



NIDA \$100,000 Startup Challenge

OVERVIEW

PainQx aims to tackle the opioid epidemic by providing an objective pain measurement tool to physicians thereby addressing the over and under dosing of medication, and consequently reducing opioid abuse.

RESEARCH IDEA

Chronic pain affects 116 million Americans more than heart disease, cancer, and diabetes combined. In 2012 healthcare providers wrote 259 million prescription painkillers enough for every American adult to have a bottle of pills. Between 1999-2014 prescription opioid overdoses killed more than 165,000 Americans¹.

Studies have demonstrated that an increase in opioid prescriptions is related to an increase in abuse and overdoses due to the increased accessibility of the drug. A 2014 study of non-medical opioid users found that 54% of opioid abusers get opioids from a friend or relative for free, 19.7% are prescribed the medication from a physician, 11% buy from a friend, 4.9% steal from a friend, and 4% buy from a dealer².

Despite the huge prevalence of chronic pain, physicians currently have no objective measure of pain to assess the clinical severity or intervention outcomes. The current Standard-of-Care is a subjective pain scale known as the visual analog scale (VAS). The VAS requires patients to verbalize their pain levels on a scale from 0-10 while non-verbal pain patients are monitored by doctors who gauge behavioral markers in order to interpret at matching VAS score³. The VAS entirely depends on patient self-report, is not reliable within nor between patients, and is not verifiable or replicable by the physician. More importantly patients struggle to differentiate between pain states in the middle of the scale 3-7.

The prevalence of chronic pain and the growing opioid epidemic go hand in hand; the VAS leads to inaccurate assessment of a patient's pain state at baseline and follow-up creating uncertainty in the appropriate dosage of medication and treatment option. As a result, patients are often over-treated or under-treated leading to adverse effects on the patient and the health care system.

- Over-treatment of patients leads to addiction as manifested by the opioid epidemic.
- Under-treatment of patients leads to unnecessary pain and suffering often having the consequence of patients switching to illicit medication or other narcotics.

By providing physicians an objective pain measurement tool PainQx believes it will allow doctors to increase the certainty in dosing and treatment thereby addressing the over and under treatment paradigm consequently reducing opioid abuse.



TECHNICAL COMPETENCE

Frank Minella is a serial entrepreneur with a background in consulting from Accenture Pharma industry group where he helped launch Prilosec, a proton pump inhibitor that decreases the amount of acid produced in the stomach commercialized by AstraZeneca and Merck. Frank also brings 12 years of military experience as US Army Officer and Captain Aviator as a MEDEVAC pilot. Frank's military experience brings valuable leadership and execution skills that translate into getting the mission completed.

Leslie Prichep is the inventor of the PainQx platform and an advisor to PainQx. Until early 2015 Dr. Prichep was the Director of the Brain Research Laboratories (BRL) and Professor of Psychiatry at New York University School of Medicine, where she remains a Professor in retirement. She has extensive experience and recognition as a pioneer in the field of quantitative electrophysiology, clinically applied translational research, source localization, and multivariate classification methodologies. She was responsible for the direction of the largest existing database of quantitative electrophysiological data from normal subjects and neuropsychiatric patients, which includes traumatic brain injury, post-concussion syndrome PTSD and dementia patients. Dr. Prichep and her colleagues at BRL were the first to publish normative equations demonstrating that features of the EEG could be lawful as a function of age. Dr. Prichep has over 136 publications that have been cited over 4,700 times, another 55 book chapters, books, published proceedings and monographs, holds a number of patents and is considered one of the preeminent research scientists in the field of computerized electrophysiological. Dr. Prichep has been working with PainQx since its inception in 2015.

PRODUCT PROTOTYPE

PainQx is a neural analytics platform that can objectively measure pain in humans. The PainQx platform achieves this by assessing neural activity from a patient's brain and decoding the data through proprietary its algorithms. The output is a scaled pain and neurological side effects biomarker that is directly correlated to a patient's pain state.

The PainQx platform is delivered to the user through a SaaS model using mobile, low-cost quantitative electroencephalography (QEEG) through cloud-based software, on a pay-per-use or subscription basis. All hardware inputs are inexpensive, lightweight, off-the-shelf ready, requiring no development from PainQx; thus providing great clinical utility and ease of use. PQX has completed human proof of concept and demonstrated the platform's predictive ability to assess a patient's pain state by decoding his/her neural activity⁴

PainQx's exclusive license to the NYU Brain Research Normative Database (BRND) is the key feature allowing PainQx to decode neural activity. The BRND is a data set of EEG records from 20,000 patients collected over 30 years. The BRND is the largest database in the world and is one of two databases of its kind available. PainQx has the ability to reference this dataset and compare chronic pain patients to it. Without access to a normative database like the BRND it is impossible to identify abnormal brain activity as normal is left "undefined". PainQx has used the



BRND to identify patterns in the over and under activation of neural activity to create an algorithm that can predict a patient's pain state.

The process to generate a pain score is simple: 5 minutes of a patient's neural activity is collected using a standard 19 lead EEG device, data is exported as an encrypted file to PainQx via the cloud to a secure data room. After receipt of the data, PainQx decodes the information in the file to produce both a pain score similar to that which would be reported on the VAS as well as brain imaging to demonstrate the patterns of over and under activation.



APPROACH & MARKET NEED:

PainQx has performed two market surveys interviewing more than 100 pain physicians demonstrating that an objective pain measurement device like the PainQx platform is sorely needed in the marketplace, and that chronic pain physicians are willing to adopt it in their practice. Below is summary of the finding from the Mass General Hospital Consulting Group:

- 64% of the 85 physicians surveyed are dissatisfied with current pain measuring methods
- 73% of the 85 physicians surveyed are very to moderately concerned about improper dosing of pain medication due to current assessments of pain
- 92% of the 85 physicians surveyed want to use an objective pain measurement tool

PainQx is currently conducting a clinical study sponsored by New York University to validate that PainQx platform can detect the analgesic effect of a therapeutic intervention.



PainQx will demonstrate this through the relationship between changes in an electrophysiological biomarker of pain and reported changes in perceived pain following the intervention. A secondary goal will be to extend and replicate preliminary data suggesting a significant regression between self-report of pain severity and abnormality in QEEG markers of pain. The study will be testing 50 chronic pain patients tested initially at their baseline pain state and then re-evaluated once they reach a therapeutic level of a pharmacological intervention.

PainQx would like to use NIDA Challenge funds to include a tertiary endpoint that measures medication consumption as a function of the correlation between the patient reported pain scores and the PainQx predicted scores. PainQx predicts that in instances where the PainQx score and the patient reported score deviate substantially patients will be more likely to report medication abuse. The research will provide a rational process for identifying patients as likely to abuse medication and thereby can benefit from improved pain management. Managed care organization, employers, and other groups interested in responding to calls for improved pain management from professional and governmental organizations and accrediting bodies can combine these biomarkers with intervention programs to improve the quality of care and reduce unnecessary health care costs.

REFERENCES

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