



Product and Product Category Backgrounder

Product Overview: The MCI Screen

Medical Care Corporation is a neuroinformatics company specializing in the development of technologies for the precise measurement and monitoring of cognitive performance. The company's flagship product is the MCI Screen, is the most precise memory assessment tool cited in the medical literature. It enables physicians to distinguish between subtle memory loss due to normal aging and memory loss due to underlying medical conditions with 97% accuracy. It is fast, easy to administer, and specifically designed for implementation in a busy clinical practice.

The MCI Screen is delivered online and a standardized software interface is used to guide the test administrator in delivering the assessment. Such delivery eliminates test variability and minimizes administrator bias. Additionally, the intuitive software interface minimizes training required to administer the test and a non-credentialed individual with a few minutes of training can achieve the same accuracy as a physician or neuropsychologist. Finally, technology and informatics not only increase accuracy and precision in administration, but also deliver sophisticated evaluation of the patient's performance immediately upon test completion. After administering an MCI Screen, a complete report is generated with personalized and detailed information about the subject's performance as well as next steps a professional should take to care for that patient. Please see the MCI Screen Interpretation Guidelines for additional information.

Product Category





The MCI Screen is a neuropsychological assessment for testing short-term memory, working memory, and judgment. However, unlike traditional neuropsychological assessments, the MCI Screen incorporates technology and informatics, increasing the accuracy of its results, the level of analysis of the subject's performance, and the ease of administration.

Neuropsychological assessments have traditionally been administered by neuropsychologists or other specialists. The tests can be divided into broad categories including: cognitive assessments and functional or behavioral assessments. Cognitive assessments objectively measure specific cognitive functions such as memory, attention and judgment. Functional and behavioral assessments are subjective in nature and evaluate the activities of daily living and may often be completed by a caregiver.

Cognitive assessments often assess different lobes of the brain by evaluating function that is directed within a particular lobe. The following table shows the functions associated with the various brain lobes and some tests used to assess those functions.



Product and Product Category Backgrounder

Part of Brain	Functions Controlled	Type of Tests Used to Assess Function
 Medial Temporal Lobe	<ul style="list-style-type: none"> Gathering and Packaging of Information Short-term memory 	<ul style="list-style-type: none"> Visual Recall tests Word Recall tests Paired Association tests
 Lateral Temporal Lobe	<ul style="list-style-type: none"> Orientation Object recognition Hearing and language 	<ul style="list-style-type: none"> Object recognition tests Counting digits backwards
 Parietal Lobe	<ul style="list-style-type: none"> Object tracking Sensation Comprehension 	<ul style="list-style-type: none"> Drawing Tasks Reading comprehension
 Frontal Lobe	<ul style="list-style-type: none"> Personality Mood Movement Executive function 	<ul style="list-style-type: none"> Immediate Recall Tests Trail making tests The Stroop Color and Word Test Clock drawing test

Most neuropsychological assessments are delivered as a battery of tests and tend to be lengthy, requiring more than one hour to complete. These tests may use cue cards or other accessories and are accompanied by lengthy manuals that assist in the administration, scoring and interpretation of the results. Specialized training and licensing is generally required to purchase these assessments and administer them in a medical practice. As a result, these assessments have been historically delivered by neuropsychologists.

In addition to these neuropsychological examinations, many short questionnaires and tests have been developed for clinical use. Most of these are either mental status exams (questionnaires that evaluate multiple functions and brain areas in a very short time period) or functional questionnaires.

The Mini Mental Status Exam (MMSE) is probably the most well known of the brief questionnaires. For over 20 years, it has been used for both clinical use and research. It is a paper-based test that evaluates several functions including: orientation, registration, attention and calculation, recall and language. Since credentials are not required, primary care physicians who do assess for dementia and cognition, tend to use the MMSE although it is not sensitive in detecting early stages of decline.

Another popular test available in the public domain is the Clock Drawing Test during which the subject is given a piece of paper with a blank circle and is asked to draw a clock depicting a certain time. Such a test assesses function in the parietal lobe. While it is useful in assessing dementia, it usually does not identify those with memory impairment or mild impairment.

Medical Care Corporation’s MCI Screen is a short test and can be administered by any health care professional, similar to the short questionnaires. However, the accuracy of the MCI Screen for discriminating between subjects with normal function and those with early stage memory decline is far



Product and Product Category Backgrounder

superior to other assessments including the longer neuropsychological tests scored using rudimentary methods. The MCI Screen is the most accurate product commercially available for identifying memory loss at its earliest stages.

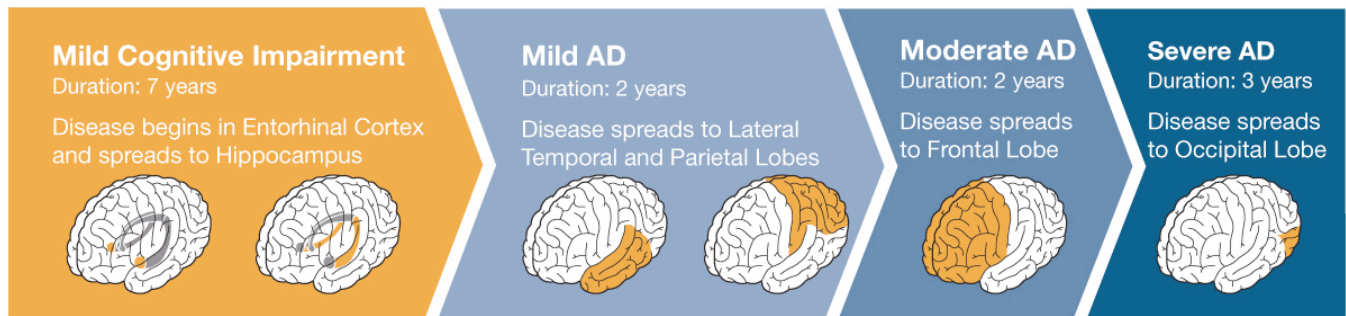
Focus on Memory Loss and Alzheimer’s Disease

The MCI Screen is a test of short-term memory, working memory, and judgment. While the MCI Screen detects memory loss due to any medical condition (please see the Memory Loss Backgrounder), it is optimized for detecting memory loss due to progressive disorders such as Alzheimer’s disease.

Alzheimer’s disease starts in the entorhinal cortex and hippocampus and progresses over the course of the disease to other parts of the brain. The first cognitive function impaired is learning and short-term memory. Thus, assessing the ability to learn and remember in the short-term enables a clinician to then diagnose a patient with Alzheimer’s disease at its earliest stage. Assessments that identify impairment in cognitive domains affected later in disease progression (for example, using the Clock Drawing Test to assess Executive Function), will only identify patients whose disease has progressed considerably while missing those who have earlier stages of impairment.

Currently up to 95% of Alzheimer’s disease cases are diagnosed when the disease has progressed to the moderate stage. This generally occurs about 7-10 years after the first symptoms and not until considerable brain damage as occurred. At this late stage, treatment efficacy is greatly reduced.

While any clinician may use the MCI Screen, it will yield the greatest patient benefit in the hands of a primary care physician as they are often the first point of contact in the healthcare system for a patient who might have complaints about memory loss. As such, they are in position to make the most timely diagnosis and intervention against a memory impairing medical condition. However, the nature of a general practice is not well-suited (minimal specialization and tight time constraints) to the administration of neuropsychological tests. The MCI Screen solves this problem since it requires no special training and can be administered by a member of physician’s staff in about 10 minutes. This reimbursable procedure uses advanced mathematics and yields more accurate results than what neuropsychologists achieve using traditional methods.



↑ The MCI Screen can detect impairment with 97% accuracy

↑ Up to 95% of diagnoses currently occur here



Product and Product Category Backgrounder

Validation and Accuracy

Medical Care Corporation’s MCI Screen is the most accurate test published in scientific literature for identifying short-term memory loss and mild cognitive impairment (MCI), which is the earliest clinical stage of Alzheimer’s disease. It is 97.3% accurate in discerning mild cognitive impairment (MCI) from normal aging, and 99% accurate in discerning mild dementia from normal aging.

The MCI Screen was originally validated in a study on 471 community dwelling adults whose scores on the Clinical Dementia Rating Scale ranged from 0 (normal: N=119), 0.5 (mild cognitive impairment: N=95), to 1 (mild dementia: N=257). The MCI Screen showed overall accuracy of 98% with sensitivity of 96% for mild cognitive impairment or mild dementia, and 91% specificity for normal aging. The accuracy of the MCI Screen was published in the Proceedings of the National Academy of Sciences (Shankle, 2005).

	Overall Accuracy	Sensitivity	Specificity
MCI vs. Normal	97%	95%	88%
MCI/Mild Dementia vs. Normal	98%	97%	88%
Mild Dementia vs. Normal	99%	96%	99%

The MCI Screen was further validated in a study on 182 patients in a primary care setting. The study found that 22% of patients had cognitive impairment related to underlying brain pathology although, two-thirds of those who were diagnosed as impaired had no outward symptoms or functional decline. The MCI Screen enabled the diagnosis of pre-symptomatic patients and identified impaired patients much more accurately than other assessments that have traditionally been used by clinicians. The MCI Screen showed over all accuracy of 97%, while MMSE and CDT showed 76% and 69%, respectively.

	Overall Accuracy	Sensitivity	Specificity
MCI Screen	97%	96%	99%
Mini Mental Status Exam	76%	72%	68%
The Clock Drawing Test	69%	52%	70%

Additional clinical studies on the MCI Screen have been completed in Japan (Reference: Cho A. et al. Jap. J. Clin. Exp. Med. 2007; 84(8): 1152-1160). One study evaluated 63 patients at the Fukuoka University memory clinic using the Clinical Dementia Rating (CDR) Scale to identify a sample of 52 MCI (CDR= 0.5) and 11 normal aging (CDR=0) patients. These patients were given a standard diagnostic workup including the MCI Screen, the Depression Screen, brain SPECT and/or quantitative MRI. After excluding 7 patients diagnosed with depression, the neuroimaging and MCI Screen results of the remaining 56 patients were compared. Among the 48 MCI patients, 46 were correctly classified by the MCI Screen (96% sensitivity), and 37 (80%) had specific AD/ADRD etiology diagnosed by neuroimaging. The 8 normal aging patients were correctly identified by both the MCI Screen and the neuroimaging studies. These findings support the use of the Japanese version of the MCI Screen followed by SPECT or quantitative MRI in early detection and diagnosis of MCI.



Product and Product Category Backgrounder

Technology and Informatics

The MCI Screen is based on an established and well-validated test, the word recall test from the CERAD battery (Consortium to Establish a Registry for Alzheimer's Disease), which has been extensively validated and commonly used by dementia specialists for the past decade.

The full CERAD battery contains more than ten separate tests, takes approximately 90 minutes to administer and evaluates almost every part of the brain. Of all the tests in the CERAD battery, the CERAD word recall test was found to be the most sensitive in identifying Mild Cognitive Impairment.

The original version of the CERAD word recall test is administered on paper as described here. The patient is read 10 words and is asked to recall them across three learning trials. These "Immediate Free Recall trials" assess the individual's working memory and the frontal lobe of the brain. The patient is then distracted (MCI Screen uses an animal comparison task for the distraction), after which, the patient is asked to recall the ten-word list as a means of assessing short-term memory. The original test, similar to other pen and paper tests, is scored in a rudimentary manner by totaling the number of words recalled and making a judgment using predetermined scales and cutoffs to identify patients with impairment.

Over a ten-year period, Medical Care Corporation gathered response data on the CERAD word recall test for several hundred subjects who also were subjected to complete physiological, neurological, and psychological exams. Using advanced mathematics, we distilled their response patterns and compared them to their diagnostic status (normal vs. impaired). By analyzing over one trillion response patterns, the MCC scoring algorithm in the MCI Screen identifies the earliest stages of memory loss with 97% accuracy.

Medical Care Corporation

19782 MacArthur Blvd., Suite 310, Irvine, CA 92612 USA

Phone (949) 838 0154 / Fax (949) 838 0153

www.mccare.com

Page 5 of 5