COGNISION™ System

NEURODIAGNOSTIC CHALLENGES

Diagnosing patients with cognitive disorders such as Alzheimer's dementia is notoriously difficult, especially in the early phases of the disease. This may limit a patient's own understanding of their condition and reduce their ability to benefit from the earliest possible interventions. Furthermore, providing an exceptional level of patient care may be impractical in the current reimbursement environment.

The solution to this dilemma would be a sensitive and reliable test of cognitive impairment which can be easily integrated into any physician's practice and which can be reimbursed at an economically viable rate.

Fortunately, with the recent technological advances embodied in Neuronetrix's COGNISION™ System, that solution is available now.

THE NEURO-BIOMARKER LANDSCAPE

Providing an accurate diagnosis generally relies upon a physician's assessment of a variety of complex medical tests. These tests often provide a "biomarker", or measure of a physiologic process, which is linked in some way to the disease. Because of cost/reimbursement pressures it is important for the physician to select only the most appropriate and cost-effective biomarker test at each stage of the suspected disease.

For complex cognitive disorders, such as Alzheimer's dementia, it is especially important to evaluate biomarkers of the cognitive deficits which present as the major clinical symptoms.

While there are biomarkers which can be used to evaluate risk factors for dementia such as genotyping — and other biomarkers which are measures of the anatomy or biochemistry of the brain such as amyloid imaging or cerebral spinal fluid assays — none of these are direct measures of cognitive dysfunction which is the core criteria of Alzheimer's dementia.

Neuropsychological assessments can be used to measure cognitive function but they are not measures of brain physiology. Only electrophysiological techniques such as event-related potentials (ERP) and quantitative EEG (QEEG) provide physiologic biomarkers of cognitive processes, or cognitive biomarkers.

COGNISION™ & COGNITIVE BIOMARKERS

The COGNISION™ System provides a series of EEG-based measurements which directly reflect cognitive processing performance. These cognitive biomarkers are automatically extracted from data recorded during a 25-minute — FDA approved — test which can be administered by any clinical tech after only a few hours of training.

BEST PRACTICE AND CLINICAL NECESSITY

The tests performed by the COGNISION™ System have been recommended as part of the NINCDS-ADRDA *"best practice"* criteria in Clinical diagnosis of Alzheimer's disease: Report of the NINCDS−ADRDA Work Group under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease[1]. Additional support for tests of this type was provided in the Alzheimer's Association's new guidelines published in 2011. In their FAQ regarding the Publication of New Criteria and Guidelines for Alzheimer's Disease Diagnosis, April 2011, they recommend "biomarkers showing that nerve cells in the brain are injured or actually degenerating".[2]

A COGNISION™ test directly reflects neuronal function and is abnormal in neurodegenerative

diseases. This information may be useful to better understand complex cognitive problems in many patients.

- Discriminate dementia with an organic etiology from psychiatric disorders such as pseudodementia.[3]
- Positive test for early cognitive impairment consistent with Alzheimer's dementia.[4]
- Nominal results provide very high specificity which could reduce the number of patients who might otherwise be unnecessarily referred for extensive neuropsychological evaluations.[4]
- Provides a sensitive longitudinal measure to track or identify the early signs of cognitive decline in otherwise healthy subjects. This would help physicians to determine when and how to actively manage the disease.[5]
- Provides a sensitive measure of drug effects which can be useful for drug selection and/or to provide feedback to the patient regarding the value of maintaining treatment.[6]

PRACTICAL OFFICE IMPLEMENTATION

Easy-to-use Device

The brain of the COGNISION™ System is an easy-to-setup, wireless, handheld device which controls the test and records the electrophysiological data.

Web-based Architecture

Software to order and run a test and to review the test results can be used from any Windows® PC. All data is stored in a HIPAA-compliant manner in the cloud so that clinicians can access the test results from any of their computers.

Automated Patient Report Generation

Results and relevant measures from the COGNISION™ test are presented in a pre-formatted patient report that can be edited by the treating physician to include clinical findings.

COGNISION™ TESTING SESSION

A COGNISION™ testing session consists of three distinct procedures. Total test time does not generally exceed 45 minutes (includes set-up and clean-up time):

1. Pure tone audiometry to assess hearing deficits
2. 25 minutes of EEG recording, which includes both ERP/P300 and resting-state EEG tests (ERP includes auditory stimulus played through earphones, patient is asked to press a button

on a handheld control unit for each high pitch stimulus).

3. EEG digital analysis to help identify important features of the EEG useful in evaluating cognitive function.[7]
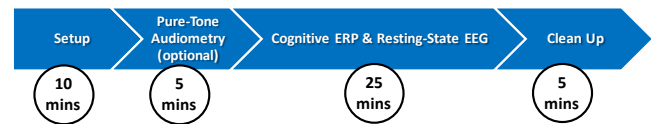
REIMBURSEMENT

These procedures are reimbursed by Medicare and other payers when the proper CPT and ICD-10 codes are used. Clients typically receive a significant reimbursement from these tests.

The most common CPT codes used by clients include 95816 and 95957.

SELECTED REFERENCES

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