

HCHS/SOL Six item Cognitive Screener- Bilingual Question by Question Instructions SIB QxQ

1. Introduction

The six-item screener, derived from the Mini-Mental Status Examination, is a short measure of global mental status. It includes 3 recall and 3 temporal orientation questions. The six-item screener was administered during the SOL baseline examination as part of a neurocognitive assessment, in conjunction with the Spanish English Verbal Learning Test, the Word Fluency Test (Part C), and the Digit Symbol Substitution Test (WAIS-R). See Visit 1 Manual 9 – Neurocognitive Assessment for details.

Starting in the spring of 2015 the six-item screener is used in HCHS/SOL to aid in the assessment of cognitive functioning under circumstances when SOL study personnel suspects that a study participant may be experiencing difficulties in recall or orientation. The six-item screener is thus used as a standardized, validated tool to record this information in the SOL database, and to guide SOL staff in determining whether a designated informant or consent by proxy are needed (according to the circumstances). The procedures described here are used study-wide, whether the encounter with the participant takes place as a part of a SOL annual follow-up interview, a recruitment call, or in the course of a SOL examination visit on the premises of the SOL field center.

Used as described here, the six-item screener is not intended to systematically assess cognitive functioning in the SOL participants but to assist SOL personnel in identifying study participants who may experience cognitive difficulties, in order to address potential concerns about their safety, to provide the participant with the means for ethical and effective participation in the SOL, and to do so in a way that is consistent across SOL study sites and over time.

2. When is the Six-item Screener Used?

If in the course of an interaction with a study participant SOL study personnel perceives that that the participant may experience difficulties in cognitive functioning the six-item screener is incorporated in the interview or data collection encounter, to inform such an impression with the help of a standardized screening tool. These circumstances may apply to an interview conducted over the phone, a recruitment call, or to face-to-face interaction with the SOL participant at a field center. Refer to HCHS/SOL protocol manuals 2 (Field Center Procedures) and 3 (Retention and Follow-up Procedures) for factors that trigger the use of the six-item screener, the use of transition statements, and for action taken by SOL staff based on the six-item screener results.

3. Procedures

The setting and interviewer behavior may affect the results. During administration of the six-item screener there should be no extraneous background noise or interruptions in the interviewer's immediate surroundings. Instructions and questions should be presented at a measured pace (not too fast). If a participant is hard of hearing, speaking in a lower tone is often more effective than trying to speak more loudly.

Other factors could hinder a participant's optimal cognitive performance. These include significant hearing loss, distractions, or extraneous background noise at the participant's location if the interview is conducted over the phone. When, in the interviewer's judgment, administration of the six-item screener is unduly influenced by extraneous factors such as distracting noise or not possible (such as hearing loss), the six-item screener is discontinued and the reason noted under item 1.a). If administration of the six-item screener is interrupted for some reason and not completed, the interviewer should attempt to re-contact the participant at a convenient time. The six-item screener may also be completed at a home interview.

It is important for the interviewer's attitude to be friendly, non-threatening, reassuring and supportive. Do not indicate whether specific responses are correct or incorrect, however. Participants who express concern about missing an item or two on the six-item screener may be reassured that "you're doing fine" or that "many people can have difficulty at times with some of the questions."

Some participants selected for the administration of the six-item screener may feel challenged, some may feel insecure and others possibly even hostile. It is important for the interviewer's attitude to be professional and friendly, non-threatening, reassuring and supportive. If the interviewer senses frustration or other negative reaction on the part of the interviewee, SOL staff should provide positive reinforcement (e.g., "you're doing fine").

Participants are often curious as to how well they did on "this test." The interviewer can reassure a participant who asks that he/she did as well as others who have taken this test. Do not indicate to the participant whether specific responses are correct or incorrect.

4. Administration of the Six-item Screener

Only trained and certified SOL personnel administer the six-item screener. Following the introductory script in the form header the interviewer proceeds with the instructions for the six-item screener.

Script: "Before we continue I would like to ask you some questions that will help us to decide the best way to conduct this SOL interview/visit. Specifically, I will ask you to use your memory. I am going to name three objects. Please wait until I say all three words, then repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat these words for me: BLUE – PEAR – SOFA."

Say these words distinctly, at the rate of ~1 second per word. The participant may repeat the words in any order. At the end of the presentation say, "Tell me the three words again" and score according to the response to this request. Do not repeat the words for the participant until after the first trial (i.e., until after all three words have been presented).

If the participant begins to repeat a word after each word is read by the examiner (instead of waiting until the interviewer has said all three words), stop, and say: "Let's try it again. This time wait until I have said all three words, and then say them back to me."

If the participant is unable to repeat all three words back correctly, the words may be repeated up to 3 times. For example, if on the first attempt the participant repeats back, "Blue", "Pear", "Party",

the interviewer would say, "let's try that again" and would said the words again (this would be trial number 2). If the participant again cannot say the words back correctly, the interviewer would again say, "let's try it one more time" and would say the words again (this is the third and final trial).

As another example, if the participant repeats back on the first trial, "Blue, Sofa" and says "what did you say was the third word?" the interviewer would repeat back all three words (this would count as the second trial).

If the participant fails to repeat all three words correctly after three attempts, this portion of the test (i.e., recall of the three words) is discontinued. In this case, the examiner marks Item 2 as No. If Item 2 is recorded as No, questions 6-8 should not be asked, and instead recorded as Not Attempted/Refusal.

Next, the examiner asks the orientation questions and records the appropriate response. Without the aid of a calendar or watch, the participant is asked to name the year, is asked to name the month, and without the aid of a calendar or watch the participant is asked to name the day of the week.

Script: "Now, without looking at a calendar or watch: What year is this??"

Script: "[Now,] without looking at a calendar or watch: What month is this?"

Script: "[Now,] without looking at a calendar or watch: What is the day of the week?

If the participant gives the date when asked for the day, say: "Good, and what day of the week is it?

Record the appropriate response next to each item. Do not offer extra help or provide any feedback as to whether a response is correct or incorrect.

Do not wait for a response longer than ~15 seconds, before prompting for a response by repeating the question. After the question is repeated wait ~10 seconds for a response before moving on to the next item. The lack of a response after a reasonable period is marked as "Not Attempted / Refusal."

Then ask the participant to recall the three words presented earlier.

Script: "Now, what were those three words I asked you to remember?"

The words may be repeated in any order. Record the appropriate response next to each item. Recalled words are considered correct whether stated in Spanish or English, regardless of the language in which the original words were provided.

Record correct if "Blue" was recalled.

Record correct if "Pear" was recalled.

Record correct if "Sofa" was recalled.

Allow reasonable time for recall. If a participant is too quick to give up, pause, and encourage him/her to at least make an attempt. Please note that no hints are allowed.

5. Recording the Responses

All responses to questions 3 – 8 on the six-item screener are recorded as Correct (or Self-corrected), Incorrect (which includes Don't know), or Not Attempted/Refusal. An incorrect response includes a response of "I don't know" or "I can't remember." A self-corrected response is recorded as "Correct." If an item is not attempted due to a physical impairment (such as hearing loss), verify that Item 1.a is recorded as "Hearing loss" or Other, if another disability. In this instance, continue on to the next question without delay.

When no response is received after a reasonable amount of time check "Not Attempted/Refusal."

6. Scoring the Six-item Screener

The numeric score thresholds used in SOL to identify impaired memory and disorientation to time were selected on the basis of validation studies of the six-item cognitive screener reported in the literature, and for consistency with other population-based studies that use this instrument.

The six-item screener is administered as a form included in the SOL data entry and management system (CDART), and scoring is performed by the system. Instead of numeric scores, the system displays information on whether the participant's performance on the screener suggests an impairment in cognitive functioning (Alternate/Proxy Indicated), or otherwise (Alternate/Proxy Not Indicated). Administration of the six-item screener on a hard copy of the form is considered an exception to standard protocol that requires authorization by a supervisor.

7. Acting on the Information Identified with the Six-item Screener

7.1 Annual Follow-up Interviews

In the setting of AFU interviews, if a six-item screener is scored as 'Alternate/Proxy Indicated' future annual follow-up interviews should be conducted with an alternate respondent. If the six-item screener score is reported as 'Alternate/Proxy Not Indicated' the interviewer is to proceed interviewing the participant (instead of an alternate), unless other barriers are present that make an interview challenging or uninformative. The scoring of the six-item screener also provides a third category that asks the interviewer to consult with the supervisor about future interviews with this participant, and whether an alternate respondent should be contacted.

For further details refer to protocol manual 3 (Retention and Follow-up Procedures).

7.2 Recruitment for Visit 2

In the setting of recruitment for, or scheduling a Visit 2 examination, if a six-item screener is scored as 'Alternate/Proxy Indicated' a proxy participant should be identified to accompany the SOL cohort member to his/her Visit 2. Refer to HCHS/SOL protocol manual 2 (Field Center Procedures) for the qualifications of a proxy participant. If a proxy participant is deemed necessary for Visit 2, subsequent AFU interviews should be conducted with an alternate informant; a proxy participant

may serve as an alternate informant if familiar with the participant's circumstances and health events.

If the six-item screener score is reported as 'Alternate/Proxy Not Indicated' the interviewer proceeds to schedule the Visit 2 examination unless there is evidence that the participant will find the exam, or its interviews to be challenging. The scoring of the six-item screener also provides a third category that asks the interviewer to consult with the supervisor about the need for a proxy participant.

8. Closing out the Interview

Thank the participant. Participants may express concerns about their cognitive functioning and ask about the need for further evaluation. The interviewer may reassure the participant that these questions are just a research test and do not make a clinical diagnosis, so more detailed information about performance is not available. The interviewer may also note that if the participant is concerned about memory and thinking this should be discussed with their provider of health care. Each SOL field center has available the names of physicians in the local area for participants who do not have a primary care provider.