

SAFE MANAGEMENT OF NON-PALLIATIVE PAIN FOR PRIMARY CARE PROVIDERS IN SONOMA COUNTY

Guideline Goals:

The Safe Management of Non-Palliative Pain Guidelines support the appropriate use of opioid medication for the management of acute and chronic non-palliative pain. The Guidelines offer a standard approach to the management of acute and chronic pain with opioid medications. This approach aims to minimize the unsafe use and misuse of these medications and to mitigate subsequent morbidity and mortality. The goals are to share best practices, provide information on non-opioid alternatives to pain management, and to create community-wide Guidelines for standardized medical care for patients with pain who are prescribed opioid medication. The Guidelines are not intended to usurp the complex clinical decision-making required to provide sound medical practice when working with individuals and their unique circumstances.

Rationale:

These Guidelines were created in response to the alarming rise of unintentional opioid overdose deaths in Sonoma County. In 2010-2012, the rate in Sonoma County (12.0 per 100,000 residents) was higher than in California (10.1 per 100,000 residents). There is also a need for a standard of care for the treatment of chronic pain. Each year overdose claims scores of Sonoma County residents' lives, and the majority of these deaths are related to the misuse of medications that have been prescribed by health care providers.

Methods:

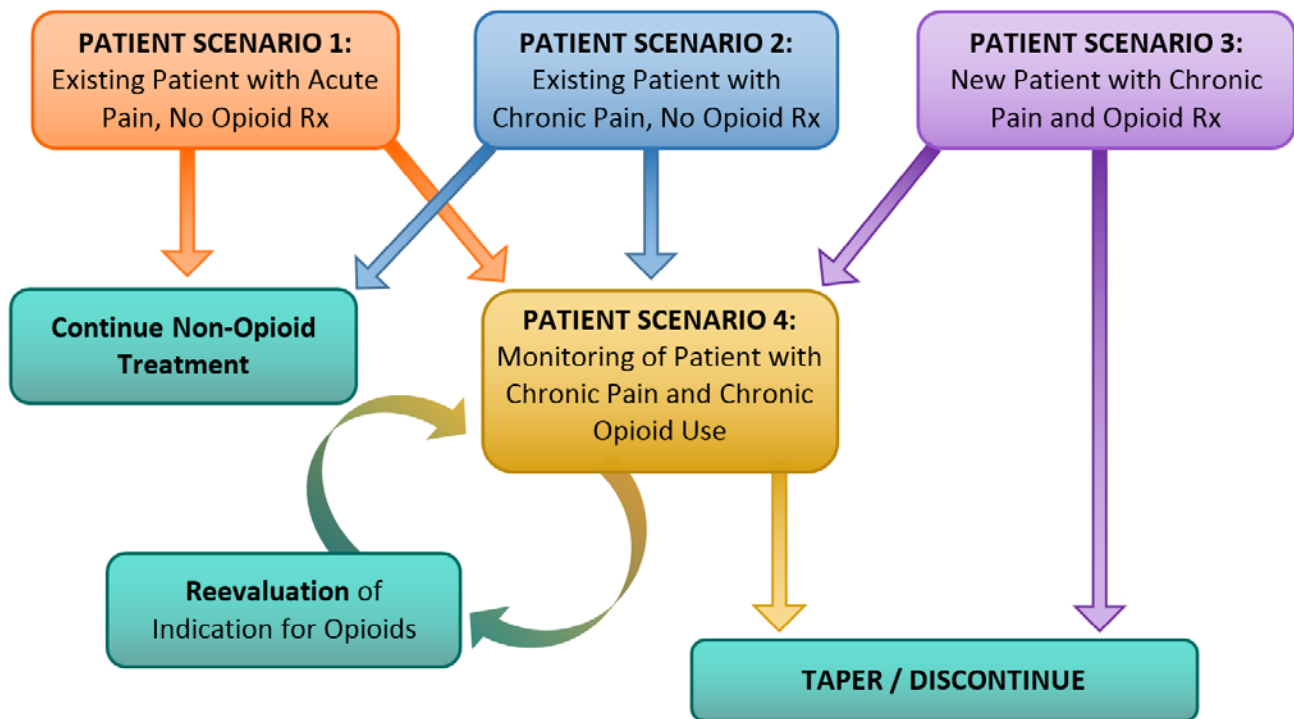
The methods used to inform the development of these Guidelines include a medical literature search for evidence-based clinical management and practice Guidelines; a comprehensive review of Guidelines at the national, state, and local level; and a facilitated process for consensus building among stakeholders through Sonoma County Health Action's Committee for Health Care Improvement's Opioid Prescribing Workgroup.

Limitations:

The treatment of chronic pain management is an evolving medical practice and there are areas where clinical controversy exists. While key stakeholders were sought, there may be important informants that were not a part of this process. Finally, there is an inherent tension between best medical practice and the feasibility to implement practice improvement, and this Guideline seeks to strike a balance between these two drivers of high quality health care.

Implementation:

Each health care agency that adopts these Guidelines is responsible for implementation and evaluation within their own organization. It is strongly recommended that each agency create their own practice infrastructure to assist with implementation of these Guidelines, including the practice management recommendations included in this document. The Opioid Prescribing Workgroup aims to create a toolkit to accompany these Guidelines in order to assist organizations with implementation.



Four Patient Scenarios

In creating these Guidelines, the Opioid Prescribing Workgroup identified four common scenarios in which health care providers grapple with decisions regarding pain management and opioid prescribing. The first three scenarios address patients for whom it is the first time a particular health care provider is considering prescribing an opioid medication. The fourth scenario involves an existing patient already on an opioid for pain and addresses the decision of whether to continue, taper, or discontinue and recommends what on-going monitoring is necessary.

- [Patient Scenario 1](#) addresses how a health care provider should **evaluate a patient (new or existing) with acute pain**. This scenario may result in starting opioid medication and addresses the initial use of medication with the result of either medication discontinuation or progression to chronic opioid use.
- [Patient Scenario 2](#) covers the situation when a health care provider has a patient (new or existing) with **chronic pain not already taking opioids and the provider is considering opioid use**. This scenario may result in starting opioid medication and addresses the initial use of medication with the result of either medication discontinuation or progression to chronic opioid use.
- [Patient Scenario 3](#) has a health care provider **evaluating a patient with chronic pain already treated with opioid medication who is new to the health care provider's practice**. In this situation, the Guidelines have recommendations for evaluation and the decision-making as to whether or not to continue that patient on chronic opioid medication.
- [Patient Scenario 4](#) manages a patient from one of the first three scenarios that has progressed to the point of having chronic pain despite chronic opioid treatment. The scenario recommends specific monitoring as well as provides **recommendations to consider tapering opioid medication**.

Management of Patients in the Four Scenarios

Patient Scenario 1:

Evaluation and management of a patient with acute pain who is currently not prescribed opioid medications.

Initial Assessment: Perform a complete initial assessment that includes the following elements:

1. take a complete history including medical history, social history, review of past medical records including any diagnostic studies, and review treatments or modalities tried previously,
2. perform a physical exam,
3. complete a functional assessment,
4. identify the pain diagnosis with supportive documentation (any diagnostic tests or imaging performed) and determine if the pain diagnosis is an indication for opioids,
5. identify functional goals,
6. evaluate contraindications and relative contraindications to opioid use (i.e. current substance abuse or history of substance abuse, use of benzodiazepines), and,
7. review other medications and allergies.

Initial Pain Management: The preferred initial pain management is a non-opioid regimen, such as non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen and/or non-pharmacologic options such as self-care, exercise, physical therapy, behavioral health, peer or other support group, mindfulness, acupuncture, yoga, chiropractic and osteopathic care.

Starting Opioid Medications: Should additional treatment be necessary and the patient's diagnosis warrants prescribing opioids, it is recommended that the provider review the California Controlled Substance Utilization Review and Evaluation System (CURES) to ensure that the patient's controlled substance prescription history is consistent with the medical history provided. When initiating opioid treatment, the health care provider should:

1. write a prescription for only a short duration (e.g., several days to a week supply),
2. start with short acting medications and use the lowest dose possible,
3. provide detailed patient education including information on the risks associated with opioid use as well as how to properly take the medication and how to properly store and dispose of the medication,
4. set functional goals for treatment, and,
5. communicate to the patient the plan for reassessment (days to two weeks' time) and possible discontinuation of the medication.

Monitoring and Reassessment: When starting a patient on opioid medication, it is critical to have follow-up visits including re-evaluation of patient status within days to two weeks' time. If the patient's pain is not resolving as expected, other interventions such as behavioral health assessment, peer or other support group, physical therapy, mindfulness, acupuncture, yoga, specialty referral (neurology, pain management, and orthopedics) should be offered. In addition, if there is no improvement in pain or functioning, consider discontinuation of opioids. Patients who are taking medication for more than four weeks require additional assessment to evaluate the pros and cons of transitioning the patient to chronic opioid use and to determine if continuation of opioid treatment is merited. Proceed with extreme caution when prescribing opioids for more than sixty days. The efficacy of long term opioid use for chronic non-palliative pain has not been established and there is a high rate of patients with chronic opioid medications who develop opioid use disorders. If opioid medication is continued for more than sixty days then the patient has transitioned to a status of chronic opioid use. Refer to Patient Scenario 4 for further guidance.

Patient Scenario 2:

Evaluation and management of a patient with chronic pain who is not already taking opioid medications.

Initial Assessment: An assessment specific to consideration of opioid medication usage should be performed:

1. review or take a complete history including medical history, social history, a review of past medical records including any diagnostic studies, and review treatments or modalities tried previously,
2. perform a physical exam,
3. do a functional assessment,
4. identify pain diagnosis with supportive documentation (any diagnostic tests performed) to determine if diagnosis is an indication for opioids,
5. discuss patient goals and identify functional goals,
6. evaluate contraindications and relative contraindications (i.e. current substance abuse or history of substance abuse, use of benzodiazepines),
7. review other medications, allergies and drug interactions, and,
8. perform risk assessments for potential medication abuse, co-morbidities, mental health issues, sleep apnea risk (e.g., ORT, PHQ, DIRE, SISAP, STOP BANG) to clarify risk for prescribing long-term opioid therapy.

Initial Pain Management: The efficacy of long-term opioid use for chronic non-palliative pain has not been established. In addition, there is high risk that some individuals on chronic opioid treatment will develop opioid use disorders. Therefore, it is critical to maximize all non-opioid options prior to starting opioid medications for chronic pain. The health care provider should consider starting a non-opioid regimen such as NSAIDs or acetaminophen as well as utilize non-pharmacologic options such as self-care, exercise, physical therapy, behavioral health, peer or other support group, mindfulness, acupuncture, yoga, chiropractic and osteopathic care.

Starting Opioid Medications: Should additional treatment be necessary and the patient's diagnosis warrants prescribing opioids, it is recommended that the provider review CURES and perform a urine drug screen (UDS). When initiating opioid treatment, the health care provider should:

1. write a prescription for only a short duration (e.g., several days to a week supply),
2. start with short or intermediate acting medications and use the lowest dose possible,
3. provide detailed patient education including information on the risks associated with opioid use as well as how to properly take the medication and how to properly store (e.g. lockboxes) and dispose of the medication at a designated medicine take-back site.
4. set functional goals for treatment,
5. communicate to the patient the plan for reassessment and possible discontinuation of the medication, and,
6. have patient sign a treatment agreement (aka medication use agreement) to clarify expectations about their pain medication. Treatment agreements should include clear language that directs patients to discuss break through pain with their primary care provider or medical practice rather than directing patients to the Emergency Department for additional pain medication.

Monitoring and Reassessment: When starting a patient on opioid medication, it is critical to plan follow-up visits including re-evaluation of patient status within days to two weeks' time. If the patient's pain is not resolving as expected, other interventions such as behavioral health assessment, peer or other support group, mindfulness, acupuncture, yoga, specialty referral (neurology, pain management, and orthopedics) should be offered. In addition, if there is no improvement in pain or functioning, consider discontinuation of opioids. Patients who are taking

medication for more than four weeks need an additional assessment to evaluate the pros and cons of transitioning the patient to chronic opioid use and determine if continuation of opioid treatment is merited. Proceed with extreme caution when prescribing opioids for more than sixty days. The efficacy of long term opioid use for chronic non-palliative pain has not been established and there is a high rate of patients with chronic opioid medications who develop opioid use disorders. If opioid medication is continued for more than sixty days, then the patient has transitioned to chronic opioid use. Refer to Patient Scenario 4 for further guidance.

Patient Scenario 3:

Evaluation and management of a patient with chronic pain already treated with opioid medication but who is new to the health care provider's practice.

Initial Assessment: An assessment specific to consideration of whether to continue the patient on opioid medication should be performed:

1. review or take a complete history: including medical history, social history, review of past medical records and any diagnostic studies completed, and review of treatments or modalities tried previously,
2. perform a physical exam,
3. do a functional assessment,
4. identify pain diagnosis with supportive documentation (any diagnostic tests performed) to determine if diagnosis is an indication for opioids,
5. discuss patient goals and identify functional goals,
6. evaluate contraindications and relative contraindications (i.e. current substance abuse or history of substance abuse, use of benzodiazepines),
7. review other medications,
8. perform risk assessments for potential medication abuse, co-morbidities, mental health issues, sleep apnea risk (e.g., ORT, PHQ, DIRE, SISAP, STOP BANG), and,
9. evaluate for dependency or substance use disorder.

Non-Opioid Pain Management: The efficacy of long-term opioid use for chronic non-palliative pain has not been established. In addition, there is high risk that some individuals on chronic opioid treatment will develop opioid use disorders. Therefore, for patients already on chronic opioid medications who continue to have pain, the health care provider should re-evaluate if non-opioid options would be of benefit. The health care provider should consider starting a non-opioid regimen such as NSAIDs or acetaminophen as well as utilize non-pharmacologic options such as self-care, exercise, physical therapy, behavioral health, peer or other support group, mindfulness, acupuncture, yoga, chiropractic and osteopathic care.

Continuation of Opioid Medications: Before prescribing opioid medications to a patient new to one's practice, the health care provider should review past records or speak to the patient's previous health care provider. The new health care provider should also review CURES and perform a urine drug screen. Even though the patient is not naive to opioid treatment, the health care provider should still:

1. write a prescription for only a short duration (e.g., several days to a week supply),
2. start with an appropriate dose based on the initial evaluation, which may be the same or lower than the opioid regimen the patient had been taking previously and use the lowest dose possible,
3. provide detailed patient education including information on the risks associated with opioid use as well as how to properly take the medication and how to properly store and dispose of the medication,
4. set functional goals for treatment,
5. communicate to the patient the plan for reassessment and possible tapering or discontinuation of the medication, and,

6. have patient sign a treatment agreement (aka medication use agreement) to clarify expectations about their pain medication. Treatment agreements should include clear

language that directs patients to discuss break through pain with their primary care provider or medical practice rather than directing patients to the Emergency Department for additional pain medication.

Monitoring and Reassessment: In patients for whom this is the first prescription written by a specific health care provider, it is critical that the health care provider re-evaluate the patient status within days or a maximum of two weeks' time to ensure safety and efficacy of the medication. If the patient's pain is not controlled as expected using their previous prescription, other interventions such as behavioral health assessment, peer or other support group, mindfulness, acupuncture, yoga, specialty referral (neurology, pain management, and orthopedics) should be offered. Consider reassessment of the diagnosis which may trigger additional medical evaluations including specialty refer. As in previous scenarios, if there is no improvement in pain or functioning, consider discontinuation of opioids. Refer to Patient Scenario 4 for further guidance on managing a patient with chronic pain and chronic opioid use.

Patient Scenario 4:

On-going evaluation and management of a patient with chronic pain and chronic opioid use.

Patient Monitoring: Health care providers should see these patients a minimum of once every three months and more frequently if the medication dose is adjusted. At each visit, the health care provider should take an interval history, (i.e., any ED visits, any overdose, other major changes in health or history including social history and function) and adjust prescription opioid regimens appropriately. Throughout treatment, providers should conduct compliance monitoring that includes urine drug screening at least annually and a review of CURES at least twice per year. If the clinical scenario merits it, (i.e. multiple requests for additional medication, other concerns from social history or behavior) the urine drug screen and/or CURES review should be more frequent.

Reevaluation of Indication for Opioid Use: At each visit, the health care provider should review the efficacy of opioid treatment by evaluating and documenting functional changes and goals including activity levels and pain levels. Health care providers should also re-examine the potential risks of opioid medication use. Key steps to consider:

1. review any medication changes, reconcile the entire medication list and evaluate for medication interactions and polypharmacy risks,
2. assess for adverse effects of opioid medication use (e.g., sedation, sleep apnea, hypogonadism), and,
3. evaluate if there are other changes in the patient's health or social situation that may change risk assessment (i.e. recent falls, stroke, etc.).

Formal risk assessments for co-morbidities, mental health issues, and medication dependency or misuse disorders should be repeated annually. If an evaluation reveals concern for mental health issues, refer a patient to a mental health professional. If evaluation reveals concern for a substance use disorder refer patients to an addiction specialist and/or a medication assisted treatment program.

Medication Dose Changes: When dose changes are required, the health care provider should schedule more frequent follow-up visits. Precautions, such as co-prescribing naloxone, should be taken if prescribing greater than 50 MEDs per day due to increased risk of overdose. In addition,

there are diminishing benefits of pain control at higher doses of opioids and therefore caution should be used with increasing doses. Use care with prescribing or adjusting fentanyl or methadone as they have higher concentrations of opioids and unique pharmacokinetics.

Indications for Tapering and/or Discontinuation: Providers should taper or discontinue if there is no clinically meaningful improvement in function and pain. Providers should consider tapering or discontinuing the medication if the patient is on 90 MEDs or more, if the risk of opioid medication use outweighs benefits, if treatment results in a severe adverse outcome that interferes with quality of life (e.g. overdose, bowel obstruction, central sleep apnea), or if the patient has current or history of substance use disorder (excluding tobacco).

The health care provider should consider immediate discontinuation of prescribing if the patient exhibits illegal activity such as stealing, forgery, diversion; if the patient attempts suicide, or if the provider is concerned about the patient's illicit drug use or significant aggressive/threatening behavior.

The health care provider should strongly consider discontinuation of opioid medications (taper when possible) if:

1. the risk of continued opioid use, as determined by consultation with the patient and family, is greater than the benefit, including medical comorbidities (sleep apnea, pulmonary disease),
2. there are safety issues such as danger to oneself or others (i.e. driving), or
3. if there is lack of efficacy of the treatment.

Health care providers should taper and discontinue opioid medication if:

1. there is noncompliance with the medication use agreement,
2. multiple pharmacies or prescribing providers have been identified,
3. there is a pattern of early refill requests,
4. the patient refuses a urine toxicology screen or indicates their prescribed medication is absent or other illicit drug is being used,
5. the patient exhibits aggressive/threatening behavior, or
6. there are physical risk factors present (sleep apnea, prolonged QT, pulmonary disease, etc.).

Tapering: Health care providers should include patients in making tapering treatment plans and document the process. Providers should explain to each patient the reason and process for tapering, as well as educate the patient as to what to expect. Patients should be encouraged to involve their families and referred to options for additional psychosocial support such as a mental health referral. Motivational interviewing may be useful while having these conversations.

Tapering speed should be selected to match the urgency of the need for tapering. A slow taper of 5-15% of morphine equivalent dose (MED) per week is preferred for patients with no acute safety concerns. Rapid tapering of 15-20% MED per week may be appropriate for more concerning situations. For individuals with high risk of severe adverse outcomes (such as overdose or substance use disorder) a rapid taper over 2-3 weeks may be indicated. Tapering should not be reversed, only slowed or paused if there is a clinical necessity. Do not start or resume opioids once they have been discontinued as they could trigger cravings and a return to use.

Patients should be monitored and the rate, intensity of duration of the speed adjusted to the patient's response. Follow up visits should be scheduled in advance to ensure adequate check-in. Providers should watch for signs of unmasked mental health disorders during taper and consult with or refer to behavioral health and substance abuse specialists if relevant. Health care providers should manage anticipated side-effects and consider adjuvants: antidepressants, anti-convulsants, anti-nausea, anti-diarrheal, hydroxyzine (insomnia, anxiety). Benzodiazepines should not be used as an adjuvant for withdrawal due to tapering.

Considerations for Special Populations

For women of reproductive age, when pregnancy is possible or if they are currently breast feeding, it is recommended that providers review the added potential risks of opioid use to the pregnancy and the fetus. Co-prescribing contraceptives is strongly recommended.

When treating the geriatric population, consider the additional level of risk that opioid medications may create—including dizziness and falls or overdoses due to challenges with medication compliance. Health care providers also need to do a complete medication reconciliation and evaluate potential drug interactions. Geriatric patients may require additional assistance such as pre-sorted pill organizers obtained through the pharmacy.

Practice Management

Health care organizations can implement systems improvements and provider-level support to improve safety in opioid prescribing. At the organizational level, medical practices may consider development of clear clinical practice Guidelines to define and implement agency practice standards including but not limited to:

1. how and when to evaluate for transition to long-term opioid use and best practices in patient management,
2. under which circumstances providers can prescribe opioids i.e., only assigned primary care provider, only during scheduled visit,
3. standard practices regarding refills,
4. standard practices regarding limits to refills, i.e. no refills prior to first appointment, no refills on weekends or evenings (if not at an assigned PCP visit), no early refills, and the requirement of a face-to-face visit and assessment is for a refill if medication is lost/stolen,
5. standard practices regarding use of treatment agreements and opioid monitoring practices, and,
6. support for tapering based on risk stratification for high MEDs or polypharmacy, and,
7. a program for Naloxone prescribing for patients on opioids at high MEDs
8. standard practices to identify patients with potential substance use disorders and refer them into treatment including programs providing medication assisted treatment.

Medical practices should consider implementation of an Opioid Oversight Committee to provide clinical decision-making support to clinicians and to support consistent, high-quality management of opioids that reflects the practice policy. The role of the Oversight Committee is to support clinicians by medical record review, multidisciplinary (mental health, pharmacy, provider) assessment of complex cases, and to provide resources to providers to implement high-quality care in a safe and confidential manner.

Health care organizations should also perform practice level data collection and reporting that supports quality improvement. Practice level feedback on measures of monitoring, average MED, and prescribing patterns are tools to drive best practices in safe management of pain. For, example, agencies enhance safety by evaluating providers' adherence to organizational policies and the extent that standards of practice using tracking metrics on polypharmacy use, the number of MEDs prescribed, and whether health care providers are adequately monitoring patients through UDS and the review of the CURES drug database.

It is advantageous to identify practice champions to lead efforts in implementing these Guidelines. It is also useful to identify practice champions with additional experience and/or expertise that can be called upon to support other providers with opioid management questions and complex cases, such as treatment of addiction in the setting of chronic pain or management of difficult patient behaviors.