

# MCI SCREEN Frequently Asked Questions

## Dementia & Mild Cognitive Impairment

### ***What is the difference between Mild Cognitive Impairment (MCI) and Dementia?***

Neither MCI nor Dementia is a disease. Rather, these two terms refer to differing degrees of reduced cognitive function.

**MCI** refers to a subtle yet measurable cognitive deficit. Persons with MCI have impairments limited to one category of cognitive function (e.g. memory, judgment, reasoning, object recognition), but impairment does not interfere with their activities of daily living (such as bathing, dressing, etc.).

**Dementia** is a more severe deficit than MCI and refers to impairment in two or more categories of cognitive function that interfere with the person's ability to function in their daily social, professional, or personal routine.

### ***What causes MCI and Dementia?***

There are many causes of MCI, most of which are entirely treatable. Among the most common are thyroid disorders, vitamin deficiencies, sleep disorders, depression, medications, poorly controlled diabetes and/or hypertension, and alcohol/substance abuse. More serious causes of MCI, which are more effectively treated when identified early, are vascular disease and early stage Alzheimer's disease.

The majority of dementia diagnoses are caused by a group of disorders called Alzheimer's disease and Related Disorders (ADRD). Approximately 60% of the cases of Dementia are due to Alzheimer's disease and another 20% are due to vascular disease. Smaller numbers of cases are caused by Parkinson's disease, Lewy Body disease, and frontal lobe dementia. Treatment efficacy for those with ADRD is highly dependent on timely intervention and can be substantially beneficial when treatment is begun early.

### ***Why is it important to identify MCI?***

Identifying MCI enables early diagnosis of the underlying disorder. Just like other conditions such as diabetes or heart disease, the earlier the diagnosis of a cognitive disorder is made, the more effective treatment will be. As summarized in this review, early detection and proper treatment of Alzheimer's disease can delay the progression of the disease by approximately 50% in some cases.

## Evaluating Cognitive Assessments

### ***What is a cognitive assessment?***

A cognitive assessment is a test that evaluates a person's cognitive function such as memory, language, recognition and judgment and reasoning by asking the patient to answer certain questions or complete specific tasks. These tests can vary, and include simple paper-based tests, computerized tests and in-person or phone interviews administered by professionals.

## ***What should one look for when evaluating a cognitive assessment?***

**Comparisons to baseline tests** - some tests establish a baseline score for patients so that subsequent test results may be compared to previous results in order to identify changes in a patient's cognitive function. Computerized tests facilitate the establishment of baseline scores and enable clinician's to more easily evaluate longitudinal results.

**Comparisons to normative data** - some tests compare an individual's results to normative data for people in their peer groups. Tests can make comparisons on one or two demographic factors (usually age and/or education level) or a wider range of factors such as overall response patterns. In general, the more sophisticated the use of comparison data, the greater the predictive power of the screen.

## ***What does a cognitive assessment identify?***

Different assessments evaluate different cognitive functions giving insight to the health of the part of the brain associated with that function. These cognitive domains include memory, judgment and reasoning, orientation, verbal fluency, and others. However, cognitive assessments do not provide a final diagnosis. They merely identify suspicious signs that should be further evaluated by a medical professional. The earlier a physician identifies the cause of any problem flagged by a cognitive assessment, the better the likelihood for a good treatment outcome.

## ***How is the accuracy of a cognitive assessment evaluated?***

The accuracy of a particular cognitive screen must be measured by its ability to correctly identify a cognitive problem (sensitivity) without incorrectly classifying a normal response as impaired (specificity). In general, the higher the sensitivity and specificity of a particular assessment tool are, the more accurate the results of that tool will be.

In evaluating the accuracy of various assessment tools, it is important to consider the minimum severity of impairment that the tool can detect. While many tests claim a high accuracy rate for detecting moderate dementia, very few are sensitive enough to identify early stages of subtler impairment classified as mild cognitive impairment or mild dementia.

## **About the MCI Screen**

### **Is the MCI Screen like the MMSE?**

Neither the MCI Screen nor the MMSE are "diagnostic tests", as neither can identify the presence or absence of any particular medical condition. While both the MMSE and the MCI Screen are used for assessing an individual's cognitive function, there are several key differences between the two. The biggest difference is accuracy. The MCI Screen is approximately 99% accurate in identifying early stage dementia, while the MMSE is approximately 70%\* accurate. For identifying a subtler stage of decline, mild cognitive impairment, the MCI Screen is 97% accurate while the MMSE is approximately 50-60%\* accurate.

*\*These are the highest published figures for the MMSE.*

The MMSE is a paper test that evaluates several functions including: orientation, registration, attention and calculation, recall and language. Such an approach is useful

when a medical problem is quite advanced and a physician is monitoring further cognitive decline.

### **How accurate is the MCI Screen?**

The MCI Screen is 97% accurate in classifying cognitive function as "within" or "below" norms for demographically adjusted peer groups.

### **What makes the MCI Screen so accurate?**

The MCI Screen is based on the 10-Word Recall Test included in the CERAD (Consortium to Establish a Registry for Alzheimer's Disease) battery, the assessment used by dementia specialists. The 10-Word Recall Test requires the subject to memorize and recall a list of 10 words.

Embic Corporation (formerly Medical Care Corporation) gathered the response patterns on the CERAD wordlist for several hundred subjects as well as complete physiological, neurological, and psychological exam data on each subject. Using advanced mathematics, Embic analyzed the responses of subjects in the database to isolate differences in the response patterns of healthy subjects compared to those with well-characterized memory disorders. By classifying over one trillion response patterns, Embic developed methods to accurately classify response patterns as "within" or "below" norms on a demographically adjusted basis.

### **Can I administer the MCI Screen on paper?**

Administering the MCI Screen on paper is possible but not recommended. Since the test is scored electronically, the data must be input into a computer before results can be tabulated. As such, online administration eliminates this necessary data-entry step. Further advantages of online administration include automatic randomization of the wordlist for a given subject and real-time report generation.

### **Has the accuracy of the MCI Screen been validated?**

Yes. The MCI Screen was originally validated in a study of 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 classifying mild cognitive impairment or mild dementia, and 91% specificity for classifying normal aging. The accuracy of the MCI Screen was published in the Proceedings of the National Academy of Sciences (Shankle WR. et al. PNAS. 2005; 102(13): 4919-4924).

The MCI Screen was further validated in a study of 182 patients whose FAST stage ranged from 1 (normal) to 4 (mild to moderate dementia) in primary care settings, and was also compared to Mini Mental State Exam (MMSE) and Clock Drawing Test (CDT). The MCI Screen showed over all accuracy of 97%, while MMSE and CDT showed 76% and 69%, respectively. (Trenkle DL. et al. JAD. 2007; 11(3):323-335.)

### **Can anyone administer the MCI Screen?**

Yes. After becoming familiar with the test protocol, anyone can reliably administer the MCI Screen with a high degree of accuracy. No specific training or credentials are required.

## **Will a patient's personally identifiable information collected by Embic Corporation be used for research?**

No. All patient data is completely protected by HIPAA regulations and cannot be used in any manner that requires patient identity. However, Embic Corporation does use de-personalized, aggregated data for research and development purposes.

## **Is the MCI Screen designed for a specific age group?**

The data set from which the underlying algorithm was developed included individuals ranging in age from 30 to 89. As such, the technology is most accurate when used on patients across that age range.

## **To whom will the MCI Screen test results be compared?**

For each patient, their performance is compared to a group of demographically similar test subjects (same age, gender, race, and level of education).

## **Adding Memory Assessment Service to Your Practice**

### **How much time do I need to incorporate memory assessment services into my practice?**

The time required is minimal. Establishing your online account requires about ten minutes. From there, each individual who will be testing patients should administer two practice tests; this training will take about 20-30 minutes. After those steps have been taken, you will be ready to begin assessing patients. Each patient assessment will likely take between 8 and 13 minutes depending on the cognitive health of the patient.

### **How much does it cost to get started?**

If you have a computer with an Internet connection in your practice, then you have everything needed to get started. There are no set-up costs or other software or hardware purchases required.

### **How much does it cost to use Embic Corporation's products?**

Embic Corporation charges on a per use basis as follows: MCI Screen, \$29; Depression Screen, \$10; Prevention Report; \$20, Memory Screen; \$15. Included in Embic's system is free use of the Functional Assessment Staging Test (FAST) tool for all patients. Invoices are due upon receipt. Embic will invoice you on a monthly basis in accordance with your use of the system. Invoices are payable upon receipt.

### **Do Medicare and other major payers reimburse for using the MCI Screen to assess for memory loss?**

Yes. Given the high medical costs associated with patients who have cognitive deficits, it has become increasingly important to motivate physicians to be vigilant against emerging signs of memory loss. This is evidenced by the federal mandate to "identify cognitive impairment" in the Medicare Annual Wellness Visit and in the "Welcome to Medicare" exam. Please review our Reimbursement Guideline for further details.

### **Does Embic Corporation provide patient education materials?**

Yes. To our customers, we provide a free brochure on memory loss, which can be placed in waiting rooms and exam rooms. Please download the brochure from our website.

## Account Administration

### What happens when I create a trial account?

Once an account has been established, you will gain access to our technology and you will have 15 days to evaluate the system free of charge. When you login after 15 days, you will see a pop-up window asking you to accept our Payment Terms. For continued access to the system, you will need to accept the Payment Terms, which will grant you unlimited access going forward. You will be invoiced at the beginning of each month for all your activity during the prior month. You will only be invoiced for those assessments done after you accepted the payment terms.

### Is it possible to share patient profiles with another doctor in our group?

Yes. We can link two or more accounts so that all patient records created within a medical group are available to each member of the group. If you would like to have your accounts linked, please contact us at [mciscreen@embic.us](mailto:mciscreen@embic.us). We will need the User ID (email address) for each account.

### There are multiple doctors in our practice using the product. May we be invoiced as a group?

Yes. Invoices are generated for each user. If you would like multiple users to be included on one invoice please let us know by us at [mciscreen@embic.us](mailto:mciscreen@embic.us).

### I have forgotten my password. What do I do?

You may click "Forgot Password" on the login page and type in the email address you used to create your account. A new password will be emailed to you immediately. You may change your password by logging into our system and clicking on the "change password" link. If you need further assistance, please contact us at [mciscreen@embic.us](mailto:mciscreen@embic.us).

### I have been locked out of my account. What do I do?

If you are not certain of your password and make several attempts to login with an incorrect password, our system will lock you out for security purposes. Please contact us at [mciscreen@embic.us](mailto:mciscreen@embic.us) to have your account unlocked.

## Products Other Than the MCI Screen

### What is the Depression Screen?

The Depression Screen is a short electronic questionnaire used to assess an individual's depression status. It is based on the DSM-IV criteria for major depressive disorder and is useful in ruling-out depression as a cause of memory loss. In most circumstances, assessing a patient with the Depression Screen qualifies for reimbursement from Medicare and other major payers.

### What is the Prevention Report?

The Prevention Report is an electronic questionnaire, which summarizes dementia risk factors by checking an individual's medical history, life style, and family medical history. After completing the questionnaire, a personalized report is generated containing risk factor identification and analysis, and other educational information about the prevention of

ADRD. The Prevention Report is based on a comprehensive review of published literature and evidence-based medicine research.

### **What is FAST Staging?**

The Functional Assessment Staging Test (FAST) is an electronic version of the most accepted clinical framework for measuring the course of Alzheimer's Disease. It can be used to accurately stage Alzheimer's patients under your care.