CLINICAL PRACTICE GUIDELINES FOR THE MANAGEMENT OF CHRONIC PAIN IN PATIENTS WITH SUBSTANCE USE DISORDERS

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Guideline Structure and Formulation

This guideline represents the work of a year-long task force commissioned by the Massachusetts Society of Addiction Medicine (MASAM) to provide clinical practice recommendations to clinicians practicing at the intersection of pain and substance use disorders. The task force sought to reconcile the relative lack of evidence-based guidance in such a way as to provide useful clinical recommendations to practicing clinicians. The guideline is structured to answer a series of 10 key clinical questions. The guideline authors and contributors are listed below; some authors chose to remain anonymous.

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Preface

Patients have chronic pain. Patients also use, or have used, substances. When the latter is the case, clinicians tend to shy away from the former for understandable reasons: there are few effective treatments for chronic pain, they are widely variable in effectiveness for a given patient, and by the time the patient is seeing us, they likely have tried many of them. Pain generally doesn't have an easy treatment, leading to ongoing uncertainty and even a sense of futility for clinicians.

Not addressing pain, however, does not make it go away for our patients and they—like anyone else—will work to find relief. The well-documented consequences of ongoing pain include harms

from ongoing non-prescribed use, including overdose, harm, and death from a lethal drug supply.

MASAM (MASAM, the Massachusetts chapter of the American Society of Addiction Medicine) is committed to supporting clinicians and patients facing this common difficulty. We do so because the current situation ill-serves patients and clinicians alike while conferring harm to patients that could—and should—be mitigated.

One approach to this circumstance would be to prescribe full agonist opioids for patients also taking opioid agonist treatment (OAT) with methadone or buprenorphine. By using a standardized, licit medication, this approach can both mitigate a patient's pain and consequently reduce the harms of their using non-prescribed opioids such as illicitly-manufactured fentanyl (IMF).

Prescribing full agonist opioids for a patient with opioid use disorder (OUD) is fraught and there is, despite the prevalence of chronic pain with substance use disorders, almost no related evidence from the medical literature. The situation is one of high risk for patients in their status quo, virtually no research to inform us, and risks of both commission and omission.

We are not aware of formal guidance from any specialty organization regarding chronic pain and OUD or other substance use disorders (SUDs). We do not anticipate such guidance occurring soon as the clinical situation eludes an evidence base that is generally relied upon to inform guidance. This evidence base would require substantial resources for interventions that are not under patent. Also, treatment of chronic pain is highly individualized—all the more so when combined with SUDs—and thus resists standard algorithmic guidelines based on studies of large populations. The situation is a double bind: high-stakes for patients and clinicians yet resistant to the usual means of useful recommendation.

Our guidance includes a thorough review of the known medical literature concerning the treatment of chronic pain for patients with substance use disorders, especially opioid use disorder. We take this existing evidence and apply a patient-centered framework that explicitly acknowledges the challenges of this care and the importance of thoughtfully acting, in the face of uncertainty, to improve patient-centered outcomes and avoid patient harms.

Introduction

Though opioids have been used for millenia for euphoric reasons, their most common use is for unrelenting pain. These two uses were conflated in the early days of the American opioid epidemic when medication for pain was promulgated in ways that made its use for euphoria much easier. More than a quarter century after the advent of OxyContin, the dominant narrative concerns the "getting high" part of opioids.

What is obscured in this narrative is the predominant interest people had—and have—in relieving their pain and related suffering.[40] For people who have developed an opioid use

disorder (OUD), due attention is paid to co-occurring mental health disorders. But the most common co-occurring condition in OUD is chronic pain (Table 1). Chronic pain is disproportionately prevalent among people who have OUD and other substance use disorders; in a majority of people, chronic pain is what leads to their use of non-prescribed opioids.[21] This chronic pain has predictable and severe adverse consequences (**Table 1**).

Once people develop an OUD, they describe how standard medical care ignores their chronic pain. The predictable consequence is that people do not seek medical care because their current use is helping their pain—though dangerous—or, once in care, they disenroll early for the predictable alleviation of pain from non-prescribed opioids.

Certain patients have found that their use of full agonists for pain, in addition to buprenorphine or methadone, substantially improves their quality of life and reduces their use of an unsafe non-prescribed supply. Initial reports that full agonists added to opioid agonist treatment (OAT) do not provide analgesia and can instead precipitate withdrawal—reports which led to perioperative patient harm—have since been disproven.[9,24,53] Patients are understandably are interested in receiving a safe form of these opioids from a clinician through a predictable, formal prescription—even though they may also be in treatment with OAT.

For their clinicians, the situation is fraught. They are surveilled by regulatory bodies, watched by their peers, and have understandable hesitancy about providing both OAT with a separate full agonist for pain. But they also recognize patients face the high stakes of unrelenting debilitating pain, ongoing use from a lethal supply, and increased risk of leaving formal life-saving OAT treatment. Clinicians face both errors of omission (not alleviating pain and attendant patient risks) or commission (prescribing a full agonist for pain and facing related insurance, professional, and license risks). In qualitative studies, clinicians recognize that patients with OUD “deserve the right to adequate pain management” while also describing how they are uncomfortable providing this care.[12] Patients are caught in this understandable clinical ambivalence.

Current guidelines provide few directions for the management of chronic pain in people with OUD, besides the use of OAT, which may not provide sufficient pain management to many patients with co-occurring chronic pain and OUD.[5]
Rather than continue to avoid the situation, MASAM has developed guidance based upon the natural history of OUD, the evidence base as it exists, and the acknowledgement that not acting is itself a form of harm. Our operating principle is as fundamental as the clinician-patient relationship itself. We recognize that this relationship is the expertise that is needed instead of the usual guidance for “specialist”care. The clinician in this longitudinal healing relationship becomes an expert in an individual patient and, combined with clinical skill, is able to evaluate the full set of potential benefits and risks unique to this patient. It is because these risks include near-term harm and suffering, up to and including death, that co-prescription of OAT with a full agonist for pain can be in the patient’s interest and failure to do so predictably increases their risk of profound harm.

The following recommendations are based on principles of medical ethics that include autonomy and beneficence as well as principles of harm reduction. The recommendations explicitly recognize errors of both commission (taking an action that is harmful) and omission (not taking an action that is helpful). And because the situation is both inherently uncertain and has high stakes, the recommendations emphasize the importance of thoughtful ongoing assessment by the primary clinician.

Table 1

Epidemiology of Chronic Pain and Substance Use Disorders

Among patients with OUD in a large healthcare system, 64% endorsed severe chronic pain. 61.8% of them had chronic pain before their OUD diagnosis.[26]
Nearly half (47%) of patients report their chronic pain is worse on opioid agonist treatment (OAT) and 47% report chronic pain being a primary reason for return to use.[20]
Among people with OUD who are untreated, over 90% report having chronic pain.[46]
In outpatient treatment programs for OAT, as many as 80% of patients endorse physical pain and 64% endorse severe chronic pain.[29]
Among adolescents (12–17 years) and young adults (18–25 years), over half endorsed pain relief as the reason for their prescription opioid misuse.[47]
Compared with those without chronic pain, patients seeking treatment for OUD who had chronic pain reported significantly more depression, anxiety, and trauma symptoms; more difficulty with mental health functioning; lower quality of life; more sleep disturbance; and worse physical function.[25]

Consequences of Untreated or Ineffectively Treated Chronic Pain

A majority of males (72.3%) and females (81.2%) reported that they engaged in nonmedical prescription opioid (NMPO) use to treat their physical pain.[21,43]
Untreated chronic pain is often self-treated with non-prescribed opioids, alcohol, and other substances.[13,15]
Endorsement of pain was associated with greater frequency of treatment dropout, and higher levels of pain intensity predicted increased rates of dropout.[22]
Denial of opioid pain medication for people who use drugs can lead to nonfatal overdose.[27,44]
People using illicitly-manufactured fentanyl (IMF) reported the relationship of pain to their street opioid use as follows: Self-medication (65.4%); Lost access to prescription opioids (10.8%); Prescription opioids not strong enough (19.2%); Unable to get prescribed opioids (10.0%); Unrelated (6.9%).[32]

Key Clinical Questions

1) *For patients with OUD on MOUD (buprenorphine or methadone) who require management of an episode of acute pain (e.g. secondary to surgery, trauma, etc), may full agonist opioids be used?*
    a) As in patients without a history of a substance use disorder, we recommend that initial treatment of any episode of acute pain include optimized non-opioid medicines and approaches. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    b) A history of OUD, active or in remission, with or without treatment with MOUD, is not a contraindication to treatment with full agonist opioids for acute pain. This includes both planned acute pain (e.g. scheduled surgery) as well as unplanned (e.g. acute trauma, unscheduled cesarean delivery). [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    c) If treatment with opioids is known to be more effective for a given cause of acute pain than non-opioid treatments, or if the standard of care for a given condition is treatment with opioids, then we recommend that patients with OUD also be offered opioids. We recommend clinicians liaise with appropriate colleagues to consider the usual duration of treatment with opioids, realizing some patients with OUD may require a longer duration of treatment potentially in a tapering fashion. Clinicians should appropriately titrate doses to goal efficacy; this is especially true of patients on buprenorphine for MOUD. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    d) We recommend that MOUD be continued during treatment with full agonist opioids rather than discontinued. Given the potential for clinically significant drug-drug interactions, we recommend that clinicians ensure non-opioid treatments will not decrease MOUD levels inadvertently. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    e) Some clinicians would consider altering buprenorphine dosing from QD or BID dosing to Q4-8H (TID- QID) dosing given some data to indicate this leads to better pain control. Similarly some clinicians would consider substantially increasing the dose buprenorphine to treat the acute episode of pain. Doses up to 32 mg/day (eg. 8 mg QID) have been shown to provide analgesic benefit. Similarly, some clinicians would consider split dosing of methadone (changing to BID from daily dosing) for the same reasons. We urge clinicians to weigh the risks and benefits of these approaches in the context of their own clinical experience and the patient's specific context and characteristics.
    f) Our group was unable to provide a recommendation regarding timing of administration of buprenorphine with relation to full agonists given the paucity of data and the large variation of patient experience. We urge clinicians to work with patients to determine the best approach to dosing while also recognizing that prescriptions recommending separation of doses and splitting of buprenorphine films and tablets may not be accepted by pharmacies.
    g) Patients with OUD and acute pain may choose to decline full agonist opioids out of fear of return to use or simply desire to avoid these medicines. This decision to

decline opioids should be respected, frequently readdressed, and not be taken as an indicator of concern. [GRADE: 1C (Strong recommendation, low-quality evidence)] Physicians may remind patients that they do not have to suffer in pain just because they have a history of a substance use disorder; rather, physicians may support them to use opioids safely to address pain if needed.

h) We recommend that hospitals have systems in place to confirm outpatient doses of MOUD medicines to ensure they may be safely continued as part of the treatment of acute pain. While awaiting confirmation, clinicians should use clinical judgment to provide appropriate interim dosing that addresses both withdrawal prevention and acute pain control while minimizing the risk of over- or underdosing. [GRADE: 1C (Strong recommendation, low-quality evidence)]

2) *What is the preferred management strategy for patients with OUD and moderate-severe chronic pain?*
    a) We recommend all patients with OUD and moderate to severe chronic pain be managed by clinicians following evidence-based interventions to treat chronic pain. This is ideally managed by a multidisciplinary team approach, however we acknowledge such teams are rare and many such patients will be managed by solo clinicians in a primary care setting. Many excellent reviews exist regarding said management; we suggest the excellent reviews by Matta et al (https://www.psychiatrist.com/pcc/multimodal-approaches-pain-management-analgesics-adjuvants-nonpharmacologic-interventions/# and https://www.psychiatrist.com/pcc/strategies-treatment-pain-context-alcohol-substance-use-disorders/#). To whatever extent possible, we recommend clinicians consider referrals that focus on physical / occupational therapy, interventional pain management, and optimization of comorbid mental health concerns. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    b) We recommend that clinicians managing patients with OUD and moderate to severe chronic pain document their impression of the relevant risks, harms, and benefits of treating or not treating pain in the medical record. We have provided example language below. [GRADE: 1C (Strong recommendation, low-quality evidence)]
    c) Given the complexity of managing patients with OUD and moderate-severe chronic pain, some clinicians may choose to review these cases with colleagues or regional consultation networks at regular intervals and document said consultation as part of their assessment. We recommend against making this a requirement, given the variety of clinical practice environments that exist, provided clinicians adequately document their rationale as detailed above.
3) *For patients with OUD on buprenorphine and moderate-severe chronic pain refractory to optimized non-opioid treatments, should full agonist opioids be considered? If so, how should the management be approached?*
    a) We believe it may be reasonable in selected patients to offer treatment with full agonist opioids to patients with OUD on buprenorphine and moderate-severe chronic pain refractory to optimized non-opioid treatments. [GRADE: 2C (Weak recommendation, low-quality evidence)]

b) Our group explicitly states a goal of avoiding causing patients to experience destabilization (or further destabilization) of their use disorder as this can lead to a return to unsafe use, overdose, and death in addition to other well-documented morbidity.
c) We recommend continuing buprenorphine rather than decreasing or discontinuing the dose during treatment with full agonists for the purposes of decreasing the possibility of accidental overdose and death, either from prescribed full agonists or from ongoing use of non-prescribed full agonists. In select circumstances decreasing the buprenorphine dose may lead to improved analgesic outcomes for patients (given the usual stated analgesic dose of buprenorphine is in the microgram range), however this must be balanced against the decreased potential for overdose prevention at total daily doses below 8mg. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
d) Some clinicians would recommend changing buprenorphine dosing frequency to TID-QID given some data supporting improved analgesia. Others would prefer to retain the usual QD or BID dosing scheme for simplicity for patients. Available evidence shows significant individual variation in both the quality of analgesia offered by buprenorphine and whether increased frequency is helpful or not; as such, we recommend clinicians consider patient preference around frequency of buprenorphine dosing.

4) *For patients with OUD on methadone and moderate-severe chronic pain refractory to optimized non-opioid treatments, should full agonist opioids be considered? If so, how should the management be approached?*
a) We believe it may be reasonable in selected patients to offer treatment with full agonist opioids to patients with OUD on methadone (currently dispensed by an opioid treatment program or OTP) and moderate-severe chronic pain refractory to optimized non-opioid treatments. [GRADE: 2C (Weak recommendation, low-quality evidence)]
b) Our group explicitly states a goal of avoiding causing patients to experience destabilization (or further destabilization) of their use disorder as this can lead to a return to unsafe use, overdose, and death in addition to other well-documented morbidity.
c) We recommend continuing methadone rather than decreasing or discontinuing the dose during treatment with full agonists for the purposes of decreasing the possibility of accidental overdose and death, either from prescribed full agonists or from ongoing use of non-prescribed full agonists. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
d) Some clinicians would strongly recommend split dosing of methadone given some data supporting improved analgesia. We recommend hospital-based clinicians consider this strategy for patients admitted for a pain-related reason.
e) We strongly suggest that clinicians managing chronic pain coordinate with the patient's OTP to consider split dosing when it may benefit the patient's ongoing analgesic needs. We also strongly recommend establishing clear, two-way

communication between the OTP and the clinicians managing full agonist opioids outside the OTP to support patient safety and optimize care.

5) *In patients with OUD on MOUD (buprenorphine or methadone) and moderate-severe chronic pain for whom full agonist opioids are being considered, which agents are preferred?*
    a) We recommend a trial of a potent short-acting oral full agonist (e.g. oxycodone or hydromorphone) at the lowest effective dose on an as needed basis as an initial trial. Patients on buprenorphine often need higher doses to overcome the mu receptor blockade and attain analgesia, though some are able to attain excellent analgesia at lower doses. We recommend starting doses of oxycodone 10-15mg or hydromorphone 2-4mg in most patients on MOUD at an otherwise appropriate frequency with a low threshold to personalize doses and frequencies based on patient response. [GRADE: 1C (Strong recommendation, low-quality evidence)]
    b) Treatment with other opioid agonists may be reasonable in select patients as indicated by their specific clinical situation and the expertise of their clinician, though many carry disadvantages compared to oxycodone or hydromorphone. For example, methadone seldom has a fast enough onset to be effective on an as needed basis, morphine may not be potent enough to overcome the mu blockade of buprenorphine, and tramadol may disrupt buprenorphine's blockade given similar binding affinity.
6) *In patients with a history of OUD in remission not on MOUD and moderate-severe chronic pain for whom opioids are being considered, which agents are preferred?*
    a) We suggest a trial of buprenorphine rather than other opioids given its improved safety profile and data suggesting its efficacy is at least equivalent to other opioids for management of chronic pain. [GRADE: 2B (Weak recommendation, moderate-quality evidence)]
    b) In general, we suggest initial buprenorphine doses in the microgram range (proprietary formulations: Butrans, Belbuca) for patients whose use of non-prescribed opioids is remote (i.e. months-years). For patients whose use of non-prescribed opioids is more proximate, we suggest initial buprenorphine doses in the milligram range (proprietary formulations: Suboxone, Zubsolv) given the additional benefit of accidental overdose prevention at those doses.
    c) A thorough understanding of buprenorphine dosing for pain management is lacking in the medical literature though ongoing trials are being conducted, in particular to determine the potential efficacy of buprenorphine doses over 32mg per day. Clinicians should consider the outcomes of these ongoing trials in deciding on optimal dosing for patients.
    d) In patients for whom buprenorphine is not a reasonable initial option (due to insurance coverage or availability), we suggest a trial of misuse deterrent extended-release oxycodone at the lowest effective dose assuming potential benefits outweigh the substantial risks of this formulation. [GRADE: 2C (Weak recommendation, low-quality evidence)]
7) *In patients with non-OUD use disorders (notably alcohol use disorder and benzodiazepine use disorder) and moderate-severe chronic pain refractory to optimized*

non-opioid treatments, should opioids be considered? If so, how should the management be approached?

a) As with recommendation #6, we would suggest a trial of buprenorphine rather than other opioids given its improved safety profile and data suggesting its efficacy is at least equivalent to other opioids for management of chronic pain. [GRADE: 2B (Weak recommendation, moderate-quality evidence)]
b) Patients who are opioid naive should be started with initial buprenorphine doses in the microgram range (proprietary formulations: Butrans, Belbuca). Strict attention should be paid to oversedation and respiratory depression since these adverse events are increased in patients who use other CNS depressant substances.

8) *For patients with OUD and moderate-severe chronic pain for whom full agonist opioids are being considered, what sort of follow up and monitoring should be recommended?*
   a) For patients with OUD and moderate-severe chronic pain for whom full agonist opioids are being considered, we recommend a follow up cadence that balances both patient safety with the burdens of frequent visits. Some clinicians may recommend initial weekly visits and spacing to monthly visits thereafter. Telehealth should be used liberally to decrease patient burden of visits while providing opportunity for ongoing clinician monitoring and frequent touch points. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
   b) We recommend patient monitoring include assessment of PDMP as well as intermittent GC/MS drug testing for prescribed medicines. This need not be done at every visit as this does not have evidence to improve patient outcomes. We agree with the ASAM approach of offering testing at all visits and allowing patients to decline testing.
   c) For patients with significant risk of ongoing non-prescribed use or those with other risk factors for accidental overdose (e.g. also prescribed chronic benzodiazepines, underlying lung disease), we suggest clinicians consider prescribing very short courses (e.g weekly or even three-four day supply) with frequent follow up opportunity. [GRADE: 2C (Weak recommendation, low-quality evidence)]
   d) For all patients with OUD and moderate-severe chronic pain prescribed full agonist opioids, we strongly recommend a focus on home safety including storing medicines in a lock box and ensuring availability of naloxone as well as counseling and education to the patient at each visit regarding risks. [GRADE: 1A (Strong recommendation, high-quality evidence)] Furthermore we encourage clinicians to adopt an approach of open communication to ensure the patient feels comfortable communicating increasing cravings or risk of return to use.
   e) For all patients with OUD and moderate-severe chronic pain prescribed full agonist opioids, we urge clinicians to ensure clear documentation of their current pain management plan and planned interval of reassessments as this is likely to be beneficial to other providers, pharmacists charged with filling medicines, and also from an insurance payer standpoint.

9) *For patients with OUD on MOUD and moderate-severe chronic pain for whom full agonist opioids are being considered, what are the considerations relevant to pharmacists, insurance companies, and state agencies?*
    a) We recommend against policies that prohibit long-term use of full agonists for patients with OUD in remission for whom the benefits outweigh the risks. We expect relevant agencies to recognize that any patient in this situation has a baseline high risk of severe harm and death from return to use, accidental overdose, and suicide. Given this risk and our stated goal of mitigating this risk, wide latitude should be given to treatment types and durations. [GRADE: 1C (Strong recommendation, low-quality evidence)]
    b) We strongly urge insurance companies and state agencies to support policies that increase access to all relevant buprenorphine formulations for diagnoses of both OUD and chronic pain given the nuances of care described above. Our group is overall agnostic regarding the choice between buprenorphine/naloxone and buprenorphine monoproduct. In our experience some patients do not tolerate the combination product and do well with the monoproduct and recommend insurance companies not restrict access since buprenorphine monoproduct still has an improved safety profile compared to full agonist opioids.
    c) We recommend that insurance companies and state agencies collaborate to ensure dispensing regulations and formularies allow access to full agonist opioids for patients on MOUD, provided that there is appropriate supervision, routine co-prescribing of naloxone, and medication counseling to promote safe use.
    d) We strongly urge community pharmacists to proactively reach out to prescribers to clarify any questions they have regarding concomitant use of MOUD and full agonist opioids. Furthermore we strongly urge the DEA and other relevant state and federal agencies to lessen or remove the restrictions on pharmacies on ordering above stated formulations of opioids.
10) *For patients with OUD who are approaching the end of life and are participating in palliative care and/or hospice programs, may opioids be used?*
    a) As in patients without a history of a substance use disorder, we recommend that palliative treatment of episodes of acute pain include optimized non-opioid medicines and approaches. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    b) A history of OUD, active or in remission, with or without treatment with MOUD, is not a contraindication to treatment with full agonist opioids for acute pain in patients participating in palliative care and/or hospice programs.
    c) If treatment with opioids is known to be more effective for a given cause of acute pain than non-opioid treatments, or if the standard of care for a given condition is treatment with opioids, then we recommend that patients with OUD also be offered opioids. [GRADE: 1B (Strong recommendation, moderate-quality evidence)]
    d) We urge clinicians caring for patients with OUD who are approaching the end of life and are participating in palliative care and/or hospice programs discuss with patients the risks and benefits of continuing or discontinuing MOUD medicines as

part of their pain plan. We make particular note that ongoing research seeks to determine whether methadone in particular may have improved palliative pain management characteristics compared to other opioids; these data are forthcoming.

e) We recommend that clinicians maintain open communication with outpatient addiction treatment providers to ensure continuity of MOUD and pain management plans throughout transitions into and out of palliative care or hospice settings.
f) We recommend that palliative and hospice teams have ready access to addiction medicine or pain specialists (in person or via telehealth) to support complex decision-making around opioid dosing, rotation, or tapering when standard protocols do not adequately control acute pain in patients with OUD.

MASAM Medical Decision Making Rationale Template

As _____'s primary care physician for over ____ years and as an Addiction Medicine specialist, I have evaluated the full set of potential benefits and risks associated with this medication regimen. At this time, the regimen:

1. Is substantially improving the patient's quality of life.
2. The combination of medication is not leading to any adverse effects
3. The regimen is making it significantly easier for the patient to be medically and psychologically stable
4. The regimen is helping to reduce major harms to the patient.

For these reasons, I am continuing the medication regimen and will continue to evaluate every 2-4 weeks or more frequently as indicated.

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