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

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

Dear Dr. Schwab:

The staff of the NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 08/31/2021) plans to conduct a cognitive interviewing study to examine physician opioid questions for the Division of Healthcare Statistics (DHCS).

We propose to start recruiting for volunteer participants as soon as we receive clearance and to start testing as soon as possible after that.

Background: Project Specific Questions

The physician opioid questions were compiled and developed by the National Pain Strategy Workgroup. Questions 1 and 2 are standard questions included on national physician surveys such as the National Ambulatory Medical Care Survey (NAMCS) and the National Electronic Health Records Survey (NEHRS). Questions 4 and 5 were developed directly by the National Pain Strategy Workgroup to gather specific screening information[1-4]. The rest were developed by the National Pain Strategy Workgroup based on survey instruments, findings, and/or recommendations from previous studies[2-6].

Plan of Study

The methodological design of the proposed study is consistent with the design of most NCHS/CCQDER cognitive interviewing studies. The purpose is to identify various patterns of interpretation that respondents consider when formulating an answer to a survey question, as well as any difficulties, confusion, or response error that occurs during administration. Interviews are in-depth and semi-structured. Analysis will be conducted using the constant comparative qualitative method and will focus on the constructs captured by each question, consistency of patterns across respondent groups, and potential causes of response error. Findings (like all CCQDER studies) will be documented in a final report and made publicly accessible on a searchable website at https://wwwn.cdc.gov/QBank.

Study Protocol: The physician opioid questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic OMB clearance package (No. 0920-0222, exp. 08/31/2021). Additionally, the interview will conclude with a card-sorting activity. Card, or pile sorting, is a structured social science data collection method that allows researchers to explore how individuals and groups perceive and organize a given cultural domain. In short, card sorting is a proximity method to explore the relationships within a cultural domain that produces unconstrained clusters of the items being grouped, which represent a cultural taxonomy[7]. In this case, we are specifically interested in

how respondents organize and understand pain management drugs[8]. This card-sorting activity was included as part of an evaluation of opioid questions within the general population (Protocol #2016-16 NCHS Laboratory-Based Questionnaire Design Amendment #22 Cognitive Interviewing Study of Opioid Use and Pain Questions on Household Surveys). The activity is included in the present study with the goal of understanding how professionals conceptualize and categorize opioids as compared to non-professionals. The cards are included as Attachment 2.

We propose to recruit 20 English-speaking adults (aged 18 and over) who are physicians in various sub-specialties including general practice, internal medicine, neurology, anesthesiology, internal medicine, rheumatology, orthopedic surgery, pediatrics and geriatric medicine.

Physicians in the Washington, DC area will be recruited through contacts of the National Pain Strategy Workgroup. The workgroup will email an advance letter to their physician contacts. Additionally, the workgroup will provide a list of contacts. As a follow-up to the advance letter, CCQDER staff will call individuals to talk to them about the study, what they will be asked to do, and to ascertain their interest in participating in the study. The advance letter used to recruit respondents is shown in Attachment 3. The 5-minute screener used to determine eligibility of individuals is shown in Attachment 4. 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 50 individuals may need to be screened in order to recruit 20 participants.

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. All interviews conducted in the Questionnaire Design and Evaluation Research Laboratory will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. Interviews conducted off-site will only be audio recorded. These recordings will allow researchers to ensure the completeness and accuracy of their interview notes. Recordings will only be used by researchers from CCQDER and DHCS who are working on the project. Recordings will remain under CCQDER staff control. There will be no external sharing of the recordings.

Video or audio recording is required for this project except in the rare case that a study participant initially agrees to be video recorded during the telephone screening, but changes their mind. In that case, they will be asked if they agree to be audio recorded. If they decline to be audio recorded the interview will proceed without recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select “yes” for allowing the 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.

NCHS government issued encrypted laptops will be used to video and audio record the interviews conducted off-site. Due to the size of the video recordings, the internal drive of the encrypted laptop is not sufficient for storage of the recordings. Recordings will be saved to an NCHS government issued encrypted flash drive. The encrypted flash drive is FIPS 140-2 compliant and approved for use by Office of the Chief Information Security Officer (OCISO).

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. Once the video and audio recordings are transferred to the Questionnaire Design Research Laboratory Network, the recordings will be deleted from encrypted flash drive. Once deleted, the files are no longer available for use.

The initial retention period of the audio recordings is 2 years after project completion. After the initial retention period, the recordings will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness, and qualitative value for likely use in question evaluation research. If it is determined by the CCQDER Director in conjunction with CCQDER project-relevant staff that there is no valid reason to retain the recording, it will be destroyed by designated CCQDER staff. If the interview continues to be of value (defined as ongoing use by research staff, topic relevance, likely use for federal questions evaluation research), reassessment of the recording will occur again in either 2 years.

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 5). 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 6). 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 physician knowledge and awareness of opioid guidelines and their use of opioid prescription for pain management. 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 Director of NCHS (Attachment 7), a copy of the informed consent document, and $100.

We propose giving participants $100 incentives, which is our standard incentive for physicians. In total, for this project, the maximum respondent burden will be 26 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 advance letter)	50	1	5/60	5
Questionnaire	20	1	55/60	19
Respondent Data Collection Sheet	20	1	5/60	2
Total	90			26

Attachments (7)
cc:
S. King
J. Zirger
DHHS RCO

References

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