

Opioid Treatment Guidelines for Chronic Pain Part 1

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I. Introduction

The Department of Veterans Affairs (VA) and Department of Defense (DoD) Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the “...Health Executive Council on the use of clinical and epidemiological evidence to improve the health of the population across the Veterans Health Administration and Military Health System,” by facilitating the development of clinical practice guidelines (CPGs) for the VA and DoD populations.^[1] This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with chronic pain who are on or being considered for long-term opioid therapy (LOT).

In 2010, the VA and DoD published the *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (2010 OT CPG), which was based on evidence reviewed through March 2009. Since the release of that guideline, there has been growing recognition of an epidemic of opioid misuse and opioid use disorder (OUD) in America, including among America’s Veterans, as documented in the [Background](#) section. At the same time, there is a mounting body of research expanding detailing the lack of benefit and severe harms of LOT.

Consequently, a recommendation to update the 2010 OT CPG was initiated in 2015. The updated CPG, titled *Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (OT CPG), includes objective, evidence-based information on the management of chronic pain. It is intended to assist healthcare providers in all aspects of patient care, including, but not limited to, diagnosis, treatment, and follow-up. The system-wide goal of this guideline is to improve the patient’s health and well-being by providing evidence-based guidance to providers who are taking care of patients on or being considered for LOT. The expected outcome of successful implementation of this guideline is to:

- Assess the patient’s condition, provide education, and determine the best treatment methods in collaboration with the patient and a multidisciplinary care team
- Optimize the patient’s health outcomes and function and improve quality of life
- Minimize preventable complications and morbidity
- Emphasize the use of patient-centered care

II. How to Use This Clinical Practice Guideline

This guideline can be used in a variety of ways. It can be used by general clinicians or specialists to study and consider the latest information on opioid therapy (OT) and how and whether to incorporate that information or recommendations into their practice. It can be used to provide specific information to guide a patient encounter, such as looking up the dosing of a medication used less frequently or the meaning of the urine drug testing (UDT) result. The section on tapering and its accompanying appendix can be used to assist in the development of a framework for guiding an individualized, informed discussion when tapering is being considered. Patients can examine the guideline to educate themselves and better understand their care. A health care system can use the CPG to assure that its clinicians and patients have the resources available to compassionately, effectively, and safely evaluate and deliver LOT in a timely, culturally sensitive manner. The guideline can also be used to suggest specific education for identified gaps.

This guideline is not intended as a standard of care and should not be used as such. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advances and patterns evolve. Today there is variation among state regulations, and this guideline does not cover the variety of ever-changing state regulations that may be pertinent. The ultimate judgement regarding a particular clinical procedure or treatment course must be made by the individual clinician, in light of the patient's clinical presentation, patient preferences, and the available diagnostic and treatment options. As noted previously, the guideline can assist care providers, but the use of a CPG must always be considered as a recommendation, within the context of a provider's clinical judgment and patient values and preferences, in the care for an individual patient.

III. Recommendations

The following recommendations were made using a systematic approach considering four domains as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as detailed in the section on [Methods](#) and [Appendix E](#). These domains include: confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability).

Given the relevance of all four domains in grading recommendations, the Work Group encountered multiple instances in which confidence in the quality of the evidence was low or very low, while there was marked imbalance of benefits and harms, as well as certain other important considerations arising from the domains of values and preferences and/or other implications. In particular, the harms due to the potential for severe adverse events associated with opioids, particularly overdose and OUD, often far outweigh the potential benefits. As such, in accounting for all four domains, these factors contributed to Strong recommendations in multiple instances.

#	Recommendation	Strength*	Category†
Initiation and Continuation of Opioids			
1.	<ul style="list-style-type: none"> a) We recommend against initiation of long-term opioid therapy for chronic pain. b) We recommend alternatives to opioid therapy such as self-management strategies and other non-pharmacological treatments. c) When pharmacologic therapies are used, we recommend non-opioids over opioids. 	<ul style="list-style-type: none"> a) Strong against b) Strong for c) Strong for 	Reviewed, New-replaced
2.	<p>If prescribing opioid therapy for patients with chronic pain, we recommend a short duration.</p> <p>Note: Consideration of opioid therapy beyond 90 days requires re-evaluation and discussion with patient of risks and benefits.</p>	Strong for	Reviewed, New-added
3.	For patients currently on long-term opioid therapy, we recommend ongoing risk mitigation strategies (see Recommendations 7-9), assessment for opioid use disorder, and consideration for tapering when risks exceed benefits (see Recommendation 14).	Strong for	Reviewed, New-replaced
4.	<ul style="list-style-type: none"> a) We recommend against long-term opioid therapy for pain in patients with untreated substance use disorder. b) For patients currently on long-term opioid therapy with evidence of untreated substance use disorder, we recommend close monitoring, including engagement in substance use disorder treatment, and discontinuation of opioid therapy for pain with appropriate tapering (see Recommendation 14 and Recommendation 17). 	<ul style="list-style-type: none"> a) Strong against b) Strong for 	Reviewed, Amended
5.	<p>We recommend against the concurrent use of benzodiazepines and opioids.</p> <p>Note: For patients currently on long-term opioid therapy and benzodiazepines, consider tapering one or both when risks exceed benefits and obtaining specialty consultation as appropriate (see Recommendation 14 and the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders).</p>	Strong against	Reviewed, New-added

#	Recommendation	Strength*	Category†
6.	<p>a) We recommend against long-term opioid therapy for patients less than 30 years of age secondary to higher risk of opioid use disorder and overdose.</p> <p>b) For patients less than 30 years of age currently on long-term opioid therapy, we recommend close monitoring and consideration for tapering when risks exceed benefits (see Recommendation 14 and Recommendation 17).</p>	<p>a) Strong against</p> <p>b) Strong for</p>	Reviewed, New-replaced
Risk Mitigation			
7.	<p>We recommend implementing risk mitigation strategies upon initiation of long-term opioid therapy, starting with an informed consent conversation covering the risks and benefits of opioid therapy as well as alternative therapies. The strategies and their frequency should be commensurate with risk factors and include:</p> <ul style="list-style-type: none"> ■ Ongoing, random urine drug testing (including appropriate confirmatory testing) ■ Checking state prescription drug monitoring programs ■ Monitoring for overdose potential and suicidality ■ Providing overdose education ■ Prescribing of naloxone rescue and accompanying education 	Strong for	Reviewed, New-replaced
8.	We recommend assessing suicide risk when considering initiating or continuing long-term opioid therapy and intervening when necessary.	Strong for	Reviewed, Amended
9.	We recommend evaluating benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months.	Strong for	Reviewed, New-replaced
Type, Dose, Follow-up, and Taper of Opioids			
10.	<p>If prescribing opioids, we recommend prescribing the lowest dose of opioids as indicated by patient-specific risks and benefits.</p> <p>Note: There is no absolutely safe dose of opioids.</p>	Strong for	Reviewed, New-replaced
11.	<p>As opioid dosage and risk increase, we recommend more frequent monitoring for adverse events including opioid use disorder and overdose.</p> <p>Note:</p> <ul style="list-style-type: none"> ■ Risks for opioid use disorder start at any dose and increase in a dose dependent manner. ■ Risks for overdose and death significantly increase at a range of 20-50 mg morphine equivalent daily dose. 	Strong for	Reviewed, New-replaced
12.	<p>We recommend against opioid doses over 90 mg morphine equivalent daily dose for treating chronic pain.</p> <p>Note: For patients who are currently prescribed doses over 90 mg morphine equivalent daily dose, evaluate for tapering to reduced dose or to discontinuation (see Recommendations 14 and 15).</p>	Strong against	Reviewed, New-replaced
13.	We recommend against prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of long-term opioid therapy.	Strong against	Reviewed, New-replaced
14.	<p>We recommend tapering to reduced dose or to discontinuation of long-term opioid therapy when risks of long-term opioid therapy outweigh benefits.</p> <p>Note: Abrupt discontinuation should be avoided unless required for immediate safety concerns.</p>	Strong for	Reviewed, New-added

#	Recommendation	Strength*	Category†
15.	We recommend individualizing opioid tapering based on risk assessment and patient needs and characteristics. Note: There is insufficient evidence to recommend for or against specific tapering strategies and schedules.	Strong for	Reviewed, New-added
16.	We recommend interdisciplinary care that addresses pain, substance use disorders, and/or mental health problems for patients presenting with high risk and/or aberrant behavior.	Strong for	Reviewed, New-replaced
17.	We recommend offering medication assisted treatment for opioid use disorder to patients with chronic pain and opioid use disorder. Note: See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.	Strong for	Reviewed, New-replaced
Opioid Therapy for Acute Pain			
18.	<ul style="list-style-type: none"> a) We recommend alternatives to opioids for mild-to-moderate acute pain. b) We suggest use of multimodal pain care including non-opioid medications as indicated when opioids are used for acute pain. c) If take-home opioids are prescribed, we recommend that immediate-release opioids are used at the lowest effective dose with opioid therapy reassessment no later than 3-5 days to determine if adjustments or continuing opioid therapy is indicated. <p>Note: Patient education about opioid risks and alternatives to opioid therapy should be offered.</p>	<ul style="list-style-type: none"> a) Strong for b) Weak for c) Strong for 	Reviewed, New-added

*For additional information, please refer to the section on [Grading Recommendations](#).

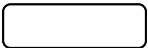


†For additional information, please refer to the section on [Recommendation Categorization](#) and [Appendix H](#).

IV. Algorithm

This CPG follows an algorithm that is designed to facilitate understanding of the clinical pathway and decision making process used in management of LOT. The use of the algorithm format as a way to represent patient management was chosen based on the understanding that such a format may promote more efficient diagnostic and therapeutic decision making and has the potential to change patterns of resource use. Although the Work Group recognizes that not all clinical practices are linear, the simplified linear approach depicted through the algorithm and its format allows the provider to assess the critical information needed at the major decision points in the clinical process. It includes:

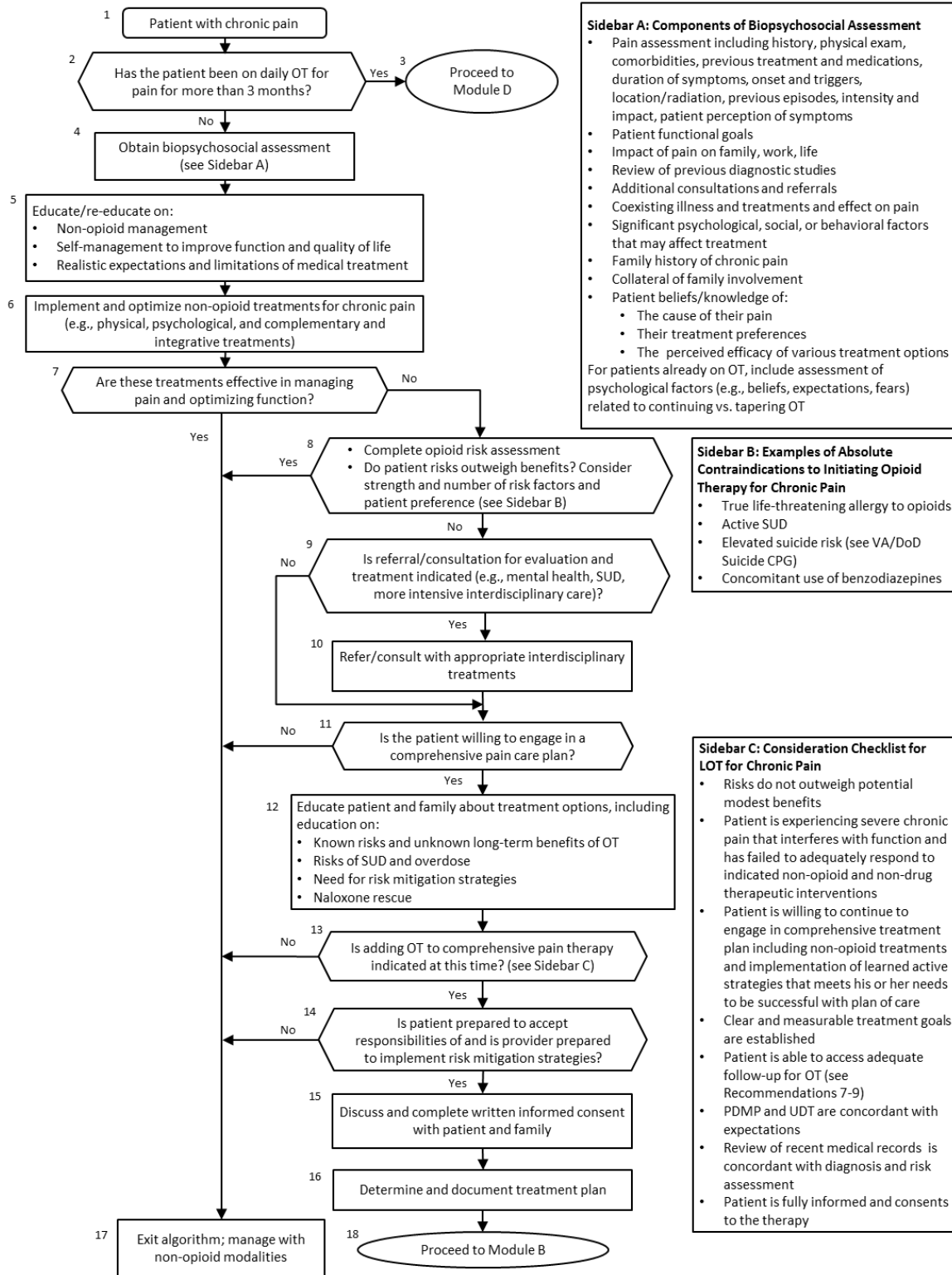
- An ordered sequence of steps of care
- Recommended observations and examinations
- Decisions to be considered
- Actions to be taken

For each guideline, the corresponding clinical algorithm is depicted by a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm, and arrows connect the numbered boxes indicating the order in which the steps should be followed.^[2]

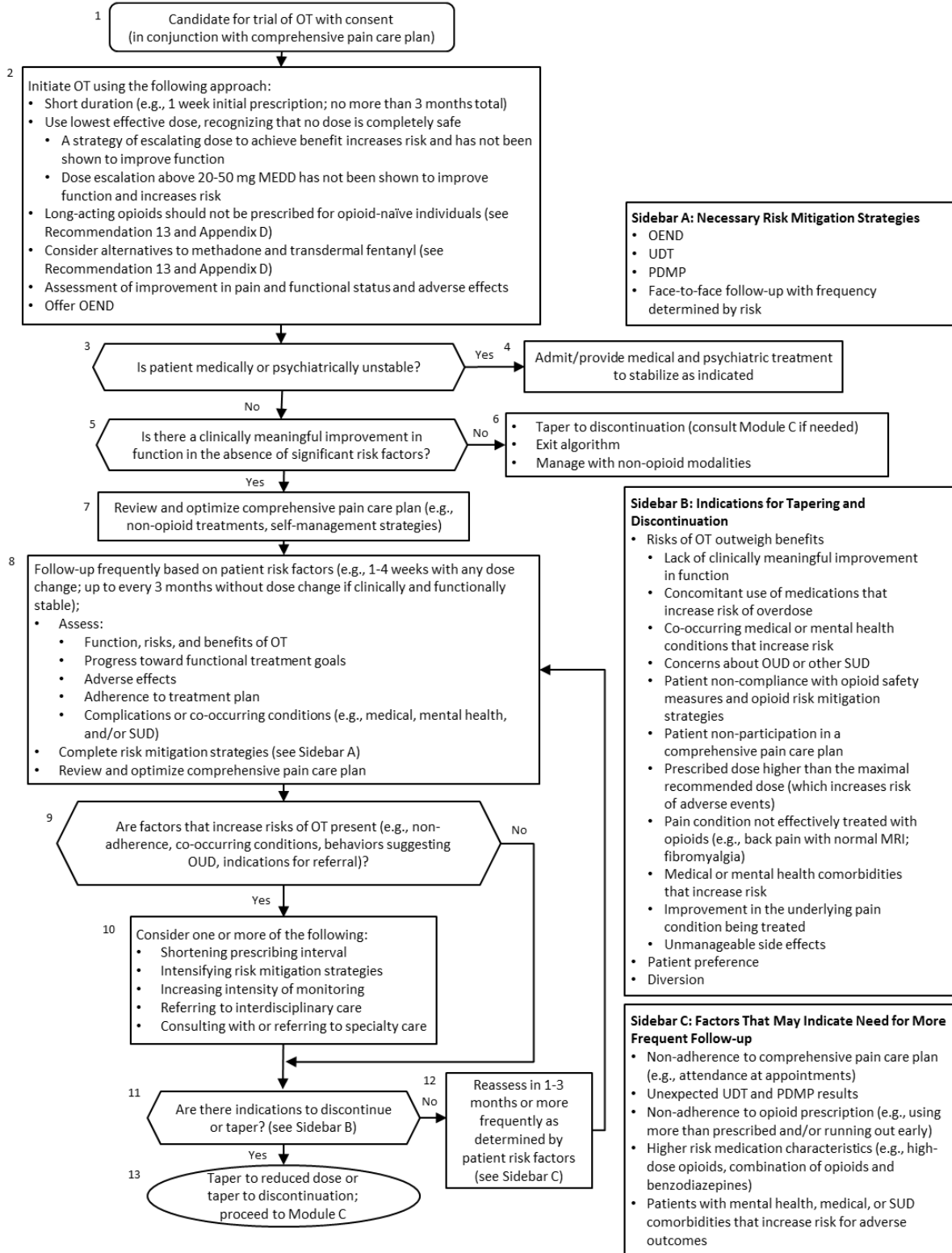
	<p>Rounded rectangles represent a clinical state or condition.</p>
	<p>Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No.</p>
	<p>Rectangles represent an action in the process of care.</p>

A. Module A: Determination of Appropriateness for Opioid Therapy

Note: Non-pharmacologic and non-opioid pharmacologic therapies are preferred for chronic pain.

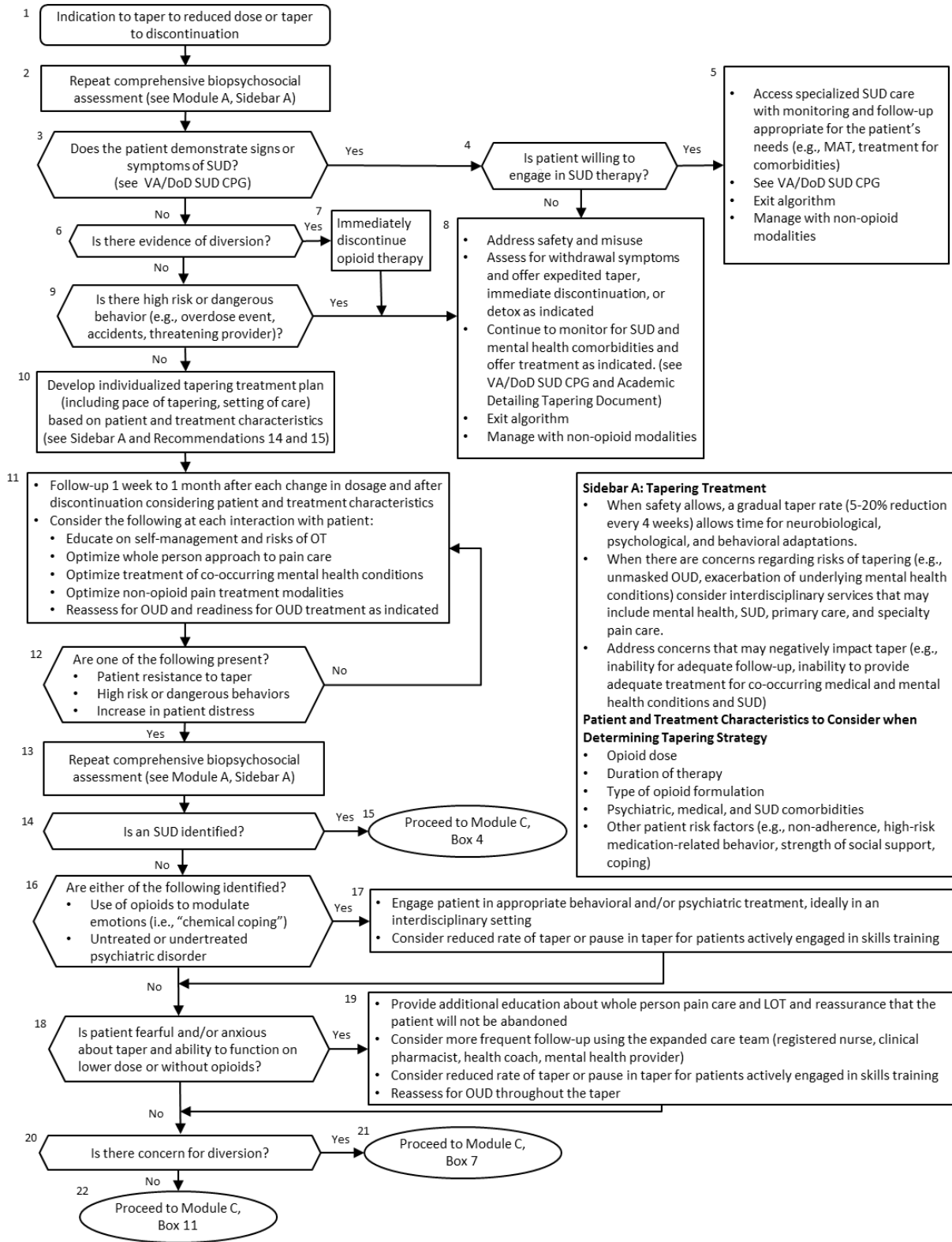


B. Module B: Treatment with Opioid Therapy



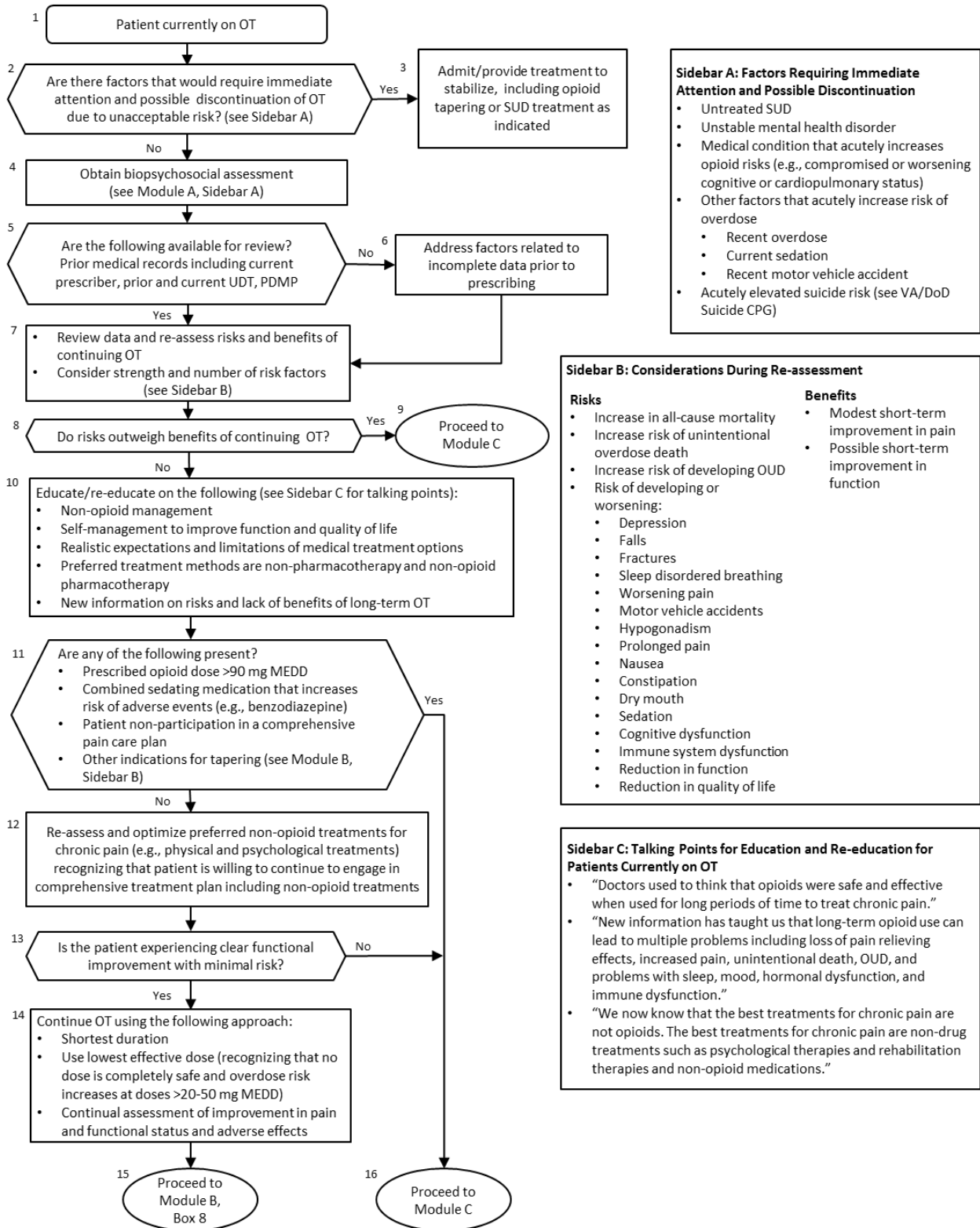
Abbreviations: MEDD: morphine equivalent daily dose; mg: milligram(s); MRI: magnetic resonance imaging; OEND: Overdose Education and Naloxone Distribution; OT: opioid therapy; OUD: opioid use disorder; PDMP: Prescription Drug Monitoring Program; SUD: substance use disorders; UDT: urine drug test

C. Module C: Tapering or Discontinuation of Opioid Therapy



Abbreviations: LOT: long-term opioid therapy; MAT: medication assisted treatment; OT: opioid therapy; OUD: opioid use disorder; SUD: substance use disorders; VA/DoD SUD CPG: VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders

D. Module D: Patients Currently on Opioid Therapy



Abbreviations: MEDD: morphine equivalent daily dose; mg: milligram(s); OT: opioid therapy; OUD: opioid use disorder; PDMP: Prescription Drug Monitoring Program; SUD: substance use disorders; UDT: urine drug test; VA/DoD Suicide CPG: VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide

V. Background

A. Opioid Epidemic

Chronic pain is a national public health problem as outlined in the 2011 study by the National Academy of Medicine (previously the Institute of Medicine [IOM]).^[3] At least 100 million Americans suffer from some form of chronic pain. Until recently, the treatment of chronic pain with opioids was increasing at an alarming rate. The increase in prescriptions of these medications has been accompanied by an epidemic of opioid-related adverse events.

From 2000 through 2010, the proportion of pain visits during which opioid and non-opioid pharmacologic therapies were prescribed increased from 11.3% to 19.6% and from 26% to 29%, respectively.^[4] In 2012, for every 100 persons in the United States (U.S.), 82.5 opioid prescriptions and 37.6 benzodiazepine prescriptions were written by healthcare providers.^[5] In the emergency department, at least 17% of discharges included prescriptions for opioids.^[6,7]

There has been limited research on the effectiveness of LOT for non-end-of-life pain. At the same time, there is mounting evidence of the ill effects of LOT, including increased mortality, OUD, overdose, sexual dysfunction, fractures, myocardial infarction, constipation, and sleep-disordered breathing.^[8-10] Despite increasing awareness of the known harms of opioids, 259 million opioid prescriptions were still written in 2012.^[11]

The increase in opioid prescribing is matched by a parallel increase in morbidity, mortality, opioid-related overdose death rates, and substance use disorders (SUD) treatment admissions from 1999 to 2008.^[12,13] In 2009, drug overdose became the leading cause of injury-related death in the U.S., surpassing deaths from traffic accidents.^[14] In 2014, 1.9 million Americans were affected by an OUD related to non-medical use of prescription pain relievers,^[15] and in the same year, 18,893 individuals died as a result of a prescription drug overdose.^[16] There has been a four-fold increase in the absolute number of deaths associated with use of opioids since 2000, and a 14% increase between 2013 and 2014 alone.^[17] In a survey of patients prescribed opioids for chronic non-cancer pain (CNCP) and their family members, 34% of patients reported that they thought they were “addicted” or “dependent” on opioid pain medication, 34% said that they used the medication for “fun” or to “get high,” while 22% used the medication to relieve day-to-day stress.^[18]

Concurrent with the increase in prescription opioid use, the rate of heroin overdose deaths increased nearly four-fold between 2000 and 2013.^[19] According to a survey of patients entering SUD treatment for heroin use, the prescription opioid epidemic has resulted in a marked shift in how and which opioids are abused. In the 1960s, 80% of people entering treatment for heroin use started using heroin as their first opioid, while in the 2000s, 75% of people entering treatment for heroin use started using prescription opioids as their first opioid.^[20] This increase in the use of opioids, as well as associated morbidity,

mortality, and other adverse outcomes, has called attention to the need for a paradigm shift in pain and in the way it is treated. Consult the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders (VA/DoD SUD CPG)¹ for further information.

B. Paradigm Shift in Pain and Its Treatment

The U.S. is in the midst of a cultural transformation in the way pain is viewed and treated. The biomedical model of pain care, in which the pain experience is reduced to a pain generator and pain treatment is aimed at fixing or numbing pain with medications, interventions, or surgery, dominated the 1990s and the first decade of the 2000s. As the cost, potential harm, and limited effectiveness of this approach to chronic pain was becoming apparent, the National Academy of Medicine issued a call for the transformation of pain care to a biopsychosocial, multimodal, interdisciplinary model.^[3]

A paradigm shift in the use of OT for chronic non-terminal pain has paralleled this transformation in pain care. Prior to the 1980s, OT was rarely used outside of severe acute injury or post-surgical pain, primarily due to concern for tolerance, physical dependence, and addiction. As the hospice and palliative care movement began defining end-of-life care in the U.S. during the 1980s and emphasizing the importance of pain relief, OT increasingly became a mainstay for cancer and end-of-life pain. Efforts to destigmatize the use of prescription opioids for chronic non-terminal pain encompassed primary care providers and the public. The efforts led to an unprecedented increase in opioid prescribing for chronic non-terminal pain. Chronic pain management became synonymous with LOT in the 1990s and the first decade of the 2000s with significant numbers of patients in pain clinics receiving LOT.^[21] Despite the absence of long-term safety or efficacy data, OT for chronic non-terminal pain became a mainstay of therapy. However, as observational and epidemiologic data of harm from LOT accumulated, a much more cautious approach to OT for chronic non-terminal pain has emerged in the decade of the 2010s.

The accumulation of evidence of harms and the absence of evidence of long-term benefits has warranted a newly cautious approach to LOT that prioritizes safety. This approach coupled with the evidence of both the safety and efficacy for non-pharmacologic and non-opioid pharmacologic pain therapies has led to the current transformation in the way in which pain is viewed and treated. The biopsychosocial model of pain recognizes pain as a complex multidimensional experience that requires multimodal and integrated care approaches. Within this context, non-pharmacologic treatments and non-opioid medications are the preferred treatments for chronic non-terminal pain. OT has a limited role, primarily in the treatment of severe acute pain, post-operative pain, and end-of-life pain.

C. Prioritizing Safe Opioid Prescribing Practices and Use

The increasing use of opioids, as well as the accompanying rise in morbidity and mortality associated with opioid use, has garnered increasing attention from federal and local officials as well as other policy makers.

¹ See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders. Available at: <http://www.healthquality.va.gov/guidelines/mh/sud/index.asp>.

This public health issue, which has been labelled an epidemic,[\[22\]](#) became a focus of the President's National Drug Control Strategy in 2010 and has since remained a focus. Two main goals introduced in the 2010 strategy included curtailing illicit drug consumption in America and improving the health and safety of the American people by reducing the consequences of drug abuse.[\[23\]](#) The 2015 strategy, and an accompanying presidential memorandum on preventing prescription drug abuse and heroin use, released in October 2015, encouraged the improvement of health and safety using evidence-based methods by calling for change in a number of key areas including preventing drug use in communities, seeking early intervention opportunities, and integrating SUD treatment and supporting recovery.[\[24,25\]](#)

With the passage of the Patient Protection and Affordable Care Act (PPACA) in March 2010, the Interagency Pain Research Coordinating Committee was created to coordinate pain research efforts throughout federal government agencies. The Committee was tasked with summarizing advances in pain care research, identifying gaps in research, and developing recommendations regarding ways to minimize duplicative efforts, disseminate pain care information, and expand public/private research partnerships and collaborations. The Committee published the National Pain Strategy in March 2016 in response to the call from the National Academy of Medicine to increase awareness of pain as a significant public health issue in the U.S.[\[3\]](#) The strategy made recommendations in a number of areas including prevention and care, professional education and training, and population research. The plan is aimed at decreasing the prevalence of all types of pain (acute and chronic) in the U.S., as well as the disability and morbidity associated with pain.[\[26\]](#)

Government agencies, including the VA, DoD, and Substance Abuse and Mental Health Services Administration (SAMHSA), have also launched initiatives to improve the study and treatment of pain and adverse events associated with opioid analgesics such as OUD and overdose.[\[27\]](#) By August 2013, the VA deployed the Opioid Safety Initiative (OSI) requirements to all Veterans Integrated Service Networks (VISNs) with the aim of ensuring opioids are used in a safe, effective, and judicious manner. The goals of the OSI related to such topics as increased education, monitoring, use of safe and effective prescribing and management methods, tool development, collaboration, and use of alternative pain treatment. The OSI uses the Veterans Health Administration (VHA's) electronic health record to identify patients who may be high-risk for adverse outcomes with use of opioids and providers whose prescribing practices do not reflect best evidence so that patient care can be improved. The OSI requirements include specific indicators (e.g., the number of unique pharmacy patients dispensed an opioid, the unique patients on LOT who have received UDT).[\[28\]](#) As part of the OSI, the VA launched the Opioid Overdose Education and Naloxone Distribution (OEND) program, which was implemented as a risk mitigation strategy aimed at reducing deaths from opioid overdose. The program components included education and training regarding the following topics: opioid overdose prevention, recognition, and rescue response; risk mitigation strategies; and issuing naloxone kits, which can be used as an antidote to opioid overdose.[\[29,30\]](#)

Other initiatives are aimed at improving the safe use of opioids, including the OSI Toolkit and the patient guide *Taking Opioids Responsibly for Your Safety and the Safety of Others: Patient Information Guide on Long-term Opioid Therapy for Chronic Pain*. The OSI Toolkit was developed to provide clinicians with materials to inform clinical decision-making regarding opioid therapy and safe opioid prescribing.[\[31\]](#) The toolkit materials can be found at the following link:

https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_Toolkit.asp. *Taking Opioids Responsibly for Your Safety and the Safety of Others: Patient Information Guide on Long-term Opioid Therapy for Chronic Pain* is aimed at providing information to patients as well as their providers regarding the safe use of opioids. More information can be found at the following link:

<http://www.healthquality.va.gov/guidelines/Pain/cot/OpioidTherapyforChronicPainPatientTool20May2013print.pdf>. To further promote safety and patient centered care, the VHA issued a policy in 2014 requiring standardized education and signature informed consent for all patients receiving LOT for non-cancer pain.[32]

The aforementioned presidential memorandum of October 2015 mandated that executive departments and agencies shall, to the extent permitted by law, provide training on the appropriate and effective prescribing of opioid medications to all employees who are health care professionals and who prescribe controlled substances as part of their federal responsibilities and duties. The DoD Opioid Prescriber Safety Training Program, launched accordingly, includes modules on pain management and opioid prescribing safety, the recent Centers for Disease Control and Prevention (CDC) guideline (see the below paragraph), and the identification of substance misuse and referral to specialized services. Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is sponsoring the training and related management support. Training is available online at <http://opstp.cds.pesgce.com/hub.php>.

The CDC released its *Guideline for Prescribing Opioids for Chronic Pain*, directed toward primary care physicians, on March 15, 2016.[33] The aim of the guideline is to assist primary care providers in offering safe and effective treatment for patients with chronic pain in the outpatient setting (not including active cancer treatment, palliative care, or end-of-life care). It is also aimed at improving communication between providers and patients and decreasing adverse outcomes associated with LOT. The CDC guideline, similar to the VA/DoD OT CPG, covered topics including initiation and continuation of OT, management of OT, and risk assessment and use of risk mitigation strategies. It also used the GRADE system to assign a grade for the strength for each recommendation which includes assessment of the quality of the evidence and consideration of the balance of desirable and undesirable outcomes, patient values and preferences, and other considerations (e.g., resource use, equity) during recommendation development (see [Grading Recommendations](#) for more information on the use of GRADE in updating this CPG).

On July 22, 2016, the Comprehensive Addiction and Recovery Act (CARA) was enacted with the aim of addressing the epidemic of overdoses from prescription opioids and other prescription drugs and heroin.[34] While this act was primarily focused on opioid abuse treatment and prevention, it also gave specific instruction to the VA in regard to broad aspects of OT including consideration of the CDC guideline in revising the prior VA/DoD OT CPG and adopting it for the VA. There are, however, some important distinctions between the CDC guideline and the VA/DoD OT CPG.

The VA/DoD OT CPG was developed with a specific patient population in mind—Service Members, Veterans, and their families—that has unique characteristics and needs related to the military culture and communities to which they return. Throughout the VA/DoD OT CPG, attention is paid to the characteristics and needs of these patients, particularly regarding specific risk factors such as risk for suicide, SUD, and other medical and mental health co-occurring conditions that may complicate management of pain for these patients. Further, these recommendations were made keeping in mind the implications they would have within the VA/DoD healthcare settings, particularly regarding considerations such as resource use,

accessibility, and equity related to each recommendation. Finally, the recommendations were developed keeping in mind the urgent need for rigorous attention to the balance of risks and benefits for patients within the VA/DoD specifically.

There were also some differences in the methodology used between the development of the VA/DoD OT CPG and the CDC guideline. Along with a clinical evidence review, during which the evidence was evaluated using GRADE, the CDC guideline developers also considered the findings of a contextual evidence review. Further, the CDC Core Expert Group, which consisted of subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline methodology, reviewed recommendations drafted by the CDC and evaluated how the evidence was used in the development of the recommendations, rather than developing the recommendations themselves (as was the VA/DoD OT Work Group's role in development of the VA/DoD OT CPG). While experts provided feedback on the CDC recommendations and their development, the CDC determined the final recommendations. CDC also used a review process considering and incorporating feedback from federal partners (e.g., SAMHSA, VA, DoD), stakeholders (e.g., professional organizations, delivery systems, community organizations), and other constituents (e.g., clinicians, prospective patients). The CDC guideline development process included notice in the *Federal Register* for a public review and comment period as well as peer review. Thus, the recommendations made in the CDC guideline, although similar to those made in this CPG, were likely based on a slightly different evidence base and revised based on the feedback of individuals who were considering a larger group of potential patients relative to the VA/DoD.

Thus, while the VA/DoD OT Work Group was aware of the release of the CDC guideline and considered potential implications, the CDC guideline did not form the basis of the deliberations on the strength or direction of these recommendations. The Work Group followed the VA/DoD Guideline for Guidelines, a document that details the process by which VA/DoD guidelines will be developed, including the use of the GRADE methodology.^[1] As required by Congress in CARA, the Work Group reviewed and considered the CDC guideline and its inclusion in the VA/DoD OT CPG.^[34]

D. Taxonomy

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage...Pain is always subjective...It is unquestionably a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience.”^[3,35] All of these facets signify the complexity of pain as a condition by itself and how it relates to both the brain and the body.^[36] Pain as a symptom is multifaceted and is described and characterized by many factors such as its quality (e.g., sharp versus dull), intensity, timing, location, and whether it is associated with position or movement.

Chronic pain is defined as pain lasting three months or more.^[37] It is often associated with changes in the central nervous system (CNS) known as central sensitization.^[38] Whereas acute and subacute pain are thought to involve primarily nociceptive processing areas in the CNS, chronic pain is thought to be associated with alterations in brain centers involved with emotions, reward, and executive function as well as central sensitization of nociceptive pathways across several CNS areas.^[39-41]

There are many causes of chronic pain. Pain arising from persistent peripheral stimulation could be mechanical or chemical/inflammatory in nature typically leading to well-localized nociceptive mechanism

pain. Mechanical or inflammatory pain with a visceral origin may produce a less localized pain. Neuropathic pain due to injury or disease of the central or peripheral nervous system (e.g., spinal cord injury, diabetic neuropathy, radiculopathy) may lead to poorly localized symptoms such as diffuse pain, burning, numbness, or a feeling of skin sensitivity.

A comprehensive pain assessment includes a biopsychosocial interview and focused physical exam. Elements of the biopsychosocial pain interview include a pain-related history, assessment of pertinent medical and psychiatric comorbidities including personal and family history of SUD, functional status and functional goals, coping strategies, and a variety of psychosocial factors such as the patient's beliefs and expectations about chronic pain and its treatment.[36] Patients with chronic pain may also experience worsened quality of life, mental health, immune system function, physical function, sleep, employment status, and impaired personal relationships.[3,42-44] Worsening of some of these factors (e.g., quality of life, change in employment status) seems to also be associated with pain severity and the presence of psychiatric comorbidities.[45,46] Patients with chronic pain report psychological complaints (e.g., depression, anxiety, poor self-efficacy, poor general emotional functioning) more often than patients without chronic pain.[47] Further, there can be social and psychological consequences such as decreased ability to successfully maintain relationship and career roles and increased depression, fear, and anxiety as a result of pain.[3,11]

E. Epidemiology and Impact

a. General Population

Chronic pain is among the most common, costly, and disabling chronic medical conditions in the U.S.[48-50] In the U.S., approximately 100 million adults experience chronic pain, and pain is associated with approximately 20% of ambulatory primary care and specialty visits.[3,4,11] As noted above (see [Opioid Epidemic](#)), since the late 1990s and early 2000s, the proportion of pain visits during which patients received opioids has increased significantly, as have opioid-related morbidity, mortality, overdose death, and SUD treatment admissions.[4,12,13] Approximately one in five patients with non-cancer pain or pain-related diagnoses is prescribed opioids in office-based settings.[4] According to the CDC, sales of prescription opioids U.S. quadrupled from 1999 and 2014.[12] The absolute number of deaths associated with use of opioids has increased four-fold since 2000, including by 14% from 2013 to 2014 alone.[17] Between 1999 and 2015, more than 183,000 people died from overdoses related to prescription opioids.[51] In one survey, approximately one-third of patients receiving OT for CNCP (or their family members) indicated thinking that they were “addicted” to or “dependent” on the medication or used the medication for “fun” or to “get high.”[18] From 2000 through 2013, the rate of heroin overdose deaths increased nearly four-fold.[19] In the 2000s, the majority of people entering treatment for heroin use used prescription opioids as their first opioid.[20]

b. VA/DoD Population

From fiscal years 2004 to 2012, the prevalence of opioid prescriptions among Veterans increased from 18.9% to 33.4%, an increase of 76.7%. The groups with the highest prevalence of opioid use were women and young adults (i.e., 18-34 years old).[52] In a sample of non-treatment-seeking members of the military who were interviewed within three months of returning from Afghanistan, 44% reported chronic pain and 15% reported using opioids—percentages much higher than in the general population.[53,54] Chronic pain

was also associated with poorer physical function, independent of comorbid mental health concerns in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) Veterans.[55]

In a study of Veterans with chronic pain who had been on opioids for at least 90 days, over 90% continued to use opioids one year later and nearly 80% continued to use opioids after completion of the 3.5 year follow-up period; while, in a study of civilian patients who had been on opioids for at least 90 days, approximately 65% remained on opioids through the 4.8 year follow-up period.[56,57] Rates of continuation in Veterans, based on this study, appeared to be related to age, marital status, race, geography, mental health comorbidity, and dosage. Compared to others, those who were age 50-65 years, were married, were a race other than African American, and who lived in a rural setting were more likely to continue using opioids. Veterans on higher doses of opioids were more likely to continue their use. Notably, those with mental health diagnoses were less likely to continue opioids, including those with schizophrenia and bipolar diagnoses.[56]

F. Chronic Pain and Co-occurring Conditions

Individuals with conditions that result in or co-occur with chronic pain may have different needs or respond to treatment differently than individuals with chronic pain alone. Many different physical and psychological conditions have a pain component that can be difficult to distinguish from the underlying mechanism of illness. Furthermore, the treatment of co-occurring pain and other conditions may vary or require special considerations during their management. Readers are encouraged to consult other VA/DoD CPGs for further information (see VA/DoD Clinical Practice Guidelines website: www.healthquality.va.gov).

G. Risk Factors for Adverse Outcomes of Opioid Therapy

The risk factors with the greatest impact for development of opioid-related adverse events are the duration and dose of opioid analgesic use. Beyond duration and dose of OT, many factors increase the risk of adverse outcomes and must be considered prior to initiating or continuing OT ([Box 1](#)).

Given the insufficient evidence of benefit for LOT, the clinician must carefully weigh harms and benefits and educate the patient as well as his or her family or caregiver prior to proceeding with treatment. As patient values and preferences may be impacted by other clinical considerations, some patients with one or more risk factors for adverse outcomes may differ with the clinician's assessment that the risks of OT outweigh the potential for modest short-term benefits. Thus, it is important to consider patients' values and concerns, address misconceptions, express empathy, and fully explain to patients with one or more risk factors that they may not benefit from, and may even be harmed by, treatment with OT.

Conditions that significantly increase the risk of adverse outcomes from LOT are listed below. Patients for whom LOT is initiated should be carefully monitored, and ongoing assessment of risk should be performed with vigilance for the development of additional risk factors and adverse outcomes (see [Recommendations 7-9](#)). Consider consultation with appropriate specialty care providers if there is uncertainty about whether benefits of OT, such as improved function (e.g., return-to-work), outweigh the risks.

Box 1: Selected Significant Risk Factors

- Duration and dose of OT
- Severe respiratory instability
- Sleep disordered breathing (e.g., sleep apnea)
- Acute psychiatric instability or intermediate to high acute suicide risk
 - Suicidality (see [Recommendation 8](#); VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide [VA/DoD Suicide CPG], available at: <http://www.healthquality.va.gov/guidelines/MH/srb/>)
- Mental disorders
 - Current or history of SUD (see VA/DoD SUD CPG, available at: <http://www.healthquality.va.gov/guidelines/mh/sud/index.asp>)
 - ◆ Untreated SUD confers additional risk (see [Recommendation 4](#))
 - Depression or history of depression (see VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder [VA/DoD MDD CPG] as appropriate, available at: <http://www.healthquality.va.gov/guidelines/MH/mdd/>)
 - Generalized anxiety disorder
 - Borderline personality disorder
 - Antisocial personality disorder
 - Posttraumatic stress disorder (PTSD) (see VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder [VA/DoD PTSD CPG], available at: <http://www.healthquality.va.gov/guidelines/MH/ptsd/>)
- History of drug overdose
- Under 30 years of age (see [Recommendation 6](#))
- Co-administration of a drug capable of inducing fatal drug-drug interactions (e.g., see [Recommendation 5](#))
- QTc interval >450 milliseconds (ms) for using methadone
- Evidence for or history of diversion of controlled substances
- Intolerance, serious adverse effects, or a history of inadequate beneficial response to opioids
- Impaired bowel motility unresponsive to therapy
- Traumatic brain injury
- Pain conditions worsened by opioids (e.g., fibromyalgia, headache)
- True allergy to opioid agents (that cannot be resolved by switching agents)

a. Significant Risk Factors

- **Duration and dose of OT:** See [Recommendation 2](#) for more guidance on duration of OT and [Recommendations 10-12](#) for more guidance on dosing of OT.
- **Severe respiratory instability or sleep disordered breathing:** This would include any co-occurring condition that significantly affects respiratory rate or function such as chronic obstructive pulmonary disease (COPD), asthma, pneumonia, sleep apnea, or a neuromuscular condition (e.g., amyotrophic lateral sclerosis). Two large observational studies of patients with a history of COPD and sleep apnea who were prescribed opioids showed a weak but positive association with opioid-related toxicity/overdose and overdose-related death.[\[58,59\]](#)
- **Acute psychiatric instability or intermediate to high acute suicide risk:** Intermediate to high acute suicide risk, severe depression, unstable bipolar disorder, or unstable psychotic disorder precludes the safe use of self-administered LOT.[\[60\]](#) Im et al. (2015) (n=487,462) found that a diagnosis of a mood disorder was significantly associated with suicide attempts for the chronic use of short-acting and long-acting opioids compared with no diagnosis of a mood disorder.[\[61\]](#)

In a study of patients on opioids, Campbell et al. (2015) reported that those with bipolar disorder had 2.9 times the odds of a suicidal ideation within the past 12 months as well as 3.2 times the odds of a lifetime suicide attempt compared to those with no bipolar disorder.[62] See [Recommendation 8](#) and the VA/DoD Suicide CPG² for more information on suicidality. See the VA/DoD Clinical Practice Guideline for Management of Bipolar Disorder in Adults (VA/DoD BD CPG) for more information on bipolar disorder.³ Merrill and colleagues found that high dose chronic opioid therapy for pain was associated with depressed mood.[63] Treatment for chronic pain with movement, exercise and cognitive-behavioral therapy for pain may have benefit in treating depression, PTSD, and in reducing suicide risk.[64]

- **Mental health disorders:**

- **Current or history of SUD:** For patients with untreated SUD, see [Recommendation 4](#). For patients with diagnosed OUD, see [Recommendation 17](#). Frequent requests for early refills or atypically large quantities required to control pain can signal an emerging SUD as well as diversion (see [Evidence for or history of diversion of controlled substances](#)). See the VA/DoD SUD CPG.⁴
 - **Depression or history of depression:** Zedler et al. (2014) reported that among patients being treated by the VHA system that received opioids, a history of depression was significantly associated with opioid-related toxicity/overdose compared to no history of depression.[58] LOT has been associated with worsening depressive symptoms.[63] See the VA/DoD MDD CPG.⁵
 - **PTSD:** Seal et al. (2012) (n=15,676) noted that among patients on OT, a prevalence of self-inflicted injuries was significantly higher among patients with a history of PTSD (with or without other mental health diagnoses) as compared to patients with other (or no) mental health diagnoses.[65] For more information, see the VA/DoD PTSD CPG.⁶
- **History of drug overdose:** A history of overdose is a red flag and providers should proceed with utmost caution when considering LOT for these patients.
 - **Under 30 years of age:** See [Recommendation 6](#).

² See the VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk of Suicide. Available at: <http://www.healthquality.va.gov/guidelines/MH/srb/>

³ See the VA/DoD Clinical Practice Guideline for Management of Bipolar Disorder in Adults. Available at: <http://www.healthquality.va.gov/guidelines/MH/bd/>

⁴ See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders. Available at: <http://www.healthquality.va.gov/guidelines/mh/sud/index.asp>.

⁵ See the VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder. Available at: <http://www.healthquality.va.gov/guidelines/MH/mdd/>

⁶ See the VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder. Available at: <http://www.healthquality.va.gov/guidelines/MH/ptsd/>

- **Co-administration of a drug capable of inducing fatal drug-drug interactions:** Providers should carefully rule out and avoid potential drug interactions prior to initiating LOT. For example, the following combinations are dangerous:[\[66\]](#)
 - Opioids with benzodiazepines (compared to patients with no prescription, the odds ratio [OR] and 95% confidence interval [CI] for drug-related death was OR: 14.92, 95% CI: 7.00-31.77 for patients who filled a prescription for opioids and benzodiazepines; OR: 3.40, 95% CI: 1.60-7.21 for patients who filled only an opioid prescription, and 7.21, 95% CI: 3.33-15.60 for patients who filled only a benzodiazepine prescription) (see [Recommendation 5](#)) [\[66,67\]](#)
 - Fentanyl with CYP3A4 inhibitors
 - Methadone with drugs that can prolong the QT interval (the heart rate's corrected time interval from the start of the Q wave to the end of the T wave) (e.g., CYP450 2B6 inhibitors)
- **QTc interval >450 ms for using methadone:** Unlike most other commonly used opioids, methadone has unique pharmacodynamic properties that can prolong the QTc interval (the heart rate's corrected time interval from the start of the Q wave to the end of the T wave) and precipitate torsades de pointes, a dangerous or fatal cardiac arrhythmia. Patients who may be at risk include those with other risk factors for QTc prolongation, current or prior electrocardiograms (ECGs) with a prolonged QTc >450 ms, or a history of syncope. Therefore, ECGs before and after initiating methadone are highly advised (see [Methadone Dosing Guidance](#)).
- **Evidence for or history of diversion of controlled substances:** The clinician should communicate to patients that drug diversion is a crime and constitutes an absolute contraindication to prescribing additional medications. Because suspicion is subjective and may be based on impression, bias, or prejudice, it is important that providers who suspect diversion base treatment plans on objective evidence. Suspicions may be confirmed by a negative mass spectrometry/liquid chromatography UDT for the substance being prescribed in the absence of withdrawal symptoms in someone who is receiving opioids. A negative UDT for the prescribed opioid could also by itself be a sign of diversion. Signs of diversion may also include frequent requests for early refills or atypically large quantities required to control pain. Routine UDT, however, may not reliably detect synthetic opioids (e.g., methadone, fentanyl, tramadol) or semi-synthetic opioids (e.g., oxycodone, hydrocodone, hydromorphone). When there is evidence that the patient is diverting opioids, discontinue opioids according to [Recommendations 14 and 15](#) and assess for underlying OUD and/or psychiatric comorbidities. Consultation with a pain specialist, psychiatrist, or SUD specialist may be warranted. Also consider consultation with local risk management and/or counsel. For patients with OUD, keep in mind that sudden discontinuation of opioids due to suspected diversion may place them at high risk for illicit opioid use and resulting opioid overdose (see [Recommendation 17](#)).
- **Intolerance, serious adverse effects, or a history of inadequate beneficial response to opioids:** Serious harm may occur should patients be prescribed additional (or different) opioids if prior administration of opioids led to serious adverse effects or was not tolerated. It is also inadvisable to prescribe opioids to patients who already have had an adequate opioid trial (of

sufficient dose and duration to determine whether or not it will optimize benefit) without a positive response.

- **Impaired bowel motility unresponsive to therapy:** Opioids inhibit bowel peristalsis. Their use with patients with impaired bowel motility can increase the risk of severe constipation/impaction or possible obstruction.
- **Headache not responsive to other pain treatment modalities:** LOT is an ineffective treatment modality for patients with migraine headaches (with or without aura), tension-type headaches, occipital neuralgia, or myofascial pain and may result in worsening of the underlying headache condition through factors such as central sensitization and withdrawal.
- **Traumatic brain injury (TBI):** Patients with a history of TBI who use chronic short-acting and long-acting opioids are more likely to attempt suicide.[\[61\]](#)
- **True allergy to opioid agents:** Morphine causes a release of histamine that frequently results in itching, but this does not constitute an allergic reaction. True allergy to opioid agents (e.g., anaphylaxis) is not common, but does occur. Generally, allergy to one opioid does not mean the patient is allergic to other opioids; many times, rotating to a different opioid may be effective. When an opioid allergy is present and OT is being considered, consultation with an allergist may be helpful.

VI. About this Clinical Practice Guideline

This OT CPG is in line with the efforts described above to improve our understanding and treatment of pain, as well as to mitigate the inappropriate prescribing and ill effects of opioids. It is intended for VA and DoD healthcare practitioners including physicians, nurse practitioners, physician assistants, physical and occupational therapists, psychologists, social workers, nurses, clinical pharmacists, chaplains, addiction counselors, and others involved in the care of Service Members and their beneficiaries, retirees and their beneficiaries, or Veterans on or being considered for LOT. In conjunction with other efforts already under way, this CPG is aimed at improving safe and appropriate prescribing and use of opioids to treat chronic pain.

As with other CPGs, there are limitations, including significant evidence gaps. Further, there is a need to develop effective strategies for guideline implementation and evaluation of the effect of guideline adherence on clinical outcomes. Thus, as stated in the qualifying statements at the beginning of the CPG, this CPG is not intended to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns evolve. This CPG is based on evidence available by December 2016 and is intended to provide a general guide to best practices. The guideline can assist healthcare providers, but the use of a CPG must always be considered as a recommendation, within the context of a provider's clinical judgment and patient values and preferences, for the care of an individual patient.

A. Scope of this Clinical Practice Guideline

This OT CPG is designed to assist healthcare providers in managing or co-managing patients on or being considered for LOT. Specifically, this CPG is intended for adults, including Veterans as well as deployed and non-deployed Active Duty Service Members, their beneficiaries, and retirees and their beneficiaries, with chronic pain who are receiving care from the VA or DoD healthcare delivery systems. This CPG is not intended for and does not provide recommendations for the management of pain with LOT in children or adolescents, in patients with acute pain, or in patients receiving end-of-life care. As is so for any pharmacotherapy, any decision about prescribing opioids, or alternative medications for pain, for pregnant women should be made with due caution and cognizance of applicable U.S. Food and Drug Administration (FDA) labeling. Any patient in the VA or DoD healthcare system should be offered access to the interventions that are recommended in this guideline after taking into consideration the patient's specific circumstances.

While these guidelines are broadly recommended, their implementation is intended to be patient-centered. Thus, treatment and care should take into account a patient's needs and preferences. Good communication between healthcare professionals and the patient about the patient's pain experience, treatment goals, and challenges is essential and should be guided by evidence-based information tailored to the patient's needs. An empathetic and non-judgmental (versus a confrontational or adversarial) approach to communication with a patient is highly recommended in order to build trust and facilitate frank discussions relating to the social, economic, emotional, and cultural factors that influence patients' perceptions, behaviors, and decision making.

The information that patients are given about treatment and care should be culturally appropriate and also available to people with limited literacy skills. It should also be accessible to people with additional

needs such as physical, sensory, or learning disabilities. Family involvement should be considered if appropriate.

The systematic review conducted for the update of this CPG encompassed interventional studies (primarily randomized controlled trials [RCTs]) published between March 2009 and December 2016 and targeted nine key questions (KQs) focusing on the means by which the delivery of healthcare could be optimized for patients on or being considered for LOT. Because a comprehensive review of the evidence related to LOT was not feasible, the nine selected KQs were prioritized from many possible KQs. Therefore, many of the 2010 OT CPG recommendations were considered for inclusion in the updated version of the guideline without an updated review of the evidence. The section on [Recommendations](#) delineates whether or not the current CPG recommendations were based on an updated evidence review. [Appendix H](#) delineates whether the 2010 OT CPG recommendations were considered for inclusion in the update based on an updated evidence review or based on the evidence included in the 2010 OT CPG. The section on [Recommendation Categorization](#) further describes the methodology used for the categorization.

B. Highlighted Features of this Clinical Practice Guideline

The 2017 version of the VA/DoD OT CPG is the second update to the original CPG. It provides practice recommendations for the care of populations with chronic pain already on or being considered for LOT. Although there are many other approaches to the treatment of chronic pain, the scope of this CPG is to focus on the use of opioids for chronic pain rather than being comprehensive about all treatment options. A particular strength of this CPG is the multidisciplinary stakeholder involvement from its inception, ensuring representation from the broad spectrum of clinicians engaged in the treatment and management of patients with chronic pain on or being considered for LOT.

The framework for recommendations in this CPG considered factors beyond the strength of the evidence, including balancing desired outcomes with potential harms of treatment, equity of resource availability, the potential for variation in patient values and preferences, and other considerations (see [Methods](#) for more information). Applicability of the evidence to VA/DoD populations was also taken into consideration. A structured algorithm (see [Algorithm](#)) accompanies the guideline to provide an overview of the recommendations in the context of the flow of patient care and clinician decision making and to assist with training providers. The algorithm may be used to help facilitate translation of guideline recommendations into effective practice.

C. Methods

The current document is an update to the 2010 *VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain*. The methodology used in developing the 2017 CPG follows the VA/DoD Guideline for Guidelines,^[1] an internal document of the VA and DoD EBPWG. The VA/DoD Guideline for Guidelines can be downloaded from <http://www.healthquality.va.gov/policy/index.asp>. This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (“Champions”) and other subject matter experts from within the VA and DoD, known as the “Work Group,” and ultimately, the development and submission of an updated OT CPG. The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified two clinical leaders,

Jack Rosenberg, MD, FASAM from the VA and Christopher Spevak, MD, MPH, JD from the DoD, as Champions for the 2017 CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical practice recommendations and writing and publishing a guideline document to be used by providers within the VA and DoD healthcare systems. Specifically, the Champions and the Work Group were responsible for identifying the KQs – those considered most clinically relevant, important, and interesting with respect to the management of patients with chronic pain on or being considered for LOT. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in October 2015, with participation from the contracting officer's representative (COR), leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review about the management of LOT. The group also identified a list of clinical specialties and areas of expertise that were important and relevant to the management of LOT, from which Work Group members were recruited. The specialties and clinical areas of interest included: Anesthesiology, Addictive Disorders and Addiction Medicine, Clinical Neurophysiology, Family Medicine, Geriatrics, Internal Medicine, Mental/Behavioral Health, Neurology, Nursing, Pain Management, Pain Medicine, Pain Psychology, Palliative Care, Pharmacy, Physical Medicine and Rehabilitation, Physical Therapy, Primary Care, Psychiatry, Psychology, and Social Work.

The guideline development process for the 2017 CPG update consisted of the following steps:

1. Formulating and prioritizing KQs (or evidence questions)
2. Conducting the systematic review of the literature
3. Convening a face-to-face meeting with the CPG Champions and Work Group
4. Drafting, revising, and submitting a final CPG about the management of LOT to the VA/DoD EBPWG

[Appendix E](#) provides a detailed description of each of these tasks.

b. Grading Recommendations

The Champions and Work Group used the GRADE system to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:[68]

- Confidence in the quality of the evidence
- Balance of desirable and undesirable outcomes
- Patient or provider values and preferences
- Other implications, as appropriate, e.g.,:
 - Resource use
 - Equity
 - Acceptability
 - Feasibility
 - Subgroup considerations

Using this system, the Champions and Work Group determined the direction (for or against) and relative strength (strong or weak) of each recommendation.[68] The direction indicates that the desirable effects of the recommendation outweigh the undesirable effects of the recommendation (for) or that the opposite is true (against). The strength indicates the Work Group’s level of confidence in the balance of desirable and undesirable effects of the recommendation among the intended patient population.[69] A strong recommendation indicates the Work Group is confident in this balance (e.g., that the desirable effects outweigh the undesirable effects). A weak recommendation indicates that the balance is still likely, but the Work Group’s confidence in the balance is lower than for a strong recommendation.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or “We recommend offering this option ...”)
- Weak For (or “We suggest offering this option ...”)
- Weak Against (or “We suggest not offering this option ...”)
- Strong Against (or “We recommend against offering this option ...”)

The grade of each recommendation made in the 2017 OT CPG can be found in [Recommendations](#). Additional information regarding the use of the GRADE system can be found in [Grading Recommendations](#).

c. Reconciling 2010 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence or as scheduled, subject to time-based expirations.[70] For example, the United States Preventive Services Task Force (USPSTF) has a process for refining or otherwise updating its recommendations pertaining to preventive services.[71] Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The 2017 OT CPG is an update of the 2010 CPG. Thus, the structure and content of the 2017 CPG is reflective of the previous version of the CPG, but modified where necessary to reflect new evidence and new clinical priorities.

The Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the Work Group considered the current applicability of other recommendations that were included in the previous 2010 OT CPG without complete review of the relevant evidence, subject to evolving practice in today's environment.

To indicate which recommendations were developed based on the updated review of the evidence versus recommendations that were carried forward from the 2010 version of the CPG, a set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE).^[72,73] These categories, along with their corresponding definitions, were used to account for the various ways in which older recommendations could have been updated. In brief, the categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current patient care environment and inside the scope of the CPG. Additional information regarding these categories and their definitions can be found in the section on [Recommendation Categorization](#). The categories for the recommendations included in the 2017 CPG can be found in the [Recommendations](#) section. The categorizations for each 2010 CPG recommendation can be found in [Appendix H](#).

Between the development of the 2010 and 2017 versions of the OT CPG, VA/DoD adopted a new evidence rating system. The CPG Work Group recognized the need to accommodate this transition in evidence rating systems from the USPSTF system in the 2010 CPG to the GRADE system in the 2017 CPG. In order to report the strength of all recommendations using a consistent format (i.e., the GRADE system) the Work Group converted the USPSTF evidence grades accompanying the carryover recommendations from the 2010 guideline to the GRADE system. As such, the CPG Work Group considered the strength of the evidence cited for each recommendation in the 2010 OT CPG as well as harms and benefits, values and preferences, and other implications, where possible.

In cases where a 2010 OT CPG recommendation was covered by a 2017 KQ, peer-reviewed literature published since the 2010 OT CPG was considered along with the evidence base used for the 2010 CPG. Where new literature was considered in converting the strength of the recommendation from the USPSTF to the GRADE system, it is referenced in the discussion following the corresponding recommendation, as well as in [Appendix G](#).

The CPG Work Group recognizes that, while there are practical reasons for incorporating findings from a previous systematic review, previous recommendations, or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive systematic review and, therefore, may introduce bias.^[74]

d. Peer Review Process

The CPG was developed through an iterative process in which the Work Group produced multiple drafts of the CPG. The process for developing the initial draft is described in more detail in [Drafting and Submitting the Final Clinical Practice Guideline](#).

Once a near-final draft of the guideline was agreed upon by the Champions and Work Group, the draft was sent out for peer review and comment. The draft was posted on a wiki website for a period of 14 business days. The peer reviewers comprised individuals working within the VA and DoD health systems as well as experts from relevant outside organizations designated by the Work Group. External organizations that participated in the peer review included the following:

- American Academy of Addiction Psychiatry (AAAP)
- American Academy of Pain Medicine (AAPM)
- American Physical Therapy Association (APTA)
- American Society of Addiction Medicine (ASAM)
- University of Kentucky
- University of Minnesota

VA and DoD Leadership reached out to both the internal and external peer reviewers to solicit their feedback on the CPG. Reviewers were provided a hyperlink to the wiki website where the draft CPG was posted. For transparency, all reviewer feedback was posted in tabular form on the wiki site, along with the name of the reviewer. All feedback from the peer reviewers was discussed and considered by the Work Group. Modifications made throughout the CPG development process were made in accordance with the evidence.

D. Implementation

This CPG, including its recommendations and algorithm, is designed to be adapted by healthcare providers for the treatment of individual patients, bearing in mind patient-level considerations as well as local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of care.

Although this CPG represents the recommended practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating based on published information. New technology and more research will improve patient care in the future. Identifying areas where evidence was lacking for the 2017 CPG can help identify priority areas for future research. Future studies examining the results of OT CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

E. Summary of Patient Focus Group Methods and Findings

When forming guideline recommendations, consideration should be given to the values of those most affected by the recommendations: patients. Patients bring perspectives, values, and preferences into their healthcare experience, and more specifically their pain care experience, that can vary from those of clinicians. These differences can affect decision making in various situations, and should thus be

highlighted and made explicit due to their potential to influence a recommendation’s implementation.[75,76] Focus groups can be used as an efficient method to explore ideas and perspectives of a group of individuals with an *a priori* set of assumptions or hypotheses and collect qualitative data on a thoughtfully predetermined set of questions.

Therefore, as part of the effort to update this CPG, VA and DoD Leadership, along with the OT CPG Work Group, held a patient focus group on December 14, 2015, at the Washington DC VA Medical Center. One additional family caregiver was interviewed separately at a later date. The aim of the focus group and interview was to further the understanding of the perspectives of patients receiving OT within the VA and/or DoD healthcare systems. The focus group and interview explored patient perspectives on a set of topics related to management of OT in the VA and DoD healthcare systems, including knowledge of OT and other pain treatment options, delivery of care, and the impact of and challenges with OT and chronic pain.

It is important to note the focus group was a convenience sample and the Work Group recognizes the limitations inherent in the small sample size. Less than 10 people were included in the focus group consistent with the requirements of the federal Paperwork Reduction Act, 1980. The Work Group acknowledges that the sample of patients included in this focus group may not be representative of all VA and DoD patients on or being considered for OT for chronic pain. Further, time limitations for the focus group prevented exhaustive exploration of all topics related to pain care in the VA and DoD and the patients’ broader experiences with their care. Thus, the Work Group made decisions regarding the priority of topics to discuss at the focus group and interview. These limitations, as well as others, were considered as the information collected from the discussion was used for guideline development. Recruitment for participation in the focus group was managed by the Champions and VA and DoD Leadership, with assistance from coordinators at the facility at which the focus group took place.

The following concepts are ideas and suggestions about aspects of care that are important to patients and family caregivers and that emerged from the discussion. These concepts were needed and important parts of the participants’ care and added to the Work Group’s understanding of patient values and perspectives. Additional details regarding the patient focus group methods and findings can be found in [Appendix F](#).

OT CPG Focus Group Concepts	
A.	Using shared decision making, consider all treatment options and develop treatment plan based on the balance of risks, benefits, and patient-specific goals, values, and preferences
B.	Modify treatment based on patient response, considering patient-specific goals, values, and preferences
C.	Involve family caregivers in accordance with patient preferences and maintain open, trusting, and respectful relationship with patients and family caregivers
D.	Educate patients regarding treatment plan, alternative treatment options, and monitoring
E.	Within and between healthcare systems, work with appropriate providers to ensure continuity of high quality care
F.	Organize treatment to encourage patient adherence and participation
G.	Acknowledge and minimize effects of potential medical error and take action to prevent future medical error

F. Conflict of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in

the past 24 months. Verbal affirmations of no COI were also used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., ProPublica).

If a project team member reported a COI (actual or potential), measures were in place to mitigate the introduction of bias into the guideline development process. Identified COIs would be reported to the Office of Evidence Based Practice and disclosed to the CPG Work Group in tandem with their review of the evidence and development of recommendations. The Office of Evidence Based Practice and the OT CPG Work Group would then determine whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If deemed necessary, action would have been taken by the co-chairs and the Office of Evidence Based Practice, based on the level and extent of involvement, to mitigate the COI.

No OT CPG Work Group members reported relationships and/or affiliations which had the potential to introduce bias; thus, no further action was taken to mitigate COIs for this particular CPG.

G. Patient-centered Care

VA/DoD CPGs encourage clinicians to use a patient-centered care approach that is tailored to the patient's capabilities, needs, goals, prior treatment experience, and preferences. Regardless of setting, all patients in the healthcare system should be offered access to evidence-based interventions appropriate to that patient. When properly executed, patient-centered care may decrease patient anxiety, increase trust in clinicians,^[77] and improve treatment adherence.^[78] Improved patient-clinician communication through patient-centered care can be used to convey openness to discuss any future concerns.

As part of the patient-centered care approach, clinicians should review the patient's history including previous treatment approaches, their results, and any other outcomes with the patient. They should ask the patient about his or her willingness to accept a referral to an addiction or other behavioral health specialist when appropriate. Lastly, they should involve the patient in prioritizing problems to be addressed and in setting specific goals regardless of the selected setting or level of care. The below approach may be used in setting SMART (Specific, Measurable, Action Oriented, Realistic, Timed) goals for the patient ([Table 1](#)).

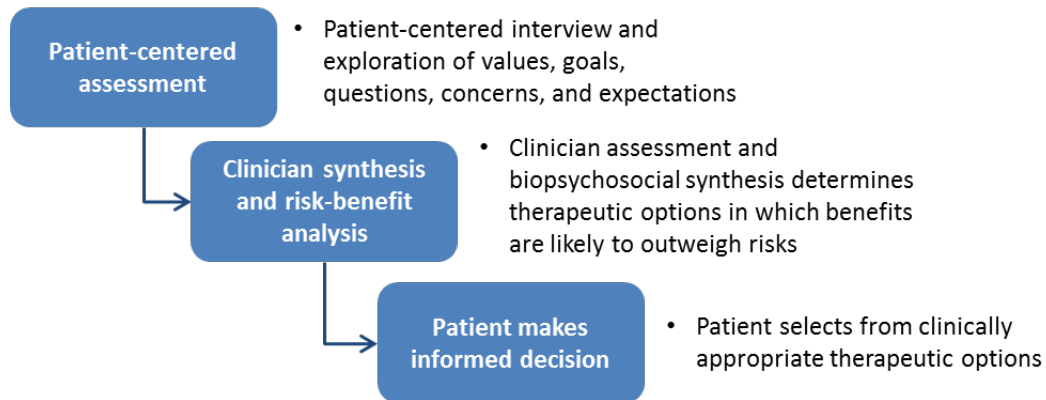
Table 1. Guide in Setting SMART Goals [79]

<u>Specific</u>	A goal should be clear and concise. It is difficult to know when action toward a goal has been started and when it has been completed if it is not specific.
<u>Measurable</u>	A goal should be measurable so that Veterans can track their progress. Veterans need to have clear criteria for progress and completion when taking action on a goal. Keeping tabs on progress can be inspiring.
<u>Action Oriented</u>	A goal should include action. And that action should be in direct control of the Veteran.
<u>Realistic</u>	A goal should be largely within the reach of the Veterans. It is best to work on small lifestyle changes that are doable. Avoid the pitfalls of having Veterans see only the big picture and not the small steps.
<u>Timed</u>	A goal should be tied to a timetable for completing specific, measurable and realistic action.

H. Shared Decision Making

The shared decision making process for chronic pain treatment planning is based on the foundation of a patient-centered assessment of risks and benefits and a clinical synthesis performed by the provider (Figure 1). The patient-centered assessment incorporates a patient-centered interview, and exploration of patient values, goals, questions, concerns, and expectations. Next, the clinician performs a biopsychosocial assessment and determines clinically appropriate therapeutic options in which benefits are likely to outweigh risks. The process culminates in a shared decision making process to develop a patient-centered treatment plan by the patient selecting from the clinically appropriate treatment options generated in the first two steps.

Figure 1. Shared Decision Making for Chronic Pain Treatment and Long-Term Opioid Therapy

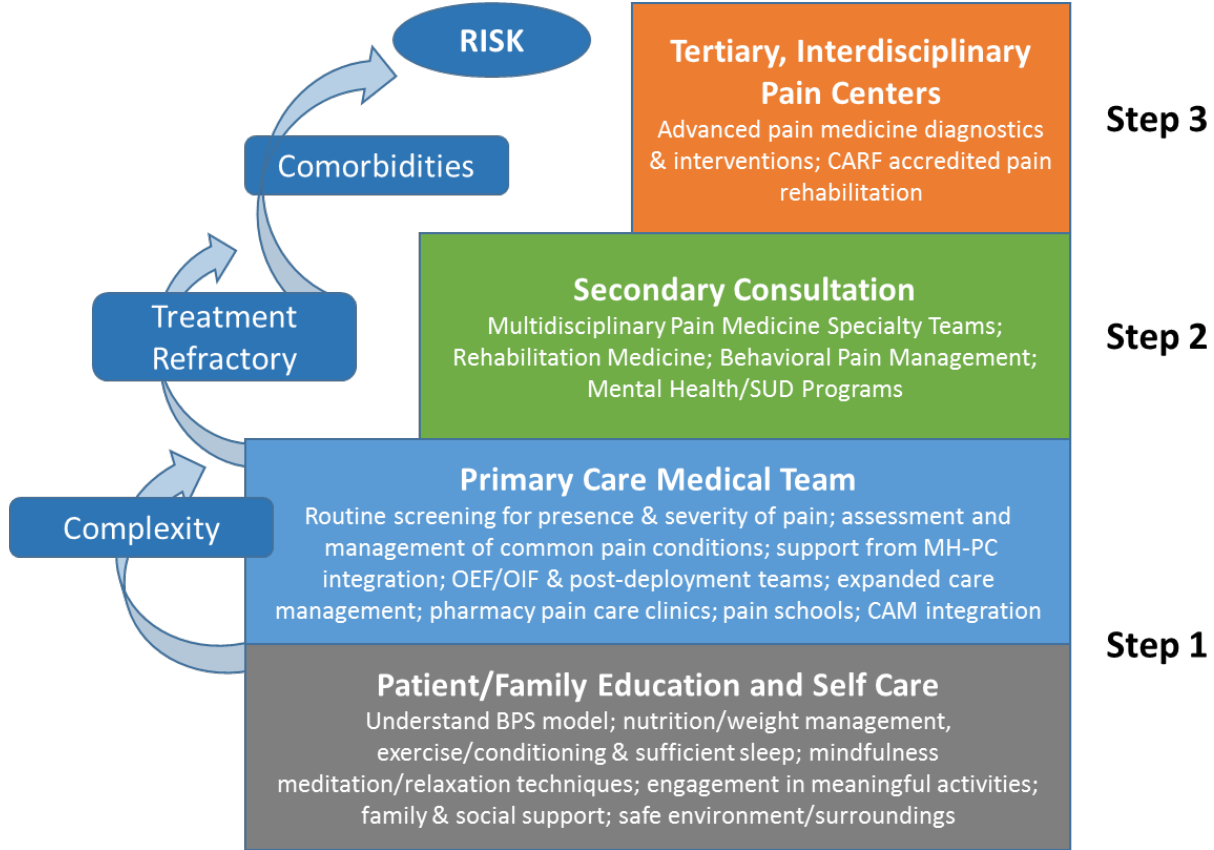


I. Stepped Care Model for Pain Management

The Stepped Care Model for Pain Management, developed by VA, has been implemented within both the VHA and Military Health System (MHS) with the aim of providing a continuum of effective, coordinated, and patient-centered treatment to patients with pain. With education, self-care, and whole-health approaches to wellness as the foundation, this model provides progressively more intensive biopsychosocial care within increasingly specialized settings as patients become more complex, have a greater degree of comorbidity, and present higher risk. Psychological, physical, complementary and

alternative, and medication therapies are often combined to create a multimodal pain care plan. The goals of the Stepped Care Model for Pain Management include functional rehabilitation, improvement in quality of life, and prevention of the pain becoming chronic and associated deterioration in function (Figure 2).

Figure 2. Stepped Care Model for Pain Management*



*Adapted from the Interagency Pain Research Coordinating Committee’s National Pain Strategy (2016) [26]
 Abbreviations: BPS: biopsychosocial; CAM: complementary and alternative medicine; CARF: Commission on Accreditation of Rehabilitation Facilities; MH-PC: Primary Care-Mental Health; OEF: Operation Enduring Freedom; OIF: Operation Iraqi Freedom; PACT: Patient Aligned Care Team; SUD: substance use disorders

J. Transfer of Care

As the entire medical community is moving toward a greater understanding of the need for opioid safety, it is possible that a provider may receive, as a result of a transfer of care, a patient on a high-risk opioid regimen that raises concerns related to the provider’s and patient’s current understanding of opioid risks. Some universal approaches should be used in the management of care for the patient regardless of the location from which that patient is transferred.

- Clinicians should provide each new patient with a full evaluation, understanding that chronic pain is a complex process that requires a comprehensive assessment of the whole individual as well as their social circumstances. The general goals of the interview with the patient are to do more than just gather information. This process should build a therapeutic relationship as well as facilitate behavior change when necessary. It is important to understand the situation from

the patient's perspective, elicit a pain-specific history to aid in establishing the correct pain diagnosis, identify patient-specific coping strategies, identify patient-specific pain interference with functioning, and identify important co-occurring conditions. The transferring provider should also communicate the patient's medical history to the receiving provider to ensure it is taken into account along with the patient's perspective. This can aid the clinician in synthesizing the full biopsychosocial story.

- Clinicians should review previous medical records to determine what diagnostic and therapeutic options have already been tried. In addition, previous medical records can help to determine the patient's risk of a non-overdose opioid-related adverse event, overdose risk, and risk of having developed or developing OUD. It can also help to determine co-occurring conditions that will need to be evaluated and treated in order to put together a comprehensive approach to this patient's pain.
- Clinicians should determine what the patient knows about current concerns related to OT and how comfortable he or she is with an approach that will be addressing opioid safety along with an integrated whole person approach to pain. Each patient may arrive from other providers with a different understanding of the current concerns related to OT, and educational gaps will need to be acknowledged and addressed.
- Clinicians should offer all new patients a physical exam to help to determine the cause of the pain as well as co-occurring conditions that may complicate pain symptoms and/or treatment.
- Clinicians should provide each patient an assessment that outlines the specifics related to opioid safety.
 - What is the diagnosis for which opioids are prescribed?
 - What non-opioid therapies have been trialed and/or is the patient currently using?
 - Are there co-occurring conditions or medication doses/combinations that would increase the risk of OT?
- Clinicians should use standard opioid risk mitigation strategies such as checking the Prescription Drug Monitoring Programs (PDMPs); making sure the patient has participated in shared-decision making about OT and signed and understands the opioid informed consent (see [Appendix A](#)); obtaining consent for and performing a UDT (see [Appendix B](#)); and offering OEND. See [Recommendation 7](#) for more information on risk mitigation.

One frequently asked question is how to proceed when a patient requests to transfer an opioid prescription that the receiving provider has determined to be too risky to continue. For patients transferred from within the VA and/or DoD system, clinicians should employ risk stratified tapering strategies (see [Recommendations 14 and 15](#)). Clinicians should engage patients in shared decision making including consideration of the patient's values, goals, concerns, and preferences prior to tapering. It is also important that clinicians assess for and treat OUD when present (see [Recommendation 17](#)).

For patients who are transferring from outside of the VA and/or DoD, there may be some unique issues to consider.

- Are complete medical records available that would inform treatment planning? Until full record review and communication with the previous prescriber are completed, there are significant risks of taking over opioid prescribing even if it is with intent to taper.
- Has the new plan of care been communicated to the previous prescriber and the patient? If it is felt that the regimen is too risky to take over the management with the resources available, then it is important to communicate this to the patient as well as the previous prescriber so that they can begin an exit plan for the patient as indicated. If the new provider feels comfortable taking over the OT, even if it is to start a taper, then this needs to be communicated to the previous prescriber as soon as possible to avoid duplication of prescriptions.

K. Clinical Decision Support Tools

There are electronic tools to facilitate clinical risk assessment and adherence to risk mitigation. Two tools currently used in the VA are the Opioid Therapy Risk Report (OTRR) and the Stratification Tool for Opioid Risk Mitigation (STORM). The OTRR allows VA providers to review clinical data related to opioid pain treatment within the electronic medical record (EMR), providing an efficient way of monitoring the data. The STORM tool incorporates co-occurring medical and mental health conditions, SUD, opioid dose, co-prescribed sedatives, and information about prior adverse events and generates estimates of patients' risk or hypothetical risk when considering initiation of opioid therapy. It quantifies risk for poisoning or suicide-related events and for drug-related events, accidents, falls, and drug-induced conditions over a three-year window. Further, it provides suggestions as to what alternative treatments have not been tried and what risk mitigation strategies need to be applied. Evidence supporting their use is poor but they facilitate providers' determination of current, past and potential therapies and strategies.

The Opioid Therapy for Chronic Pain Work Group.
(2017, February).
VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.
Department of Veterans Affairs, Department of Defense.

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