



Q & A WITH DR. CHARLES DUFFY

Founder and CEO of Cerebral Assessment Systems and inventor of Cognivue

Please address the importance of brain health monitoring and cognitive assessment, particularly as a large segment of the population turns 65 and older:

Today, the annual global cost of dementia care is over \$600 billion and rising steadily. In the US alone, over 5 million Americans are living with Alzheimer's disease, and that number is expected to triple by 2050. The entire world is experiencing an unprecedented demographic shift towards an older population. This includes a substantial projected rise in those most susceptible to late-life cognitive decline, people aged 85 or older. Late-life cognitive decline is the focus of Cerebral Assessment Systems, Inc. (CAS) and our solution, *Cognivue*®. CAS's mission is to bring cognitive care to primary care physicians and provide accurate, accessible, and affordable brain health monitoring and the early signs of dementia for every patient.

How will early cognitive assessment lead to better patient care/outcomes and help reduce costs from the perspective of both the physician and the hospital/IDN?

Peter Drucker's rule applies: *that which is not measured cannot be improved*. In healthcare, that means that we must have fast, reliable, low-cost approaches to confront our patient's problems in a positive, productive manner. *Cognivue* brain health monitoring will lead to better patient care/outcomes and lower costs in 5 key ways;

1. *Cognivue* enables front line providers (doctor, nurse practitioners, and physician assistants) to inexpensively and consistently measure and track a patient's cognitive health.
2. Where impairment can be identified early in the course of decline, the treatment of reversible causes can return patients to improved function, leading to better patient outcomes and lower costs.
3. When irreversible impairments are identified, further evaluation and focused care can be promptly provided and enable a more efficient use of hospital resources.
4. *Cognivue* monitoring will also enable assessment of cognitive changes over time to recognize and treat cognitive impairment from procedures and polypharmacy associated with older adult care, reducing costs.
5. Wide-spread deployment of *Cognivue* will also expedite the development and validation of new therapies for individualized cognitive care and hopefully provide a complete or functional cure.

How long has *Cognivue* been available to hospitals and physician practices?

Until recently, *Cognivue* has been generally available only as part of our research protocols for obtaining FDA clearance. We began commercial deployment at the beginning of Q2 2016. Soon we will be announcing distribution agreements with several large national medical device sales organizations.

Prior to the availability of *Cognivue*, what cognitive assessment tools have been available? How does *Cognivue* differ from these other tools?

Doctors currently rely on paper-and-pencil tests, or 1st generation computerized adaptations based on these tests. Clearly the paper and pencil tests have the disadvantage of requiring an experienced professional for test administration and scoring, both being subject to substantial variability across practitioners and test sites. *Cognivue* is based on a **new** technology derived from extensive psychophysical and neurophysiological research.

Please explain how the *Cognivue* system works.

The *Cognivue* system is a fully automated solution that systematically presents controlled visual stimuli on a computer screen, calibrated for speed and screen brightness for each individual patient to derive a quantitative analysis of brain sub-system performance and a composite score of overall brain functional integrity.

What types of physicians or physician practices are most likely to use Cognivue?

Cognivue is appropriate for application in a wide range of practice settings. Its rapid, patient-administered test format, and ease of test interpretation and explanation make it well suited for all primary care settings, clinics, long term care facilities, specialists, and hospitals.

How big (physically) is the device? How much space is required?

The *Cognivue* computerized mobile workstation occupies less than a 3 foot X 3 foot space suitable for any medical exam room or office.

What potential concerns might physicians at independent practices and hospital supply chain contracting executives have regarding the cost and efficacy of Cognivue?

Cognivue presents a highly cost-effective solution to the pervasive need to assess patient's brain function in the clinic, on the wards, in same-day treatment settings, and emergency and urgent care settings.

Although a benefit is accrued through direct reimbursement, there are also tremendous potential economic benefits to due to cost-avoidance, using *Cognivue* to screen instead of using costlier technologies or specialists.

Finally, there is also a growing realization that treatments (i.e. procedures) that may have cognitive side-effects demand monitoring, especially prior to patient discharge from care, both because of quality of care and practice liability concerns.

How should the distributor reps who work with physicians address the above concerns with their customers?

The direct reimbursement and cost avoidance benefits of using *Cognivue* provide strong incentives for adoption in diverse care settings. Nevertheless, providers at all levels are primarily attracted by the opportunity to enhance the quality of care in their practices by addressing the #1 healthcare concern of older Americans, that of cognitive decline.

Similarly, how would you address the concerns of hospital supply chain/contracting executives who must balance cost with physician buy-in?

Practitioners are very conservative about adopting new technology, both by their nature and by their training. We are all trained with the Hippocratic mantra of, "First, do no harm." *Cognivue* provides a readily realized opportunity to do a great deal of good for a wide variety of patients with an exceptionally low hazard/risk profile.

Nevertheless, we at CAS take it as a primary responsibility to couple our technology, with empowering Continuing Medical Education (CME) material. This information guides practitioners through the integration of *Cognivue* testing into practice work-flow, the brief instruction needed to allow office staff to initiate testing on patients, the interpretation of *Cognivue* test reports, and an overview of how practitioners should use those test results to enhance patient care.

Does Medicare/Medicaid reimburse physicians for the test? If so, what is the CPT and/or ICD-10 code?

CAS provides access to information on billing for the appropriate clinical use of *Cognivue* testing. That information was prepared by billing professionals who are familiar with all aspects of these issues. CAS is respectful of regulatory restrictions on the provision of billing advice by medical device manufacturers.