ResultsOHIO

Veteran Suicide Prevention: A Feasibility Assessment of Prospective Pay for Success Approaches

Completed On:

June 13, 2024

Introduction and Objective

Ohio is home to a significant U.S. miliary veteran population. As of 2022, Ohio's veteran population stood at 602,318.[1] This is the most recent year for which data is available. Over the past ten years, Ohio has followed the national trend of increased suicide among its residents over the past ten years. Ohio's suicide rate ranks 18th among all 50 states with 15 suicide deaths per 100,000 residents.[2] Suicide is the 5th leading cause of death among individuals aged 15 to 64, with 1,416 suicide deaths recorded within that age cohort in 2022.[3] Five Ohioans die by suicide every day.[4]

Suicide rates and trends among Ohio's civilian population are alarmingly amplified within the state's veteran population. According to an analysis generated by the U.S. Department of Veterans Affairs, "...the veteran suicide rate was not significantly different from the national veteran suicide rate," but was "significantly higher than the national general population rate."[5] In 2021, the most recent year for which data is available, 242 Ohio veterans died by suicide.[6] Ohio's veteran suicide rate per 100,000 in population was 33.9 which matched the national veteran suicide rate of 33.9.[7] The suicide rate among Ohio veterans ages 18 to 34 was a shocking 65.0 per 100,000 in population.[8] Ohio's suicide mortality rate within this age group is substantially higher than the companion national rate of 49.6.[9] The Ohio and U.S. veteran suicide rates among those age 18 to 34 is shockingly higher than the companion civilian rate of 18.8 per 100,0000 in population.

---

[1] https://usafacts.org/topics/veterans/state/ohio/

[2] America's Health Ranking, UnitedHealth Foundation. https://www.americashealthrankings.org/explore/measures/suicide/OH

[3] Data Snapshot: Suicide in Ohio, Health Policy Institute of Ohio (2023), https://www.healthpolicyohio.org/files/publications/datasnapshotsuicidefinal.pdf

[4] Data from the Household Pulse Survey, 2020-2023, as compiled by Kaiser Family Foundation. "Adults Reporting Symptoms of Anxiety or Depressive Disorder During COVID-19 Pandemic." KFF. Accessed June 13, 2023.; Suicide Demographics and Trends, Ohio, 2021. Ohio Department of Health, 2023.

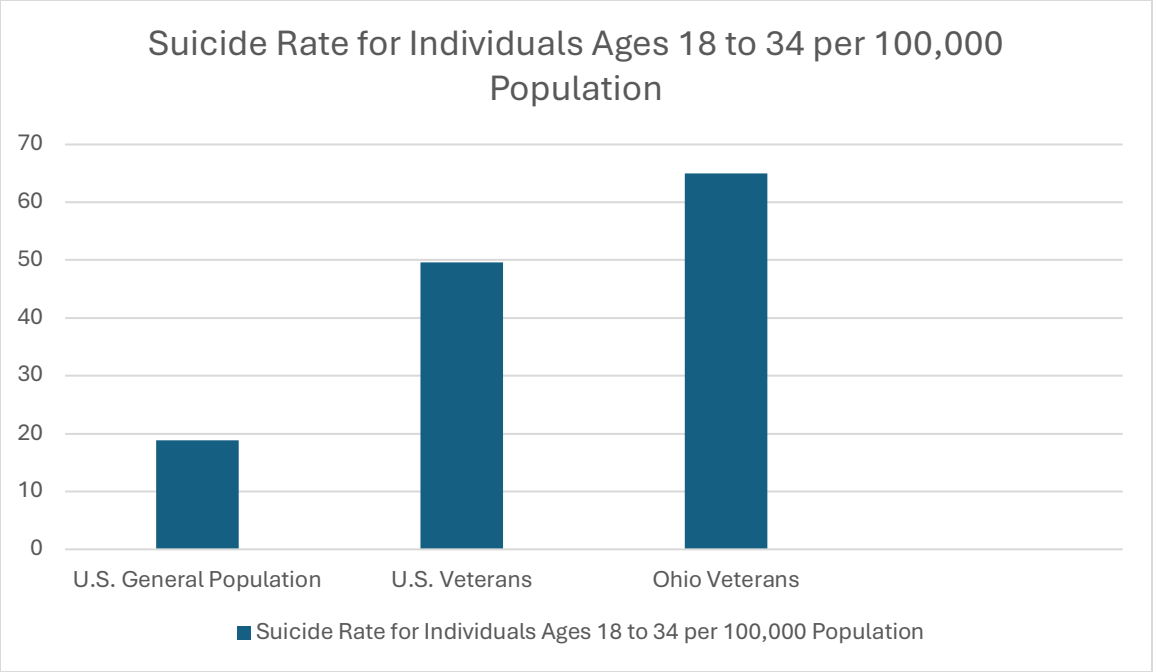
[5] Ohio Veteran Suicide Data Sheet, U.S. Department of Veterans Affairs (2023), https://www.mentalhealth.va.gov/docs/data-sheets/2021/2021-State-Data-Sheet-Ohio-508.pdf

[6] *Supra*

[7] *Supra*

[8] *Supra*

[9] *Supra*



The Ohio Treasurer of State has created a "Pay For Success" program entitled "ResultsOHIO." Through "ResultsOHIO," private investors and/or private philanthropists fund innovative projects which address some of Ohio's most intractable socioeconomic and public health problems. This model allows for the creation of unique, experimental social service delivery services and mechanisms which government may not have the flexibility to execute within prevailing legal, logistical, or financial conditions. Projects are designed to have measurable outcomes which are capable of being objectively quantified and verified by third party evaluators. Upon verification that a project has successfully met predefined success metrics, public funds which have been pre-appropriated to solicit and fund potential projects are used to reimburse the investor/philanthropist upon certification of successful program completion. The purpose of this report is to explore the feasibility of utilizing "ResultsOHIO" to fund a mobile mental health clinic for Ohio veterans with the goal of preventing veteran suicide. The mobile unit will serve as an intake and evaluation center for veterans experiencing symptoms consistent with post-traumatic stress, traumatic brain injury, substance dependence, and other mental health issues which increase suicide risk among veterans. The forerunner of this concept was the successful execution of a "Pay for Success" mobile vision unit which conducted eye exams and provided eyeglasses to underserved children in several of Ohio's Appalachian counties. The mobile delivery of critical health services aims to enhance the delivery of healthcare services to vulnerable populations while reducing costs and improving individual long term health outcomes.

Clinicians who staff the unit will evaluate veteran patients and supply them with all necessary support to obtain necessary mental health treatment services. In addition to existing mental health treatment options, clinicians will screen veterans to determine individual interest and diagnostic eligibility to receive treatment with a class of novel therapeutics known as neuroplastogens. This therapeutic class is part of an emergent field of neuroscience which appears to offer breakthrough efficacy for the amelioration of conditions which are resistant to currently available modalities. Conditions for which neuroplastogens have demonstrated significant promise in research studies include treatment-resistant depression, treatment-resistant anxiety, severe post-traumatic stress, substance misuse, and traumatic brain injury. All of these morbidities are substantial contributors to suicidality and suicide. All are disproportionally prevalent within the veteran population across the United States. There is an urgent need to develop and deploy novel therapeutics and therapeutic systems which can address the severe complexities of veterans' mental health needs, especially in the aftermath of almost 23 continuous years of wartime deployments by an all-volunteer force since September 11, 2001.

Veteran Suicide Trends, Available Treatments, and Treatment Efficacy

On June 21st, 2021, The Watson Institute for International and Public Affairs at Brown University published findings related to veteran suicide trends and causes within an ongoing research project entitled "Costs of War." Within a set of research papers entitled, "20 Years of War: A Costs of War Research Series," Thomas Howard Suitt, III authored a specific paper entitled, "High Suicide Rates among United States Service Members and Veterans of the Post-9/11 Wars."[10] Suitt observes that:

> An estimated 30,177 active duty service members and war veterans of the post-9/11 wars have died by suicide, significantly more than the 7,057 killed in "Global War on Terror" military operations. This marks a failure by the military and U.S. society to manage the mental health cost of our current conflicts.[11]

Suitt goes on to critique various treads which he and his research team identified through data analysis:

---

[10] Howard Suitt, I., PhD, Boston University, Neta Crawford, Stephanie Savell, & Heidi Peltier. (2021). High Suicide Rates among United States Service Members and Veterans of the Post-9/11 Wars. *Costs of War*. https://watson.brown.edu/costsofwar/files/cow/imce/papers/2021/Suitt_Suicides_Costs%20of%20War_June%2021%202021.pdf

[11] *Supra at Pg. 3 citing* U.S. Department of Defense. (2021). Casualty Status as of 10 a.m. EDT May 10, 2021. https://www.defense.gov/casualty.pdf

> This trend is deeply alarming. The increasing rates of suicide for both veterans and active-duty personnel are outpacing those of the general population, marking a significant shift. Historically, suicide rates among active component service members have been lower than suicide rates among civilians. Elizabeth P. Van Winkle, the U.S. Department of Defense's (DoD) Executive Director of Force Resiliency, explained, "suicide rates for active component and reserve members [were] comparable to U.S. population rates after accounting for age and sex." The DoD reiterates that point in its annual suicide reports; however, the current rate has increased to meet the age-adjusted civilian suicide rate and has now surpassed it. That the current rate is commensurate with the civilian rate after historically being far lower ought to raise concerns. Meanwhile, suicide rates among post-9/11 war veterans surpass civilian rates. The growing crisis is especially pressing because veterans of post-9/11 conflicts are disproportionately dying by suicide compared to previous military service eras.[12]

The disproportionate rate of suicide among post-9/11 veterans receives extensive analytical attention throughout the paper. Suitt observes that there are common contributors to suicide and suicidal ideation which are common to all armed conflicts. He defines these contributors as including high exposure to physical, mental, moral, and sexual trauma; stress and burnout; and the difficulty of reintegrating into civilian life.[13] Given these commonalities within wartime experiences, Suitt proceeds to examine factors which differentiate post-9/11 conflicts from those of the past. He writes:

> For example, since the post-9/11 wars began, we have seen a tremendous rise of improvised explosive devices (IEDs) in warfare, significantly increasing the number of traumatic brain injuries (TBIs) and polytrauma cases among service members.9 TBIs have affected as many as 20 percent of post-9/11 service members, with many experiencing more than one during their career.10 Simultaneously, the length of the war and advances in medical care have allowed service members to redeploy after severe physical trauma. These compounding traumas contribute to worsening suicide rates as service members deploy and redeploy after sustaining severe injuries. Together, these and other factors may account for current veteran and active duty suicide rates.[14]

---

[12] *Supra at Pg. 3, Elizabeth P. Van Winkle as cited in* Lopez, C. T. (2019, September 26). DOD Releases Report on Suicide Among Troops, Military Family Members. U.S. Department of Defense. https://www.defense.gov/Explore/News/Article/Article/1972793/dodreleases-report-on-suicide-among-troops-military-family-members/

[13] *Supra at Pg. 3.*

[14] *Supra at Pg. 5 citing* Polytrauma is a combination of significant secondary injuries (both mental and physical) in addition to a primary traumatic brain injury (TBI) usually stemming from blast-related events. This may include severe burns, spinal, auditory, or visual injuries, and post-traumatic stress disorder. 10 Bryan, C. J., & Clemans, T. A. (2013) *and* Repetitive Traumatic Brain Injury, Psychological Symptoms, and Suicide Risk in a Clinical Sample of Deployed Military Personnel. JAMA Psychiatry, 70(7), 686-691.

Throughout the course of his assessment, Suitt provides a detailed analysis of each contributing factor to veteran suicide and suicidal ideation which are common to all wars. He also explores those factors which are unique to post-9/11 conflicts, placing particular emphasis on the frequency of re-deployments, the advent of improvised explosive devices along with repeated exposure of soldiers to the concussive injuries they produce, and the prevalence of traumatic brain injuries among post-9/11 veterans. He also identifies the significant peak in suicides among veterans age 18 to 34, reality which is tragically acute in Ohio. Suitt draws the following explanatory conclusions to illuminate the unique factors which drive suicide among post-9/11 veterans:

> At least four times as many service members and war veterans of post-9/11 conflicts have died of suicide than ever died in combat. As the war nears the end of its second decade, respective suicide rates for both active duty personnel and veterans have worsened, finding new peaks particularly among 18- to 34-year-olds. Factors like exposure to trauma – physical, mental, sexual – stress, burnout, mental health disorders, the onset of PTSD, moral injury, access to lethal means, the difficulty of civilian reintegration, and certain military cultural frames have all played a part. To these, the Global War on Terror has seen a huge increase in IED exposure with an attendant rise in TBIs. Modern medical advances have also allowed service members to survive physical traumas and return to the frontlines for multiple deployments, even though the combination of multiple traumatic exposures, chronic pain, and lasting physical wounds is linked to suicidal behaviors. The sheer length of the war has kept service members in the fight longer, providing more opportunities for traumatic exposure. The U.S. government's inability to address the suicide crisis is a significant cost of the U.S. post-9/11 wars, and the result is a mental health crisis among our veterans and service members with significant long-term consequences.[15]

PTSD, TBI, and chronic pain related to blast exposure are all identified as explanatory contributors to the significant numbers and rates of suicide among post-9/11 veterans. All these contributory factors have been exacerbated by the length and frequency of deployments. The nature of post-9/11 deployments as well as their consequences are materially different from prior U.S. military conflicts.

Despite the allocation of significant resources, the buildout of significant mental health services, and creation of delivery infrastructure by the U.S. Department of Veterans Affairs, veteran suicide rates have continued to climb. Suitt provides the following assessment of the scope and efficacy of existing suicide prevention efforts:

> The U.S. military and the Department of Veteran Affairs have spent a tremendous amount of money in recent years to combat service member and veteran suicide, yet the funding continues to climb even as suicide rates do not improve. Congress provides $20 million annually to Department of Defense suicide prevention

[15] *Supra at Pgs. 27 – 28.*

> programs and research, including tens of millions of dollars in research and resilience programs.[139] Additionally, the V.A. receives billions of dollars every year to combat suicide. For example, the F.Y. 2021 budget for the V.A. has $10.2 billion set aside for veteran suicide prevention, a 7 percent increase over 2020.[140] Between the DoD and V.A., there is an abundance of resources, programs, and research opportunities that ought to benefit service members and veterans alike.[16]

The deployment of immense sums of money and suicide prevention services remain are a demonstrably inadequate response to veteran suicides. Given this reality, it is imperative to explore novel solutions which may provide breakthrough therapeutic relief of the conditions which drive veteran suicide.

The U.S. Department of Veterans Affairs "2023 National Veteran Suicide Prevention Annual Report" echoes many of Thomas Suitt's 2021 observations and conclusions. It also provides additional context related to the prevalence of mental health or substance use issues among veterans who interfaced with the Veterans Health Administration as well as time-related trends. In 2001, 27.8% of the annual cohort of "Recent Veteran VHA Users" had mental health and substance use disorder diganoses.[17] By 2021, the most recent years for which figures were available, that number had risen to 41.9%.[18] A mental health or substance use diagnosis was documented in 60.9% of 2021 suicides, an almost 5% increase from the rate of 56.1% which was recorded in 2001.[19] The report provides the following breakdown of diagnosed conditions among documented cases of veteran suicide:

> Among those who died from suicide in 2021, the prevalence of depression diagnoses was 38.4%, anxiety 27.6%, posttraumatic stress disorder (PTSD) 25.4%, alcohol use disorder 19.7%, bipolar disorder 8.7%, cannabis use disorder 8.4%, opioid use disorder 4.2%, personality disorder 4.2% and schizophrenia diagnoses 3.5%. • Conversely, 39.1% of Recent Veteran VHA Users who died from suicide in 2021 did not have a documented VHA mental health or SUD diagnosis.[20]

Within the report, the VA recommends the ongoing expansion of, "evidence-based psychotherapies like Cognitive Behavioral Therapy for Suicide Prevention, Problem Solving Therapy for Suicide Prevention, Dialectical Behavioral Therapy for Suicide Prevention, safety planning in the emergency department, REACH VET, secure storage of firearms, crisis

---

[16] *Supra at Pg. 28 citing* Kamarck, K. N. (2019, October 2). Military Suicide Prevention and Response (Rep. No. 7-5700). Congressional Research Service. https://fas.org/sgp/crs/natsec/IF10876.pdf *and* U.S. Department of Veterans Affairs, Office of Public Affairs Media Relations. (2020, February 10). VA strengthens care and benefits for Veterans with $243 billion budget request for fiscal year 2021 [Press release]. https://www.va.gov/opa/pressrel/includes/viewPDF.cfm?id=5393

[17] U.S. Department of Veterans Affairs, 2023 National Veteran Suicide Prevention Annual Report, Pg 52. https://www.mentalhealth.va.gov/docs/data-sheets/2023/2023-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-508.pdf

[18] *Supra at Pg.52*

[19] *Supra at Pg. 52*

[20] *Supra at Pg. 52*

line interventions, and more."[21] The VA also recognizes that most of these interventions require active engagement with mental health services delivery systems in order to be effective. Given the fact that almost 40% of all veteran suicides involve individuals who do not carry a mental health or substance use disorder diagnosis, there is a significant need to reach well beyond the boundaries of existing treatments and service infrastructures for the purpose of driving interventional innovation. For further reading related to the most recent research on contributing factors related to veteran suicide, please see Veteran and Military Mental Healh Issues.[22]

The Ohio State University College of Medicine has a dedicated treatment program for veterans who are coping with the effects of trauma as well as those who are at independent risk of suicide. The Suicide and Trauma Reduction Initiative for Veterans (STRIVE) "provides free psychological treatment for current service members and veterans for both post-traumatic stress disorder (PTSD) and suicidal thoughts and behaviors (STB)."[23] STRIVE treatment programs run between two weeks and three months. Any veteran is eligible to participate in the program. Its treatment focus is on post-traumatic stress. A separate suicide prevention program exists to treat current service members, veterans, and first responders without military service history, and the family members of these individuals who are experiencing suicidal thoughts and behaviors. The program utilizes, "highly trained clinicians in brief cognitive behavioral therapy for suicide (BCBT) developed by STRIVE researchers."[24] BCBT is described as being:

> ...very effective and is one of two therapies endorsed by the DoD, VA and the National Academy of Medicine. BCBT is a 12-session treatment where you meet individually with one of our clinicians for 60-minute sessions. Participants in the BCBT program will be enrolled in a research study to help us improve treatment outcomes and better understand how to help veterans overcome STB. As part of this study, we will conduct assessments with you and ask you to complete various questionnaires before, during and after treatment.[25]

STRIVE is enrolling participants on an ongoing basis. There are no published studies or data available to evaluate either the scale or efficacy of the STRIVE program at this time.

---

[21] *Supra at Pg. 81*

[22] Inoue, C., Shawler, E., Jordan, C. H., Moore, M. J., & Jackson, C. A. (2023, August 17). *Veteran and Military Mental Health Issues*. StatPearls - NCBI Bookshelf. https://www.ncbi.nlm.nih.gov/books/NBK572092/

[23] https://medicine.osu.edu/departments/psychiatry-and-behavioral-health/strive/treatments-and-services

[24] *Supra*

[25] *Supra*

Novel Therapeutics

Transcranial Magnetic Stimulation

Transcranial magnetic stimulation (TMS) has been an available and generally accepted treatment modality for adults with major depressive disorder since its approval by the FDA in 2008. It is an externally worn, non-invasive device which uses magnetism to affect electrical activity within the brain. A physician who offers the treatment will place a TMS device on an patient's head and administer treatment in an out-patient setting. It does not produce any pain-related side effects. According to the Cleveland Clinic, TMS has been formally approved by the FDA to treat major depressive disorder, obsessive compulsive disorder, migraines, and to help induce smoking cessation.[26] There are ongoing research trials measuring the efficacy of TMS for treatment of addictions, Alzheimer's Disease, bipolar disorder, borderline personality disorder, chronic pain, eating disorders, essential tremor, fibromyalgia, Parkinson's Disease, post-traumatic stress, schizophrenia, stroke complications, tinnitus, and traumatic brain injury.[27] TMS was approved as a therapeutic for treatment resistant depression by the FDA in 2008.

According to the Mayo Clinic, the treatment involves delivering repeated magnetic pulses to the brain through the scalp.[28] An electromagnetic coil is placed against the scalp and, "delivers magnetic pulses that stimulate nerve cells in the region of your brain involved in mood control and depression."[29] TMS is utilized when other treatments fail to ameliorate symptoms. Side effects are temporary and mild. They include headaches,[30] pain around the scalp or neck, tingling of the muscles of your face or scalp, temporary tinnitus, and hypersensitivity to sound.[31] There are no serious risks or complications. There is a 1 in 10,000 risk of experiencing a seizure.[32]

A study published on August 10, 2022 discussed findings related to the application of TMS to individuals suffering from treatment resistant depression, a significant contributory cause of suicide. Entitled, "Efficacy of Transcranial Magnetic Stimulation in Treatment Resistant Depression," the study evaluated 38 patients with treatment resistant depression for a placebo-controlled administration of 20 sessions of TMS to the prefrontal cortex.[33] Within the control group, there was no significant reduction in reported depression symptoms following application of placebo. However, within the group which received

---

[26] https://my.clevelandclinic.org/health/treatments/17827-transcranial-magnetic-stimulation-tms
[27] *Supra*
[28] https://www.mayoclinic.org/tests-procedures/transcranial-magnetic-stimulation/about/pac-20384625
[29] *Supra*
[30] *Supra*
[31] *Supra*
[32] *Supra*
[33] Akpınar K, Oğuzhanoğlu NK, Uğurlu TT. Efficacy of transcranial magnetic stimulation in treatment-resistant depression. Turk J Med Sci. 2022 Aug;52(4):1344-1354. doi: 10.55730/1300-0144.5441. Epub 2022 Aug 10. PMID: 36326400; PMCID: PMC10387872.

actual TMS, 63% of all participants responded positively to treatment, 15% partially responded, and 42% reached remission.[34] TMS supplants conventional pharmacological anti-depressants and supplements talk therapy. It's mechanism of action is unknown although it is believed to cause "changes in membrane potential, changes in the release of neuromodulators (dopamine, etc.) and neurotrophic factors (BDNF, etc.), neuroplasticity, neurogenesis, cortical excitability, and neuromodulation."[35]

MDMA

MDMA is the abbreviation for the synthetic compound 3, 4-methylenedoixymethamphetamine.[36] MDMA has gone through the FDA's four-stage clinical trial process. Its approval as a breakthrough treatment for post-traumatic stress is currently pending with the FDA. On June 4th, 2024, the FDA advisory board on neuropharmacology issued a non-binding recommendation that MDMA not be approved pending the performance of additional clinical trials to further demonstrate safety and efficacy. The FDA's decision on final approval is expected in August of 2024.

Within popular culture nomenclature, the pill form of MDMA is known as "Ecstasy" while its crystalline powder form is known as "Molly." Although first synthesized in 1912, MDMA was listed as a banned Schedule-I substance by the DEA in 1985.[37] A Schedule-I substance is defined as one with, "high abuse potential with no accepted medical use; medications within this schedule may not be prescribed, dispensed, or administered."[38] MDMA was defined as an "enacotgen" by David E. Nichols in 1986.[39] He distinguished MDMA from other hallucinogens classified as psychedelics by elaborating on the roots of its descriptor:

> The name is derived from roots that indicate that entactogens produce a "touching within." Rather than having significant psychostimulant, or hallucinogenic effects, MDMA powerfully promotes affiliative social behavior, has acute anxiolytic effects, and can lead to profound states of introspection and personal reflection. Its mechanism of action is now established as involving transport of MDMA by the neuronal serotonin reuptake carrier followed by carrier-mediated release of stored neuronal serotonin.[40]

---

[34] *Supra*
[35] Supra
[36] Dunlap LE, Andrews AM, Olson DE. Dark Classics in Chemical Neuroscience: 3,4-Methylenedioxymethamphetamine. ACS Chem Neurosci. 2018 Oct 17;9(10):2408-2427. doi: 10.1021/acschemneuro.8b00155. Epub 2018 Jul 12. PMID: 30001118; PMCID: PMC6197894.
[37] *What is the history of MDMA? | National Institute on Drug Abuse*. (2021, April 13). National Institute on Drug Abuse. https://nida.nih.gov/publications/research-reports/mdma-ecstasy-abuse/what-is-the-history-of-mdma
[38] Gabay M. The federal controlled substances act: schedules and pharmacy registration. Hosp Pharm. 2013 Jun;48(6):473-4.
[39] Nichols DE. Entactogens: How the Name for a Novel Class of Psychoactive Agents Originated. Front Psychiatry. 2022 Mar 25;13:863088. doi: 10.3389/fpsyt.2022.863088. PMID: 35401275; PMCID: PMC8990025.
[40] *Supra*

Despite its Schedule-I status, researchers who recognized MDMA's potential therapeutic benefits proceeded to explore its efficacy within psychosocial treatment settings. "Psychological research suggests that MDMA increases prosocial feelings and behaviors, which, in turn, appears to reduce negative mood when subjects are asked to think of a difficult memory (Bedi et al., 2009, 2010; Carhart-Harris et al., 2014; Frye et al., 2014; Hysek et al., 2012, 2014)."[41] This research-driven suggestion found specific therapeutic expression through the application of MDMA to individuals affected by post-traumatic stress:

> A growing body of research suggests that traumatic events lead to persisting personality change characterized by increased neuroticism. Relevantly, enduring improvements in Post-Traumatic Stress Disorder (PTSD) symptoms have been found in response to 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy. There is evidence that lasting changes in the personality feature of "openness" occur in response to hallucinogens, and that this may potentially act as a therapeutic mechanism of change.[42]

Based on an accumulation of research which replicated MDMA's efficacy as a breakthrough treatment for PTSD, the FDA granted MDMA-assisted therapy (MDMA-AT) "Breakthrough Therapy" designation in 2017.[43] This designation facilitates expedited research, development, and delivery of therapeutics which demonstrate enhanced ability to treat serious conditions which represent a "substantial improvement over available therapies on clinically significant endpoints."[44] According to a press release issued by MDMA's developer on February 9th, 2024:

> Lykos Therapeutics (formerly MAPS Public Benefit Corporation) ("Lykos"), a company dedicated to transforming mental healthcare, announced that the U.S. Food and Drug Administration ("FDA") has accepted its new drug application ("NDA") for midomafetamine capsules ("MDMA") used in combination with psychological intervention, which includes psychotherapy (talk therapy) and other supportive services provided by a qualified healthcare provider for individuals with post-traumatic stress disorder ("PTSD"). The FDA has granted the application priority review and has assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 11, 2024. If approved, this would be the first MDMA-assisted therapy and psychedelic-assisted therapy.[45]

---

[41] Wagner MT, Mithoefer MC, Mithoefer AT, MacAulay RK, Jerome L, Yazar-Klosinski B, Doblin R. Therapeutic effect of increased openness: Investigating mechanism of action in MDMA-assisted psychotherapy. J Psychopharmacol. 2017 Aug;31(8):967-974. doi: 10.1177/0269881117711712. Epub 2017 Jun 21. PMID: 28635375; PMCID: PMC5544120.

[42] *Supra*

[43] https://lykospbc.com/research-and-development/mdma-assisted-therapy-for-ptsd/

[44] *Supra*

[45] https://news.lykospbc.com/2024-02-09-Lykos-Therapeutics-Announces-FDA-Acceptance-and-Priority-Review-of-New-Drug-Application-for-MDMA-Assisted-Therapy-for-PTSD

Lykos' application included the results of two Phase-3 trials which were published in *Nature Medicine.*[46] On May 20, 2024, *The Intercept* reported that internal documents obtained from the U.S. Department of Veterans Affairs revealed that the agency is quietly preparing to deliver expedited access to MDMA therapy for its patients throughout its 150-facility health system.[47] Planning includes ensuring coverage through veteran health plans in order to guarantee treatment availability to all veterans who choose to utilize it.[48] Implementation planning is occurring expeditiously in anticipation of the FDA's anticipated approval of MDMA as a treatment for post-traumatic stress in the fall of 2024.[49]

Psilocybin

Psilocybin is the psychoactive component of certain mushroom species. Since 2018, there has been an explosion of pharmacological research on psilocybin's treatment efficacy for treatment resistant depression, treatment resistant depression, and alcohol dependence. There are currently over 100 ongoing FDA-approved psilocybin clinical trials in the United States.

On May 12, 2020, Dr. David E. Nichols published an article entitled *Psilocybin: From Ancient Magic to Modern Medicine*.[50] Within the article, Dr. Nichols provides a succinct history of humanity's history with the substance:

> Psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine) is an indole-based secondary metabolite produced by numerous species of mushrooms. South American Aztec Indians referred to them as teonanacatl, meaning "god's flesh," and they were used in religious and healing rituals. Spanish missionaries in the 1500s attempted to destroy all records and evidence of the use of these mushrooms. Nevertheless, a 16th century Spanish Franciscan friar and historian mentioned teonanacatl in his extensive writings, intriguing 20th century ethnopharmacologists and leading to a decades-long search for the identity of teonanacatl. Their search ultimately led to a 1957 photo-essay in a popular magazine, describing for the Western world the use of these mushrooms. Specimens were ultimately obtained, and their active principle identified and chemically synthesized. In the past 10-15 years several FDA-approved clinical studies have indicated potential medical value for psilocybin-assisted psychotherapy in treating depression, anxiety, and certain

---

[46] *Supra* citing Mitchell JM, Bogenschutz M, Lilienstein A, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 609 2021;27:1025–33; and Mitchell JM, Ot'alora MG et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med. 2023 Sept 14 doi: 10.1038/s41591-023-02565-4. Online ahead of print.
[47] https://theintercept.com/2024/05/20/va-veterans-mdma-ptsd/
[48] *Supra*
[49] *Supra*
[50]Nichols DE. Psilocybin: from ancient magic to modern medicine. J Antibiot (Tokyo). 2020 Oct;73(10):679-686. doi: 10.1038/s41429-020-0311-8. Epub 2020 May 12. PMID: 32398764.

> addictions. At present, assuming that the early clinical studies can be validated by larger studies, psilocybin is poised to make a significant impact on treatments available to psychiatric medicine.[51]

The history of pharmacological research of psilocybin's properties and applications within the U.S. is set forth in *DARK Classics in Chemical Neuroscience: Psilocybin*.[52] The authors state:

> In the late 1950s Albert Hofmann, of Sandoz Laboratories, identified and synthesized the psychoactive compounds psilocybin and psilocin which are found in psilocybe mushrooms. Psilocybin was marketed by Sandoz as Indocybin for basic psychopharmacological and therapeutic clinical research. Psilocybin saw a rapid rise in popularity during the 1960s and was classed as a Schedule I drug in 1970. This led to a significant decrease in psilocybin research. Recently, however, preliminary studies with psilocybin have shown promise as potential for the treatment of obsessive compulsive disorder, alcohol addiction, tobacco addiction, and major depressive disorder, and the treatment of depression in terminally ill cancer patients.[53]

Dr. Roland Griffiths was a pioneering psychedelics reasearcher who led the John Hopkins Center for Psychedelics and Consciousness Research. He was a lead author on an article entitled *Psilocybin Occasioned Mystical-Type Experiences: Immediate and Persisting Dose-Related Effects*.[54] Dr. Griffiths and his colleagues provide the following description of the reported experiences of those who received varying doses of psilocybin in the study, the outcomes of which are the subject of the article:

> Psilocybin produced acute perceptual and subjective effects including, at 20 and/or 30 mg/70 kg, extreme anxiety/fear (39% of volunteers) and/or mystical-type experience (72% of volunteers). One month after sessions at the two highest doses, volunteers rated the psilocybin experience as having substantial personal and spiritual significance, and attributed to the experience sustained positive changes in attitudes, mood, and behavior, with the ascending dose sequence showing greater positive effects. At 14 months, ratings were undiminished and were consistent with changes rated by community observers. Both the acute and persisting effects of

---

[51] *Supra*

[52] Geiger HA, Wurst MG, Daniels RN. DARK Classics in Chemical Neuroscience: Psilocybin. ACS Chem Neurosci. 2018 Oct 17;9(10):2438-2447. doi: 10.1021/acschemneuro.8b00186. Epub 2018 Jul 16. PMID: 29956917.

[53] *Supra*

[54] Griffiths RR, Johnson MW, Richards WA, Richards BD, McCann U, Jesse R. Psilocybin occasioned mystical-type experiences: immediate and persisting dose-related effects. Psychopharmacology (Berl). 2011 Dec;218(4):649-65. doi: 10.1007/s00213-011-2358-5. Epub 2011 Jun 15. PMID: 21674151; PMCID: PMC3308357.

psilocybin were generally a monotonically increasing function of dose, with the lowest dose showing significant effects.[55]

Since the discovery of psilocybin's significant therapeutic effects on major depressive disorder, treatment resistant depression, and alcoholism in 2018, there has been an abundance of research activity related to its potential clinical applications. The FDA granted Breakthrough Therapy designation to psilocybin for treatment resistant depression in 2018 and major depressive disorder in 2019.[56] Since 2004, there have been 134 clinical trials with psilocybin in the U.S. for 54 separate clinical indications.[57] One hundred and two trials have been initiated just since 2019.[58] Four of these trials are in active Phase 3 status.[59] There is an active and expanding psilocybin clinical trial occurring at the Cleveland Clinic to research psilocybin's application to treatment resistant depression.[60] Likewise, Ohio State University is also conducting a clinical trial with psilocybin as a therapeutic for treatment resistant depression.[61]

Ibogaine

Ibogaine is a naturally occurring alkaloid which is found in a variety of West African botanical sources, with its highest concentrations existing in the Tabernanthe Iboga shrub.[62] Based on an abundance of open label observational studies which have generated a dearth of data that is a mountain high and decades wide, ibogaine has been known as a profoundly effective interrupter of opioid dependence for almost sixty years. Over the past decade, thousands of U.S. Special Forces Operators have travelled to ibogaine clinics in Mexico to receive ibogaine treatment for post-traumatic stress, traumatic brain injury, and substance dependence. Its neurological effect on the human brain was the subject of a seminal research study published one of the world's most prestigious medical journals earlier this year.

Ibogaine has been used in religious and cultural ceremonies of the Bwiti people who inhabit the nation of modern-day Gabon.[63] On December 30, 2021, *A Systematic Literature Review of Clinical Trials and Therapeutic Applications of Ibogaine* was published

---

[55] *Supra*
[56] Heal, D., Smith, S., Belouin, S., & Henningfield, J. (2023). Psychedelics: Threshold of a therapeutic Revolution. *Neuropharmacology*, *236*, 109610. https://doi.org/10.1016/j.neuropharm.2023.109610
[57] Norring SA, Spigarelli MG. The Promise of Therapeutic Psilocybin: An Evaluation of the 134 Clinical Trials, 54 Potential Indications, and 0 Marketing Approvals on ClinicalTrials.gov. Drug Des Devel Ther. 2024 Apr 10;18:1143-1151. doi: 10.2147/DDDT.S443177. PMID: 38618282; PMCID: PMC11016263.
[58] *Supra*
[59] *Supra*
[60] https://newsroom.clevelandclinic.org/2024/03/06/cleveland-clinic-expands-psychedelic-research-and-launches-first-psilocybin-trial-in-northeast-ohio
[61] https://wexnermedical.osu.edu/departments/innovations/psychnews/psilocybin-assisted-psychotherapy
[62] Köck, P., Froelich, K., Walter, M., Lang, U. & Dürsteler, K. M. A systematic literature review of clinical trials and therapeutic applications of ibogaine. *J. Subst. Abus. Treat.* 138, 108717 (2022).
[63] *Supra*

with Dr. Patrick Köck as lead author. Dr. Köck and his colleagues conducted a systematic review and analysis of 734 published records and 24 studies which included 705 individuals who received ibogaine or its metabolite, noribogaine, for a variety of substance use issues.[64]

In this article, the psychoactive effects of ibogaine are described as follows:

> Research has divided the ibogaine experience into three phases (Alper, 2001). Phase I has been described as oneiric ("waking dream") state in which the individual experience visual and other sensory perception changes and panoramic recall of earlier life events (duration 4–8 h). After phase I, the experience changed to a subtler experience. Phase II has been described as evaluative, emotionally neutral, and reflective. Phase II lasts between 8 and 20 h. Phase III has been titled as a residual phase comprising heightened awareness, mild stimulation, and, eventually, perturbed sleep patterns. Phase III can last up to 72 h after ingestion (Alper, 2001; Glick et al., 2001). Reports suggest that ibogaine can cause a more intense psychedelic experience than previous experiments with high doses of psilocybin. Participants have mentioned insights relating to the meaning of life, the evolution of the universe, life-after-death, and feeling relieved from guilt (Heink et al., 2017).[65]

The aggregation and review of extensive data allowed Köch and his colleagues to form this conclusion releated to ibogaine's unique effects on substance dependence:

> Although we do not yet fully understand their complete pharmacological mechanisms, available data suggest efficacy in the treatment of opioid use disorder (OUD), cocaine use disorder (CUD), and other substance use disorders (SUD). Previous research points out the necessity of conducting safe study designs and controlled clinical studies (dos Santos et al., 2016). [66]

They go on to address known safety concerns related to ibogaine ingestion as well as the current research landscape pertaining to ibogaine's therapeutic potentials:

> Treatments with ibogaine are considered safe when properly medically supervised. However, several case reports have been published about fatalities or adverse events associated with the ingestion of iboga plant material or ibogaine. Global medical and legislative regulatory consensus is absent. Although classical hallucinogens have been studied and are currently under investigation for a wide array of psychiatric conditions, including SUDs (Bogenschutz and Johnson,

[64] *Supra*
[65] *Supra*
[66] *Supra*

> 2016; Bogenschutz and Ross, 2018), controlled clinical trials with ibogaine are still scarce.[67]

Based on the totality of their research, Köch and his team come to the following conclusion:

> Treatment of SUDs and persisting comorbidities requires innovative treatment approaches. Rapid- onset therapies such as the application of ibogaine may offer novel treatment opportunities for specific individuals. Rigorous study designs within medical settings are necessary to warrant safe application, monitoring, and, possibly, medical intervention.[68]

Ibogaine's novel therapeutic potential as a profound interrupter of opioid and, perhaps, polysubstance dependence has been observed through open label studies for decades. This potential has been dramatically augmented by the discovery of its effects on those affected by traumatic brain injury and post-traumatic stress. In what can only be described as the release of seminal findings in the internationally renowned medical journal *Nature Medicine*, Stanford Neuropsychiatrist Dr. Nolan Williams and his research team released the results of a study involving 30 U.S. Special Forces veterans which demonstrated that ibogaine results in substantial symptomatologic remission of symptoms associated with traumatic brain injury.[69] Using a treatment protocol identified as MISTIC (Magnesium Ibogaine Stanford Traumatic Injury to the CNS), 30 male Special Operations Veterans received a single treatment for predominantly mild traumatic brain injury.[70]

Observing that veterans make up 6.4% of the general population but 20% of all suicides in the U.S., the prevalence of TBI among veterans of post-9/11 military conflicts is an acknowledged result of blast exposure.[71] Symptoms which flow from traumatic brain injury include post traumatic stress, major depressive disorder, treatment resistant depression, and anxiety disorders.[72] Dr. Williams, et. al., explain that traumatic brain injury produced by blast exposure causes detrimental structural changes to the brain which include adverse objective impacts on white matter, cerebral blood flow, and functional connectivity.[73] In what can only be described as a singularity in the history of modern neuroscience, the following results are described:

---

[67] *Supra*
[68] *Supra*
[69] Cherian, K. N., Keynan, J. N., Anker, L., Faerman, A., Brown, R. E., Shamma, A., Keynan, O., Coetzee, J. P., Batail, J., Phillips, A., Bassano, N. J., Sahlem, G. L., Inzunza, J., Millar, T., Dickinson, J., Rolle, C. E., Keller, J., Adamson, M., Kratter, I. H., & Williams, N. R. (2024). Magnesium–ibogaine therapy in veterans with traumatic brain injuries. *Nature Medicine*. https://doi.org/10.1038/s41591-023-02705-w
[70] *Supra*
[71] *Supra*
[72] *Supra*
[73] *Supra*

> In summary, we prospectively investigated the safety and efficacy of MISTIC for SOVs with a history of TBI and repeated blast/combat exposures. At baseline, study participants experienced clinically meaningful levels of disability, PTSD, depression and anxiety. After MISTIC, participants showed a remarkable reduction in these symptoms with large effect sizes (Cohen's $d > 2$ on clinician-rated psychiatric assessments) and the benefits were sustained at the 1-month follow-up. Indeed, disability measures continued to improve and psychiatric symptom remission and response rates 1 month post-MISTIC remained high. Neuropsychological testing (NPT) revealed areas of improvement after treatment, particularly in processing speed and executive function, without any detrimental changes observed. With regard to safety, no serious or unexpected adverse events (AEs) occurred and management of AEs was uncomplicated.[74]

Furthermore:

> This is possibly the first study to report evidence for a single treatment with a drug that can improve chronic disability related to repeated TBI from combat/blast exposures. Moreover, there is no currently available US Food and Drug Administration (FDA)-approved treatment for chronic sequelae of combat-related TBI. Current treatment options include cognitive rehabilitation, psychotherapy and medications that target specific symptoms, but there is limited evidence of efficacy. Given the alarming rates of suicide in veterans, as well as evidence that military-related TBI increases the risk of suicide in veterans (as TBI also does in the general population, the substantial reduction in SI that we observed—which must be interpreted cautiously as an exploratory analysis—is noteworthy. TBI also is associated with increased impulsivity a well-known risk factor for suicide and MISTIC resulted in a measurable improvement in cognitive inhibition.[75]

Crucially, Dr. Williams, et.al., acknowledged the significance of their research findings considering other scientific discoveries related to the therapeutic application of substances defined as "psychedelic":

> Although outside the context of TBI and veterans, our findings are consistent with previous studies suggesting benefits of treatment with psychedelic substances across several psychiatric disorders. Recent studies of 3,4-methylenedioxymethamphetamine (MDMA)-facilitated psychotherapy, for example, showed promise in the treatment of PTSD. Similarly, psilocybin has demonstrated improvements in depression, substance use and anxiety. Other substances such as lysergic acid diethylamide (LSD) and ayahuasca have also shown notable improvements in depression and anxiety for most patients.[76]

---

[74] *Supra*
[75] *Supra*
[76] *Supra*

Safety, efficacy, and the need for replication formed the conclusory components of the article:

> In summary, our study provides initial evidence to suggest that MISTIC could be a powerful therapeutic for the transdiagnostic psychiatric symptoms that can emerge after TBI and repeated exposure to blasts and combat, including suicidality, but replication of our findings is needed, particularly in non-mild TBI cases. Considering that the average time since discharge from the military in our sample was nearly 8 years, these findings further suggest that MISTIC may be effective even when administered years after the injuries. Our results also raise the possibility that this therapy may be beneficial in other populations suffering from sequelae of repeated head trauma. Importantly, our results indicate that ibogaine can be administered safely to an SOV population when combined both with magnesium and with appropriate screening, precautions and medical monitoring. Last, concerns that the use of certain psychedelics as therapeutics risks fostering a new addiction are mitigated by ibogaine's apparent anti-addictive properties. Although these conclusions must be considered preliminary, they support the need for further testing of MISTIC in larger, controlled trials.[77]

Insofar as replication is necessary to reinforce substantiation, the design and execution of a ResultsOHIO project which has the potential to reinforce these findings will provide compelling assistance to the advancement of groundbreaking neuropharmacological advances which can treat conditions which currently have no available treatment – conditions which disproportionally affect U.S. veterans nationwide.

Funding Analysis

ResultsOHIO utilizes a "Pay for Success" model to solicit project proposals from private investors or philanthropists. Grant projects are pre-defined and are intended to address singular or multiple persistent socioeconomic ills which adversely impact Ohioans. Projects must have a dedicated appropriation of public funds which are set aside to reimburse the private funder upon the completion of a project, assuming pre-defined success metrics have been independently verified by a third-party evaluator. Projects cannot be announced until public funding has been earmarked for purposes of reimbursing the private investor's successful execution of the project.

[77] *Supra*

While researching potential public funding sources, the following search criteria were used:

1. Does the funding source focus on the delivery of treatment to veterans who are impacted by traumatic brain injury, mental health or substance use issues, and/or suicidality?

2. Does the funding source permit access to novel therapeutics for treatment of traumatic brain injury, substance misuse, or other mental health conditions?

3. Is the funding source compatible with a "Pay for Success" model wherein funds are pre-appropriated and expended to reimburse a private investor for the successful execution of a project at the project's conclusion?

An extensive search of U.S. Government grant databases failed to yield any funding source which aligned with these criteria. A summary of federal research results is attached to this report at Appendix I.

To execute this project, funds will need to be procured through a state or local revenue source. The funding source needs to provide the necessary flexibility to execute a novel treatment access and evaluation program within the context of delivering veteran-focused suicide prevention services through a mobile clinic.

Program Design

Staffing, Resources, and Metrics

The following constitute recommended success metrics for the proposed program:

1. The mobile mental health clinic (MMHC) must be staffed by credentialed mental health professionals including but not limited Licensed Clinical Social Workers, Psychologists, Psychiatric Physician Assistants, and Nurses with relevant experience providing mental health treatment which includes experience with veteran populations.

2. The MMHC and its staff must be supplied with all current diagnostic tools which are used to assess mental health status and elevated risk factors which contribute to suicidality. Staff must also be supplied with appropriate field-testing protocols to assess for traumatic brain injury.

3. MMHC staff must be equipped with all local, regional, and state mental health treatment and suicide prevention services, especially those which are veteran-specific, throughout the state of Ohio. These are the services to which MMHC clients must be connected and referred by MMHC staff. MMHC staff will maintain

a patient file on each evaluated veteran and follow-up as necessary to ensure interface with relevant service providers has occurred for each client who wishes to seek services.

4. The MMHC must screen and evaluate 300 veterans within 12 months.

5. All veterans must be given the option to connect with a mental health care provider. MMHC staff will facilitate referral to the veteran's chosen care provider. MMHC staff will document the number of veterans who have been referred to and have received care from conventional treatment providers. The MMHC should aspire to facilitate 100 confirmed referrals of at-risk veterans to qualified mental health care professionals for relevant treatment services.

6. MMHC staff will also supply clinical information related to transcranial stimulation as well as MDMA if approved by the FDA. Furthermore, MMCH staff will supply clinical information related to psilocybin as well as its efficacy for major depressive disorder and treatment resistant depression. Patients will receive information and, upon request, assistance enrolling as a clinical trial participant at either Ohio State University or the Cleveland Clinic. The costs of transcranial stimulation and likely MDMA will be covered by veteran health plans. There is no anticipated cost associated with participation in either of Ohio's psilocybin clinical trials.

7. MMHC staff will supply clients impacted by traumatic brain injury, post traumatic stress, and/or substance dependence with information related to ibogaine treatment including clinics which focus on the delivery of ibogaine treatment to veteran populations.

8. Utilizing the MMHC as an intake and evaluation center, treatment staff will help facilitate the referral of 20 to 30 veterans for ibogaine treatment at clinics with an established record of safely and effectively treating veterans with diagnosed traumatic brain injury, post traumatic stress, substance dependence, and/or other mental health issues for which ibogaine has demonstrated therapeutic efficacy based on open label studies. Veterans electing ibogaine treatment will receive a treatment voucher covering treatment costs. Veterans would select their preferred provider based on available provider options.

9. Veterans who elect to receive transcranial stimulation, MDMA, psilocybin, or ibogaine will be evaluated before and after treatment by a third-party research entity which can verify and quantify treatment outcomes. Departments within The Ohio State University and the Cleveland Clinic have the capacity to serve as third-party evaluator. For purposes of evaluating treatment efficacy, the following conditions should be evaluated for the following symptomatologic responses at 30-day, 60-day, 90-day, six-month, and one-year time markers following the treatment date:

Post-Traumatic Stress – Reductions in or the elimination of self-reported anxiety, depression, sleep disturbance, sleep deprivation, nightmares, night terrors, flashbacks, recurrent traumatic memories, guilt, grief, and suicidal ideation.

Traumatic Brain Injury – Reductions in or the elimination of self-reported anxiety, depression, irritability, anger, brain fog, disorientation, confusion, agitation, memory loss, headache, suicidal ideation, or any other form of ascertainable cognitive impairment. Improvements in mood, affect, emotional regulation, executive functioning, and improved performance of activities of daily living.

Substance Dependence (Including Alcohol Dependence) – Reduction in or complete cessation from illicit substance use as well as reduction in or complete cessation from use of prescribed medications which can produce physiological dependence (e.g. opioids, SSRIs, and other dependence-producing psychotropic medications)

10. Upon certification of treatment referral, delivery and outcomes by the third-party evaluator, the project will be deemed successfully completed.

Recommended Timeline

The following is a recommended timeline from the project's announcement through its conclusion. This timeline assumes full project completion by January of 2027.

1. 30 Days: Project Announcement and Solicitation of Proposals.
2. 30 Days: Proposal Review and Selection.
3. 90 Days: Staff, Supply, and Roll-Out MMHC
4. 12 Months: Service Provision
5. 90 Days: Prepare and Deliver Evaluation Results
6. 30 Days: Certification of Success and Reimbursement of Private Investor

Liability Management

The chief liability issue associated with the execution of this project arises from referrals to and receipt of mental health treatment services. While this will not be an exhaustive legal analysis of Ohio's jurisprudence on provider liability, it will cover the broad contours of all liability angles as well as the best options with which to address them.

At the outset, it is important to note that the entire liability analysis rests upon the premise that the MMHC will always function as a mental health screening, evaluation, and information center. It will not deliver treatment services, make treatment recommendations, direct individuals to receive specific treatment or treatment provider, or function as an agent of any treatment provider. No physician-patient nor provider-patient relationship will be formed between any MMHC staff and any individual who receives screening and service referral within the MMHC.

Conventional Treatments

Liability for the delivery of conventional treatments through established clinics, hospitals, or other mental health treatment offices will rest with the individual provider. Just as a disseminator of health care service information does not assume the liabilities of the providers of those services, so that MMHC will not assume legal liability for any veteran's mental health care provider. **MMHC staff must provide the equivalent of network mental health service information to veterans. It must not direct a veteran's choice of provider or treatment, explicitly or implicitly.**

Transcranial Stimulation and MDMA

Transcranial stimulation is currently available treatment modality which is utilized by a variety of mental health care providers who are properly credentialed to administer it. With the impending approval of MDMA by the FDA, it will also be available as a treatment which can be prescribed by a qualified provider in existing mental health treatment systems. Liability will attach to the individual treatment provider. **MMHC staff must provide the equivalent of network mental health service information to veterans. It must not direct a veteran's choice of provider or treatment, explicitly or implicitly.**

Psilocybin

Psilocybin treatment would occur within the context of a clinical trail currently being executed at either The Ohio State University or the Cleveland Clinic. Liability for treatment delivery would attach to the entity at which treatment is received. **MMHC staff must provide the equivalent of network mental health service information to veterans. It must not direct a veteran's choice of provider or treatment, explicitly or implicitly.**

Ibogaine

Liability management related to ibogaine treatment must begin with the creation of a firm wall of separation which removes MMHC staff from the facilitation of treatment delivery. The MMHC has three responsibilities related to ibogaine treatment:

1. Provide educational information related to ibogaine treatment for veterans whose conditions would qualify for its administration.

2. Provide a treatment voucher covering the cost of treatment at a clinic which has an established history of safely and effectively treating veterans affected by traumatic brain injury, post-traumatic stress, substance dependence, and/or other mental health conditions for which it has demonstrated efficacy in observational studies.

3. Obtain executed informed consent agreements which memorialize that the MMHC has provided information related to treatment, treatment access, and a treatment voucher covering the treatment's cost. The MMHC and the veteran must acknowledge that the veteran has sole discretion and elective choice to pursue the treatment of his/her choice with the voucher and that the election of ibogaine treatment is not a condition of receiving the voucher.

This is the framework through which liability related to ibogaine treatment must be managed. The negotiation of indemnification and hold harmless agreements with network clinics which shield the MMHC operation from any liability are also worthy of consideration. One non-profit organization with deep experience in this area has offered to provide technical assistance related to all logistical and legal considerations pertaining to offering ibogaine treatment opportunites.

Potential Partners

There are several 501(c)(3) organizations which have the interest, mission, expertise, infrastructure, and resources to execute this project. Each of them has a focused interest in eliminating veteran suicide and a willingness to create novel therapeutic access for individuals who may wish to utilize them in a clinically controlled medical setting.

Cost Estimate

The iSee project received a $1.2 million appropriation from the General Assembly. At the end of the project, the iSee mobile vision clinic had performed vision screening on almost 4,000 children and had issued prescription glasses to approximately 3,400. The $1.2 million allocation for a mobile screening clinic is the baseline expense for this two-year project with a properly equipped vehicle staffed by qualified mental health professionals. The provision of novel treatment access to veterans, inclusive of travel costs, should assume $300,000 of added expense. Pre- and post-treatment diagnostic assessment by

qualified clinical evaluators within Ohio can be safely estimated at an additional $500,000. The total estimated project cost is $2,000,000.

Conclusion

On May 14th, 2024, the *Military Times* reported on remarks delivered by U.S. Department of Veterans Affairs Undersecretary of Health Shereef Elnahal who oversees all of the department's health services. In remarks delivered at "Horizons – NYC," Undersecretary Elanahal announced that the VA is preparing to spend millions of dollars to create clinical trails to expedite the development and delivery of psychedelic therapies. [78] Given anticipated demand for MDMA once approved by the FDA, Elnahal affirmed the VA's willingness to explore novel treatment solutions which include psilocybin and ibogaine.[79] The *Times* reported:

> "This initial request for proposals is supposed to be the spark that fuels even more research," Elnahal said. "Chances are that — because of the similar mechanisms of action, similar effect areas in the brain — we can see unique benefits of some of these other compounds. We're proving the case that the federal government is no longer afraid to engage in this."

The applied science of psychedelic research and development is leading a revolution in modern neuropharmacology, leading to treatments which will completely transform therapeutics, treatment systems, and individual lives. Assuring that all willing hands lend themselves to the expeditious development and delivery of these therapeutics is a generational humanitarian opportunity which Ohio can now lead.

[78] https://www.militarytimes.com/news/your-military/2024/05/14/psychedelic-therapy-data-speaks-for-itself-va-official-says/
[79] *Supra*

Appendix I
Federal Funding Sources

Federal Funding Sources

Background

Research was performed to determine the availability of federal grant funds to facilitate a ResultsOHIO project based on a Pay for Success funding model. Grant opportunities related to veteran's mental health as well as substance misuse were queried. In addition, specific queries were made for federal pay for success funding announcements. The analogous phrase "Social Impact Bond(s)" was also used. In order to provide context for the scope and complexity of federal grant funding opportunities, 7,273 grant announcements have been issued over the past year. There are a total of 171,829 grant notices available for review. There are 44,061 grant notices from the Health and Human Services Department and another 25,279 notices from the National Institutes of Health. 810 specifically relate to veterans.

Congressionally Directed Medical Research Programs

https://cdmrp.health.mil/search.aspx

Synopsis:

The Congressionally Directed Medical Research Program originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders-the American public, the military, and Congress.

Hallmarks of the CDMRP include:

- investing in groundbreaking research
- targeting critical gaps
- reviewing application using a two-tier formal review with no standing peer review panels and no "pay line"
- involving consumer advocates throughout the program cycle
- supporting both the next generation of researchers and established scientists.
- funding the full pipeline of research development, including basic, translational, and clinical research.
- fostering (or employing) collaboration and synergy

The CDMRP fills research gaps by funding high impact, high risk and high gain projects that other agencies may not venture to fund. While individual programs are unique in their focus, all of the programs managed by the CDMRP share the common goal of advancing paradigm shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The CDMRP strives to transform health care for Service Members and the American public through innovative and impactful research.[80]

Fiscal Year 2023 CDMRP Research Funding:

The Consolidated Appropriations Act, 2023 provides medical research funding for the following programs managed by the Department of Defense, Congressionally Directed Medical Research Programs (CDMRP):[81]

- **Alcohol and Substance Use Disorders** Research Program - $4.0 million
- **Amyotrophic Lateral Sclerosis** Research Program - $40.0 million
- **Autism** Research Program - $15.0 million
- **Bone Marrow Failure Disease** Research Program - $7.5 million
- **Breast Cancer** Research Program - $150.0 million
- **Chronic Pain Management** Research Program - $15.0 million
- **Combat Readiness Medical** Research Program - $5.0 million
- **Duchenne Muscular Dystrophy** Research Program - $10.0 million
- **Epilepsy** Research Program - $12.0 million
- **Hearing Restoration** Research Program – $5.0 million
- **Joint Warfighter Medical** Research Program - $25.0 million
- **Kidney Cancer** Research Program - $50.0 million
- **Lung Cancer** Research Program – $25.0 million
- **Lupus** Research Program - $10.0 million
- **Melanoma** Research Program - $40.0 million
- **Military Burn** Research Program - $10.0 million
- **Multiple Sclerosis** Research Program - $20.0 million
- **Neurofibromatosis** Research Program - $25.0 million
- **Orthotics and Prosthetics Outcomes** Research Program - $15.0 million
- **Ovarian Cancer** Research Program - $45.0 million
- **Pancreatic Cancer** Research Program - $15.0 million
- **Parkinson's** Research Program - $16.0 million
- **Peer Reviewed Alzheimer's** Research Program - $15.0 million
- **Peer Reviewed Cancer** Research Program (20 topics) - $130.0 million
- **Peer Reviewed Medical** Research Program (50 topics) - $370.0 million
- **Peer Reviewed Orthopaedic** Research Program - $30.0 million
- **Prostate Cancer** Research Program - $110 million

[80] https://cdmrp.health.mil/aboutus
[81] https://cdmrp.health.mil/pubs/press/2023/funding_press_release23

- **Rare Cancers** Research Program - $17.5 million
- **Reconstructive Transplant** Research Program - $12.0 million
- **Spinal Cord Injury** Research Program - $40.0 million
- **Tick-Borne Disease** Research Program - $7.0 million
- **Toxic Exposures** Research Program - $30.0 million
- **Traumatic Brain Injury and Psychological Health** Research Program - $175.0 million
- **Tuberous Sclerosis Complex** Research Program - $8.0 million
- **Vision** Research Program - $20.0 million

Open Program Funding Opportunities: Application Submission Deadline for FFY 23 passed. Pre-announcements and comprehensive program announcements will be forthcoming. No date is specified.

Relevant Past Funding Opportunities:

FFY 21 Alcohol and Substance Abuse Disorders Research Program – Consortium Award
https://cdmrp.health.mil/funding/pa/FY21-ASADRP-CA.pdf

FFY 23 Traumatic Brain Injury and Psychological Health Research Program for the Focused Program Award
https://cdmrp.health.mil/funding/pa/HT9425-23-S-TBIPH2_FPA_GG.pdf

Pay For Success Compatibility: Congressionally Directed Medial Research Programs (CDMRP) provide direct funding for pre-approved projects. It does not appear that projects funded and executed with private dollars can be reimbursed through a CDMRP grants.

U.S. Department of Health and Human Services

Advanced Learning and Health Care Research in Outpatient Mental Health Treatment Settings – HHS/NIH
https://grants.nih.gov/grants/guide/pa-files/PAR-24-118.html

"Advanced Learning and Health Care Research" – Defined
https://grants.nih.gov/grants/guide/pa-files/PAR-24-118.html

Relevant Focus: This grant opportunity seeks to fund apply the "Learning Health Care Research" concept within community mental health treatment systems to bridge the gap between theoretical clinical research and real-world applied outcomes. The development of learning health care research projects which focus on underrepresented or underserved populations are prioritized for consideration. Among the populations so defined are racial and ethnic minorities, disabled individuals, and individuals living in rural areas. "Projects that examine the mechanisms by which recovery support services and/or psychiatric

rehabilitation services may improve engagement, continuity, utilization, quality, and outcomes of evidence-based services in outpatient mental health and substance use treatment settings."[82]

Pay for Success Compatibility: This NOFO requires a completed proposal which is capable of being implemented upon award and receipt of funding by the grantor. It is not compatible with a Pay for Success Model.

U.S. Department of Veterans Affairs Office of Research and Development

The U.S. Department of Veterans Affairs Office of Research and Development is the only federal research program "focused entirely on veterans' needs."[4] Research funded and supported by this office is defined as "intramural" which limits access to VA employees.[5] However, VA-funded research grant projects may be undertaken by VA employees in collaboration with academic research institutions. This framework would prohibit the issuance of a grant award to any state or local governmental unit, limiting VA opportunities to academic researchers who are working in concert with a VA employee. Furthermore, there is no Pay for Success funding programs or mechanisms within the VA's grant system.

Staff Sergeant Parker Gordon Fox Suicide Prevention Grants

The Commander John Scott Hannon Veterans Mental Health Care Improvement Act was signed into law on October 17, 2020. It provides $174,000,000 for a three year community-based grant program which aims to provide resources to organizations serving "certain veterans and their families across the country."[6]

Organizations can apply for grants worth up to $750,000 and may apply to renew awards from year to year throughout the length of the program. Grants will be awarded to organizations that provide or coordinate suicide prevention services for eligible individuals at risk of suicide and their families that qualify, including:

- Outreach to identify those at risk of suicide;
- Baseline mental health screening for risk (required of all grantees for participants ages 18+);
- Education on suicide risk and prevention to families and communities;

[82] https://grants.nih.gov/grants/guide/pa-files/PAR-24-118.html
Part 2 Section 1 "Research Objectives"
[4] https://www.research.va.gov/funding/
[5] *Supra*
[6] https://www.mentalhealth.va.gov/ssgfox-grants/

- Provision of clinical services for emergency treatment;
- Case management services;
- Peer support services;
- VA benefits assistance for eligible individuals and their families;
- Assistance with obtaining and coordinating other benefits provided by the federal government, a state or local government, or an eligible entity;
- Assistance with emergent needs relating to health care services, daily living services, personal financial planning and counseling, transportation services, temporary income support services, fiduciary and representative payee services, legal services to assist the eligible individual with issues that may contribute to the risk of suicide, and childcare;
- Nontraditional and innovative approaches and treatment practices, as determined appropriate by the VA; and
- Other services necessary for improving the mental health status and well-being and reducing the suicide risk of eligible individuals and their families as VA determines appropriate

The VA may prioritize grant awards to organizations that focus on areas with limited access to medical services, in rural communities, on tribal lands, in U.S. territories, in areas with a high number or percentage of minority Veterans or women Veterans, or in areas with a high number or percentage of calls to the Veterans Crisis Line.[7]

A comprehensive list of grant recipients is maintained online. The Community Action Program of Washington-Morgan Counties, Ohio is the only Ohio-based Staff Sergeant Fox grant recipient. This grantee lists the following as its offering of suicide prevention services:

Outreach; Education; Case Management; Coordinating VA Benefits and Federal Government Benefits Assistance; Legal Services; Personal Financial Planning and Counseling Assistance; Transportation Services Assistance; Child Care Assistance; Income Support Services; General Suicide Prevention Assistance

The Staff Sergeant Parker Gordon Fox Suicide Prevention Grant opportunity aligns with a mobile mental health clinic concept which aims to provide mental health and suicide prevention services to veterans who are at risk of suicide. As with almost all other federal

[7] *Supra*

grants reviewed, this grant opportunity does not appear to have a Pay for Success mechanism which would facilitate reimbursement of a private investor or philanthropist. Dollars must be spent on direct service delivery within the year of the award's issuance. Grantees are eligible to re-apply throughout the three-year term of nationwide grant funding.

Federal Pay for Success Programs

U.S. Department of Treasury:

This NOFA details $40.9 million for social impact projects targeted at children ages 0 to 19. It does not contain any criteria which would provide an opportunity to to secure SIPPRA funding for a mobile mental health clinic for veterans.

https://home.treasury.gov/system/files/226/SIPPRA-NOFA.pdf

https://www.federalregister.gov/documents/2023/11/30/2023-26174/social-impact-partnerships-to-pay-for-results-act-projects

Other Federal Grant Sources Reviewed

U.S. Department of Health and Human Services
Health Resources and Services Administration
Rural Communities Opioid Response Program – Impact
HRSA-24-014
https://www.grants.gov/search-results-detail/349409

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
The National Center for Mental Health Dissemination, Implementation, and Sustainment Cooperative Agreement
SM-24-010
https://www.grants.gov/search-results-detail/352059
*Forecasted Opportunity

U.S. Department of Health and Human Services & National Institutes of Health
Innovative Mental Health Services Research Not Involving Clinical Trials
PAR 23-095
https://www.grants.gov/search-results-detail/345280
https://grants.nih.gov/grants/guide/pa-files/PAR-23-095.html
*Services are to be delivered to greatest number of individuals possible. This does not support a veteran focus.

U.S. Department of Health and Human Services & National Institutes of Health
Silvio. O. Conte Centers for Basic Neuroscience or Translational Mental Health Research
https://www.grants.gov/search-results-detail/340764
https://grants.nih.gov/grants/guide/pa-files/PAR-23-095.html
*This is a strictly research-oriented grant which does not include the actual delivery of mental health services.

U.S. Department of Health and Human Services
Health Resources and Human Services
HRSA-24-093
https://www.grants.gov/search-results-detail/349415
*This is a forecasted opportunity to secure a grant which "is intended to establish new behavioral health care service lines provided and billed for by RHCs (Rural Health Clinics).

U.S. Department of Health and Human Services
National Institutes of Health
NIMH/Exploratory/Developmental Research Grant
PA-21-235
https://www.grants.gov/search-results-detail/333420
https://www.grants.gov/search-results-detail/349409
*Detailed review of this grant announcement revealed that it is intended to "supports research to inform biobehavioral strategies to prevent and optimally treat HIV, promote basic and clinical neuroscience research on HIV infection, advance the use of data science, methodologies and technologies, and understand the mental health effects of living with HIV."

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Strategic Prevention Framework – Partnerships for Success Communities, Local Governments, Universities, Colleges, and Tribes/Tribal Organizations
SP-23-004
https://www.grants.gov/search-results-detail/347282
https://www.samhsa.gov/sites/default/files/grants/pdf/fy-2024-spf-pfs-states-nofo.pdf
*This grant seeks to enhance the delivery of mental health and substance dependence treatment services to underserved and vulnerable populations by leveraging the grantor's ability to coordinate the delivery of monetary resources to local sub-recipients. A mobile mental health clinic for veterans, or perhaps multiple mobile clinics, could fit within this framework. However, grant work must begin within 45 days of the receipt of funds. The financial delivery structure is not compatible with a Pay for Success model.

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Strategic Prevention Framework – Partnerships for Success for States
SP-23-003
https://www.grants.gov/search-results-detail/347278
https://www.samhsa.gov/sites/default/files/grants/pdf/fy-2023-spf-pfs-states-nofo.pdf
*This grant seeks to reduce the onset of substance misuse "by supporting development and delivery of state and community substance misuse prevention and mental health promotion services." Grant funds are to assist states with the delivery of resources to local providers who will employ evidence-based programs to address behavioral health issues which contribute to substance misuse. The grant could apply to a mobile mental heatlh clinic. The financial model and spending timelines are not consistent with a pay for success model.

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Building Communities of Recovery
TI-24-003
https://www.grants.gov/search-results-detail/349682
https://www.samhsa.gov/grants/grant-announcements/ti-24-003
*This grant seeks to fund increased recovery support capacity within states and localities for treatment of individuals with substance use disorder, co-occurring substance use, and mental health disorders. Eligibility is limited to Recovery Community Organizations "which are wholly or principally governed by people in recovery from substance use disorders and/or co-occurring substance use and mental disorders who reflect the community being served."

U.S. Department of Health and Human Services
National Institutes of Health
Innovative Mental Health Services Research Not Involving Clinical Trials
PAR-23-095
https://grants.nih.gov/grants/guide/pa-files/PAR-23-095.html
*This grant seeks to fund a research project which will "inform and support the delivery of high-quality, continuously improving mental health services to benefit the greatest number of individuals with, or at risk for developing, a mental illness." Ironically, the F.O.A. expressly disqualifies, "Applications whose scope of work primarily involves the provision of direct services."

National Institutes of Health
National Institutes of Mental Health
Innovative Pilot Mental Health Services Research Not Involving Clinical Trials
PAR-23-105
https://grants.nih.gov/grants/guide/pa-files/PAR-23-105.html

*The purpose of this grant is to fund research which will improve the efficiency, reach and clinical impact of existing mental health services. It is intended to support non-clincal trials research, clinical epidemiology, development and evaluation of new research methods, measures, financing approaches, or statistical approaches related to mental health services research. This grant is restricted from funding the actual delivery of mental health treatment services.

National Institutes of Health
Health Care Models for Persons with Multiple Chronic Conditions from Populations that Experience Health Disparities: Advancing Care towards Health Equity
PAR-22-092
https://grants.nih.gov/grants/guide/pa-files/PAR-22-092.html
Review of this NOFO confirms that a focus on veteran's mental health would be too narrow for viable consideration.

Agency for Healthcare Research and Quality
AHRQ Health Services Demonstration and Dissemination Grant
PA-18-793
https://grants.nih.gov/grants/guide/pa-files/PA-18-793.html
Review of this grant confirms a focus on physical as well as mental health associated with a broad and diverse participant population. While a mobile clinic may be an appropriate project for grant development, it could not be limited to mental health and/or substance abuse, nor could it be confined to veterans.

National Institutes of Health
National Institutes of Mental Health
Effectiveness Trials for Post-Acute Interventions and Services to Optimize Longer-term Outcomes
PAR-21-210
https://grants.nih.gov/grants/guide/pa-files/PAR-21-210.html
This grant aims to fund projects which measure and improve long term mental health treatment outcomes among youth, adults, and elderly individuals. "Youth" are defined as individuals 18 years of age or younger.

National Institutes of Health
National Institutes of Mental Health
Lethal Means Safety Suicide Prevention Research in Healthcare and Community Settings
RFA-MH-25-120
https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-120.html
This grant seeks to fund research into suicide prevention/interventions which utilize "lethal means safety" techniques to reduce suicide, with an emphasis on those who self-store firearms.

National Institutes of Health
National Institutes of Mental Health
Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions
PAR-21-131
https://grants.nih.gov/grants/guide/pa-files/PAR-21-131.html
This grant focuses on mental health treatment and suicide prevention across a broad population spectrum. It also requires the creation and execution of a clinical trial.

National Institutes of Health
National Institutes of Mental Health
Social Disconnection and Suicide Risk in Late Life
PAR-23-238
https://grants.nih.gov/grants/guide/pa-files/PAR-23-238.html
PAR-23-239
https://grants.nih.gov/grants/guide/pa-files/PAR-23-239.html
These grant opportunities require projects which focus activity on the research of mechanisms of social disconnection among a broadly diverse population of elderly individuals. A veteran-specific focus would be too narrow to qualify for viable consideration.