

# SOLACE: An Early Warning System for Adolescent Suicidality

A Translational Science Benefits Model case study



## NAME/TITLE OF INVESTIGATOR:



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## SUMMARY OF THE PROJECT

The goal of this work is to create technology that uses physiological measures to help adolescents identify worsening symptoms of stress dysregulation associated with worsening suicidality (SI). This will allow early identification and interventions to prevent emergency department visits and suicide attempts (SA). Dr. Sheridan and his team are in the process of testing technology that will be available in wearable devices such as smartwatches. This technology measures activity, sleep, and heart rate variability in adolescents with acute suicidality. Once the technology proves to be accurate in measuring these physiological outcomes (current wearable technology provides low quality data on metrics that cannot be relied upon for this level of medical intervention), algorithms will be set so that patients receive timely feedback on their stress levels so that they can implement their own coping strategies (e.g., meditation, deep breathing, reaching out to informal supports). This, in turn, will help prevent SI/SA because patients are informed of their own biological responses and then empowered to act in order to prevent their own potential SI. This data feedback loop is parallel to a person with diabetes checking their blood sugar in order to prevent serious highs and lows.

This research project received an OCTRI Biomedical Innovation Program (BIP) award in 2017. Approximately 10 months prior, Dr. Sheridan worked with an engineering team to develop the technology and a wearable wrist device. The research team includes engineers with medical device expertise, Steven Baker PhD, and computer science expertise, Ryan Dehart as well as research coordinator, Nancy Le. Dr. Sheridan then was able to secure a K12 award from the National Institute of Mental Health through the Department of Emergency Medicine. His mentors include Bonnie Nagel PhD, Matthew Hansen MD MCR, Craig Newgard MD MPH, Cindy Morris PhD and Aditi Martin PhD to further his project.

Currently, a pilot project is underway to collect patient data and verify the accuracy of the measured physiological outcomes. Additionally, these data will be used to create an algorithm to recognize when a patient's stress levels exceed prescribed norms and immediately alert the patient. A larger clinical trial, scheduled to be

completed in 2022, will collect additional data which will result in a refinement in the technology and assessing the ability of therapeutic interventions to modify these physiologic parameters. Assuming on the market technology will improve the ability to collect accurate physiologic data, this technology has the ability to be incorporated into existing technology around 2025. Long-term impacts such as decreased SI/SA and cost effectiveness will occur after that.

## SIGNIFICANCE OF THE PROGRAM

This project was motivated by a substantial increase in suicidal patients presenting in the emergency room, especially adolescents. Suicide is the second leading cause of death in youth ages 10-24<sup>i</sup>. Emergency Department (ED) visits of suicidal adolescents has doubled in the past nine years, with estimated annual visits for SA/SI between 2007 and 2015 increasing from 580,000 to 1.12 million<sup>ii</sup>. Additionally, there is an economic cost to suicide in the United States. In 2013, the Centers for Disease Control estimated that the United States lost \$50.8 billion dollars in medical and work loss costs<sup>iii</sup>.

## SIGNIFICANCE OF THE APPROACH

### PROJECT TIMELINE

- February 2016: David Sheridan and Engineering team partnership formed.
- June 2016: Temporary device developed: A wearable watch was developed to collect physiological data in the pilot and clinical trial.
- January 2017: David Sheridan receives OCTRI's Biomedical Innovation Program Award
- July 2019: NIMH K12 grant
- Spring 2020: Data from pilot test analyzed.
- 2022: Clinical trial results.
- 2022: Algorithm developed.
- 2025: Technology refined and incorporated into existing wearable technology.
- Measure longer-term impacts like cost savings. etc. (No date set)

Using technology to monitor mental health is a huge paradigm shift, as there is low use of physiological monitoring to prevent suicide. Currently, suicidality is assessed primarily via pen-and-paper measures administered by a mental health professional; this method can be overwhelming and cumbersome during a mental health crisis and is not designed to prevent SI. Additionally, access to mental health providers is not always possible due to costs and availability.

Another significance of this approach is that it puts the data, and therefore the assessment and ability to act, in the patients' control so they are empowered to act on their stress in a timely manner.

## TRANSLATIONAL SCIENCE BENEFITS SUMMARY

Benefit	Domain	Indicator
Help prevent SI using physiological metrics.	 CLINICAL	Diagnostic Procedures
Support the prevention of SI/SA by identifying increased dysregulation in patients.	 CLINICAL	Therapeutic Procedures
Development of wearable device technology measures physiological responses.	 CLINICAL	Biomedical Technology
Development of wearable device technology will provide feedback to patients on patient physiological stress.	 CLINICAL	Software Technologies
Technology to help prevent suicide attempts will be worn in the community.	 COMMUNITY	Community Health Services
Data from wearable device can help prevent SI/SA, a public health issue	 COMMUNITY	Consumer Software
Provide patient and family with the data needed to implement coping skills during times of higher stress.	 COMMUNITY	Healthcare Delivery
Support access to mental healthcare by providing data direct to patient without needing assessments given by mental health provider.	 COMMUNITY	Healthcare Accessibility
Provide data direct to patient about their wellbeing so they can act on it to reduce stress.	 COMMUNITY	Disease Prevention & Reduction
Reduction of SI/SA by notifying patients to implement coping skills in times of stress.	 COMMUNITY	Life Expectancy and Quality of Life
Establishment of an intellectual property license for the algorithms and the technology.	 ECONOMIC	License Agreements
Development of a start-up to develop and manufacture wearable device technology.	 ECONOMIC	Non-Profit or Commercial Entity
Patents and copyrights will be filed for the technology.	 ECONOMIC	Patents
Fewer SI/SA-related ED visits in adolescents.	 ECONOMIC	Cost Effectiveness
Fewer SI/SA-related ED visits in adolescents.	 ECONOMIC	Cost Savings
Saved lives	 ECONOMIC	Societal & Financial Cost of Illness

## BENEFITS OF THE PROGRAM

This research has clinical, community, and economic implications.

### Clinical

Dr. Sheridan and his team have developed wearable device technology to monitor the physiological responses of adolescents with acute suicidality. As of December 2019, pilot data have been collected on 75 adolescents who were admitted to the Emergency Department with acute suicidality; results from this pilot will be ready in Spring 2020 and will help determine the accuracy of the physiological data gathered from the wearable device technology as well as its associations with reported suicide severity scores. From these results, algorithms will be set to have the wearable device signal the patient and their family when to act on stress levels through already-established coping mechanisms. Currently, there are no physiological standards for SI/SA and the paper standards are cumbersome.

By 2022, results of a clinical trial (n = 200) will be assessed to validate pilot results, and the wearable device technology will be fine-tuned for wider distribution. The end result will be the availability of technology that can be incorporated into already-existing wearable devices. This technology will create physiological analytics that can be monitored in the community by the patient and their family to create a therapeutic window to address precursors to SI. Many people with SI already have the tools to cope, but do not use them until times of high crisis. By monitoring physiologic responses, the wearable device can signal to the patient when – and how – to implement those tools before a crisis is experienced.

### Community

One of the benefits of this technology is the ability for patients to use it in the community. Levels of stress and dysregulation will be monitored by the patient in the outpatient world to diagnose stressful times that can lead to SI/SA. By providing patients with data they can act on with coping skills, this can decrease the need for mental health providers that aren't always available due to large caseloads, patient costs, insurance coverage, or geographic availability.

Another benefit is that the algorithms used to signal the patient are designed to help prevent, rather than react to, acute suicidality. Suicide is a public health concern given its high economic and social costs to individuals, families, and communities. This device has the potential to signal dysregulation and stress in a patient so they can act to prevent SI. This, in turn, can prevent SA and ED overuse, as well as improve quality of life for not only the patient, but those around them.

### Economic

Shorter-term economic benefits include license agreements and patents to protect the intellectual property of both the algorithms and the technology itself; this process is underway. Once the technology is refined, a start-up company will be developed to manufacture the components of the wearable technology.

Longer-term economic benefits include the cost savings and effectiveness; this may occur through a reduction in the 1.2 million annual ED visits due to SI/SA. This technology doesn't just have the capacity to save money, however; this technology is designed to save lives.

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<sup>i</sup> National Institute of Mental Health. Suicide. Accessed online at <https://www.nimh.nih.gov/health/statistics/suicide.shtml> on December 17, 2019.

<sup>ii</sup> Burstein, B., Agostino, H., Greenfield, B. (2019). Suicidal attempts and ideation among children and adolescents in US emergency departments, 2007-2015. *JAMA Pediatrics*, 173, 598-600.

<sup>iii</sup> Florence, C., Simon, T., Haegerich, T., Luo, F., & Zhou, C. Estimated Lifetime Medical and Work Loss Costs of Fatal Injury. United States 2013. *Morbidity and Mortality Weekly Report* 2015; 64(38), 1078-1082.