COGNITIVE ASSESSMENT

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1. Introduction

This chapter contains information about cognitive assessment in MOST. At the 60-month follow-up time point, the Fillit Cognitive Screen was administered to participants 65 years-old or older at the clinic visit, or for those participants unable or not willing to participate in the 60month clinic visit but who completed a Missed Clinic Visit Telephone Interview (MCVTI), the Fillit screen was administered during the MCVTI. At the 84-month time point, the Callahan Six-Item Screener is administered to participants 70 years of age or older during the 84-month telephone interview and, beginning in July 2012, the screener is also administered at the clinic visit regardless of the telephone interview score. Those participants who score 3 or more on the Callahan Six Item Screener on either the telephone interview or at the clinic visit are administered the more extensive Mini-Mental State Examination-2 (MMSE-2) Standard Version during the 84-month clinic visit. The data collection forms for the Fillit Cognitive Screen are in the 60-month Clinic Visit Workbook and 60-month Missed Clinic Visit Telephone Interview Workbook. The data collection forms for the Callahan Six-Item Screener are in the 84-month Telephone Interview Workbook, 84-month Clinic Visit Workbook, and the 84-month Missed Clinic Visit Telephone Interview Workbook. The data collection forms for the MMSE-2 are 84month floating forms.

At the end of the 60-month and 84-month clinic visit interview and the 72-month telephone interview, the interviewer is asked to rate how reliable they think the participant's responses are. This reliability rating is done for all participants, no matter what age they are.

2. Background and rationale

Cognitive function may decline as a result of certain risk factors and diseases. This in turn could adversely impact the physical functioning and quality of life of older adults. After a certain level of decline, dementia can develop. Dementia is a major illness and cause of disability among the elderly.

The purpose of assessing cognitive function at follow-up in MOST is to define those with cognitive stability or decline at follow-up so responses to questionnaires can be adjusted for in data analysis as appropriate.

The Fillit Cognitive Impairment Screen is a brief telephonic survey to screen for cognitive impairment in the Medicare managed care population.

The Callahan Six-Item Screener² is a brief and reliable cognitive screener for identifying study participants with cognitive impairment which can be administered over the telephone or during a face-to-face interview.

The Mini-Mental State Examination (MMSE-2) Standard Version³ is a widely used test of cognitive function among the elderly. It includes tests of orientation, registration, attention, calculation, recall, and visual-spatial skills. The MMSE asks the participant to provide information on temporal orientation and to perform certain tasks. As for most

neuropsychological tests, it is influenced by age and education. The interviewer scores the responses or performance as correct, error/refused or not attempted/disabled.

3. Equipment and supplies

- Data collection forms all assessments
- Pen all assessments
- #2 pencil (with eraser) MMSE-2 exam
- Several pieces of blank paper MMSE-2 exam
- Square, triangle, and circle diagram (MMSE Card #1) MMSE-2 exam
- "Open your mouth" card (MMSE Card #2) MMSE-2 exam
- Intersecting pentagons (MMSE Card #3) MMSE-2 exam

4. Safety issues and exclusions

Participants are eligible for the cognitive assessment interview (Fillit, Callahan Six-Item Screener) based on age at the time of the interview, and eligible for the MMSE-2 examination based on the Callahan Six-Item Screener score. There are no exclusions for these interviews or exam for those who are eligible. A cognitive assessment can appear to be intrusive and, therefore, examiners must pay close attention to the participant and avoid an emotional reaction that may disrupt the performance level.

5. Participant and exam room preparation (for clinic administration)

Cognitive assessments should be administered in a quiet place, with minimal distractions (without the presence of family members/friends). The MMSE-2 exam should be done in a room with a desk or table that the participant can use to write on. Unless it is policy at the clinic for examiners to never knock or open a closed examination room door, we strongly encourage that a special sign be posted indicating that an interview or examination is being administered and to please not interrupt. If a temporary condition that could interfere with a participant's optimal performance cannot be removed, the interview / examination should be done in a different location.

For the MMSE-2 examination, ask the participant if they are comfortable. Reassure them that this is a routine test of concentration and memory which is important to the study.

6. Detailed measurement procedures

Examiners should thoroughly familiarize themselves with the data collection forms, testing procedures and the scoring criteria before administering cognitive assessments.

6.1 Administration of Fillit Cognitive Screen

In the administration of the Fillit Cognitive Screen, give at least 3 seconds for a response, but do not converse or offer extra help. When a participant gives an incorrect answer the examiner scores accordingly and proceeds to the next item. If the participant asks how they are doing, say, "We appreciate your effort."

O by O **6.1.1** Age

Question 1 – "Is participant 65 years old or older?"

Do not ask participant. Look at the Telephone Interview Data from Prior Visits Report to see if participant is 65 years or older. Do not administer the test unless the participant is 65 years or older.

6.1.2 Registration

Ouestion 2 – "I am going to say three words for you to remember. Please don't write them down or ask others for assistance. Now repeat them after I have said all three words: Apple, Table, Penny."

- Make sure the participant is attentive when beginning the question.
- Say the three words distinctly at the rate of 1 second per word.
- The participant may repeat the words in any order.
- If the participant repeats after each word is read by the examiner, at the end of your presentation say, "Tell me the three words again" and mark the score according to the responses to this request.
- Do not repeat the words for the participant until after the first trial. Be sure to score the test after the first trial. When there are errors on the first trial, repeat the items up to six times until they are all learned (total of seven presentations).
- Be sure that the correct suffix of the word is repeated. For example, do NOT accept "apples" for "apple" or "pennies" for "penny." The exact form of the word must be repeated.
- Record the number of presentations necessary for the participant to repeat the sequence (up to seven).

6.1.3 Help with medications

Question 3 – "How frequently do you need help with remembering to take your medications?" Never, Rarely, Sometimes, Frequently, Always (Show Card #26)

- If you are administering the test in person, show the participant the response card.
- Record responses. Note that if a participant does not take any medications, choose the Participant takes no medications response option.

6.1.4 Help with planning trip for errands

Question 4 – "How frequently do you need help with planning a trip for errands?" Never, Rarely, Sometimes, Frequently, Always (Show Card # 26)

- If you are administering the test in person, show the participant the response card.
- Record responses.

6.1.5 Second recall of three words

Question 5 – What three words did I ask you to remember earlier?

- Administer this item even when the participant could not repeat the words when they were originally introduced.
- The words may be repeated in **any** order.

6.1.6 Scoring

- If the participant repeats an incorrect form of the correct word, e.g., "apples" for "apple" or "tables" for "table," record "Error/Refused."
- The scoring is based on the first attempt.
- If the participant cannot get the correct answer even after multiple attempts, check "Error/Refused."
- Be sure to give the participant at least 3 seconds to recall the words.

6.2 Administration of Callahan Six Item Screener

Examiners should thoroughly familiarize themselves with the testing procedures and the scoring criteria before administering the cognitive screen.

In the administration of the cognitive screen, give at least 3 seconds for a response, but do not converse or offer extra help. When a participant gives an incorrect answer the examiner scores accordingly and proceeds to the next item. If the participant asks how they are doing, say, "We appreciate your effort."

Q by Q **6.2.1** Age

Question 20 – "Is participant 70 years old or older?"

Do not ask participant. Look at the Telephone Interview Data from Prior Visits Report to see if the participant is 70 years or older. Do not administer the test unless the participant is 70 years or older.

6.2.2 Registration

Question 21 – "I would like to ask you some questions that 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: APPLE--TABLE—PENNYI,"

- Make sure the participant is attentive when beginning the question.
- Say the three words distinctly at the rate of 1 second per word.
- The participant may repeat the words in **any** order.
- If the participant repeats after each word is read by the examiner, at the end of your presentation say, "Tell me the three words again" and mark the score according to the responses to this request.
- Do not repeat the words for the participant until after the first trial. Be sure to score the test after the first trial. When there are errors on the first trial, repeat the items up to three times until they are all learned (total of four presentations).
- Be sure that the correct suffix of the word is repeated. For example, do NOT accept "apples" for "apple" or "pennies" for "penny." The exact form of the word must be repeated.
- Record the number of presentations necessary for the participant to repeat the sequence (up to four). If the participant cannot repeat the sequence after four presentations, proceed to Ouestion 22.

6.2.3 Year

Question 22 – "What year is this?"

Record the year the participant says in 4 digits. If the response is correct, fill in the "Correct" bubble. If the response is not correct, fill in the "Error/Refused" bubble.

6.2.4 Month

Question 23 – "What month is this? "

• Record the first three letters of the month the participant says in capital letters (for example "MAR" for March). If the response is correct, fill in the "Correct" bubble. If the response is not correct, fill in the "Error/Refused" bubble.

6.2.5 Day

Question 24 – "What is the day of the week?"

• Record the first three letters of the day of the week the participant says in capital letters (for example "THU" for Thursday). If the response is correct, fill in the "Correct" bubble. If the response is not correct, fill in the "Error/Refused" bubble.

6.2.6 Second recall of three words

Question 25 – "What were the three objects I asked you to remember?"

- Administer this item even when the participant could not repeat the words when they were originally introduced in Question #21.
- The words may be repeated in any order.
- If the participant repeats an incorrect form of the correct word, e.g., "apples" for "apple" or "tables" for "table," record "Error/Refused."
- If the participant cannot get the correct answer even after multiple attempts, check "Error/Refused." Be sure to give the participant at least 3 seconds to recall the words.

6.2.7 Scoring

Item 26 – Combine score for Questions #22 (Year), #23 (Month), #24 (Day), and #25 (Second recall of three words), and record the total in the box.

6.3 Administration of MMSE-2 Examination

Examiners should thoroughly familiarize themselves with the testing procedures and the scoring criteria before using the MMSE-2 test in formal assessment.

In the administration of the MMSE-2 exam, give at least 2 seconds for a response, but do not converse or offer extra help. If the participant says "I don't know" or is unable to give an answer, the examiner may prompt once with the statement, "Please try," or "Give it a try." When a participant gives an incorrect answer the examiner scores accordingly and proceeds to the next item. If the participant asks how they are doing, say, "We appreciate your effort."

Although there is no time limit for the examination, it is best to time the examination at a reasonable pace. The participant should never be told of any time limit on any item.

Q by Q

6.3.1 Level of Consciousness

Question 1 – Assess the participant's level of consciousness

- Before beginning the test, the examinee will estimate the participant's level of consciousness using a 100-point scale line. Place an "X" along the continuum at the place that best estimates the individual's level of consciousness from zero (0) as alert/responsive to one hundred (100) as comatose/unresponsive. Enter the estimate in the number box and then proceed to the next question.
- Signs that the participant is more alert/responsive:
 - Wide-eyed
 - Alert
 - Quick to respond
- Signs that participant is more comatose/unresponsive:
 - Heavy eyes
 - Sluggish (shoulders/walk/pace)

6.3.2 Registration

Introduce the test to participant.

- Script: "Good morning, Mr./Ms. . I am _____, a nurse/physician/etc. Are you comfortable? I would like to ask you a few questions that require concentration and memory. Some are a little bit more difficult than others. Some questions will be asked more than once. If any of my questions are too difficult, we can stop." [Pause] "Now I'd like to ask you some questions about your memory."
- Read each question from the form and mark the appropriate level of response.
- Always read the bolded scripts (on the form) exactly as written.
- Give at least 2 seconds for the participant to initiate an answer.

Question 2 – "Listen carefully. I am going to say three words. You say them back after I stop. Ready? Here they are... EGG [pause], CONFIDENT [pause], AFTER [pause]. Now repeat those words back to me." After the last trial, say "Now keep those words in mind. I am going to ask you to say them again in a few minutes."

- Make sure the participant is attentive when beginning the question.
- Say the three words distinctly at the rate of 1 to 2 seconds per word.
- The participant may repeat the words in **any** order.
- Be sure that the correct suffix of the word is repeated. For example, do NOT accept "eggs" for "egg" or "confidently" for "confident." The exact form of the word must be repeated.
- Do not repeat the words for the participant until after the first trial. Be sure to score the test after the first trial. When there are errors on the first trial, repeat the items up to three times until they are all learned (total of four presentations).

If the participant repeats after each word is read by the examiner, or is unable to repeat the words after four presentations, at the end of your presentation say, "Now keep those words in mind. I am going to ask you to say them again in a few minutes" and proceed to the next question.

6.3.3 Orientation to time

- Record the response in the provided line.
- Mark the "correctness" of the answer after the examination.
- If you are unsure about what to score, write down the provided answer and mark the "correctness" of each answer after the test. Contact the CC if you are still unsure.
- If no response is given, record an "X" in the space, and mark "Error/Refused".

Question 3 – "What day is today?"

The answer to this question may vary. Some participants will give the entire date. Wait for a response and then proceed to the next question. The response to this question will not be recorded.

Question 3a – "What is the year?"

Record the response in the provided line. The answer should be the exact year.

Ouestion 3b – "What is the season?"

Since distinctions between seasons can be difficult during certain months, the following schedule has been created. For months with two seasons listed, either answer is correct.

<u>Month</u>	Correct Response
January	Winter
February	Winter
March	Winter or Spring
April	Spring
May	Spring
June	Spring or Summer
July	Summer
August	Summer
September	Summer or Fall (Autumn)
October	Fall (Autumn)
November	Fall (Autumn)
December	Fall (Autumn) or Winter

- Local terms for the seasonal patterns such as "dry season" and "monsoon season" can be used.
- If no response is given, write an "X" in the space, and mark "Error/Refused."

Question 3c – "What is the month of the year?"

• Record the response in the provided line.

Question 3d – "What is the day of the week?"

• Record the response in the provided line spelling out the day of the week as follows:

Sunday Monday Tuesday Wednesday Thursday Friday

Saturday

Question 3e – "What is the date?"

The answer to this question may vary. Some participants will give the entire date, for example, April 1, 2011. It is acceptable for the participant to respond with April 1st, the 1st of April, the 1st of the month, or the 1st. Record the response in the provided line.

6.3.4 Orientation to place

- Record each response in the provided line.
- Alternative words may be used.
- Do not delay the test by assessing the correctness of the answer. If you are unsure, write down the answer and mark the "correctness" bubble after the test.

Question 4 – "Where are we now?"

The answer to this question may vary. Do not record the response for this question.

- For questions #4a-4e, record the response in the provided line. If no response is given, record an "X" in the space, and mark "Error/Refused."
- Mark the "correctness" of the answer after the examination.
- For questions #4a-4e, the answers may vary. Alternative words are acceptable in accordance to the setting.

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Question 4a – "What is the state?" (exact response only)
Question 4b – "What is the county?" (city/town are acceptable)
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Question 4c - "What is the city/town?" (part of city/neighborhood are acceptable)

Question 4d – "What is the building?" (name or type are acceptable)

Question 4e – "What is the floor of the building?" (room number or address are acceptable)

6.3.5 Recall

Question 5 – "What were those three words I asked you to remember?"

- Make sure the participant is attentive when beginning the question.
- Do not offer any hints to help the participant recall the words (EGG, CONFIDENT, AFTER). You may encourage the participant by saying "Take your time."
- The participant may repeat the words in **any** order.
- Be sure that the correct suffix of the word is repeated. For example, do NOT accept "eggs" for "egg" or "confidently" for "confident." The exact form of the word must be repeated.

6.3.6 Attention and calculations (serial 7s)

Ouestion 6 – Ask the question "Now I'd like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I tell you to stop."

- After the first question, say "Keep going" until the participant has provided 5 (total) subtractions.
- The answer is correct if it is 7 less than the previous answer even if the previous answer

6.3.7 Naming

- This set of questions tests whether or not the participant can name each of the pointed body parts (mouth and nose).
- Do no offer any hints (including body gestures [bobbing head, etc.]).
- If the participant gives a scientific or medical version of the name for any of the body parts (i.e., "oropharynx" [mouth]), ask them to provide the common name.
- If the participant cannot name the item or gives an incorrect answer, do not help or question again. Mark "Error/Refused".

Question 7a – "What is this?" (MOUTH)

- Point to your own MOUTH and then ask the question.
- Correct responses for Question 7a include:
 - Mouth
 - Lip(s)

Question 7b – "What is this?" (NOSE)

• Point to your own NOSE and then ask the question.

6.3.8 Repetition

Question 8 – "Repeat what I say: IT IS A LOVELY, COOL DAY BUT TOO WINDY"

- Pronounce the individual words distinctly and slowly but with normal tempo of a spoken sentence.
- You may repeat the phrase a second time if the participant said that they did not hear you.
- Record the response in the provided line.
- Mark "Correct" when the sentence is repeated exactly.

6.3.9 Comprehension

Question 9 – "Listen carefully because I am going to ask you to do something." Hold up MMSE Card #1 and say, "Look at these pictures and point to the triangle, then point to the square, and then point to the circle."

- Pronounce the individual words clearly and slowly but without pauses between the commands.
- Mark "Correct" if the participant points to the object in the correct order.
- If the participant refuses to or cannot perform the task due to vision problem, encourage the participant to do the task anyway. If the participant still refuses, then mark "Not attempted/Disabled".

6.3.10 Reading

Question 10 – Hold up MMSE Card #2 (OPEN YOUR MOUTH) and say, "PLEASE DO WHAT THIS SAYS TO DO."

- Do not offer any hints.
- If the participant does not open their mouth within 5 seconds, mark "Error/Refused".
- If the participant refuses to or cannot perform the task due to vision problems, encourage the participant to do the task anyway. If the participant still refuses, then mark "Not attempted/Disabled".

6.3.11 Writing

Question 11 – "Please write a sentence." If the participant does not respond, say "Write about where you live."

- Provide a pen/pencil and a piece of paper.
- Mark "Correct" if the participant writes a comprehensible sentence that contains a subject and verb.
- If the participant provides more than one sentence, record only the first sentence he/she
- The following are considered acceptable:
 - o Spelling and grammar errors
 - o Printing or cursive writing

- o All capital letters
- Self corrected errors
- If the participant refuses to or cannot perform the task due to vision problems, encourage the participant to do the task anyway. If the participant still refuses, then mark "Not attempted/Disabled".

6.3.12 Drawing of two pentagons

Question 12 – "Please copy this design." *Hold up MMSE Card #3*.

- Provide a pen/pencil and a piece of paper.
- If the participant is still working at the end of one minute, allow them to complete the task for the sake of rapport and morale.
- Requirements for the drawing (see Appendix 5 for examples of correct and incorrect drawing performance):
 - o each pentagon should consist of 5 approximately equal sized sides
 - o the lines should be straight, not round (they do not have to be perfectly straight)
 - o the figure formed by the intersection of the two pentagons should have four sides, like a diamond
- Do not penalize for self-corrected errors, tremors, minor gaps, or overshoots.
- When gaps are found in the drawing, they are permissible if the shape of the pentagon can be perceived.
- If the participant does not attempt the task due to a functional disability such as visual impairment or severe arthritis, etc., mark "Not attempted/Disabled".

6.3.13 Special problems

Ouestion 13 - If physical/functional disabilities or other problems exist which cause the participant difficulty in completing any of the tasks, record the nature of the problem listed below (mark all that apply):

- vision
- hearing
- writing problems due to injury or illness
- illiteracy/lack of education
- langua ge
- other (please record the specific problem in the provided line)

The way to determine the above listed disability or problem will be by examiner's observation or participant's self-report. For example, if the participant has an obvious difficulty hearing the examiner, or clearly says, "I can't see," the examiner would mark the appropriate bubble next to the listed problem.

6.3.14 Scoring

The MMSE-2 examination asks the participants to provide information and to perform specific tasks as instructed by the examiner to assess cognitive function. Based on the response or performance of the task, the interviewer marks the appropriate level of "correctness" of the response.

The maximum score of the examination is 30 points. However, due to the complexity of the scoring mechanism in this exam, examiners will not be asked to tally a preliminary score for each participant. The MMSE-2 scores will be generated by a computer algorithm after data entry.

- If a task is not attempted due to a physical limitation such as vision or hearing impairment, severe arthritis, or illiteracy, encourage him/her to do the task anyway. If the participant still refuses, then mark "Not attempted/Disabled". If a task is scored "Not Attempted/Disabled," the reason the task was not completed must be specified in Question #13. Please indicate the questions that were affected.
- Mark "Error/Refused" if the task is not successfully completed for any other reason. This includes errors due to cognitive dysfunction, refusals when no physical or functional disability is present, lack of response, or the participant says they can't remember.
- Let the participant attempt all tasks unless you determine that the participant cannot do the task. In these cases, score the question "Error/Refused." This includes instances in which you perceive:
 - o the participant is unable to do the task;
 - o the participant appears to be experiencing excess stress; or
 - o no response is received from the participant after a reasonable time period.

In these as in all cases, continue on to the next question without delay. If you are unsure about how to score the answer (Questions #3, #4, and #6), write down the answer in the provided line and mark the "correctness" of each answer after the exam.

7. Alert values/follow-up/reporting

When the interview is complete, thank the participant without offering specific feedback on their performance. You might say, "Thank you for doing this interview."

8. Reliability question

At the end of the 60-month and 84-month clinic visit interview and the 72-month telephone interview the interviewer is asked, based on their judgment of the participant's responses to the questionnaire, to rate how reliable they think the participant's answers are. The interviewer is asked to choose one of the following response options.

- Very reliable
- Fairly reliable
- Not very reliable
- Don't know

See Appendix 4 for the reliability question data collection form.

9. Quality assurance

9.1 Training requirements

The examiner requires no special qualifications or prior experience to perform this assessment. Training should include:

- Read and study Cognitive Assessment Operations Manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Discuss problems and questions with local expert or QC officer

9.2 Certification requirements

- Complete training requirements
- Explain how to score a question if:
 - o participant does not respond or can't remember
 - o participant has a physical limitation, making task impossible
- Conducts exam using three test scripts while being observed by OC officer or their delegate

9.3 Quality assurance checklist

9.3.1 Fillit Cognitive Screen Quality Assurance Checklist
☐ Correctly determines whether participant is eligible for cognitive screen (Fillit)
☐ Exam performed in quiet, private area without interruptions
☐ Correct instructions given in clear, slow speaking voice
☐ Reads slowly, speaks clearly and uses appropriate inflection when speaking
☐ Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
☐ Able to elicit accurate and complete information using non-directive probes
☐ Keeps interview on track by presenting questions at a regular pace
☐ Focuses participant's attention on questions while always being polite
☐ Treats participants with respect
☐ Maintains a professional and friendly manner; leaves participant with overall feeling of well-being
☐ List of three objects read slowly and evenly (one per second)
☐ Three objects repeated until learned, up to six times (seven altogether)
☐ Medication help question asked verbatim
☐ Errand help question asked verbatim
☐ Waits at least 3 seconds for recall of three objects
☐ Reviews form for completeness
☐ Correctly completes form
9.3.2 Callahan Six Item Screener Quality Assurance Checklist
The Callahan Six Item Screener Quality Assurance Checklist is integrated into the 84-month Telephone Interview Quality Assurance Checklist. The following checklist items apply specifically to the Callahan Six Item Screener:
☐ Correctly determines whether participant is eligible for cognitive screen (Callahan Six-Item Screener)
☐ Correct instructions given in clear, slow speaking voice
☐ Reads slowly, speaks clearly and uses appropriate inflection when speaking
☐ Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
☐ Able to elicit accurate and complete information using non-directive probes
☐ Keeps interview on track by presenting questions at a regular pace
☐ Focuses participant's attention on questions while always being polite
☐ Treats participants with respect
☐ Maintains a professional and friendly manner; leaves participant with overall feeling of well-being
☐ For cognitive screen, list of three objects read slowly and evenly (one per second)
☐ Cognitive screen three objects repeated until learned, up to three times (four altogether)
☐ Waits at least 3 seconds for recall of three objects during cognitive screen
☐ Correctly enters score for cognitive screen

9.3.3 MMSE-2 Quality Assurance Checklist

Ш	Correctly determines whether participant is eligible for the MMSE-2 cognitive
	assessment exam
	Correct instructions given in clear, slow speaking voice
	Reads slowly, speaks clearly and uses appropriate inflection when speaking
	Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
	Able to elicit accurate and complete information using non-directive probes
	Keeps interview on track by presenting questions at a regular pace
	Focuses participant's attention on questions while always being polite
	Treats participants with respect
	Maintains a professional and friendly manner; leaves participant with overall feeling of
	well-being
	Assesses level of consciousness
	List of 3 objects read slowly and evenly
	Writes down responses on form
	Correctly subtracts 7 from number given by participant (total of 5 subtractions)
	Repeat spoken sentence
	Pentagon drawing correctly scored
	Special problems (impairment, illiteracy, etc.) recorded in exam comments
	Responses correctly coded
	Reviews form for completeness
	Correctly completes form
	Discuss problems and questions with local expert or QC officer

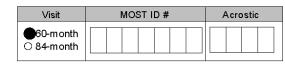
10. References

- 1. Fillit H, Mohs RC, Edelman Lewis B, Sewell, MC, Mills CS, Tsymuk M, Hill J. A Brief Telephonic Instrument to Screen for Cognitive Impairment in a Managed Care Population. JCOM 2003; 10: 419-429.
- 2. Callahan CM, Unversagt FW, Hui SL, Perkins AJ, Hendrie, HC. Six-Item Screener to Identify Cognitive Impairment Among Potential Subjects for Clinical Research. Med Care 2002; 40:771-781.
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Appendix 1: Fillit Cognitive Screen Data Collection Form

	53668	Visit 60-month 84-month	MOST ID #	Acrostic	Staff ID#	#25
og	jnitive Sci	reen			<u>M(</u>	981
		te: Review Data fron		Report.		
1.	Is participant 6	65 years old or older? Yes			○ No	
	Complete	egnitive coreon. Co to	Ougetion #2	СТ	OB. Co to post tost	
	Complete d	ognitive screen. Go to	Question #2.	51	OP. Go to next test.	
2.		say three words that I	will ask you to	o remember. Now	repeat them after I	have said all
	three words.	Apple, ⁻	Гable, Penny			
		ote: Name three obj				
	order. If the	e participant until af re are errors on the	first trial, repe	eat the items up		
	learned. Red	cord responses to <u>fi</u>	<u>rst</u> attempt be	elow.)		
			Correct F	Error/ Refused		
		a. Apple	0	0		
		b. Table	0	0		
		c. Penny	0	0		
		d. Numbers of pre	he participant	presentation	ns	
		to repeat the se	equence:			
_	Ask particip					
3.	How frequentl (Examiner No.	y do you need help wi ote <i>: REQUIRED. Sho</i>	ith rememberii w Card #26.)	ng to take your m	iedications?	
		O Never (0)				
		O Rarely (1)				
		○ Sometimes	(2)	○ Participa	ant takes no medicat	ions
		 Frequently 	(3)			
		O Always (4)				
		O Don't know.	/Refused			
			◆Page 30◆	,		53668
Hit			-		MOST Follow-up	33000









Cognitive Screen

- 4. How frequently do you need help with planning a trip for errands? (Examiner Note: REQUIRED. Show Card #26.)
 - O Never (0)
 - O Rarely (2)
 - O Sometimes (4)
 - O Frequently (6)
 - O Always (8)
 - O Don't know/Refused
- 5. What three words did I ask you to remember earlier?

(Examiner Note: The words may be repeated in any order.)

	Error/		
	Correct	Refused	
a. Apple	O (0)	o (2)	
b. Table	O (0)	O (2)	
c. Penny	o (0)	O (2)	

Scoring

OPTIONAL - Combine score for questions #3, 4, and 5.

Total: _____ (0 - 18)

Fillit

◆Page 31◆

MOST Follow-up Clinic Visit Workbook EU





Appendix 2: Callahan Six-Item Screener Data Collection Forms

	Visit	MOST ID #	Acı	ostic	Staff ID#	
403.43	○ 60-month	М				
18343	● 84-month					VOCE
Cognitive Scre	₽n	● First	screen	○ Repe	eat screen	MOST
Evaminar Nota:	Poviou Data	from Prior Visits Re	nort			
20. Is participant 70			φοιτ.			
	Yes			\bigcirc	No	
Complete cog	nitive screen.	Go to Question #21.		STOF	P. Go to Pag	je 7b.
I am going to ask APPLETABLE-	vait until I say cyou to name -PENNY.	all three words, then them again in a few i	repeat the minutes. F	em. Ren Please r	nember wha epeat these	at they are because words for me:
(Examiner Note	e: Interviewer	may repeat 3 times		sary bu	t repetition	not scored.)
			ror/ fused			
	a. Apple	O O	0			
	b. Table	0	0			
	c. Penny	0	0			
	d. Numbers of necessary	of presentations for the participant ne sequence:	preser	itations		
			((0)			
22 . What year is this	?		rrect (0) or/Refuse	ed (1)		
23. What month is th	is?		rect (0) or/Refuse	ed (1)		
24 . What is the day o	of the week?		rrect (0) or/Refuse	ed (1)		
25. What were the th (Examiner Note		asked you to rememb <i>may be repeated in</i>		r.)		
		Correct	Refused			
	a. Apple	0 (0)	O (1)			
	b . Table	O (0)	0 (1)			
	c. Penny	O (0)	0 (1)			
Scoring 26. Combine score for (Examiner Note: If score			Total :	(0 -	,	MMSE-2 at Clinic Visit.)
Callahan Six-Item Screener		◆Page 7a◆			<u> </u>	18343
		-		Tele	MOST Follow-up aphone Interview ersion 3.2 7/9/12 C9	

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		Visit	MOST ID#		Acrostic	Staff ID#	
	18343	○ 60-month	M				
	10343	84-month					MOST
Cogr	nitive Scre	en	OF	irst scre	en ●Rep	eat screen	MOST
E	Examiner Note:	Review Data	from Prior Visits	Report.			
20.	ls participant 70		der?		_	S NI-	
		O Yes ↓				⊃ No -	
	Complete cog	nitive screen.	Go to Question #2	21.	STO	P. Go to Paç	ge 7b.
(objects. Please v	wait until I say k you to name		en repea	at them. Re	member who	oing to name three at they are because words for me:
	(Examiner Note	e: Interviewer	may repeat 3 tin		cessary bu	ut repetition	not scored.)
			Correct	Error/ Refused	i		
		a. Apple	0	0			
		b. Table	0	0			
		c. Penny	0	0			
		necessary	of presentations for the participant ne sequence:	pro	esentations	i	
22. \	What year is this	6?		Correct Error/Re	(0) fused (1)		
23. \	What month is th	nis?		Correct (Error/Re	(0) fused (1)		
24. \	What is the day	of the week?		Correct Error/Re	(0) efused (1)		
			asked you to reme may be repeated	in any o Erro	or/		
		a. Apple	Correc ○ (0)				
		b . Table	(0) (0)		•		
		c. Penny	O (0)				
26 . (‡22, 23, 24, and 2: either the Telephon		` `	-6) sit, administer	r MMSE-2 at Clinic Visit.)
Callahan	Six-Item Screener		◆Page 28	a◆			18343
						MOST Follow-up ic Visit Workboo ersion 3.3 7/9/1	k 1881 - 19

Appendix 3: MMSE-2 Data Collection Form

Visit MOST		ndard Version Date of Form Completed Staff ID#
O 84-month		Month / Day / Year MOST
estimates the individual's le hundred (100) would mean Examiner note: Refer to DF 0 10 20	vel of consciousness. "comatose/unrespons PVR for MMSE-2 eligib 30 40 50	ility.
Responsive	Enter the number	Unresponsive
Instructions: Words in boldfact read aloud clearly and slowly to Begin by introducing the test: New you some questions about you. 2. Listen carefully. I am going the You say them back after I stote they are EGG [pause], CON AFTER [pause]. Now repeat the tome.	the examinee. ow I'd like to ask ur memory. o say three words. op. Ready? Here FIDENT [pause],	3c. What is the month of the year? O Correct O Error/Refused O Not attempted/Disabled 3d. What is the day of the week? O Correct O Error/Refused O Not attempted/Disabled
	3 times, but score Frror/ Not attempted/ efused Disabled O O O	3e. What is the date? O Correct O Error/Refused O Not attempted/Disabled
2c. AFTER O Now keep those words in mi ask you to say them again in		4. Where are we now? (Examiner Note: Alternative place words are appropriate for the setting and increasingly precise)
3. What day is today? 3a. What is the year? O Correct O Error/Refused O Not attempted/Disable 3b. What is the season? O Correct O Error/Refused	Year led	may be substituted and noted.) 4a. What is the state? O Correct O Error/Refused O Not attempted/Disabled 4b. What is the county? O Correct O Error/Refused O Not attempted/Disabled County
O Not attempted/Disable	Season	O Not attempted/bisabled

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	Visit O 84-month	MOST ID # A crostic
MMSE-2 Standard		MOST
4c. What is the city/town? O Correct O Error/Refused O Not attempted/Disabled	City/Town	6c. If needed, say: Keep going. O Correct O Error/Refused Answer O Not attempted/Disabled
4d. What is the building (name/typ O Correct O Error/Refused O Not attempted/Disabled	e)? Building	6d. If needed, say: Keep going. O Correct O Error/Refused O Not attempted/Disabled Answer
4e. What is the floor of the building address)? O Correct O Error/Refused O Not attempted/Disabled	rg (room #/	6e. If needed, say: Keep going. O Correct O Error/Refused O Not attempted/Disabled Answer
5. What were those three words I a remember? [Do not offer any hint Erro Correct Refus	s.] r/ Not attempte	7a. What is this? [Point to mouth.] O Correct O Error/Refused O Not attempted/Disabled 7b. What is this? [Point to nose.] O Correct O Error/Refused O Not attempted/Disabled
6. Now I'd like you to subtract 7 from keep subtracting 7 from each at tell you to stop. (Examiner Note: An answer is concorrect if it is 7 less than the previous answer was in the previous and the previous answer was in the previous and the previous answer was in the previous and the previous answer was in the previous answer was in the prev	nswer until I nsidered ous answer,	8. Now I am going to ask you to repeat what I say. Ready? IT IS A LOVELY, COOL DAY BUT TOO WINDY. Now you say that. (Examiner Note: Wait for examinee response and record response verbatim. Repeat up to one time. (Examiner Note: Mark correct only if the examinee repeats the sentence exactly. You may repeat the phrase one time if the examinee says that he or she did not hear you.)
O Correct O Error/Refused O Not attempted/Disabled	Answer	O Correct O Error/Refused O Not attempted/Disabled
Mini-Mental State Examination (MMSE Standard Version	-2)Red ◆P	age 2◆ MOST MMSE PB

Version 1.0p Sept 2021 Cognitive Assessment

Visit	MOSTID#	Acrostic	
O 84-month			MOST

MMSE-2 Standard

9. Listen carefully because I am going to ask you to do something. [REQUIRED. Show Card MMSE #1.] Look at these pictures and point to the triangle, then point to the square, and then point to the circle.

	Correct	Error/ Refused	Not attempted/ Disabled
9a. Triangle	0	0	0
9b. Square	0	0	0
9c. Circle	0	0	0

10. Please do what this says to do. [REQUIRED. Show Card MMSE #2. Record the response in the space below.]

OPEN YOUR MOUTH

(Examiner Note: It is acceptable for the examinee to read the sentence aloud before doing the task, but give credit only if the examinee does what the sentence says, without prompting.)

- O Correct
- O Error/Refused
- O Not attempted/Disabled
- 11. Please write a sentence.

(If examinee does not respond, say: Write about where you live.)

(Examiner Note: Place a blank piece of paper in front of the examinee and provide a pen or pencil. Mark correct if the sentence is comprehensible and contains a subject and a verb. Ignore errors in grammar or spelling.)

- O Correct
- O Error/Refused
- O Not attempted/Disabled

12. Please copy this design.

(Examiner Note: REQUIRED. Show Card MMSE #3. Place a blank piece of paper in front of the examinee and provide a pen or pencil. Mark correct if the drawing consists of two 5-sided figures that intersect to form a 4-sided figure.)

- O Correct
- O Error/Refused
- O Not attempted/Disabled
- 13. (Examiner Note: If physical/functional disabilities or other problems exist which cause the participant difficulty in completing any of the tasks, record the nature of the problem listed below. Mark <u>all</u> that apply.)
 - O Vision
 - O Hearing
 - O Writing problems due to injury or illness
 - O Illiteracy or lack of education
 - O Language
 - O Other (Please specify:

Mini-Mental State Examination (MMSE-2) Red Standard Version

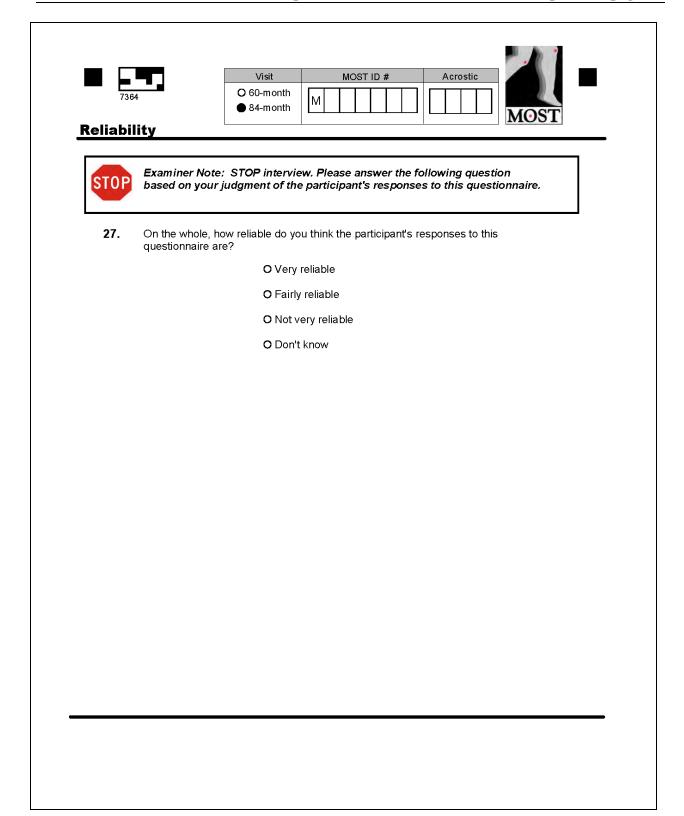
◆Page 3◆

MOST MMSE





Appendix 4: Reliability Question Data Collection Form



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Appendix 5: Sample Correct/Incorrect Drawing Performance: MMSE Question #12

