



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and
Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

May 1, 2018

Margo Schwab, Ph.D.
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Dr. Schwab:

The NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, Exp. Date 07/31/2018) proposes to conduct a cognitive interviewing study to evaluate questions pertaining to opioid-use for population-based household surveys. Most of the questions intended for this study currently appear on the Substance Abuse and Mental Health Services Administration's (SAMHSA's) National Survey on Drug Use and Health (NSDUH) (OMB No. 0930-0110, Exp. Date 08/31/2020) but have not been fully evaluated, and it is not certain whether or not, and the degree to which, the questions capture the constructs required by the CDC. Recruitment of respondents and interviewing would begin as soon as approval is received. Interviews will be conducted in up to seven diverse regions in the United States.

Cognitive Interviewing Methodology

The methodological design of this proposed study is consistent with the design of most NCHS/CCQDER cognitive interviewing studies: the purpose is to identify the various patterns of interpretation that respondents consider when formulating an answer to a survey question as well as any problems experienced. Findings demonstrate the construct captured by each question, consistency of patterns across respondent groups, and potential sources of response error. Interviews are in-depth and semi-structured; analysis is conducted using qualitative methodologies. Findings from all CCQDER studies are documented in a final report and made publicly accessible on a searchable website at <https://wwwn.cdc.gov/QBank>.

Cognitive Interviewing Study of Opioid-Related Questions

Background: Much of CDC's information on opioid use comes from disparate sources of survey and commercial data sets of varying levels of quality that produce inconsistent estimates. For example, CDC relies on data from SAMHSA's NSDUH to understand various aspects of opioid use, misuse, and disorder. However, compared to other commercial data sources like IQVIA – which reports to collect 90% of prescriptions – the prevalence of

opioid use from NSDUH appears much higher (IQVIA: 19.2% vs. NSDUH: 37.8%, Han et al., 2017¹). At the same time, NSDUH estimates of misuse and opioid-use disorder appear to be lower than what is expected. Currently, it is not clear which source is the more exact for opioid-use, and there is strong speculation that not all NSDUH opioid items are fully capturing accurate information.

Study Research Questions: The primary goal of this study is to investigate the ways in which existing opioid questions perform in differing socio-cultural contexts within the United States and, more specifically, to better understand barriers to accurate reporting of opioid use, misuse, impairment and addiction on household surveys. It is not the intention of this study to produce a fully valid set of opioid-related questions, although it will contribute to this likely future endeavor. Household surveys may hold specific data quality limitations that other sources of data do not, and it is necessary to fully explore the cognitive and interpretative processes that produce opioid survey data in order to assess those limitations. Furthermore, findings from a previous CCQDER study showed that, when formulating answers to opioid impairment questions, respondents' interpretations of such questions were directly linked to their personal experience and circumstance,² suggesting the need to examine the comparability of interpretive patterns across socio-economic and cultural groups. Not doing so could lead to differing levels of quality in terms of understanding the opioid crisis in the various affected communities.

Thus, this study aims to address the following research questions:

1. When answering questions about opioid use, what kinds of medication do respondents consider? How is it defined, and what are the parameters for these considerations? Does this vary according to respondents' background, experiences with the medical system, and/or their socio-cultural context?
2. How do respondents understand the concept of misuse? For those whose actions would be defined as misuse by the CDC, how do they make sense of or rationalize their actions? How do these personal explanations impact their response to questions about misuse? How consistent are these patterns across differing groups of respondents?
3. How do respondents conceptualize the concept of opioid impairment? Are there differences across respondent groups? How do these conceptualizations impact responses to impairment questions?
4. Regarding the opioid addiction questions, are respondents able to reflexively examine their actions and accurately report back as would be intended by the CDC? What are the factors that lead to response error? Do these factors vary by question topic? By respondent group?
5. In terms of answering questions about usage, are there any cognitive tasks that are over-burdensome to the extent that data quality is compromised? If so, what are the characteristics of those questions? Does this differ across respondents?

¹ Han B, Compton WM, Blanco C, Crane E, Lee J, Jones CM. Prescription opioid use, misuse, and use disorders in U.S. adults: 2015 National Survey on Drug Use and Health. *Ann Intern Med.*2017;167:293-301.

² Willson, S. (2017). Cognitive Interview Evaluation of Survey Items to Measure Substance Use and Impaired Driving. National Center for Health Statistics. Hyattsville, MD. <https://wwwn.cdc.gov/QBank/Report.aspx?1186>. Accessed 4/9/2018.

6. Should some types of opioid-related questions be deemed as too sensitive to ask on face-to-face, household surveys? What are the characteristics of those questions? Does this vary across respondents?

Collaboration: On March 15, CDC convened a working group of CCQDER staff as well as representatives from the National Center for Injury Prevention and Control (NCIPC) to discuss the proposed project to assess the validity of opioid questions on household surveys. NCHS/CCQDER staff presented 1) an overview of the CCQDER program and cognitive interviewing methodology, 2) findings from a previous study pertaining to opioids, and 3) the purpose and goal for the proposed study (i.e. to study the feasibility of asking opioid questions on household surveys). NCIPC staff presented CDC's overall strategy for handling the opioid crisis, data sets used to track the opioid crisis, and data quality concerns that are outlined in the above section. From this discussion, the group developed a research agenda for the proposed study as well as a proposed questionnaire—much of what comes from the NSDUH.

On April 10, the workgroup met with SAMHSA representatives to describe the current project and to initiate a collaboration. As part of the collaboration, NSDUH staff provided necessary materials for the interviews, including past testing reports, and it was agreed that SAMHSA colleagues will have access to cognitive interview recordings, will be kept abreast of the study, and will receive a final report. It was also agreed that, if possible, the two agencies would co-author study-related papers.

Study Protocol: The opioid use, misuse, impairment and use disorder questions to be examined are included as Attachment 1. The proposed questions for cognitive testing have appeared on the 2017 NSDUH survey; however these questions have not been formally evaluated according to OMB Statistical Policy Directive No.2: Standards and Guidelines for Cognitive Interviews. Additional questions on general health, and access to care are used to frame respondents' answers to the opioid questions. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic clearance package (OMB No. 0920-0222, Exp. Date 07/31/2018).

We propose to recruit up to 200 English-speaking adults (aged 18 and over) with a range of experiences (in the past 30 days versus 12 months) with pain and opioid use. Within these constraints, we plan to recruit participants with some demographic variety (particularly in terms of regional wealth, urban/rural, education, age, race/ethnicity, and gender).

Recruitment will be carried out through a combination of a newspaper advertisements/flyers, word-of-mouth, as well as a database of predetermined volunteers. The newspaper advertisement/flyer used to recruit respondents is shown in Attachment 2. The 5 minute screener used to determine eligibility of individuals responding to the newspaper advertisement/flyer is shown in Attachment 3a. The 5 minute screener used to determine eligibility of individuals from the CCQDER Respondent Database is shown in Attachment 3b. Note that wording of the template has been approved and is contained within our umbrella package. Only project specific information has been added to the document. It is anticipated that as many as 360 individuals may need to be screened in order to recruit 200

participants. Interviews will be conducted in as many as seven diverse locations in the United States, possibly including the Northeast, South, Southwest, Pacific Northwest, Midwest, and Mid Atlantic.

Interviews averaging 60 minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by CCQDER staff members with English speaking respondents. Interviews will be conducted in the Questionnaire Design and Evaluation Research Laboratory as well as at off-site locations. Interviews conducted in the Questionnaire Design and Evaluation Research Laboratory and those off-site will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. These recordings will allow researchers to ensure the quality of their interview notes. In the rare case that a study participant initially agrees to a recording during the telephone screening, but changes their mind and checks “no” to allowing the interview to be recorded on the informed consent document, the interview will proceed without any recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select “yes” for allowing the interview recording on the informed consent form, but “no” for retaining the recording for future research (final text before signatures on informed consent form), will be allowed to participate in the study.

After respondents have been briefed on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent (Attachment 4). Only project specific information has been added to the document. Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 5). This document is contained in our umbrella package. The burden for completion of this form is captured in the interview.

The interviewer will then ask the respondent to confirm that he/she understands the information in the Informed Consent, and then state that we would like to record the interview. The recorder will be turned on once it is clear that the procedures are understood and agreed upon.

The interviewer will then orient the respondent to the cognitive interview with the following introduction:

[fill staff name] may have told you that we will be working on some questions that will eventually be added to national surveys. Before that happens, we like to test them out on a variety of people. The questions we are testing today are about pain and opioid use. We are interested in your answers, but also in how you go about making them. I may also ask you questions about the questions—whether they make sense, what you think about when you hear certain words, and so on.

*I will read each question to you, and I'd like you to answer as best you can. Please try to tell me what you are thinking as you figure out how to answer. Also, please tell me if:
there are words you don't understand,
the question doesn't make sense to you,
you could interpret it more than one way,*

*it seems out of order,
or if the answer you are looking for is not provided.*

The more you can tell us, the more useful it will be to us as we try to develop better questions. Okay? Do you have any questions before we start? If yes, answer questions. If not, let's get started.

After the interview, respondents will be given the thank-you letter (document contained in umbrella package) signed by the Charles J. Rothwell, Director of NCHS (Attachment 6), a copy of the informed consent document, and \$40.

Extreme care will be taken with all recordings and paperwork from the interviews conducted off-site. Recordings and identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point they will be transferred to the usual secured locked storage cabinets.

We propose giving participants \$40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 230 hours. A burden table for this project is shown below:

Form Name	Number of Participants	Number of Responses/ Participant	Average hours per response	Response Burden (in hours)
Screener (recruited from newspaper or database)	360	1	5/60	30
Questionnaire	200	1	60/60	200

Attachments (7)

cc:

V. Buie

J. Zirger

DHHS RCO