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

June 26, 2017

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. Date 07/31/2018) plans to conduct a cognitive interviewing study to evaluate questions on health care utilization, smoking and selected topics about children for the National Health Interview Survey (NHIS OMB No. 0920-0214, expires 1/31/2019).

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 Information about Cognitive Testing of Questionnaires

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. The purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative.

Proposed project: Testing of Questions on Health Care Utilization, Smoking and Selected Topics about Children

These questions are being tested in preparation for the upcoming redesign of the National Health Interview Survey. Rationales for testing and inclusion are detailed below:

1. Utilization - usual place of care, well visits, urgent care
   Questions on places for usual source of care are being updated for the NHIS redesign to better reflect the complete spectrum of places where the U.S. population may receive care when sick. At the same time, this longer list of locations may contain some that are unfamiliar to respondents, so the full response list should be tested. These response categories are also used in the item on location of most recent preventive visit.

The redesigned NHIS will include revamped questions on preventive healthcare to better monitor impacts of health care access on preventive care visits. This new approach asks specifically about the length of time since and location of the most recent preventive care visit as a way to anchor respondents who may have multiple preventive care visits per year. However, the respondent interpretation of "preventive visit" should be tested to ensure that the intended types of visits are being captured in these items.

The urgent care item matches the structure of an existing NHIS item on emergency room care. However, the definition of what facilities constitute "urgent care" may be more difficult for respondents to comprehend.

2. Mental health
   The questions on mental health are new to the NHIS content redesign and have not been previously cognitively tested. One of the goals of the redesign is update the content. This includes collecting information on mental health need and use. The five new mental health questions are attempting to assess use of medication and non-medication treatment of mental health and lack of access due to cost. Cognitive testing will examine how respondents determine their answers to these new questions. Comments from both the National Institutes of Mental Health (NIMH) and the Substance Abuse and Mental Health Services Administration (SAMHSA) were taken into consideration in the development of these items.

3. Doctor advising Quitting Smoking
   This is one of three questions added to address the U.S. Preventive Services Task Force (USPSTF) recommendations on content of care. (The others are related to alcohol consumption and physical activity.) The recommendation (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1) suggests that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and FDA-approved pharmacotherapy.

   The decision was made to keep the doctor's advice question connected to the cigarette smoking questions to ensure better continuity for the respondent. The proposed question, SMKTLK_A (noted below) is similar in concept as an item that was on the 2015 Cancer Control Supplement, but extends the questions further to get at the USPSTF recommendation:

   “In the past 12 months, has a medical doctor, dentist, or other health professional advised you to quit smoking, or to quit using other kinds of tobacco?”

4. E-cigarettes and using e-cigarettes in smoking cessation
   After the release of the Data Brief on e-cigarette use among adults, one question that arose from Health and Human Services (HHS)/Assistant Secretary for Planning and Evaluation (ASPE) was whether there was any way to use NHIS data to determine the proportion of current or former smokers who used e-cigarettes to help them quit

smoking regular cigarettes. This set of questions was developed by starting with the approach used in Food and Drug Administration's (FDA's) Population Assessment of Tobacco and Health item on using e-cigarettes to quit smoking "regular cigarettes:"

Thinking back to the last time you tried to quit smoking in the past 12 months, did you use: any different tobacco product, such as smokeless tobacco, snus , dissolvable tobacco or e-cigarettes to help you quit smoking regular cigarettes? Please select all that apply.

This approach needed to be reconciled with the current approach used in the NHIS Cancer Control Supplement for the collection of cigarette smoking cessation methods, which specifies each product rather than a mark all that apply response, and also separates questions for current smokers ("when you tried to quit") and former smokers ("when you stopped smoking completely")
Current smokers:
Thinking back to when you tried to QUIT smoking in the PAST 12 MONTHS, did you use ANY of the following PRODUCTS:
A nicotine patch?
Yes/No/R/DK
Former smokers:
Thinking back to when you stopped smoking completely, did you use ANY of the following PRODUCTS:
A nicotine patch?
Yes/No/R/DK

5. Adverse life events for children
   A set of four questions, derived from the Adverse Childhood Experiences Study has been selected to be part of the NHIS redesign, which have been previously used in other national surveys, including the National Survey of Children's Health (OMB No. 0607-0990, Exp. Date 04/30/2019). However, these questions were not tested at the time and were administered over the phone. Cognitive testing will help to determine how parents interpret and conceptualize these potentially sensitive questions during a face-to-face interview.

6. Physical activity for children
   A set of five questions has been selected for cognitive testing that explore a child's level of physical activity, as well as their potential for physical activity. Questions come from multiple surveys including the Youth Risk Behavior Survey (OMB No. 0920-0493, Exp. Date 11/30/2019), the National Household Travel Survey (OMB No. 2125-0545, Exp. Date 10/31/2018), and the HealthStyles Survey developed by Porter Novelli, a social marketing and public relations firm. As there is some concern about parents reporting on the physical activity of their adolescents, cognitive testing will be particularly valuable for this subpopulation. Two additional questions that were slightly modified from the National Household Travel Survey about walking to school are also included in cognitive testing.

7. Screen time for children
   Three questions have been crafted to explore the topic of screen time among children, borrowing from the National Survey of Children's Health and the American Academy of Pediatrics guidelines[1]. As technology has evolved, the use of screen time has become more common among children and new questions that capture the various ways children utilize screens are necessary. Cognitive testing will help to determine how well these questions accomplish this task.

8. Sleeping for children
   One question on sleep has been selected for cognitive testing which mirrors that asked of adults. Cognitive testing will help determine how difficult a question asking about a 24 hour period is for parents to answer about their child, with a focus on how parents of adolescents respond to such a question. This question is based off of guidelines from the American Academy of Sleep Medicine[2].

The 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. Date 07/31/2018).

We propose to recruit 40 English speaking adults (aged 18 and over) who 1) are non-smokers, current or former smokers and/or 2) are parents/guardians of children 2-17 years old and/or 3) have seen a health care provider in the past 12 months.

Recruitment will be carried out through a combination of a newspaper advertisements, flyers, special interest groups, and word-of-mouth. The newspaper advertisements/flyers used to recruit respondents are shown in Attachment 2a&b. The 5 minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3. Within these constraints, we plan to recruit participants with some demographic variety (particularly in terms of gender, education, and race/ethnicity).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 72 individuals may need to be screened in order to recruit 40 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 both video and audio recorded to allow CCQDER staff working directly on the project to analyze the video

[1] *American Academy of Pediatrics, Task Force on Children and Television. Report on children, adolescents, and television. News Comments.1984;35 :8*

[2] Panel, C. C., Watson, N. F., Badr, M. S., Belenky, G., Bliwise, D. L., Buxton, O. M., ... & Kushida, C. (2015). Joint consensus statement of the American Academy of Sleep Medicine and Sleep Research Society on the recommended amount of sleep for a healthy adult: methodology and discussion. *Journal of clinical sleep medicine: JCSM: official publication of the American Academy of Sleep Medicine*, *11*(8), 931.

recordings. Once CCQDER staff working directly on the project have completed their analysis of the cognitive interviews, the video recordings will be deleted and only the audio recordings will be kept and stored on CCQDER's isolated and secured CCQDER LAN. Interviews conducted off-site will only be audio recorded. These recordings will allow researchers to ensure the quality of their interview notes. In the rare case that a study participant initially agrees to audio 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 audio recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select "yes" for allowing the audio 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 health care utilization, smoking and selected topics about children. 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 46 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	72	1	5/60	6
Questionnaire	40	1	60/60	40

Attachments (6)
cc:
V. Buie
T. Richardson
DHHS RCO