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 15, 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 Spanish language cognitive interviewing study examining opioid-related questions that will run concurrently with the English language study that was approved by you on May 3, 2018. The Spanish language testing protocol follows the exact same procedures and uses the same forms used in the approved English language 10-day package with the exception that Research Support Services will carry out recruitment, conduct the cognitive interviews, and interviews will be audio-recorded, as opposed to video-recorded.

As was stated in the previous package, the majority of questions for the 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). Since the questions have not been fully evaluated, it is not certain whether or not, and the degree to which, the questions capture the required constructs. While the previous English-language study sets out to address this issue, this study adds an additional component whereby the Spanish translation will be examined to assess comparability between English and Spanish versions. Recruitment of respondents and interviewing would begin shortly after approval is received. Interviews will be conducted in up to three diverse regions in the United States.

Cognitive Interviewing Methodology

The methodological design of this proposed study is consistent with the design of the English-language study, as well as most other 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

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 – Spanish language testing

Background: As indicated in the previous package, much of CDC's information on opioid use comes from various sources of survey and commercial data sets producing inconsistent estimates. CDC, for example, 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., 2017[1]). 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 the English-language 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. The study is not intended to produce a fully valid set of opioid-related questions, although it will contribute to this likely future endeavor. A major focus of the English-language study will be to examine the comparability of interpretive patterns across socio-economic and cultural groups. The necessity of this focus is illustrated by a previous CCQDER study that showed, when formulating answers to opioid impairment questions, respondents' interpretations were directly linked to their personal experience and circumstance.[2] Significantly, lack of comparability can lead to differing levels of quality in terms of understanding the opioid crisis in the various affected communities. A Spanish-language study occurring simultaneously with the English-language study will provide an understanding of the ways in which comparability can be impeded by translation processes as well as the socio-cultural factors associated with those in Spanish-language communities.

The research questions presented in the English-language package are identical, although the focus of this study will be in the comparison between English and Spanish-speaking respondents. Those questions include:

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

[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.

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?
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: To develop the protocol for the English-language study, CCQDER staff met with representatives from the National Center for Injury Prevention and Control (NCIPC) as well as SAMHSA representatives. The package approved on May 3, 2018 more fully describes this collaboration. In regards to the Spanish-language study, all collaborators support this development and agree on its significance. SAMHSA, in turn, provided the Spanish translation of NISDUH questions, specifically, those pertaining to use, misuse, disorder, and perceptions of risk. NCIPC provided the Spanish translation of impairment questions which are not part of the NISDUH.

Study Protocol: The Spanish language opioid use, misuse, impairment, use disorder and perception of risk 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 60 Spanish-speaking adults (aged 18 and over, preferably monolinguals) with a range of experiences (in the past 30 days verses 12 months) with pain and opioid use. Within these constraints, we plan to recruit participants with some demographic variety in terms of country of origin, age, gender, and education.

Recruitment will be carried out by Research Support Services (RSS) (a frequently used CCQDER contractor for conducting Spanish cognitive interviews) through a combination of a newspaper advertisements/flyers, and word-of-mouth. 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 3. 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 96 individuals may need to be screened in order to recruit 60 participants. Interviews will be conducted in as many as three diverse locations in the United States, possibly Chicago, Massachusetts, and Texas.

Interviews averaging 60 minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by RSS with primarily monolingual Spanish-speaking respondents. Interviews will be conducted in a private room of a community-based organization or at a mutually agreed upon location with an individual respondent and an interviewer. Interviews will be audio recorded to 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.

RSS staff conducting the Spanish cognitive interviews will complete NCHS Confidentiality training at https://www.cdc.gov/nchs/training/confidentiality/training/ and sign a Nondisclosure Affidavit (provided by NCHS). The contractor will send hardcopies of the NCHS Confidentiality Training certificates and original signed hardcopies of the Nondisclosure Affidavits to Karen Whitaker, Program Specialist, CCQDER.

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 68 hours. A burden table for this project is shown below:

Form Name	**Number of Respondents**	**Number of Responses/ Participant**	**Average Burden per response (in hours)**	**Total Burden Hours**
Screener (recruited from newspaper or database)	96	1	5/60	8
Questionnaire	60	1	1	60
Total				68

Attachments (7)
cc:
V. Buie
J. Zirger
DHHS RCO