



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and
Prevention

National Center for Health Statistics
3311 Toledo Road
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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 Center for Questionnaire Design and Evaluation Research (CQDER) (OMB No. 0920-0222, exp. 07/31/2018) plans to conduct a Spanish cognitive interviewing study to examine Traumatic Brain Injury questions developed by CDC's National Center for Injury Prevention and Control (NCIPC). The questions proposed for the Spanish language testing are exactly the same as the English language testing submitted to you on June 3, 2016 except that we will not be recruiting teens (ages 12-17).

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. As you know, 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: Evaluation of Traumatic Brain Injury Questions for CDC's National Center for Injury Prevention and Control (NCIPC) Spanish lanugage testing

Traumatic brain injuries (TBIs) are a significant public health concern in the United States, contributing to an estimated 2.2 million Emergency Department (ED) visits, 280,000 hospitalizations, and 50,000 deaths in 2010 [1]. These numbers, however, underestimate the true public health and economic burden of TBIs in the U.S. because they are based on healthcare administrative data that only capture information on the number of ED visits, hospitalizations, and deaths identified as TBI-related [2, 3]. As a result, current national estimates do not account for TBIs treated by physicians during office visits or other outpatient settings [2], those who received care at a Federal facility (e.g., Veterans Affairs hospital), TBIs that co-occurred with more serious non-brain injuries [3, 4] or undiagnosed TBIs [5-7]. Furthermore, the current data lacks critical contextual information related to the

mechanism of injury leading to TBI, such as specific activity or environmental characteristics [4, 8].

Similar gaps have been identified with respect to the calculation of national incidence estimates of sports- and recreation-related concussions among youth. In recognition of these gaps, the Institute of Medicine (IOM) recommended in its 2013 report, *Sports-Related Concussions in Youth: Improving the Science, Changing the Culture*, that the CDC develop a national surveillance system to capture health information on concussion in the United States [9]. While studies have reported on the incidence of TBIs in high school- and NCAA athletes [10-12], data on the incidence of such injuries in non-academic settings and for youth younger than high school-age are lacking. A system which can collect data that addresses these limitations can aid in the formulation of policies and prevention strategies related to TBIs among adults as well as youth who sustain sports- and recreation-related (SRR) TBIs. Data collected will help to guide and evaluate progress in reducing the public health burden of TBI for both adults and youth, regardless of injury mechanism.

Question Provenance

Adult Disability: These questions are consistent with the questions used in the most recent version of the survey for the *Behavioral Risk Factor Surveillance System (BRFSS)* [13]. The follow up questions linking the disability to a head injury were developed for this study by the CDC TBI team and retained experts.

Past 12 Months TBI: These questions were drafted by the CDC TBI team and retained experts after reviewing *The Second Injury Control and Risk Survey* [14].

Signs and Symptoms: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *The Second Injury Control and Risk Survey* [14], *The Colorado Traumatic Brain Injury Study* [15], *The Ohio State University TBI Identification Method* [16], the *Abbreviated OSU TBI-ID for BRFSS Module (version 2.1)* [20]. Proxy and direct adolescent versions of questions were developed based on recent research into parent reporting and adolescent reporting of TBI [17].

SRR Initial Question: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *The Consumer Styles Survey* and the *National High School Sports-Related Injury Surveillance System (RIO)* [21].

Military Questions: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *Health-Related Behaviors of Military Personnel* [18].

Mechanism and Location: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *The Colorado Traumatic Brain Injury Study* [15], *The Ohio State University TBI Identification Method* [16], *The Consumer Styles Survey* and the *Abbreviated OSU TBI-ID for BRFSS Module (version 2.1)* [20].

SRR cause: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *National High School Sports-Related Injury Surveillance System (RIO)* [21].

SRR Specific Follow Ups: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *National High School Sports-Related Injury Surveillance System (RIO)* [21].

SRR Organized Activity: These questions drafted by the CDC TBI team and retained experts for the adult interview after reviewing *Abbreviated OSU TBI-ID for BRFSS Module (version 2.1)* and the *National High School Sports-Related Injury Surveillance System (RIO)* [21].

Medical Care: These questions drafted by the CDC TBI team and retained experts for the adult interview after reviewing *The Second Injury Control and Risk Survey* [14], *The Consumer Styles Survey* and the *National Health Interview Survey: Unintentional Injuries Supplement* [19].

Lifetime TBI: These questions were drafted by the CDC TBI team and retained experts for the adult interview after reviewing *The Colorado Traumatic Brain Injury Study* [15] and the *Ohio State University Traumatic Brain Injury Identification Method* [16].

Adult Demographics: These questions drafted by the CDC TBI team and retained experts for the adult interview after reviewing the *National Alcohol Survey, ICF International* [22].

Child Proxy Demographics: These questions drafted by the CDC TBI team and retained experts for the adult interview after reviewing the *National Alcohol Survey, ICF International* [22].

Injury Description, Return to play, Return to school, Return to work, Still Experiencing S/S, SRR Activity Selector: These questions were drafted by the CDC TBI team and retained experts.

The Spanish language Traumatic Brain Injury questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in CQDER's generic OMB clearance package (No. 0920-0222, exp. 07/31/2018).

We propose to recruit 10 Spanish-speaking respondents: Adults (ages > 18).

Thus, we will recruit:

1. Adults (ages >18) to answer questions about their own head and neck injuries. (Adult respondent)
2. Adults (ages >18) who are parents of children ages 5-17 to answer questions about their children's head and neck injuries. (Proxy respondent)

Recruitment will be carried out through a combination of a newspaper advertisement, flyers, 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. 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 48 individuals may need to be screened in order to recruit 10 participants.

Interviews will be conducted by Research Support Services (a frequently used CQDER contractor for conducting Spanish cognitive interviews) with Spanish-speaking respondents for up to 60 minutes (including the completion of a Respondent Data Collection Sheet). 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. All interviews will be audio recorded. These recordings will allow researchers to insure the quality of their interview notes.

Research Support Services staff conducting the Spanish cognitive interviews will complete NCHS Confidentiality training at http://www.cdc.gov/nchs/about/policy/confidentiality_training/index.html 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, CQDER.

After respondents have been briefed on the purpose of the study and the procedures that CQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent document (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 head or neck injuries [your/your child] may have experienced. 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. After the cognitive interview is over, respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 7). There will be no coercion and the respondents will be told that they can call and reverse the decision at any time if they change their minds. If respondents do sign the special consent form they will be given a copy of that as well.

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 14 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	48	1	5/60	4
Questionnaire	10	1	1	10

Attachments (7)

cc:
V. Buie
T. Richardson
DHHS RCO

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