AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

January 13, 2016

Thomas Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Re: Docket No. CDC-2015-0112; Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Frieden:

There is no question that there is an opioid misuse epidemic and that efforts need to be made to control it. The Centers for Disease Control and Prevention (CDC) is applauded for its steps to undertake this lofty effort. However, based on the American Academy of Family Physicians' (AAFP's) review of the guideline, it is apparent that the presented recommendations are not graded at a level consistent with currently available evidence. The AAFP certainly wants to promote safe and appropriate prescribing of opioids; however, we recommend that the CDC still adhere to the rigorous standards for reliable and trustworthy guidelines set forth by the Institute of Medicine (IOM). The AAFP believes that giving a strong recommendation derived from generalizations based on consensus expert opinion does not adhere to evidence-based standards for developing clinical guideline recommendations.

The AAFP's specific concerns with the CDC's methodology, evidence base, and recommendations are outlined below.

Methodology and Evidence Base

- All of the recommendations are based on low or very low quality evidence, yet all but one are Category A (or strong) recommendations. The guideline states that in the GRADE methodology "a particular quality of evidence does not necessarily imply a particular strength of recommendation." While this is true, it applies when benefits significantly outweigh harms (or vice versa). When there is insufficient evidence to determine the benefits and harms of a recommendation, that determination should not be made.
- When evaluating the benefits of opioids, the evidence review only included studies with outcomes of at least one year. However, studies with shorter intervals were allowed for analysis of the benefits of nonopioid treatments. The guideline states that no evidence shows long-term benefit of opioid use (because there are few studies), yet the guideline reports "extensive evidence" of potential harms, even though these studies were of low quality. The accompanying text also states "extensive evidence" of the benefits of non-opioid treatments, yet this evidence was from shorter term studies, was part of the contextual review rather than the clinical systematic review, and did not compare non-opioid treatments to opioids.

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- The patient voice and preferences were not explicitly included in the guideline. This raises concerns about the patient-centeredness of the guideline.

Recommendations

- Recommendation 1: Nonpharmacologic and nonopioid pharmacologic therapies are preferred for treatment of chronic pain.
    - The Category A recommendation is too strong. This recommendation is intended to be based on Key Question 1, which addressed a direct comparison between opioid and non-opioid treatments. However, there is insufficient evidence to answer the question; therefore, there is insufficient evidence to make a strong recommendation for nonpharmacologic and nonopioid pharmacologic therapy.
    - There is limited evidence regarding the treatment of common conditions (i.e., low back pain, headache, and fibromyalgia) with opioids. However, it is unfair to make the assumption that opioids are ineffective for all causes of chronic pain based on a few conditions and limited evidence. In addition, low back pain is not a single disorder. It is a heterogeneous condition, so it is unfair to make assumptions about treatment without evidence.
    - While the AAFP agrees that exercise therapy is beneficial, there is little guidance for implementation of such a recommendation, particularly for patients who have pain from significant hip or knee osteoarthritis and extreme difficulty moving.
    - Non-steroidal anti-inflammatory drugs (NSAIDs) are recommended, but the harms associated with NSAID use for conditions commonly seen in primary care (e.g., hypertension, chronic kidney disease) and risks associated with NSAID use in the elderly are not adequately addressed.
    - The AAFP is concerned that the guideline mentions non-FDA approved treatments for fibromyalgia (e.g., gabapentin), and it does not address abuse potential and other harms associated with the use of pregabalin.

- Recommendation 2: Treatment goals should be established before initiating opioid therapy, and treatment should be discontinued if there is no meaningful improvement in pain or function.
    - The AAFP agrees with the spirit of this recommendation;

- Recommendation 3: Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.
    - The AAFP supports this recommendation

- Recommendation 4: When prescribing opioids, physicians should prescribe immediate-release opioids and not extended-release/long-acting opioids (ER/LA).
    - The basis for this recommendation seems to be a single new U.S. Department of Veterans Affairs study of fair quality and expert opinion. Although the AAFP agrees with this recommendation, it is not appropriate to make a Category A recommendation on the basis of this level of evidence.

- Recommendation 5: The lowest effective dose of opioids should be prescribed and providers should use precaution when increasing dosages to ≥50 morphine milligram equivalents (MME) per day. Physicians should avoid increasing dosage to ≥90 MME per day.
    - The AAFP agrees with the recommendation to use the lowest effective dose, but is concerned about the cut-off points as they are based on expert opinion rather than quality evidence.

- Recommendation 6: Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, physicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe

enough to require opioids. Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery.
    - The AAFP supports this recommendation with the omission of the last sentence "Three or fewer days…." Basing the time limits (i.e., three or fewer days) on evidence from emergency medicine literature is not applicable or appropriate in guidelines for primary care.
- Recommendation 7:
    - The AAFP supports this recommendation
- Recommendation 8:
    - The AAFP supports this recommendation
- Recommendation 9:
    - The AAFP supports the use of PDMPs. We recognize, however, that these vary greatly state to state and we support proper funding and standardization of PDMPs.
- Recommendation 10:
    - The AAFP in general is supportive of intermittent urine drug testing (UDT) to assess adherence as well as to monitor for illicit drug use. This topic is complicated by the number of UDTs available, some of which don't test for all opioids. Clinicians need guidance on what the appropriate test is for chronic opioid users. We appreciate the clarification that clinicians should not use UDT results to terminate patients from their practice.
- Recommendation 11:
    - The AAFP agrees that co-prescribing of benzodiazepines and opioids should be avoided whenever possible. However, based on the level of evidence, this should not be a category A recommendation.
- Recommendation 12:
    - The AAFP supports this recommendation.

The AAFP appreciates the opportunity to provide the above comments and are happy to discuss in more detail or answer any questions.

Sincerely,

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