

Draft CDC Guideline for Prescribing Opioids for Chronic Pain, 2016: Summary of Constituent Comments and CDC Response

Overview

CDC hosted two constituent engagement webinars on September 16 and 17, 2015 for comment on the Draft CDC Guideline for Prescribing Opioids for Chronic Pain, 2016. Approximately 765 people participated in the live webinars and over 1200 verbal and written comments were received during the webinars or via email until September 18, 2015. Constituents were able to hear about the scope, audience, and development process, and review the draft recommendation statements on the webinars. A summary of the problem, intended purpose and use, clinical practices addressed, and guideline development process was posted on the CDC Injury Center website at <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. Comments were received from physicians and other health care providers, pharmacists, professional organizations, pain advocacy organizations, state and local health departments, and patients.

CDC subject matter experts carefully reviewed each comment individually and considered modifications to the guideline document in response. Comments were categorized into themes which are presented below, with example comments highlighting each theme. Comments were diverse and have been organized by recommendation statement and consistent themes that emerged. This summary captures the larger constructive themes of the constituent's written comments, and is not inclusive of all the individual comments received. Similarly, this summary captures the more substantive edits made to the guideline in response to constituent engagement and is not inclusive of all the edits made. The summary reflects edits made after all constituent comments were reviewed and feedback from CDC clearance reviewers on the revision was received. CDC thanks participating constituents for providing comments that will improve the quality, credibility, and implementability of the recommendations for opioid prescribing.

Comments about Specific Recommendations

Determining when to initiate or continue opioids for chronic pain outside end-of-life care

- 1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.**

Theme 1a: Reduced access

Questions about whether this will limit or reduce access to opioids for people for whom they are needed and effective.

- *...The only treatment left for me is pain medication. Please don't tie [physician's] hands for this treatment as it's all I have left.*
- *There is no way I could live without my medicine for pain...I've tried many times to get off of it, but no other medication works as well to give me quality of life.*
- *Opioids may not be the "preferred" treatment for chronic pain conditions, but for some of us, opioids are the only effective treatment currently available.*
- *Chronic pain patients don't deserve this. If painkillers get taken away from us suicide rates will [go] up.*

Theme 1b: Details on non-pharmacologic therapies

List non-pharmacological therapies and provide information on efficacy and evidence of these therapies.

- *Do you plan list common non opioid and non-pharma therapies?*

- *What do you mean by non-pharmacological therapy?*
- *Specific non-pharmacologic therapies that have shown benefit for chronic pain could be suggested.*
- *List non-opioid pharma therapy and maybe efficacy of these agents if available.*
- *Include in the recommendation to include behavioral health in the treatment of complex pain.*

Theme 1c: Limitations to non-pharmacologic/non-opioid pharmacologic therapy

Addresses barriers to non-pharmacologic therapy (e.g., cost, insurance reimbursement, and access) or limitations of non-opioid pharmacologic therapy (e.g., inability to take NSAIDs).

- *Non-pharmacological therapies are not accessible to all—many are not paid for by insurers.*
- *Insurance companies often do not pay for other than pharmacological therapies.*
- *Reimbursement needs to be addressed.*
- *I would suggest that insurance companies or payers be encouraged to pay for non-pharmacological therapy and include psychological/behavioral strategies.*
- *Many patients cannot take NSAIDs due to gastric issues or being on blood thinners, etc.*
- *It often takes weeks, if not months, for non-pharmacological therapy (and especially non-opioid therapy) to reduce pain to the point where a patient who might need opioids does not any more.*
- *Inappropriately endorses all non-opioid analgesics over opioids. For example, you would not recommend prescribing an NSAID to a patient with renal insufficiency, and hemophiliacs should never receive aspirin or NSAIDs because of bleeding risk...This might be better stated as: “Opioid analgesia may be a consideration for patients in whom non-opioid analgesics are clinically contraindicated.”*

Theme 1d: Details on risks and benefits

Define risks and benefits and explain methods for evaluating.

- *Benefits > risks is rather subjective and in the eye of the beholder. Can CDC provide more specifics?*
- *No mention of recommended methods to evaluate risk of opioids.*
- *Exactly where is the risk/benefit list coming from?*
- *May consider inclusion of specific recommended tools for evaluation of opioid use risk vs. benefits.*

Theme 1e: Opioids if other treatment fails

Add to the recommendation that opioids should be considered if non-pharmacologic therapy and non-opioid pharmacologic therapy is ineffective.

- *Suggest changing ‘are preferred’ to ‘should be tried first’.*
- *...Alternative therapies exhausted prior to starting opioid therapy.*
- *It may not be appropriate to try every non-pharmacologic or non-opioid approach first, depending on the severity and progression of pain.*
- *Including that opiates should be considered after non-opioid options have failed?*

Theme 1f: Agreement

General statements of support for this recommendation.

- *Agree with Draft Recommendation 1.*
- *This is good as it follows the World Health Organization analgesia treatment ladder.*

CDC Response

- *CDC edited the guideline to further clarify that the risks discussed are risks to the patient specifically, provide definitions of chronic pain and long-term opioid therapy, review the evidence of the effectiveness of opioids in improving pain and function for specific conditions such as low back*

pain and fibromyalgia, provide additional information on multimodal and multidisciplinary strategies, discuss barriers to treatment such as insurance coverage and cost, and specify preferences for use of non-opioid pharmacologic therapy and non-pharmacologic therapy in combination with opioid therapy when opioid therapy is used. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., types of pharmacologic and non-pharmacologic treatments including cognitive behavioral therapy, exercise therapy, and interventional treatments; risks of alternative treatments including the risks for heart attack and stroke with NSAIDs; and evaluation of risks and benefits including improvements in pain or function and risks of abuse, dependence, overdose, and myocardial infarction).

- 2. Before starting long-term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.**

Theme 2a: Details on meaningful improvement

Define meaningful improvement and provide information on measurement (e.g., criteria, frequency).

- *Can you define clinically meaningful improvement?*
- *Make sure that clinically meaningful improvement is defined including specific criteria.*
- *Please provide suggested time intervals for evaluation of clinically meaningful improvement.*
- *This guideline is fundamental to attaining any meaningful measure of improvement in this inherently subjective issue of pain. Patients too often have unrealistic expectations of their medications, and providers use medications without considering the long term goals of therapy.*

Theme 2b: Details on measuring treatment goals

Provide information and tools on measuring function.

- *It would be helpful if the CDC would recommend specific functional scales.*
- *How will function be assessed, monitored, and reported?*
- *What are monitoring and/or auditing criteria once treatment goals are established?*
- *Need to recommend instruments for measuring pain and function.*
- *Inclusion of examples of functional assessment/screening tools to track progress.*

Theme 2c: Emphasis on function

Place more emphasis on, or sole emphasis on, clinically meaningful improvement in function over pain.

- *It is important to clarify that the goal of therapy should be limited to significant improvement in functioning, not pain. Pain as a goal, or endpoint, is too broad and would not limit the current over-utilization of opioid pain medicines.*
- *Pain scale should be removed as a judge of pain when weighing pain and function in this process.*
- *I think the ordering of the goals should be changed to function and pain, to emphasize that function is the primary measurable objective.*
- *Would remove pain from the last sentence.*
- *I don't believe it's reasonable or objective have pain as a goal or measurable for improvements. We really should only be considering function. Pain improvement will follow function.*

Theme 2d: Emphasis on pain

Comments highlight the need to address pain.

- *I believe that keeping pain and function at baseline may be acceptable, not necessarily meaningful improvement in function as that may not be possible.*
- *Pain improvement needs to be [considered].*

- *Disagree with the comments that pain should not be measured. Function is important, but chronic pain can be a chronic disease it may not improve. These patients should not be denied treatment.*
- *Studies in general seem to indicate that there is no clinically significant improvement in function with chronic opioid therapy.*
- *Treatment goals to include decreased level of pain which should increase function. Please listen to the patient if they are still reporting pain, and refer to a pain specialist if uncomfortable about increasing dosage.*

Theme 2e: Patient-centered approach

Comments highlight the need to consider individualized history and treatment goals for each patient.

- *The treatment goals should be tailored to each individual's needs.*
- *This should be revised to be more patient-centered. Pain is a subjective matter and should be treated as such. Clinically meaningful needs to be determined in collaboration with the patient.*
- *Need to make sure you allow provider to take into considerations the patients past history and not assume that everyone starts baseline non-opioids.*
- *Recommendation does not acknowledge that there are patients who suffer from rare pain conditions who have already failed regular pain therapy may need to be treated by a pain specialist.*
- *This recommendation will be difficult if not impossible for those with impaired cognition and many elderly patients. There is no mention here of the role of family caregivers in the treatment goals discussion, and there should be a note of their importance for these patient populations.*

Theme 2f: Details on risk assessment

Provide more information about risk, including when and how to measure.

- *It would be helpful if the CDC would recommend specific risk assessment tools as part of the assessment process.*
- *Document in guideline what CDC would constitute risk.*
- *Would refer clinicians to available validated tools to assess risks of long-term opioid use.*
- *Should include performing a risk assessment prior to starting and periodically during opioid therapy.*

Theme 2g: Written agreement

Recommendation should require written agreement between patient and prescriber.

- *Contract or agreement terminology does not matter, what does matter is a written agreement between the patient and the prescriber. This should be signed by the patient.*
- *The most appropriate terminology/language should be used in the crafting of a written document between the patient and the prescriber. There should be a concerted effort to standardize such a document.*
- *This needs to be done through a pain contract which is signed by both patient and provider.*

CDC Response

- CDC edited the document to further clarify the use of treatment goals for patients already receiving opioids. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., definition of meaningful improvement being a 30% improvement in scores for both pain and function; measurement of treatment goals and use of validated instruments to track patient outcomes such as the "Pain average, interference with Enjoyment of life, and interference with General activity" – PEG – assessment scale; emphasis on both pain and function; and guidance indicating that studies on available risk assessment instruments are sparse with inconsistent results so it is very difficult for providers to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients).

3. Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.

Theme 3a: Tools on risks/benefits

Provide prescribers tools to discuss risks and realistic benefits with patients.

- *Does the guideline provide advice and/or specific tools on how discussion with patients re: risks and realistic benefits can be put into practice?*
- *Would be helpful to have “Comments for Discussing Opioids with Patients” in the appendix.*
- *Can this then include “risks” printed given that I could then use to show a printed remark to a patient?*
- *Would recommend more specific CDC-developed education regarding opioid risks.*
- *This is helpful as part of standard therapy for any chronic condition to evaluate what the benefits versus risks of treatment. Useful resources for help in guiding discussion about specific harms versus potential benefits would help providers follow this guideline better.*

Theme 3b: Written documentation

Recommendation should include written documentation of provider-patient discussion.

- *Add patient should have full understanding of likely risks and benefits of opioids...this should be documented in easily-understood and mutually-agreed upon informed/written consent.*
- *Should mention the use of an opioid treatment agreement between physician and patient.*
- *It would be optimal to incorporate written informed consent with attested education and a treatment/provider and patient responsibilities contract.*
- *Should discuss with [patient] and record in writing.*
- *A national uniform contract would be helpful.*
- *Providers should discuss and document their discussion and outcome of discussion in office notes. Documentation in office notes allows for accountability of both parties.*

Theme 3c: Realistic benefits

Recommendation should focus realistic benefits on function over pain.

- *“Opioid medications are to improve your functioning and not to necessarily remove all pain.” I tell them that this is to decrease pain to manageable and able to live with some pain. Pain will always be with us in many cases regardless of medications.*
- *With minimal evidence for benefit > risk, what will be said about benefits?*
- *Realistic benefits should qualify that pain cannot be eliminated, usually only 30% improvement and should focus on functional improvement.*
- *Note that the emphasis should be on function and be realistic that opioids cannot eliminate pain.*

Theme 3e: Patient-centered approach

Comments highlight the importance of focusing on individual patient’s treatment goals.

- *Who decides on the benefits of the therapy doctor or patient? It should be based on patient’s belief if it helps.*
- *The benefit is up to the patient and not the doctor.*
- *This should also consider the patient’s health beliefs.*
- *The patient-centered piece is not stressed; the patient’s expectation should be realistically addressed.*
- *We need to make sure that during the reviews that patients who are determined to need opioid medications are not treated with bias. Pain relief and increase function are indicators that are equally important. The patient needs to feel respected in these discussions.*

Theme 3f: Clarify periodically

Clarify and provide more details about “periodically.”

- *At what intervals are more extensive medical assessments indicated?*
- *Need to be clearer on what is meant by periodically and risks/benefits need to be developed so that providers are clear and consistent.*
- *Seems too vague. It should give specific intervals for pain contract.*
- *Please provide suggested time intervals/ranges for providers “periodically” discussing risks and realistic benefits with patients.*

CDC Response

- CDC edited the document to further include information about strategies to address common adverse effects such as constipation. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on how to talk to patients about benefits and risks of opioids and planned use of precautions to reduce risks; the importance of meaningful communication with patients over just documentation; and time intervals for evaluation of benefits and risks). CDC will also develop translation tools to accompany the guideline to assist with managing opioid therapy with patients.

Opioid selection, dosage, duration, follow-up, and discontinuation

4. When starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release/long-acting opioids.

Theme 4a: Details on transition

Provide details on transitioning patients from short-acting to extended-release/long-acting opioids.

- *Would be nice if document outlines amount of time before changing from short-acting to long-acting therapy.*
- *Provide guidance on how long to keep a patient on short-acting opioids before switch to ER/LA opioids*
- *Consider patients who have already been on short-acting and assist providers in knowing when it is appropriate for long-acting.*

Theme 4b: Patient-centered approach

Requests to allow provider flexibility in decision-making for individual patient situations.

- *Please include some room for clinical care consideration and clinical uncertainty. This is an extremely restrictive recommendation.*
- *Would add ‘in most cases’ because everything should be dependent on the situation.*
- *With the low level of evidence available, it seems that the prescriber is in the best position to make this decision based on the patient’s circumstances.*
- *Consideration for patients in constant pain such as sleep-depriving maladies, should be considered on a case-by-case basis.*
- *This statement seems to be more relevant to non-cancer pain; cancer patients benefit from LA and this distinction would be relevant.*
- *Please advise/discuss when a long-acting opioid may be appropriate for trial over short-acting opioids due to certain factors.*

Theme 4c: Strengthen

Strengthen the recommendation against using extended-release/long-acting opioids.

- *Long-acting should be avoided whenever possible in non-cancer pain.*
- *Need to keep recommendations against or even strengthen recommendations against extended-release opioids*
- *Long-acting extended-release opioids are not useful in acute pain and while they may help in chronic pain, patients must be opioid tolerant to truly benefit from their use.*

Theme 4d: Against short-acting opioids

Comments regarding efficacy of short-acting or similar/greater risks of extended-release/long-acting.

- *Short-acting opioids should not be prescribed on a chronic basis.*
- *Poorly treated acute pain can result in engrained pain signal in nerve path which cannot be reverted...starting with low dose long-action would be appropriate.*
- *Opioid treatment IR or ER pose same risks.*
- *Pharmacologically and pharmacokinetically, not necessarily. Individuals at risk for addiction typically get a larger dopamine surge from IR versus ER.*
- *Short-acting opioids simply mean that many patients will have to take more pills to get through a tough pain period. This seems a little contradictory to your goals.*
- *Short-acting medications allow for more cycles of pain, which wear down a patient's resilience and strength. ER and LA allow patients to rest.*

CDC Response

- CDC edited the document to further clarify the applicability of the recommendation for opioid therapy for chronic pain (i.e., how it applies to both patients starting and continuing opioid therapy), add information about FDA labeling and communication about use of ER/LA opioids, and include information about abuse-deterrent technologies. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on use of and transitions between short-acting and extended-release formulations).

5. **When opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to ≥ 50 MME/day and should avoid increasing dosages to ≥ 90 MME/day.**

Theme 5a: Patient-centered approach

Comments highlight the need to consider individual patient needs and specific conditions (e.g., metabolic disorders, cancer, and genetics).

- *Concerned about the role of genetic metabolites is not considered here and doesn't consider cancer pain.*
- *Patients with metabolic issues might need a higher dosage.*
- *There should be no upper limits as it is all individual, based on genetics.*
- *All relevant to the patient's condition and treatment goals.*
- *It fails to take into consideration individual variability in opioid responsiveness.*
- *For legitimate, compliant pain patients...this is a sentence to increased disability and pain and even suicide.*

Theme 5b: Comments on specific dosages referenced

Comments raised with regard to specific dosages and/or processes for deriving them.

- *There is no “hard” inflection point of daily dose versus risk. The language of this recommendation must be adjusted accordingly.*
- *Having exact numbers limits prescribing.*
- *Humans process medications differently. Putting limits in milligrams is unacceptable.*
- *Part of the problem with various currently available guidelines is precisely the lack of dose limits, which makes it very difficult for managed care institutions to implement quantity level limit criteria.*
- *This should be done on a case-by-case basis, not one size fits all. That’s why providers are seeing the patients as individuals.*
- *Setting dosage limits here that are inconsistent with other established guidelines may also create confusion and conflict.*
- *Dose limits are VERY important in guidelines; please do not remove.*
- *As these guidelines are directed at primary care, it is presumed this would be the threshold level to refer to a pain specialist. Good for business but this will possibly create a barrier to access.*

Theme 5c: Details on specific dosage limit

Provide more information about the specific limits in this recommendation (e.g., evidence, difference from existing guidelines).

- *VA and Department of Defense guidelines have used 45mg and 100mg as opposed to 50mg and 90mg respectively. What is the evidence behind these doses?*
- *Some previous recommendations have mentioned 100 or 120 mg per day in morphine equivalents as a “conventional” maximum.*
- *Specify evidence for the 90 mg/d upper limit—this is low for patients with severe pain regardless of etiology (i.e., cancer or non-cancer [pain]).*
- *Note that the Washington State MED was 120 and recently reduced to 80. Again what is the evidence?*

Theme 5d: Guidance on titrating dose

Provide guidance on titrating patients’ dosage.

- *Should include how long to wait before considering increasing the dose.*
- *Please include titration guidance.*
- *Should also include by what percent a dose should be increased each time.*
- *Need to provide guidance on proper assessment of opioid withdrawal.*

Theme 5e: Guidance for need > 90 MME/day patients

Provide guidance on what to do with patients currently > 90 MME/day.

- *Needs to provide what other options are available if dosages are needed above 90 morphine equivalents.*
- *What do providers do if these doses are reached?*
- *Add what are options if patient is at or above 90 mg including referral to specialist, increased monitoring, tapering off opioids.*
- *May want an additional recommendation or comment for patients who are already above 90 MME and what should be done in those situations (recommendations about counseling about high dose and immediate tapering).*
- *Add that patients receiving higher dosages should be weaned to lower dosages, with close support and supervision from the prescriber or another appropriate member of the treatment team, such as a clinical pharmacist.*

Theme 5f: Guidance on MME conversion

Provide guidance on MME conversion.

- *Prescribers need established and evidence-based morphine equivalent guidelines in order to follow this guideline*
- *Table with ME for other opioids would make this much more usable. Oral morphine thought to be poorly absorbed so chart of MME would be helpful.*
- *Is the CDC going to issue recommendations on MED calculations for medications like methadone that have a variety of recommendations?*

5g: Define additional precautions

Clarify what “additional precautions” are recommended.

- *Suggest further definition of “implement additional precautions.”*
- *The document should express what additional precautions would be, if possible.*
- *What is meant by additional precautions? Naloxone?*

CDC Response

- CDC edited the document to further clarify that caution should be used when prescribing opioids at any dosage, recommend that dosage be increased by the smallest practical amount, recommend re-evaluation of patients after increasing dosage, and add information about importance of compliance with state requirements for clinical protocols at specific dosage levels. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., information about decision-making for dosage threshold, information about state policies with different limits, titration guidance and resources, and defining additional precautions).

- 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.**

Theme 6a: Comments on duration

Comments specific to the reference of three or fewer days as usually sufficient for non-traumatic pain.

- *The recommended duration of 3 days would be too short for many medical illnesses, often requiring hospitalization, for which major surgery is not indicated.*
- *This is a well stated recommendation. Agree.*
- *The recommendation of 3 or fewer days will barely get patients through a weekend, and they will end up in the emergency department.*
- *Agree with 3 or fewer days but when necessary amount and duration should be tied to anticipated tissue recovery.*
- *Maybe more like a 5-7 day supply for a short duration for non-traumatic pain. If patient needs further evaluation they often do not have access to that evaluation within 3 days.*
- *Most acute pain situations take more than three days to resolve. To prevent the onset of Centralized Pain Syndrome acute pain must be treated quickly and adequately.*
- *I strongly support and agree with a supply for “three or fewer days” of opioid use for non-traumatic pain not related to major surgery. Thank you.*

Theme 6b: Evidence for three days

Provide evidence supporting recommendation of three or fewer days

- *Want to see the evidence supporting this 3 day limit as it relates to specific medical conditions.*
- *I would be interested in knowing the background evidence for three or fewer days use and not longer.*

- Overall, important concept for all providers to realize and discuss with patients. Additional recommendations for time course of typical acute traumatic injuries would be helpful (if such data exists). ...Evidence showing shorter duration would help support this guideline.
- Question the limitation of three days, since it seems arbitrary. It is important for the guidelines to share the empirical basis or research that supports the three day limit.

Theme 6c: Patient-centered approach

Concerns this recommendation does not consider individual patient needs and specific conditions

- Pain is individualized, so a three day limit except for major surgery, fails to recognize this and under-treated pain could lead to a chronic condition.
- This is not sufficient for sickle cell patients who have both acute and chronic pain. Also, their pain is non-traumatic and may often last more than 3 days.
- Too many patients are being summed up as if they are not individualized. Treatment needs to be specific to individual patients and account for metabolism and severity of condition as well as history with opioids.
- The capping of dose and duration are based upon group mean population statistics, not individual need. Therefore flexibility must be given to patients who fall outside these group parameters.

Theme 6d: Increases barriers

Questions whether this will increase barriers to accessing treatment (e.g., emergency department wait times, insurance reimbursement).

- This will have major implications for follow up in emergency rooms and primary care and may decrease access and increase wait times.
- Be aware that a three day timeframe will be fodder for insurance company and utilization review denial. I agree with the general application...but offer caution for the unintended consequences.
- If too few prescribed these are the patients that end up in the emergency rooms suffering from poor relief, such events become costly and are not necessary if done correctly.

Theme 6e: Define lowest effective dose

Provide more information about lowest effective dose and how it is determined.

- Who determines lowest effective dose?
- Determining lowest effective dose is significant challenge giving varying individual responses to opioids.

CDC Response

- CDC edited the document to further clarify the applicability to outpatient settings, provide a definition for acute pain, and add guidance on determining the lowest effective dose. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., rationale for three day default for most nontraumatic pain not related to major surgery).

- 7. Providers should evaluate patients within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long-term opioid therapy every 3 months or more frequently for benefits and harms of continued opioid therapy. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.**

Theme 7a: Details about patient evaluation

Provide more information about patient evaluation, including how to evaluate and at what frequency, and for risk/benefit assessment tools.

- *What constitutes a good evaluation should be described.*
- *Evaluate how? In person? Over the phone? Virtually? Are nurses or other medical staff allowed to gather evaluation data from patient for provider review or must it be done only by the prescribing provider?*
- *How is the provider supposed to determine whether benefits outweigh harms? Is there an algorithm or some other standard way to do that?*
- *Need to define benefit vs. harm*
- *An opportunity to provide guidance about how to evaluate risks and benefits.*

Theme 7b: Focus on function

Recommendation should focus patient evaluation on function.

- *Assessment of function language will likely be important to add.*
- *Use objective measures of function rather than some vague number of complaint.*
- *Emphasize that function should be tracked and documented because it is more objective.*

Theme 7c: Three months too long

Recommendation should require evaluation more frequently than every three months.

- *Evaluation could possibly be more frequent than every 3 months.*
- *Please review the evidence about the 90-day cliff (i.e., patients taking chronic opioids > 90 days are at much higher risk of addiction so 90 days should be avoided). This frequency of re-evaluation would not allow mitigation of this 90-day chronic use situation.*
- *Recommend that follow on period be reduced to 1 month to ensure close monitoring of improvements in pain and function. Three months perpetuate problem of tracking improvement.*

Theme 7d: Patient-centered approach

Highlights importance of individual patient needs and specific conditions.

- *Consideration needs to be made for patients who live at a distance from their healthcare provider.*
- *Should not apply to cancer patients, even if not end of life. Bone and metastatic breast cancer patients may live a long time in agony.*
- *Many patients with chronic pain are treated successfully with opioids and never develop addiction. It is inappropriate to advocate withdrawing and limiting effective treatment for such patients.*

Theme 7e: Resources on tapering

Provide resources on tapering therapy and more information on discontinuing opioids.

- *Is the CDC going to issue recommendations on opioid weaning, including prescriber tools...and patient materials to help with coping?*
- *Be mindful of the general lack of resources for assisting patients to discontinue therapy.*
- *Resources to help with weaning patients off opioids would be helpful.*
- *A recommendation(s) on how to discontinue chronic opioids should be included.*
- *When a patient cannot continue opioid therapy, an alternative treatment plan should be developed between the provider and patient. This is where insurers are significantly lacking in stepping forward to cover this gap where patients may turn to heroin or other illegal drugs in attempting to manage their chronic pain.*

CDC Response

- *CDC edited the document to further clarify the focus on opioid therapy for chronic pain, specify regular assessment of all patients receiving long-term opioid therapy, note the potential for earlier*

follow-up to provide the greatest opportunity to prevent the development of opioid use disorder, and add guidance on use of virtual visits and follow-up. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., focus on function, use of assessment tools, and resources on tapering).

Assessing risk and addressing harms of opioid use

- 8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related harms are present.**

Theme 8a: More on risk factors

Provide more details about risk factors for opioid-related harms, including assessment tools.

- *Provide specific examples of what risk factors for opioid related harms might be (alcohol use, benzos, previous addiction, etc.)*
- *The research is very definitive that a formalized risk assessment tool be used. Many physicians are assessing risk by “gut feelings” and these have been shown to be wrong a significant percentage of the time. This needs to be stronger in that a risk assessment should be formalized evidence-based tool.*
- *Experts need to give input as to what are risk factors to evaluate, perhaps give statistically valid tools, etc.*
- *Could include recommendation to use one of the standardized screening tools to assess risk for opioid abuse.*

Theme 8b: Tapering to mitigate risk

Recommendation should include require tapering when risk factors are present.

- *Should also include tapering/discontinuing the opioid in addition to offering naloxone.*
- *Consideration to non-opioid alternatives to avoid dependency, misuse, diversion. If risk is identified, weaning and discontinuing opioids.*
- *Anyone on opioids which are higher than new ceiling dosages then effort will be made to not abandon patient but to gradually taper dosage while offering non opioid therapies.*
- *If there is a patient at risk for overuse, reduction of opioid as in taper and referral to treatment may be needed.*

Theme 8c: Clarify offering naloxone

Provide more information and guidance about offering naloxone.

- *Please be much more specific in terms of this recommendation in relation to offering naloxone in treatment, this is especially in light of the increased cost of “abuse-resistant” opiates.*
- *If naloxone is specifically being recommended, it needs to be further elucidated the type of patients who need to be prescribed naloxone.*
- *Naloxone is only indicated if there is an assessed risk of overdose. It will not mitigate other opioid-related harms. The wording is misleading.*
- *Would be cautious because industry is likely pushing for [naloxone]; is there good evidence for it?*
- *Elaborate and clarify use of naloxone. This needs separate recommendation.*
- *This recommendation could be strengthened with additional guidance on selection of patients for consideration of naloxone prescribing.*

Theme 8d: Strengthen naloxone recommendation

Strengthen recommendation of providing naloxone to mitigate risk for opioid-related harm.

- *I recommend making the naloxone recommendation stronger. I would recommend that prescribers default to co-prescribing naloxone unless there's a good clinical reason not to.*
- *Naloxone can be considered whenever high dose opioid are prescribed- as a safety measure even for the household of a cancer patient- diversion followed by overdose can occur.*
- *Certainly co-prescription should be encouraged with any ER or high-dose opioid prescription.*
- *Make this stronger. High risk of diversion. Chronic pain scripts should always come with naloxone.*
- *Naloxone should be co-prescribed.*

CDC Response

- CDC edited the document to further clarify the time periods for evaluating risk factors and provide resources for prescribing naloxone in primary care settings. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., details about risk factors, use of assessment tools, and guidance on offering naloxone).

9. **Providers should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him/her at high risk for overdose. Providers should review PDMP data when starting opioid therapy and periodically during long-term opioid therapy (ranging from every prescription to every 3 months).**

Theme 9a: Mandated use

Make recommendation stronger to require PDMP review before every prescription.

- *PMP should be mandated!*
- *Should be consult the PDMP for every prescription not a range to every 3 months.*
- *PDMP data review before first prescription is written should be required. Ongoing review of PDMP data for every prescription should be required.*
- *Providers should be mandated to use state PMP data to prescribe opioid therapy.*

Theme 9b: State connections

Recommendation should encourage and support state interoperability or interstate access (e.g., data sharing, national PDMP).

- *One of the problems with PDMPs is the lack of coordination among states, including adjacent states. Does the CDC have plans to address that issue?*
- *Need national PDMP especially near state borders.*
- *Would be very useful to have the CDC create a national prescription drug monitoring program.*
- *Also, having inter-state access to prescription drug monitoring [program] should be mandatory, especially in areas like the mid-Atlantic region where states are smaller and closer together and patients can move from state to state easily.*
- *For patients and doctors who live in or practice in areas near state lines, both states' PDMPs should be checked.*

Theme 9c: Address limitations

Highlights existing limitations of PDMPs (e.g., not every state has PDMP, provider access, data not timely, data not complete, systems vulnerable to fraud, systems not user-friendly.)

- *Recommendations should be made about states that do not have state monitoring program. It is also difficult for monitoring close to state lines where patient can go between multiple states.*
- *Not all pharmacies are swift to report these types of prescriptions.*

- *Need to address issue of not all pharmacies are entering data into PMP especially when patients are paying cash for prescriptions.*
- *Our state does not have a Prescription Drug Monitoring Program, any other recommendations?*
- *CDC should recommend that entities other than physicians have access to the PDMP sites for each state (e.g., PBMs, third party workers comp administrators, and other authorized and appropriate organizations).*
- *Multiple and fake IDs make it difficult. Need access to state's driver's license database to validate ID.*
- *Recommendations for appropriate set up of PDMPs should be included to decrease variation and problems with the systems (updated data, ease of use).*

Theme 9d: Data interpretation

Provide guidance and tools on how to interpret PDMP data and clarify “excessive opioid dosages or dangerous combinations.”

- *Would mention that data indicates that > 4 or more prescribers/pharmacies in one year raises concern for doctor shopping.*
- *Would really like to know what is a “dangerous combination”? Currently some say benzo and opioid, or is it benzo, opioid, muscle relaxant, or what?*
- *If managed within a primary care office, there should not be multiple prescribers involved. The flag should go up if receiving from multiple providers.*

Theme 9e: Guidance if problem identified

Provide guidance on what a provider should do if a problem is identified during PDMP review.

- *Patients should not be given ultimatums that remove their access to opioid therapy if unable to attend recommended adjunct therapies due to cost prohibited issues.*
- *Guidelines could incorporate discussion on what physicians should do when they identify a patient with a potential substance use disorder, aside from not prescribing...CDC needs to start highlighting the need to address substance use disorder.*
- *This recommendation must further state that providers must be trained on evidence-based actions to take based on PDMP data. There are many examples of providers dropping patients who may have untreated pain or addiction problems. That is an inappropriate response, and that needs to be made clear.*
- *Recommendation should be included regarding appropriate use of PDMPs and not using data to automatically dismiss patients.*
- *PDMP results [should] not be misapplied to categorically deny or discontinue opioid prescribing for patients with records indicative of receipt of other controlled substances, including methadone for treatment of substance use disorders.*

CDC Response

- *CDC edited the document to further clarify checking of PDMP data when patients are receiving high dosages and the applicability of the recommendation for opioid therapy prescribed for chronic pain. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., information about state policies and accessibility, discussion of barriers, and guidance about interpreting PDMP data for clinical decision making).*

10. Providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually in all patients on long-term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

Theme 10a: Frequency based on risk

Revise recommendation to clarify that frequency of urine drug testing should be based on risk (e.g., increased risk, increased frequency).

- *That is not what evidence based studies have recommended. Should be more than one a year. Should be based on risk. High risk should be each time prescribed etc.*
- *Providers should consider evidence based guidelines and group patients by low, medium and hi risk and conduct drug screening based on risk level.*
- *The minimum frequency of required UDT is inconsistent with the PDMP requirement of 3 months. The latter should be extended to at least annually, with more frequent encouraged as clinically indicated.*
- *Recommend risk stratification for all patients, this will guide frequency of testing.*
- *At least annually but should clearly address/emphasize...the greater the real or perceived degree of risk the greater the frequency of UDS.*
- *UDS testing frequency should be adjusted for opioid risk factors, results of prior testing, adherence.*

Theme 10b: Type of testing

Provide details and guidance on which types of tests are recommended and effective.

- *UDT must be not only quick in house panel of enzyme testing but also alcohol metabolites and broad sensitive and specific tests such as liquid chromatography, mass spectroscopy for 150 agents.*
- *General testing for opioids does not test for all opioids (i.e., fentanyl, methadone, buprenorphine, oxycodone are examples of opiates that will not show as a positive in a general opioid screening).*
- *Are there any recommendations for measuring alcohol use that is not in most UDS?*
- *Needs to be more than just a dip stick, needs to be immunoassay, sent to lab. Dip sticks are not accurate and can be easily fooled.*
- *You need to be more specific about what urine drug testing screens are most appropriate as some antibiotics and other drugs can mimic opioids in the urine drug screen.*
- *Witnessed, chain of command, methodology used, substances tested for, normal values, etc. are all potential variables in the term "urine drug testing."*

Theme 10c: Guidance if problem identified

Provide guidance on what a provider should do if a problem is identified in urine drug test results.

- *The use of urine drug screens in gauging suitability for chronic opioid therapy is also complicated by the evolving legal landscape around medical and recreational marijuana, which should not be regarded as a contraindication for opioid therapy.*
- *Should be some mandate that a follow up test be done by outside lab for inappropriate testing outcomes.*
- *A statement of the obvious is implied, but should be stated: any patient who tests positive for illicit drugs should not be prescribed opioid analgesic therapy.*
- *If failed tests, MD should be required to take action for failed screens and non-compliance.*
- *Please include information about how to use the results of the testing to further define risks and care planning needs of the patients rather than defining the patient as non-compliant and breaching "pain contracts" resulting in a provider "firing" the patient.*

Theme 10d: Address barriers

Highlights barriers to urine drug testing (e.g., cost, transportation).

- *May create a severe burden on patients who do not easily have access to transportation, severely disabled, elderly or have absolutely no risk factors.*
- *Does the guideline describe specific facilitators and barriers to application of urine drug testing?*

- *Who is going to pay for all the drug testing? Pain patients don't have extra money for the testing, not on government help.*
- *These tests tend to be very expensive, and are sometimes not covered by insurance. The burden of these tests often then falls on patients, who may be unable to access needed opioid therapy because of inability to pay for drug tests.*

Theme 10e: Patient-centered approach

Stresses importance of individual patient needs and specific conditions.

- *Suggest including a comment about excluding certain populations.*
- *Should not apply to cancer patients. This urine testing adds to the stigma of pain management, for cancer patients.*
- *Does not take into consideration that all humans process medications differently. Many patients have been wrongly accused of drug diversion because prescribed drugs were not found upon urine testing.*
- *Shouldn't this be between the provider and patient?*

Theme 10f: Random testing

Recommendation should include that urine drug testing be random.

- *Should be randomly done during visits.*
- *Wording should include random urine drug testing.*
- *Needs to be done randomly by calling a person into the office.*

Theme 10g: Pill counts

Add to recommendation doing random pill counts.

- *A random pill count would be very beneficial as well.*
- *Further consider pill counts as part of monitoring use of medications to screen for overuse/abuse/diversion.*

CDC Response

- *CDC edited the document to further clarify guidance on random drug testing, burden for patients, inclusion of high risk patients, and testing of urine compared to saliva. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on types of testing, interpretation of findings, and how to use the findings in practice).*

11. Providers should avoid prescribing of opioid pain medication and benzodiazepines concurrently whenever possible.

Theme 11a: Other drug classes

Recommendation should include other classes of drugs that increase risk when combined with opioids (e.g., muscle relaxants, sedatives, hypnotics, sedative-hypnotics, CNS depressants, psychoactives, atypical antipsychotics, stimulants, OTC sleep medications).

- *Patients taking opioids with medications such as benzodiazepines and other sedative-hypnotics are at increased risk.*
- *Appreciate this recommendation that combination opioid-BZP use has higher risks than opioids alone. ...Recommend adding comment about combination opioid use with "muscle relaxant medications..." In fact the "trinity" of opioid + muscle relaxant + BZP is well known and of even greater risk. Please add information on use of muscle relaxant meds in combination with opioids.*
- *Include other drug interactions...with potential adverse effects.*

- *Should also refer to not prescribing additional opioids for pain in those receiving methadone or other opioid therapy for opioid dependence.*
- *Need to be more specific. May need additional resources to guide clinicians.*

Theme 11b: Patient-centered approach

Stresses importance of individual patient needs and specific conditions.

- *I disagree with opioid and benzo combo. I have GAD and severe pain. I was dropped from these meds cold turkey a year ago and find it hard to function.*
- *For those with anxiety disorders there is no reasoning for this.*
- *This should also be considered on a case-by-case basis as some conditions requires both types of medications.*
- *Long-acting benzos can be helpful when treating chronic pain who suffer from other symptoms along with pain.*
- *While there are risks...there are substantial benefits for some patients who are treated with...the long-acting benzodiazepine clonazepam...along with long-acting opioids for pain relief.*

Theme 11c: Coordinating care

Recommendation should encourage coordination of care with other prescribers.

- *So glad to see this recommendation. ...Make [prescribers] aware that patients may be receiving from more than 1 provider.*
- *Many times specialists place patients on one of these medications while primary care maybe using the other class of medication.*
- *Agree strongly. And find out why opioid or benzo—see under-treated anxiety.*
- *It may be important for physicians to coordinate patient care closely and check the state PDMP to avoid the concurrent prescribing of benzodiazepines and opioids.*
- *These medications may not be prescribed by the same provider. Word it so that it is clear that this has to do with any provider.*

Theme 11d: Patients on both

Provide guidance about what should be done for patients prescribed both opioid pain medication and benzodiazepines.

- *Fine to discourage initiation, but also important to acknowledge appropriately managed tapers for the many that already have co-prescriptions.*
- *Alternative therapies to replace the benzos?*
- *If benzodiazepine is required, mental health provider should be contacted to be in concurrence of both benzodiazepine and opioid use.*
- *Providers should consider non-opioid alternatives for claimants that require other medications for anxiety, depression.*

Theme 11e: Alcohol

Recommendation should provide guidance about risk of alcohol use with opioid pain medication.

- *Could we include risk of alcohol?*
- *Alcohol use should be included in this list.*

Theme 11f: Explain risk

Recommendation should include description of risk and encourage patient education on risk.

- *It should be spelled out that risk increases with combined use of these agents.*
- *Patients should also be strongly counseled about the risks of these medications while on opioid therapy.*
- *Would strengthen this appropriate recommendation with “can result in death.”*

- *Add to this one “and without educating the patient about the dangers of taking these meds together.”*

CDC Response

- CDC edited the document to further clarify recommendations for circumstances when a patient is already receiving benzodiazepines. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on consultation with other providers, consideration of alcohol use, and patient education).

12. Providers should offer or arrange evidence-based treatment (usually opioid agonist treatment in combination with behavioral therapies) for patients with opioid use disorder.

Theme 12a: Expand opioid agonist treatment

Broaden recommendation beyond opioid agonist treatment to include medication-assisted treatment (e.g., naltrexone, Suboxone, buprenorphine).

- *Change “opioid agonist therapy” to “medication-assisted treatment” to include naltrexone when indicated.*
- *Is this medication-assisted treatment?*
- *Should say “medication-assisted treatment” in place of “opioid agonist treatment” as naltrexone is gathering an increasing evidence base and is an opioid antagonist rather than an opioid agonist.*

Theme 12b: Address barriers

Highlights existence of barriers to treatment (e.g., access, cost).

- *I completely agree however we have poor resources available to patients.*
- *There are no Suboxone clinics closer than 2 hours from where we live.*
- *Treating opioid use disorder may require certain state-specific certifications for treating substance abuse.*
- *Opioid agonist is very expensive [for] chronic pain patients without government assistance.*
- *Allow prescribing (following mandatory education) by all prescribing disciplines.*
- *Buprenorphine is cost prohibitive. Increasingly, patients have to pay out of pocket for these medications. Cost is a very important consideration.*
- *Urge CDC to recommend that all opioid prescribers obtain training and apply for a waiver to prescribe buprenorphine, particularly in light of well-documented treatment gaps.*

Theme 12c: Expand behavioral therapy

Broaden the recommendation around behavioral therapies (e.g., not just for patients with opioid use disorder).

- *This is critical as many PCP do not believe addiction is a chronic condition; very important to be part of initial opioid plan as long term use typically leads to this, most times unintended. Consider expounding information on brain disease of addiction.*
- *Behavioral therapy must be provided and should not be an option. Evidence-based practice requires all patients receive behavioral health as most have co-occurring disorders and should not be untreated during course of care.*
- *Cognitive behavior therapy is useful not just for those with opioid use disorder, but for anyone with chronic pain.*
- *Providers should offer or arrange evidence-based treatment in combination with behavioral therapies for all patients, not just those with opioid use disorder.*

Theme 12d: Guidance on discontinuing

Provide additional guidance on discontinuing opioids.

- *Add patients who are not adhering to treatment agreement or appear to be abusing opioids or other addictive substances should be strongly encouraged to accept linkage to alternative treatment including opioid replacement therapy.*
- *Opioid use disorder and concurrent chronic should only use non-opioid for pain and MAT then only for craving and not pain.*
- *Any recommendation to discontinue opioids due to safety concerns or concern for opioid use disorder should include a discussion of the potential risks of a patient transitioning themselves to non-prescription opioids including heroin. Patients with a diagnosis of opioid use disorder do need to be offered maintenance treatment with ORT such as methadone or Suboxone.*
- *Patients can be admitted for detox however there is no “bridge” for them from detox and their future.*
- *Consideration to functional restoration programs in conjunction with weaning or detox programs for patients on long term opioids.*

Theme 12e: Define opioid use disorder

Provide more information on opioid use disorder.

- *Please clarify opioid use disorder. All patients who use opioids are not addicts and don't have a mental health disorder.*
- *Given that these recommendations are for the general PCP, define opioid use disorder.*
- *The use of the term opioid use disorder is very vague. This term could apply to anyone taking prescribed opioids. The term addiction should be used.*
- *As written, the guideline does not convey its meaning to someone who is not already familiar with the language of pain management and addiction therapy specialists.*

CDC Response

- CDC edited the document to further clarify “opioid agonist treatment” by specifying medication-assisted treatment, clarify evidence for medication-assisted treatment and behavioral therapies, mention barriers such as insurance coverage and patient cost, and provide resources for information about evidence-based psychosocial treatment. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., definitions of medication-assisted treatment, behavioral therapy, and opioid use disorder, and guidance on opioid discontinuation).

General Comments

13. Guidelines methods and evidence

Theme 13a: Explain quality of evidence and strength of recommendation

Describe how quality of evidence and strength of recommendation relate.

- *Link between strong rec and low quality of evidence warrants comment.*
- *Eleven of the twelve recommendations are strong recommendations, yet all are based on low or very low quality evidence. It is impossible to know if this is appropriate without seeing the evidence.*
- *Strongly recommend that the CDC make clear that these guidelines should never preclude an individualized approach to meeting patients' legitimate needs. Any guideline with a “strong recommendation” should be downgraded when there is only “low quality evidence.”*

- *Please explain the classification schema GRADE, which separates ratings of recommendation from ratings of evidence (i.e., strong recommendation, weak evidence). This dichotomy seems irrational & allows for subjective, arbitrary conclusion.*
- *I really feel like most of these recommendations could be much stronger. To affect change we need to be stronger in our recommendations and guidelines.*
- *I heartily endorse in principle a guideline for pain management based on systematic review of the medical literature using the GRADE methodology.*

Theme 13b: Evidence review and data

Comments about the scientific evidence used to develop recommendations and potential limitations.

- *The systematic review is flawed...it reaches very different conclusions—in large part due to raising standards for inclusion of studies in the newer review to the point where no study of effectiveness or efficacy now met inclusion criteria.*
- *A wholesale adoption of guidelines that do not embody up-to-date, diverse medical perspectives could exacerbate the prescription drug abuse epidemic.*
- *Are there valid statistics indicating differences in opioid conversions by practitioner types, which may lead to situations of opioid overdose?*
- *Is CDC considering synthesizing literature studies on the efficacy (pain, function) of opioids for chronic non-cancer pain? Is CDC considering publishing a synthesis of risks of chronic opioid therapy (e.g. side effects, misuse, abuse, addiction, overdose)?*
- *Reassess evidence associated with current draft recommendations that may translate to unintended consequences resulting in increased burdens and poor outcomes for the patient with chronic pain.*
- *Request that the pain management guidelines be held to the same standard of evidence that other studies are; quotes there is no evidence that opiates are effective long term, but do you have evidence that acetaminophen, massage, or other treatments are effective long term? Without those studies, how can we deny opiate pain medication?*
- *Will CDC comment/describe evidence base for specific non-pharmacologic therapy and non-opioid pharmacologic therapy for chronic pain? I agree also that the evidence for chronic opioids for chronic pain is weak to non-existent. I suggest that this statement be made clearly in the recommendations!*

Theme 13c: Review and reconciliation with other guidelines

Complete a comparative examination of existing opioid prescribing guidelines for chronic pain (e.g., state guidelines, WHO, FDA).

- *CDC should review and consider the draft National Pain Strategy when making any determinations about opioid prescribing guidelines.*
- *FDA issued voluntary prescribing guidelines for long-acting opioids (opioid REMS). These guidelines were wholly inadequate, thus I strongly recommend that, to the extent that there is overlap between the two sets of guidelines, that CDC work with FDA to implement the new CDC guidelines...*
- *American Pain Association is working on some guidelines as well in this direction protecting interests of real pain patients and doctors who will like to appropriately treat pain. Really commend CDC in taking a good initial step in the right direction, against this huge epidemic killing many young ones.*
- *Concerned that, CDC draft guidelines inconsistent with established best practices, they will potentially make it difficult for patients who rely on them for pain control to access them from clinicians who are clear on how best to use them.*
- *Doesn't mention the World Health Organization 3-step ladder of treatment.*

Theme 13d: Peer review process

Comments about the inclusion and engagement of partners; qualification of reviewers; and transparency of the constituent engagement process.

- *Please make sure that your expert panel includes valuable representation.*

- *Share expert panel and conflict of interest (COI) statements before this is finalized; would like to see a listing of the names of expert panel involved.*
- *Are the state HDs considered Stakeholders for review purposes?*
- *We urge CDC to publish these recommendations in order to gain the broadest input and extend the comment period.*
- *Challenging to comment on guidelines without seeing the accompanying text or the evidence report.*
- *Pharmacists play a critical role in all facets of the chronic pain care management. It is important that pharmacists and other relevant health care professionals are included in the development, refinement, and finalization of the Guidelines.*

CDC Response

- CDC edited the document to further explain the GRADE approach, and revised terminology to be consistent with other CDC efforts; specifically, terminology used within recommendations issued by the Advisory Committee for Immunization Practices (ACIP). ACIP uses the GRADE approach, with terms that better organize the level of evidence and strength of recommendations.
- In this guideline, using the ACIP GRADE approach, CDC clarified that the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence had in the effect of a clinical action on health outcomes. The categories include the following types of evidence:
 - Type 1 evidence: randomized controlled trials, or over-whelming evidence from observational studies; equivalent to “high” quality evidence
 - Type 2 evidence: randomized controlled trials with important limitations, or exceptionally strong evidence from observational studies; equivalent to “moderate” quality evidence
 - Type 3 evidence: observational studies, or randomized controlled trials with notable limitations; equivalent to “low” quality evidence
 - Type 4 evidence: clinical experience and observations, observational studies with important limitations, or randomized controlled trials with several major limitations; equivalent to “very low” quality evidence
- The ACIP GRADE approach used in this guideline likewise presents recommendations in the following two categories:
 - Category A: recommendations: apply to all persons in a specified group and indicate that most patients should receive the recommended course of action (equivalent to a “strong” recommendation)
 - Category B recommendations: indicate that there should be individual decision making; different choices will be appropriate for different patients, such that providers must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (equivalent to a “weak” recommendation)
- CDC clarified that Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs.
- CDC also added information about the quality of evidence for alternative treatments and medication-assisted treatment/psychosocial treatment for substance use disorder.
- Please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., detailed clinical and contextual evidence reviews; explanation of GRADE methodology; inclusion of names of core experts, stakeholders, federal partners, and peer reviewers; discussion of conflict of interest protocols for the core expert group; and consideration of other guidelines).
- The plan for constituent engagement, stakeholder review, and peer review was placed on the NCIPC Peer Review Agenda website prior to the constituent, stakeholder, and peer reviewer engagement (<http://www.cdc.gov/injury/fundedprograms/peerreview.html>). CDC posted a fact sheet on the

guideline and the clinical practices addressed within on the Injury Center website (<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>).

14. Implementation and dissemination

Theme 14a: More provider education

Comprehensive prescriber/provider education is needed.

- *Any doctor prescribing pain medication should be trained in addiction—I have worked for over 20 years treating addiction in jail ... What I see is that Pain Management doctors often miss glaring indications of misuse, abuse and addiction.*
- *Recommend national educational goals for use of opioid pain relievers, both in the short term for current providers, and ongoing as part of continuing medical education.*
- *What the CDC should require as a first step is a requirement for a minimum number of hours of education/training/pain in medical, nursing, etc.*
- *Inform PCP to anticipate tolerance, dose escalation, and planning how to address long-term dependence.*

Theme 14b: Develop translation documents and evidence-based tools

Providers need practical tools to adopt guidelines; focusing on screening pain patients for risk factors, managing pain patients, and identifying when patients are abusing medications.

- *Many prescribers have no idea what evidence based measures they should be taking.*
- *An algorithm for prescribing opioids should be followed for function and observed pain only.*
- *You mention specifically morphine equivalents. Will there be published standard conversion ratios?*
- *Should include a hot line for providers to discuss cases with a qualified pain management doctor.*
- *Include what prescriber responsibilities are for management? Such as using PDMPs & checking UDS*
- *Facilitate screenings and referrals to high-quality, on-demand treatment for substance use disorders and commonly co-occurring conditions, such as HIV and hepatitis C.*
- *Recommend implementation of evidence-based practices when controlled medications are prescribed...treatment contracts, using an instrument such as the addiction behavior checklist.*
- *Please assist prescribers with a public information campaign to the public to assist this change in the prescribing environment.*

CDC Response

- CDC is dedicated to developing translation documents and evidence-based tools that will be disseminated after guideline publication and available on the Injury Center website. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., needs for education and mentions of available resources).

15. Health and psychological implications

Theme 15a: Stigma

Comments about treating/labeling opioid use as negative and the associated stigmatization, harassment, discrimination, and social bias.

- *Provide clarification and dispel myths, especially the false dichotomy of legitimate patients vs. abusers; all are patients and yes harm occurs in non-medical users but a clear acknowledgement that harm also occurs in medical users.*
- *The guidelines place the burden of proof on both the doctor and patient. If a patient has a chronic pain condition, they have to prove it to their physician. What it will do is further complicate proper and appropriate pain treatment options and negatively stigmatize the much larger group of people who rely on these medications.*

- *The risk for drug overdose by chronic pain sufferers is very low. Don't group chronic pain sufferers in with the abusers.*
- *Regarding comment re: "drug seeker"—Many are trying to treat their withdrawal symptoms; stigmatizing language.*
- *I have already been demonized by doctors, pharmacists, nurses etc. for taking narcotic painkillers.*
- *Chronic pain people are taking their own lives, since the medical governing boards have caused so many obstacles to obtaining relief.*

Theme 15b: Consequences of interfering with access

Comments about whether reducing access for those with legitimate need and denying care to people with chronic pain may lead to unnecessary suffering, depression, disability and even suicide.

- *Please do not make it more difficult for those of us who suffer daily pain to get proper medication so that we can function on daily basis, go to work, etc.*
- *Encourages CDC to adopt evidence-based best practices for the prescribing of controlled substance, which reflect the need to ensure that patients with legitimate need for controlled substances have access to their medications while reducing the risk of diversion, misuse, and abuse.*
- *People with severe chronic pain will be punished due to the actions of careless abusers. Institute a tougher monitoring plan, but please do not cause people like me to suffer even more. It would be inhumane.*
- *People who abuse prescription medications obtain them illegally (theft, black market, fraud). Hindering legitimate access to treatment will not prevent a single overdose, nor save a single life.*
- *Opioids are just one tool among many and discussions focused predominantly on restricting access reinforce the misconception that narcotics are the most important tool in the minds of both patients and health care professionals.*
- *Reevaluate what guidelines can be put into place to protect, not punish those of us who are responsible. While I agree that controlling the illegal distribution and recreational use of prescription medication is very important, our needs are also important.*

Theme 15c: Mental health and substance abuse

Address patients with co-occurring substance use disorders or other mental health disorders and their right to effective pain management, which may include chronic opioid therapy.

- *Consideration must be given to the potential for these guidelines to inadvertently discourage effective pain management strategies for people with substance use disorders, a vulnerable and often stigmatized population...CDC should therefore make an explicit statement against bias and stigma, and affirming the right to effective pain management for patients with substance use disorders.*
- *Recs are great but are not strong enough on mental health/comorbidities and should stress need to have psychologists/etc. to help.*
- *Chronic pain is a significant comorbidity for many people with substance use disorders, and under treatment of pain in this population may exacerbate substance use disorders or compromise effective treatment and recovery.*
- *Provide information on neurobiology of addiction. I work with PCP who are completely uninformed.*

CDC Response

- CDC considered comments about access and stigma in reviewing the framing and orientation of the guideline. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., effects of prescribing policies on access and existence of mental health conditions and other comorbidities).

16. Considerations for clinical decision-making and clinical care

Theme 16a: Patient-centered care and rare conditions

Take a patient-centered approach and consider specific medical conditions (e.g., rare pain disorders).

- *Your guidelines do not address chronic pain such as RSD/CRPS, Fibromyalgia, Rheumatoid Arthritis, etc. It is well documented that RSD/CRPS pain is rated higher on the McGill pain index than cancer pain yet you only mention cancer patients in your guidelines.*
- *I now suffer from Adhesive Arachnoiditis and the only quality of life I can muster relies on my access to opioid medications. Please reconsider these strict guidelines that are ONLY going to make life unlivable for legitimate, law-abiding citizens.*
- *I have autoimmune disorders, severe neuropathy, Stiff Person Syndrome and autonomic dysfunction. I do take tramadol to get me through the day but do keep hydrocodone on hand for very bad days.*
- *Would like to see a recommendation against treating chronic LBP, HA, and FMS in working aged adults with opioids.*

Theme 16b: Treatment planning and protocols

Multidisciplinary approach needed to provide useful and effective treatment interventions.

- *A strength to this guideline is that it strongly emphasizes the responsibility of clinicians to establish treatment goals and to weigh progress in relation to risks to patient safety. This basic philosophy is found throughout the summary and is commendable.*
- *Contract needs to be required when prescribing opioid therapy and should be reviewed throughout the course of treatment.*
- *Specify that all patients with chronic pain should be treated with multidisciplinary approaches targeted at simultaneously reducing pain severity and increasing physical and psychological functioning.*
- *Are there specific pain condition treatment plans in the pipeline (i.e. nociceptive, neuropathic, etc.)?*
- *Effective chronic pain care requires access to a wide range of treatment options, including biomedical, behavioral health and complementary treatment.*
- *Consider including a standalone recommendation to include behavioral health in the treatment of complex chronic pain.*

Theme 16c: Abuse-deterrent formulations

Include information on using abuse-deterrent formulations to reduce opiate prescriptions and overdoses.

- *Given the discussion around risk of addiction, consider adding in abuse-deterrent opioids as a benefit in the risk benefit assessment equation.*
- *Prescribe controlled substances with abuse-deterrent formulations to reduce the risk of diversion, misuse, and abuse.*
- *Encourage CDC to take into consideration impact that abuse deterrent opioids could have on abuse and diversion...Prescribers should be encouraged to prescribe the most abuse deterrent medicine that is appropriate for their patients.*
- *Providers who prescribe long-term opioid therapy should consider, as the first choice, an FDA approved opioid with abuse-deterrent properties described in the labeling*

Theme 16d: Doctor-patient relationship

Consider the competence of providers and the integrity of the doctor-patient relationship.

- *... I refill under my doctor's supervision. I am sure if he felt I was growing dependent or requesting refills too often, he would let me know. I think you need to TRUST the doctors' decisions. They are the experts when it comes to diagnosis and treatment.*
- *Please let doctors view their patients case by case and not force the doctors to have to withhold valuable much needed medication for us to survive. Is the CDC now going to do a study on how many*

of us will end up in divorce, death due to suicide, on street drugs ourselves, on welfare because we are bed bound and unable to care for our own families? This will all be due to loss of the meds.

- *Doctors should be allowed to determine best care for their patients -- How about you let physicians be physicians and choose the course of treatment they deem fit. Not long ago physicians were being sued for NOT controlling pain, now they are being dictated to for trying to relieve pain.*
- *We need to find a way to monitor writing habits more effectively. There are Drs out there who prescribe haphazardly.... who write scripts knowing they aren't needed. That should be stopped.*

CDC Response

- CDC edited the document to further clarify evidence and guidance about multimodal and multidisciplinary treatments and abuse-deterrent formulations. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., applicability to common conditions; provider-patient relationship and communication strategies).

17. Suggested content

Theme 17a: Requests for clarification, explanation, or indications of uncertainty

Clarify meaning, provide rationalization, or explain intent within the content or supporting documentation for recommendations.

- *It was stated that guidance is for primary care physicians and not experienced pain specialists, but it needs to be made repeatedly clear in every recommendation. Otherwise, guidelines are likely to be misunderstood and misapplied.*
- *Clearly articulate intended population (e.g., that these guidelines do not pertain to patients receiving end-of-life care (palliative care)).*
- *There is no distinguishing between cancer and non-cancer chronic pain.*
- *Agree that these guidelines are generally appropriate for non-cancer related pain. However...pain should be treated according to its severity and impact on function and revised in observation of the outcomes of treatment. Contrasting cancer and non-cancer-related pain too starkly risks trivializing all chronic pain of non-cancer origin. Would take great care in wording related to this issue.*
- *Will document include background data explaining/defining expected benefits or anticipated risks?*
- *Use practitioners instead of the term providers.*
- *Delete "chronic" from the title of the guidance. Several of the guidelines pertain to treating acute pain instead or in addition to chronic pain (specifically, guideline #3, #4, #5, #6, #8, #9, #11 and #12). Clarify that the guidelines do not apply to chronic cancer pain, in addition to end-of-life care.*
- *The risk to whom? Does this include the risk to the prescriber of regulators who don't like professionals who prescribe opioids?*
- *Include a description of how to appropriately document the need for a guideline exception.*
- *Why is the target audience limited to Primary Care Providers? Should include all providers who prescribe. Excluding prescribers suggests they have 'carte blanche' to prescribe whatever they wish.*
- *Will CDC be recommending any monitoring by CMS, NCQA, JCAHO of following of these recommendations?*
- *At what point should a PCP refer to a Pain Specialist; how can a PCP determine which Pain Specialty providers are legit?*
- *Very important for patients to understand the risks and therefore mixed messages about 'safety/efficacy' should not in general be promoted.*
- *Is there an expected minimal medical exam and laboratory work up prior to initiating opiate therapy for chronic pain?*

Theme 17b: Suggested recommendations/other guidelines/regulation needs

Opioid prescribing practices, additional guidelines, necessary regulations, and recommendations statements for consideration.

- *Will there be guidelines for acute pain?*
- *This should be law to review before all prescriptions for controlled substances.*
- *Any chance that dispensing guidelines are going to be addressed also? As a pharmacist... there are no clear-cut guidelines other than our better judgment on how & when to dispense these medications.*
- *There needs to be better control over pain clinics.*
- *Consider including an additional recommendation to include that patient should be locked in to one opioid prescriber and one pharmacy.*
- *I would just like to emphasis the need and importance for robust guidelines that do take a stance on max dose/quantity etc. to help curb the current opioid epidemic.*
- *Would like to see an explicit recommendation against the use of Methadone.*
- *Add a recommendation to avoid administration of parenteral opioids for patients already on chronic opioids, especially in ED/Urgent Care settings.*
- *We believe that the guidelines should also include guidance on appropriate opioid prescribing of acute/chronic non-cancer, non-end of life pain for patients on methadone or buprenorphine therapy.*
- *Is there a plan for guidelines for pain specialists who follow people long term on opioid therapy?*
- *Chronic pain pathophysiology (nociceptive, neuropathic, and sensory hypersensitivity) should be assessed prior to selecting the appropriate first line pharmacologic and non-pharmacologic therapy.*
- *Add guideline that cautions against opioid analgesia for pregnant women. Pregnant women with a diagnosis of opioid abuse disorder should be treated consistently with guideline #12*
- *Does this include marijuana? How do we incorporate the use of marijuana in treatment safely?*

Theme 17c: Additional resources, data, and citations

Suggested research studies, guidelines, and evidence for consideration.

- *Take Massachusetts guidelines into consideration during its review process. The CDC guidelines comport to a large degree with the MMS guidelines with the exception ...the MMS guidelines do not apply to patients with cancer, patients in hospice or palliative care and inpatients of hospitals and nursing homes.*
- *VA Opioid Taper Guidelines*
- *[Current Access to Opioids—Survey of Chronic Pain Patients](#), Practical Pain Management, March 2014—Cited reasons for suicidal ideation were increased pain (100%) and opioid withdrawal (35.5%).*
- *Emergency department opioid prescribing guidelines adopted by Maryland Hospital Association.*
- *Please see CLAAD's National Strategy ...which has been vetted and endorsed by more than 30 not-for-profit health and safety organizations, as well as the recently published article: A Call for Differential Diagnosis of Non-Specific Low Back Pain To Reduce Opioid.*
- *Updated Medical Board of California guidelines represent more flexible and mindful approach*
- *Ziegler, S.J. (2015). The proliferation of dosage thresholds in opioid prescribing policies and their potential to increase pain and opioid-related mortality. Pain Medicine (accessible via Early View, first published online in advance of print: 27 JUN 2015 | DOI: 10.1111/pme.12815); October 2015 is anticipated hard copy issue.*

CDC Response

- *CDC edited the document to further clarify the scope and audience of the guideline and the patients to which it applies (excluding active cancer treatment, palliative care, and end-of-life care), provide definitions for terms (e.g., acute pain, chronic pain, long-term opioid therapy), and indicate that the guideline offers recommendations rather than prescriptive standards and that providers should consider the circumstances and unique needs of each patient. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within*

the supporting text in the full guideline document (scope and audience of the guideline, policy considerations, and resources).