

A Novel Physiological Vital Sign for Behavioral Health

By David Yonce, Arjun Ramakrishnan, and Michael Platt

DETECTING BRAIN SIGNALS with wearable solutions could provide a step between traditional clinic-based neuroscience assessments and invasive permanent implants, but few of the wearable products on the market today can match the data quality of either when it comes to brain information. In fact, as of the end of 2020, about 90% of wearable technologies on the market were designed to be worn on the wrist.² While many products demonstrate impressive vital sign assessment of physical parameters such as heart rate, blood pressure, and blood oxygenation, extrapolation of cognitive and emotional states from peripheral physiological signals can only go so far. To address this

unmet need, we at Cogwear have furthered a novel concept incubated by the company's founders in a neuroscience research laboratory at the University of Pennsylvania – namely unlock clinical-grade cognitive and emotional information, comfortably and discretely, for people doing everyday activities in real-world environments. Powered by nanotechnology sensors, a gamified decision-making app, and novel machine-learning-derived algorithms, our platform adds cognitive and emotional data to other peripheral physiological measures, thereby unlocking the potential to advance human health, safety, and performance (for more detail, see **INSET 1**).

We targeted the first application of our platform to the identification, measurement, and trending of anxiety and stress. Currently, no solutions exist that provide a quantitative measure of anxiety based on measuring underlying brain activity; current best practices instead utilize standardized questionnaire-based assessments of the patient's feelings, mental healthcare checklists based on the DSM-V, and increasingly peripheral physiological measures like heart rate or heart rate variability (HRV) derived from wrist-based wearables. Questionnaires are subjective, time-consuming, and can lead to significant reporting bias and demand effects; as a result, questionnaires lack an easy and reliable way to trend results in real-time. ▶

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Additionally, the lack of quantitative quality metrics limits our understanding of pharmaceutical and therapeutic intervention; provides difficulty for payers to assess effective treatment regimens; and contributes to the fallout of children prematurely from therapy. These needs and lack of quality metrics combine to create a difficult-to-validate, trial-and-error approach to chronic mental health conditions. Although widely available, wrist-based measures of heart rate and HRV provide limited insight into anxiety or other mental health conditions and are therefore not considered reliable decision support tools for psychiatric care.³

Backed by studies of nearly 1,000 people across different age groups, cultures and conditions, our five-minute assessment can identify the type and magnitude of anxiety based upon underlying brain activity, providing the possibility of speeding time-to-care, preventing relapse, and increasing the precision of pharmaceutical therapies for more than a quarter of a billion people worldwide.

Mental and Behavioral Health: Unmet Needs

Mental health widely impacts society, with the National Alliance on Mental Illness (NAMI) reporting one-in-five adults in the U.S. experiencing a mental illness annually.⁴

Further, NAMI, the National Institute of Mental Health (NIMH), and the Anxiety and Depression

Association of America report that, of this population, between 30 to 40 million adults in the U.S. live with anxiety disorders and approximately 37%, or 15 million adults, seek treatment annually.^{5,6} On a worldwide basis, the number of people living with anxiety disorders soars to over 264 million.

Further increasing the prevalence of these disorders has been the arrival of the COVID-19 pandemic, resulting in shortages of therapists, limited access to care, and evidence that one-in-three COVID-19 survivors may suffer from PTSD.^{7,8} Most practicing mental health clinicians themselves are experiencing significant increases of anxiety, depression, and other disorders, taxing an already overwhelmed segment of healthcare.^{9,10} Moreover, the CDC reported a peak three-fold increase in the number of people showing anxiety and depression symptoms since the start of the pandemic.¹¹ In light of these data, these experts identified the need for real-time monitoring of mental health states and developed a platform to help those especially in at-risk sectors.¹²

This large group forms a vastly underserved patient population that is only beginning to receive the attention that is needed to provide more effective solutions. Evidence of this can be seen from numerous mental health mobile applications that have recently come to market^{13,14,15} and expanded coverage from the Centers for Medicare

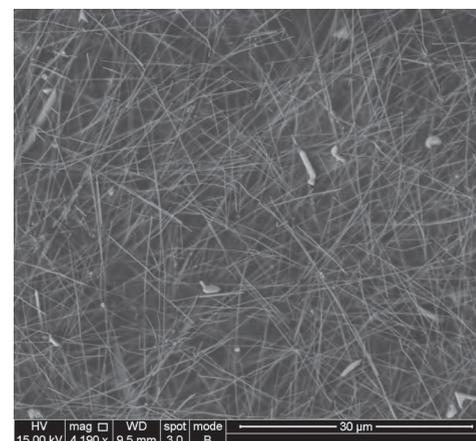


Figure 1: This is a scanning electron microscope image of the surface of the novel nanotechnology-derived EEG electrode. An intertwined layer of nano-scale wires forms the skin contacting surface and provides high conductivity, strength, and flexibility.

and Medicaid Services (CMS) for telemental health sessions.¹⁶ Despite these advances, significant unmet needs still exist within the care pathways for these patients.

Not surprisingly, as attention to mental health has grown, so has the ability to identify previously undiagnosed patients resulting in a consequent increase in their number. Our discussions with clinical psychologists, therapists, and psychiatrists ▶

INSET 1

Physiological Measurements: Moving from clinical laboratory measurements to wearables

We are at the beginning of a rapid explosion in understanding how the brain works and how it goes awry in disease or injury. Advancements in brain-computer interfaces have the potential to help victims of spinal cord injuries overcome paralysis and help better identify and assess brain issues ranging from behavioral disorders to Alzheimer's Disease. In the past two decades, we have seen the advent of deep brain stimulation to treat Parkinson's Disease and neurostimulation used in diverse applications such as improving cardiac function and relieving symptoms of an overactive bladder. The impacts of new neurological treatments are so significant that brain-computer interfaces were recently listed as one of the moonshot radical technologies that could revolutionize society, alongside other cutting-edge technologies such as 6G telecom networks, next generation batteries, and electrical vertical take-off-and landing vehicles.¹

Yet our understanding of brain function outside of the laboratory or clinic environment is extremely limited. Neuroscience research depends upon technologies such as electro-encephalograms (EEG) and magnetic resonance imaging (MRI) to view the brain reaction to various stimuli. These expensive tools require expert users, significant capital expenditure, and are usually limited to sedentary applications. Several companies are leaping towards implantable brain-computer interfaces to create more permanent data gathering and to ultimately close the therapeutic loop to treat neurological disorders.

Taking a cue from physical medicine, where vital signs such as temperature, weight, and blood pressure are used at nearly every patient interaction to assess physical health, a vital sign created from a brain-computer interface could be

utilized to assess cognitive and emotional health. If done through an easy-to-use, non-invasive, and relatively inexpensive system, a cognitive vital sign could become as ubiquitous in its use as a biomarker to assess patients for behavioral health disorders, identify and trend memory function, and measure overall cognitive performance.

We at Cogwear are developing such a wearable platform to provide cognitive insights virtually anywhere, anytime (see **Figure 3**). Cogwear has the potential to shift the standard-of-care in the mental health space by utilizing our clinical-grade EEG wearable and proprietary algorithms to create the first anxiety biomarker – what we call an “anxiety thermometer” – based upon underlying brain physiological function. Currently no solution exists to do this and instead of relying on questionnaires and visual cues, our physiological measures can be performed quickly in the office or remotely between sessions to help clinicians better understand the mental state of their patient, trend progress, and potentially shorten recovery time. This will enable better and faster patient triage to ensure few new patients fall out from care, ensure the most severe patients are seen quickly, and augment the information available during mental health sessions. Finally, utilizing a physiological measure of anxiety based upon biology may show earlier effectiveness of anti-anxiety pharmaceuticals or help stratify patients into dosing regimens. Building upon this, researchers have published results predicting the effectiveness of anxiety medications based upon EEG data; our device provides a platform to implement these predictive algorithms, further improving pharmaceutical selection. For more information, see www.cogweartech.com.

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indicated that many of them are constantly at the maximum number of patients they can treat concurrently. To help address time and cost constraints, there has been a rapid growth of remote measurement tools, thereby adding quantitative power to telemedicine. Prior to the pandemic, telemedicine had an estimated compound annual growth rate (CAGR) of 25%; with the onset of COVID-19 in the US, telemedicine has since experienced a massive shift upwards in growth.¹⁷ While this growth has been driven by the demands of practitioners and patients who have relied increasingly on digital mental health applications, many practitioners report mixed results with their patients. (See **INSET 2** for market dynamics).

We can do better than surveys: Review and uptake by practitioners

Therapists, clinical psychologists, and psychiatrists responded positively to our product concept. Eighty-five percent of clinicians in our initial customer insight research in the spring of 2019 and 100% of in our latest research during the heart of the pandemic in 2020 showed strong interest in having such a wearable. Further, our concept discussions with clinicians identified other areas where the Cogwear system could help. Besides routine trending, therapists could also use a real-time anxiety measure to help ensure anxiety is triggered during exposure therapy, such as for PTSD, thereby improving efficacy and shortening recovery time. A real-time physiological measure is especially beneficial when treating children and adolescents who cannot verbalize their feelings as well as adults. (For a parent's perspective on the importance of better measures, see

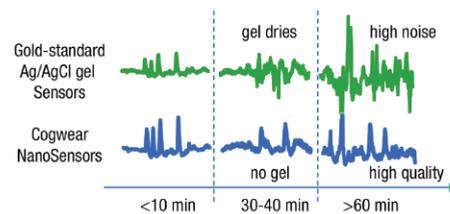


Figure 2: Cogwear EEG sensors combine the best qualities of dry and wet electrodes. The unique construction enables signal quality of industry-standard Ag/AgCl wet electrodes, yet this is maintained over time. As wet electrodes dry out, signal quality suffers until the conductive gel is replenished, usually requiring support personnel, and limiting continuous monitoring time.

INSET 3). Finally, beyond speeding the selection of a pharmaceutical for a particular patient, our measure could provide a quantifiable measure of efficacy in anxiety-related clinical trials.

Cogwear Platform

The Cogwear platform is enabled by two core technologies: nanotechnology-based sensor electrodes and algorithms inspired by neural mechanisms that combine the result of a computer game with EEG data. These algorithms were tuned by machine-learning and have been proven by multiple human studies.

Nanotechnology Sensor Electrodes

Current clinical-grade EEG devices are expensive, use an uncomfortable gel smear to enhance electrode contact and require the user to be tethered to a single location. Consumer-grade, mobile, wearable EEG devices are typically less expensive and simpler to use, but lack clinical-grade EEG signals, minimizing the efficacy for all but

the simplest of brain measurements. To overcome these limitations, we have developed novel sensor electrodes that are formed by encapsulating nano-filaments within a flexible polymer. This design creates a dry sensor electrode that provides superior electrical conductivity and high longevity with a very low-profile. **Figure 1** shows a scanning electron microscope image of the electrode surface.

This combination of features enables the sensor electrode to mimic the mechanical properties of human skin and conform to the user's head (or other body parts as applications grow). The conformable electrode enables this next-generation, cognitive wearable that can be easily applied, exhibits clinical-grade data maintained during active and mobile situations, and allows long-duration studies without pausing to adjust or refresh the EEG electrodes. Testing of the technology to-date has shown their effectiveness in a variety of active situations, including during sporting activities. As shown in **Figure 2**, the sensors exhibited clinical-grade signal quality and longevity over extended test durations, far exceeding what can be obtained from industry-standard Ag/AgCl electrodes.

Because these sensors are flexible and low profile, they are readily incorporated into a variety of form factors. We are currently developing our next-generation headgear as a washable, soft-goods headband that can be quickly and easily applied, as shown in **Figure 3**. With the sensing electronics, battery, and wireless communications built into the band, our headgear serves not only as a main component of our anxiety vital sign detector but is designed to be used for a variety of other neurological monitoring applications in the future. Gathering physiological cognitive data is the first piece of the

INSET 2

Market Dynamics and Addressing Unmet Needs

Market dynamics have led to unmet needs that have not been addressed with current solutions:¹⁸

Coverage and payers: The market is beginning to shift from cash-pay sessions to insurance coverage for mental health, but patient treatment remains cost-constrained.

Improved patient screening and triage: Practitioners report an overwhelming patient burden with no easy way to rank patients for severity or measure progress. Validated anxiety questionnaires are the only quantitative way today to trend treatment progress, yet these questionnaires are rarely used because they are time-consuming and subject to significant reporting bias and demand effects. Further, one hospital CEO likened these surveys to an eye chart; the "right" answers are easy to memorize and select, often obfuscating mental health components to emergency room visits.

Less exhaustive telemedicine: The rapid shift to telemental health counseling due to social distance measures has made it more difficult, and mentally taxing, to pick up nonverbal cues from the patient that would be accessible in an office

visit. Therapists and clinical psychologists report a much higher level of exhaustion following telemental health sessions compared with those in-person.

Improved pharmaceutical selection: Prescribing mental health drugs is a trial-and-error process that can be frustrating and time consuming. Individuals respond differently to various anti-anxiety pharmaceuticals, and it is not known at the outset which drug will be effective for a particular person. This can lead to a delay of months from the time when the clinician identifies that a pharmaceutical is necessary to when an effective drug has been prescribed. This phenomenon has been exacerbated with the progression of COVID-19.

Reduced costs through improved physiological quality metrics: The lack of objective and physiological quality metrics creates a trial-and-error approach to mental health care, contributes to patients prematurely falling out of therapy, and contributes to uncertainty of beliefs regarding the efficacy of therapeutic interventions. Finally, this also confounds the insurance payers by providing no objective measure to assess quality of care; this creates a "blank-check" risk for payers covering the management of this often-chronic condition.



Figure 3: Cogwear headgear is designed to provide clinical-grade EEG monitoring in an easy-to-use and comfortable soft-goods form factor.

puzzle; the second piece of the puzzle is the algorithms to unlock insights into cognitive function.

Anxiety Sensing Algorithms

We developed algorithms by applying machine learning models to two complementary measures: EEG signals and behavior elicited by an ecologically valid, computer-based game that mimics the

activity of foraging, which requires regulating the trade-off between sticking with a depleting resource and investing time and energy, and overcoming uncertainty, to find a better one. On average, humans, like all animals, make this decision nearly optimally by implementing a simple computation deeply stamped into our brains by evolution.¹⁹⁻²⁴ Trait anxiety (biologically predisposed

anxiety) disturbs these computations, leading to a reluctance to explore and persistence for immediate reward. This resembles “tunnel vision” and a subjective fear of exploration often reported in people suffering from anxiety. By contrast, state anxiety (stress-based) presents as over-active urge to explore by seeking rewards elsewhere. Intuitively, stress provokes us to search for new options even when our current circumstances are reasonably good.

Our technology begins with a 5-minute screening using the foraging game. If the patient’s behavior shows signs of anxiety, we follow up with a second screening with simultaneous EEG measurements while the patient again plays the foraging game. Foraging behavior depends on a circuit connecting the anterior cingulate cortex (ACC) to the locus coeruleus (LC). The ACC regulates the threshold for deciding to explore in part by stimulating the LC, which broadcasts norepinephrine widely across the brain. Norepinephrine is directly implicated in anxiety disorders, panic, and depression. Furthermore, another neurochemical involved in stress response, cortisol, directly modulates the neural activity in the ACC through abundant glucocorticoid receptors. By simulating and monitoring foraging decisions while collecting EEG signals shaped by the ACC and LC, we can identify, measure, and trend anxiety based upon underlying brain biology.

Our confirmation of the algorithm starts first with the analysis of the results showing that foraging decisions are ecologically valid, that anxiety disturbs the underlying neural computations, and that we can determine low and high anxiety states with high accuracy (see **Figure 4**).²⁵ Consolidation of data from studies with

INSET 3

Case Study: The Winding Path of Generalized Anxiety Disorder and the Potential for Better Care

Some of us know all too well how difficult the journey to diagnosis and effective treatment can be for young people with anxiety – and consequently one of the most painful and often helpless experiences one can have as a parent. One of our sons – we’ll refer to him as Robert to preserve his privacy – began developing headaches and stomach pains while in elementary school, often spending hours in the nurse’s office until one of his parents could pick him up and take him home. As the physical complaints persisted, his parents brought him to the pediatrician, who performed the standard tests that failed to provide any clear answers. This whole process was repeated several times over months until the pediatrician suggested a visit to a therapist. Like many boys, Robert had little insight into the source of his symptoms so standard questionnaire-based assessments were no more effective than the physiological tests performed by the pediatrician. It took several years to obtain a firm diagnosis of generalized anxiety disorder (GAD).

But that was just the beginning. Standard of care in psychiatry is empirical: try one medication, typically a selective serotonin reuptake inhibitor (SSRI) like Zoloft – the first anxiolytic prescribed for Robert – and wait 1-2 months to gauge the effects. If no benefit is obtained, the next step is typically to increase the dosage, and then wait again. If symptoms do not improve, the psychiatrist will either change medications or add one or more to create a “cocktail” aiming to treat not only the original problem but any drug-induced side effects. Unfortunately, it took years, and several hospitalizations, to develop an effective cocktail for Robert through trial and error.

Cogwear could have made a major difference in Robert’s case. He could have been screened with the gamified decision-making app during his visit to the pediatrician. Given that Robert’s core problem is GAD, or trait anxiety, he likely would have been flagged for additional testing with Cogwear’s nano-technology-based EEG headband, given the high sensitivity of the Cogwear platform (Figure 9). While receiving pharmacological treatment, application of the Cogwear platform at home could have provided his clinician a more robust and precise measure of changes in Robert’s underlying brain biology, permitting medication adjustments on-the-fly. A Cogwear-enabled approach could have dramatically shortened Robert’s course of treatment, preventing needless suffering and speeding return to school or work.

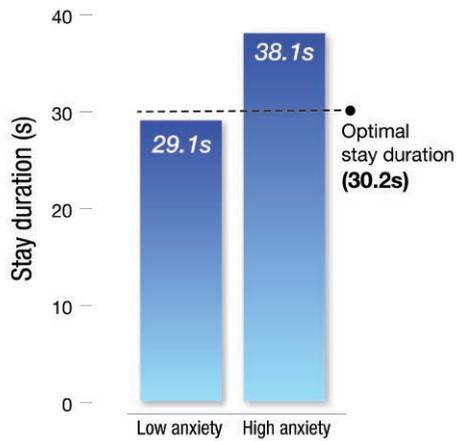


Figure 4: The Cogwear algorithm utilizes an ecologically valid computer game that mimics foraging, which requires regulating the trade-off between sticking with a depleting resource and investing time and energy, and overcoming uncertainty, to find a better one. The time one takes to make the trade-offs is correlates to anxiety levels.

nearly 1,000 individuals over tens of thousands of trials proves the robustness of our approach.

Second, EEG provides a much more robust indicator of anxiety than other biological measures such as skin conductance and heart rate. EEG can identify a stressed individual with 86% accuracy and, as shown in Figure 5, represents a 32% increase in predictive accuracy compared with just heart rate (HR) and heart-rate variability (HRV), the current wrist-based wearable standard²⁶ (e.g., smart watches, fitness trackers).

Third, the combination of our gamified algorithms, EEG, and heart-rate data can predict trait anxiety with an 84% accuracy, representing a 25% improvement in predictive accuracy compared with standard-of-care questionnaires and a 58% improvement over consumer wearables as illustrated in Figure 6.²⁷

Fourth, Figure 7 illustrates that the complete algorithm can predict the trait anxiety of a new individual outside of the training sample and can be used as a continuous measure beyond just high and low categorization of anxiety levels. This provides a method to measure anxiety magnitude and trend more subtle changes over time. We show an improved explained variance

(defined as $1 - [\text{error variance}]$) compared with utilizing skin conductance response and we expect that the repeatability of a single individual's samples will drive a much lower variance rate when trended over time.

Finally, our machine learning algorithms can be tailored to trade-off specificity (of trait being tested) and sensitivity (of magnitude of response), by moving along a Receiver Operating Characteristic Curve (ROC)*. Figure 8 shows a plot of the ROC;

by selecting points on the left-most portion of the plot, we can optimize the performance of the measurement in terms of true and false positives depending upon the situation. For instance, when used as an initial screen of patients for anxiety, selecting point (A) on the Figure 8 ROC plot equals a false positive rate of 23% (specificity of 77%) at a true positive rate of 90% (sensitivity of 90%).

Figure 9 shows the relative sensitivity and specificity of the Cogwear algorithm relative to the validated surveys (standard-of-care). With a much higher Cogwear sensitivity vs current standard-of-care (90% vs 44%) at the same specificity (77%), we can potentially flag twice as many patients during initial screens without bringing any additional false positive patients needlessly into the care pathway. However, our approach also allows us the potential to further adjust the sensitivity for patients under treatment. Once into treatment, we can utilize point (B) on the Figure 8 ROC plot that provides a higher sensitivity to provide greater measurement dynamic range for improved patient trending. At this point in care, patients are already being treated for anxiety, so the risk and expense of false positives is minimized and the trade-off of a higher sensitivity for a lower specificity is worthwhile to improve patient trending.

System Architecture

In Figure 10, we show a diagram of the system architecture and data flow. The Cogwear EEG wearable is composed of three main architecture components: the wearable EEG headband (image 1 in Figure 10), a mobile application (image 2), and a cloud-based, online database (image 3).

The EEG headband incorporating our nanotechnology sensor electrodes forms the wearable portion of the system and provides the main hardware interface with the patient.

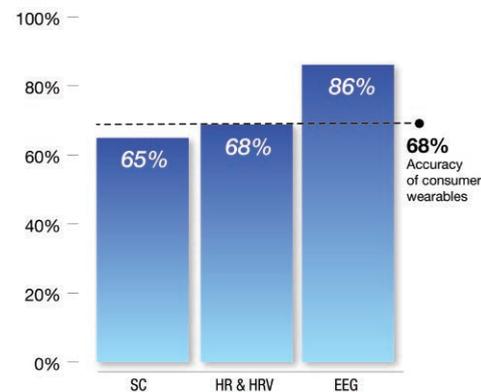


Figure 5: EEG is the best way to identify and monitor stress. In our studies, EEG accurately identified a high stressed individual 86% of the time compared with heart rate and heart rate variability (68%) and skin conductance (65%), measures commonly available on wrist-worn wearables.

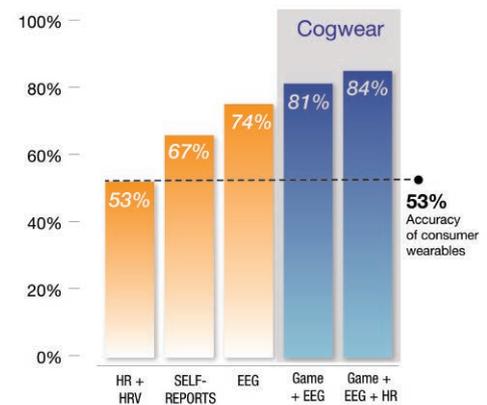


Figure 6: Our algorithm combining the computer game and EEG identifies low, medium, and high anxiety with an 81% predictive accuracy, increasing to 84% when heart rate is included. This represents a 25% increase in the ability of standard-of-care questionnaires to identify anxiety (67% predictive accuracy) and a 58% increase over heart rate and heart rate variability (53% predictive accuracy), two measures commonly available on consumer wrist-worn wearables.

To perform a measurement, the patient fits the wearable headband with electrodes on their forehead. Once powered, the wearable is paired with the user's mobile phone and begins relaying sensed EEG data via Bluetooth or WiFi.

The Cogwear mobile application forms the main user interface with the wearable hardware. Additionally, the foraging game is incorporated into the app which the user completes as a stand-alone activity for initial screening or in conjunction with an EEG measurement for the most accurate results.

As data is collected through the mobile application, it is relayed through encrypted data transfer to the Cogwear cloud-based data platform. This is a HIPAA-compliant system with individual, private accounts for each user. It is at this location where the EEG data is processed along with the foraging game results to calculate the physiological anxiety measure. Once the anxiety measure is calculated, the immediate test result is saved and trended along with past test results from the same patient, allowing the user or provider to view current patient status and progress over time. The data platform will be accessible via the app or a website interface (image 4 in Figure 10) for both the provider and the patient (image 5).

Future Development Pathway

To date we have illustrated proof-of-concept for our system and algorithms through pilot headgear, prototypes showing brain data transfer to a cloud-based data platform and proven our anxiety algorithms with human studies with nearly 1,000 people. Our company focus is to convert these proof-points into a commercial product that is easy to use, fits within current practice workflows, and

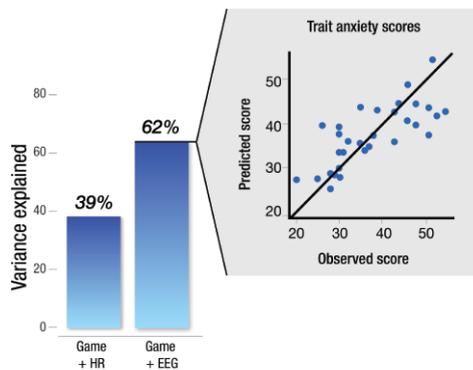


Figure 7: Our algorithms can also be used as a continuous measure for higher resolution monitoring of anxiety. Our EEG approach provides the highest accuracy: the game in conjunction with EEG provides a 62% explained variance (explained variance = 1 – error variance) compared with a 39% explained variance using a combination of the game and heart rate.

enables precision and personalized medicine in the behavioral health space. We anticipate completing development in the near future and working with the FDA and other international regulatory bodies to launch a clinical study to show efficacy of our vital sign in clinical practice. Quantitative targeted endpoints being contemplated include: accuracy of our vital sign and screening effectiveness that would greatly surpass current measures (e.g., surveys); reduction in patient ER visits with

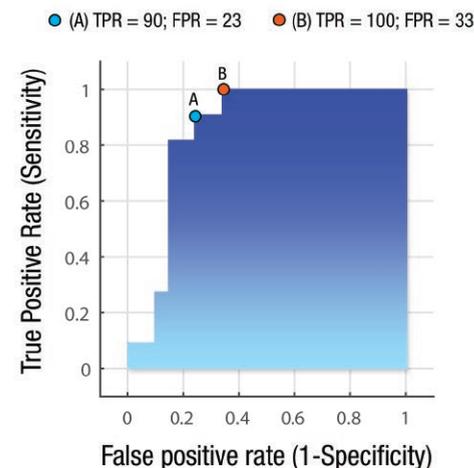


Figure 8: The receiver operator curve shows a trade-off of measurement sensitivity and specificity for purposes of optimizing the anxiety algorithm. For initial screens, we adjust the algorithm to point (A), which creates a 90% true positive rate and a 23% false positive rate, matching the false positive rate of today's standard of care, validated surveys. Once a patient has been identified and has entered treatment, the likelihood of that patient of being a false positive is low, so we can adjust the algorithm parameters to point (B), providing a greater true positive rate of 100% for improved trending with a tolerable increase in the false positive rate to 33%.

a diagnosis of panic or anxiety; reduction in overall treatment visits; and overall cost impacts.

Beyond anxiety, we see the potential to create a suite of behavioral health tools. Initial research shows that our approach can be expanded beyond anxiety to other behavioral and mental health ailments such as depression, ADHD, and potentially Alzheimer's Disease screening. Initial studies have been performed with depression patients undergoing transcranial magnetic stimulation and pilot studies indicate that the combination of our EEG data and algorithmic approach could be useful for preliminary assessment of ADHD.

The algorithms and approach appear robust based upon our studies completed to-date and we foresee a potential path to reach our first objective, namely, a physiological vital sign of anxiety. Our next steps to implementation in clinical practice start first with completion of the gamified portion of our algorithm with the caveat that the patient must be cognitively aware and physically capable of completing the task. This may be difficult for mental health patients having severe episodes or those patients suffering from neurological diseases that impact dexterity, such as Parkinson's Disease.

Second, in the case of a patient undergoing anxiety therapy and working with a clinician, we anticipate having a headband dedicated to each patient to enable remote monitoring between sessions. With this model, pricing can be on par with other remote monitoring devices and fits within existing CMS and private insurance codes.

In the case of initial screening, however, it would

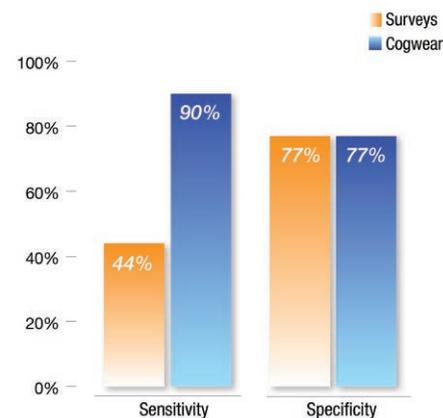


Figure 9: When optimized, the complete algorithm identifies low, medium, and high anxiety at approximately twice the sensitivity of validated surveys (90% vs 44%) with the same specificity (77%). This means that we expect to properly capture twice the number of anxiety patients during screening without increasing the number of patients falsely identified.

not be cost-effective to create a headband for each patient. Moreover, the COVID-19 pandemic has heightened our awareness regarding cleanliness and sterility, especially when products are shared amongst patients. To address this issue, we are considering two approaches: a washable headband and cleaning procedure at the site-of-care and a tiered version of our product using only the gamified algorithm. With the latter approach, we could provide a low-cost, tablet version of our assessment that would provide better accuracy than existing surveys but less overall accuracy than the

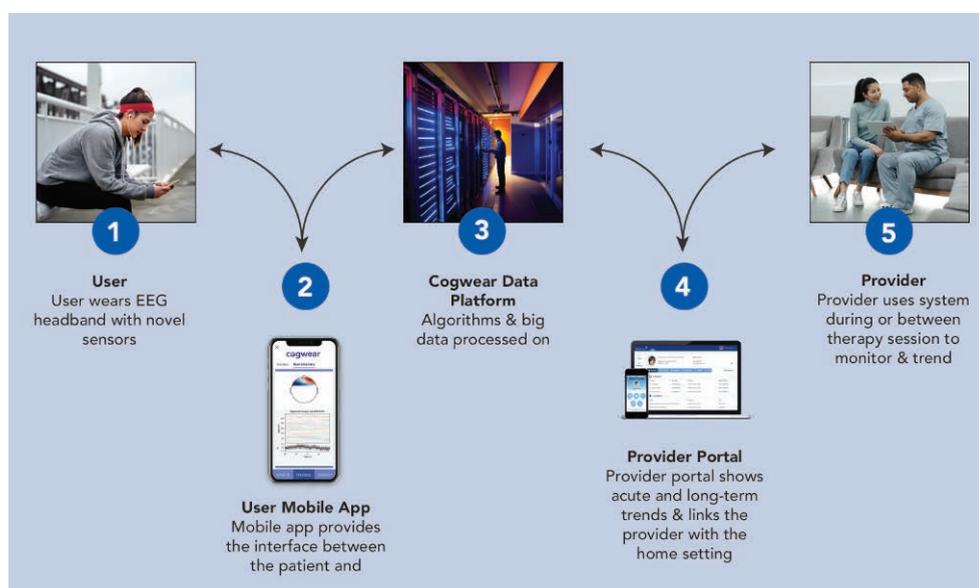


Figure 10: The Cogwear system consists of three main components: a wearable EEG, a mobile device application, and data platform. Data is collected from the wearable EEG from the mobile device, which also houses the game portion of the algorithm. Data is streamed to a HIPAA-compliant data platform for processing, storage, and long-term trending. Both the patient and clinician would have the ability to review individual anxiety measurements and patient trends.

combination of the gamified algorithm and EEG. With this method, self-reporting bias and demand effects of surveys would still be avoided, and a two-step process could be employed where EEG is utilized in a repeat test in cases with questionable results or where more specific information is necessary.

Future Impacts

Cogwear is well-positioned to help the 260 millionplus people worldwide suffering from anxiety disorders. By creating a precise, physiological measure of anxiety, behavioral healthcare has the potential to leverage a true vital sign to impact the standard-of-care. This will provide clinicians with a better screening capability of mental and behavioral health and give patients greater insight into the triggers of their anxiety and better ways to mitigate their response. Patients in therapy or longer-term care will have a method to provide remote monitoring of their conditions between sessions and the predictive nature of our method creates a quick and inexpensive method to personalize selection of treatments (e.g., pharmaceuticals or talk therapy) while providing data to treatment effectiveness in a shorter period of time. Payers will have a record of a physiological measure – treatment paradigm to help assess care quality and an indicator of how to continue to improve cost effectiveness.

In a final note: during our discussions with clinicians, administrators, and payers, one executive commented that a strategic push of their organization is determining how to address the next pandemic: the exploding mental health crisis. Anxiety is just the first application of the Cogwear system with expansion potential into depression, ADHD, and Alzheimer's Disease. With added precision of physiological measures of behavioral and mental well-being, we have the promise to slow this growing problem. ^{KPM}



David Yonce

David Yonce is the CEO of Cogwear and a 23-year veteran of the medical device industry. Prior to Cogwear, he has held management and executive positions at a variety of medical device companies including Guidant, American Medical Systems, Endo Health Solutions, and DSM Biomedical. He has a track record of turning-around and positioning companies for growth and acquisition, has helped deliver more than 50 products to market, and has been awarded 54 patents. He is an advisor for start-up companies Artemedics and Trace Orthopedics, serves as grant reviewer and advisor for the North Carolina Biotechnology Center and the University City Science Center, and guest lectures at the University of Pennsylvania within Organizational Dynamics and the Wharton School. David holds an MBA from the University of Chicago Booth School of Business, an MS in Electrical Engineering from the University of Maryland, and a BS in Electrical Engineering from Cornell University.



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Michael Platt

Michael Platt is a founder and scientific advisor of Cogwear and is the James S. Riepe University Professor at the University of Pennsylvania with triple appointments in the Department of Psychology, the Perelman School of Medicine, and the Wharton School of Business. He recently published the book, *The Leader's Brain*, which applies neuroscience concepts to business. Michael is published in numerous scientific journals and serves as a scientific advisor to Amplio, Neuroflow, Blue Horizon International, and Progenity, Inc. He previously served as the president of the Society for Neuroeconomics and served on the World Economic Forum's Global Council on Neurotechnology. Michael holds a PhD in Bio. Anthropology from the University of Pennsylvania and a BA in Bio. Anthropology from Yale University.

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- * ROC curves are typically used to assess the diagnostic ability of a binary classifier as a function of expected (true) vs false positives by varying the discrimination threshold.
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