Idea:

There are currently 2.6 million Americans struggling with opioid addiction[1]. For those individuals who are trying to attain sobriety, the annual relapse rate is up to 60% [2]. In 2013, it was estimated that this epidemic costs the U.S. \$78.5 billion annually in healthcare expenses and lost wages[3]. Extensive research has demonstrated that the presence of positive, sober relationships in an individual's social network can have a tremendous impact on maintaining sobriety[4]–[7], and that the inability to escape social triggers in the environment that promoted drug use is a major barrier to abstinence[8], [9]. Other studies have shown that automatic notification systems are effective for behavioral modification in addiction[10], yet no technology to date has combined this with social communication patterns to provide 24/7 support for individuals struggling with addiction. Furthermore, the notion of 'digital phenotyping' is gaining momentum in the behavioral and mental health arenas under the hypothesis that information

collected digitally through passive mobile sensing will lead to insights about complex disorders that are strongly influenced by social and environmental factors[11], [12]. This in turn can inform personalized treatment protocols for individual patients.

Hey, Charlie is a non-invasive mobile behavioral modification platform designed to help individuals in recovery rebuild their social environments as well as enrich relationships with healthcare providers in order to build more targeted recovery strategies. This is realized through a series of automatic behavioral nudges on a mobile device that urge the patient to avoid communication with people and places that are unhealthy and negative to their recovery and to pursue and enrich relationships with people and places that are positive to their recovery. The goals of Hey, Charlie are two-fold: to determine if valuable behavioral modification can be achieved



Figure 1: Red regions show where an individual in recovery is alone during the day and required to self-enforce abstinence techniques.

in a recovery population through our smartphone platform, and to collect behavioral data through a patient's smartphone that can be assessed for digital phenotypes of recovery and delivered back to a healthcare provider for more effective intervention.

The collection of moment-to-moment behavioral data from individuals in recovery would provide a foundation for an entirely new way of studying addiction and understanding the patient experience. As OUD does not discriminate in the type of individual that it affects, this disease has an incredibly heterogeneous presentation and every patient's experience is unique. Collection of behavioral data from a diverse group of individuals in recovery would allow us to parse out different types of behavior patterns into 'digital phenotypes' that may lead to a better definition of subtypes of OUD and therefore a better understanding of personalized recovery strategies.

Figure 1 illustrates the amount of time in an individual patient's day where they are not immediately supported by a healthcare provider or recovery group and more vulnerable to environmental triggers. This represents a particularly well-supported individual, and most patients do not have daily sponsor calls, outpatient appointments, and recovery support group meetings. With an average relapse rate of 60% in this population, it is critical that these vulnerable time periods are addressed, but current tools to do so are lacking. With the ubiquity of smartphones, however, it is possible to develop new tools to fill these gaps and provide 24/7 support. The data collected using the Hey, Charlie platform will enable future work in two major domains. First, it will allow for personalized tailoring of behavioral 'nudges' to send to a patient in real-time in response to their actions in such a way that provides appropriately-timed interventions to help patients cope with triggers to relapse. Second, it will allow for a mechanism by which meaningful data can be relayed to a healthcare provider at the appropriate times when a patient is most vulnerable and most in need of external support.

Technical Competence:

Our core team consists of Dr. Emily Lindemer, Vincent Valant, and Ben Pyser. In May of 2017 Emily Lindemer completed her PhD in Harvard Medical-MIT's joint division of Health Sciences and Technology (HST) in Medical Engineering and Medical Physics. In this program, she published four first-author papers that all implemented data science methods to analyze and determine clinical outcomes from human subjects neuroimaging data. Within HST she had both course-based and hands-on clinical training through Harvard Medical School. To this end, Emily brings experience in human subjects research, behavioral science, grant writing, medical practice, and study design to the team. In May of 2017 she was awarded "Boston's 40 Under 40 for Healthcare Innovation" for her work in HST as well as with Hey,Charlie.

Vincent Valant is a management consultant with 6 years of experience working in the pharmaceutical industry. Vinny holds both Bachelor's and Master's degrees in Bioengineering from the University of Pennsylvania with a concentration in entrepreneurship that was geared at developing scientific research into medical products. Previously, Vinny has worked in small biotech companies at various stages in their lifecycle helping to develop and improve the production of their technologies. He has experience with the FDA approval process and the medical reimbursement landscape which will be essential for future adoption of Hey, Charlie.

Benjamin Pyser will contribute the majority of his efforts towards completing the development of the patient-side mobile application. As a full-stack engineer, he is well-versed in over ten languages, has developed in over ten frameworks, and has wide management and deployment experience. Pyser has over five years of experience in mobile application development at four different companies, one of which he is a co-founder. Pyser also heavily incorporates design and user experience into his products which will be of the utmost importance in the post-pilot design iterations of the Hey, Charlie platform.

Protoype:

Hey, Charlie takes effective components of cognitive behavioral therapy (CBT) to support patients 24/7 in the challenge of rebuilding their social environments. In addition directly helping patients. Hey Charlie also provides targeted feedback to healthcare providers to enhance the clinical experience with an ultimate goal of reducing relapse rate and improving quality of life during the recovery process. The core features of Hey, Charlie are based on the results of extensive

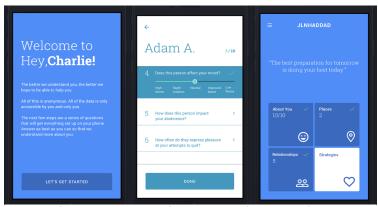


Figure 2: Onboarding screens for the patient-facing Hey, Charlie application onboarding process.

patient and clinician interviews that have been conducted by our team over the past six months. Onboarding: During initial onboarding, the patient will work with their clinician to set up the Hey, Charlie system for proper adoption, but they can also complete the onboarding process on their own. Hey, Charlie asks the patient to answer objective questions about individuals in their mobile contacts list that relate to recovery support and stress levels (Figure 2). These questions are taken from standardized behavioral science questionnaires and responses to these questionnaires have been demonstrated in the literature to be able to identify people that correspond with patients' recovery successes. Hey, Charlie uses response from these questions to calculate a "risk score" for each contact in the back end. The risk score also takes information into account such as how avoidable particular contacts are – i.e. if they are a roommate or a co-

worker, as well as situational factors such as time of day. Patients additionally identify *places* that are positive negative to their recovery and frequently-visited locations such as home, work,

and clinic. These processes mirror one of the first steps of CBT, during which patients assess how different components of their life – such as relationships and places – contribute to their recovery process. Beyond this, there is no daily input on behalf of the patient. The passiveness of the day-to-day experience with Hey,Charlie on the user end is a key feature, in that it does not add burden to a patient's daily life, but rather, it *reacts* to a patient's behavior as they move through their environment.

Notifications: The patients using the Hey, Charlie platform will receive automatic notifications which are designed to encourage communication with positive influences and away from risky individuals, based on the risk scores calculated during the onboarding process. Whenever communication is initiated with a risky individual – via text or phone call -- the patient receives a notification asking "Are you sure you want to talk to this person right now?" This moment of pause offers the patient a chance to stop and think before continuing communication, in an attempt to break impulsive behavior patterns (Figure 3). Likewise, if patients are within a certain radius of a negative location, they will receive a notification suggesting they go elsewhere. For prolonged communication with safelist individuals. patients receive positive feedback. These are techniques that have

been shown to work in addiction therapy, but have not yet been

made available to patients' moment-to-moment lives in an effective

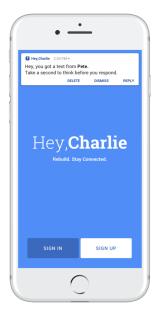


Figure 3: An example of a real-time notification sent to a Hey, Charlie patient immediately upon receiving a text from a 'risky' contact.

<u>Clinician Dashboard:</u> On the clinician end of Hey, Charlie, we will offer a dashboard of patient progress based on their communication and location patterns (Figure 4). With patient consent, providers receive summaries that inform them of changes in their patient's communication pattern that may be important to their recovery status. One of our

long-term goals is to develop datadriven algorithms that can additionally suggest likelihood of relapse based on communication and location patterns. This feedback maintains patient privacy by offering anonymized scores that inform the patient of increased or decreased negative communication patterns, but not information about specific individuals or places. Not only does this clinician dashboard offer the potential to intervene at critical moments of patient vulnerability, but at a more immediate level it also has potential to improve the rehabilitation experience by allowing for deeper and richer conversations between patient and

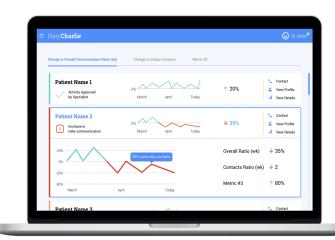


Figure 4: Example of clinician-facing Hey, Charlie dashboard with accredate behavioral data collected from a patient's smartphone.

provider, which would allow for more fine-tuned strategies for patients to remain in recovery.

Methods:

<u>Work to date:</u> The Hey,Charlie team has been conducting extensive market research to both refine the concept and asses the market potential. Through interviews with experts in the field such as treating clinicians and social workers as well as with people who are currently in recovery, we have developed a thorough understanding of the unmet needs facing this population. This data has driven the Hey,Charlie designs, processes, and mock-ups which have been supported by a successful technical proof of concept. The aims through this challenge are to take Hey,Charlie the final step and complete the MVP which can be piloted in real end-users. We have a set of potential pilot centers and will be looking to pilot in a few months, upon completion of the MVP.

<u>Piloting Sites:</u> While conducting market research we have developed relationships in the addiction space which we plan to leverage for a fast pilot launch. These relationships have developed into leads for potential pilot sites across a variety of settings. The first potential pilot site, Boston Medical Center, has been a strong collaborator Hey, Charlie currently has an IRB-backed usability test ongoing in one of their clinics and addiction specialists who treat both adults and adolescents have expressed their excitement for a pilot with Hey, Charlie. Behavioral Health Innovators (BHI) is an organization which facilitates adolescent recovery programs and works closely with recovery high schools. We were able to connect with BHI and they are excited about the idea of having a product that would help their therapists and recovery coaches connect more deeply with their adolescent client base. ColumnHealth is an privately owned organization that runs outpatient addiction clinics. We have been in touch with the medical director of ColumnHealth who has provided feedback on the platform. He has also expressed interest in Hey, Charlie to help them stay more consistently connected with their patients and to empower data-driven treatment decisions and provide a comprehensive patient experience.

Data Collection: The Hey,Charlie platform will be data driven by socially-tagged communication patterns. This novel data will be anonymously collected and aggregated in the long term to determine the efficacy of the platform and quantify behavioral patterns associated with SUD with a long term goal of developing 'digital phenotypes' of recovery. During the course of this NIDA challenge, however, the proposed pilot will be focusing on more tangible data points. Some of the data which will be collected during the pilot will include: reactions to various types of notifications at various times in order to better understand and refine the user experience, weekly self-reported PHQ-4 surveys to assess changes in mood as they relate to communication patterns, and we will conduct interviews with the app users and their clinicians to more deeply understand each sides' experience and determine further unmet needs that may be addressable. The platform thus far has been shaped by research and experts in the field and will continue to be shaped from real-world quantitative feedback.

<u>Validation:</u> There will be a few ways in which we will measure the market potential for Hey,Charlie. Continued usage of the platform as measured by technical activity logs and follow-ups with pilot participants will be a strong indicator of real-world compliance. We will also conduct interviews with clinicians to understand how they and their patients are using the system to gain a better understanding of various use-cases. Different use-cases will have different drivers and barriers for adoption and it is important to characterize them so that the value provided can be quantified for future monetization. After early feedback of successful pilots, discussions with purchasing departments will be conducted to negotiate continued usage of the platform and access to their patients data and insights. As our healthcare system moves to a more value-based approach to purchasing and reimbursement, we aim to provide an tool to generate value through keeping their patients engaged with this platform which will lead to better adherence to treatment programs and higher overall recovery success rates.

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