APA Clinical Practice Guideline for the Treatment of Chronic Musculoskeletal Pain in Adults

American Psychological Association

Guideline Development Panel for the Treatment of Chronic Musculoskeletal Pain in Adults

Author Note

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Please refer to pp. 71-73 of this guideline for a statement on conflicts of interest as well as p. 80 for acknowledgements.

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Abstract

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Intended Use of Guidelines

This guideline is aspirational in nature and not intended to create a requirement for practice. It is not meant to restrict scope of practice in licensing laws for psychologists or for other independently licensed professionals, nor limit coverage for reimbursement by third- party payers. The guideline is also not intended to be used within a legal or judicial context to imply that psychologists or other independently licensed professionals are required to comply with any of its recommendations.

The term “guidelines” refers to statements that suggest or recommend specific professional behavior, endeavor, or conduct for psychologists, and may also be useful for other clinicians. They differ from standards in that the latter are mandatory and may be accompanied by an enforcement mechanism. Thus, guidelines are aspirational and intended to facilitate the continued systematic development of the profession and to help assure a high level of professional practice by psychologists. Guidelines are not intended to be mandatory or exhaustive and may not be applicable to every professional and clinical situation. They are not definitive, and they are not intended to take precedence over the judgment of psychologists. Please refer to the APA’s (2015a) *Professional Practice Guidelines: Guidance for Developers and Users* for a discussion of the several types of guidelines produced by APA. Clinical practice guidelines are an important tool for determining intervention options, but not the only resource.

Clinicians are encouraged to consider the report from the APA Presidential Task Force on Evidence-Based Practice (2006), *Evidence-Based Practice in Psychology*, as well as APA’s (2021) *Professional Practice Guidelines on Evidence-Based Psychological Practice in Health Care*, which emphasizes the integration of best available research; patient characteristics, culture and preferences; and clinical expertise for making treatment decisions.

In reviewing the recommendation statements, the panel reminds the reader that a lack of evidence about a treatment does not imply that a particular treatment is not efficacious. Multiple

reasons may account for the findings reported in this document, including (but not limited to) gaps in the literature related to particular treatments or limitations in the specific literature reviewed by the panel, based on methodological constraints, all of which will be discussed later in the guideline document. Ultimately, when clinicians are developing treatment plans, they are encouraged to do so in a shared decision-making process with the patient in which all relevant information about options is presented to help inform the process.

Executive Summary

Scope

This guideline is intended to provide recommendations for the treatment of chronic musculoskeletal pain (including low back [LBP], neck, hand, hip, knee, hand osteoarthritis [OA] and other widespread pain[1]) in adults, based on systematic reviews of the scientific evidence. Three current systematic reviews and meta-analyses (Geraghty et al., 2021; Skelly et al., 2020; Williams et al., 2020) that were determined to be most relevant to the panel's scope served as the basis for this guideline. This guideline addresses the efficacy of nonpharmacologic (i.e., psychological therapies, exercise[2], physical modalities, manual therapies), and complementary and integrative treatments (e.g., acupuncture, mindfulness practices, mind-body practices, multidisciplinary rehabilitation), as well as the comparative effectiveness of nonpharmacologic, nonopioid pharmacologic approaches (i.e., NSAIDs and acetaminophen), complementary and integrative treatments, and combined approaches. In addition, the guideline addresses harms and burdens of treatment and patient[3] values and preferences. The panel defined pain according to the International Association for the Study of Pain's (IASP) definition as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (Raja et al., 2020, p. 2). The reviews underlying this guideline did not specifically address acute and subacute pain, diagnostic approaches, cancer

[1] While Geraghty et al (2021) included "fibromyalgia" in its review, fibromyalgia was outside the scope of this guideline.
[2] The AHRQ review by Skelly and colleagues (2020) included a broad category for "exercise" and the panel recognizes that there are multiple definitions of exercise that include physical, psychological, and mind-body practices. Please refer to Appendix A of the guideline for the list of key terms and definitions.
[3] To be consistent with discussions of evidence-based practice in other areas of health care, we use the term patient to refer to the adult, older adult, couple, family, group, organization, community, or other populations receiving psychological services. However, we recognize that in many situations there are important and valid reasons for using such terms as client, consumer, or person in place of patient to describe the recipients of services.

pain, and headache and facial pain[4]. The guideline also did not address the management of chronic pain in children and adolescents. These topics are important and discussed as appropriate, but the guideline does not contain specific recommendations in these domains. The Process and Methods section details the panel's decision making throughout guideline development. It is important to note that the phrase "insufficient evidence" indicates that there was not enough data to provide definitive recommendations. This lack of data can be due to a situation where (a) no relevant studies existed within the time frame of this review, (b) a very small number of relevant studies existed, (c) multiple relevant studies existed but only provided equivocal findings, or (d) the studies that were available included samples of treated groups that were of inadequate size. In addition, the lack of relevant studies can exist even if multiple studies compared certain interventions but did not provide robust findings, and no studies were conducted that included comparisons between various interventions.

Background

Chronic pain is among the most prevalent, disabling, and costly conditions, exceeding both the prevalence and cost for cancer, diabetes, and heart disease combined in the United States (Institute of Medicine, 2011c; Mills et al., 2019; Nahin et al., 2023; Yong et al., 2022). In recent decades this has been even more pointed given the opioid crisis. Specific to the current guideline, chronic musculoskeletal pain is the most common among chronic pain conditions and one of the most frequent reasons individuals seek healthcare (Institute of Medicine, 2011c) not to mention it is globally a leading disability cause (Global Burden of Disease Study 2013 Collaborators, 2015). Given the public health significance of chronic musculoskeletal pain, it is imperative to have guidance on evidence-based options for individuals with this debilitating

[4] While the panel initially thought of including headache/facial pain within the guideline, it later decided to exclude this as it may involve different modalities that would be outside the scope of the guideline.

condition. The current guideline thus strives to provide this comprehensive, evidence-based information to providers, patients and their families, and the broader public.

Process and Method

APA develops its clinical practice guidelines in accordance with best practices for guideline development set forth by the former Institute of Medicine (now National Academy of Medicine; IOM, 2011a). Undertaking the creation of a guideline requires several key decisions. APA's Advisory Steering Committee issued a call for nominations (including self-nominations) for individuals to serve as panel members from a variety of backgrounds (patient, psychology, social work, nursing, occupational medicine, physical therapy) with content knowledge, clinical experience, or methodological expertise. Conflicts of interest (financial and non-financial) were considered and managed both during panel member selection and throughout the guideline development process. The panel used the Population, Interventions, Comparators, Outcome, Timing, and Settings (PICOTS) framework (a systematic approach to conducting a comprehensive literature review of a clinical subject matter; Samson & Schoelles, 2012) as a guide to the panel in its initial question formulation stage.

In selecting which outcomes were most critical for making decisions about treatment, the panel decided that physical functioning and performance (e.g., activities of daily living, disability, impairment, pain-related interferences, changes in strength or stamina, range of motion) and mental health and emotional functioning (e.g., anxiety, depression, anger, pain coping [e.g., fear avoidance, pain catastrophizing, acceptance of pain]) were critical. The panel further decided that the following additional outcomes were important: health-related quality of life (e.g., impacts on social activities, usual role, vitality, general health, sleep), pain intensity[5], patient self-

[5] The panel acknowledges that although pain reduction was an important outcome to consider, the treatments included in the guideline were not designed to be "curative" nor were they designed to eliminate pain, rather they were designed as rehabilitative.

efficacy, patient global impression of change, employment status / disability benefits, and adverse events.

The guideline was developed in a series of phases, based on three recent systematic reviews and meta-analyses. The panel began the process with reviewing the systematic review published by the Agency for Healthcare Research and Quality (AHRQ; Skelly et al., 2020) *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update*, as it met closely with its PICOTS framework. It was supplemented with two more systematic reviews in order to fill in the gaps the primary systematic review did not address. One review addressed self-management interventions for chronic widespread pain (Geraghty et al., 2021) and another one, published by Cochrane, addressed psychological interventions for chronic pain, excluding headache in adults (Williams et al., 2020). The panel also considered using two additional reviews, one on return to work (Wainwright et al., 2019) and another one that examined whether opioid use was reduced through integrative medicine for the treatment of chronic pain (Hassan et al., 2020). However, after reviewing feedback received from the 30-day public comment period in late 2021 it decided to exclude these two reviews. The panel discovered that while the review by Hassan and colleagues (2020) was initially consistent with its PICOTS framework, it did not contain effect sizes that could be used to develop treatment recommendations. The panel excluded Wainwright and colleagues' (2019) systematic review due to the narrow scope. The panel also considered including a recent network meta-analysis that examined psychological interventions for treating chronic, non-specific LBP (Ho et al., 2022), but after further review it had concerns about methodologies within some of the individual studies included in the meta-analysis that precluded incorporating the conclusions of the authors. The panel utilized systematic reviews/meta-analyses that were current within the past five years at the time the panel made its recommendation decisions that met IOM (2011b) or A Measurement Tool to Assess Systematic Reviews-Second Version (AMSTAR-2) quality standards (Shea et al., 2017). While this is consistent with rigorous guideline development, the

panel noted this approach can be limiting in that studies exploring the efficacy of psychotherapy are not conducted equally across modalities and are not regularly updated every five years due, in part, to psychotherapy research funding. Altogether, systematic reviews and meta-analyses conducted more than five years ago were not examined by the panel.

The panel considered four factors as it drafted recommendations based on IOM standards (2011a): 1) overall strength of the evidence; 2) the balance of benefits vs. harms/burdens; 3) patient values and preferences; and 4) applicability. Based on the combination of these factors, the panel made a recommendation or conditional recommendation for or against each particular treatment or concluded that there was insufficient evidence to be able to make a recommendation either for or against an intervention. The panel used a tool called a “Grid” to document its decision-making process for each recommendation statement, which can be found in the supplemental materials (linked separately).

Discussion

Chronic pain is a prevalent and debilitating condition and one of the leading causes of seeking healthcare (Institute of Medicine, 2011c; Mills et al., 2019; Nahin et al., 2023; Yong et al., 2022). Given the public health significance, the APA panel developed a clinical practice guideline providing evidence-based information to providers, patients and their families, and the broader public.

Although some other guidelines on chronic pain have been published, they differ from the current guideline in several ways. The current guideline focuses on non-pharmacological treatments for chronic musculoskeletal pain in a broad population, is organized into first- and second- line treatments in the short, intermediate, and long terms, is recent [i.e., published within the last five years], and follows the IOM (2011a) standards for guideline development.

The panel also noted various considerations when implementing treatment. For example, these include:

- Considerations for what patients need to know as part of informed consent,

- The role of provider and patient factors in treatment for chronic musculoskeletal pain,
- Barriers to treatment,
- Treatment engagement,
- Professional competence,
- Monitoring the response to treatment, and
- Cultural and diversity competence.

The panel also noted areas in which more research is needed. These areas include protocol specification such as improving definitions, details, and reporting, methodology recommendations such as integration of results, increased sample size and length of follow-up, and increasing research with diverse populations. Additional areas included more research on patient preference and increased evidence reporting, such as reporting adverse events. Lastly, additional information is needed regarding the numbers of potential participants recruited for studies, the number randomized, attrition and dropout rates, numbers available at completion of treatment and follow-ups, as well as the reasons why any were not included (e.g., CONSORT charts).

Treatment Recommendations

In reviewing the recommendations from the panel, it is important for the reader to be familiar with the definition of several terms as follows:

- **Treatment as usual (TAU)** refers to the care that is customarily provided in a particular situation. The panel notes the challenge of a consistent definition of TAU given that the exact definition can vary by study.
- **No treatment** means that no active treatment was provided (i.e., waitlist).
- **Efficacy** is defined as the impact of an intervention compared to an inactive control.
- **Comparative effectiveness** is defined as comparing at least two different active treatments to each other to assess for the benefits of one (or combination) versus the other (or combination).
- **Attention control** refers to an inactive treatment that does include attention from a provider usually comparable to the attention provided with the active treatment(s).

The recommendations below are organized into three tiers: first-line, second-line, and other treatments reviewed. **First-line** recommendations are the strongest and worded as **recommend (Strength/Direction: Strong For)** or **recommend against (Strength/Direction: Strong Against**), while **second-line** recommendations are less strong and worded as **suggests (Strength/Direction: Conditional For)** or **suggests against (Strength/Direction: Conditional Against)**. When there is **insufficient evidence** to be able to make recommendations for or against interventions, these interventions are organized in the **other treatments reviewed** tier to inform guideline users about the available evidence at the time of the publication of the underlying systematic reviews.

290 **First-line Recommendations**

Recommendation Statement (Strength/Direction)	Rationale
For patients with **chronic musculoskeletal pain**, the panel **recommends** offering[6] patients the following interventions **(Strength/Direction: Strong For)**: ❖ **Multicomponent self-management interventions** over no treatment or usual care. ❖ **Cognitive-Behavioral Therapy (CBT)** over TAU or another active intervention.	Based on the literature reviewed that met the AMSTAR-2 requirements, the panel recommends offering patients with chronic musculoskeletal pain multicomponent self-management interventions as the overall balance of benefits vs. harms/burdens strongly favors multicomponent self-management interventions on goals of treatment. However, it is important to note that the balance could be lower depending on the particular components of self-management included. Based on the literature reviewed that met the AMSTAR-2 requirements, the panel recommends offering patients with chronic musculoskeletal pain CBT as the balance of benefits and harms/burdens slightly favors CBT.
For patients with **chronic LBP**, the panel **recommends** offering patients the following interventions over usual care / attention control **(Strength/Direction: Strong For)**: ❖ For **short-term[7] low back pain (LBP) management**, the panel **recommends** offering patients **exercise**. ❖ For **short, intermediate, and long-term LBP management**, the panel **recommends** offering patients **psychological therapy[8]**.	Based on the literature reviewed that met the IOM standards or AMSTAR-2 requirements, for short-term LBP management, the panel recommends offering patients exercise as there is low risk of serious harm and the balance of benefits to harms/burdens moderately favors exercise. Based on the literature reviewed that met the IOM standards or AMSTAR-2 requirements, for short, intermediate, and long-term LBP management, the panel recommends offering patients psychological therapy (CBT, Progressive Muscle Relaxation) as the overall balance of benefits vs. harms/burdens of psychological therapy is moderate.
For patients with **osteoarthritis (OA) knee pain**, the panel **recommends** offering patients **exercise** over usual	Based on the literature reviewed that met the IOM standards or AMSTAR-2 requirements, the panel recommends offering patients with OA knee pain exercise as the overall balance of

[6] Throughout the recommendation statements, the panel uses the term “offering” to support patient autonomy.
[7] The duration between post-intervention and follow-up were categorized as follows: short-term (1 to <6 months), intermediate term (≥6 to <12 months) and long-term (≥ 12 months).
[8] The following therapies fell into the broad umbrella of “psychological therapy” within the systematic review that was used as the underlying evidence for this recommendation statement: cognitive-behavioral therapy, respondent therapy [progressive muscle relaxation], and operant therapy (Skelly et al., 2020).

Recommendation Statement (Strength/Direction)	Rationale
care, attention control, or no intervention **(Strength/Direction: Strong For)**	benefits vs. harms/burdens slightly favors exercise.

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Second-line Recommendations

Recommendation Statement (Strength/Direction)	Rationale
For patients with **chronic LBP**, the panel **suggests** offering patients the following interventions over , usual care, attention control, or another intervention (**Strength/Direction: Conditional For**). ❖ Spinal manipulation ❖ Mindfulness-based stress reduction (MBSR)	Based on the literature reviewed that met the IOM standards, the panel suggests offering patients with chronic LBP spinal manipulation and MBSR, ensuring that the clinician attends to patients' values and preferences when suggesting these modalities.
❖ Exercise over yoga, based on slight risk of harms of yoga. However, if the patient prefers yoga, the panel suggests offering yoga as there is essentially no difference in outcomes and only quite low risk associated with yoga. Contrast to yoga, exercise is usually supervised by the physical therapist or exercise physiologist who will have expertise and training in this domain.	Based on the literature reviewed that met the IOM standards, the panel suggests offering patients with chronic LBP exercise over yoga based on slight risk of harms in yoga and the low strength of evidence. However, the panel suggests first considering the patients' values and preferences and offering yoga if the patient prefers that over exercise.
❖ Acupuncture for **short-term pain management** ❖ Multidisciplinary rehabilitation over exercise for **short and intermediate-term pain management**	Based on the literature reviewed that met the IOM standards, the panel suggests offering patients acupuncture for short-term LBP relief as the balance of benefits and harms/burdens slightly favors acupuncture, although this was from one study (Thomas et al., 2006) that had low strength of evidence. Based on the literature reviewed that met the IOM standards, the panel suggests offering patients multidisciplinary rehabilitation over exercise for short and intermediate-term LBP relief, based on the small benefit shown in multidisciplinary rehabilitation.
For patients with **chronic neck pain**, the panel **suggests** offering patients **acupuncture** over sham, placebo, or usual care for **short and intermediate-term** pain relief **(Strength/Direction: Conditional For)**.	Based on the literature reviewed that met the IOM standards, the panel suggests offering patients acupuncture for short and intermediate-term chronic neck pain relief, as the balance of benefits and harms/burdens slightly favors acupuncture, though the strength of evidence was low.
For patients with **OA hip pain**, the panel **suggests** offering patients **exercise** over usual care **(Strength/Direction: Conditional For)**.	Based on the literature reviewed that met the IOM standards, the panel suggests offering patients exercise for OA hip pain, based on the small benefit of exercise.

Recommendation Statement (Strength/Direction)	Rationale
	However, the overall strength of evidence was low.

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294 **Other Treatments Reviewed**

Other Treatments Reviewed (Insufficient Evidence)	Rationale
For patients with **chronic musculoskeletal pain**, there is **insufficient evidence** for the panel to recommend one intervention over the other intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. ❖ Self-management intervention vs. active intervention. ❖ Behavioral therapy vs. active control or vs. treatment as usual ❖ Acceptance and commitment therapy [ACT] vs. active control or vs. treatment as usual. Though there were two studies that showed a large benefit in patients who received ACT over TAU.	Based on the literature reviewed that met AMSTAR-2 requirements, there was insufficient evidence for the panel to be able to recommend for or against the listed interventions. For self-management intervention, the panel did not find any evidence that the self-management interventions within the review differed significantly from other components that are part of self-management. There is no evidence that self-management interventions differ significantly from other components that are part of the self-management intervention. While two studies showed a large benefit in patients who received acceptance and commitment therapy over treatment as usual (Luciano et al., 2014; McCracken et al., 2013), the evidence was insufficient for the panel to recommend for or against the intervention. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources.
For patients with **chronic LBP**, there is **insufficient evidence** for the panel to recommend for or against one intervention over the other intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. ❖ Psychological therapy vs. exercise ❖ Low-level laser therapy vs. exercise therapy ❖ Massage vs. exercise for **short- and long-term** pain management. ❖ Qi Gong vs. exercise therapy ❖ Spinal manipulation vs. exercise ❖ Multidisciplinary rehabilitation vs. usual care or vs. exercise for **long-term** LBP relief	Based on the literature reviewed that met the IOM standards, there was insufficient evidence for the panel to be able to recommend for or against the listed interventions or treatment comparisons. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources.
For patients with **chronic neck pain**, there is **insufficient evidence** for the panel to recommend one intervention over the other	Based on the literature reviewed that met the IOM standards, there was insufficient evidence for the panel to be able to

Other Treatments Reviewed (Insufficient Evidence)	Rationale
intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources ❖ Exercise vs. attention control, no treatment, or waitlist or vs. NSAIDs and muscle relaxants ❖ Relaxation training vs. no intervention or vs. exercise ❖ Traction vs. attention control ❖ Massage vs. exercise or vs. attention control or waitlist control ❖ Alexander Technique, Acupuncture plus usual care vs. usual care alone ❖ Basic body awareness therapy vs. exercise ❖ Acupuncture vs. sham, placebo, or usual care for **long-term** neck pain management ❖ Acupuncture vs. pharmacological care	recommend for or against the listed interventions or treatment comparisons. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources.
For patients with **OA knee pain**, there is **insufficient evidence** for the panel to recommend one intervention over the other intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. ❖ Exercise vs. pharmacological therapy (acetaminophen and NSAIDS) or vs. usual care, attention control, or no intervention. ❖ CBT / Motivational interviewing / Pain coping skills training vs. usual care ❖ Pain coping skills training vs. exercise ❖ Manipulation vs. usual care or vs. exercise ❖ Massage vs. usual care ❖ Tai Chi vs. attention control ❖ Acupuncture vs. usual care, no treatment, waitlist, or sham or vs. exercise	Based on the literature reviewed that met the IOM standards, there was insufficient evidence for the panel to be able to recommend for or against the listed interventions or treatment comparisons. The panel recommends that decisions be based on shared decision-making with the patient, consideration of available resources, and concurrently addressing other comorbid factors that can potentially impact the clinical situation (e.g., weight reduction).
For patients with **OA hip pain**, there is **insufficient evidence** for the panel to recommend one intervention over the other intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making	Based on the literature reviewed that met the IOM standards, there was insufficient evidence for the panel to be able to recommend for or against the listed interventions. The panel recommends that decisions be based on shared decision-making with the patient, consideration of

Other Treatments Reviewed (Insufficient Evidence)	Rationale
with the patient and consideration of available resources. ❖ Manipulation vs. usual care or vs. exercise.	available resources, and concurrently addressing other comorbid factors that can potentially impact the clinical situation.
For patients with **OA hand pain**, there is **insufficient evidence** for the panel to recommend one intervention over the other intervention or vice-versa for the following interventions. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. ❖ Exercise vs. usual care. ❖ Multidisciplinary rehabilitation vs. waitlist.	Based on the literature reviewed that met the IOM standards, there was insufficient evidence for the panel to be able to recommend for or against the listed interventions. Patients with chronic hand pain may benefit from being referred to a hand specialist as therapy from a hand specialist can be useful by introducing alternative mechanisms for performing activities of daily living. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources. The panel was unable to form conclusions whether to recommend for or against multidisciplinary rehabilitation or waitlist as the study included within the systematic review did not meet the definition for multidisciplinary rehabilitation. The multidisciplinary rehabilitation study reported in Skelly and colleagues (2020) did not follow the usual pattern of care offered in most multidisciplinary rehabilitation programs. Therefore, no conclusions could be drawn from this study. The panel recommends that decisions be based on shared decision-making with the patient and consideration of available resources.

Implementation Considerations

The following implementation considerations are based on expert consensus or review of the literature, which can include literature that might not have met criteria for inclusion in the above reviews, such as some observational literature, etc.

- The panel recommends that treatment planning is based on a shared decision-making model comprised of clinical judgment, patient preference and safety, with consideration of available resources.
- The panel recommends thoroughly screening patients for any psychiatric, psychosocial, behavioral history prior to beginning treatment.
- The panel recommends that clinicians remain aware of patient access and issues related to disparities across racial/ethnic groups, sexual orientation / gender identity, socioeconomic status, and rural and urban populations.
- The panel recommends that clinicians remain aware that efficacy trials may have included a narrower group (i.e., no comorbidities) and thus the treatment being tested within the efficacy trial may not be applicable to a broader population.
- The panel recommends that clinicians consider whether the treatment may need to be modified for it to be delivered effectively in a routine clinical setting (i.e., intensity, frequency, duration, or all the above).
- The panel recommends practicing socially competent care and recognizing the potential for unintentional bias.
- The panel strongly supports reimbursement of services that improve functioning in individuals with chronic musculoskeletal pain.
- If appropriate that the patient engages in a weight reduction plan, consider referring the patient to a health care professional and/or dietitian.

Recommendations for Research

- The panel recommends more research on implementing the recommended interventions to real world clinical settings.
- The panel recommends identifying the types of clinicians that provide the recommended interventions. It encourages developing a formula for the types of clinicians that can provide the services (e.g., whether it be a pain physician, pain psychologist, etc.).
- The panel recommends increasing research on the interventions where there was insufficient evidence to recommend for or against a specific intervention and ensuring there are adequate sample sizes in randomized controlled studies.
- The panel recommends more research on long-term follow-up after patients receive services for chronic musculoskeletal pain.
- The panel recommends more research on addressing the comorbidities that patients may present in a clinical encounter that may involve adapting the recommended treatments.
- The panel recommends more research on populations that were not well represented in the studies included within the systematic reviews that served as the underlying evidence base for the recommendation statements. It recommends adequate reporting of subgroup analyses.
- The panel recommends further standardization and understanding of what constitutes “treatment as usual” or “usual care”. The panel also recommends that future studies include full definitions of the control conditions.
- The panel recommends including “quality of life” as one of the outcomes in future research studies.
- The panel recommends defining a minimum standard for “patient engagement” in clinical research.

Background and Justification: The Scope of the Problem

Definition of the Problem

Chronic pain is one of the most prevalent, disabling, and costly conditions in the United States. In 2011, the Institute of Medicine (now National Academy of Medicine) released a seminal report documenting the impact of chronic pain - *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* This report included prevalence (up to 100 million people) and cost ($650 billion annually) estimates for chronic pain in the United States (Institute of Medicine, 2011c). To put these prevalence and cost estimates in a public health context; they both exceed those reported for heart disease, cancer, and diabetes combined (Institute of Medicine, 2011c). Since 2011, the public health impact of chronic pain has become more apparent by an ongoing opioid crisis.

Specific to the APA clinical practice guideline, musculoskeletal pain is the largest subset of chronic pain conditions (Institute of Medicine, 2011c), increases the risk of opioid prescription (Moshfegh et al., 2019), and is among the costliest conditions to many health systems in the United States (Dieleman et al., 2020). Furthermore, while chronic musculoskeletal pain is one of the most common reasons people seek health care (Institute of Medicine, 2011c), it paradoxically remains a leading cause of disability globally (Global Burden of Disease Study 2013 Collaborators, 2015). This pattern of “diminished returns” is untenable, and significant changes in clinical research and practice are needed to correct this paradox. Indeed, this issue of diminishing returns for patient outcomes from chronic musculoskeletal pain, is at the heart of the National Academy of Medicine’s call for a transformation in patient care (Institute of Medicine 2011c).

Clinical practice guidelines potentially play an influential role in the transformation of care by identifying evidence-based options for patients with chronic musculoskeletal pain. Indeed, there is convergence in clinical practice guidelines for spine pain (the most common type of

musculoskeletal pain) in recommending non-pharmacologic treatments (Dowell et al., 2016; Qaseem et al., 2017). However, what patients receive when seeking care often does not follow these guidelines. For example, the National Ambulatory Medical Care Survey indicated 21.5% of new visits for chronic musculoskeletal pain included opioid prescriptions while only 10.0% included a prescription for a guideline recommended non-pharmacologic treatment option like physical therapy (Feldman et al., 2020). Routine treatments not being guideline concordant is especially concerning given that the vast majority of care for chronic musculoskeletal pain will be conservative. That is, for low back pain, it has been estimated that up to 98% of those seeking care will receive some form of treatment (Kim et al., 2019) and those receiving guideline concordant care earlier are less likely to have indicators of low value care (e.g., advanced imaging, lumbar injections or surgery, and opioid prescription; Childs et al., 2015). This APA clinical practice guideline then is designed to inform providers, patients, and health system administrators on treatment options that are recommended to be part of routine care pathways, especially if those pathways are intended to reflect the current evidence base for effective non-pharmacologic options.

Large numbers of patients with chronic pain appear to receive poor quality treatment. Chronic pain patients frequently do not receive any of the current evidence-based behavioral or nonpharmacological treatments (Rasu et al., 2013). In particular, these patients frequently receive solely pharmacological treatment, including opioids. In a study examining data from the National Ambulatory Medical Care Survey (NAMCS) from 2000 to 2007, Rasu and colleagues (2013) found that 99.7% of treatments for common nonmalignant chronic pain included at least one common medication, and medications in the opioid class were the third most common type of medication prescribed, after nonsteroidal anti-inflammatory drugs (NSAIDS) and antidepressants. Nonpharmacological therapies were only reported in approximately 26% of patient visits, with exercise (14.9%) and diet/nutrition (11.2%) the most common modalities.

Psychotherapy was reported in only 8.6% of visits. The Institute of Medicine (2011c, p. 145) reported that "patterns of opioid prescribing may reflect a need for better education of physicians in this area." A survey of U.S. adults with chronic pain and their management found that of the 31,916 participants only 3.8% reported using psychological therapies for managing their chronic pain (Groenewald et al., 2022).

The over-prescription of opioids for the treatment of chronic pain is a major contributor to the opioid epidemic in the U.S., which is a current public health emergency. The CDC attributed the increase in unintentional drug overdose death rates to the increased prescription of opioid analgesics, reporting on their website (https://www.cdc.gov/drugoverdose/epidemic/index.html) that the quantity of prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly quadrupled from 1999 to 2010 (Paulozzi et al., 2011; US Department of Justice, 2011), despite the fact that there had been no overall change in the amount of pain Americans reported (Chang et al., 2014; Daubresse et al., 2013). Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999 (Centers for Disease Control and Prevention, 2016).

Available Treatment Guidelines for the Problem

At the time APA considered a guideline on chronic pain, several guidelines were available that addressed smaller subpopulations of individuals with pain. These include: *Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians* (Qaseem et al., 2017), the *2017 HIV Medical Association of Infectious Diseases Society of America Clinical Practice Guideline for the Management of Chronic Pain in Patients Living with HIV* (Bruce et al., 2017), a guideline for treatment of *Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy* produced by the State of Colorado Division of Workers' Compensation (2017), the *VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain* (2022a), a guideline on osteopathic

treatment of low back pain produced by the American Osteopathic Association (2016), a guideline for management of chronic pain in cancer survivors produced by the American Society of Clinical Oncology (Paice et al., 2016), and a guideline for assessment and management of low back pain and sciatica produced by the United Kingdom's National Institute for Health and Care Excellence (NICE, 2016).

Several guidelines addressed pharmacological interventions for chronic pain. These include the *VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (2022b), the *VA/DoD Clinical Practice Guideline for the Primary Care Management of Headache* (2020), the CDC Guideline for Prescribing Opioids for Chronic Pain (Dowell et al., 2016), the Washington State Department of Labor and Industry Guideline for Prescribing Opioids to Treat Pain in Injured Workers (2015), the *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain* from the American Academy of Pain Medicine (Chou et al., 2009), and a document produced by the National Institute for Health and Care Excellence (2013) titled *Neuropathic Pain in Adults: Pharmacological Management in Non-Specialist Settings*.

A few guidelines addressed noninvasive, nonpharmacological treatment for chronic pain, but they described psychosocial treatments very briefly and did not review the efficacy data. These four documents are: (1) State of Colorado Department of Labor and Employment's *Chronic Pain Disorder Medical Treatment Guideline* (2017), (2) Pain: Assessment, Non-opioid Treatment Approaches and Opioid Management, produced by the Institute for Clinical Systems Improvement (2016), (3) Assessment and Management of Pain by the Registered Nurses' Association of Ontario (2013), and (4) Practice Guidelines for Chronic Pain Management by the American Society of Anesthesiologists (2010).

The guideline that comes the closest to the current guideline is approximately 10 years old. This is *Management of Chronic Pain: A National Clinical Guideline* produced by the Scottish Intercollegiate Guidelines Network in 2013. The document describes and reviews the efficacy data for several noninvasive, nonpharmacological treatments: multidisciplinary pain

management programs, unidisciplinary education, behavioral therapies, cognitive behavioral therapy, mindfulness meditation and acceptance and commitment therapy, as well as manual therapy (hands-on massage and similar), exercise, acupuncture, and electrical stimulation.

Since then, after the panel began its work, the National Institute of Health and Care Excellence (NICE) updated its guideline in 2021 which includes information on assessing all chronic pain and managing primary chronic pain in individuals 16 and older. This updated guidance included information on nonpharmacological management of chronic primary pain, such as psychological therapies (acceptance and commitment therapy and cognitive-behavioral therapy), acupuncture, and electrical physical modalities and pharmacological interventions (NICE, 2021). The CDC also updated its guideline on prescribing opioids for chronic pain (Dowell et al., 2022). Further, Kaiser Permanente published a guideline in 2021 on non-specific back pain and included newer studies within the guideline, though this guideline did not follow the IOM (2011a) standards for developing clinical practice guidelines. The Tennessee Department of Health released a guideline on outpatient management of chronic non-malignant pain (2020) and two academic medical centers have also released guidelines on managing low back pain in the ambulatory setting (Chiodu et al., 2020; Tiemeiers & Meers, 2020) though these guidelines may not have followed the IOM (2011a) criteria in guideline development. A best practice guideline on chiropractic management of patients with chronic musculoskeletal pain was released in 2020 (Hawk et al., 2020). The SIGN guideline noted earlier also went through an update in 2019. Lastly, the American Physical Therapy Association updated its clinical practice guideline for the treatment of acute and chronic low back pain (George et al., 2021).

The APA Clinical Practice Guideline for the Treatment of the Problem

National Academy of Medicine Standards as the Basis for this CPG

In accordance with best practices for guideline development, APA follows the standards set forth by the former Institute of Medicine (IOM; now National Academy of Medicine) 2011 report (IOM, 2011a) to develop high quality and trustworthy clinical practice guidelines. These standards include ensuring that (1) the development process is transparent, (2) that any potential conflicts of interest are reviewed and managed, (3) that the guideline panel is multidisciplinary with balanced expertise and including patient/patient representative member(s), and (4) that is it informed by a quality systematic review of the literature. Further, (5) each recommendation is to be based on clearly explained rationale including the balance of potential benefits vs. harms, strength of the underlying evidence and includes a rating of the recommendation strength and is articulated clearly with the wording indicating its strength. Finally, (6) each guideline should go for external review by a variety of stakeholders and a plan noted for future guideline updates (IOM, 2011a).

Evidence-Based Practice in Psychology

This guideline is predicated on the three dimensions mentioned in the American Psychological Association Presidential Task Force on Evidence-Based Practice (2006) and APA's (2021) *Professional Practice Guidelines on Evidence-Based Psychological Practice in Health Care:* (1) grounding in the best available science; (2) practitioner expertise in application decisions; and (3) patient preferences, culture, and values. These three areas were consistent with earlier work by the National Academy of Medicine (former Institute of Medicine) and are universally accepted in medicine. In addition, the Advisory Steering Committee and guideline development panel made every effort to fully apply the standards set forth by the IOM of the National Academy of Sciences, Engineering, and Medicine for developing independent, reliable, and high-quality clinical practice guidelines (IOM, 2011a & b).

Treatment Outcomes Considered in the Guideline

The panel discussed several different options for considering treatment outcomes and decided to follow a framework that emphasized the physical functioning and/or performance. These outcomes could be assessed through self-report (i.e., patient reported outcome measures (PROM)), with the following PROM outcomes considered "in scope" as outcomes for this guideline:

- Mental health and emotional functioning [e.g., anxiety, depression, anger]
- Health-related quality of life [e.g., impacts on social activities, usual role, vitality, general health, sleep]
- Pain coping [e.g., fear avoidance, pain catastrophizing, acceptance of pain]
- Pain intensity
- Adverse effects
- Patient self-efficacy
- Patient global impression of change
- Employment status / disability benefits

In addition to considering PROM's the panel also considered data collected via direct observation (i.e., range of motion, physical performance test, strength, or endurance/stamina) "in scope" as outcomes for this guideline.

Key Questions and Analytic Framework of the Systematic Reviews

This guideline attempted to address the following key questions that were included in the Agency for Healthcare Research and Quality's (AHRQ) systematic review of noninvasive, nonpharmacological treatments for chronic low back pain, chronic neck pain, and OA-related pain (knee, hip, hand; Skelly et al., 2020, p. 4):

1. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care [i.e., treatment as usual (TAU)]

2. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy (e.g., opioids, nonsteroidal anti-inflammatory drugs, acetaminophen, antiseizure medications, antidepressants, topical agents, medical cannabis, and muscle relaxants)?
3. What are the benefits and harms of noninvasive nonpharmacological therapies compared with exercise?
4. Do estimates of benefits and harms differ by age, sex, presence of comorbidities (e.g., emotional or mood disorders), or degree of nociplasticity/central sensitization?

There were however gaps identified within the AHRQ systematic review, which included an unclear definition of “multidisciplinary interventions” (i.e., whether relaxation, coping skills training, pacing, “pain journaling/diary” as well as “self-management” was included in this category). The review excluded head-to-head comparisons among noninvasive nonpharmacological interventions as due to limited resources these were considered outside the scope of the review (Skelly et al, 2020). Other gaps identified within this systematic review were not including some relevant nonpharmacological interventions (e.g., biofeedback, exercise, complimentary and integrative medicine, self-management interventions), and some important outcomes (e.g., health-related quality of life, patient global impression of change), and settings beyond medical office encounter. To address these gaps, the panel supplemented the AHRQ review with two recent systematic reviews: one that addressed self-management for chronic widespread (Geraghty et al., 2021) and another one that addressed psychological interventions for chronic pain, excluding headache (Williams et al., 2020).

Process and Methods for the CPG

Scoping

At its first videoconference call and several subsequent calls, the panel began discussion of the topic scope of the guideline and continued to discuss scope over several subsequent calls. The panel followed a “PICOTS” (Population, Intervention, Comparator, Outcomes, Timing, and Setting; Samson & Schoelles, 2012) approach to scoping. Using this approach, each PICOTS element served to frame decision-making about scope. In determining its audience, the panel noted that practitioners from various disciplines (e.g., psychology, nursing, physical therapy) provide non-pharmacological interventions such as cognitive-behavioral therapy (CBT) and mindfulness-based stress reduction (MBSR) for the treatment of subacute and chronic pain. It agreed that the guideline would be developed with multiple audiences in mind, including practitioners from various disciplines, individuals with chronic musculoskeletal pain and their significant others, and policy makers.

Panel members considered the differentiation between acute and chronic pain, including whether to address secondary prevention as it is relevant to preventing the progression from acute to chronic pain. Relevant to this point, members discussed potential interventions including behavioral enhancement to reduce avoidance of pain as well as self-management to prevent the transition from acute to chronic pain. It considered creating two separate clinical practice guidelines, one on interventions that would address prevention of chronic pain while the other one would address treatment of chronic pain. It sought feedback from the Advisory Steering Committee (ASC); however, the ASC was not sure whether there was sufficient research literature to serve as the basis for developing a second clinical practice guideline that would address the prevention of chronic pain. The ASC was also concerned about the broad scope of developing a second guideline for preventing chronic pain.

Members also discussed whether to operationalize “prevention” as “preventing pain” or “preventing disability related to pain.” They noted that the latter operational definition of

preventing functional disability from developing due to chronic pain would narrow the scope further.

In the early stages of scoping, the panel used the Delphi method to complete an outcomes prioritization survey. On this survey, panel members rated outcomes from 1 “not important” to 9 “critical” for deciding about what treatment to recommend. The panel narrowed its list of outcomes to nine outcomes. Based on the results of this survey, panel members found “physical functioning and performance (e.g., activities of daily living, impairment, pain-related interference, changes in strength or stamina, range of motion)” and “mental health and emotional functioning (e.g., anxiety, depression, anger, pain coping [e.g., fear avoidance, pain catastrophizing, acceptance of pain])” as its two most critical outcomes. Scoping decisions about which populations, interventions, comparators, outcomes, timing, and settings to include as well as the key questions are noted in the Scoping section of the Executive Summary.

Vetting and Appointment of Members to the GDP

The Advisory Steering Committee (ASC) put out a call for nominations (including self-nomination) to include researchers and clinicians across various professional disciplines (psychology, social work, physical therapy, nursing, occupational medicine) who had content expertise in the topic area of chronic musculoskeletal pain as well as in biostatistics or methodology. The ASC sought those with knowledge of treatment issues related to various dimensions of diversity (such as race/ethnicity, socioeconomic status, culture, gender/sex, sexuality, physical and mental abilities) and treatment settings to seat a panel with diverse perspectives on chronic musculoskeletal pain and its treatment that could discuss the research data and its applicability to those seeking treatment. Additionally, the ASC initially sought community members who self-identified as having had chronic pain (currently or in the past) or were a close family member of someone with chronic pain and who had relevant leadership experiences such as leadership of groups that looked to enhance public awareness and access

to services, however APA staff did a targeted recruitment of community members due to low nominations received in this area.

In constituting the panel, there was an effort to incorporate members who represented a broad range of experiences and expertise in the treatment of chronic pain, including variation in terms of psychotherapy models, populations (e.g., adult, older adult, underserved populations), settings (academic, community, primary care), roles (clinician providers, researchers, health care administrator, health care consumer), and disciplines (psychology, nursing, social work, physical therapy, occupational medicine). While it would not be possible for a panel of this size to represent all constituencies and interests in a truly equitable fashion, the mandate to the panel was to include as broad a perspective as possible when reviewing the literature. Once the ASC reviewed the nominations, it sent its recommended nominees for review to the Board of Professional Affairs (BPA) and Board of Scientific Affairs (BSA). Once reviewed and vetted by BPA and BSA, the final nominations were then sent to the Board of Directors for final review and provisional appointment.

Conflicts of Interest

Before confirming the appointment to the guideline development panel, nominees provided information about possible conflicts of interest, a significant issue in the IOM standards and current best practices in guideline development. *Conflicts of Interests (COI)* are defined as,

> a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing (Institute of Medicine, 2011, p. 78; the definition is drawn from Schünemann et al., 2009, p. 565).

The IOM report additionally discusses intellectual conflicts of interest relevant to clinical practice guidelines, defined as "academic activities that create the potential for an attachment to

a specific point of view that could unduly affect an individual's judgment about a specific recommendation" (IOM, 2011, p. 78; the definition is drawn from Guyatt et al., 2010, p. 739). Candidates to the guideline development panel each completed an APA Conflicts of Interest disclosure form. Emphasis was placed on disclosing all potential conflicts for the APA staff and ASC members to review and decide upon. While intellectual affiliations were expected, no panel members were to be singularly identified with particular interventions nor were they to have significant known financial conflicts that would compromise their ability (or appearance thereof) to weigh evidence fairly. The ASC understood however that some "adversarial collaboration" (Mellers et al., 2001) or standing for different points of view was expected and encouraged as part of the process.

Once the panel was formed, members verbalized any actual or potential conflicts in their meetings, so all members of the guideline development panel would be familiar with the diversity of perspectives and range of possible influences and biases. COI forms were updated annually, and panel members and staff were asked to give more frequent updates if there were any changes in their disclosures that could be relevant to the development of an unbiased guideline.

Multiple strategies were used to identify and manage COI. Panel members (and ASC members and associated staff) all completed a disclosure form on an annual basis that was reviewed by APA staff. Panel members were expected to disclose potential COI at all meetings and on phone calls whenever new COI emerged. This was structured in the agendas for the meetings. Several strategies were used to manage COI and typically these involved some combination of recusing from the discussion of a particular topic, recusing from voting on certain issues or a combination of the two. The APA conflicts of interest policy and disclosure form is in Appendix C.

Comprehensive Search of the Professional Literature

A *systematic review* involves a methodical and organized search for studies and evidence of efficacy and effectiveness of the treatment under consideration (IOM, 2011b). A *meta-analysis* is the use of quantitative statistical methods in a systematic review to integrate the results of included studies. Briefly, a systematic review or meta-analysis involves searching a variety of scientific databases using selective search terms to find relevant studies. The identified individual studies are then assessed to decide whether they meet inclusion criteria and assessed, using pre-defined criteria to assess risk of bias. Results are then compiled and analyzed.

The IOM (2011a) standards require the use of one or more systematic reviews for guideline development. The panel was advised to select the fewest number of systematic reviews needed to address the panel's identified scope in order to keep the guideline development process manageable. Ideally the panel will use reviews that are at most three years old (2018-present) so that the reviews are not more than five years old at the time of guideline approval and publication (estimated around 2023), given that a systematic review is considered outdated after five years. For the current guideline, the panel used a systematic review of the literature focused on comparisons of noninvasive nonpharmacological interventions for the treatment of chronic pain, including low back, neck, OA-related (knee, hip, hand), fibromyalgia, and chronic tension headache (Skelly et al., 2020). While the panel, at first, was interested in including chronic tension headache as this could be muscular or vascular in nature, after reviewing the public comments on its PICOTS and identified systematic reviews, it decided to exclude headaches. Fibromyalgia was also excluded as it was outside the scope of the guideline. Due to gaps in the type of treatment comparisons and approaches as well as outcomes included in the first review, two more reviews were identified and used to address the limitations of the initial review (Geraghty et al., 2021; Williams et al., 2020). Gaps found by the panel included self-management, adjunctive noninvasive nonpharmacological interventions,

head-to-head comparisons of noninvasive nonpharmaceutical interventions, health-related quality of life, and patient global impression. The panel followed best practices of using reviews current within the past five years.

Skelly and colleagues (2020) defined chronic pain as “pain lasting 3 months or longer or persisting past the normal time for tissue healing” (the definition is drawn from IOM, 2011c). Please refer to *Appendix A. Search strategies* of Skelly et al., (2020) for the list of keywords used in searches for articles of the review. The second systematic review by Geraghty and colleagues (2021) examined self-management interventions for chronic widespread pain and within the review only included interventions that met the definition of “self-management” from Miles et al. (2011). According to Miles et al (2011), the self-management intervention had to address at least two of the following five intervention components: “psychological, physical activity, mind-body, lifestyle, and medical education” (p. 775). Please refer to *Supplement 2: MEDLINE search strategy* in Geraghty et al (2021) for the list of keywords used in searches for articles of the review. The third and final review addressed psychological interventions for chronic pain in adults excluding headache and defined chronic pain as “reporting pain of at least three months’ duration in any body site, not associated with a malignant disease” (Williams et al., 2020, p. 8). Please refer to *Appendix 1. Search strategies* in Williams et al., (2020) for the list of keywords used in searches for articles of the review.

Decisions Regarding Assessment of Inclusion / Exclusion Criteria

Decisions on the assessment and inclusion/exclusion of studies varied based on the particular systematic review/meta-analysis. Please refer to the systematic reviews/meta-analyses for specific details. However, broadly, the reviews included only randomized controlled trial (RCT) studies as those studies met quality criteria for questions regarding efficacy. The panel observed that the Skelly et al. (2020) review excluded chronic pain related to neuropathy, radiculopathy, rheumatoid arthritis, lupus, and other conditions. In terms of the “intervention” category, it was unclear whether psychological interventions were included in Skelly and

colleagues (2020) “multidisciplinary interventions” as well as whether psychological components were included in its “exercise interventions.” The panel agreed to supplement a review that examined solely psychological interventions (which included behavior therapy, acceptance and commitment therapy (ACT), and cognitive-behavioral therapy (CBT)) for treating chronic pain (Williams et al., 2020). The review also excluded self-management interventions, which warranted the panel to include a supplementary review that addressed these interventions (Geraghty et al., 2021).

Assessing Strength of Evidence

Strength of evidence was rated as either “insufficient/very low”, “low”, “moderate”, or “high” based on the combined results of analyses of risk of bias, inconsistency, indirectness and imprecision. While APA staff prepared the grid for the panel based on information extracted from the reviews and studies, the panel made all the decisions regarding the evidence and recommendations. Specifically, APA staff inserted information from the reviews and studies on quality ratings, outcomes examined and associated effect sizes, harms and burdens of interventions (as described in more detail below), study results on patient values and preferences, and study participant descriptions the panel might want to reference for discussions on applicability. As the panel discussed the grid, APA staff transcribed the panel’s decisions into each cell of the grid.

Types of Comparisons (controls) Used by Studies

The types of controls that were used in the AHRQ systematic review (Skelly et al., 2020) were sham treatment, waitlist, usual care (defined as care that might be provided or recommended by a primary care provider; also known as TAU), no treatment, and attention control intended to control for nonspecific events (e.g., time, attention, patient expectations). Interestingly, the AHRQ (Skelly et al., 2020) review’s comparators were more stringent than what the panel noted in its PICOTS framework, in that it excluded surgical interventions, studies

examining the incremental value of adding noninvasive nonpharmacological intervention to another noninvasive nonpharmacological intervention and comparisons within nonpharmacological interventions. The systematic review that examined multicomponent self-management interventions defined their comparators as placebo, waiting list control, usual care, and head-to-head comparison of one self-management intervention versus another self-management intervention (Geraghty et al., 2021). The final review that examined psychological interventions for chronic pain excluding headache defined their comparators in two tiers: active control (e.g., physical therapy, education, or medical intervention) and TAU, which was defined according to the specific study included in the systematic review (waiting list control was also merged with TAU in the review; Williams et al., 2020).

Development and Use of Grid

The Grid is a document used by panel members to summarize and evaluate the evidence generated in the systematic review or meta-analyses, along with any supplemental information. Panel ratings and judgments were documented on the grid to aid in the formulation of recommendations (Treweek et al., 2013). These tables allow panel members to document decisions, compare consistency across decisions, and give transparency to reviewers and users of the guideline document. The four main domains of decision-making are as follows: 1) strength of evidence; 2) the balance of benefits vs. harms and burdens of interventions; 3) patient values and preferences; and 4) applicability of the evidence across PICOTS.

Completion of Grid

The four domains below formed the basis on which each treatment recommendation and its strength were decided. For each recommendation, text description and a justification for the recommendation were included on the Grid (see separate link).

Rating of Aggregate/Global Strength of Evidence. For each of the cells within the Grid, *aggregate/global strength of evidence* was based on the strength of evidence from the

review for the two critical outcomes, namely, physical functioning and performance and mental health and emotional functioning. The panel followed the GRADE (Grading of Recommendations Assessment, Development and Evaluation) consortium guidance that the aggregate strength of evidence could be no higher than the lowest individual strength of evidence for each of the critical outcomes (Guyatt et al., 2013). For example, if one critical outcome had 'high' strength of evidence but the other critical outcome had 'low' strength of evidence, the global quality of evidence for that particular decision table or column in the grid would be 'low,' since that is the lowest strength of evidence for an individual critical outcome.

Assessing Magnitude of Benefits. One of the key components of the decision-making process for the guideline developmental panel was assessment of the balance between benefits and harms. This required the quantification of both benefits and harms.

Quantification of benefits was based on data from the quantitative meta-analyses for each of the important and critical outcomes that the panel had selected at the start of the guideline development panel process for those interventions that had at least low quality of evidence for the critical outcome, response to treatment. For each of the outcomes on the grid, the panel rated the magnitude of benefits as "large", "modest"[9], or "small" benefit of Treatment 1 relative to Treatment 2 and the reverse or "No difference in effect" or "Unable to rate". The rating system was used for assessing harms/burdens.

Assessing Magnitude of Harm/Burdens. Harms were differentiated from burdens that were identified as disruptions associated with treatment (i.e., time spent, homework/need to practice, cost, convenience) rather than as injury. As discussed earlier, the review of the treatment literature did not generate sufficient data on harms and burdens of interventions because, unfortunately, this information is not routinely reported in studies of psychosocial

[9] However, the panel later decided that it preferred the term "moderate" instead of "modest."

interventions. In light of this deficit, the APA Task Force to Revise the Journal Article Reporting Standards (JARS) for quantitative research included in the new standards the suggestion that randomized controlled trial (RCT) researchers report data regarding harms and burdens including indicating “none” if there were none (Appelbaum et al., 2018).

The panel also discussed the issue of attrition as a possible harm. Because attrition in a randomized trial can signify different things (e.g., stopping because treatment is not acceptable or tolerable versus discontinuing due to early symptom relief) the panel did not consider it to be a harm unless information regarding the reasons for attrition were specified.

Finally, to supplement the limited information on harms and burdens gleaned from published research, clinicians on the panel reported their experiences in delivering, supervising, or training, in particular interventions and the concerns noted by colleagues. Likewise, consumer members reported on their own and peer’s experiences with various interventions. In general, many of the identified harms and burdens pertaining to psychosocial interventions were more general and common to most psychosocial treatments, for example, the potential for short-term exacerbation of symptoms (harm) or the time necessary for multiple psychotherapy sessions (burden). Further, clinicians and consumer members reported various side effects as potential harms of medication treatment. Though it was important to obtain all available sources of information on patient values and preferences, due to the inclusion of both anecdotal (i.e., clinician and patient report) and peer reviewed article information, the strength of evidence on these topics was rated as insufficient/very low.

Once possible harms and burdens were identified, panel members then compared these with the benefits of the interventions. On the grid the panel rated whether the balance of benefits to harms/burdens strongly or slightly favors Treatment 1 over Treatment 2 or the reverse, the balance of benefits to harms/burdens was the same, or it was unable to determine the balance of benefits to harms/burdens between Treatment 1 and Treatment 2.

Assessing Patient Values and Preferences. In addition to assessing the benefits and the harms/burdens associated with specific interventions, the panel attempted to ascertain patient values and preferences. As described above, to ascertain this information, the panel relied on a search of the literature as well as clinicians and consumers/community members on the panel who voiced their perspectives about preferences for different interventions as well as the value that patients might place on different outcomes or harms/burdens associated with particular treatments. The strength of evidence (SOE) for all this information was very low because it included observational studies and "expert" (i.e., panel member) opinion.

Applicability of Evidence. The final determinant that panel members considered, before making recommendations, was the *applicability (generalizability*) of the evidence to various populations and settings. To organize information on applicability, panel members applied the PICOTS framework (referring to Populations, Interventions, Comparators, Outcomes, Time, and Settings; Samson & Schoelles, 2012) to review specific information from the studies to determine if there were any concerns pertinent to applicability about the population, interventions, comparators, outcomes, timing, or settings to be noted in each cell on the grid.

Each panel member received a clear opportunity to raise any questions or concerns about the process of completing the grid. The panel was divided into subgroups and reviewed the grid to identify any questions or concerns that users of the guideline (including patients, clinicians, scientists, and administrators) might raise. After completing the grid, the panel globally reviewed it to assess ensure consistency in decision-making across recommendations. For purposes of consistency across all clinical practice guidelines, the Advisory Steering Committee established voting procedures that may be found in Appendix D.

Diversity of Samples Included in Reviews

In the first review by Skelly and colleagues (2020), most samples included in the studies identified as female, non-Hispanic White and the average age range fell in the typical range in

reporting chronic pain. Skelly and colleagues (2020) abstracted the study participants' sex (i.e., % of females), number of years of having the condition, average age, and percent of non-White participants within the studies included in the review (please see Appendix D of Skelly et al [2020] for more details). The percent of female participants across the included studies in Geraghty et al. (2021) ranged between not reported and 100%, with most studies having around 96-100% female participants. Geraghty and colleagues (2021) did not conduct subgroup analyses of the percent of participants who identified as non-White, which impacts the applicability of self-management interventions for this particular population. For more information on the demographics of the studies included in Geraghty et al (2021), please refer to supplemental file 3 of the systematic review. In the third review by Williams and colleagues (2020), most of the participants within the included studies were on average 50 years old and the studies were mostly conducted in high-SES countries.

Comorbidity of Samples Included in Reviews

The AHRQ systematic review (Skelly et al., 2020) noted a significant gap in the literature in differentiating the types of chronic pain conditions and that there was lack of research on the efficacy of noninvasive nonpharmacological interventions for pregnant or breastfeeding individuals with chronic pain. Skelly and colleagues (2020) also excluded patients with chronic pain and comorbid medical conditions (e.g., cancer, HIV, neuropathy) and addiction. Most patients within the included studies of the Geraghty et al (2021) review had chronic widespread pain or fibromyalgia and the review authors did not report any comorbidities. The final review that examined psychological interventions for chronic pain (Williams et al., 2020) had studies that excluded patients with comorbid psychiatric disorders.

Decision-Making Regarding Treatment Recommendations

Based on the ratings of these four factors (strength of evidence, balance of benefits versus harms/burdens, patient values and preferences, and applicability), the panel then

decided its recommendation for a particular treatment or comparison of treatments. The options ranged from strong (recommend) or conditional (suggest) recommendation either in support of or against a particular treatment based on the combination of these factors. The panel could also choose to decide that there was insufficient evidence to make a recommendation about a particular treatment, which would therefore be moved to the third tier "other treatments reviewed". Panel members were divided into subgroups to complete the Grid and, after each working call, APA staff sent out a voting poll where the first subgroup would review the second subgroup's draft recommendation statements (and vice-versa). Based on its review of the evidence and treatment recommendations, the Panel then drafted the next two types of consensus-based recommendations recently approved by the Advisory Steering Committee:

- **Implementation Considerations** – these statements are focused more on context and can cover areas such as the following:
    - Equity, diversity, and inclusion
    - Barriers to treatment
    - Comorbidities
    - Training / competency
    - Implementation
    - Treatment engagement
    - Change processes
- **Recommendations for Research** – the Panel drafted recommendations for future research prioritization based on its review of the evidence and gaps noted.

External Review Process

This draft document will be posted on the APA website and public feedback will be solicited for 60 days. That draft document will be revised based on that feedback. Detailed responses to public comments will be made available on the APA website.

The final document will be reviewed within seven to ten years following adoption as policy. A decision to sunset, update or revise the guideline will be made at that time.

Considerations for Treatment Implementation

Shared Decision-Making

The panel emphasizes the importance of shared decision-making between the provider and patient. Shared decision-making is when a “health care provider and patient work together to make a health care decision based on what is best for the patient” (Agency for Healthcare Research and Quality [AHRQ], 2020). The AHRQ (2016) developed a SHARE approach with five important steps that go into the shared decision-making process between the health care provider and patient:

STEP 1: Seek your patient’s participation

STEP 2: Help your patient explore and compare treatment options

STEP 3: Assess your patient’s values and preferences

STEP 4: Reach a decision with your patient

STEP 5: Evaluate your patient’s decision

The panel encourages clinicians to refer to the AHRQ’s (2016) SHARE approach for more information on how to apply these steps during a patient encounter. It is important that the patients’ values, preferences, and culture are considered as, for example, there are differences between Hispanic [Latin-x/e/o/a] and non-Hispanic Whites preference for how they will want to engage with the physician in the shared decision-making process (Katz et al., 2011).

There is a wealth of evidence that shows the benefits of developing an equal partnership between patients and their health care providers in determining what is best for the patient who presents with chronic musculoskeletal pain and patients identify “shared decision-making” as the top priority in research and clinical practice (Beneciuk et al., 2020). Equally important is how the patient perceives their pain as this could impact treatment choice, uptake, and effectiveness (Bee et al., 2016; Brown et al., 2010). Indeed, patients who expect to receive high-quality treatment may respond with improved pain and psychological outcomes (Cormier et al., 2016).

There needs to be adequate time to allow shared decision-making to occur between the provider and patient while respecting the patient's autonomy in treatment choice. Shared decision-making needs to be communicated to the patient in an understandable form.

The panel strongly supports reimbursement of services that improve functioning in individuals with chronic musculoskeletal pain.

Informed Consent: What Patients Need to Know

For a person with pain, it is vital that they have a clear understanding of what it means to provide an informed consent to participate in any form of research. Given the limited knowledge of research by the average person, it is important to consider the following details when creating an informed consent document:

- First and foremost, it is recommended that the reading level be no greater than eighth grade level to ensure the form is understandable.
- Participant's consent is completely voluntary, and they may withdraw from the study at any point.
- Clearly state the purpose of the study, time involved, location, possible risk and benefits, and other requirements of the participant.
- Ensure confidentiality of all personal information.
- Provide the study name, the name of the PI, and contact information for the institution conducting the study.

Before asking for a signature, give the participant time to read the consent form, review major points, ask if they have any questions, and have the person presenting the form sign and date it also.

Appropriate evaluation by a healthcare professional is important before beginning an exercise program. Occasional reinforcement from a healthcare professional and support from peers is important as well.

Role of Patient and Provider Factors in Treatment for the Problem

Living a life with chronic pain is filled with many obstacles, both seen and unseen. It is a long journey from the initial start of the pain until it becomes chronic. Along the way there are numerous twists and turns in the diagnosis, treatment, and management of pain. A health care professional (HCP) needs to keep in mind that people with pain (PWP) are often defensive and skeptical toward recommendations and advice from HCP.

Such responses from PWP may be because they have been through so much as they journey through the health care system. PWP have been faced with skepticism, doubt, and outright accusations of malingering. It is critical that PWP have their report of pain believed if together you are to progress toward any type of meaningful partnership. PWP need validation knowing the HCP believes their report of pain. This may help PWP lower their defenses and be more willing to work as equal partners of the treatment team. It is recommended that PWP participate in all decisions made about their care and treatment. To achieve this, HCP can ask patients to identify their treatment goals. What is it the PWP want to get out of their interaction with the health care team? The HCP might be surprised at the responses (American Chronic Pain Association, n.d.).

It is important to understand that Decision-making about treatment, including consideration of treatment effectiveness information, needs to be a shared decision with the PWP as an active participant rather than as a passive patient. PWP will become more invested in their care and treatment when they are an integral part of discussions and decisions. Offering a treatment such as physical therapy may be appropriate. However, physical therapy alone will not help PWP engage. One therapy alone may not help. Most PWP have already tried a singular or even multiple approaches. The key to successful therapy and treatment for a PWP is the right combination of treatments and therapies designed for that individual, considering their needs, desires, and values.

Many personal factors may impact a patient's choice of treatment (e.g., desire for physical activity, social functioning). HCPs are encouraged to educate the patient about the potential benefits vs. harms of treatments. For example, with exercise, "fear of pain" or "fear of falling" are commonly identified in patients and may impact their motivation to exercise. HCPs can also consider the timing of treatment and other related patient preferences.

Barriers to Treatment

There are multiple barriers to treatment. The studies that examined CBT vs. TAU in individuals with chronic pain is skewed to individuals with higher incomes and in metropolitan regions, yet there are just as many if not more individuals who are living in rural areas who have chronic pain (Dahlhamer et al., 2018). These individuals may face increased challenges with accessing services in smaller rural areas. Other barriers to psychological treatments range from the time involved in treatment to worrying about not doing the meditation correctly (Cattanach et al. 2021).

Further barriers identified for patients with knee OA include cost (Selten et al., 2016), poor communication between patient and provider, side effects from pharmacotherapy, and fear that pain will worsen if they were to exercise (Spitaels et al., 2017). Interestingly, patients also assumed that the knee pain they were experiencing was part of the "normal aging process" and that further intervention was not warranted (Spitaels et al., 2017). Additionally, assumptions by HCPs that PWP who seek opioid treatment want drugs may impede patients in pursuing effective treatment (Driscoll et al., 2018). Many barriers beyond these brief examples exist. Taken altogether though, these examples highlight the need for HCPs to be aware of and assess for barriers to facilitate effective and appropriate treatment to alleviate chronic pain.

Treatment Engagement

To facilitate effective treatment, it is recommended that HCPs also consider ways to engage patients in treatment. For example, a qualitative study of the perspectives from

individuals with LBP found they placed great importance on receiving further explanation for the cause of their LBP beyond diagnosis as they engage in shared decision-making (Dima et al., 2013). Further, a focus group study of patient and HCP's perspectives of chronic pain management, found that patients desired providers with strong, trustworthy, and nonjudgmental communication skills; providers noted systemic barriers ranging from insurance coverage to lack of resources that significantly impedes patient outcome; providers also emphasized early education (Kim et al., 2021). Similarly, patients with shoulder pain and their HCPs also noted that the collaborative relationship between patient and provider is critical for deciding which treatment will work best for the particular patient (Maxwell et al., 2022).

Particularly given the isolation of PWP, it is important to help patients know that they are not alone in their journey. Offering group sessions with other people with similar lived experiences, when available, can be valuable to complement other types of therapies in addition to individual treatment. HCPs may want to explain the link between pain and emotions. HCPs might also consider that past experiences may have an impact on the way one copes with life situations, including pain. Further, consider that many PWP have been told, when seeking treatment, that their pain is not real, over-exaggerated, or all in their head. Validation of PWP's hurt is one key to helping them move forward. Taken altogether, taking time to engage patients in treatment is critical to addressing and alleviating chronic pain.

Professional Competence

When seeking treatment, it is important that care be delivered by an individual with demonstrated competence in the field in which they practice. Maintaining licensure is a bare minimum standard for engaging in independent clinical activity in any state but, unfortunately, cannot by itself ensure an HCP is working within their scope of practice. Specifically, licensure alone is often not sufficient to guarantee that a clinician possesses proficiency in pain care. Board Certification and fellowship training may be helpful standards, but they are not universal

in the treatment of pain across different professions. Not all fields offer board certification, and the availability of formal training varies dramatically by profession.

Fishman and colleagues (2013) proposed a set of interprofessional core competencies be held by individuals involved in the study or practice of pain and categorized them into four domains: 1) The multidimensional nature of pain: what is pain? 2) Pain assessment and measurement: how is pain recognized? 3) Management of pain: how is pain relieved?; and 4) Clinical Conditions: How does context influence pain management? The concepts of this comprehensive framework have been applied in nursing and psychology (Herr et al., 2015, Wandner et al., 2019). While attempts have been made to create a universal pain certification (e.g., American Society of Pain Educators Exam), there has been no widespread adoption. The vast number of subspecialties involved in the treatment of pain makes such an endeavor challenging; however, emerging trends toward interprofessional core competencies may help ensure that all practitioners involved in pain treatment are at least operating based on the same standard of care. In psychology, formal pain training is available, but no board specialization currently exists for this field, making it challenging to find clinicians with this expertise. With a dearth of pain specialists to treat chronic musculoskeletal pain in all populations, patients may resort to medications more than evidence-based interdisciplinary pain management programs.

Implementing Research in Practice

The panel also recommends clinicians refer to the five steps of translating research into action, according to the RE-AIM framework (Holtrop et al., 2021, p. 3):

- **Reach** the target population
- **Effectiveness** or efficacy of the intervention
- **Adoption** by target staff, settings, systems, and communities
- **Implementation** consistency, costs and adaptations made during delivery
- **Maintenance / sustainment** of intervention effects in individuals and settings over time

Comorbidities

Before beginning treatment, the panel recommends thoroughly screening patients for any psychiatric, psychosocial, and behavioral history. The panel recommends screening the following areas (Dworkin et al., 2005):

- Pain (e.g., Visual Analogue Scale)
- Physical functioning (i.e., Multidimensional Pain Inventory Interference Scale or Brief Pain Inventory)
- Emotional functioning (i.e., Beck Depression Inventory or Profile of Mood States)
- Patient global impression of change
- Symptoms and adverse events

Clinicians are encouraged to be aware that efficacy trials may have included a narrow group (i.e., no comorbidities) and might not apply to a broader population. The panel acknowledges that the efficacy trials that were included in the systematic reviews that served as the underlying evidence for the recommendation statements carries one of these limitations and it is discussed in the recommendations for research section.

Monitoring Treatment Response

It is important for HCPs and patients to monitor treatment responses and assess treatment adherence by both the clinician and the patient learning whether implemented interventions are effective, and whether barriers to successful implementation exist (e.g., socioeconomic, cultural, logistic, etc.). Reviewing such data facilitates the modification of treatment plans to better meet patient needs; however, creating successful, dynamic, person-centered treatment plans requires a reliable standard of measure.

Even though pain may occur in conjunction with an objective medical condition, the assessment of pain outcomes relies primarily on measures based on individual reports (PROs). In randomized controlled trials (RCTs)of treatments for pain, current scientific standards for assessing the effectiveness of pain treatments are summarized in a consensus statement by

Dworkin and colleagues (2008), called the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). IMMPACT recommends that the assessment of pain in clinical trials include five dimensions of outcome: level of pain, physical functioning, emotional functioning, patient satisfaction, and the appearance of adverse symptoms. Except for adverse symptoms, all these variables are typically assessed by self-report.

More generally, the Director of the National Institutes of Health (NIH) led an initiative in 2002 to chart “a roadmap for medical research in the 21st century” (NIH, 2002). A central function of the NIH roadmap was to define the dimensions of treatment outcomes in a manner independent of diagnosis. The goal was to develop methods of assessing treatment for all diagnosed conditions, whether medical or behavioral, using the same dimensions. To this end, all branches of NIH oversaw this project, as no single Institute alone was able to address the full scope of the endeavor. A steering committee of seven researchers was appointed to coordinate a collaboration of seven universities, and this committee was in turn overseen by an independent scientific review panel. A decision was made to adopt the World Health Organization’s International Classification of Functioning as the conceptual framework. This was followed by a review of prior research, consultation with content experts, conducting multiple patient focus groups, and obtaining input from academic, government, and industry stakeholder groups.

The NIH roadmap to the future process culminated in the identification of a core set of outcome measures. These dimensions were pain intensity, pain interference, physical functioning, fatigue, social functioning, depression, anxiety, and sleep. This approach to outcome assessment has considerable overlap with the IMMPACT recommendations and adds additional dimensions as well. Both the IMMPACT and the NIH Roadmap variables recognize that pain is a dimension of treatment outcome that is intrinsically related to other multiple dimensions of outcome, which include physical, social, and psychological variables.

Accordingly, when assessing pain treatment outcomes, it is important to consider including these other variables if they are potentially relevant to the study.

Cultural and Diversity Competence

Understanding and implementing evidence-based treatment models is not sufficient to guarantee successful outcomes. Social, cultural, and economic variables are known to impact a person's experience of pain and response to treatment (Cunningham et al. 2012; McGeary et al., 2016; Meints et al., 2016; Tait & Chinball, 2014). Lower socioeconomic status alone has been consistently associated with nearly all aspects of poor health, including increased risk for pain (Poleshuck & Green, 2008). More recent studies have identified the presence of socioeconomic and racial disparities in access to care that may contribute to the poorer treatment outcomes observed within these populations (Hsiang et al., 2019; Licciardone, et al., 2022). It is thus critically important for clinicians involved in pain care to be aware of the myriad of complex relationships among contextual factors, how these may impact care, and that they engage in a process to overcome the identified obstacles. It is also important for PCPs to understand the characteristics of the patient samples included in published clinical trials.
The panel recommends practicing socially competent care and recognizing the potential for unintentional bias. For example, physician implicit biases toward Black patients have been documented (Hall et al., 2015) and disparities in accessing care are evident in the LGBTQIA+ community (Abd-Elsayed et al., 2021). Vulnerable populations, such as Native Americans who report the highest prevalence of pain compared to other populations (Zajacova et al., 2022), may only have access to certain treatments, such as medications.

It is important to attend to the patients' values, preferences, culture, and other individual characteristics and consider them when delivering and adapting treatment to fit the patient. For example, a systematic review of pain beliefs, cognitions, and behaviors found cross-cultural and cross-racial differences in pain management, specifically that African American patients reported using prayer as one way to cope with pain (Orhan et al., 2018). In addition to

increasing awareness in adapting interventions that meet the patients' values, preferences, and culture, it is also important to consider additional barriers individuals with intellectual disabilities may experience when seeking treatment for chronic musculoskeletal pain. Assessing individuals with intellectual disabilities who present with chronic musculoskeletal pain symptoms via self-report alone may not be sufficient for treatment decision-making (Doody & Bailey, 2017). Treatments may need to be adapted to meet the reading level of the patient with an intellectual disability who is presenting with chronic pain symptoms and caregivers may need to be involved in the treatment process (McManus et al., 2014). These brief examples demonstrate the importance of attending to the patients' needs to ensure they receive effective care.

Enhancing Therapeutic Alliance and Other Principles/Processes of Change

In considering treatment effect, it is also important to consider the change process through which treatment has an effect. This section provides a brief high level descriptive overview of change processes and then provides a brief descriptive summary of this area specific to chronic pain. Please note this section is not based on a systematic review of the literature, rather it provides several examples. Traditionally, the section provides neither any formal recommendations nor comprehensive list of all change processes in chronic pain treatment.

Change processes are defined in three main domains: *change mechanisms*- those factors that drive therapeutic change as you would see, for example, via a mediational analysis (Kazdin, 2007; Laurenceau et al., 2007; Lorenzo-Luaces et al., 2015); *change principles*- characteristics or conditions that can predict the outcome of treatment (e.g., relationship, components of treatment) (APA Presidential Task Force on Evidence-Based Practice, 2006; APA, 2021; Castonguay & Beutler, 2006; Goldfried, 1980); and *change events*- interactions between the therapist and patient in the session that are associated with the outcome of treatment (Greenberg, 1986). Additional details for each of these domains follow.

Numerous studies have examined *change mechanisms* in depression treatment literature. For example, a systematic review by Lemmens et al. (2016) sought to identify mediators for treatments of depression. Results indicated that change in depression symptoms was mediated by rumination, worry, and mindfulness skills, automatic negative thoughts, and dysfunctional attitude changes. Some reviews indicate that symptom change is indicated by things such as cognitive change (Lorenzo-Luaces et al., 2015), worry, rumination, compassion, mindfulness, and meta-awareness (Velden et al., 2015), and practicing learned skills during homework (Kazantzis et al., 2010; Terides et al., 2017) depending on the type of therapy. Additional examples of mechanisms include various levels of support for things such as less maladaptive representations and relationship rigidity, higher insight, maturity, and reflective functioning (Barber et al., 2013, Minges et al., 2017; Zilcha-Mano, Chiu, et al., 2016a; Zilcha-Mano, Muran, et al., 2016b) and emotional processing (Auszra et al., 2013; Pos et al., 2009; Pos et al., 2003), leading to better outcomes.

Various c*hange principles* have been identified, particularly in the depression psychotherapy literature (Beutler et al., 2006; Castonguay & Beutler, 2006). These include such things as the role of a positive therapeutic relationship (Cuijpers et al., 2012a), and the participant (patient) and their personality, attachment, and coping style (Beutler et al., 2006; Bernecker, 2012), readiness to change, and expectations. This domain also includes technical components, such as improving interpersonal functioning, cognitive reappraisals, changing behaviors and associated reinforcements, and the structure of the therapy session (Auszra et al., 2013; Follette & Greenberg, 2006; Missirlian et al., 2005; Pos et al., 2003; Whelton, 2004).

Finally, *change events* include those that occur in the session between therapist and patient. Examples include addressing ruptures in alliance (Safran & Muran, 1996), “unfinished business” (Greenberg & Malcolm, 2002), and resolution of problematic reactions (Watson, 1996). A few mixed-method, small studies have linked change events with outcomes for depression treatment in particular (Greenberg, 1986; Greenberg & Newman, 1996).

While there is much information available on change processes in the depression literature, less literature exists on change processes specific to chronic pain treatment. Lutsch and colleagues (2022) hypothesized that “pain self-efficacy” and “pain-related disability” may be the driving force of change in digital CBT for patients with low back pain, there were no significant differences found in the study. Given the heterogeneity in the type of chronic pain one experiences, the mechanisms of change could be identified through personalizing psychological interventions (McCracken, 2023) as well as patients having the opportunity to discuss with one another their experiences of pain and ways of coping through peer support interventions (Stenberg et al., 2023). How providers communicate with patients regarding managing and coping with chronic pain has been identified as one of the key change mechanisms in treatment adherence and acceptability (Rizzo et al., 2023). Patients feeling acknowledged and heard about their pain may also be one of the mechanisms of change seen within the interventions and key to improved outcomes (Nicola et al., 2022). Overall, more research is needed in identifying the potential mechanisms of change in the interventions for individuals with chronic pain.

Discussion

How the APA CPG Compares to Other Treatment Guidelines for the Problem

Several other organizations and professional associations have also developed or updated guidelines on treating chronic musculoskeletal pain. This section will highlight recent guidelines for treating chronic musculoskeletal pain in adults from the following state, national and international organizations: Tennessee Department of Health (2020), State of Colorado Division of Workers' Compensation (2022), US Department of Veterans Affairs/Department of Defense (2022), US Centers for Disease Control and Prevention (Dowell et al., 2022), Canadian Family Physicians (Korownyk et al., 2022), Scottish Intercollegiate Guidelines Network (SIGN, 2019), and the UK's National Institute for Health and Care Excellence (NICE, 2021).

The Tennessee Department of Health's (2020) *Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain* focused on best practices for assessing chronic non-malignant pain before initiating opioid treatment as well as best practices for initiating and monitoring opioid therapy for chronic non-malignant pain and monitoring ongoing opioid therapy. The guidelines are based on a review of national and state guidelines for prescribing opioids and developed consensus-based recommendations for initiating opioid therapy for chronic non-malignant pain. The appendices list resources ranging from mental health assessment tools to a protocol for tapering opioid therapy. The guidelines differ from APA's guideline in that the APA guideline does not address opioid therapy for the management of chronic pain.

The State of Colorado's Division of Workers' Compensation updated its medical treatment guidelines for low back pain in 2022 and developed recommendations based on a review of the evidence and expert and/or consensus judgment. The guidelines emphasize educating the patient, family, community, employer, insurer, and policy maker on the treatment and management of low back pain as well as implementing shared decision-making during treatment planning. The guidelines also recommend active interventions, such as therapeutic

exercises, and to consider including passive interventions as a facilitator to the active modalities and avoiding bed rest. Surgical and other medical interventions, such as epidural injections, are also mentioned in the guidelines if at six-week follow-up appointments there is minimal improvement in pain. The guidelines differ from APA's guideline in that they only focus on low back pain while APA's guideline includes other chronic musculoskeletal pain conditions.

The U.S. Department of Veterans' Affairs and Department of Defense (VA/DoD) recently updated its guideline for the management of low back pain (2022) and followed the IOM (2011a) standards for guideline development. The VA/DoD guideline focuses on adults with acute, subacute, or chronic low back pain with or without neurological symptoms. While this guideline focuses on acute, subacute, and chronic low back pain, APA's guideline also includes chronic neck, knee, hip, hand osteoarthritis and other widespread pain. The VA/DoD has two "strong for" recommendation statements, both of which are related to conducting a comprehensive evaluation that includes assessing the history and physical and neurological presentation of the patient with low back pain as well as referring for further diagnostic testing, if necessary. The APA guideline does not examine the assessment of chronic musculoskeletal pain. The VA/DoD suggests CBT for chronic low back pain while APA's guideline has a strong recommendation for CBT for short, intermediate, and long-term low back pain management and overall chronic musculoskeletal pain.

The CDC's clinical practice guideline for prescribing opioids for pain emphasizes offering nonopioid approaches first and discusses the benefits and harms of opioid therapy if the patient presents with acute pain (Dowell et al., 2022). The CDC guideline also notes using nonopioid pharmacologic approaches, such as NSAIDs or acetaminophen, to alleviate acute pain. For subacute and chronic pain, the CDC guidelines also emphasize the importance of using nonpharmacologic and nonopioid approaches that include exercise, psychological therapy, and other physical and mind-body modalities. Importantly, the CDC discourages opioid therapy as a first-line treatment. The CDC's guideline addresses a variety of pain populations, including

cancer pain, postoperative pain, and dental pain, whereas APA's guideline only addresses chronic musculoskeletal pain.

The Canadian Family Physician's guideline for managing chronic low back, osteoarthritic, and neuropathic pain in the primary care setting recommends physical activity for managing osteoarthritis and chronic low back pain (Korownyk et al., 2022). The guideline also suggests CBT or MBSR as treatment options for managing chronic pain overall. While the APA chronic pain panel reaches a similar conclusion to the Canadian Family Physician's suggestion of offering MBSR for chronic pain, the APA guideline panel has a stronger recommendation for CBT for chronic pain. While pharmacologic approaches to managing chronic musculoskeletal pain are outside the scope of the APA guideline, Korownyk and colleagues (2022) found opioid and cannabinoid therapies to carry more harms than benefits.

The Scottish Intercollegiate Guideline Network (SIGN) updated its guideline on the management of chronic pain (2019) and recommends referring patients to a pain management program as well as engaging in exercise and exercise therapies. It also recommends that patients with chronic low back pain remain active and that insufficient evidence exists for clinician advice alone. The SIGN guidelines also recommend that clinicians offer self-management interventions, which is a similar recommendation to the APA guideline.

The UK's National Institute for Health and Care Excellence (NICE) also updated its guidance in 2021 on the assessment of all chronic pain and management of chronic primary pain. In managing chronic pain, the NICE guideline recommends exercise programs and physical activity while it notes to consider acceptance and commitment therapy (ACT) or CBT. The latter was inconsistent with the APA panel's conclusions that insufficient evidence exists to recommend for or against ACT for chronic musculoskeletal pain. The NICE guideline (2021) notes that more research is needed on the following psychological interventions for treating chronic primary pain: mindfulness, psychodynamic psychotherapy, and relaxation therapy.

The remaining guidelines that were developed during the development of this guideline were published by Kaiser Permanente (2021), two large academic medical centers (Chiodo et al., 2020; Tiemeier & Meers, 2020), and an independent guideline that focuses on chiropractic management of chronic pain (Hawk et al., 2020). Kaiser Permanente's (2021) guideline focuses on non-specific back pain and organizes their recommended interventions by patient complexity (low, medium, high pain) based on the STarT back scoring. The Kaiser Permanente (2021) guideline reaches similar conclusions to APA's guideline regarding the overall goal of the guideline: the patient is an active participant and that interventions focus on improving quality of life and functioning. Kaiser Permanente's (2021) guideline differs from APA's guideline in that acute, subacute, and chronic levels of pain are included whereas APA's guideline only includes recommendations for treating chronic musculoskeletal pain.

The guideline published by the University of Michigan Medicine (Chiodo et al., 2020) addresses low back pain in adults in an ambulatory setting. This guideline notes that biofeedback and self-hypnosis, which were not included in any of the systematic reviews underlying APA's guideline, could be useful but evidence on these modalities is limited (Chiodo et al., 2020). Chiodo and colleagues (2020) also suggest MBSR over usual care for short-term pain intensity and physical functioning outcomes, however significant differences were not evident in long term outcomes. The guideline also recommends multicomponent self-management intervention for chronic low back pain, which is a similar conclusion to APA's guideline, however it notes to consider adding pain neuroscience education to the intervention. The Ohio State University Wexner Medical Center's guideline (Tiemeier & Meers, 2020) is similar to that of the University of Michigan in that it addresses chronic pain in an ambulatory setting. The final guideline by Hawk and colleagues (2020) develops recommendations based on a review of the literature and expert consensus on chiropractic management for chronic pain. While the guideline's scope is on chiropractic care for chronic pain, it includes similar recommendations to other guidelines, noting the importance of considering multiple approaches

in managing pain. Other recommendations like APA's guideline include emphasizing the biopsychosocial approach to treatment and combining active and passive interventions, with an emphasis on the patient being an active participant in treatment (Hawk et al., 2020).

Strengths and Limitations of the Systematic Reviews

At the outset, the panel was encouraged to identify systematic reviews or meta-analyses that would address the identified scope. To do this, APA staff conducted a search and provided the panel with a set of systematic reviews and meta-analyses published within the last five years. Ultimately, the selected systematic reviews included both strengths and limitations.

The panel began by selecting a paper by Skelly et al., (2020) based upon similarities in scope and the high quality of the review. This systematic review was conducted by an evidence-based practice center designated by the Agency for Healthcare Research and Quality (AHRQ) and guided by IOM's (2011b) standards for systematic reviews. Additional strengths included the breadth of the review, risk of bias assessments to determine the quality of individual studies, and a standardized strategy for grading the strength of the evidence. However, a limitation of this review was that it did not cover all the disorders (neuropathy, TMJ/facial pain, headache), interventions (self-management, occupational therapy, and the combination of noninvasive, nonpharmacological interventions) or outcomes (return to work) that the panel wished to address. Therefore, the panel reviewed additional publications.

A systematic review and meta-analysis by Geraghty et al., (2021) and a systematic review by Williams et al., (2020) were added to the Skelly et al., (2020) systematic review. These publications were selected based upon Measurement Tool to Assess systematic Reviews (AMSTAR) 2 confidence ratings, with an overall confidence rating for Geraghty et al., (2021) as Moderate (more than one non-critical weakness) and for Williams et al., (2020) as High (no or one non-critical weakness). One potential limitation of the systematic review and meta-analysis by Geraghty et al., (2021) was that the definition of self-management was large and may have increased variability across outcomes.

Overall, limitations of all the reviews included heterogeneity that may impact applicability. Specifically, there was variability in how individual studies operationalized chronic pain. There was substantial variability in the number of sessions, length of sessions, duration of treatment, the presence/absence or length of follow-up, and clinician experience across studies. The panel was also limited by the current literature's operationalization of treatment as usual and usual care conditions. The panel also was unable to clarify the exact treatment that was rendered in some cases. For example, treatment labeled as CBT may have been administered by a variety of HCPs using somewhat different paradigms, thus rendering the results difficult to describe within a guideline structure. Additional limitations were that the majority of trial participants were female, and participants tended to be older, which may limit the applicability of recommendations and outcomes for younger, male individuals with chronic pain. However, most patients seeking treatment for chronic pain are female. Further, data presented in the extant literature was insufficient to determine the impact of comorbidities.

There are inherent limitations in using systematic reviews. Any high-quality articles that were published after the dates of the literature review for the systematic reviews are not included in our assessment. In particular for the Skelly et al (2020) review, the article search was limited to September 2017 through September 2019; however, this systematic review updated a prior report and thus included a large selection of the relevant literature proceeding their current search dates. The Williams 2020 review was also an update of a previous systematic review that had included articles from 2011 forward. The literature search cessation date for the Williams review was April 2020. The Geraghty 2021 review assessed literature from December 2017 through June 2020. It is important to note that most literature from April 2020 forward was not included in our report. Significant RCTs of high quality that might affect the recommendations in this guideline could have been published after April 2020 and therefore it is recommended that the reader considers new research when clinicians develop final treatment recommendations.

Meta-analyses and systematic reviews include numerous criteria (e.g., minimum sample size, outcome criteria used) in determining what studies are appropriate for inclusion and the set of relevant and appropriate studies to incorporate in the analyses. They have their own unique methods for establishing the quality of each study included and the strength of the evidence of each study. There are several limitations inherent in each meta-analysis, thus it is important to acknowledge these when generating recommendations based upon them (Moore et al., 2022, 2023). They require a number of years to perform, prepare, and publish. Thus, they may be dated at the time this guideline was prepared. It is important that clinicians monitor new research for up-to-date and evidence-based treatments and observe that studies are published over many years and some improvements have already been made in more recent studies. New efforts to develop procedures for “live meta-analyses” have been established in which regular updates are developed to build on the original conclusion of meta-analyses and subsequent recommendations based on the analyses (Elliott et al., 2017). These efforts would be a valuable addition to developing future guidelines for the treatment of chronic musculoskeletal pain.

There are significant limitations to the studies included in this guideline and therefore the recommendations (e.g., Flather et al, 1997; Moore, 2021). Overall, the evidence is not comprehensive or of sufficient quality to make definitive recommendations about the effectiveness of various nonmedical and nonpharmacological interventions for treating patients with musculoskeletal pain and pain-related disability. Thus, it is recommended that clinicians balance the guideline recommendations with their expertise and knowledge of their individual patients and patient preferences.

Additional Issues Not Addressed Above

Although guidelines based on evidence-based reviews and meta-analyses are advances over the sole reliance on expert opinions, there are limitations inherent in systematic reviews that are also are present in those that rely exclusively on opinion-based recommendations.

Perhaps most concerning is the potential for guidelines to unwittingly incorporate various types of bias, that include but are not necessarily limited to selection bias, attrition bias, selective outcome reporting, and publication bias (Owens, 2021). Some biases, as well as specific study design features, are difficult to detect in evaluating the results of research, even with careful examination of the individual studies included (or excluded) from systematic reviews. Selection biases pose major difficulties in interpreting the conclusions of systematic reviews. One potential influence on study selection is an investigator's preference for one type of treatment compared to another (i.e., "allegiance bias"). This type of bias may hinder treatment comparators and may have a profound effect on outcomes. For example, if an investigator designed a study to compare a psychological treatment with physical therapy for patients with low back pain in which both treatments were provided by psychological therapists, the limited expertise of the psychological therapist in physical therapy might bias against the success of the physical treatment. In this example, the investigator allegiance along with limitations in providers' training would be difficult to rule out in evaluating the differential treatment effects.

The individual studies selected as the basis for guidelines may also include methodological design characteristics that undermine comparator treatments (e.g., lack of comparability of attention provided to groups, and preferences and experience of treatment providers). Yet another confounder may be the failure of investigators to adequately blind treatment providers and to provide sufficient training and supervision to assure the fidelity of the comparator treatments.

From the outset, decisions as to the studies selected for inclusion in guideline development, as well as meta-analyses (selection bias), will greatly influence conclusions regarding the effectiveness of various treatments under consideration. Thus, it is unlikely that the authors of the current guideline would be able to determine whether selection (allegiance) bias, study design, and treatment fidelity affected the results of individual studies, and, accordingly, the results of the systematic reviews on which they relied. Unfortunately, no

consensus exists on how to identify or measure all potential sources of bias (Yoder et al., 2019). It is important to acknowledge this potential role in study outcomes and the interpretation of the results. Although a review of currently available literature does not provide any discussion of the impact of such various sources of bias, concerns have been addressed in psychotherapy outcomes research, generally (Budd & Hughes, 2009; Falkenström et al, 2013; Leichsenring et al, 2017), and can accordingly have a potential confounding impact on the systematic reviews that were utilized for the current guideline.

Finally, behavioral treatments as well as physical modalities are often grouped together as consisting of homogeneous sets. Yet there are a number of different psychological and physical treatments with different conceptual bases and therapeutic components. Thus, categories of treatments are not monolithic and the possibility that investigators and treatment providers are influenced by their allegiance to a specific therapy (e.g., mindfulness vs. CBT, conditioning exercise vs. spinal manipulation) exists. Accordingly, clinicians must be cautious when making treatment decisions based on guidelines that combine behavioral and physical therapies.

Needs for Research and Reporting of Clinical Trials

Examination of the studies included in the primary systematic reviews and meta-analyses used in the current guideline reveals several important areas that need to be addressed in future research and in the reporting of important information in publications. A comprehensive analysis and discussion of the many research needs is beyond the scope of this document (see Moore et al., 2020, 2023). Thus, we have organized here and summarized in Table 1 the necessary information to improve the strength of the recommendations for nonpharmacological and nonmedical treatments of patients with musculoskeletal pain and pain related disabilities in three sections: Protocol Specification, Methodology, and Evidence Reporting.

Table 1

Recommendations Regarding Research Needs and Reporting

Protocol Specification
❖ Improve definitions of what Treatment as Usual (TAU) or waitlist control entails.
❖ Improve definitions and more details regarding the components of treatment (e.g., physical therapy, CBT, ACT) as well as dosage (e.g., 6, 12, or more treatment sessions), frequency of treatment (e.g., daily, weekly), and specifics of treatment format (e.g., group, individual, internet delivered).
❖ Include verification methods used to confirm treatment fidelity (e.g., training to follow specific treatment protocol, procedures for monitoring provider adherence).
❖ Improve reporting of the level and expertise of providers/clinicians guiding treatment.
Methodology
❖ Integrate results from efficacy, effectiveness, and implementation trials.
❖ Increase sample size.
❖ Develop research that targets diverse diagnostic groups.
❖ Increase length of follow-up.
❖ Develop methods/Standards to assess patient adherence.
❖ Include sensitivity analyses to evaluate treatment effects.
❖ Conduct retrospective responder analyses to identify the characteristics of patients who benefit from treatments.
❖ Identify treatment responders so that treatment matching to specific patient phenotypes can occur.
❖ Include patient preferences.
❖ Include objective outcome data instead of solely relying on patient-reported outcomes.
❖ Develop research addressing both specific and non-specific factors of treatment as well as including mediators and moderators that contribute to outcomes.
❖ Promote diversity, equity, and inclusion when developing research methodology.
Evidence Reporting
❖ Include adverse events reporting.
❖ Report and reduce all potential sources of bias (e.g., investigator bias, funding source)
❖ Promote preregistration of clinical trials (e.g., ClinicalTrials.gov, Eudra-CT) and meta-analyses (e.g., PROSPERO, Cochrane, PRISMA guidelines, AMSTAR-2).
❖ Include CONSORT charts.

Protocol Specification

To evaluate the efficacy and effectiveness of any clinical trial, it is important to be clear to specify essential details from the protocol of the treatment(s) being evaluated and comparison groups. This includes reporting a number of important details, several of which are outlined below.

If the active treatment is being compared to “treatment as usual” (TAU) or a waitlist control, there needs to be a description of what was included under the generic rubric of TAU and waitlist and what treatments, if any, are provided routinely to patients. For example, are there accepted standards for the treatment to which the treatment to be evaluated are to be compared? In a particular study, does TAU and waitlist include active components such as clinician attention, medication, and physical therapy? Will the patients in the active treatment receive these in addition to the components of the treatment under investigation or will they be modified or withheld? These details need to be specified in clinical trials that compare an active treatment of TAU or waitlists.

In relation to specifying the components of treatments, general terms are often used but these treatments may have very different components. For example, the generic term “physical therapy” may incorporate a range of modalities (e.g., type of manipulations) and types of exercise (e.g., aerobic, flexion, extension) and psychological treatments even when more specific, such as CBT and ACT, can include different treatment components (e.g., relaxation, cognitive-restructuring, problem solving, distraction). It is important that investigators clarify the nature of comparative treatments to better examine and compare effects (e.g., specific nature/forms/content/targets of physical therapy, psychological treatments, other non-medical/non-pharmacological treatments).

For non-medical and non-pharmacological treatments, the dosage (e.g., 6, 12, more treatment sessions), frequency of treatment sessions (e.g., daily, weekly), and details of the treatment format (e.g., group, individual, internet delivered) are required for adequate

determination of outcome. Research is needed to supplement clinical outcomes in general but to also establish the necessary and sufficient characteristics required to achieve the optimal outcome with any treatment. This will not be accomplished if the details surrounding the treatment provided are not available.

When providers are asked to follow a particular protocol, it is essential that the investigators include some means of verifying the treatment protocol is being followed and to confirm treatment fidelity (e.g., training to follow specific treatment protocol [not just years of experience and expertise], procedures for monitoring and addressing provider adherence). Often the details of the experience, training, and monitoring of providers are not described in sufficient detail to assure the fidelity of the treatment described and, hence, the conclusions about the benefits of the treatment.

Methodology

The methodology used by investigators in designing and conducting their trials are essential to assist clinicians in their assessment of the validity of the results and for informing their decisions regarding which of the treatments will provide the greatest benefit for their patients.

The current guideline includes recommendations based on carefully controlled randomized clinical trials. These types of trials (efficacy trials) are meant to address the specific question of whether a particular treatment “can work” under carefully specified conditions. This type of study has numerous limitations regarding the second question, which is “Does the treatment work in practice?”. These studies are labeled effectiveness (“real-world”) trials. Although there are benefits to effectiveness trials, they have their own limitations (e.g., lack of control, absence of placebo treatments). Both types of trials are valuable, and the results can complement one another. Research is needed into the integration of results from both types of trials to assist clinicians in making decisions as to the applicability of the treatments for their patients.

The panel also noted a gap in implementation research. Implementation research builds upon both efficacy and effectiveness research by studying the application of evidence-based interventions within systems of care. Research that focuses on how best to implement research findings into daily practice while addressing real-world issues such as insurance payers, patient co-morbidities, treatment and provider availability, and treatment adherence would benefit the field.

The majority of studies that served as the basis for this guideline included small sample sizes and a small number of studies evaluating each treatment's efficacy. Increasing both the sample sizes included in clinical trials and the number of trials to replicate results are important areas of research (Moore et al., 1998). This seems critical given the small number of studies and sample sizes included in the diverse comparison that were considered when determining the recommendations in this guideline.

The recommendations in this guideline are based on studies for the treatment of musculoskeletal pain disorders. This is a broad category that varies by location and mechanisms (e.g., osteoarthritis of the knee, neck and back pain, fibromyalgia). This potential heterogeneity of the diagnostic criteria can limit generalization across the diagnoses under the general rubric musculoskeletal pain. Often the studies available focus on only one of the diagnoses and it may not be appropriate to extrapolate from any specific diagnosis to the entire group. Research is needed to target the specific, diverse diagnostic groups as it is less than desirable to have to extrapolate from results with one diagnostic group to others.

Many of the studies considered in developing this guideline included relatively short follow-up periods of six months or less. Thus, it is difficult to confirm the maintenance of any treatment effects obtained and on which to base recommendations. Longer-term follow-up (at least six months and preferably one year) would be optimal. However, there is a recognition that this may increase the risk that patients will be lost to follow-up.

Many of the nonmedical and nonpharmacological treatments considered in this guideline require patients to engage in some form of home practice. There need to be methods or standards to assess patient adherence with treatment requirements. Research is needed to establish what criteria are used to determine an adequate “dose” of treatment was received/acceptable for inclusion in making a determination of treatment efficacy.

Since clinical trials often report that significant percentages of those who receive treatment terminate participation prematurely and varying percentages of patients who complete treatment are lost to follow-up, it is recommended that investigators include sensitivity analyses (e.g., treatment completers, baseline observation carried forward) in evaluating treatment outcomes to verify treatment effects.

Even patients with the same chronic musculoskeletal diagnosis are not homogeneous. Thus, it might be predicted that patients with different physical, psychosocial, behavioral, and contextual characteristics would differ in responses to diverse treatments. Examination of the percentage of patients who obtain positive benefits of treatment is imperative. It is recommended that trials include large enough samples to permit the performance and reporting of the percentage of patients who achieve statistically significant and clinically meaningful responses. It is important that future research addresses the question of “what treatments are effective for whom?” Retrospective responder analyses would be useful to identify the characteristics of patients who benefit from treatments under investigation. The results of these analyses could then be used to develop and match specific treatments to patients who would be most likely to benefit. If research identified treatment responders, prospective treatment matching to specific patient phenotypes could be conducted. The results would inform clinician decisions regarding treatments to be offered to their patients that are best matched to treatments demonstrated to be most effective for their patients.

It is imperative to acknowledge the differences between statistical and clinical significance. Large samples require smaller changes in outcomes to be statistically significant.

Because a large clinical trial reports statistically significant results does inevitably lead to the conclusion that the results are clinically meaningful. Research needs to demonstrate that not only are outcomes statistically significant but that patients view these results as important to them.

It is also critical that researchers identify and address the health disparities that currently exist in racial/ethnic diverse individuals with chronic musculoskeletal pain. The National Institute on Aging has developed a framework that can guide researchers in developing research agendas aimed at addressing chronic musculoskeletal pain in underserved populations (Patel et al., 2022).

The panel acknowledged a need for patient engagement in clinical trials. There is a need for patient input in areas such as adherence to treatment and dropout as well. It is more likely that study participants will remain adherent and stay involved with a study if the study is personally meaningful to them. Thus, it is important to include community members to help develop recruitment strategies, design of trials, selection of meaningful outcomes, and dissemination of results (Holzer et al., 2022).

Most clinical trials adopt outcomes that investigators believe are important as their primary criteria to establish the benefits of treatments. There has been growing attention to what outcomes are meaningful to the *patients* (e.g., Turk et al., 2008). Research is needed to determine the outcomes that patients will accept as meaningful to them (e.g., function rather than pain intensity, and inclusion of quality-of-life measures). These outcomes then need to be included in clinical trials.

The primary outcomes in most clinical trials for musculoskeletal pain are based on patient-reported outcomes. Although self-report is important, they can be influenced by a number of personal and contextual factors. Research is needed to develop methods to assess outcomes that can supplement self-reports such as objective outcome data (e.g., actigraphy, behavioral observation, quantitative sensory testing (QST, Georgopoulos et al., 2019),

conditioned pain modulation (CPM, Imai et al., 2016), brain imaging (Ng et al., 2018)). It is recommended that the results of such research be integrated with results of self-report measures to provide more comprehensive analyses of treatment outcomes.

Psychosocial treatments are often based on differing conceptualizations of the essential components of treatments and a number of nonspecific factors incorporated in treatment protocols (e.g., therapeutic alliance, patient expectations, motivation) (Thorn & Burns, 2011). Research is needed to verify the additive (synergistic) contributions of the specific and nonspecific treatment components to the outcomes. This would be helpful to identify the necessary and sufficient components of treatment. Further, research is needed to examine mediators and moderators that contribute to the outcomes observed.

It is understood that when developing research methodology, it is important that every effort be made to promote diversity, equity, and inclusion in research studies. Many of the studies reviewed for these clinical guidelines did not represent the entire population. It is important for researchers to also broaden research participation to ensure fair representation in clinical trials.

Evidence Reporting

The reporting of the results of clinical trials to evaluate the efficacy and effectiveness of specific treatments is essential to assist clinicians' interpretation and decision-making regarding the use of any treatment with their patients. Thus, it is important the investigators are scrupulous in the reporting of the outcomes of clinical trials performed. It is important that investigators adhere to standards to ensure the accurate reporting of the results of their research.

Adverse events are common in pharmaceutical and medical treatments and are reported in clinical trials. Adverse events are less commonly included in clinical trials of nonpharmacological and nonmedical treatments as evident in the studies included in the development of this clinical guideline. However, there may be adverse events associated with any clinical intervention. For example, physical therapy can increase levels of pain or even

injuries (e.g., being more active increase the likelihood of falls and subsequent pain), and psychosocial treatments might increase emotional distress (e.g., identifying interpersonal difficulties). It is important that investigators report adverse events in all clinical trials, including reporting when none occurred. For if they are not reported it is not possible to determine whether none occurred or whether they were simply not recorded in the study reported.

There are several potential sources of bias in the conduct and reporting of clinical trials (e.g., investigator bias, selective recruiting, funding source). Clinical investigators as well as treatment providers have different allegiances to several types of treatment and investigators and providers may have subtle biases regarding the desire to see their preferred treatment demonstrate positive effects compared to alternative treatments. It is important that such potential biases be acknowledged. Additionally, funding sources may consciously or unconsciously steer the direction of trial designs and reporting of results. For example, research suggests that RCTs with the improper or unclear influence of funders seemed to have a larger effect size than those with the clear impact of industrial funding (Fuentes et al., 2020). It is recommended that investigators report any potential, actual or perceived bias by the providers of treatments to inform clinicians of these contributing factors that are important when evaluating the validity of results.

The bias towards publishing studies that confirmed a preexisting hypothesis is well known and is being addressed by the requirement to preregister clinical trials in governmental registries (e.g., ClinicalTrials.gov, Eudra-CT). Meta-analyses are formal methods to combine results from clinical trials and serve as the basis for the current guidelines. Some limitations to meta-analyses were described previously. To reduce potential biases in interpretation of meta-analyses, it is recommended that they are pre-registered in appropriate venues and databases, such as the International Prospective Register of Systematic Reviews (PROSPERO; Stewart et al., 2012). The Cochrane initiative has developed standard procedures for combining data across studies and publishes summaries of evidence for or against pain management

interventions (Higgins et al. 2021). Other rigorous guidelines have been developed to improve the quality of meta-analyses, for example PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), and AMSTAR 2 (A MeaSurement Tool to Assess systematic Reviews: a critical appraisal tool for systematic reviews that include randomized or non-randomized studies of healthcare interventions, or both; Shea et al., 2017).

All clinical trials involve the recruitment of patients to participate. For clinicians to interpret the generalizability of the results of clinical trials, they need to understand the sample of patients included. The inclusion and exclusion criteria for patients are reported in trials, however, the participant flow also needs to be present. To assist in the review, standards have been developed to understand patient inclusion (CONSORT, Consolidated Standards of Reporting Trials, Boutron et al., 2008). To assist clinicians in their review of clinical trials, it is recommended that investigators include CONSORT flow diagrams, including the number of potential participants in trials who were screened on telephone, and how many participants were invited to participate accepted and declined (reasons for declining would be useful). It is recommended that CONSORT flow diagrams be included in all clinical trials going forward as details of recruitment, treatment completers, and follow-up numbers have not always been provided in published reports.

Conclusion

Overall, the panel found both strengths and limitations in the underlying evidence base. Thus, the panel makes recommendations pertaining to efficacy and comparative effectiveness of treatments following the IOM (2011a) criteria for rigorous guideline development but recognizes there are limits to the scope of its recommendations. The field is encouraged to address research issues related to protocol specification, methodology, and evidence reporting. Moreover, clinicians are encouraged to attend to issues of informed consent, the role of provider and patient factors in treatment for chronic musculoskeletal pain, barriers to treatment, treatment engagement, professional competence, monitoring the response to treatment, and cultural and diversity competence as outlined in the panel's implementation considerations. Altogether, this guideline makes a significant contribution to the treatment of chronic pain and adds to current knowledge with its focus on non-pharmacological treatments for chronic musculoskeletal pain, and its organization into first- and second-line treatments in the short, intermediate, and long terms, and recency. Further, this guideline was developed following best practices for trustworthy guidelines in accordance with IOM (2011a) standards. Lastly, this guideline stems from APA's policy on evidence-based practice that is grounded on the three domains noted by both the NAM (formerly IOM) and APA (American Psychological Association Presidential Task Force on Evidence-Based Practice, 2006; American Psychological Association, 2021) that integrate practitioner expertise; best available research, and patients' values, culture, and preferences. It is hoped that the current APA guideline will serve as a trustworthy and helpful evidence-based resource that will ultimately help to alleviate suffering among adults with chronic musculoskeletal pain and their loved ones.

Conflicts of Interest

Before final appointment to the panel, candidates completed a conflict of interest (COI) form that was then reviewed by the advisory steering committee or APA staff to ensure there were no identified conflicts that would prohibit participation, with the understanding that some "adversarial conflict" representing different points of views was to be expected and encouraged in this process. While intellectual affiliations were expected, no panel members had been singularly identified with particular approaches to intervention nor had significant known financial conflicts. Once the panel was formed, all panel members completed an educational module on conflicts of interest that underscored the importance of identifying and managing any potential conflicts, both financial and intellectual. The APA conflicts of interest policy and disclosure form are included in Appendix C.

All panel members and staff affiliated with development of the chronic pain clinical practice guideline updated their conflicts of interest form on an annual basis and were asked to provide more timely updates if changes in their disclosures were perceived to be relevant to the development of the guideline. All were asked to disclose all potential conflicts of interest with the understanding that these would be reviewed and evaluated, and a decision would be made regarding how to manage identified conflicts. Conflicts of interest included not only possibilities for financial or professional gain but also strong intellectual viewpoints that might then limit someone from objectively reviewing the evidence. Emphasis was placed on disclosing all potential conflicts and allowing the staff and chair (or other appropriate individual in the case of the chair) to review the disclosures and determine whether such information could reasonably be construed as a source of possible influence on the guideline development process. Furthermore, upon first joining the initiative and at the initial meeting, panel members were asked to verbalize their conflicts, so all present would be familiar with the diversity of perspectives and range of possible influences. This practice continued at subsequent meetings.

All panel members and staff were required to disclose their intellectual interests, financial and professional interests, interests related to APA, and other relevant interests. They were also required to disclose interests of family members, defined as “a spouse, domestic partner, parent, child, or other relative with whom [they] have a comparably close tie.” Authors were asked to disclose the following potential conflicts of interest: scientific/educational/professional communications, communications to a general audience, roles at APA or other organizations, relevant honoraria, endorsements, research funding or royalties, payment for services or training, and serving as expert witnesses. None of the reported potential conflicts of interest precluded a nominated candidate from serving on the guideline development panel. Excluding all guideline development panel candidates with any potential conflicts of interest risks excluding the level and type of expertise needed to fully evaluate treatment benefits and risks. The most knowledgeable individuals can be conflicted because of expertise in their areas of interest, and they may possess both financial and intellectual conflicts of interest from participating in research and serving as consultants to industry. However, these experts may possess unique insight into appropriate health care needs and recommendations.

There is growing recognition that financial relations to the pharmaceutical industry threaten the integrity of research and of clinical practice guidelines. However, the issue is still contentious, and exclusion of all potential guideline development panel members with such conflicts may itself be seen as biased against pharmacological treatments or particular medical specialties. Similarly, experts with respect to psychotherapy tend to have intellectual passions for specific types of psychosocial interventions that also constitute potential conflicts. Yet, such individuals may be difficult to replace because of their unique insights, as well as their status in the eyes of key stakeholders (IOM, 2011b). Hence, rather than exclude topic experts and risk minimizing expertise, APA follows the principle of adversarial collaboration in which competing interests are balanced on panels and committees, rather than avoided. This approach is also

used by other leading developer of clinical practice guidelines, such as the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines (American College of Cardiology Foundation & American Heart Association, 2010; IOM, 2011b). Conflict of interest forms for all authors are available by request for public review.

Author Disclosures

The Clinical Practice Guideline Development Panel reported the following disclosures during the development and approval of this guideline. The following points, drawn from panelists' disclosures, were among the information noted in assessing and managing potential financial and intellectual conflicts of interest.

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Lt. Col. Joseph T. Norris, JR, USAF, Ret., actively participates as a consultant/patient partner in a Patient-Centered Outcome Research Institute study focusing on communication and chronic pain at Cedars-Sinai Medical Center. Mr. Norris has authored several articles that addresses his personal experience of living with pain and currently serves as head of the American Chronic Pain Association Members' Advisory Committee.

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Developer

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Appendix A

Descriptions of Treatments Derived from the Research Included in the Systematic Reviews / Meta-Analyses

Adults with Chronic Musculoskeletal Pain (including low back, neck, knee, hip, and hand pain)		
Psychological	Acceptance and Commitment Therapy	A third-wave cognitive-behavior therapy that teaches patients how to sit with their thoughts and feelings, notice them from a third point of view, and accept them as they are without judgment while aligning with their values.
Psychological	Behavioral Therapy	Seeks to identify and help change potentially self-destructive or unhealthy behaviors and functions on the idea that all behaviors are learned and that unhealthy behaviors can be changed. The focus of treatment is often on current problems and how to change them.
Psychological	Biofeedback	A feedback loop intervention where patients are taught through psychological and physiological monitoring machines such as EEGs, ECGs, EKGs how to modify their bodily sensations.
Psychological	Cognitive-Behavioral Therapy	Utilizes behavioral and cognitive strategies, particularly exposure, cognitive restructuring, changes in behavior, and development of coping skills, to address learned and conditioned behaviors, thoughts and emotional and psychophysiological reactions.
Psychological	Computerized CBT	Using a computer or the Internet to provide CBT.
Psychological	Motivational Interviewing	A collaborative approach where the therapist assists the patient in identifying the behaviors they want to change and problem-solve the barriers behind making these behavioral changes.
Psychological	Operant Therapy	A cognitive-behavioral strategy where behavior can be modified based on rewards and punishments.
Psychological	Pain Coping Skills Training	A training that combines CBT and motivational interviewing principles that teaches patients how to identify and modify maladaptive thinking patterns about pain and how to apply these principles in their everyday lives.
Psychological	Psychoeducation	A psychological intervention that educates patients about the cause and management of chronic pain.
Psychological	Relaxation Training / Progressive Muscle Relaxation	Individual learns how to reduce external distractions and concentrate on specific thoughts, feelings, or images.
Pharmacological	Acetaminophen	An over the counter or prescribed medication used to alleviate chronic pain.
Pharmacological	Non-Steroidal Anti-Inflammatory Drug (NSAID)	A class of medications used to alleviate chronic pain. Types of NSAIDs include ibuprofen,

		naproxen, diclofenac, celecoxib, mefenamic acid, etoricoxib, indomethacin, and low-dose aspirin.
Physical Exercise [Muscle Performance]	Resistance Training (strength, power, or endurance exercises)	Involves a variety of physical exercises with the goal being to strengthen muscles and improve flexibility.
Physical Exercise [Muscle Performance]	Sling Exercise	Involves using suspension devices such as ropes or slings to strengthen the entire body.
Physical Exercise [Muscle Performance]	Aquatic Therapy/Exercise	Physical exercises that are performed in the water.
Physical Exercise [Muscle Performance]	Musculoskeletal Rehabilitation	A variety of treatments employed by multidisciplinary specialists to rehabilitate and improve muscle function.
Physical Exercise [Muscle Performance]	Pilates	A physical exercise technique that involves controlling muscle stretches and breathing exercises.
Physical Exercise [Neuromuscular Re-Education]	Motor Control Exercises (MCE)	A physical exercise technique where patients use their muscles through completing simple tasks.
Physical Exercise [Neuromuscular Re-Education]	Trunk Coordination / Trunk Strengthening	A physical exercise that strengthens and conditions stomach muscles.
Physical Exercise [Neuromuscular Re-Education]	Stabilization Exercises	A type of exercise with the goal of strengthening the core muscles.
Physical Exercise [Neuromuscular Re-Education]	Posture Training	A type of training that improves how the patient sits, walks, and stands that will then reduce pain.
Physical Exercise [Mobility, Flexibility]	McKenzie/Directional Preference	“A biopsychosocial system of musculoskeletal care emphasizing patient empowerment and self-treatment” (The McKenzie Institute, 2023).
Physical Exercise [Mobility, Flexibility]	Stretching	A type of physical exercise where the muscles are elongated in order to improve flexibility and coordination.
Physical Exercise [Mobility, Flexibility]	Lumbar Flexion Exercises	A type of physical exercise that improves flexibility and strengthens muscles in the lower back.
Physical Exercise [Mobility, Flexibility]	Other Mobility or Flexibility Exercises	Other exercises not noted above.
Physical Exercise [Cardiovascular/Aerobic]	Cardiovascular Training	A type of training that requires the use of the heart, lungs, and blood vessels.
Physical Exercise [Cardiovascular/Aerobic]	Aerobic Training	A type of training that requires the use of oxygen.
Physical Exercise [Cardiovascular/Aerobic]	Walking	A mode of personal transportation and exercise.
Physical Exercise [Cardiovascular/Aerobic]	Aquatic Therapy / Exercise (aerobic-focused)	Performance of aerobic exercises in the water.
Physical Exercise [Combined Exercise]	Combined Exercise	Intervention combining exercises from two or more of the above categories.

Physical Modalities	Low-Level Laser Therapy	“A non-invasive light source treatment that generates a single wavelength of light” (Physiopedia, 2023).
Manual Therapies	Massage	A type of manual therapy that involves a licensed therapist rubbing the muscle to reduce pain and improve flexibility.
Manual Therapies	Spinal Manipulation	A type of manual therapy employed by Chiropractors or Doctor of Osteopathic Medicine (DO) that manipulates a specific part of the body to reduce pain and improve flexibility.
Mind-Body Practices	Alexander Technique	A type of therapy that involves teaching patients how to be aware of their current posture and ways to improve their posture to reduce pain.
Mind-Body Practices	Basic Body Awareness Therapy	A type of physiotherapy where it trains patients to increase their awareness of their body sensations while engaging in movement.
Mind-Body Practices	Qi-Gong	Pronounced “chi-gong”, it is a mind-body practice with roots in Eastern medicine that involves improving body posture, breathing, and meditative exercises.
Mind-Body Practices	Tai Chi	A form of exercise where patients form a posture and focus and meditate on the specific posture.
Mind-Body Practices	Yoga	A system of physical postures, breathing techniques, and sometimes meditation designed to promote physical and emotional well-being.
Mindfulness Practices	Mindfulness-Based Stress Reduction (MBSR)	An eight-week group program where patients are trained with a variety of mindfulness and meditation skills with the goal of improving emotion regulation.
Complementary/Integrative Treatment	Acupuncture	A technique where practitioners apply needles to certain areas of the patients’ body in order to relieve pain.
Complementary/Integrative Treatment	Multicomponent Self-Management Interventions	A treatment model that integrates multiple physical, psychological, educative, and occupational exercises with one of the goals being improving self-efficacy in being able to manage pain.
Complimentary/Integrative Treatment	Multidisciplinary Rehabilitation	A rehabilitative approach that involves multiple specialties (psychological, physical therapy, medicine, nursing, social work, occupational therapy) in treating and managing chronic pain.

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Appendix B

Definition of Key Terms

Advisory Steering Committee (ASC). The Advisory Steering Committee is a group of distinguished psychologists appointed by the APA Board of Directors (BOD) to oversee APA's CPG development process. The ASC selects which nominated topics will be considered for guidelines and assembles the panels who write the guidelines, but they are not directly involved in conducting SRs, nor in writing CPGs. In addition, while the ASC reports to the BOD, the ASC operates autonomously from APA governance to prevent real or perceived COIs.

Agency for Healthcare Research and Quality (AHRQ). An agency within the US Department of Health and Human Services, AHRQ supports research that helps people make more informed decisions and improves the quality of health care services. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans, with the following focus areas: comparing the effectiveness of treatments; quality improvement and patient safety; health information technology; prevention and care management; and health care value. AHRQ develops systematic reviews on topics of greatest public health impact. Topic nomination is an open process through AHRQ's Effective Healthcare Program; APA uses this as one mechanism to support SRs for CPG development.

AMSTAR-2 (A MeaSurement Tool to Assess Reviews-Version 2). A tool designed to systematically assess the quality of the methods used to conduct systematic reviews. Further information about AMSTAR-2 can be found at: https://www.bmj.com/content/358/bmj.j4008)

Applicability. Consistent with the aim of comparative effectiveness research, that is, to help consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. Applicability is analogous to external validity or generalizability (IOM, 2011a).

Benefit. A positive or valued outcome of an action or event (IOM, 2011a).

Bias. A systematic deviation or process that favors one outcome over others (Gluud, 2006). Bias may lead to under- or over-estimation of treatment effects. It is impractical and most likely impossible to quantify every potential source of bias that may influence an individual study (Chavalarias & Ioannidis, 2010); however, a number of specific methodological flaws or limitations in research design, implementation, analysis, and evaluation often produce biased outcomes.

Cochrane. Founded in 1993, Cochrane is an international nonprofit organization whose mission is "to produce trusted synthesized evidence, make it accessible to all, and advocate for its use." Cochrane meets its mission in part by not accepting commercial or financial interests in the production and dissemination of systematic reviews and training manuals. Its manuals and systematic reviews of the treatment for particular health conditions are provided for free to researchers, health care professionals, policy makers, and the general public. Additional information about Cochrane can be found at: https://www.cochrane.org/

Comparative effectiveness research (CER). The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to help consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. Also referred to as clinical effectiveness research (IOM, 2011a).

Confidence interval (CI). A confidence interval is a range around an estimate that conveys how precise the estimate is; for example, an estimate of the risk of an event occurring or an estimate such as a risk ratio that compares the risk with and without an intervention. The confidence interval is a guide to how sure we can be about the quantity we are interested in. The narrower the range between the two numbers, the more confident we can be about what the true value is; the wider the range, the less sure we can be. The width of the confidence interval reflects the extent to which chance may be responsible for the observed estimate (with a wider interval reflecting more chance). 95% Confidence Interval (CI) means that we can be 95 percent confident that the true size of effect is between the lower and upper confidence limit. Conversely, there is a 5 percent chance that the true effect is outside of this range (Treweek et al., 2013).

Effectiveness. The impact of an intervention compared to active treatment.

Efficacy. The impact of an intervention compared to an inactive control.

Estimate of effect. The observed relationship between an intervention and an outcome expressed as, for example, a number needed to treat to benefit, odds ratio, risk difference, risk ratio, standardized mean difference, or weighted mean difference.

Evidence. Information on which a decision or guidance is based. Evidence is obtained from a range of sources, including randomized controlled trials, observational studies, and expert opinion of clinical professionals or patients (IOM, 2011b).

Functional impairment. Limitations to carry out certain function the social and occupational spheres of life due to physical or mental illness.

GRADE (GRADE collaboration and Framework). The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group, which began in the year 2000, is an international collaboration of scholars with an interest in addressing the shortcomings of present grading systems for CPGs in health care. The working group has developed a sensible and transparent framework for grading quality of evidence and strength of recommendations, typically referred to as “GRADE” (or the GRADE system). Many international organizations provided input into the development of the approach and have started using it (for further information, see http://www.gradeworkinggroup.org/).

Guideline Development Panel (GDP). A multidisciplinary Guideline Development Panel is assembled for the purpose of developing a specific CPG. GDPs are tasked with generating treatment recommendations from systematic reviews and drafting the content of the CPGs. These activities take place independently from APA governance/staff, the ASC, and Systematic Review Teams, who play no part in developing the CPG recommendations. There is some interaction between the SRT and GDP to ensure that the systematic review will meet the needs of the CPG developers; yet the nature of the interaction is transparent and circumscribed to maintain the objectivity and validity of both the systematic review and the CPG.

Harm. A hurtful or adverse outcome of an action or event, or with regard to CPGs, a treatment or health care decision/recommendation, whether temporary or permanent (IOM, 2011b).

Institute of Medicine (IOM, now National Academy of Medicine). A private, nonprofit institution that provides objective, timely, authoritative information and advice concerning health and science policy to the government, the corporate sector, the professions, and the public under a congressional charter.

Meta-analysis. The use of quantitative statistical methods in a systematic review to integrate the results of included studies.

Neuropathic Pain. A type of pain that may be associated with nerve damage (Fitzcharles et al., 2021).

Nociceptive Pain. A type of pain that may be associated with overstimulation of the sensory neurons (Fitzcharles et al., 2021).

Nociplastic Pain. A type of pain that is widespread and not due to tissue or nerve damage (Fitzcharles et al., 2021).

Outcome. A change resulting from an intervention. In evaluations, a potential consequence of an intervention that is measured after the intervention has been implemented, that is used to assess the potential beneficial and harmful effects of the intervention. **Critical outcomes** are the outcomes of greatest importance for answering key questions in systematic reviews. **Health outcomes**, also referred to as **patient-centered outcomes**, are clinical outcomes that affect how patients feel, live or survive, such as quality of life, rate of survival, and patient satisfaction (Boyd et al., 2012).

Patient-centeredness. Respect for and responsiveness to individual patient preferences, needs, and values; helps ensure that patient values and circumstances guide clinical decisions (IOM. 2011a).

PICOTS (questions). Systematic reviews seek to answer clearly formulated key questions that will simplify decision-making about real world practices, and thereby inform CPG recommendations. These key questions are developed using the PICOTS framework, an acronym denoting the following components that should be specified in each key question: Patient populations (P), Interventions (I), Comparison conditions (C), Outcomes (O), Timing or timeframe (T), and Settings (S) (Samson & Schoelles, 2012). For this reason, the key questions in systematic reviews are frequently referred to as *PICOTS* (or *PICOTS questions)*. *Timing* and *Settings* are newer additions to the framework; hence, key questions may also be called PICOS (or PICO questions) by some investigators.

Publication bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g., only outcomes or sub-groups where a statistically significant difference was found).

Quality of evidence. The extent to which one can be confident that the estimates of an intervention's effectiveness are adequate to support a particular decision or recommendation (IOM, 2011b; Schünemann et al., 2011). AHRQ uses “strength of evidence” (SOE) to refer to the same basic concept.

Randomized controlled trial (RCT). An experiment in which two or more interventions, often including a control intervention or no intervention, are compared by randomly allocating participants to the interventions. The term ‘trial’ is sometimes used to refer to randomized controlled trials (RCTs); however, the term may also be used to refer to quasi-randomized trials (which do not randomly assign participants to groups).

Relative Effects. A quantitative measure for evaluating harms and benefits of treatment, expressed as the ratio of two indicators of the frequency of the outcome. A *risk ratio* (RR) is the ratio between

the risk (incidence) of the outcome event in the intervention group and the risk in the control group. For example, if the risk of the outcome event in the intervention group is 5% (5 per 100) and the risk in the control group is 20% (10 per 100), the RR is .05 / .20 = .25. If the RR is less than 1, the risk of the outcome event in the intervention group is less than the control group. If the RR is equal to 1, the risk in the two groups is equal. If the RR is greater than 1, the intervention increases the risk of the outcome compared to the control group.

An odds ratio (OR) is also a measure of relative effects, in this case, the odds (not risk) in the intervention group compared to the odds (not risk) in the control group. An odds is a mathematical formula for the probability of an event happening divided by the probability of that event not happening or, mathematically: odds = p / (1-p). Thus, if the risk in the intervention group is 5% (i.e., .05), then the odds in the intervention group is .05 / .95 = .05 (with rounding). If the risk in the control group is .20, then the odds in the control group is .20 / .80 = .25. The odds ratio is then .05 / .25 = .20. Odds ratios can be interpreted similarly to risk ratios. However, when the risk of the outcome event is high, the odds ratio will be different from the risk ratio.

Risk of bias. The extent to which flaws in the design and execution of a collection of studies could bias the estimate of effect for each outcome under study (IOM, 2011b).

Strength of Evidence. The extent to which one can be confident that the estimates of an intervention's effectiveness are adequate to support a particular decision or recommendation (IOM, 2011b; Schünemann et al., 2011). GRADE uses “quality of evidence” to refer to the same basic concept.

Strength of Recommendation. The strength of a recommendation reflects the extent to which one can be confident that the desirable outcomes of a treatment alternative outweigh the undesirable outcomes, across the range of patients to whom the recommendations apply (IOM, 2011b; Schünemann et al., 2011).

Study Quality. For an individual study, study quality refers to all aspects of a study’s design and execution and the extent to which bias is avoided or minimized. A related concept is internal validity; that is, the degree to which the results of a study are likely to be true and free of bias (IOM, 2011b).

Systematic Review (SR). A rigorous approach to synthesizing data from research studies on the benefits, harms and effectiveness of alternative treatment options that pertain to a particular clinical population (IOM, 2011b). Systematic reviews use pre-specified criteria for screening, selecting, appraising, grading, and synthesizing outcomes, from a body of research studies, to answer specific clinical questions in areas of uncertainty. SRs seek to minimize bias by using explicit, standardized procedures (Chandler et al., 2021). The use of standardized criteria enhances the reliability of the findings and confidence in the conclusions about the relative advantages of alternate treatment approaches (IOM, 2011a).

Transparency. Methods are explicitly defined, consistently applied, and available for public review so that observers can readily link judgments, decisions, or actions to the data on which they are based. Allows users to assess the strengths and weaknesses of the systematic review or CPG (IOM, 2011a).

Treatment Recommendation. In the context of CPGs, treatment recommendations are statements that propose a course of action with respect to a specific health care service, test, psychotherapy or pharmacotherapy etc., or procedure. Well-constructed recommendations specify what should be offered or provided to patients, as well as under what specific conditions the recommendation

applies (Rosenfeld & Shiffman, 2009; Shiffman, 2009). In addition, the IOM (2011b) specifies that CPG recommendations should include alternative treatment options.

Appendix C

APA Declarations / Conflicts of Interest Form

Clinical Practice Guideline Initiative

CONFLICT OF INTEREST POLICY

AND

DECLARATION OF INTERESTS

_____

Year

Covered Individual:

Name: _____

Please indicate your role in the initiative:

____ Advisory Steering Committee (ASC) Member

____ Guideline Development Panel (GDP) Member

→ *If GDP Member, please name the topic of the panel:* _____

____ Guideline Update Panel (GUP) Member

→ *If GUP Member, please name the topic of the panel:* _____

____ Consultant

____ APA Staff

Instructions:

Please read the APA Conflict of Interest Policy and complete the Declaration of Interests form and sign the statement at the end. (*ASC Members: Please also read supplementary instructions.*)

Conflict of Interest Policy

It is the aim of the American Psychological Association ("APA") to transact all its business, including the APA clinical practice guideline initiative, lawfully and impartially. In some situations, the relationship of a Covered Individual (as defined below) with a third party, financial or otherwise, could reasonably be construed to create a conflict between the interests of APA and the interests of the Covered Individual.

Covered Individuals are required to disclose to APA any actual, potential, or perceived conflict of interest ("COI") with APA or with their role in the clinical practice guideline initiative, including conflicts from the past 12 months and expected conflicts in the upcoming 12 months. A COI may be of a financial, intellectual, or other nature, as defined below. APA requires Covered Individuals to disclose COIs prior to official appointment to a committee/panel or as a consultant, as well as at the time points noted below. The existence of COIs will not necessarily preclude participation in the guideline initiative, although it may require limiting a Covered Individual's role. APA staff involved in the initiative may also be asked by their supervisors to disclose COIs, following the same policy as for Covered Individuals.

This policy is designed to promote transparency, to protect the integrity of the guideline initiative, and to provide a mechanism to help protect Covered Individuals and APA from legal concerns associated with conflicts of interest.

Covered Individuals: This policy applies to members of the Advisory Steering Committee and the Guideline Development Panels of the APA clinical practice guideline initiative and to consultants who are formally engaged by APA for work on the initiative.

Term: Covered Individuals shall be bound by this conflict-of-interest policy during the official term of their position on the committee/panel or as a consultant.

Definition of COI: A 2011 report from the Institute of Medicine ([IOM] now called the National Academy of Medicine) includes the following definition of COI: "a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing." (See IOM, 2011, p. 78; the definition is drawn from Schünemann et al., 2009, p. 565).

The IOM report also discusses intellectual COIs relevant to clinical practice guidelines, which it defines as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation" (IOM, 2011, p. 78; the definition is drawn from Guyatt et al., 2010, p. 739).

COIs can arise in various situations and may involve the individual or a member of the individual's family (spouse, domestic partner, parent, child, or another close relative). Examples of potential COIs include, but are not limited to, the following:

- Receiving payment for directly providing, or training other professionals to provide, health services related to the topic(s) of the guideline(s) being developed.
- Receiving honoraria for presentations or discussions of scientific or clinical issues related to the topic(s) of the guideline(s) being developed.

- Receiving royalties for books or other materials that address scientific or clinical issues related to the topic(s) of the guideline(s) being developed.
- Receiving funding, in the form of grants or contracts, for research on scientific or clinical issues related to the topic(s) of the guideline(s) being developed.
- Serving in a governance or other volunteer position in an organization that provides health services, promotes research related to health services, or develops or advocates for health service policies, related to the topic(s) of the guideline(s) being developed.
- Having strongly held opinions or other intellectual biases that might compromise objectivity in addressing the topic(s) of the guideline(s) being developed.
- Having a significant ownership interest in or significant capacity to influence decisions of a firm or organization that is an APA competitor, customer, or supplier, or a firm that conducts research or provides health services related to the topic(s) of the guideline(s) being developed.
- Being employed by or performing other work (including consulting) for a competitor, customer, or supplier of APA, regardless of the nature of that work.
- Conduct of APA business of any kind, or arranging for such business, with a firm that one owns or controls.
- Acceptance of any money, property, or anything of value from a person or firm doing or seeking to do business with APA.
- Receipt of direct or indirect economic benefit as a consequence of acquisition, lease, or sale by APA of any property, facilities, materials, or services.

COI Reporting: Covered Individuals must complete a Declaration of Interests form (appended below) disclosing any actual, potential, or perceived COIs prior to appointment to a committee/panel or as a consultant, and thereafter on an annual basis. If, during the year, a change occurs in a Covered Individual's COIs or in their family members' COIs, the Covered Individual must report that information immediately to APA staff who work on the clinical practice guideline initiative, who will share it with the relevant committee/panel Chair or Vice Chair. Covered Individuals are expected to provide any updates regarding their COIs orally at the beginning of all official committee/panel meetings.

In addition, Covered Individuals should disclose any professional papers or presentations on which they are listed as authors, prior to publication or delivery, that pertain to the topic(s) of the guideline(s) with which they are involved. This disclosure should be made to APA staff involved in the initiative.

If a Covered Individual is unsure whether particular information should be reported, or if the information is sensitive or confidential, the Individual may first consult with APA staff involved in the initiative about whether and how to report it. With the individual's permission, the staff may then seek further guidance from the Chair or Vice Chair of the relevant committee/panel.

Disclosure of any actual, potential, or perceived COI is the responsibility of everyone participating in the clinical practice guideline initiative. In general, if any Covered Individual or APA staff member is aware of circumstances that may constitute a COI involving another participant in the initiative, then the individual should first discuss it with that participant. If such a discussion is not appropriate or if the discussion does not produce a satisfactory result, then they should discuss it with APA staff and/or the relevant committee/panel Chair or Vice Chair.

COI Review and Management: Each Covered Individual's completed Declaration of Interests form will be reviewed by APA staff and by the Chair and/or Vice Chair of the relevant committee/panel (or only by APA staff for consultants). The individual's resume or curriculum vitae, as well as publicly available materials about the individual, may also be examined in the course of the review. The primary purpose of the review is to determine whether the individual has any actual, potential, or perceived COIs that would preclude the individual from participation in the clinical practice guideline development initiative or require resignation from any role that they already have in the initiative.

Having one or more COIs does not necessarily mean that a Covered Individual cannot be involved in the initiative. If the reviewers determine that an individual's COIs do not preclude participation, then the reviewers will identify what actions, if any, may be needed to resolve or manage the impact of the COIs on the integrity (both actual and perceived) of the initiative. Examples of such actions may include limitations on the individual's participation in discussions, deliberations, or voting on specific matters and not being counted in determining a quorum for all or portions of a particular committee/panel meeting. Such actions would not prevent the individual from briefly stating their position or answering questions on relevant matters. Possible actions for managing the impact of COIs will be discussed with the Covered Individual, but final decisions on which actions are taken are made by APA staff in consultation with the relevant committee/panel Chair and/or Vice Chair. In some cases, the APA General Counsel may participate in making such decisions. Also, in some cases in which the Covered Individual is a member of a Guideline Development or Update Panel or a consultant, the Chair and/or Vice Chair of the Advisory Steering Committee may participate in making such decisions.

If any new COIs are reported or discovered during the period after a Declaration of Interests form has been submitted, APA staff and the relevant committee/panel Chair and/or Vice Chair will determine whether any further actions are required for managing their impact on the initiative.

For Covered Individuals who are members of a committee/panel, information about all actual, potential, and perceived COIs are shared with all other members of the committee/panel. Information about all actions taken to resolve or manage the impact of COIs are also shared with all members of the committee/panel.

Record of COIs: APA retains a copy of all completed Declaration of Interests forms and related documents. Both summary and individual information about Covered Individuals' COIs and of actions taken to manage their impacts may be made available for public view; this information potentially includes completed Declaration of Interests forms.[10] Information about COIs and actions taken may also appear in meeting minutes and summaries, which will also be available for public view.

[10] Note, no information will be publicly released about people who are nominated or considered for positions on a committee/panel or as consultants but not selected.

References

Guyatt, G., Akl, E. A., Hirsh, J., Kearon, C., Crowther, M., Gutterman, D., Lewis, S. Z., Nathanson, I., Jaeschke, R., & Schünemann, H. (2010). The vexing problem of guidelines and conflict of interest: A potential solution. *Annals of Internal Medicine, 152*(11), 738–741. https://doi.org/10.7326/0003-4819-152-11-201006010-00254

Institute of Medicine. (2011). *Clinical practice guidelines we can trust*. National Academies Press. http://www.nap.edu/catalog.php?record_id=13058

Schünemann, H. J., Osborne, M., Moss, J., Manthous, C., Wagner, G., Sicilian, L., Ohar, J., McDermott, S., Lucas, L., & Jaeschke, R. (2009). An official American Thoracic Society policy statement: Managing conflict of interest in professional societies. *American Journal of Respiratory Critical Care Medicine, 180*(6), 564–580. https://doi.org/10.1164/rccm.200901-0126ST

Declaration of Interests

The purpose of this Declaration is to identify your actual, potential, and perceived conflicts of interest with APA and with your role in the APA clinical practice guideline initiative. Having conflicts of interest does not necessarily preclude participation in the initiative. Decisions about how conflicts should be managed will be made by APA staff in consultation with the Chair or Vice Chair of any committee or panel of which you are a member.

Please answer the following questions by marking either 'Yes' or 'No' and then explaining any 'Yes' answers in the space immediately following or by attaching supplementary materials. When responding, please think about the full range of research, teaching, practice, writing, service work, and professional relationships in which you and your family members are involved. (You may consult with APA staff in advance if you have any questions or concerns about what information to provide on this form.)

The questions are organized into four sections:

I. Intellectual Interests
II. Financial and Professional Interests
III. Interests Related to APA
IV. Other Relevant Interests

For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.

Please attach a CV, resume, or other materials if these are needed to provide complete answers.

(Questions begin on next page.)

OVERVIEW

I. Intellectual Interests

1. Scientific/educational/professional communications
2. Communications with general audiences
3. Expert witness
4. Treatment and/or research approach
5. Topic proposals

II. Financial and Professional Interests

1. Payment for services or training
2. Honoraria
3. Royalties
4. Endorsements
5. Research funding
6. Employer
7. Roles in organizations
8. Influence/ownership/stock in health-related firms

III. Interests related to APA

1. APA roles
2. Influence/ownership/stock in firms of interest to APA
3. Paid work with other firms that do business with APA
4. Business ties to APA
5. Ties to others seeking business with APA
6. Other economic benefits related to APA business

IV. Other relevant interests

1. Other professional activities
2. Legal proceedings
3. Misconduct
4. Additional activities
5. Relationships

I. *INTELLECTUAL INTERESTS*

(The questions in this section concern only you, not family members.)

1. Scientific/educational/professional communications

a.	Over the past 12 months, have you had any scientific, educational, or professional publications (*including in-press*) or made any scientific, educational, or professional presentations related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? Has your name been included on a relevant speakers' bureau list? *Please include both paid and non-paid work.*	___ No ___ Yes	*If 'Yes,' please explain:**
b.	Do you expect that, over the next 12 months, you will have any such publications or presentations or that your name will be included on a speakers' bureau list?	___ No ___ Yes	*If 'Yes,' please explain:**

** If 'Yes' to any of these questions, please provide a list of the relevant publications, presentations, courses, and speakers' bureaus. You may attach a copy of your CV or resume at the end of this form but please make sure to add any items that do not yet appear on those documents.*

2. Communications with general audiences

a.	Over the past 12 months, have you made presentations to a general (*non-academic, non-scientific*) audience that address research, clinical, or policy issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? Have you been involved in organizing any events that include such presentations?	___ No ___ Yes	*If 'Yes,' please explain:**
b.	Over the past 12 months, have you published articles or books for a general audience or produced materials for television, radio, or the Internet (e.g., blogs, online petitions, Facebook, LinkedIn, TED Talks, Twitter, YouTube) that address these issues? *Please include both paid and non-paid work. You need not include formal research publications for academic or scientific audience.*	___ No ___ Yes	*If 'Yes,' please explain:**
c.	Do you expect that, over the next 12 months, you will be involved in any such activities?	___ No ___ Yes	*If 'Yes,' please explain:**

** If 'Yes' to any of these questions, please provide a list of the relevant publications, presentations, courses, and speakers' bureaus. You may attach a copy of your CV or resume at the end of this form but please make sure to add any items that do not yet appear on those documents.*

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3. Expert witness

a.	Over the past 12 months, have you served as an expert witness in a court case or other legal proceeding on a matter related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you will serve as an expert witness in a legal proceeding?	___ No ___ Yes	*If 'Yes,' please explain:*

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4. Treatment and/or research approach

Do you identify yourself as having a particular approach or orientation to treatment and/or research (theoretical, methodological, societal, etc.)? Do you believe others perceive you as having a particular approach or orientation?

____ No ____ Yes

If 'Yes,' please explain:

5. Topic proposals

Have you previously proposed to APA or another organization that it develop (a) a clinical practice guideline on a particular topic or (b) a systematic review of research on a particular topic that could serve as a foundation for subsequent guideline development?

____ No ____ Yes

If 'Yes,' please describe the topic, the organization, and the form by which you proposed it:

II. *FINANCIAL AND PROFESSIONAL INTERESTS*

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

1. Payment for services or training

a.	Over the past 12 months, have you or a family member received payment for directly providing, or training other individuals to provide, health services related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing (*Health services include professional, community-based, and peer support services*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will receive payment for such activity?	___ No ___ Yes	*If 'Yes,' please explain:*

2. Honoraria

a.	Over the past 12 months, have you or a family member received any honoraria for presentations or discussions of scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing (*Please include honoraria that were donated to charity*)?	___ No ___ Yes	*If 'Yes,' please explain:*

b.	Do you expect that, over the next 12 months, you or a family member will receive any such honoraria?	___ No ___ Yes	*If 'Yes,' please explain:*

3. Royalties

a.	Over the past 12 months, have you or a family member received royalties or advance payments for books, films, or other materials that address scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing (*Please include royalties that were donated to charity*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will receive any such royalties or advance payments?	___ No ___ Yes	*If 'Yes,' please explain:*

4. Endorsements

a.	Over the past 12 months, have you or a family member received monetary or other material compensation for endorsing a product or service related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing (*Please include compensation that was donated to charity*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will receive such compensation for an endorsement?	___ No ___ Yes	*If 'Yes,' please explain:*

5. Research funding

a.	Over the past 12 months, have you or a family member received funding, in the form of grants, fellowships, or contracts, for research or research training on scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will receive any such funding?	___ No ___ Yes	*If 'Yes,' please explain:*

6. Employer

a.	Over the past 12 months, have you or a family member held a job with an employer that has economic, policy, or other interests in healthcare guidelines in general or in the particular topic(s) of the guideline(s) that you will be involved in developing or overseeing (*Please consider both full- and part-time positions and both permanent and temporary positions*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will hold a job with an employer that has such interests?	___ No ___ Yes	*If 'Yes,' please explain:*

7. Roles in organizations

a.	Over the past 12 months, have you or a family member served in a governance, advisory, or other position in an organization (other than APA) that provides health services, promotes research related to health services, or develops or advocates for health service policies, related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?	___ No ___ Yes	*If 'Yes,' please explain:*

b.	Do you expect that, over the next 12 months, you or a family member will serve in such a position?	___ No ___ Yes	*If 'Yes,' please explain:*

8. Influence/ownership/stock in health-related firms

a.	Over the past 12 months, have you or a family member had significant capacity to influence decisions of a firm or organization that conducts research or provides health services related to the topic(s) of the guideline(s) being developed (*Health services include professional, community-based, and peer support services*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Over the past 12 months, have you and/or any family member(s) held an ownership interest greater than 5% in such a firm? Have you and/or any family member(s) owned stock in such a firm that exceeded $10,000 in value at any time during the past 12 months (*Please consider the total amounts held by you and family members, e.g., whether the stock that your spouse and your parent own adds up to more than $10,000 in value*)?	___ No ___ Yes	*If 'Yes,' please explain:*

c.	Do you or any family member hold stock options of any value in such a firm?	___ No ___ Yes	*If 'Yes,' please explain:*
d.	Do you expect that, over the next 12 months, you or a family member will have such capacity to influence a firm or have such ownership or stock interests?	___ No ___ Yes	*If 'Yes,' please explain:*

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III. *INTERESTS RELATED TO APA*

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

1. APA roles

a.	Over the past 12 months, have you or a family member been a member of any APA governance group, task force, or advisory body (*Please include roles in APA divisions*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will serve as a member of such an APA group?	___ No ___ Yes	*If 'Yes,' please explain:*

2. Influence/ownership/stock in firms of interest to APA

a.	Over the past 12 months, have you or a family member had a significant capacity to influence decision of a firm or organization that is an APA competitor, customer, or supplier?	___ No ___ Yes	*If 'Yes,' please explain:*

b.	Over the past 12 months, have you and/or any family member(s) held an ownership interest greater than 5% in such a firm? Have you and/or any family member(s) owned stock in such a firm that exceeded $10,000 in value at any time during the past 12 months (*Please consider the total amounts held by you and family members, e.g., whether the stock that your spouse and your parent own adds up to more than $10,000 in value*)?	___ No ___ Yes	*If 'Yes,' please explain:*
c.	Do you or any family member(s) hold stock options of any value in such a firm?	___ No ___ Yes	*If 'Yes,' please explain:*
d.	Do you expect that, over the next 12 months, you or a family member will have such capacity to influence a firm or have such ownership or stock interests?	___ No ___ Yes	*If 'Yes,' please explain:*

3. Paid work with other firms that do business with APA

a.	Over the past 12 months, have you or a family member been employed by or performed other work (*including consulting*) for a competitor, customer, or supplier of APA, regardless of the nature of that work?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will be engaged in such employment or work?	___ No ___ Yes	*If 'Yes,' please explain:*

4. Business ties to APA

a.	Over the past 12 months, have you or a family member conducted APA business of any kind, or arranged for such business, with a firm that is owned or controlled by you or a family member?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will conduct or arrange for such business?	___ No ___ Yes	*If 'Yes,' please explain:*

5. Ties to others seeking business with APA

a.	Over the past 12 months, have you or a family member accepted any money, property, or anything of value from a person or firm doing or seeking to do business with APA?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will accept any money, property, or anything of value from a person or firm doing or seeking to do business with APA?	___ No ___ Yes	*If 'Yes,' please explain:*

6. Other economic benefits related to APA business

a.	Over the past 12 months, have you or a family member received any direct or indirect economic benefit as a consequence of acquisition, lease, or sale by APA of any property, materials, or services?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Over the past 12 months, have you or a family member received any other direct or indirect economic benefit related to APA business that are not covered in the previous questions?	___ No ___ Yes	*If 'Yes,' please explain:*

c.	Do you expect that, over the next 12 months, you or a family member will receive any such economic benefit?	___ No ___ Yes	*If 'Yes,' please explain:*

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IV. *OTHER RELEVANT INTERESTS*

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

1. Other professional activities

a.	Over the past 12 months, have you or a family member engaged in any other scientific, academic, clinical, business, or policy activities, either paid or unpaid, related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing (*This question is asking about activities not already addressed in answers to the previous questions*)?	___ No ___ Yes	*If 'Yes,' please explain:*
b.	Do you expect that, over the next 12 months, you or a family member will engage in other such activities?	___ No ___ Yes	*If 'Yes,' please explain:*

2. Legal proceedings

At any point over the last 12 months, have you or a family member been under prosecution for a crime? Have you or family member been involved in any civil legal proceedings as either defendant or plaintiff (*Please include all such legal proceedings, including those not related to the topic(s) of the guideline(s) you will be involved in developing or overseeing*)?

____ No ____ Yes

If 'Yes' to either question, please explain:

---

3. Misconduct

At any point over the last 12 months, have you or a family member been under formal charges of misconduct by any organization? This may be any type of misconduct (ethical, academic, professional, research, financial, etc., including harassment and discrimination). What is the current status of any such charges or related investigation? If charges have been resolved, what was the outcome? (*Please include all such charges, including those not related to the topic(s) of the guideline(s) you will be involved in developing or overseeing.*)

____ No ____ Yes

If 'Yes,' please explain:

4. Additional activities

Is there any other information regarding your or your family members' activities, including interactions with organizations and individuals, that you believe is relevant to the guideline(s) that you will be involved in developing or overseeing or to your working with APA (*Please focus on activities that may constitute actual, potential, or perceived conflicts of interest, and include activities that occurred* **more than 12 months ago or are expected to occur more than 12 months from now**)?

____ No ____ Yes

If 'Yes,' please explain:

---

5. Relationships

Do you have any concerns that your work on guideline development or with APA could have a significant negative impact on any **professional or personal relationships** you have with mentors, students, trainees, colleagues, supervisors, funders, friends, or relatives (*For this question, please consider all relatives in addition to spouse, domestic partner, parents, and children*)?

____ No ____ Yes

If 'Yes,' please explain:

Finally, please read, complete, and sign the following statement:

I, _____, have read and understood the requirements of **APA's Conflict of Interest Policy** above and I agree to abide by the Policy throughout the official term of my position in the APA clinical practice guideline initiative.

I have also fully and truthfully answered the questions in the **Declaration of Interests** above about all actual, potential, and perceived conflicts of interest.

If any new actual, potential, or perceived conflicts of interest arise, I agree to disclose them as soon as possible, but within no more than 30 days, to APA staff and to the Chair or Vice Chair of any committee or panel of which I am a member.

_____ _____

DocuSign® Signature **Date**

Please attach your current CV, resume, or other materials, as needed, before submitting the DocuSign® form by clicking on the paper clip icon.

Please also sign the separate Intellectual Property Statement.

For any questions, please contact the APA Clinical Practice Guidelines Team at cpg@apa.org.

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For APA Staff Use Only

Appendix D

Voting Procedures Established by the Advisory Steering Committee (ASC)

1) What % should be considered a majority for winning a vote?

The ASC agreed that at least 70% of the whole constituted panel would constitute a strong recommendation. For conditional recommendations, agreement among more than 50% with less than 20% of panel members preferring an alternative recommendation must be reached. The denominator for voting will be the number of the entire panel membership, except in special cases, to be determined by the ASC. Such cases could include the lack of participation by a particular member in the guideline development process. APA staff will consult with ASC liaisons to panels as needed regarding special cases. However, panel members who are normally participatory, but have missed crucial conversations and/or votes due to extenuating circumstances, will still be allowed to share their opinions.

2) Should dissenting opinions from members that disagree be added to recommendation statements?

The ASC agreed that there may be a section in final guideline documents for any dissenting opinions that panel members have. A footnote will disclose the number of dissenting panel members and possibly their names.

Appendix E

Study Eligibility Criteria

Table E1

Study Eligibility Criteria: Populations, Interventions, Comparators, Outcomes, Timing, and Settings (PICOTS) Framework

Category	Definition
Population (P)	Adults (18 years and older) with chronic musculoskeletal pain (including temporomandibular joint [TMJ] pain).
Interventions (I)	Behavioral / psychological content, curriculum-based interventions (any curriculum-based intervention / program as long as there is a psychological / behavioral component within the intervention / program) and is delivered by a health care professional. Multimodal treatments are included.
Comparators (C)	Waitlist, control (active or placebo), treatment as usual (TAU) / usual care, medical or physical interventions (e.g., physical therapy, pharmacological treatment, or other medical interventions including surgery), complementary and integrative health. Multimodal treatments are included.
Outcomes (O)	Physical functioning and performance [e.g., activities of daily living (ADLs), disability, impairment, pain-related interference, changes in strength or stamina, range of motion] based on objective data and/or Patient Reported Outcomes (PROMs) Patient Reported Outcomes (PROMs) could reflect any of the outcomes: • Mental health and emotional functioning [e.g., anxiety, depression, anger] • Health-related quality of life [e.g., impacts on social activities, usual role, vitality, general health, sleep, pain coping (e.g., fear avoidance, pain catastrophizing, acceptance of pain)] • Pain intensity • Adverse effects • Patient self-efficacy • Patient global impression of change • Employment status / disability benefits
Timing (T)	Pre-treatment to Post-treatment Studies will be included that have follow-up at any time interval. There will be no limitations on the duration or frequency of interventions or contacts.
Setting (S)	Outpatient or inpatient settings.

Appendix F

AMSTAR-2 Ratings
Methodological Quality of the Included Systematic Reviews / Meta-Analyses

Critical Domain										
Systematic Review	Overall Confidence Rating	Included components of PICO	A priori study design	Explained selection of study designs for inclusion	Comprehensive literature search	Duplicate study selection and data extraction	List of excluded studies and justify exclusion	Adequate detail of included studies	Assessed Risk of Bias (RoB) in **RCTs**	Assessed RoB in **non-RCTs**
Geraghty et al., 2021	Moderate	Y	Partial Y (did not note deviations from protocol)	N	Partial Y (did not consult content experts nor examine grey lit)	Y	Partial Y (did not provide list of excluded studies)	Y	Y	Includes only RCTs
Williams et al., 2020	High	Y	Y	Y	Partial Y (did not search for grey lit.)	Y	Y	Y	Y	Includes only RCTs

	Reported sources of funding for studies included in review	Appropriate methods to combine **RCT** findings (meta-analysis)	Appropriate methods to combine **non-RCT** findings (meta-analysis)	Assessed potential impact of RoB in each study in meta-analysis results	Discussed likely impact of RoB in each study on results of review	Discussed heterogeneity	Likelihood of publication bias assessed	Conflict of Interest stated
Geraghty et al., 2021	N	Y	Includes only RCTs	Y	Y	Y	Y	Y
Williams et al., 2020	Y	Y	Includes only RCTs	Y	Y	Y	Y	Y

High (*no or one non-critical weakness*): the systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest.

Moderate (*more than one non-critical weakness):** the systematic review has more than one weakness but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review.

Low (*one critical flaw with or without non-critical weaknesses*): the review has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.

Critically Low (*more than one critical flaw with or without non-critical weaknesses*): the review has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies

*Multiple non-critical weaknesses may diminish confidence in the review, and it may be appropriate to move the overall appraisal down from moderate to low confidence.

Adapted from:

Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E., & Henry, D. A. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ, 358*, Article j4008. https://doi.org/10.1136/bmj.j4008

Appendix G

Dose, Timing and Session Duration of Treatments

Information to be added to the final document.

Appendix H

Select Demographic Characteristics of Studies Reviewed from the Systematic Reviews / Meta-Analyses

Information to be added to the final document.