Chronic Pain: assessment and management

NICE National Institute for Health and Care Excellence

Consultation on draft guideline – deadline for comments 5pm on Monday 14 September 2020 email: Chronicpain@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment. In addition to your comments below on our guideline documents, we would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) 4. The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication. See Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	National Pain Advocacy Center (applied for stakeholder status).

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Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None
Name of commentator person completing form:	Kate M. Nicholson, Executive Director National Pain Advocacy Center
Type	[office use only]

Comment number	Document [guideline, evidence review A, B, C etc., methods or other (please specify which)]	Page number Or 'general' for comments on whole document	Line number Or 'general' for comments on whole document	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.

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1	Guideline	general	general	Thank you for the opportunity to comment on the draft NICE Guideline on "Chronic Pain: assessment and management." The National Pain Advocacy Center is a new alliance of US-based clinicians, human rights advocates, and individuals with lived experience of pain. We are a 501c3 non-profit organization that advocates for the health and human rights of people in pain. We promote individualized care, including access to a range of therapeutic modalities, so that people in pain can lead full and productive lives. We accept no pharmaceutical industry or other funding that may create actual or perceived conflicts. We write to express our concern that a guideline that recommends certain therapies for all "chronic primary pain" to the exclusion of others departs from the goals of individualized and multimodal pain medicine. We represent a community of persons with severe pain that has been negatively affected by a well-intentioned, consensus-based Guideline in the US. Because the agency that issued this Guideline has since confirmed these adverse effects and addressed them by issuing a clarification, we offer a strong cautionary statement as the United Kingdom considers a similar path. After the US Centers for Disease Control and Prevention (CDC) released the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, various US policy actors - states, medical boards, law enforcement agencies, pharmacy benefit plans, pharmacy chains, and healthcare systems - lacking clear understanding of the Guideline, improperly applied it. As we explain below, the misapplication of the CDC Guideline had devastating effects on people in severe pain, including those it was never intended to cover, such as individuals with cancer and sickle cell disease. Three years after the issuance of the Guideline, these effects and this misapplication were acknowledged publicly in corrective statements by the CDC, the Food and Drug Administration, the US Department of Health and Human Services, and in the scientific literature. Widespread misapplication of the Guideline led to harmful downstream effects: abrupt medication tapering (in some cases across entire populations), increased barriers to access to necessary medication for patients with cancer, sickle cell, and other serious chronic conditions, and the refusal or reluctance of physicians to care for patients who use opioids to manage pain. As a result, patients experienced damage to their physical

2	Equality Impact Statement	general	general	NICE states that the Guideline on Chronic Primary Pain is not expected to have adverse impact on people with disabilities, noting the availability of adaptive exercise therapy. Although providing adaptive therapy is important and laudable, no single accommodation to one available treatment modality will suffice to mitigate potential harms to people with disabilities. Disabilities are not homogeneous; they are varied and often involve complex co-morbid conditions. A multimodal individualized care plan (which may include medication) cannot be simply "swapped out" for exercise or physiotherapy that is adapted to accommodate certain disabilities, especially where a combination of effective treatment modalities may well be what enables the patients to engage in such exercise. In addition, when NICE proposes access to alternative treatments, it may not be considering the availability of such treatments across populations that differ by ability to transport, to engage in various forms of treatment out of the home or in the home, or to engage in such treatment in the presence of competing responsibilities that may include childcare or work outside the home. There is every reason to be concerned, based, for example, on the literature regarding access to Yoga therapy for pain, that actual utilization and accessibility of such treatment—even when offered free of charge—will differ according to populations based on ability, economics, race and gender.
3	Guideline	8	1-6	We believe that clinicians should not be advised to deny treatments on the basis of a finding of "primary" or "secondary" chronic pain syndromes, and that the full range treatments should remain available to appropriately screened patients in situations where more conservative and less expensive treatments have failed to prove effective.

4	Guideline	9	10-24	Weighing the limited evidence base, the unique risks associated with opioid medication, and the unique risks of undertreating severe disabling pain, we recommend that individualized risk/benefit analysis for pharmacological therapy remain available as an option in all long-term pain conditions, including fibromyalgia and primary pain syndromes. One, but certainly not the only, approach for balancing these considerations was suggested in the EFIC (European Pain Federation) 2020 draft position paper: "opioids should only be used [for certain conditions] in selected patients after interdisciplinary specialist assessment as part of a multimodal treatment approach and with close surveillance." https://europeanpainfederation.eu/advocacy/position-papers/

5	Guideline	11	1-3	ICD-11 codes distinguish between primary and secondary pain, yet this is a fairly new addition. The IASP published its proposed system of categories to guide work going forward only in January 2019. Promulgating policy that withholds treatment options based on such new categories is, at this juncture, premature and may well result in harm to patients. As the EFIC (European Pain Federation) 2020 draft position paper "Opioids for Non-Cancer Pain" acknowledges, "primary pain" and "secondary pain" are, to some degree, still artificial distinctions: https://europeanpainfederation.eu/advocacy/position-papers/ People with primary pain and people with secondary pain may share the same diagnosis. Some patients may have primary pain and secondary pain at the same time. Some pain diagnosed as "primary pain" may have secondary pain from an undiagnosed condition. Patients with secondary pain may also be misdiagnosed as having "chronic pain syndrome." When the term "nociplastic," referring to dysfunctional pain processing in the nervous system, was introduced as a mechanism for primary pain, the authors themselves acknowledged there is no test to identify nociplastic pain: Kosek, E., Cohen, M., Baron, R., Gebhart, G. F., Mico, J.-A., Rice, A. S. C., … Sluka, A. K. Do we need a third mechanistic descriptor for chronic pain states? PAIN. 2016; 157(7): 1382–1386. doi:10.1097/j.pain.0000000000000507 Aydede, M., & Shriver, A. Recently introduced definition of "nociplastic pain" by the International Association for the Study of Pain needs better formulation. PAIN. 2018; 159(6): 1176–1177. doi:10.1097/j.pain.0000000000001184 In various peer-reviewed publications, we have seen pain from certain conditions (chronic pancreatitis, interstitial cystitis/bladder pain syndrome, Crohn's disease, etc.) categorized in every possible category: "nociceptive," "visceral," "neuropathic," "nociplastic," "primary," and "secondary." EFIC (European Pain Federation) lists Complex Regional Pain Syndrome (CRPS) as [illegible]

6	Guideline	24	17-25	It is true that there is a lack of high quality data studying the efficacy of opioids for chronic pain lasting beyond 12 weeks, but it is also the case that most medications approved for the treatment of pain reflect studies of similar duration. This is partly because long-term, placebo-controlled trials with real human beings who are suffering present practical and ethical challenges. Conversely, there is also little clinical evidence showing that opioids lack clinical efficacy for such patients. More to the point, the lack of evidence of long-term efficacy is true for all therapies, whether medicinal or not. We believe that, in a situation where each possible treatment for long-term pain has no better than weak average effectiveness and where only a minority of patients derive benefit from each possible treatment, opioids should retain a place where other treatment modalities have failed. Both the US (CDC) and Canadian guidelines provide a place for opioids as a later line of treatment. These concerns about the nature of available evidence were recently affirmed by the US Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force: “CDC cited the lack of clinical trials with a duration of one year or longer as lack of evidence for sustained clinical effectiveness of opioids in chronic pain. The Task Force respectfully points out that there is little clinical trial evidence showing that opioids lack clinical efficacy for such patients. Furthermore, Tayeb et al. found that lack of long-term efficacy is true for all common medication and behavioral therapy studies.” https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf Tayeb BO, Barreiro AE, Bradshaw YS, Chui KKH, Carr DB. Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate? *Pain Med Malden Mass.* 2016;17(11): 2036- 2046. doi:10.1093/pm/pnw245 Recent reviews of the literature on opioids do find evidence of modest on average efficacy relative to placebo, including a recent review conducted for the US Agency for Healthcare Research and Quality (AHRQ) and a review cited as part of the update of the German prescribing guideline, which found benefit vs. placebo for relief of over 30%: Chou R, Hartung D, Turner J, Blazina I, Chan B, Levander X, McDonagh M, Selph S, Fu R, Pappas M. Opioid Treatments for

7	Guideline	26	20-29	While reducing use of prescribed opioids to manage chronic primary pain may enable some patients to return to the workforce, the negative effects of stopping treatment go *far* beyond "increased resource use" to include risk of harm to patient safety. It has been presumed that stopping opioid treatment produces a benefit. While this will be the case for some patients who voluntarily undertake that process, the last 2 years have seen publication of numerous studies evincing the harms of opioid tapering and cessation in other patients. Some of these studies suggest—perhaps counter-intuitively—that reductions in prescribing can actually *increase* risk of drug-related adverse events. Coffin PO, Rowe C, Oman N, Sinchek K, Santos GM, Faul M, et al. Illicit opioid use following changes in opioids prescribed for chronic non-cancer pain. *PLoS One*. 2020;15(5). doi:10.1371/journal.pone.0232538 Oliva Elizabeth M, Bowe Thomas, Manhapra Ajay, Kertesz Stefan, Hah Jennifer M, Henderson Patricia et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation *BMJ.* 2020; 368 :m283 doi: https://doi.org/10.1136/bmj.m283 Binswanger IA, Glanz JM, Shetterly SM, Narwaney KJ, Xu S. Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy. *JAMA Netw Open.* 2019;2(4):e192613. doi:10.1001/jamanetworkopen.2019.2613 Tami L. Mark, William Parish. Opioid medication discontinuation and risk of adverse opioid-related health care events. Journal of Substance Abuse Treatment, 2019; ISSN 0740-5472, https://doi.org/10.1016/j.jsat.2019.05.001 Perez, H., M. Buonora, C., Cunningham, M. et al., Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study, J Gen Intern Med 2019. https://doi.org/10.1007/s11606-019-05227-9 James, J.R., Scott, J.M., Klein, J.W. et al. Mortality After Discontinuation of Primary Care–Based Chronic Opioid Therapy for Pain: a Retrospective Cohort Study, J GEN INTERN MED (2019) 34: 2749. https://doi.org/10.1007/s11606-019-05301-2 In the US, as prescribing for chronic pain has dropped precipitously, people have been involuntarily tapered off of medications on which they have relied for years. The above-cited studies have confirmed that dose reductions are often happening abruptly and with devastating effects on patients. The US FDA has called this a dangerous practice, which has greatly exacerbated the suffering of those already in serious pain, who report

8	Guideline	28	4-5	NICE acknowledges that "There is no medical intervention, pharmacological or non-pharmacological, that is helpful for more than a minority of people with chronic pain." As such, we are concerned to see NICE recommend "do not offer" with regard to certain therapies, when those therapies may be immensely helpful for a subset of patients. (TENS for musculoskeletal pain, intravesical topical treatments for bladder pain, intravenous ketamine for CRPS, etc.) Many people do recover from chronic pain using the therapies NICE recommends. However, the NICE draft guideline departs substantially from others, including that of the CDC and Canada, by recommending that patients who do not benefit from first-line therapies be left without access to later-line therapies.
9	Evidence Review J	48	7-12	Long-term opioid use for chronic pain is controversial, but not always unwarranted. Even in a system with limited resources, treatments that benefit only a few should still be offered to those few, if more conservative and less expensive treatments have failed those individuals.
10	Evidence Review J	48	20-24	In addition to studying the harms associated with long-term opioid use, there is a need to study long-term benefits, including workforce participation, mobility, and participation in life activities, especially for people with severe disabilities.
11	Evidence Review J	63	28	Within the broad umbrella of "chronic pain," each diagnosis and phenotype (and indeed each individual patient) will find different treatments helpful and unhelpful.

12	Evidence Review J	68	7-13	Where evidence from randomized controlled trials is limited or unavailable (as with long-term opioids), one committee's consensus should not guide treatment decisions for an entire nation. At the very least, that committee should include patient representatives, especially people with disabilities who benefit from the medications under review. There is a long and devastating history of health care decisions being made for and about individuals with disabilities—decisions that deeply affect their lives and the quality of their lives—without them.
13	Evidence Review J	143-164	general	To inform a guide on primary pain, NICE's literature search terms include certain diagnoses: fibromyalgia, complex regional pain syndrome, interstitial cystitis/bladder pain syndrome, etc. These terms are not likely to yield a representative sample of patients with primary pain, given that 1) some of these conditions involve inflammation, recurring lesions, and secondary pain, 2) other conditions (not included in search terms) do involve primary pain, and 3) both types of pain may be present with the same diagnosis or in the same person.
14	Evidence Review J	300-316	general	Given the individualized nature of pain medicine, excluding publications other than randomized controlled trials excludes people with disabilities who are unable to participate in RCTs - the very people who most benefit from medications and other treatments for chronic pain. As the US disability rights organization National Council on Independent Living wrote to the CDC in 2020: "studies have high dropout rates and ethical issues with leaving patients incapacitated on placebo when they could be participating in life activities. These individuals may never appear in the literature at all, except as part of observational studies."

15	Methods	34	29	To prevent disparate impact on people with disabilities, whenever cost/benefit analysis is done informally by committee, that committee should include patient representatives, especially people with pain-related disabilities who benefit from the medications under review.

Insert extra rows as needed

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- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include **page and line number (not section number)** of the text each comment is about.
- Combine all comments from your organisation into 1 response. **We cannot accept more than 1 response from each organisation**.
- Do not paste other tables into this table – type directly into the table.
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- Spell out any abbreviations you use
- For copyright reasons, **do not include attachments** such as research articles, letters or leaflets. We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments, but it must be received by the deadline.
- **We have not reviewed the evidence for the recommendations shaded in grey. Therefore, please do not submit comments relating to these recommendations as we cannot accept comments on them.**
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You can see any guidance that we have produced on topics related to this guideline by checking NICE Pathways.

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