Opioid Workgroup

Board of Scientific Counselors, National Center for Injury Prevention and Control Centers for Disease Control and Prevention

Terms of Reference

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of the Opioid Workgroup (OWG) under the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC), Centers for Disease Control and Prevention (CDC). The primary purpose of the Opioid Workgroup is to review a draft, updated and/or expanded Guideline for opioid prescribing (as prepared by CDC) and to develop a report that will provide the workgroup's findings and observations about the draft guideline to the BSC/NCIPC (i.e., the "parent" committee comprised of all appointed BSC/NCIPC members). The BSC/NCIPC will subsequently review the Opioid Workgroup's report, discuss, deliberate, and provide advice and recommendations for CDC to consider as part of the potential update and/or expansion of the Guideline. The updated and/or expanded Guideline is anticipated to be released in 2022.

BACKGROUND

For the millions of Americans that experience pain each year, receipt of appropriate pain management is an essential component of patient care and warrants careful consideration of the balance of benefits and harms of available treatment options. In the United States, opioid analgesics are commonly prescribed for the treatment of pain. At the same time, opioids have well-documented risks of its misuse, use disorder and overdose. In 2018, opioid-involved drug overdoses accounted for 46,802 deaths, with 14,975 involving prescription opioids.

The *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (the Guideline) provided twelve recommendations for prescribing opioid pain medications for outpatients aged ≥18 years in primary care settings. Recommendations focused on the use of opioids in treating chronic pain (defined as pain lasting longer than three months or past the time of normal tissue healing). The guideline was not intended for use in active cancer treatment, palliative care, or end-of-life care.

Following the release of the Guideline, accelerated decreases in overall and high-risk prescribing (e.g., co-prescribing an opioid and a benzodiazepine; high-dosage opioid prescribing) were documented. In the Guideline, CDC indicated the intent to evaluate and assess the Guideline as new evidence became available and to determine when closure of research gaps would prompt an update to the Guideline.

In order to identify whether evidence gaps are sufficiently addressed to warrant updates to, or expansion of, the Guideline, CDC funded the Agency for Healthcare Research and Quality (AHRQ) through an interagency agency agreement to conduct five systematic reviews on the effectiveness of opioid, nonopioid pharmacologic, and nonpharmacologic treatments for acute and chronic pain. As of April 2020, AHRQ's Evidence-Based Practice Centers have completed three systematic reviews which include new evidence related to the treatment of chronic pain. Two additional systematic reviews on treatments for acute pain are expected to be available late 2020, which will help inform the decision of whether to further expand the Guideline into the treatment of acute pain. In addition to assessment of the systematic evidence reviews, key steps to facilitate CDC's updating and possibly expansion of the Guideline include formation of an expert BSC/NCIPC workgroup to provide input on an updated Guideline to the BSC/NCIPC

DESCRIPTION OF ACTIVITIES

Opioid Workgroup members will be provided with the draft updated/expanded 2022 Guideline and other supporting materials to assist with tasks related to providing input and observations on the draft Guideline (items #1-4 below). These tasks include:

1. Reviewing the quality and implications of clinical and contextual evidence reviews.
2. Reviewing each guideline recommendation statement and accompanying rationale.
3. Considering for each recommendation:
    a. The quality of the evidence supporting the recommendation (assessing the accuracy of the evidence quality rating; i.e., evidence "type");
    b. The balance of benefits and risks associated with the recommendation (including the degree to which the benefits of issuing the recommendation can be anticipated to outweigh the harms);
    c. The values and preferences of clinicians and patients related to the recommendation (including the degree to which there is variability or uncertainty in values and preferences);
    d. The cost feasibility of the recommendation (including the degree to which implementation is anticipated to be feasible for health systems and patients financially); and
    e. The category designation of the recommendation (whether Category A or Category B is justified). Category A recommendations apply to all patients; Category B recommendations require individual decision making where different choices will be appropriate for different patients so that clinicians must help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.
4. Developing a summary report, including points of agreement and disagreement, of the workgroup's observations associated with items #1–3 above for the draft updated/expanded 2022 Guideline.

The OWG will also develop expert input and observations on other matters which might arise related to the opioid crisis and provide input and observations to the BSC/NCIPC for consideration, if requested by the NCIPC Director through the BSC/NCIPC to meet evolving public health needs, and within the scope of the CDC's FACA guidance and in accordance with the BSC Charter.

MEMBERSHIP

The OWG membership will include at least two current BSC NCIPC Special Government Employees. One of the BSC members will serve as chair. A CDC/NCIPC subject matter expert will serve as the OWG Designated Federal Officer (DFO) in consultation with the BSC/NCIPC DFO. The OWG will be composed of 12–25 persons, including the chair and at least one other member from the BSC/NCIPC and ex officio members from agencies listed in the BSC/NCIPC charter. Workgroup members will also include diverse areas of expertise such as clinical medicine, dentistry, pharmacology, epidemiology, research methodology, ethics, and public health, as well as opinion. Workgroup members will also include expertise from academia, persons with chronic pain and families, and state/local health departments. In accordance with HHS policy, other non-Federal ad hoc consultants may be invited to participate as needed for other perspectives or viewpoints.

MEETINGS, ADMINISTRATION, AND TIMELINES

1) Administrative Oversight: The OWG Chair and the OWG DFO will work cooperatively to plan and arrange meetings, document meeting proceedings, and report to the BSC/NCIPC on workgroup findings and outcomes. NCIPC staff may be asked by the OWG DFO to perform specific tasks such as assisting with arranging meetings and documenting meeting proceedings.

2) Meeting Frequency: At a minimum, the OWG will meet at least three times in a 12-month period, but may convene more often as necessary to conduct its activities on this urgent public health issue.

3) Meeting Structure: Meetings must include the OWG Chair, at least one additional BSC Member who belongs to the workgroup, and the OWG DFO in attendance. Meetings may be conducted in person or via teleconference. The OWG Chair will work with the OWG DFO to develop an agenda in advance of each meeting. The Chair and OWG DFO will also work collaboratively with other workgroup members to arrange for any presentations or advance materials to inform the workgroup's activities. In addition, the OWG DFO may request that, workgroup members, or non-Federal external experts be invited to provide presentations or other information to inform the workgroup's activities. Workgroup meetings will be closed to allow examination of an area in detail, to enable thorough review of information and to focus in a manner that most effectively uses members' time. Further, certain information may be proprietary or otherwise confidential. Although the meetings are closed, documents may be subject to public disclosure pursuant to applicable law.

4) Confidentiality and Conflicts of Interest: OWG members must complete the Conflict of Interest and Confidentiality Certification for Work Group Members (CDC Form 0.1473) and the addendum to disclose interests (e.g., employment, special interests, grants, or contracts) that a reasonable person might view as a conflict or potential conflict of interest. Workgroup members will also disclose at each meeting any potential or actual conflict of interest and will be advised to recuse themselves from participation in Workgroup discussions that implicate such a conflict of interest concern. The discussions of the Workgroup may include information that is unpublished, protected, privileged, or confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information unless required or pursuant to applicable law.

5) Timelines: OWG Chair and OWG DFO will report to the BSC/NCIPC during its regular meetings with topics including the workgroup's efforts, findings, observations, and outcomes. The OWG will continue to meet and provide updates until its dissolution by the BSC/NCIPC.

6) Subject Matter: The findings, observations, and outcomes of the OWG members' reviews will be discussed at workgroup meetings. The findings, observations, and outcomes of the OWG will be reported to the BSC/NCIPC during its regular meetings for discussion, deliberation, and decision.

7) CDC Staff Involvement: The OWG may seek input from CDC subject matter experts for consultation or informational presentations that contribute to the workgroup's activities. Participation by and contributions of CDC staff will be transparent and evident, to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the workgroup. The BSC/NCIPC DFO and OWG DFO will ensure that the OWG report/products are appropriate and not unduly influenced by CDC, ATSDR or by any special interest group.

RECORDKEEPING AND REPORTING

Minutes of OWG meetings will include at a minimum the meeting logistics (e.g., date, location), participant list, account of verbal conflict of interest assessment, outcomes or observations, and action items, if applicable. The finalized minutes will be submitted for informational purposes to the BSC/NCIPC.

The OWG Chair will present meeting summaries to the BSC/NCIPC for discussion, deliberation, and decision. BSC/NCIPC recommendations derived from the work of the OWG will be included in the BSC/NCIPC annual report.