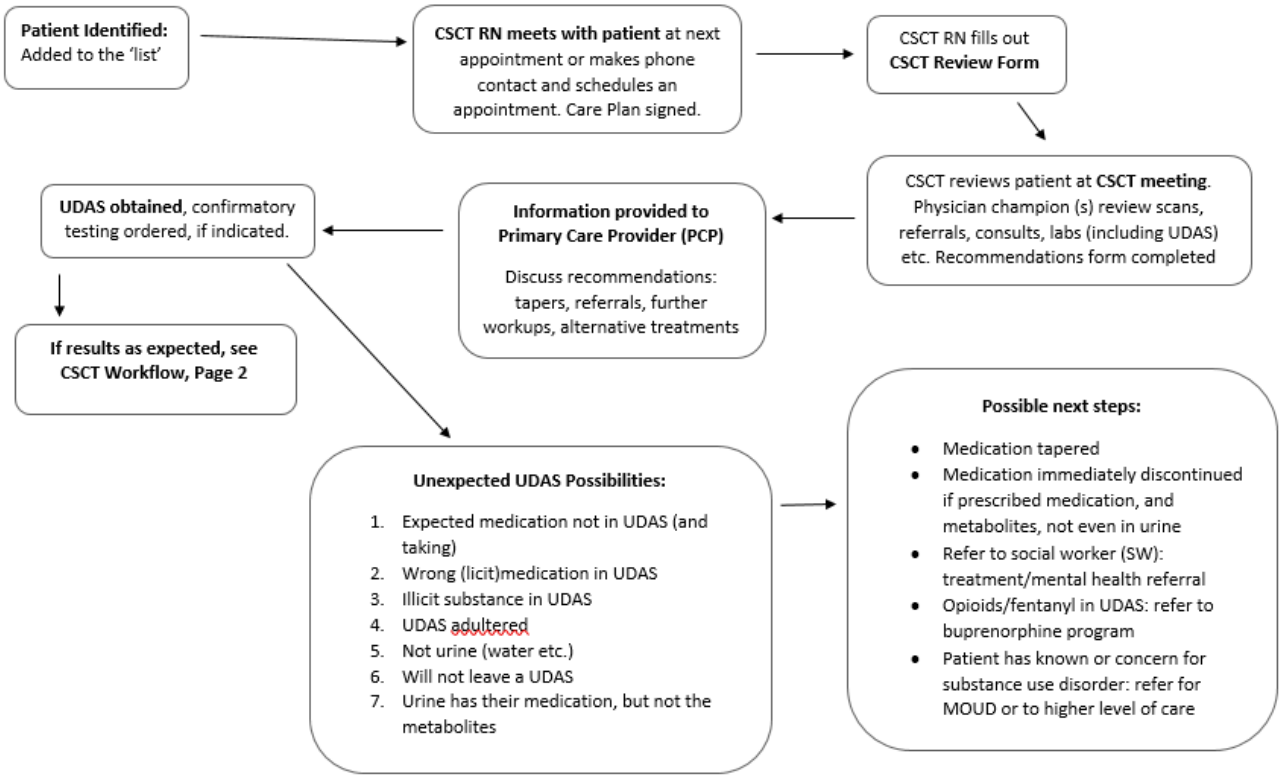
_____

Morphine Equivalents Table

Prior Oral Opioid	Multiply Dose by a Factor Of
Codeine (mg)	0.15
Fentanyl	0.15
Buccal or SL tablets, or lozenge/troche (mcg)	0.13
Film or oral spray (mcg)	0.18
Nasal spray (mcg)	0.16
Patch (mcg)	7.2
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Meperidine (mg)	0.1
Methadone (mg)	
>0, ≤20	4
>20, ≤40	8
>40, ≤60	10
>60	12
Morphine (mg)	1
Oxycodone (mg)	1.5
Oxymorphone	2
Tramadol (mg)	0.1

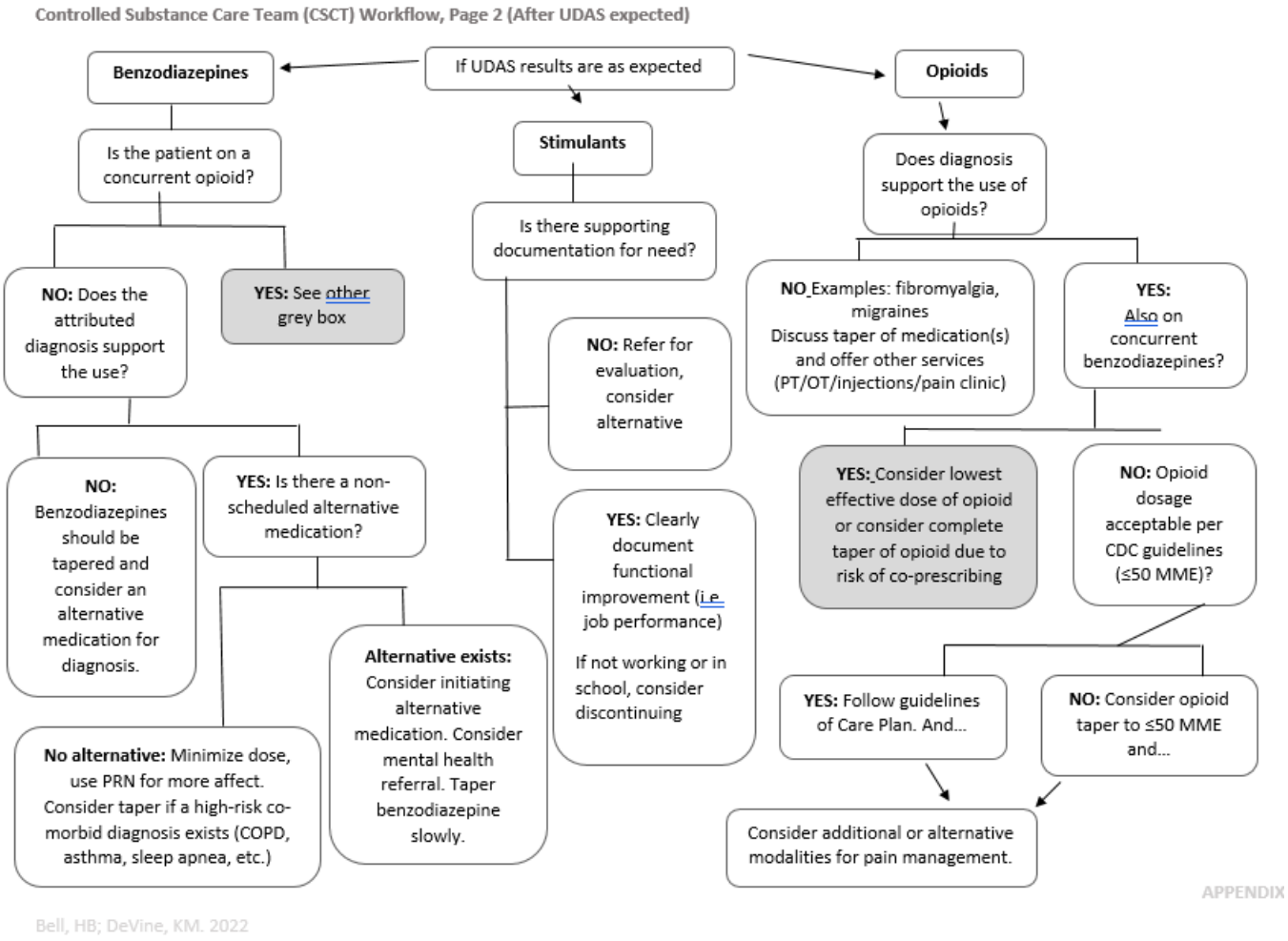
Controlled Substance Care Team (CSCT) workflow page 1

Controlled Substance Care Team (CSCT) workflow page 1

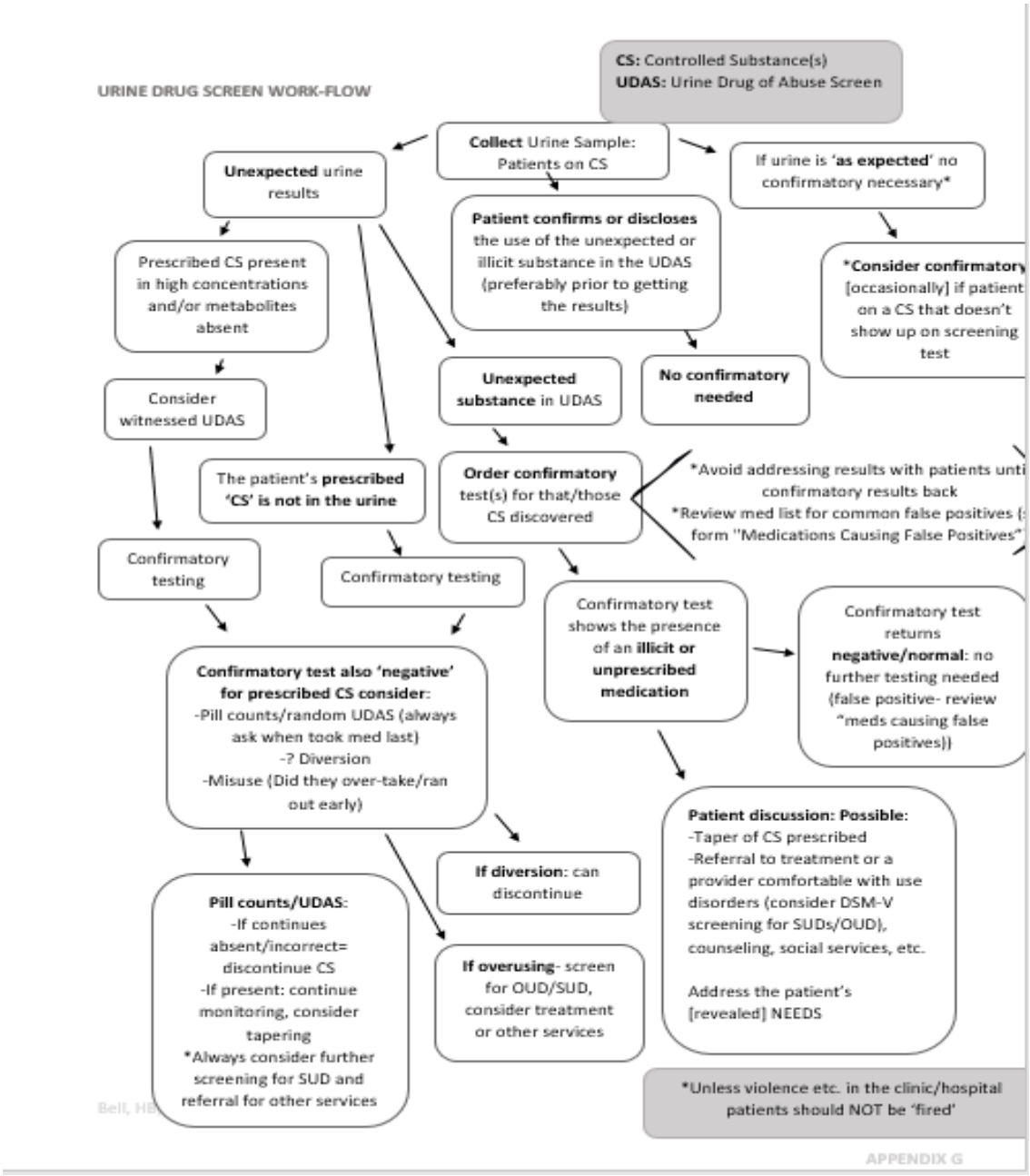


Bell, HB; DeVine, KM. 2022

Controlled Substance Care Team (CSCT) Workflow, Page 2 (After UDAS expected)



Urine Drug Screen Workflow



Urine Drugs Screen (UDAS) Results and Interpretation

Substance	Screen Results	Confirmatory	Ratio
Amphetamine	AMPH	AMPH	N/A
Methamphetamine	METH, AMPH	METH/AMPH	3:1
MDMA	Possibly METH, AMPH	MDMA/MDA	N/A

Pearls

- Amphetamine is one of the most common false positives on a screening test
- Meth (+), Amph (-) is likely a false positive
- Amphetamine might be “cut” with MDMA and vice versa

Benzodiazepines

Note: Most UDAS test for the presence of oxazepam

Medication	[Likely] Result on Screening UDAS	Confirmatory Test Result
Alprazolam (Xanax®)	--	Alpha-oh-alprazolam
Clonazepam (Klonopin®)	--	7-NH-clonazepam
Diazepam (Valium®)	+	Nordiazepam, oxazepam, temazepam (1:1:1)
Lorazepam (Ativan®)	--	Lorazepam
Oxazepam (Serax®)	+	Oxazepam
Temazepam (Restoril®)	+	Oxazepam/temazepam only
Triazolam (Halcion®)	--	Alpha-oh-triazolam
Clorazepate (Tranzene®)	+	Oxazepam
Flurazepam (Dalmane®)	--	2-hydroxyethy/lorazepam
Midazolam (Versed®)	--	Alpha-hydroxy midazolam glucuronide

URINE DRUG SCREEN (UDAS) LIMITATIONS AND QUICK TIPS

Important Quick Tips Concerning UDAS:

- Always ask, and document, when the patient took each controlled substance
- Do not make clinical decisions about or address the patient about the results, on screening UDAS. Wait for confirmatory test results

Things to Consider Regarding Urine Collection:

- [Typically] need a quantity of: 30mL
- Temperature: 90°-100°
- Specific gravity: 1.002-1.030
- pH: 4.6-8.0
- Oxidants should be NEGATIVE

Concerns Regarding the Urine Collected:

- Bubbly or cloudy
- Specific gravity: >1.0010 or <1.0030 (or urine too dark or too clear)
- pH: <3 or ≥11
- High or low temperature
  - *Can order a urine adulterants confirmatory test. Common adulterants (see below)

What to consider regarding limitations:

What is NOT on a [typical 10 panel] UDAS:

- Fentanyl (and analogs)
- Tramadol
- Synthetic cannabinoids
- Alcohol
- Certain benzodiazepines (see below)
- Tapentadol (Nucynta®)
- Kratom
- Tianeptine
- K2

- “Designer Drugs”
- “Club Drugs”

“Which benzodiazepines do not show as “present” on [most] screening UDAS

- Alprazolam (Xanax®)
- Clonazepam (Klonopin®)
- Midazolam (Versed®)
- Triazolam (Halcion®)
- Most designer benzodiazepines
    - Confirmatory Test Pearls:
- High level of parent compound without metabolite -> consider patient adding a piece of their medication to their urine (did not digest/metabolize)
- Parent compound low and no metabolite: may mean metabolite is below the threshold to detect or they just took their med before the UDAS done
- High metabolite with no parent compound: patient took the medication [likely awhile a go] or they are a fast metabolizer
- Low metabolite with no parent compound: took the medication and now at the end of the drug’s duration of action or metabolic cycle

Quick Tips

Adulterant	Composition	Mode of Action
Ammonia	Ammonia	Interferes with detection of benzoylecgonine and phencyclidine (PCP)
Bleach	Sodium hypochlorite	Interferes with immunoassay; may cause degradation of analyte for gas chromatography
Goldenseal (*Hydrastis canadensis)*	Herbal diuretic	Dilution to below cutoff level; decreases immunoassay sensitivity to amphetamines and THC
Klear, Whizzies	Potassium nitrite	Interferes with THC immunoassay and gas chromatography/mass spectrometry analysis
Powdered urine	Dried human urine residue	Substitution

Opioids

Medication	Result on Screening UDAS	Confirmatory
Codeine	+ Opiate	Codeine, hydrocodone, hydromorphone, dihydrocodeine, morphine
Hydrocodone	+/- Opiate	Hydrocodone, hydromorphone, dihydrocodeine
Morphine	+ Opiate	Morphine, normorphine, hydromorphine
Hydromorphone (Dilaudid®)	+/- Opiate	Hydromorphone
Oxycodone	+ Oxycodone + Opiate Occasionally (NOT always)	Oxycodone, oxymorphone

Drug Detection Window by Test Type

Substance	Urine	Hair	Oral Fluid	Sweat	Blood
Alcohol	10-12 hours EtG—Up to 48hours	N/A	Up to 24 hours	N/A	12 hours
Amphetamines[+#]	2-4 days	Up to 90 days	1-48 hours	7-14 days	12 hours
Methamphetamine[+#]	2-5 days	Up to 90 days	1-48 hours	7-14 days	1-3 days
Barbiturates[#]	Up to 7 days	Up to 90 days	1-10 days	N/A	1-2 days
Benzodiazepines[#]	Up to 7 days	Up to 90 days	1-10 days	N/A	1-2 days
Cannabis (Marijuana)[+ #]	1-30 days	Up to 90 days	Up to 24 hours	7-14 days	2-3 days/2 weeks
Cocaine[+#]	1-3 days	Up to 90 days	1-36 hours	7-14 days	1-3 days
Codeine (Opiate) [+#]	2-4 days	Up to 90 days	1-36 hours	7-14 days	1-3 days
Fentanyl	2-3 days	Up to 90 days	1-3 days	7-14 days	12 hours
Methadone[#]	Up to 14 days	For several months	Up to a few days	7-14 days	24 hours
Morphine (Opiate) [+#]	2-5 days	Up to 90 days	1-36 hours	7-14 days	1-3 days
Heroin (Opiate) [+#]	2-3 days	Up to 90 days	1-36 hours	7-14 days	1-3 days
Oxycodone[#]	Up to 4 days	Up to 90 days	Up to 4 days	7-14 days	24 hours
PCP (Phencyclidine) [+#]	5-6 days	Up to 90 days	1-10 days	7-14 days	1-3 days

Common Medications That May Result in False-Positive Results on Urine Druga Screening (UDAS)

Medication	AMP/MET	BAR	BZO	THC	LSD	MTD	OPI	PCP	TCA
Amitriptyline					X				
Bupropion	X				X				
Buspirone					X				
Carbamazepine									X
Cyclobenzaprine									X
Dextromethorphan							X	X	
Diltiazem					X				
Diphenhydramine						X		X	
Doxylamine						X	X	X	
Fentanyl					X				
Fluoxetine	X				X				
Ibuprofen		X		X				X	
Labetalol	X				X				
Lamotrigine								X	
Metformin	X								
Methylphenidate	X				X				
Metoclopramide					X				
Naproxen		X		X					
Prochlorperazine					X				
Promethazine	X								
Pseudoephedrine	X								
Quetiapine						X			X
Quinolones							X		
Ranitidine	X								
Risperidone					X				
Sertraline			X		X				
Tramadol								X	
Trazadone	X				X				
Venlafaxine								X	
Verapamil					X	X			

* False positive amphetamine results have only been seen with ofloxacin

Medication	AMP/MET	BAR	BZO	THC	LSD	MTD	OPI	PCP	TCA
AMP/MET: amphetamine/methamphetamine; BAR: barbiturate; BZO: benzodiazepine; LSD: lysergicacid diethylamide; MTD: methadone; OPI: opiate; PCP: phencyclidine; TCA: tricyclic antidepressant; THC: cannabinoid									

U. S. Pharmacist - The Pharmacist's Resource for Clinical Excellence (https://www.uspharmacist.com/article/urine-drug-screening-minimizing-false-positives-and-false-negatives-to-optimize-patient-care)

CSCT Random Pill Count Workflow

1. Nurse Care Coordinator (Nurse CC) calls patient
2. Nurse CC schedules pill count, preferably within 48hrs (≤24 hours is ideal)
3. Considerations on 'Who' to schedule pill counts with:
    a. Nurse CC for CSCT
    b. Another Nurse Care Coordinator in the clinic
    c. Clinic injection nurse
    d. Clinic coumadin nurse
    e. Other nurse in the facility
4. Pills counted, compared with last PDMP fill date
5. Results documented in the patient chart and routed to CSCT/Nurse CC and primary provider/prescriber
6. Provider notified if discrepancy
7. CSCT along with primary prescriber develop a plan if concerns are identified

Random Urine Drug Screen Workflow

1. CSCT, provider, Nurse CC requests a random urine drug screen
2. UDAS order placed by Nurse CC*
3. Patient called by Nurse CC and lab test scheduled to be done with Nurse CC or gives patient the number to schedule* (if unable to be done in the clinic with the Nurse CC)
4. Request for screen to be done within 24 hours or 48 hours at the latest
5. Upon patient arrival:
    a. Nurse CC documents:
        i. Current medications
        ii. Last dose taken of each medication
    b. If unable to be done with Nurse CC, lab documents in the electronic medical record when the patient last took their controlled medications
6. Consider the following:
    a. Prior to the patient entering the restroom, spray toilet water blue (and the tank)
    b. Personal items (purse/bag etc.) should be left with the nurse/lab personnel
    c. Turn of the water supply to the sink, if possible
7. Results of UDAS:
    a. To CSCT/Nurse CC
    b. Primary provider/prescribing provider
8. Confirmatory testing ordered [typically by Nurse CC] if indicated (See UDAS tip sheet)

If the random UDAS cannot be done by the Nurse CC:

Nurse CC, in the comment section of the lab order, should:

- List pertinent controlled substance medications the patient is prescribed

Requests lab to identify when the patient took the last dose of each of their controlled substance(s)

Worksheet for DSM V Criteria for Diagnosis of Opioid Use Disorder

Patient Name: _____

DOB: _____ MRN" _____

Diagnostic Criteria: _____

Meets Criteria? _____

Notes/Supporting: _____

_____

Within the last 12 months: Yes ☐ No ☐

Information: _____

DSM V Criteria

for Diagnosing Opioid Use Disorder

1. Opioids are taken in larger amounts or over a longer time than intended

Yes ☐ No ☐

Information: _____

2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use

Yes ☐ No ☐

Information: _____

3. A great deal of time is spent in activities necessary to obtain, use, or recover from the opioid and/or its effects

Yes ☐ No ☐

Information: _____

4. Craving, or a strong desire to use opioids

Yes ☐ No ☐

Information: _____

5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home

Yes ☐ No ☐

Information: _____

6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids

Yes ☐ No ☐

Information: _____

7. Important social, occupational, or recreational activities are given up or reduced because of opioid use

Yes ☐ No ☐

Information: _____

8. Recurrent opioid use in situations which are physically hazardous

Yes ☐ No ☐

Information: _____

9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem likely caused by or exacerbated by opioids

Yes ☐ No ☐

Information: _____

10. *Tolerance, as defined by either of the following:

(a) A need for markedly increased amounts of opioids to achieve intoxication or desired effect

(b) Markedly diminished effect with continued use of the same amount of an opioid

Yes ☐ No ☐

Information: _____

11. *Withdrawal, as defined by either of the following:

(a) Characteristic opioid withdrawal syndrome

(b) The same (or closely related) substance taken to relieve or avoid withdrawal symptoms

Yes ☐ No ☐

Information: _____

Criteria from American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.* Washington, DC, American Psychiatric Association page 541.

Total: _____

Severity: Mild: 2-3 Moderate: 4-5 Severe: 6 or more

Signed _____ Date: _____

Patient Intake

Date of Intake: _____

Patient Name: _____

Preferred pronouns: _____

DOB: _____ Age: _____

Where do you Reside? _____

Person Doing Intake: _____

Provider Assigned for Care: _____

Primary Care Provider (PCP): _____

Previous MAT/MOUD Provider (if applicable): _____

Previous MAT/MOUD Clinic (if applicable): _____

Do you Have an Active Rule 25/Chemical Use Assessment: Yes ☐ No ☐

Date completed: _____ Where: _____

Currently in Treatment? Yes ☐ No ☐

Where? _____

Have you Been to Treatment Before:

Inpatient: Yes ☐ No ☐Where? _____ When? _____

Outpatient: Yes ☐ No ☐Where? _____ When? _____

Current Legal Involvement:

County: _____ County: _____

Probation Officer: _____ Probation Officer: _____

Upcoming Court Date(s): _____

Upcoming Court Date(s):_____

Have you Had an Overdose? Yes ☐ No ☐How Many? ____ Last One? _____

Drug of Choice: Opioids (Check one): Pills ☐ Heroin ☐ Fentanyl ☐) Methamphetamine ☐

Alcohol ☐ Marijuana ☐ Cocaine Other: _____

Route: Smoke ☐ Snort ☐ Inject (IVDU) ☐ Other: _____

Share, or Have a History of Sharing, Needles (if applicable)? Yes ☐ No ☐

First Opioid Exposure (If Applicable): Provider (Prescribed) ☐ Family ☐ Friend ☐ Drug Supplier

(Dealer) ☐ Internet ☐Social Media ☐ Other ☐

Mental Health Diagnosis:

None ☐ Anxiety ☐ Depression ☐ PTSD ☐ Schizophrenia ☐ Bipolar ☐ TBI ☐ Other ☐

Infections:

HIV: Yes ☐ No ☐ On Treatment? Yes ☐ No ☐ Previous Treatment: Yes ☐ No ☐

Hepatitis:

B: Yes ☐ No ☐ Have you Been Treated? Yes ☐ No ☐

C: Yes ☐ No ☐ Have you Been Treated? Yes ☐ No ☐ Fully Treated: yes ☐ no ☐ When? ☐

Other infections? _____

Currently Pregnant: Yes ☐ No ☐ Unknown ☐ Not Applicable ☐

Contraception:

Pills ☐ Patch ☐ Ring ☐ IUD ☐ Nexplanon ☐ Surgical ☐ Condoms ☐ Depo ☐

Abstinence ☐

Family History of Use Disorders: Yes ☐ No ☐ Unknown ☐

Alcohol ☐ /methamphetamine ☐ Opioids ☐ Cocaine ☐Other ☐

Current Medications:

_____

_____

_____

_____

Their Pertinent (Chronic Health Diagnosis- Crohn's/Sleep Apnea/Pancreatitis/Sickle Cell etc.):

_____

_____

_____

_____

Social History: _____

_____

Social Needs (Including: Housing, Transportation, Insurance, Food etc.): _____

_____

Patient Signature: _____

Provider Signature: _____

Intake RN/Person Filling Out Form Signature: _____

Substance Use Assessment

Instructions: Fill out the section for each of the drugs that you have used, even if that substance was never a problem for you. If you do not remember specifics, give your best estimate.

Substance	Age of first use (ex. 16)	When did you last use? (ex. 1 month)	Frequency/Amount of most recent use. (ex. 3x per week)	By what route did you use?	Was this substance ever a problem? (yes/no)
Nicotine					
Alcohol					
Benzodiazepines (Xanax, Valium, etc.)					
Cocaine					
Crack					
Hallucinogens (LSD, mescaline, etc.)					
Heroin					
Inhalants (“Huffing”)					
Kratom/ Tianeptine					
Marijuana					
Synthetic Marijuana					
Methamphetamine					
Methadone					
MDMA (“Ecstasy”)					

Substance	Age of first use (ex. 16)	When did you last use? (ex. 1 month)	Frequency/Amount of most recent use. (ex. 3x per week)	By what route did you use?	Was this substance ever a problem? (yes/no)
PCP (“Angel Dust”)					
Prescription Medicine (Vicodin, “Oxys,” etc.)					
Fentanyl					
Kratom					

Adverse Childhood Experience Survey

Had a parent or other adult in the household often or very often… Swear at you, insult you, put you down, or humiliate you? Or act in a way that made you afraid. Yes ☐ No ☐

that you might be physically hurt? Yes ☐ No ☐

Did a parent or other adult in the household often or very often… Push, grab, slap or throw something at you? Or ever hit you so hard that you had marks or were injured? Yes ☐ No ☐

Did an adult or person older than you ever…Touch or fondle you or have you touch their body in a sexual way? Or attempt or have oral, anal, or vaginal intercourse with you? (How much older than you are/were they?) Yes ☐ No ☐

Did you often or very often feel that…No one in your family loved you or thought you were important or special? Or your family didn't look out for each other, feel close to each other, or support each other? Yes ☐ No ☐

Did you often or very often feel that…You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you? Or your parents were too drunk or high to take care of you or take you to the doctor if you needed it? Yes ☐ No ☐

Were your parents ever separated or divorced? Yes ☐ No ☐

Was your mother or stepmother: often or very often pushed, grabbed, slapped, or had something thrown at her? Or sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard? Or ever repeatedly hit over at least a few minutes or threatened with a gun or knife?
Yes ☐ No ☐

Did you live with anyone who was a problem drinker or alcoholic or who used street drugs?

Yes ☐ No ☐

Was a household member depressed or mentally ill, or did a household member attempt suicide?

Yes ☐ No ☐

Did a household member go to prison?

Yes ☐ No ☐

Add up your "yes" answers- that's your ACES score. _____

Medications for Opioid Use Disorder Options and Basics

Substance	Methadone	Buprenorphine	Naltrexone
Mechanism	Full Mu agonist	Partial agonist	Antagonist
Formulation(s)	PO liquid	Sublingual/Subcutaneous	IM or PO
Who Can Prescribe	OTP-Federal Regulation	Waivered Providers	Anyone
Dosing	Daily -> Take Homes	Office based	Monthly
Diversion Potential	↑	Moderate (more for mono-product)	↓
Overdose Potential	↑	↓	↓
Emergency Department Prescribing	-	+	-
Jail	-	+	+
Availability	Chain of Custody	Widely Available	Buy and sell
Cost	Transportation, logistics	$	$$$
Side Effects	Sleep apnea, long QT, hypogonadism in men, flat affect, drowsiness, constipation	Initial potential drowsiness, headache	Nausea, vomiting- can be severe, injection site reactions, precipitated withdrawal, LFT abnormalities
Long-Term	Jobs, safe in pregnancy, frequent medication interactions	Minimal issues, safe in pregnancy, safe with surgery	LFTs, shouldn't use in pregnancy, challenging to treat acute pain
Induction	At OTP, can start right from use	In clinic, ER, jail- need mild/moderate withdrawal	1 week off of any opioid, after full withdrawal

Key

↑ up

↓ down

- No

+ Yes

$ inexpensive

$$$ expensive

Buprenorphine Induction Protocol Guideline

Overview:

- This is a low-dose induction recommendation to follow regardless of the "dose" of opioid/Fentanyl/methadone and can be used even when Fentanyl/methadone is not present.
- Using this guideline will help minimize the risk of precipitated withdrawal by starting buprenorphine at lower doses and increasing the dose slowly.
  - Precipitated withdrawal is sudden and severe withdrawal symptoms.
- During the induction time, a patient may still have mild withdrawal symptoms so other medications can be started to help with these symptoms. (See Adjunctive Medications section below).
  - This protocol applies for buprenorphine (Subutex®) and buprenorphine-naloxone (Suboxone®) forms of Medication for Opioid Use Disorder (MOUD) (MOUD was formerly known as MAT: Medication Assisted Therapy).
  - At any point of the low-dose protocol, the doses may need to be adjusted, from what is below.
  - There are no "perfect" induction guidelines; seeking advisement from a higher level of care is appropriate if any concerns or complications arise.
  - Nursing follow up by phone the first day or two can help monitor and additionally support the patient.
  - Patients need to be advised that if any dose they take [at home] worsens their withdrawal symptoms, they should delay next dose and call for further advice.
  - Patients should be warned that increasing their dose without consulting with their provider or clinic may precipitate their withdrawal.
  - If the patient is currently using an opioid witch is NOT fentanyl or methadone, and this can be fully confirmed by a urine drug screen (UDAS) [and COWS is appropriate], first day dosing may be expedited from the below guidelines. Day 1 dosing may reach 12-16mg buprenorphine [based on patient response and symptoms.]

Dosing:

- If patient is pregnant, consider referring to a higher level of care or seeking advisement from an Addiction Professional.
  - Ideally this protocol should start when patient has a COWS ≥12-15 (see attached COWS scoring sheet).
- Key objective physical exam findings:
  - Dilated pupils
  - HR ≥100 bpm
- Day 1 (when the above criteria is met): 2.0mg once (if initial dose is in the morning, it is reasonable to give an additional 2.0mg 12 hours later)
- Day 2: 2.0mg twice a day
- Day 3: 2.0mg twice a day or 4.0mg twice a day
- Day 4^: 4.0mg twice a day or 8.0mg in the am and 4.0mg in the pm
- Day 5^ and beyond: 8mg twice a day or 16.0mg daily
  - May need to increase beyond a 16.0mg Total Daily Dose (TDD) fairly early, especially with fentanyl exposure
  - Above 24mg TDD is rarely more effective, although can be considered if patient has significant cravings/using dreams
  - ^Around Day 4/5 most or all of fentanyl is out of the system and most methadone will be out of the system. At this point, increasing doses of buprenorphine to goal dose of 16mg-24mg TDD should not result in precipitated withdrawal [if patient has maintained abstinent from additional opioids.]

Adjunctive Medications:

- Zofran for nausea (4mg three times daily (TID) as needed (PRN))
- Clonidine for tachycardia (elevated heart rate), elevated blood pressure, anxiety (0.1mg BID PRN). [Doses can be increased if necessary and as vital signs allow.]
- Hydroxyzine for anxiety (50mg BID PRN)
- Loperamide (Imodium) for diarrhea (1 tab/cap PO after each loose stool- Max 4 in 24hrs)

Medications:

- 2mg buprenorphine (Subutex) = 2mg/0.5mg buprenorphine-naloxone (Suboxone)
- 4mg buprenorphine (Subutex) = 4mg/1.0mg buprenorphine-naloxone (Suboxone)
- 8mg buprenorphine (Subutex) = 8mg/2.0mg buprenorphine-naloxone (Suboxone)

Forms*:*

- Intake Assessment OUD (Opioid Use Disorder)
- Care Plan (Patient to Sign)
- Consent for Treatment with Buprenorphine (Patient to Sign)

Other Forms:

- COWS (Clinical Opioid Withdrawal Symptom)
- Substance Use Assessment
- Patient/Family Hand Out
    - The above method is based on experience and review of literature, also assuming the patient is currently using fentanyl or methadone, or the substance is unknown. Dosing is also adjusted at times based on other factors including time since last use, current level of withdrawal, and other substances that may also be on board.

BUPRENORPHINE AT-HOME GUIDELINE [INDUCTION]

Clinic number: _____

Next Appointment: _____

If, at any point, there are questions or concerns about your medications, dosing, or symptoms you are having, please contact the clinic.

Increasing your dose to higher than recommended, may result in more severe withdrawal symptoms.

If any dose taken causes worsening withdrawal, do not take the next dose and call the clinic. On a weekend, skip the next dose then resume as instructed.

If severe symptoms or concerns, seek emergency medical care, tell them you are on buprenorphine.

- I was given _____mg (dose) buprenorphine in clinic at _____ (time)

- **I was prescribed:** buprenorphine (Subutex®) ☐buprenorphine/naloxone (Subutex®) ☐

- My buprenorphine strength prescribed is: ☐ 2mg ☐ 4mg ☐ 8mg
- (*Note: dosing below may require cutting/splitting the tab/film for the correct dose)
- **The form prescribed is:** Tablet ☐ Film ☐
- I was also prescribed:
  - ð Clonidine (for anxiety/heart racing) I can take every: ___ hours
  - ð Imodium (for diarrhea) I can take every: ___ hours
  - ð Ondansetron (Zofran®) for nausea/vomiting I can take every: ___ hours
  - ð Hydroxyzine for anxiety I can take every: ___ hours

Dosage Calendar

Day of the Week	Morning Dose to Take	Mid-Day Dose to Take	Late Day Dose to Take
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

Buprenorphine or Suboxone® (Buprenorphine/Naloxone)

Information for patients and families.

Medications for Opioid Use Disorder (MOUD)/Medication Assisted Treatment (MAT):

- Along with office-based treatment and/or in- or out- patient treatment, MOUD is a medication treatment for the disease of addiction, opioid use disorder (OUD).
- It is important to understand that the disease of addiction is a relapsing recurring disease like other chronic health conditions.
- The disease of addiction is not a “choice”, rather it is the result of genetic, environmental, psychological, and social factors.
- MOUD does not “replace one drug for another,” rather it is an active and recommended treatment, much like insulin is for a diabetic.
- Long-term use of opioids (oxycodone, heroin, methadone, fentanyl etc.) alters the brain, in essence preventing the brain from functioning normally without an opioid present.
- The brain does heal over time; however, it is not known how long this may take.
- As a patient progresses through their recovery journey and the brain heals, MOUD may be tapered to lower doses and, on some occasions, stopped.
- Completely discontinuing MOUD is typically not the goal, maintaining recovery is.
- MOUD can be a life-long medication.
- It has been shown that the risk of relapse is ~86% if MOUD is discontinued within the first 5 years of starting.
- Without MOUD, cravings and using dreams may occur and can trigger a relapse.
- Counseling or treatment may help the patient learn new coping skills.

- Positive support systems and a healthy recovery community are also important to long-term recovery.
- MOUD is part of a comprehensive treatment program that includes a physician or healthcare provider and may also include social workers, treatment facilities, support meetings (AA/NA etc.) and more.

Buprenorphine:

- Buprenorphine is a type of opioid but it does not activate the brain in the same manner as other opioids. If additional opioids are taken while the patient is taking buprenorphine, it will not allow those to activate the brain. (It will prevent the euphoria or the "high").
- Buprenorphine can also help prevent over-dose if opioids (oxycodone, heroin, methadone, fentanyl etc.) are taken while the patient is taking their buprenorphine as prescribed.

Low Dose Induction (The Process of Starting on Buprenorphine):

- If a patient has a low-dose induction there can be some differences.
- A low-dose induction is typically done when there are concerns about longer-acting opioids in a patient's system (such as fentanyl and methadone).
- If a low-dose induction is not done in these situations, precipitated withdrawal may occur.
- Precipitated withdrawal is sudden and severe withdrawal symptoms.
- To prevent precipitated withdrawal, the low-dose induction starts buprenorphine at lower doses and the dose is increased slowly over typically a week
- During this time, a patient may still have mild withdrawal symptoms so other medications can be started to help with these symptoms.
- It is important to let the provider and clinic know any symptoms or concerns that arise as each patient may have a different experience.

Naloxone (Narcan)

- Naloxone is a medication that reverses the effects of opioids and saves lives.
- It can be given by a shot or as a nasal spray and typically acts quickly.
- With very strong opioids like fentanyl, it may take a bit longer to start working or one may need multiple doses to reverse an over-dose.
- When a patient gets naloxone, it is very important for the patient to be seen by a medical provider, typically the Emergency Department, right away.
- It is especially important for family, friends, contacts of people with OUD to carry naloxone with them.

- A patient who gets naloxone should be assisted in finding an MOUD provider for treatment as they are at very high risk of overdose in the future.

Harm Reduction:

- Harm reduction utilizes ways to help patients with the disease of addiction minimize health complications related to their use disorder.
- Primary harm reduction strategies include:
  - Providing clean needles and supplies for patients who inject drugs. This is important to lessen infection risk and spread of infection for HIV, Hepatitis C, skin infections etc. as fewer needles and supplies are shared or re-used.
  - Providing naloxone kits (see above).
  - Providing fentanyl test strips. This is important so patients are able to know if fentanyl is present in their drug, so they are able to adjust their dose accordingly.

Clinical Opioid Withdrawal Scale (COWS)

For each item, write in the number that best describes the patient's signs and/or symptoms in relation to their opioid withdrawal. Consider paying particular attention to the objective findings (Denoted with *) Pupil size tends to be the 'most telling.'

Patient's Name:_____

Date:_____

Enter the first score when patient first presents then every 30-60min depending on symptom progression. After the first dose is given, continue to monitor score after 30min, 1 hr., 2 hrs., then as needed depending on how the patient is doing.

Clinical Opioid Withdrawal Scale (COWS)

Indicator	First Reading	Second Reading	Third Reading	Fourth Reading
Resting Pulse Rate*: (record beats per minute) *0 pulse rate 80 or below* *1 pulse rate 81-100* *2 pulse rate 101-120* *4 pulse rate greater than 120*				
Sweating*: 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face				
Restlessness: *Observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequently shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds				
Pupil Size*: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible				

Indicator	First Reading	Second Reading	Third Reading	Fourth Reading
Bone or Joint aches 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort				
Runny nose or tearing*: *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks				
GI upset over last ½ hour 0 No GI Symptoms 1 Stomach Cramps 2 Nausea or loose stool 3 Vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting				
Tremor observation of outstretched hands: 0 No tremor 1 Tremor can be felt, but not observed 2 Slight tremor observable 4 Gross tremor or muscle twitching				
Yawning*: *Observation during assessment*				

Indicator	First Reading	Second Reading	Third Reading	Fourth Reading
0 No yawning 1 Yawning once or twice during assessment 2 Yawning three or more times during assessment 4 Yawning several times				
Anxiety or irritability 0 None 1 Patient reports increasing irritability or anxiousness 2 Patient obviously irritable anxious 4 Patient so irritable or anxious that participation in the assessment is difficult				
Gooseflesh skin*: 0 Skin is smooth 3 Piloerection of skin can be felt or hairs standing up on arms 5 Prominent piloerection				
TOTAL COWS SCORE:				

5-12 mild; 13-24 moderate; 25-36 moderately severe; more than 36 severe withdrawal

Consent for Treatment with Buprenorphine

I understand that my provider is prescribing a buprenorphine medication to assist in managing my opioid use disorder. Buprenorphine medications are part of my overall recovery plan. Buprenorphine is an FDA approved medication for treatment of people with opioid use disorder. Buprenorphine comes in tablets or films that must be held under the tongue or between the gum and lip until dissolved completely as it will not be absorbed from the stomach if swallowed. Buprenorphine can be used for detoxification or for maintenance therapy; or as long as medically necessary. Buprenorphine is a partial opioid; however, it does not activate the opioid receptors like heroin, fentanyl, or other full opioid agonists. It can result in physical dependence and should not be suddenly discontinued. Some patients, if they suddenly discontinue buprenorphine, may have opioid withdrawal symptoms. To minimize the possibility of opioid withdrawal, buprenorphine should be discontinued gradually, usually over several weeks and with provider assistance.

Individuals should be in mild to moderate withdrawal when started (induced) on buprenorphine. If given too soon, it may cause precipitated withdrawal which could result in sudden and sometimes severe withdrawal symptoms. Ideally, the first dose should be under the guidance of a provider. Some patients may take several days to transition onto buprenorphine. During that time, patients may have very mild withdrawal symptoms which can be minimized by other medications prescribed by a provider. After stabilized on buprenorphine, other opioids will generally have much less effect. Attempts to override the buprenorphine by taking more opioids could result in an opioid overdose. Combining buprenorphine with alcohol, benzodiazepines, or other medications may also be hazardous and can result in respiratory depression or death.

Suboxone is a combination of buprenorphine with naloxone, a short-acting opioid blocker. If Suboxone is dissolved and injected (or smoked/snorted) it may result in severe opioid withdrawal.

Abstinence-based treatment is an option, however, data shows that medications for opioid use disorder (MOUD) show longer recovery and increased treatment retention and less relapse and death.

Another MOUD maintenance therapy is methadone. Methadone is a full-agonist opioid which binds to the receptor like heroin, fentanyl etc., but has a very long-half life so patients do not get the same euphoria from it. Methadone for opioid use disorder can only be given in special clinics called OTPs (historically called “methadone clinics”). If you would prefer Methadone, you can be referred for those services.

Vivitrol, in the injectable long-acting formulation of naltrexone, is another MOUD. It completely blocks the effects of opioids but has no opioid effects of its own. Vivitrol injections need to be given every 4 weeks by a medical provider or clinic. You can receive this form of treatment in our facility if requested.

The risks, benefits and side effects of buprenorphine have been explained to me. I understand there are alternatives to buprenorphine; however, at this time, I am choosing to start buprenorphine as part of my treatment plan.

Patient Signature: _____ Date: _____

Provider Signature: _____ Date: _____

Witness Signature: _____ Date: _____

Sample letter to insurance company

(Date)

(Insurance company)

(address)

(City, state, zip)

RE: Patient name: (patient name)

Policy Number: (insert policy number)

Subject: Coverage of Suboxone® (buprenorphine-naloxone)

Dear (insurance company):

I am writing to provide additional information to support my claim for the treatment of (patient name) with Suboxone® (buprenorphine-naloxone) for (diagnosis). In brief, treatment of (patient name) with Suboxone® is medically appropriate and necessary and should be a covered and reimbursed service.

This letter outlines (patient name)'s medical history, diagnosis, and treatment rationale.

Summary of Patient's History

- (Patients primary/secondary diagnoses + ICD-10)
- (Brief medical history related to diagnosis)
- (Previous therapies the patient has received for their condition)
- (Patient's response to above therapies)
- (Brief description of the patient's recent presentation)
- (Summary of your professional opinion of the patient's likely prognosis without treatment with Suboxone®) *note likelihood of relapse, overdose, and death

Rationale for Treatment

Given the patient's history, condition, and the supporting clinical information, I believe treatment of (patient name) with Suboxone® (buprenorphine-naloxone) is warranted, appropriate and medically necessary. Suboxone® (buprenorphine-naloxone) is FDA approved for treatment of moderate to severe opioid use disorder. Buprenorphine acts as a partial mixed opioid agonist at the u-receptor and as an antagonist at the k-receptor. It has a higher affinity for the u-receptor than other opioids. This medication is dosed daily, has a long half-life, and prevents withdrawal in opioid dependent patients. Given the importance of opioid substitution therapy to treatment success, and the need to reduce the risk of opioid overdose, enrollment in an approved treatment facility is not a requirement for initiating treatment with buprenorphine to reduce chance of relapse, overdose and death.

It is shown that patients should be maintained on the dose necessary to achieve a reduction of their symptoms and abstinence or a reduction in their use of opioids. It is recognized that some patients may require doses above 16 mg to achieve this state. There is no lifetime limit on the duration of buprenorphine treatment.

In summary Suboxone® (buprenorphine-naloxone) is medically necessary and reasonable for (patient name)'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

(provider's name)

(phone)

Sample letter to insurance company

(Date)

(Insurance company)

(address)

(City, state, zip)

RE: Patient name: (patient name)

Policy Number: (insert policy number)

Subject: Coverage of Subutex (buprenorphine)

Dear (insurance company):

I am writing to provide additional information to support my claim for the treatment of (patient name) with Subutex® (buprenorphine) for (diagnosis). In brief, treatment of (patient name) with Subutex® (buprenorphine) is medically appropriate and necessary and should be a covered and reimbursed service.

This letter outlines (patient name)'s medical history, diagnosis, and treatment rationale.

Summary of Patient's History

- (Patients primary/secondary diagnoses + ICD-10)
- (Brief medical history related to diagnosis)
- (Previous therapies the patient has received for their condition)
- (Patient's response to above therapies)
- (Brief description of the patient's recent presentation)
- (Summary of your professional opinion of the patient's likely prognosis without treatment with buprenorphine) *note likelihood of relapse, overdose, and death

Rationale for Treatment

Given the patient's history, condition, and the supporting clinical information, I believe treatment of (patient name) with Subutex® (buprenorphine) is warranted, appropriate and medically necessary. Subutex® (buprenorphine) is FDA approved for treatment of moderate to severe opioid use disorder and deemed necessary in the setting of pregnancy or intolerance to Suboxone (buprenorphine-naloxone). The use of this medication therapy helps reestablish normal brain functioning, reduce cravings and prevent relapse. Multiple studies demonstrate that opioid agonists are the most effective treatment of opioid use disorders and can manage the symptoms of substance use withdrawal that often prompt relapse. Buprenorphine acts as a partial mixed opioid agonist at the u-receptor and as an antagonist at the k-receptor. It has a higher affinity for the u-receptor than other opioids. This medication is dosed daily, has a long half-life, and prevents withdrawal in opioid dependent patients. Given the importance of opioid

substitution therapy to treatment success, and the need to reduce the risk of opioid overdose, enrollment in an approved treatment facility is not a requirement for initiating treatment with buprenorphine to reduce chance of relapse, overdose, and death.

It is shown that patients should be maintained on the dose necessary to achieve a reduction of their symptoms and abstinence or a reduction in their use of opioids. It is recognized that some patients may require doses above 16 mg to achieve this state. There is no lifetime limit on the duration of buprenorphine treatment.

In summary Subutex® (buprenorphine) is medically necessary and reasonable for (patient name)'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

(provider's name)

(phone)

Sublocade® (Injectable, Long-Acting Buprenorphine) Informed Consent

I, _____, have received adequate information regarding the medication Sublocade®, including the purpose, consequences, and treatment alternatives. I freely and voluntarily consent to this intervention.

I have received medication for opioid use disorder (MOUD) with an oral transmucosal (used under the tongue or inside the cheek) buprenorphine containing medication for at least 7 days and am taking a dose that controls my withdrawal symptoms.

I will receive Sublocade® by my healthcare provider, or clinical care team, as an injection just under the skin (subcutaneous) of my stomach (abdomen). I will receive Sublocade® monthly (with at least 26 days between doses).

I understand that Sublocade® is one part of my treatment program and my care team may recommend counseling, treatment or other modalities to aid in my recovery journey.

I understand the most common side effects of Sublocade® induce constipation, headache, nausea, vomiting, headache, increase in liver enzymes, tiredness and injection site pain or itching.

I understand that if I receive Sublocade®, or another opioid product, while pregnant, my baby may have symptoms of opioid withdrawal at birth. I will inform my healthcare provider if I am pregnant or plan to become pregnant.

I, or my support system, in the event of an emergency, will inform the emergency department or other care teams that I am on Sublocade®.

I understand the risks of taking other opioids, benzodiazepines, alcohol, and potentially other prescribed or illicit medications while on Sublocade® may cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

I will talk to my healthcare provider about naloxone. Naloxone is a medication that is available for the emergency treatment of an opioid overdose. If naloxone is given, one must receive emergency medical help right away.

The above points were explained to me and if I had any questions they were answered to my satisfaction.

Patient Signature:_____ Date: _____

Provider Signature:_____ Date: _____

Witness Signature:_____ Date: _____

Sample letter to insurance company

(Date)

(Insurance company)

(address)

(City, state, zip)

RE: Patient name: (patient name)

Policy Number: (insert policy number)

Subject: Coverage of Sublocade®

Dear (insurance company):

I am writing to provide additional information to support my claim for the treatment of (patient name) with Sublocade® for (diagnosis). In brief, treatment of (patient name) with Sublocade® is medically appropriate and necessary and should be a covered and reimbursed service.

This letter outlines (patient name)'s medical history, diagnosis, and treatment rationale.

Summary of Patient's History

- (Patients primary/secondary diagnoses + ICD-10)
- (Brief medical history related to diagnosis)
- (Previous therapies the patient has received for their condition)
- (Patients response to above therapies)
- (Brief description of the patient's recent presentation)
- (Summary, of your professional opinion, the patient's likely prognosis without treatment with Sublocade®) *Note likelihood of relapse, overdose, and death

Rationale for Treatment

Given the patient's history, condition, and the supporting clinical information, I believe treatment of (patient name) with Sublocade® injections is warranted, appropriate and medically necessary. Sublocade® (buprenorphine extended release) is indicated for treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine containing product, followed by dose adjustment for a minimum of 7 days. By targeting u – opioid receptors, buprenorphine plays a role in disrupting the cycle of addiction. Sublocade® was designed to continuously deliver buprenorphine plasma levels greater than or equal to 2 ng/mL and sustain an initial buprenorphine plasma concentration at this level for up to 200 days after first injection; with continued long-term treatment with Sublocade® injection, buprenorphine plasma concentrations of greater than or equal to 2 ng/mL are sustained for up to 400 days. Dosing recommendations of Sublocade® include 300 mg injection on day one, 300 mg injection on day 28, then maintenance dose of 100 mg starting on day 56. The monthly

maintenance dose may be increased to 300 mg if the 100 mg dose is tolerated but does not demonstrate a satisfactory clinical response.

Because opioid use disorder is a chronic disorder that physiologically changes the brain, there is no maximum recommended duration of maintenance for treatment. For some patients, treatment may continue indefinitely.

In summary, Sublocade® is medically necessary and reasonable for (patient name)'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

(provider's name) (phone)

Vivitrol® (Injectable Naltrexone) Informed Consent

I, _____, have received adequate information regarding the medication Vivitrol®, inducing the purpose, consequences, and treatment alternatives. I freely and voluntarily consent to this medication.

I have abstained from opioids for at least the past 7 days or I am currently the oral form of naltrexone.

I understand the blocking nature of naltrexone on the opioid receptor.

I understand that if I sustain an injury that may require treatment with an opioid, it may be more difficult to treat my pain due to the blocking nature of naltrexone.

I understand that if I attempt to override the opioid receptor blockade with opioids, there is a risk of overdose and death.

I understand that naltrexone occasionally may be associated with abnormal liver function, and I may need to undergo periodic blood tests to monitor my liver.

I understand that the risks of being on naltrexone during pregnancy are unknown and not recommended. If I should become pregnant while on naltrexone, I will immediately notify my naltrexone provider.

I understand that naltrexone is one part of a treatment program, and my care team may recommend counseling, treatment or other modalities to aid in my recovery journey.

I understand the common side effects may include: nausea, vomiting, headache, fatigue, dizziness, injection site pain, and injection site skin reaction.

The above points were explained to me and if I had any questions they were answered to my satisfaction.

Patient Signature:_____ Date: _____

Provider Signature:_____ Date: _____

Witness Signature:_____ Date: _____

Sample letter to insurance company

(Date)

(Insurance company)

(address)

(City, state, zip)

RE: Patient name: (patient name)

Policy Number: (insert policy number)

Subject: Coverage of Naltrexone (PO)

Dear (insurance company):

I am writing to provide additional information to support my claim for the treatment of (patient name) with naltrexone for (diagnosis). In brief, treatment of (patient name) with naltrexone is medically appropriate and necessary and should be a covered and reimbursed service.

This letter outlines (patient name)'s medical history, diagnosis, and treatment rationale.

Summary of Patient's History

- (Patients primary/secondary diagnoses + ICD-10)

- (Brief medical history related to diagnosis)

- (Previous therapies the patient has received for their condition)

- (Patient's response to above therapies)

- (Brief description of the patient's recent presentation)

- (Summary of your professional opinion of the patient's likely prognosis without treatment with naltrexone) *note likelihood of relapse, overdose, and death

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Rationale for Treatment

Given the patient's history, condition, and the supporting clinical information, I believe treatment of (patient name) with Naltrexone is warranted, appropriate and medically

necessary. Naltrexone is indicated for treatment of both alcohol use disorders and opioid use disorders. Naltrexone blocks the euphoric and sedative effects of opioids and alcohol. Naltrexone binds and blocks opioid receptors and helps reduce cravings, and if a relapse were to occur during treatment, Naltrexone will prevent euphoria. Opioid use disorder and alcohol use disorder are chronic relapsing brain diseases that affect both the brain's cortex and limbic system. Addiction can be devastating both psychologically and physically. While counseling can help patients work through the psychological aspects of dependence, medication, including Naltrexone, may help address the physical changes in the brain.

In summary, Naltrexone is medically necessary and reasonable for (patient's name)'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

(provider's name)

(phone)

Sample letter to insurance company

(Date)

(Insurance company)

(address)

(City, state, zip)

RE: Patient name: (patient name)

Policy Number: (insert policy number)

Subject: Coverage of Vivitrol® (Injectable naltrexone)

Dear (insurance company):

I am writing to provide additional information to support my claim for the treatment of (patient name) with Vivitrol® for (diagnosis). In brief, treatment of (patient name) with Vivitrol® is medically appropriate and necessary and should be a covered and reimbursed service.

This letter outlines (patient name)'s medical history, diagnosis, and treatment rationale.

Summary of Patient's History

- (Patients primary/secondary diagnoses + ICD-10)
- (Brief medical history related to diagnosis)
- (Previous therapies the patient has received for their condition)
- (Patient's response to above therapies)
- (Brief description of the patient's recent presentation)
- (Summary of your professional opinion of the patient's likely prognosis without treatment with Vivitrol®) *note likelihood of relapse, overdose and death

Rationale for Treatment

Given the patient's history, condition, and the supporting clinical information, I believe treatment of (patient name) with Vivitrol® is warranted, appropriate and medically necessary. Vivitrol® is indicated for treatment of alcohol dependence and to prevent relapse to opioid dependence, after opioid detoxification. Opioid use disorder and alcohol use disorder are chronic relapsing brain diseases that affect both the brain's cortex and limbic system. Addiction can be devastating both psychologically and physically. While counseling can help patients work through the psychological aspects of dependence, medication, including Vivitrol®, may help address the physical changes in the brain. Pre-treatment with oral naltrexone is not required before using Vivitrol®.

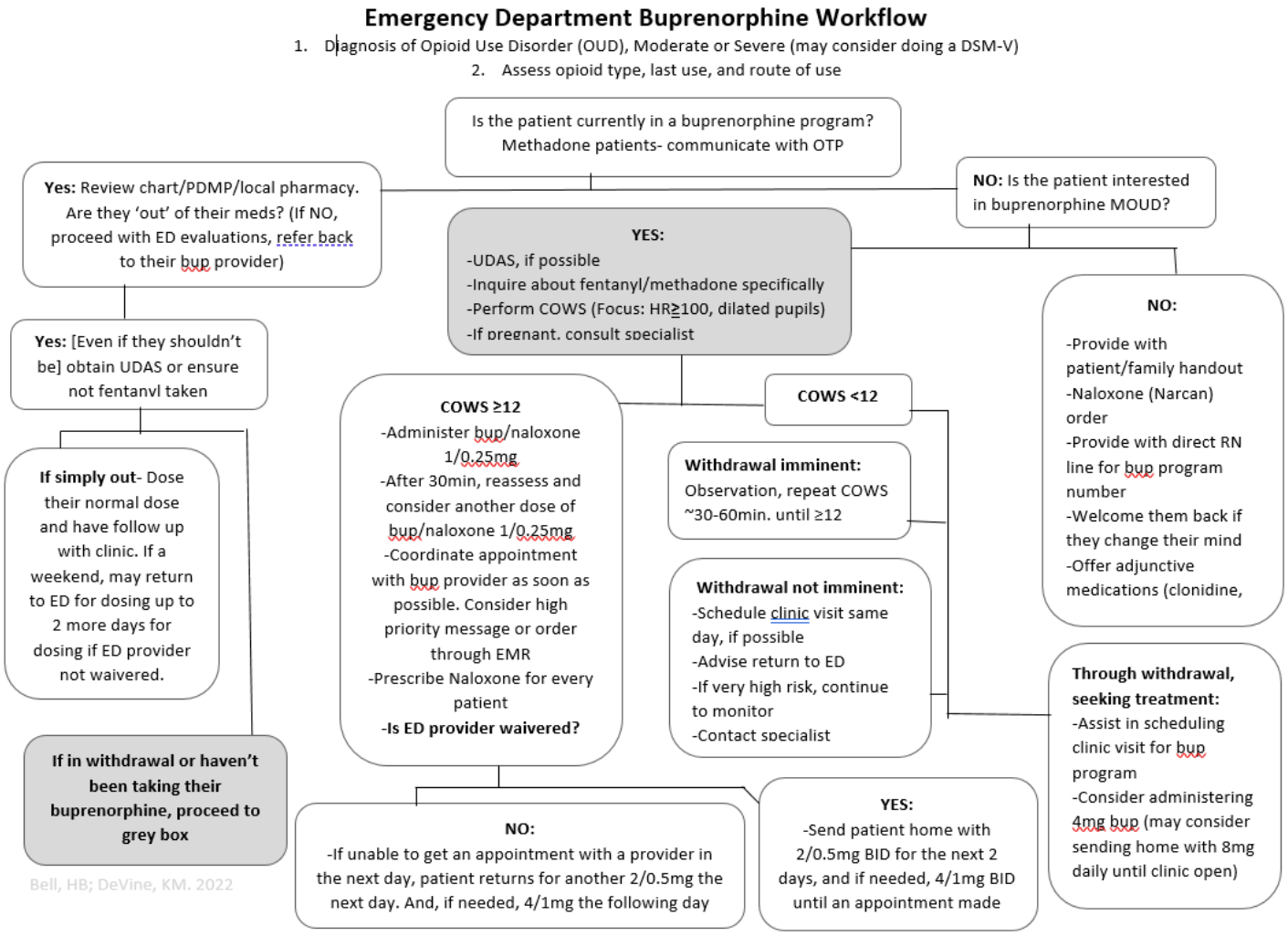
In summary, Vivitrol® is medically necessary and reasonable for (patient's name)'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

(provider's name)

(phone)

Emergency Department Buprenorphine Workflow



Emergency Department Tip Sheet:

Medications

Dosage

- 2mg buprenorphine (Subutex®) = 2/0.5mg buprenorphine/naloxone (Suboxone®)
- 4mg buprenorphine (Subutex®) = 4/1mg buprenorphine/naloxone (Suboxone®)
- 8mg buprenorphine (Subutex®) = 8/2mg buprenorphine/naloxone (Suboxone®)

Tips

- Always send in a prescription for naloxone (Narcan®).
- If a patient is pregnant, consult with a specialist.
- ED providers who are NOT waivered can prescribe from the ED buprenorphine for up to 3 days. The patient needs to return each day for dosing.
- Urine drug screen (UDAS)- if patient refuses or cannot leave a urine, emphasize the importance of divulging at least fentanyl use in the last couple of days. (Fentanyl does not show up on [most] UDAS point of care tests.)
    - Send all patients home with Buprenorphine Patient and Family Handout, regardless of starting a buprenorphine product.
    - Avoid the use of benzodiazepines. Note: alprazolam (Xanax®) and clonazepam (Klonopin®) do not show up on UDAS point of care tests.
    - Some, as on the flow sheet, do LOW-DOSE INDUCTIONS:
        - Starting doses of buprenorphine are very low: 1-2mg buprenorphine and doses are increased very slowly
        - Patients may be slightly uncomfortable for a couple of days but not acutely ill
        - After about 4 days, a patient will get to a common daily dose of buprenorphine (16-24mg total daily dose of buprenorphine)
    - Some providers do MACRO INDUCTIONS:
    - Starting doses of buprenorphine are as high as 4-8mg buprenorphine and dosing is increased to max dosing (24mg buprenorphine) quickly
        - Precipitated withdrawal is more likely to happen:
        - Patient experiences acute withdrawal after initial dose
    - Need to continue to increase dosing of buprenorphine very quickly
    - Adjunctive Medications:
        - Zofran: 4mg TID PRN Nausea/Vomiting
        - Clonidine: 0.1mg BID PRN tachycardia or anxiety
        - Hydroxyzine: 50mg BID PRN anxiety
        - Loperamide (Imodium): 1tab/cap PO after each loose stool PRN diarrhea (Max 4/24hrs)

Management of the Surgical Buprenorphine Patient

Buprenorphine is a unique partial opioid agonist that has the higher affinity for the mu receptor than any other clinically used opioids. For this reason, it can block other opioids from being affective. If buprenorphine is started inappropriately, a patient may experience withdrawal from the displacement of full agonist opioids. It requires pre-surgical planning and coordination of teams to avoid major complications including precipitated withdrawal or relapse to active opioid use disorder (OUD [if discontinued preoperative]), and unnecessary pain for the patient. Buprenorphine, when used as a treatment for OUD is in Subutex, containing only buprenorphine as well as Suboxone, which is a combination of Buprenorphine with Naloxone.

Pre-op:

Communication prior to the date of the surgery between the surgeon and buprenorphine provider is advised. This ensures that the patient is not given different instructions concerning their buprenorphine.

- Most patients should continue their buprenorphine, as prescribed, unless instructed otherwise by buprenorphine provider.
- Surgical staff acknowledge that patient is taking Buprenorphine and make other members of the surgical team aware.
- Butrans®, Zubsolv®, Bunavail®, Belbuca®, Temgesic®, Probuphine®, and Bupinex® are other Buprenorphine containing medications. These medications can be given for pain and the same consideration should be given.

Intra op:

- Avoid the use of Benzodiazepines. If they are needed, more attention to respiratory status is imperative.
- Use IV Ketamine, lidocaine, or other forms of local anesthetic, if not contraindicated.
- Use, or place, continuous regional anesthesia techniques if possible: epidural, tap blocks, peripheral nerve catheters, etc.

Post op:

- It is important to note that patients taking a buprenorphine product may require higher dosing of full agonist opioids to reach a therapeutic level, often twice the typical dose. Patients should be encouraged, and welcomed without stigma, to state they need more pain medications, especially if conservative doses were initially ordered.
- Benzodiazepines should be used with caution, especially if sent at discharge as there is an increased risk of respiratory depression with combined with buprenorphine. Patient should be aware of this risk and, if possible, be more closely monitored.
- Maintenance, or placement, of axial or peripheral nerve catheters or short-term nerve blocks or Exparel® should also be considered, if not already done.
- Consider the use of non-opioid analgesics, if appropriate: such as: Gabapentin, pregabalin, Tylenol/ofirmev®, NSAIDS.
- If full agonist opioids are needed while in-patient, consider IV/PCA Hydromorphone or Fentanyl.
- Avoid use of long-acting opioids.

Expert Consensus on the Pain Management for Patients on Buprenorphine

Pain Classifications	Examples	Treatment Recommendations (If Not Contraindicated)
Mild	Sprains, dental issues, small lacerations	Local anesthetic, Ibuprofen, acetaminophen
Moderate	Minor bone fractures, minor surgical procedures ex. Carpal Tunnel release	Local anesthetic, Ibuprofen, acetaminophen, or ketorolac
Severe	Large bone fractures, intra-abdominal (appendicitis, cholecystitis, cesarean section), trauma, large lacerations, joint replacements	Local anesthetic, Ibuprofen, acetaminophen, ketorolac. If full-opioid agonists needed: IV hydromorphone, fentanyl

General recommendations for buprenorphine:

- Continue buprenorphine, as prescribed, unless instructed otherwise by the buprenorphine provider.
- Consider the use of non-opioid analgesics such as: Gabapentin, Pregabalin, and NSAIDS.
- Patients taking a buprenorphine product may require higher dosing of full agonist opioids to reach a therapeutic level, often twice the typical dose.
- If full agonist opioids are needed while in-patient, consider IV/PCA Hydromorphone or Fentanyl.
- Avoid use of long-acting opioids.
- Use regional anesthesia techniques if possible.

Utilizing buprenorphine's analgesic properties options (note: this is not an exhaustive list of options, use discretion and medical, and shared, decision making):

Pre-op Dose	Option #1	Option #2	Option #3	Option #4
4mg daily	Maintain TDD: 4mg	2mg BID (TDD 4mg)	4mg BID (TDD 8mg)	2mg QID (TDD 8mg)
8mg BID*	Maintain TDD: 16mg	4mg QID (TDD 16mg)	8mg TID (TDD 24mg) for ~1 week	4mg 6 times daily (TDD 24mg) for ~1 week
8mg TID	Maintaining TDD: 24mg	4mg 6 times daily (TDD 24mg)	None	None

Additional information

- Doses above reflect the buprenorphine [component] dose:
  - Example:

    8mg = 8mg buprenorphine (Subutex®) = 8/2mg buprenorphine/naloxone (Suboxone®)

    *8mg BID is likely the most common dosing strategy that will be seen
- TDD: Total Daily Dose of buprenorphine (additive if utilizing split dosing)
- BID: Twice a day
- TID: Three times a day
- QID: Four times a day
- Doses above 24mg TDD rarely are more effective. A patient may benefit from addition of a full-agonist opioid when the TDD is 16mg or 24mg, if adequate pain management is not achieved.
  - If full agonist opioids are needed at discharge, consider oxycodone. Asking the patient, however, what their drug of choice was and avoiding that is recommended
  - Prescribe small quantities of pills (#10) and ensure patient has contact information
- Communication with the buprenorphine provider is important. A buprenorphine provider may volunteer to take over post-operative, post-discharge, pain management

Sample letter

To Whom It May Concern;
It is my understanding that my patient,_____ (patient name), _____ (DOB), have received adequate information regarding the medication Vivitrol®, inducing the purpose, consequences, and treatment alternatives. I freely and voluntarily consent to this medication.

Recommendations for *** surgical/procedure:

- Patient should continue their buprenorphine, as prescribed.
- Utilize local anesthesia intra-operatively, as appropriate.
- If procedure is done under a MAC, limit use of benzodiazepines as they will, in combination with buprenorphine, increase the risk of respiratory depression. If benzodiazepines are needed, close monitoring of respiratory status is recommended.
- Post-operatively, acetaminophen and/or ibuprofen is recommended, as appropriate.

If you have questions or concerns, please call ***

Thank you,

{Signature}

Sample letter to surgical team

To Whom It May Concern;
It is my understanding that my patient,_____ (patient name), _____ (DOB), have received adequate information regarding the medication Vivitrol®, inducing the purpose, consequences, and treatment alternatives. I freely and voluntarily consent to this medication.

Recommendations for *** surgical/procedure:

- Patient should continue their buprenorphine, as prescribed.
- Utilize local anesthesia intra-operatively, as appropriate.
- If procedure is done under a MAC, limit use of benzodiazepines as they will, in combination with buprenorphine, increase the risk of respiratory depression. If benzodiazepines are needed, close monitoring of respiratory status is recommended.
- Post-operatively, acetaminophen and/or ibuprofen is recommended, as appropriate.

If you have questions or concerns, please call ***

Thank you,

{Signature}

Sample letter to surgical team

To Whom It May Concern:

It is my understanding that my patient,_____ (patient name), _____ (DOB) will be having surgery on _____ . Buprenorphine should not impact their anesthesia plans. Below you will find my recommendations on managing their pain perioperatively and postoperatively.

Recommendations for *** surgical/procedure:

- Patient should continue their buprenorphine, as prescribed.
- Utilize local anesthesia intra-operatively, as appropriate.
- Limit use of benzodiazepines as they will, in combination with buprenorphine, increase the risk of respiratory depression. If benzodiazepines are needed, close monitoring of respiratory status is recommended.
- Should opioids need to be administered during or after the procedure, full opioid agonists, such as Fentanyl or Hydromorphone will be more effective. Note it may take up to 2x the standard or recommended dose to achieve therapeutic response.
- Post-operatively, acetaminophen and/or ibuprofen is recommended, as appropriate.
- Buprenorphine dose and frequency can often be utilized to achieve appropriate analgesia, further minimizing the need for prescribed opioids. Please feel free to contact me for dosing adjustments concerning their buprenorphine.
- If opioids need to be prescribed:
  - Avoid long-acting preparations
  - Limit quantity
  - Avoid the patient's drug of choice, as able (oxycodone vs hydrocodone etc.)

If you have questions or concerns, please call (___) _____ -_____

Thank you,

{Signature}

Sample letter to surgical team

To Whom It May Concern;

It is my understanding that my patient,_____ (patient name), _____ (DOB) will be having surgery on _____ . Buprenorphine should not impact their anesthesia plans. Below you will find my recommendations on managing their pain perioperatively and postoperatively.

Recommendations for _____ surgical/procedure:

- Patient should continue their buprenorphine, as prescribed.
- Utilize local anesthesia intra-operatively, as appropriate.
- Limit use of benzodiazepines as they will, in combination with buprenorphine, increase the risk of respiratory depression. If benzodiazepines are needed, close monitoring of respiratory status is recommended.
- Should opioids need to be administered during or after the procedure, full opioid agonists, such as Fentanyl or Hydromorphone will be more effective. **Note it may take up to 2x the standard or recommended dose to achieve therapeutic response.**
- Post-operatively, acetaminophen and/or ibuprofen is recommended, as appropriate.
- Buprenorphine dose and frequency can often be utilized to achieve appropriate analgesia, further minimizing the need for prescribed opioids. Please feel free to contact me for dosing adjustments concerning their buprenorphine.
- If opioids need to be prescribed:
  - Avoid long-acting preparations
  - Limit quantity
  - Avoid the patient's drug of choice, as able (oxycodone vs hydrocodone etc.)
  - At most, give one additional refill then transfer pain management to buprenorphine provider.

If you have questions or concerns, please call (____) _____ -_____

Thank you,

{Signature}

Sample letter to labor and delivery team

To _____(Obstetrical/Labor and Delivery Provider):

My buprenorphine patient _____ (DOB _____), is currently pregnant and, as she is on Medication for Opioid Use Disorder (MOUD), I wanted to reach out to minimize any fears or concerns concerning her medication. A safe and healthy delivery, birthing person, infant is always the goal. Below you will find my recommendations on managing intrapartum and postpartum analgesia (Endorsed by the current American College of Obstetrics and Gynecology (ACOG) guidelines).

Anticipated or induced vaginal delivery recommendations:

- Buprenorphine, buprenorphine-naloxone, should be maintained throughout the entire peripartum, intrapartum, and postpartum time period without any dose adjustments made, except as indicated below for cesarean section (c-section) post-op pain.
- Epidural and spinal analgesia should be offered as appropriate or as desired. Consider nitrous oxide, if offered at the facility.
- Opioid antagonists should not be given including: butorphanol, nalbuphine, and pentazocine.
- If labor analgesia is necessary, it is expected that higher doses of opioids will be needed (~2x's the 'typical' dose)
- Post-vaginal delivery the buprenorphine will offer some pain relief as well, but acetaminophen and NSAIDs should be offered per standard policy.

Post Cesarean recommendations:

- Even if scheduled, the buprenorphine product should not be adjusted, tapered, or held prior to the c-section.
- Utilize local anesthesia intra-operatively, as appropriate, such as TAP blocks.
- Ketorolac is highly effective for postpartum and post cesarean delivery pain control, and can be administered prior to leaving the operating room.
- Acetaminophen and NSAIDs should be offered per standard policy.
- Buprenorphine doses, and frequency, can be adjusted to take advantage of buprenorphine's analgesic properties.
- Increasing the patients total daily dose of buprenorphine (up to 24mg)
- Increasing the frequency to their total daily dose is divided to take every 4-6 hours.
- *If this is considered, please reach out and I can help with this.
- If additional opioid analgesics are needed, avoid long-acting opioids and be aware the patient may require 2X the standard dose to achieve analgesia. At discharge, prescribe, if needed, limited quantities (<#10).

Additional guidance:

- Always notify pediatric services of the imminent delivery.

- Breastfeeding is encouraged, except if otherwise contra-indicated.
- Rooming in and following the Eat, Sleep, Console protocol for monitoring for Neonatal Opioid Withdrawal Syndrome (NOWS)- managed by your pediatric providers.
- Discharge planning should include a close follow-up visit (2-3 days if possible) with the patient's buprenorphine provider.
- If a patient is on methadone:
  - Continue their methadone dosing
  - Immediate conversations to coordinate dosing during the stay should take place with the patient's OTP ('Methadone clinic')
  - Do NOT give the patient a buprenorphine product or any of the above opioid antagonists.
  - Many babies born to women on methadone maintenance will need more monitoring [than buprenorphine exposed infants] for NOWS.

If you have questions or concerns, please call (_____) _____ -_____

Thank you,

{Signature}

Neonatal Opioid Withdrawal Syndrome (NOWS)

What causes NOWS?

Opioid use while pregnant. This includes:

- Prescription opioids
- Illicit opioids (ex. heroin/fentanyl)
- Medications for opioid use disorder (MOUD):
  - Methadone
  - Buprenorphine

Symptoms of NOWS

- Irritability
- Jitteriness
- Frequent high-pitched crying
- Vigorous sucking
- Diarrhea
- Sweating
- Difficulty feeding
- Trouble sleeping
- Vomiting
- Frequent yawning and sneezing
- Seizures

Eat, Sleep, Console (ESC) Monitoring

- Can baby eat ≥1oz, or nurse well
- Can baby sleep undisturbed ≥1 hour
- Can baby be consoled
- If baby is able to do these things, continue to follow the Bundle of Care

Neonatal Opioid Withdrawal Syndrome (NOWS)

Bundle of Care

- Breastfeeding, if eligible
- Skin-to-skin contact
- Feeding on demand
- Swaddling
- Minimize noise and light stimulation

Top Ten Tips for Breastfeeding

1. Breastfeed within the first hours of baby's birth.
2. Breastfeed first: before bath, before meds and tests, and before visitors.
3. Limit other nipples except the breast.
4. Breastfeed every 1-3 hours or more, on demand. Frequent feeding will teach latching and increase milk production.
5. Watch for baby's feeding cues: smacking lips, hands in mouth. Feed before baby cries and becomes stressed. Rooming-in keeps baby near to feed when ready.
6. Tickle baby's upper lip with nipple until baby opens wide like a yawn, insert a nipple and a generous amount of the colored skin around the nipple.
7. Babies may take 1-3 days to latch on well. Encourage it as babies can be sleepy.
8. Do not worry about your milk supply.

   Colostrum is enough to fill your baby's sized tummy.
9. Skin to skin: place baby on your chest. No bra for mother and baby in diaper only.
10. Colostrum, your first breast milk, is the perfect food to feed baby his/her first few days of life. Mature milk comes-in days 2-4.

POLICY: CONTROLLED SUBSTANCE CARE MANAGEMENT

PURPOSE:

To identify, enroll, and facilitate care for patients receiving controlled substances for long term (greater than 3 refills of the same controlled substance in a calendar year) medication management.

POLICY:

This policy states the Controlled Substance Care Team will assess the whole person and their long-term controlled substance management therapy needs, which may include, but not limited to: opioids, stimulants, and/or benzodiazepines, needs upon enrollment and whenever there may be adjustments to the care plan.

DEFINITIONS:

Controlled Substance Care Plan (Care Plan): An agreement for long-term controlled substance medication management between a primary care provider (PCP), a patient, and theCSCT.

Controlled Substance Care Team (CSCT): Nurse Navigator, Pharmacist, Physician Champions, Mental Health Provider/Worker, and Social Worker, all as available.

CSCT review: A patient review inclusive of interview, Prescription Drug Monitoring Program (PDMP) analysis, and thorough chart review.

Onsite/Offsite: Onsite refers to health care providers at the Clinic and Hospital. Offsite refers to health care providers and adjunct stakeholders who are notemployed by the local health system.

Patient, adherent: A patient that abides by the terms of the care plan.

Patient, non-adherent: A patient that violates the terms of the care plan.

Prescription Drug Monitoring Program (PDMP): A tool used by prescribers, pharmacists and provider delegates that assists in managing patient care, detecting diversion, and the abuse/misuse of controlled substance prescriptions.

Controlled Substances: Federally controlled substances and/or substances with high potential for abuse which may lead to physical and/or psychological dependence.

Stakeholder, adjunct: non-health care provider(s) involved in patient outcomes such as family,law enforcement, and social workers.

Long Term Use/Chronic: Greater than or equal to 3 months of controlled substance use.

Procedure

1. An attempt should be made so that all patients receiving long term, chronic, controlled substances be referred by onsite or offsite health care providers and adjunct stakeholders to the CSCT. (According to State and CDC Guidelines, all patients on controlled substances should have a Care Plan or “Drug Contract”.
2. Patients referred to CSCT undergo a CSCT review.
3. A Care Plan is initiated with controlled substance management.
4. CSCT will collaborate with prescribing provider regarding appropriateness of the prescribed controlled substance(s) in the patient’s care plan.
5. Adherent patients are managed to their appropriate therapeutic management outcomes.
6. Non-adherent patients are managed towards their best outcome within the paradigm of tapering their controlled substance(s), transition to alternative treatment modalities, and/or referral to higher level(s) of care.
7. Care Plans should be renewed annually.

REFERENCES

Substance Abuse and Mental Health Services Administration (https://www.samhsa.gov/)

POLICY: CONTROLLED SUBSTANCE REFILL PLAN OF CARE

Purpose:

The purpose of this plan of care is to prevent misunderstanding or misuse of controlled medications.

Policy:

This policy defines a consistent process for the refill of controlled substancemedications prescribed by FMC clinic providers.

Procedure

- Prior to processing a refill of a controlled substance, the nurse will verify that aControlled Substance Care Plan is active and filed in the electronic medical record. If no Care Plan is on file,
- The Controlled Substance Care team will be notified via the electronicmedical record. And attempt(s) will be made until patient is able to sign the Care Plan:
  - During a regularly scheduled office visit
  - Called in for an office visit with provider
  - Called in to visit with CSCT RN
    - Copy of the signed Care Plan will be given to the patient.
    - Original copy of the Care Plan will be scanned/saved into the electronicmedical record.
    - A Medication Contract/Care Plan FYI flag will be place on the patient's electronic medical record by HIM upon scanning of the Care Plan.
    - Please see the Controlled Substance Program Care Plan Policy for controlled substance procedure.
- When initiating the refill, the prescription will be written with a Start Date. Thestart date should be written as start date 30 days post the last month refill.
- Prior to sending the Rx to the prescriber for signature, the refill request will bepopulated with the following information, to assist the prescriber:
  - Last UDAS date
  - Last Office Visit date
  - Last refill date
  - Whether there is a Care plan on file or not
  - Total Morphine Equivalents of the prescription

References

Substance Abuse and Mental Health Services Administration (https://www.samhsa.gov/)

POLICY: BUPRENORPHINE AND BUPRENORPHINE NALOXONE MEDICATION ASSISTED THERAPY/MEDICATION FOR OPIOID USE DISORDER INDUCTION

To ensure appropriate use of buprenorphine for treatment of opioid use disorder, according to Federal and State regulations; and to provide Registered Nurses with the protocol to assess opioid withdrawal and coordinate the health care delivery of opioid withdrawal.

DEFINITIONS:

Buprenorphine: Buprenorphine exerts its analgesic effect via high affinity binding to mu opioid receptors in the CNS and displays partial mu agonist and weak kappa antagonist activity.

Clinical Opioid Withdrawal Scale (COWS): Measures withdrawal symptoms with observations of the following: resting pulse rate, restlessness, pupil size, bone or joint aches, runny nose or tearing, gastrointestinal (GI) upset, tremors, yawning, anxiety or irritability and gooseflesh skin.

Induction: During induction, buprenorphine is started. The goal of induction is to start buprenorphine treatment when the client is in an appropriate state of withdrawal and to find the client's ideal dose of buprenorphine to achieve an effective level which decreases opioid cravings.

Maintenance: Because of a high relapse rate if buprenorphine is discontinued, many patients need to be maintained on buprenorphine for extended periods of time, potentially indefinitely. The goal of maintenance is to continue daily dose of buprenorphine to prevent relapse.

Stabilization: The stabilization period begins after induction and continues until the client is no longer experiencing withdrawal symptoms or intense cravings. This may last days and is different for each patient. Side effects should be minimal or none. Dose adjustment may be necessary.

Subutex®: Buprenorphine exerts its analgesic effect via high affinity to mu opioid receptors in the CNS and displays partial mu agonist and weak kappa antagonist activity.

Suboxone®: Buprenorphine and Naloxone (4:1). Buprenorphine exerts its analgesic effect via high affinity to mu opioid receptors in the CNS and displays partial mu agonist and weak kappa antagonist activity. Naloxone is a pure opioid antagonist that displaces and blocks opioids at receptor sites. Injecting Suboxone® when using opioids will cause withdrawal signs and symptoms nearly immediately. Suboxone®, due to the naloxone component, has a lower diversion rate than Subutex®.

PRESCRIBING PRACTICES AND SAFETY CONCERNS

Providers and Register Nurses:

- It is best practice to consult the Minnesota Prescription Drug Monitoring Program (PDMP) prior to initiating Medications for Opioid Use Disorder (MOUD), to assess for potential interactions and other current scheduled prescriptions.

  - Methadone, when given at an Opioid Treatment Program (OTP) for opioid use disorder (OUD) will not be listed on the PDMP.
  - Staff may not be able to see Suboxone® or other medications if given at a site that 'dispenses' medication. If Suboxone® or Subutex® is administered at an OTP, it also will not be on the PDMP.
- It is very important to obtain a complete medication history (including current and past prescriptions), medical history, and social history (including substance use history) from the patient.
  - Alcohol, with buprenorphine, may increase the risk of respiratory depression and should be monitored and counseled about.
  - Benzodiazepine use will be reviewed as a relative contraindication due to the risk of respiratory depression when co-prescribed.
- A point-of-care urine drug screen is preferred, with each client visit, for continued buprenorphine therapy to ensure that any illicit drug use is discussed.
  - If there is an unexpected urine, a confirmatory test may be recommended.
  - Confirmatory testing should be particularly done if it will change management.
  - A higher-level of care may be recommended if additional substances are resulted and the primary MOUD provider is uncomfortable with management. This may include a specialist or various treatment options.
  - Decisions of care should not be made solely on the results of the point-of-care urine drug screen.
- Patient should sign the Care Plan on the first visit.
- Patient should sign the buprenorphine consent agreement upon initiation of therapy, acknowledging they were at least made aware that other forms of MOUD are available, Methadone, Vivitrol® (injectable Naltrexone).
- Formulations of buprenorphine include:
  - Suboxone®: Buprenorphine and naloxone, in sublingual tablet or film (generic also available)
  - Subutex®: Buprenorphine, in sublingual tablet or film (generic also available)
  - Zubsolv®: Buprenorphine and naloxone sublingual tablets
  - Bunavail®: Buprenorphine and naloxone buccal film
  - Sublocade®: Extended-release buprenorphine subcutaneous injection (monthly)
  - Probuphine®: Buprenorphine implant- no longer available
  - Cassipa®: Buprenorphine and naloxone film
- Certain formulations of buprenorphine are not FDA approved for MOUD but only for pain management.

- Prescribers who treat pain with buprenorphine do not need to have their DATA 200 Waiver.
- Formulations for MOUD can be used to also treat pain as long as the primary diagnosis is OUD.

- Always document when medications are used off label.
  - Educate patients that after discontinuing any opioid, tolerance will decrease. This will result in an increased risk of overdose if re-introduced to an opioid. Buprenorphine products protect patients against overdose.
  - Educate patients that if buprenorphine daily products are abruptly discontinued, they will experience withdrawal. They should only discontinue their buprenorphine product under the guidance and advisement of a provider.
  - Provide patient with printed material detailing the prescription of buprenorphine information.
  - When a patient is discharging from care, it is important to assist them in finding an MOUD provider closer to their new location:
    - A warm handoff is preferred, when possible
      - Must obtain a Release of Information (ROI)
      - If labs or notes are requested, defer to the Health Information Management (HIM) department
    - The SAMHSA website has provider directories if needed. Consulting with a local addiction provider may also provide with preferred prescribers.

POLICY: NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS)

To establish guidelines of care for newborns with positive (non-negative) drug screen or born to a mother with a positive (non-negative) urine drug screen.

Policy:

Facility will monitor for infant withdrawal symptoms using Eat, Sleep, Console. The Registered Nurse (RN) will score the newborn at the bedside with parent or guardian present, incorporating their observations into the score. At least one parent or guardian will stay in room with newborn during the duration of the hospital stay, even after the birthing person's discharge from the hospital. The hospital will provide meals and a room for guardian providing care during stay. Infants requiring NOWS Scoring will remain inpatient and be scored/monitored for a minimum of:

- 3-4 days for short acting opioids (ex. Hydrocodone, hydromorphone, oxycodone, and heroin)
- 4-6 days for an opioid with longer half-life (ex. Methadone, buprenorphine)

DEFINITIONS

EATING:

Poor eating due to NOWS: Baby is unable to coordinate feeding withing 10 minutes of showing hunger AND/OR is unable to sustain feeding for 10 minutes at breast or with 10cc of finger- or bottle-feeding due to NOWS symptoms (e.g., Fussiness, tremors, uncoordinated or excessive suck).

Special Note: Do not indicate "yes" for poor eating if it is clearly due to non-NOWS related factors (e.g., prematurity, transitional sleepiness or spottiness in the first 24 hours of life, or inability to latch due to infant/maternal anatomical factors). If it is not clear if the poor eating is due to NOWS, indicated "yes" on the flowsheet and continue to monitor the infant closely while optimizing all non-pharm interventions.

SLEEPING:

Sleep <1 hour due to NOWS: Baby unable to sleep for more than a one hour stretch after feeding due to NOWS symptoms (e.g., fussiness, restlessness, increased startle, tremors).

Special Note: Do not indicate "yes" if sleep <1 hour is clearly due to non-NOWS related factors (e.g., physiologic cluster feeding, interruptions in sleep for routine newborn testing, symptoms in first day likely due to nicotine or SSRI withdrawal). If it is not clear if sleep <1 hour is due to NOWS, indicate "yes" on the flow sheet and continue to monitor the infant closely while optimizing all non-pharm interventions.

CONSOLING:

Unable to console within 10 min due to NOWS: Baby unable to be consoled within 10 minutes by infant caregiver effectively providing recommended Consoling Support Interventions.

Special Note: Do not indicate "yes" if infant's inconsolability is due to infant hunger, difficulty feeding or other non-NOWS source of discomfort (e.g., circumcision pain). If it is not clear if the inconsolability to console within 10 minutes is due to NOWS, indicate "yes" on the flow sheet and continue to monitor the infant closely while optimizing all non-pharm interventions.

Consoling Support Interventions (CSIs)

- Caregiver begins softly and slowly talking to infant and uses his/her voice to calm infant.
- Caregiver looks for hand-to-mouth movements and facilitates by gently bringing infant's hand to mouth.
- Caregiver continues talking to infant and places caregiver's hand firmly but gently on infant's abdomen.
- Caregiver continues softly talking to infant bringing baby's arms and legs to the center of body.
- Picks up infant, holds skin-to-skin or swaddled in a blanket, and gently rocks or sways infant.
- Offers a finger or pacifier for infant to suck, or a feeding if infant showing hunger cues.

SOOTHING SUPPORT USED TO CONSOLE INFANT

1. **Soothes with little support:** Consistently self-soothes or is easily soothes with one of first 4 CSIs above.
2. **Soothes with some support:** Soothes easily with skin-to-skin contact, being held clothes, or swaddled, rocking or swaying, sucking on finger or pacifier, or feeding.
3. **Soothes with much support or does not soothe in 10 minutes:** Has difficulty responding to all caregiver efforts to help infant stop crying OR does not soothe within 10 minutes, never self-soothes.

PARENTAL/CAREGIVER PRESENCE

- Time since last assessment that parent (or other caregiver) has spent in room with infant.

OPTIMAL FEEDING:

- **Baby feeding at early feeding cues until content** without any limit placed on duration or volume of feeding.
- **Breastfeeding:** Baby latching deeply with comfortable latch for mother, and sustained active suckling for baby with only brief pauses noted. Assist directly with breastfeeding to

achieve more optimal latch/position and request lactation consultation if any concerns present.

- **Bottle feeding:** Baby effectively coordinating suck and swallow without gagging or excessive spitting up; modify position of bottle or flow of nipple if any concerns present. Consult feeding specialist if feeding difficulties continue.

PROCEDURE: EAT, SLEEP, CONSOLE TOOL:

ENVIRONMENT

- Provide a quiet, dim room with low activity
- Rooming-in promotes family-centered care
  - Away from high traffic areas (phone, sink, etc.)
- Prepare everything before disturbing and "cluster" care
  - Limit visitors
  - Present one stimulus at a time (do not walk or sway while feeding, when dressing, bathing or changing diaper keep one hand on baby at all times to reduce stimuli)
    - Teach caregiver techniques to reduce stimuli
      - Avoid overheating
      - Encourage skin to skin

DIET

- Caloric needs may be as high as 150 to 250 Cals/kg/day.
- Frequent, small feeds
- Feed on demand

Breastfeeding is encouraged to:

- Promote bonding
- Optimal nutrition
- Passive immunity
- Decreases severity of NOWS
- Mothers on Methadone, or Subutex® (buprenorphine), and Suboxone® (buprenorphine/naloxone), regardless of dose

Contraindications for breastfeeding:

- HIV positive

- Hepatitis C positive with cracked and/or bleeding nipples
- Polydrug use
- Ongoing IVDU

Supplementation

- Frequent, small volumes of hyper caloric formula (22-24 Cal/oz) feeding may help minimize hunger and improve growth
- Soy formula may improve feeding intolerance

DURATION

Short half life

- 3-4 days of life
- Maintaining Eat, Sleep, Console requirements
- Close follow-up arranged
- Care-giver education completed
- *No other newborn indications requiring a longer length of stay

Long half life

- 4-6 days of life
- Maintaining Eat, Sleep, Console requirements
- Close follow-up arranged
- Care-giver education completed
- *No other newborn indications requiring a longer length of stay

REFERENCES

Bhatia, Jatinder, MD, FAAP. Pediatric Care Online. Neonatal Abstinence Syndrome. AAP.

Children's Hospital of Philadelphia. Inpatient Pathway for the Evaluation/Treatment of Infants with Neonatal Abstinence Syndrome.

Hudak, Mark L. & Tan, Rosemarie C. 2012, Volume 129/Issue 2. American Academy of Pediatrics.

Neonatal Abstinence Syndrome (NAS) Criteria

Criteria/Time	First Observation	Second Observation	Third Observation	Fourth observation
Eating				
Poor eating due to NAS				
Sleeping				
Sleep <1 hour due to NAS Yes/No				
Consoling				
Unable to console within 10 minutes of less due to NAS Yes/No				
Soothing support used to console infant Soothing with little support: 1 Soothes with some support: 2 Soothes with much support or does not sooth within 10 minutes" 3				
Parental/Caregiver presence				
Parental/Caregiver presence since last assessment: Not present: 0 1-59 minutes: 1 1 hr – 1 hr 59 min: 2 20hr – 2 hr 59 min: 3 3 hrs+: 4				
Management decisions				
Recommend a team huddle Yes/No				
Management decision Optimize non-pharm care: 1 Initiate medication treatment: 2 Other (please describe):				
Non-Pharm interventions				
Rooming-in Increased/reinforced				
Parental presence Increased/reinforced				
Skin-to-skin contact Increased/reinforced				
Holding by caregiver/cuddler Increased/reinforced				
Swaddling Increased/reinforced				
Optimal feeding Increased/reinforced				
Non-nutritive sucking Increased/reinforced				
Quiet environment Increased/reinforced				
Limit visitors Increased/reinforced				

Criteria/Time	First Observation	Second Observation	Third Observation	Fourth observation
Clustering care Increased/reinforced				

Minnesota Department of Health
Drug Overdose Prevention Unit
85 E 7th Place
PO Box 64882
St. Paul, MN 55164-0882
651-201-5000
health.drugodprev@state.mn.us
www.health.state.mn.us
4/28/2023