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Objective Assessment System for Cognitive Function

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Key Messages

- Horizon Scan reports provide brief summaries of information regarding new and emerging health technologies; these technologies are identified through the CADTH Horizon Scanning Service as topics of potential interest to health care decision-makers in Canada.
- Identifying cognitive conditions allows health professionals to develop tailored rehabilitation strategies and track treatment effects for people with functional impairment.
- This Horizon Scan summarizes the available information regarding an emerging technology, VoxNeuro CORE, and its software for the objective evaluation of cognitive performance, the cognitive health assessment management platform (CHAMP).

The Cognitive Health Assessment Management Platform System

Cognitive dysfunction can occur in conditions such as traumatic brain injuries (TBIs)[1] (e.g., concussion) and cognitive impairment associated with conditions such as dementia.[2] As an alternative or adjunct to cognitive behavioural assessments, VoxNeuro CORE can objectively evaluate brain performance using neurophysiological data captured by an electroencephalography (EEG) recording that can be used to inform clinical decision-making in treatment and rehabilitation.[3]

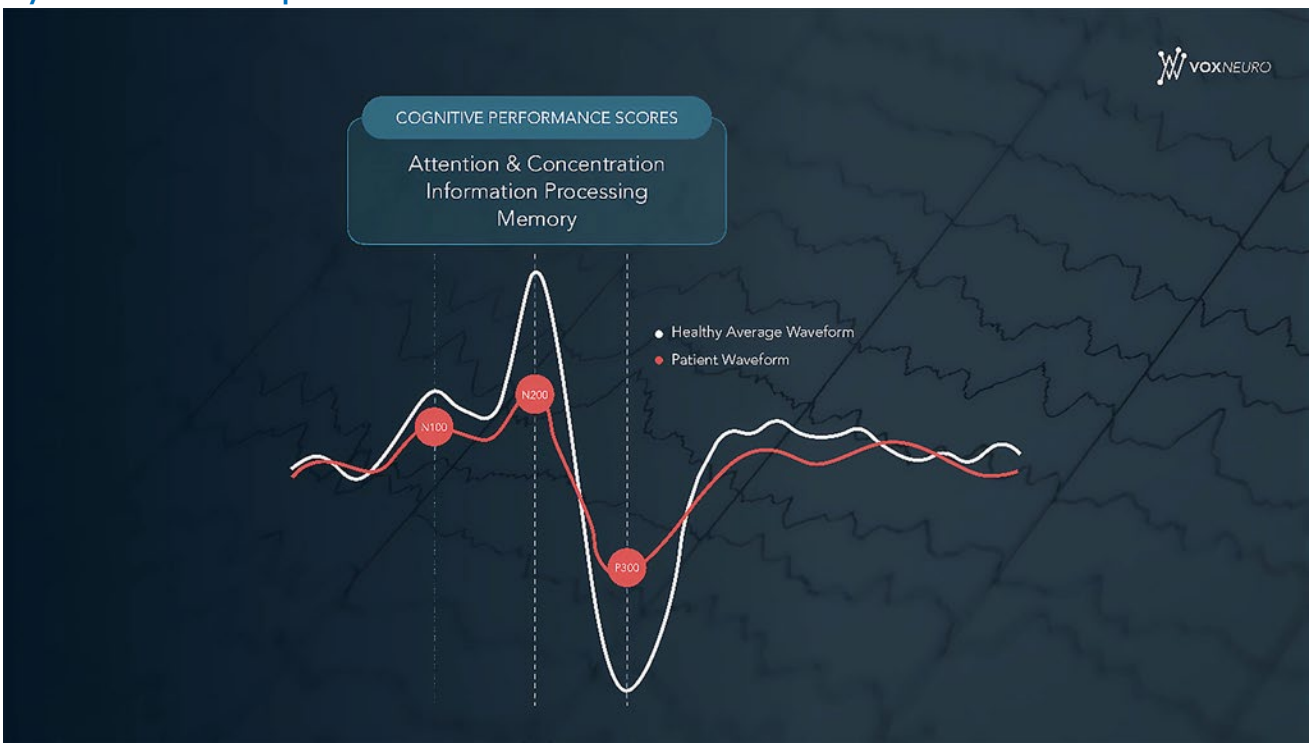
How It Works

VoxNeuro CORE is a noninvasive cognitive health assessment system designed to detect brain function using computerized cognitive and neuropsychological tests with simultaneous EEG recording of brain electrical activity.[3] Event-related potentials (ERPs), which are biomarkers of cognitive processes,[4] are captured by EEG and analyzed against a normative database to score cognitive function, including attention and concentration, information processing, and memory.[5] Figure 1 illustrates the different amplitudes of ERP components (i.e., N100, N200, and P300) as seen in EEG waveforms of a person with cognitive impairment compared with the normative database, which reflect differences in brain responses to stimuli and tasks. Decreased amplitude of a wave component can indicate impairment in attention and concentration, information processing, or memory. Using the normative database allows assessment at any time without the need for baseline cognitive scores.

VoxNeuro CORE consists of standard stationary EEG equipment with 6 electrodes attached to the head, including 1 ground electrode and 1 reference electrode (Douglas Martin, Brand Manager, VoxNeuro Inc., Toronto, ON: personal communication, April 20, 2023). The lead-based EEGs can be easily applied to patients with various hair textures, head shapes, and head sizes. The 31-minute assessment includes a 5-minute awake and drowsy test, a 3.5-minute auditory evoked potential test, a 3.5-minute visual evoked potential test, a 10.5-minute attention and concentration as well as information processing test, and an 8.5-minute memory test (Douglas Martin, Brand Manager, VoxNeuro Inc., Toronto, ON: personal communication, April 20, 2023).

VoxNeuro CORE is intended as an adjunct to standard clinical assessment. The cloud-based software compares test results against the normative database and reports patient scores for each cognitive function, providing objective data to inform rehabilitation, develop personalized treatment plans, and track recovery over time.[5]

Figure 1: Hypothetical Event-Related Potential Waveforms of a Person With Cognitive Dysfunction Compared With the Normative Database



Source: Reproduced with permission from Douglas Martin, Brand Manager, VoxNeuro Inc.

Who Might Benefit?

VoxNeuro CORE is intended for use for individuals aged 12 to 90 years experiencing functional brain impairment resulting from neurological conditions such as TBI, and cognitive impairment, including dementia. Based on microsimulation models, the Public Health Agency of Canada estimated that TBI and dementia would be 2 of the 7 most prevalent neurological conditions in Canada between 2011 and 2031.[6] In Canada, more than 6.7% of people aged 65 and older were reported to be living with dementia in 2016 to 2017.[7] VoxNeuro CORE could be used repeatedly over time to track functional brain changes and treatment effects for individuals with dementia.

More than 20,000 people are hospitalized for mild-to-severe TBI every year in Canada, and emergency department visits related to TBI increased between 1990 to 2018.[8] In addition, a 2018 publication from the

Public Health Agency of Canada reported that approximately 20% of people aged 12 years and older who experienced a TBI did not seek care within 48 hours of their injury.[9] Mild TBI, including concussion, can be difficult to diagnose due to the subtle signs and symptoms that patients experience[10] and the self-reported nature of neurocognitive tests[11] guiding the triage decision for further image investigation of brain injuries.[12] Emerging objective tests have the potential to improve the evaluation of mild TBI.[13] Moreover, patients who are in a coma, who cannot be evaluated with traditional behavioural assessments due to inability to communicate may benefit greatly from the EEG-based VoxNeuro CORE measure because it requires no verbal or behavioural responses.[5]

Other people who might benefit from VoxNeuro CORE include people with cognitive impairments caused by psychiatric disorders, such as major depressive disorder, attention-deficit/hyperactivity disorder (ADHD), and schizophrenia.[5] Psychiatric disorders contribute to the disease burden in Canada; 4.7% of people were affected by major depressive disorder in 2012,[14] 8.7% of children and youth aged 4 to 17 years were affected by ADHD in 2015,[15] 2.9% of adults aged 20 to 64 years were affected by ADHD in 2012,[16] and 1% of people aged 10 years or older were affected by schizophrenia in 2016 to 2017.[17] Cognitive impairment was reported as a symptom of major depressive disorder [18] and ADHD.[19] In addition, people with schizophrenia were found to have clinically significant greater estimated cognitive decline compared with participants without schizophrenia.[20]

Availability in Canada

Health Canada licensed CHAMP as a Class II Medical Device in 2021.[21] FDA licensed CHAMP as a Class II Exempt Medical Device in 2021.[21]

What Does It Cost?

Information on the cost of the VoxNeuro CORE was unavailable. Main economic considerations for using the assessment include leasing fees for the hardware as well as costs for equipment setup and training, and pay-per-use software subscription fees, the price of which will become lower for VoxNeuro-certified clinics as the number of assessments performed increases (Douglas Martin, Brand Manager, VoxNeuro Inc., Toronto, ON: personal communication; March 9, 2023). Time associated with online and in-person training is also part of the cost to implement VoxNeuro CORE. Additional costs for patients may include charges for the assessment used as a complement to standard cognitive assessments,[22] especially for repeated testing to track cognitive changes. According to the manufacturer, the assessment is covered by workplace insurance and the Treatment and Assessment Plan (OCF-18) in Ontario,[5] but it is unclear whether the cost is covered by other jurisdictions in Canada, thus it is likely that patients need to pay out-of-pocket or seek support from other resources.[23]

Current Practice

Assessment of cognitive performance is usually conducted using validated neuropsychological screening tools such as the Mini-Mental State Examination, the Montreal Cognitive Assessment, and the cognitive subscale of the Alzheimer's Disease Assessment Scale.[24] Validated cognitive measures recommended by the National Institute for Health and Care Excellence guideline for patients suspected of dementia include the 10-point cognitive screener, 6-item cognitive impairment test, 6-item screener, Memory Impairment Screen, Mini-Cog, and the Test Your Memory test.[25] Some of these measures detect various functions, such as attention, concentration, orientation, and memory,[26-28] while others assess specific cognitive domains by using word recall and object naming tasks.[29-31] These performance-based measures cannot be used in behaviourally unresponsive patients with conditions such as communication barriers, acute brain injury, and coma.

What Is the Evidence?

No published evidence for the use of VoxNeuro CORE or CHAMP to assess cognitive function was identified. The application of ERPs for cognitive assessment is well-documented;[4] 1 study was found that investigated the long-term cognitive consequences of concussion using ERPs, which was a 2019 cohort study led by the cofounder and chair of the VoxNeuro advisory board.[1] However, no data were collected about the effectiveness VoxNeuro CORE itself.

Safety

No evidence about the safety of VoxNeuro CORE or CHAMP was identified in published literature. VoxNeuro CORE is a noninvasive measure using EEG, which is generally considered safe and painless.[32]

Issues to Consider

The clinical utility and clinical effectiveness of VoxNeuro CORE have not been compared with other cognitive assessment measures. In addition, there are no evidence-based recommendations regarding the use of objective cognitive measures for screening or diagnosing patients suspected of cognitive dysfunction. If found to be effective, other challenges in implementation could include the upfront cost of the device and software, training of staff, and the time associated with the assessment. Although VoxNeuro CORE is designed to be easily administered by individuals with limited knowledge of EEG, training is still required for the health staff to do the assessment. Additionally, administering the assessment in combination with standard cognitive measures would add time to the clinical evaluation, especially in the long-term rehabilitation process. Finally, if cost coverage mainly relies on out-of-pocket payment and private insurance, inequitable access to the device would be an important issue to consider, particularly for equity-deserving groups.

Related Developments

Other Objective Cognitive Assessment Devices

Most EEG-based cognitive assessment systems are primarily designed to diagnose patients with cognitive impairments, such as the BrainScope,[33,34] Evoke Neuroscience and eVox Brain Health System,[35] and NeuroCatch Platform.[36] For example, BrainScope is intended to assist in the diagnosis of traumatic brain injury.[33,34]

Cognision[37] is an EEG-based device used to monitor disease progression and treatment outcomes and measure cognitive domains, including working memory, focal attention, executive function, and brain processing speed.[5,37] According to the manufacturer's website, it requires the use of specially designed hardware.[37]

The Evoke Neuroscience and eVox Brain Health System,[35] NeuroCatch Platform,[36] and Cognision[37] use a headset unlike VoxNeuro CORE, which makes them less accessible to individuals with coarse and curly hair textures, cornrows, and braids; above or below average head sizes; or severe brain injuries. Other objective cognitive assessment devices include WAVi,[38] which combines EEG and heart rate variability measures,[38] and the virtual reality–based Neuroflex.[39]

VoxNeuro CORE Used for Active Military Personnel

VoxNeuro is collaborating with the Canadian Armed Forces to investigate the cognitive consequences of intense military combat training regimens using VoxNeuro CORE before and after training.[40] The study will also explore the extent to which VoxNeuro CORE assessment results could inform clinical decision-making.[40]

Assisting in Disease Diagnosis and Prognosis

Although VoxNeuro CORE is intended to inform rehabilitation, it also has the potential to aid in diagnosis. A research team at Boston University is studying the diagnostic accuracy of ERPs for Alzheimer disease and mild cognitive impairment in collaboration with VoxNeuro.[41] In addition, researchers at VoxNeuro are investigating the application of machine learning to better identify neurophysiological biomarkers and improve disease prognosis for conditions such as coma.[42]

Looking Ahead

If proven to be effective, EEG-based cognitive assessments such as VoxNeuro CORE can be valuable tools in evaluating brain function by providing objective data independent of behavioural responses. However, further clinical studies comparing it with other cognitive assessments are needed to develop evidence-based guidelines regarding the use of such objective measures either on their own or as an adjunct to existing clinical cognitive assessments. Additionally, information on the cost of VoxNeuro CORE, including cost-effectiveness of the system compared with current behavioural assessments and/or other objective assessments, is essential to address cost and coverage issues, ensuring equitable access to people who can benefit from objective cognitive measures.

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Appendix 1: Methods

Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Embase, and PsycInfo via Ovid; Scopus; the International HTA Database; and a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were cognitive health assessment software platforms or the device names VoxNeuro or CHAMP. The search was completed on March 9, 2023, and was limited to English- or French-language documents published since January 1, 2018. Regular alerts updated the search until April 24, 2023.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was VoxNeuro CORE or a cognitive health assessment management platform. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies. These searches were supplemented by reviewing bibliographies of key papers and through contacts with industry.