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Kimberly Heard Date

Combating the Opioid Epidemic! A Project-Based Grant Proposal to Assist Transitioning Military Members and Veteran Population Struggling with Opioid Use Disorder

By

Kimberly Heard

Degree to be awarded: Master of Public Health

Program: Executive MPH Program

_____

Iris Smith, PhD

Thesis Committee Chair

_____

Keli Edwards, Pharm.D., J.D.

Thesis Field Advisor

BY

Kimberly Heard

Bachelors of Science in Pharmacy

Howard University

1993

Thesis Committee Chair: Iris Smith, PhD

Thesis Field Advisor: Keli Edwards, Pharm.D., J.D.

An abstract of

A Thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health in the Executive MPH Program

2018

Abstract

Presently, the opioid epidemic is a critical focal point on the national stage. The escalating opioid-related overdoses and deaths has caused significant, socio-economical challenges and placed heavy burdens upon the society as a whole.

This epidemic is distinctly connected and has been catalytically driven by the treatment of chronic, nonmalignant pain which has also evolved into a substantial public health problem in the United States (Debono, Hoeksema, Hobbs, (2013). Currently, the extent of usage for opioid analgesics in the United States is unprecedented in the country's history and unparalleled to anywhere else in the world. Americans make up 4.6% of the world's population and yet consume approximately 80% of the world's opioid supply (Blozen, 2013).

Researchers have identified that the states suffering the most devastation from this crisis are located along the Appalachian Mountain Region where West Virginia (WV) is glaring with the highest rate of deaths from drug overdoses than any other state. West Virginia classifies as a challenged state due to its makeup of socio-economically, disadvantaged populations and underserved, rural populations. Also, vulnerable subpopulations at highest risk include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. Distinctly, active duty military and veteran populations face unique challenges in controlling the risk factors associated with opioid abuse and dependence.

Researchers suggests that tackling the complexities of the opioid epidemic demands an urgent, multidimensional and multi-sectoral effort (ex. Coalition-Based Model- Max, Garrow, & Willis, 2018). Specific to this grant thesis, a coalition-based project will be proposed to help transitioning military members and other veterans residing in West Virginia explore the many challenges associated with bridging access to multi-modal treatment options.

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Acknowledgements

First, I would like to express my sincere gratitude to Dr. Iris Smith for her commitment and dedication to assuring my success throughout this entire thesis process. I genuinely appreciated her gentle guidance when providing constructive feedback while yet still challenging and encouraging me to stretch beyond my boundaries. I am really grateful for her efforts that helped me build confidence as I pressed forward. Secondly, I would like to extend a bountiful of gratitude to Dr. Keli Edwards who tirelessly supported, encouraged and assisted me throughout this complex and overwhelming process. Dr. Edwards directed me towards relevant literature for review and shared unique perspectives that helped guide and shape my proposal.

To my entire family, thank you for allowing me the time and space to pursue this degree. I am so grateful for your love, support and encouragement given to me throughout this strenuous journey. Lastly, I would like to extend many thanks to my friends and colleagues that kept me uplifted and cheered me on across the finish line!

Table of Contents

CHAPTER I: INTRODUCTION

Background and Rationale

Nationally, the United States is experiencing a difficult fight in combating the devastating effects of the Opioid Epidemic. This epidemic is distinctly connected and has been catalytically driven by the treatment of chronic, nonmalignant pain which has also evolved into a substantial public health problem in the United States (Debono, Hoeksema, Hobbs, (2013). Currently, the extent of usage for opioid analgesics in the United States is unprecedented in the country's history and unparalleled to anywhere else in the world. Americans make up 4.6% of the world's population and yet consume approximately 80% of the world's opioid supply (Blozen, 2013). This increased usage resulted from prescribing practices, writing for extremely large quantities as well as pharmaceutical companies flooding the market with large quantities of opioid related products. Unfortunately, the increase in opioid prescribing is matched by a parallel increase in morbidity, mortality, and opioid-related overdose death rates.

Recent trends in opioid-related data reveals an almost fourfold increase in overdose deaths from 1999 to 2008 (Jones, Viswanath, Peck, Kaye, Gill, & Simopoulos, 2018). According to Centers of Disease Control and Prevention (CDC), the rate of deaths from drug overdoses since 2000 has increased 137%, which includes a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin) (MMWR,2016). Tragically, 2016 was marked with opioids claiming over 64,000 lives

resulting in a 20% increase from the total of 52,000 drug overdose fatalities in 2015(Jones et al., 2018).

States with highest risk

Researchers have identified that the states suffering the most devastation are located along the Appalachian Mountain Region where West Virginia (WV) is glaring with the highest rate of deaths from drug overdoses over any other state (MMWR, 2016). West Virginia is a challenged state due to its makeup of socioeconomically disadvantaged populations and underserved rural populations.

Health Burden

Nationwide opioid analgesics currently rank as the main source of more overdose deaths as compared to heroin and cocaine combined. In 2014, more than 7.7 million Americans misused prescription pain relievers, with approximately 1 million using heroin, resulting in approximately 2 million individuals meeting criteria for opioid use disorder (OUD) (Snow & Wynn, 2018). According to a 2010 US National Survey of Drug Use and Health report, 4.8% of the population over the age of 12 years in the United States (i.e., 12.2 million people) reported using pain relievers non-medically (Kenan, Mack, & Paulozzi, 2012). In 2010 alone, prescription opioids were involved in 16,651 overdose deaths, as compared to heroin being implicated in 3036. Some 82% of the deaths due to prescription opioids and 92% of those due to heroin were classified as unintentional, with the remainder being attributed predominantly to suicide or “undetermined intent” (Kenan et.al, 2012).

According to the Centers for Disease Control and Prevention, 91 Americans die every day from an opioid and the majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) has quadrupled. From 2000 to 2015 more than half a million people died from drug overdoses (MMWR, 2016).

Reports from CDC (MMWR, 2016) reveal that the rate of drug overdose deaths involving synthetic opioids nearly doubled between 2013 and 2014. This category includes both prescription synthetic opioids (e.g., fentanyl and tramadol) and non-pharmaceutical fentanyl manufactured in illegal laboratories (illicit fentanyl). 2014 marked the year that more people died from drug overdoses than in any other year on record. The majority of the drug overdose deaths, approximately six out of ten, involved an opioid (MMWR, 2016). Evidence supports that overdoses from prescription opioid pain relievers are the main contributing factor for the last 15-year increase of opioid-related overdose deaths (MMWR, 2016). The amount of prescription opioids sold in the U.S. has quadrupled since 1999, however, there is not any supporting evidence of an increase or overall change in the amount of pain that Americans are reporting. Deaths from prescription opioids such as oxycodone, hydrocodone, and methadone have also quadrupled since 1999 (MMWR, 2016).

Social Determinants

There are several contributing factors such as: biological, social, environmental, psychological, and genetic factors associated with substance abuse. These factors can also include gender, race and ethnicity, age, income level, educational attainment, and

sexual orientation. Substance abuse is also strongly influenced by interpersonal, household, and community dynamic (Healthy People 20/20.gov, 2018). Several environmental stressors specific to military personnel have been linked to increased risk of the development of substance use disorders (SUDs) among military personnel and veterans, including deployment, combat exposure, and post-deployment civilian/reintegration challenges (Teeters et al., 2017)

Family, social networks, and peer pressure are listed as key influencers of substance abuse among adolescents. Understanding these factors contribute towards decreasing the number of people who abuse drugs and other harmful substances and helps improve the health and safety of all Americans (Healthy People 20/20.gov, 2018).

Behavioral Risk Factors

Addiction is a complicated disease characterized by patterns of ongoing drug use despite the negative consequences it can have in a person's life. A key driver of the overdose epidemic is underlying substance-use disorder. Many references suggest that addiction is not caused by a single factor, but rather a number of environmental, genetic, and physical factors along with the influence of other risk factors (CDC, MMWR, 2011). Addictive behavior--why do some people become addicted, while others do not? Nothing can predict whether or not a person will become addicted to drugs. Hence, if several risk factors are present, the higher the chance for addition. The following summary of risk factors for drug addiction, includes: Biology--Genes, gender, ethnicity, and the presence of other mental disorders may increase risk for drug abuse and addiction (NIDA, 2018).

According to a study by (Buu, Dipiazza, Wang, Puttler, Fitzgerald, & Zucker, 2009), final results suggests that parental psychopathology, family socioeconomic status, and neighborhood residential instability collectively are representative as important risk factors for the development of substance-use disorder and other comorbid psychopathology (Buu et al., 2009).

Environment-- Peer pressure, physical and sexual abuse, stress, and family relationships can influence the course of drug abuse and addiction in a person's life (NIDA, 2018). Although taking drugs at any age can lead to addiction, the earlier that drug use begins, the more likely it is to progress to more serious abuse (NIDA, 2018).

Populations at Risk

Vulnerable subpopulations at highest risk include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. Distinctly different amongst the aforementioned subpopulations, evidence supports that the rate of prescription opioid drug misuse is higher among Veterans than civilians (National Institute on Drug Abuse, 2013). Therefore, active duty military and veteran populations face unique challenges in controlling the risk factors associated with opioid abuse and dependence. The majority of overdose risks that veterans face during civilian readjustment are vastly grounded in their military experience and exacerbated by additional challenges (Bennett, Elliott, & Golub, (2015).

According to an observational study at the Veterans Health Administration (VHA), from fiscal years 2004 to 2012, the prevalence of opioid prescriptions among Veterans

increased from 18.9% to 33.4%, an increase of 76.7%. The groups with the highest prevalence of opioid use were women and young adults (i.e., 18-34 years old). The rate of prescription opioid drug misuse among veterans is approximately seven times higher among veterans as compared to civilians (Snow & Wynn, 2018).

Economic Burden

The economic burden of prescription opioid misuse and abuse is substantial. In 2006, the Drug Abuse Network (DAWN) reported approximately 324,000 emergency room visits that involved abuse of prescription painkillers (DAWN, 2007). Total US societal costs of prescription opioid abuse were estimated at $55.7 billion in 2007 (USD in 2009). Workplace costs accounted for $25.6 billion (46%), health care costs accounted for $25.0 billion (45%), and criminal justice costs accounted for $5.1 billion (9%). Workplace costs were driven by lost earnings from premature death ($11.2 billion) and reduced compensation/lost employment ($7.9 billion). Health care costs consisted primarily of excess medical and prescription costs ($23.7 billion). Criminal justice costs were largely comprised of correctional facility ($2.3 billion) and police costs ($1.5 billion) (Birnbaum, White, Schiller, Waldman, Cleveland & Roland, 2011). In 2007, prescription-opioid abuse cost insurers an estimated $72.5 billion which is a substantial increase over previous years (Department of Health and Human Services.gov, 2016). According to the Department of Health and Human Services (HHS), these alarming trends have led to prescription-opioid overdose deaths being deemed as an epidemic which has prompted multiple federal, state, and local actions. Most recently, according to a report from The Council of Economic Advisers, an agency that is part of the Executive Office of the President, the economic

cost of the opioid crisis in 2015 was $504 billion, which is much higher than previous estimates. According to an analysis by the National Center for Injury Prevention and Control, published in the journal Medical Care in 2016, estimated the cost of treating overdoses, abuse and dependence on prescription opioids alone costs American society some $78.5 billion per year. Prescription drug misuse cost the nation $78.5 billion in healthcare, law enforcement, and lost productivity (Florence, Zhou, Luo, Xu, 2016).

On the Political Front

On July 22, 2016, President Obama signed the Comprehensive Addiction and Recovery Act (CARA). It was enacted with the aim of addressing the epidemic of overdoses from prescription opioids and other prescription drugs and heroin. On February 2, 2016, according to The White House Office of the Press Secretary Factsheet: Proposes $1.1 Billion in New Funding to Address the Prescription Opioid Abuse and Heroin Use Epidemic (Factsheet, 2016). The President's FY 2017 Budget suggests a two-pronged approach to address this epidemic. First, it includes $1 billion in new mandatory funding over two years to expand access to treatment for prescription drug abuse and heroin use. Second, the President's Budget includes approximately $500 million -- an increase of more than $90 million -- to continue and build on current efforts across the Departments of Justice (DOJ) and Health and Human Services (HHS) to expand state-level prescription drug overdose prevention strategies, increase the availability of medication-assisted treatment programs, improve access to the overdose-reversal drug naloxone, and support targeted enforcement activities (Factsheet, 2016).

On October 26, 2017, Mr. Trump declared the opioid epidemic as a national public health emergency! According to the Fiscal Year (FY) 2019 Budget Fact Sheet, he stated: "Ending the epidemic will require mobilization of government, local communities and private organizations. It will require the resolve of our entire country (FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic)." Under the budget caps agreement, the Trump Administration is seeking nearly $17 billion in opioid-related spending in 2019 to stop the deadly spread of the epidemic (FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic).

Problem Statement

Currently, the extent of usage for opioid analgesics in the United States is unprecedented in the country's history and unparalleled to anywhere else in the world. Driven by an alarming rate of opioid abuse and misuse, drug overdose is dominating as the leading cause of accidental death in the U.S. Escalating opioid-related deaths has evolved into an emergent, national epidemic crisis with devastating economic and societal consequences.

Researchers have identified that the states suffering the most devastation are located along the Appalachian Mountain Region, where West Virginia (WV) is glaring with the highest rate of deaths from drug overdoses over any other state (MMWR, 2016). West Virginia is a challenged state due to its makeup of socioeconomically disadvantaged populations and underserved rural populations. Important to this proposal, presently, death rates from opioid overdoses in rural areas surpass urban areas, contributing to 63% of all overdose deaths (NIH.gov-PAR-18-745). Also, research indicates that rural

communities are distinctly challenged when implementing collaborative, inter-disciplined (multimodal) healthcare models (Teeters, Lancaster, Brown, & Back, (2017). Vulnerable subpopulations at highest risk include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. Distinctly different amongst the aforementioned subpopulations, evidence supports that the rate of prescription opioid drug misuse is higher among Veterans than civilians (National Institute on Drug Abuse, 2013).

The knowledge gaps lie within the complexity of this crisis and the strategies needed to fix the problem. Specific to this proposal, a pilot-project will be proposed to explore challenges associated with bridging access to multi-modal treatment strategies. Researchers suggest that tackling the complexity of the Opioid crisis demands an urgent, multidimensional and multi-sectoral research effort (ex. Coalition-Based Model- Max, Arrow, & Willis, 2018). West Virginia identifies as a state where multiple gaps in the research knowledge can be revealed and explored.

If solutions to the opioid crisis are not identified, the staggering rates of overdose deaths will continue to rise and overwhelm families, communities, first responders, and healthcare facilities nationwide, with consequences that could reverberate for generations.

Unraveling the complexity surrounding transitioning military members and current veterans dealing with opioid use disorder within West Virginia necessitates strategic,

collaborative, and multi-sectoral efforts(ex. Coalition-Based Model) that will explore and reveal precise knowledge gaps within the current body of literature.

Theoretical Frameworks

According to the University of Southern California's Library Guide, a theoretical framework is the research from previous literature that defines a study's core theory and concepts (Reference.com, 2018).

For this project-based proposal, the following theoretical lens will be applied:

The **biopsychosocial** model of health and illness is a **framework** developed by George L. Engel. George Engel formulated the biopsychosocial model as a dynamic, interactional, but dualistic view of human experience in which there is mutual influence of mind and body (Borrell-Carrió, Suchman, & Epstein, 2004) Evolving from a biomedical lens (which dominated from 1990s to early 2000) to a biopsychosocial-spiritual (BPSS) lens offered a holistic alternative with an interdisciplinary multimodal distinction. Endorsed by the American Psychological Association and the American Psychiatric Association, the biopsychosocial (BPS) framework represents an approach that emphasizes the importance of a systemic view of the individual focusing on an integration of biological, psychological, and sociocultural factors on human development and functioning (Meyers, 2008). Research suggests that a BPS approach has demonstrated to be helpful in the treatment of a number of disorders including depression, anxiety, addictions, as well as various chronic medical disorders (Meyers, 2008). Also, research supports that the biopsychosocial model requires a different

approach to treat chronic pain than is commonly used with acute pain. Chronic pain management is more complex and may require the input of multiple disciplines rather than a single provider (Debono, 2013).

SAMHSA Strategic Prevention Framework: Is a planning process for preventing substance use and misuse. The effectiveness of the SPF begins with a clear understanding of community needs and involves community members in all stages of the planning process (SAMHSA.gov).

Collective Impact (CI) Framework: The Collective Impact is a framework to tackle deeply entrenched and complex social problems. CI is the commitment of a group of actors from different sectors to a common agenda for solving a specific social problem, using a structured form of collaboration. It was first articulated in the 2011 Stanford Social Innovation Review article Collective Impact, written by John Kania and Mark Kramer (Kania & Kramer, 2011).

Purpose statement

Through the implementation of this pilot project, the purpose of this research is to explore the nuances, challenges and barriers associated with transitioning and readjustment processes as it relates to those patients (active duty/veterans) suffering from opioid use disorder. This research intends to highlight the aforementioned issues for those patients residing in high risk areas (such as WV) that disrupt the process of maintaining high quality continuity of care for opioid use disorder and pain management. Specific issues identified will be used to suggest interventions that bridge

multimodal options for pain management and improved quality of care in this patient population residing in high risk areas.

Research question or <u>project</u> addressed by the grant proposal

Under the application guidelines for NIH Funding Opportunity Announcement PAR-18-745 Research Project Grant, I propose a pilot-project named "TEAM Adapt, Conquer & Endure (ACE)." TEAM ACE will be an evolving veteran-focused coalition style project with a platform to identify knowledge gaps in current research and to develop targeted interventions. The proposal objectives are: *This initiative will support multidisciplinary exploratory/developmental research projects that examine the following: sociodemographic, cultural, economic, epidemiologic, and biological factors in opioid care specific to health disparity populations that increase the risk of OUD; the consequences of OUD; ways to improve resource availability among defined health disparity populations to reduce opioid treatment gap; and underlying mechanisms for the variation in the prevalence of OUD in health disparities populations. Research projects are encouraged to utilize rigorous innovative multi multidisciplinary approaches with integration of multiple factors that are known to cause opioid health disparities (FOA PAR-18-745).* This proposal **aims to: a)** understand the dynamics of opioid-related risks behaviors as they develop over time and to track the changing dimensions of veterans' reintegration experiences that impact substance use patterns; **b)** Propose interactive, collaborative interventions designed to aid in transitioning processes, preventing opioid misuse and decreasing opioid-related risk factors; **c)** Highlight the importance of

community-based multifaceted collaboration that multiplies options for integrative pain management care.

Research questions: 1) What are the contributing factors affecting physiological, social, and psychological opioid- related risk behaviors in the active duty/veteran populations? **2)** What are the knowledge gaps as it pertains to awareness of opioid misuse, dependence, and risk factors associated with transitioning processes (Base to Base and/or to Veteran status? **3)** What intervention strategies are being used to reduce these risks and improve patient care? **4)** Describe barriers to access for complementary care?

Significance Statement

This research proposal is important because despite what is known from the clustering of opioid-related risks among active duty and veteran subpopulations, gaps in the knowledge base still exist in reference to how these risks emerge over time. In addition, the conditions, behaviors, and events that precipitate risks need to be addressed and examined, while searching for viable solutions to fix the problem. Precipitating events and challenges faced by the veteran population include readjustment to civilian life and its numerous challenges, unemployment, homelessness, social isolation, cognitive impairment (ex. traumatic brain injury [TBI]), and mental health concerns (ex. depression, posttraumatic stress disorder [PTSD]) (Bennett et al., 2015).

Definition of Terms

1. **Coalition-Based Model:** Community coalitions have the potential to prevent and reduce substance abuse in communities. Coalitions can strengthen collaboration between public and private organizations in communities, address factors in the community that increase the risk of substance misuse, and support interventions that promote environmental strategies to address substance misuse in the community (RuralHealthInfo.org).

CHAPTER II: REVIEW OF LITERATURE

Introduction

This chapter is a review of the literature that pertains to the evolution and impact of the Opioid Epidemic, an assessment of existing efforts, and surmounting challenges still facing ahead. Although the epidemic presents as a complex, complicated terrain to navigate, application of multidisciplinary models are being explored. This review of the literature will focus on West Virginia as a troubled State, the military/veteran population, challenges associated with access to care for treatment of Opioid Use Disorder (OUD) and lastly, provide evidence to support the need for the proposed pilot-project presented in this Thesis grant proposal.

Review of Literature (ROL)

Overview and Background of Opioid Epidemic: The United States has a difficult crisis on its' hands! The abuse of prescription and non-prescription opioids is distinctly, one of the greatest public health threats in the U. S. today. Driven by an alarming rate of opioid abuse and misuse, drug overdose is dominating as the leading cause of accidental death in the U.S.

Nearly 2.5 million people in the US are suffering from opioid addiction related to prescription drugs for chronic pain. Opioid use disorders (OUD's) were most common among those who were uninsured or unemployed, were low-income individuals, or had behavioral health problems. States with the highest opioid prescriptions per capita also have the highest opioid overdose mortality. These staggering rates of overdose are overwhelming families, communities, first responders, and healthcare facilities

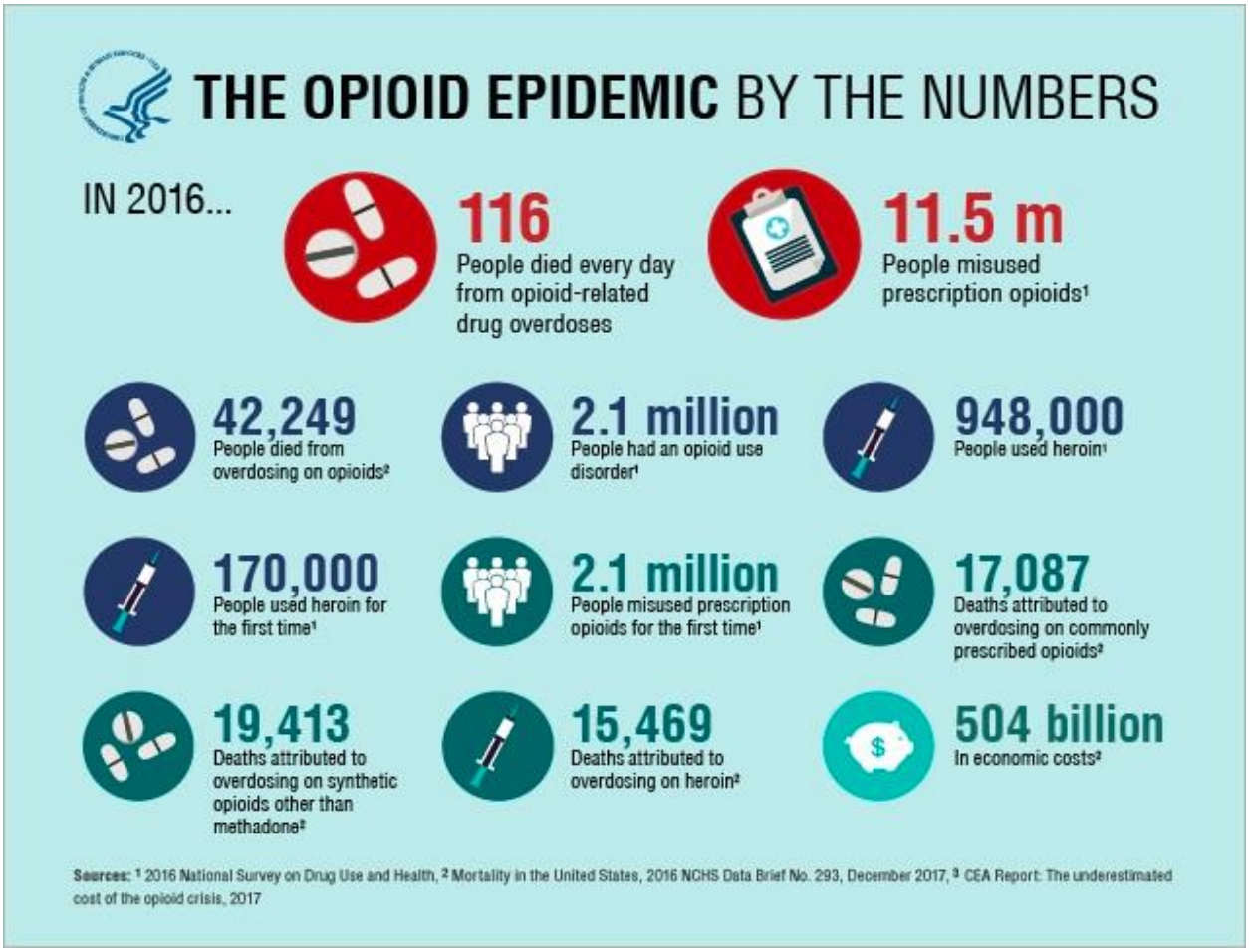
nationwide, with consequences that could reverberate for generations. Hence, the complexity of this crisis necessitates an urgent, multidimensional and multi-sectoral research effort.

On October 26, 2017, President Trump declared the opioid epidemic to be a national public health emergency (FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic). Many parties have played a role and are responsible for creating this present day epidemic. This epidemic is distinctly connected and has been catalytically driven by the treatment of chronic, nonmalignant pain which has also evolved into a substantial public health problem in the United States (Debono et al., 2013). Unfortunately, this climate has unfolded despite well-intentioned efforts by multiple industries, medical specialties associations and governmental oversight organizations (Jones, Viswanath, Peck, Kaye, Gill, & Simopoulos, 2018). Abuse of and addiction to opioids has become an extremely serious and challenging public health problem to address. Over the last two decades, deaths from drug overdose have risen steadily and have become the leading cause of injury death in the United States (CDC, 2014). Prescription drugs, specifically, opioid analgesic (a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone) used to treat both acute and chronic pain, have increasingly been implicated in drug overdose deaths over the last decade (CDC Quick Stats, 2013; Paulozzi, Jones, Mack, Rudd, 2011). From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled (CDC Quickstats, 2013). Deaths related to heroin have also increased sharply since 2010, with a 39 percent increase between 2012 and 2013(Office of The Assistant Secretary for Planning

and Evaluation (ASPE), 2015). Also glaring with concern, overdoses related to illegally manufactured fentanyl represent the greatest contribution to the death toll increase, accounting for 20,000 deaths in total; heroin accounted for 15,000 deaths; and prescription drugs for less than 15,000(Jones et al., 2018). Presently, death rates from opioid overdoses in rural areas surpass urban areas, contributing to 63% of all overdose deaths (NIH.gov-PAR-18-745). Those states with the highest opioid prescriptions per capita also have the highest opioid overdose mortality. These staggering rates are overwhelming families, communities, first responders, and healthcare facilities nationwide, with consequences that could reverberate for generations.

National Imprint (Figure 1.)-These following facts suggest that the costs of prescription opioid abuse and the overall opioid epidemic signify a substantial and growing economic burden for the society. Also, the increasing prevalence of abuse suggests an even greater societal burden in the future (Birnbaum et al. 2011).

Figure 1. The Opioid Epidemic by the Numbers



Main Source: HHS.gov, 2016; (Sources on chart: 1 2016 National Survey on Drug Use and Health, 2 Mortality in the United States, 2016 NCHS Data Brief No. 293, December 2017, 3 CEA Report: The underestimated cost of the opioid crisis, 2017)

Burden of the Epidemic

The Opioid epidemic has placed significant health and economic challenges and burdens on many subpopulations of patients, families, and the society as a whole. Vulnerable

subpopulations at highest risk include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. Evidence supports that the rate of prescription opioid drug misuse is higher among Veterans than civilians (National Institute on Drug Abuse, 2013).

Opioid analgesic extent of usage in the United States is unprecedented in the country's history and unparalleled to anywhere in the world. Use and abuse of prescription opioids have increased astronomically in the United States. Americans make up 4.6% of the world's population and yet consume approximately 80% of the world's opioid supply (Blozen, 2013). Also stunning, Americans consume 99% of the world's supply of hydrocodone, a commonly used opioid (Blozen, 2013).

In Support of Problem statement

What is known: Evidence supports that military personnel and veterans that have been exposed to combat or service-related injuries are frequently prescribed prescription opioids (POs) to manage pain (Bennett et al., 2015). Research suggests that military personnel and veterans represent a vulnerable population at disproportionate risk of opioid-related misuse and overdose (Bennett et al., 2015). Often escalated within the broader context of transitioning processes (base to base) and/or challenges associated with readjustment to civilian life, opioid-related exacerbations and accidental overdose events often occur due to mismanagement of continuity of care. Evidence shows that for those veterans returning to communities plagued by poverty, homelessness, crime, substandard housing, and unemployment, the risks of substance abuse disorders (SUDs)

and overdose may be exacerbated due to multiple environmental risk factors (Bennett et., al, 2013) Also research indicates that rural communities are challenged when implementing collaborative, inter-disciplined (multimodal) healthcare models (Teeters, Lancaster, Brown, & Back, (2017).

What is unknown: While the opioid epidemic is in the spotlight on the national stage evoking engaging discussions and planning from diverse authorities and members in government and healthcare, implementation strategies remain to be challenging tasks. Referenced tasks for examples of intervention strategies include:

*U. S. Army Base Fort Bragg implemented Operation Opioid SAFE in 2011, which provide overdose prevention training and naloxone to active-duty soldiers at risk for opioid overdose in the course of routine pain management (Bennett et al., 2015).

*In response to safety concerns of opioid drug misuse among Active Duty members and Veteran population, the Veteran's Administration (VA) in conjunction with the Department of Defense (DOD) developed the VA/DOD Clinical Practice guidelines within the Opioid Safety Initiative (U.S. Department of Veterans Affairs, 2017). Clinicians were provided a framework for opioid drug therapy to care for the unique needs of Veterans with chronic pain. The guideline describes the critical decision points in the Management of Opioid Therapy (OT) for Chronic Pain and provides clear and comprehensive evidence based recommendations incorporating current information and practices for practitioners throughout the DOD and VA Health Care systems (VA, 2017). In response, quantity tapering strategies, and naloxone education and outreach programs

have been implemented. However, despite some progress and positive results with opioid dosing and identifying at risk patients, long term resulting outcomes associated with these change efforts remain as unknown territory or gaps within the existing body of literature. For example, an unknown factor is transparency and access to multimodal treatment care plans. It seems that the VA has an advantage with multimodal care offered in house, but this approach is likely challenging in rural areas which have less access to VA care. The Veteran Choice Program (VCP) (VA.gov, 2018) is one of several programs through which a Veteran can receive care from a community-based provider, however, this program has revealed and presented several complex, difficulties for its veteran patients. Astonishing articles from different sectors of the U. S. reveal, that many veterans have reported numerous problems with the Veterans Choice program (Walsh, 2016; Sisk, 2018; VA Mission Act 2018(replacing Choice program). A KPBS News broadcast in May, 2016 reported that Congress and VA officials are currently in the middle of overhauling the program, which many say has not delivered on the promises made to veterans when it was created (Walsh, 2016).

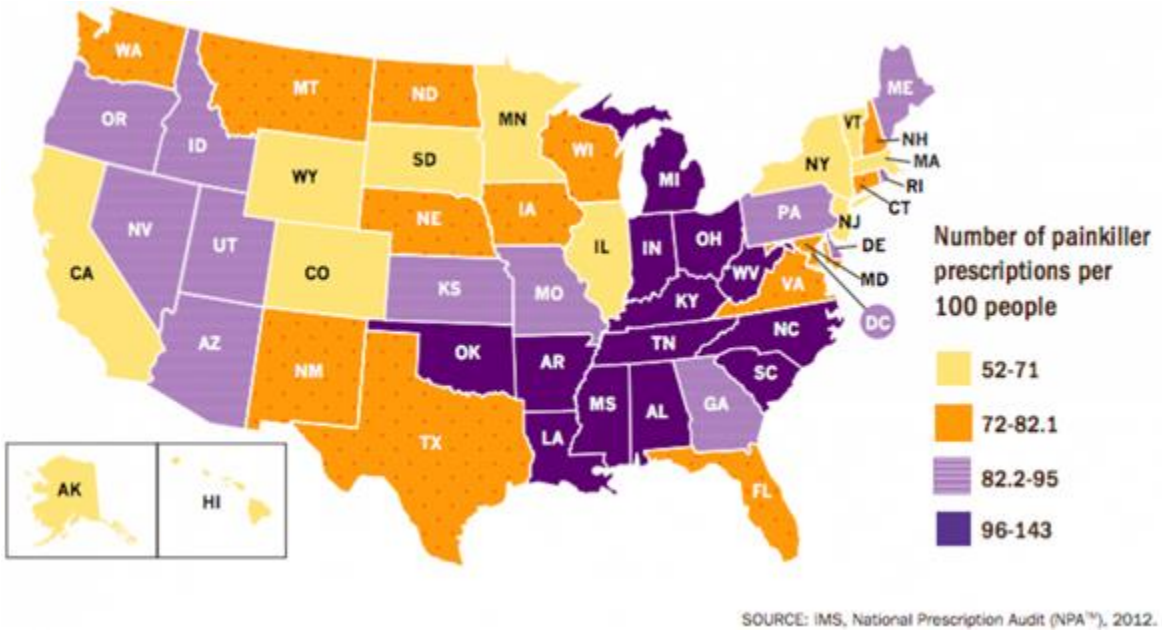
Lastly, another unknown factor to examine is assessing the readiness and feasibility of partnerships to develop collaborative care teams at federal, state and community levels. **Research on barriers to providing healthcare services in rural communities and novel strategies to improve mental health infrastructure in these settings is needed.** Such research would aid efforts to predict and create unique, specific interventions and risk mitigation strategies that minimize patient harm Also, areas of emphasis for

individualized multimodal care plan should be identified because a "one size will fit all" approach will be futile. The use of Medicated Assisted Therapies (MAT) in non-traditional settings to examine multidisciplinary approaches to treatment, holistic and non-medical models of care, should be evaluated. Lastly, the impact of education on prevention and treatment in non-medical settings should be assessed.

One example: Prescription Drug Monitoring Programs (PDMPs), which are state-run electronic databases of prescriptions for controlled substances, are considered among the most promising clinical tools to curb prescription opioid abuse (ASPE, 2015). PDMPs are used to identify patients who are potentially abusing medications. However, because organization and operation of PDMPs varies among states (e.g. which state agencies houses the PDMP, which controlled substances must be reported, how often data are collected and reported, who can access the PDMP, etc.) limitations exist and can affect appropriate tapering processes (ASPE, 2015). For the purposes of preventing opioid overdose, PDMPs combat diversion by restricting access to POs, by way of providing a tool for reduction in prescribing prescription opioids (POs). PDMPs are raising awareness and reducing misuse (especially casual misuse) among many populations. However for the veteran population, often affected by multiple comorbidities, medication tapering becomes very challenging. Unfortunately, recent evidence has shown that restricting access and tapering POs has met criticism; it is feared that some veterans will self-treat their pain with diverted POs or even switch to illicit substances, such as heroin (Bennett et al., 2015).

Another example: Because rural areas present many treatment challenges as it pertains to access to care, particularly for mental health services and other alternative pain treatment services(acupuncture, chiropractic, massage, yoga, etc.), veterans residing in rural areas lack access to these types of treatments.. Evidence supports that increased access to mental health care via Tele-Mental health (TMH) modalities may improve quality of life for veterans living in rural area. Although literature directly pertaining to the delivery of TMH services for OUDs is limited, the small body of research that specifically investigates substance use TMH treatments has revealed favorable results (Teeters et al., (2017).

Figure 2. Number of Painkiller Prescriptions per 100 People in United States



Source: (CDC Quick Stats, 2013)

Data also supports that many opioid users get the drugs from diversion through family and friends or from their primary care physician. According to (Blozen, 2013), between 1991 and 2010, opioid prescriptions increased from about 75.5 million to 209.5 million. From 2011-2012, persons aged 12 and older who had reported using prescription pain relievers non-medically in the previous 12 months:

- 54% said they obtained the drugs free from a relative or friend
- 15% bought or stole the drugs from a relative or friend
- 19% obtained the drugs from a single doctor
- only 1.8% got the drugs from more than one doctor
- Just 4.3% bought the drugs from a dealer or stranger.

Since the 1990s, chronic pain management efforts have not measured up to adequately account for the misuse of opioid drugs, thereby, resulting to the growing epidemic in America (Blozen, 2013). It is proven that opioid analgesics are beneficial for the treatment of pain in carefully selected patients, however, their increased use in the United States has contributed to an increase usage for nonmedical activities.

According to a 2011 study by the National Academy of Medicine (previously the Institute of Medicine [IOM]), chronic pain is identified as a national public health problem affecting approximately 100 million Americans. Chronic pain is defined as pain that persists for longer than 3 to 6 months with persistence beyond "normal healing time" of an injury (Debono et al., 2013). Recently noticed, the treatment of chronic pain with opioids has increased at alarming rates. This condition accounts for an estimated $560 billion to $635 billion per year in health costs and lost productivity (Committee on

Advancing Pain Research, Care, and Education, Institute of Medicine; Board on Health Sciences Policy, 2011) & (Debono) et al., 2013).

Chronic pain is usually accompanied with depression and anxiety. It is reported in one study of patients with chronic, disabling occupational spinal disorders, that 65% of patients had at least 1 psychiatric disorder and 56% had a major depressive disorder (Debono et al., 2013). Evidence has demonstrated that the care of a patient with chronic pain is best performed in collaboration with an interdisciplinary team (ex. primary care physicians, physical or occupational therapists, psychologists or psychiatrists, and pain specialists) (Debono et al., 2013). Bennett et al, (2015) suggests that when working with the veteran population, encouraging community-based interagency collaboration can help veterans connect with other veterans and seek out the services they need to realize the potential for their voices to impact policies designed to assist them.

Prescription opioids are packaged as immediate-release (IR) or extended release/long-acting (ER/LA) formulations. When used improperly, any opioid can result to serious side effects, including overdose and death. Risks substantially increases with ER/LA formulations. Also, evidence supports that prescription opioids (POs) taken in combination with other misused or abused prescription drugs such as benzodiazepines (e.g. sedatives like Xanax) and antidepressants are commonly linked to overdose deaths (ASPE, 2015).

Existing evidence shows that individuals at greatest risk for prescription opioid overdose include: (ASPE, 2015):

- White and American Indian/Alaska Native people
- Men (although overdose among women is on the rise)
- People living in rural areas (clusters in the Southeast—especially in the Appalachian region)
- Adults aged 45-54 years
- People who obtain multiple controlled substance prescriptions (especially the combination of opioid analgesics and benzodiazepines) from multiple providers
- People who take high daily doses of opioid pain relievers (some Veterans likely fall into this category)
- Nationwide opioid analgesics currently rank as the main source of more overdose deaths as compared to heroin and cocaine combined. Increased sales of opioid analgesics along with their negative effects closely mirror the fatal and nonfatal overdoses, drug poisonings and death rate involving opioid analgesics. According to a 2010 US National Survey of Drug Use and Health report, 4.8% of the population over the age of 12 years in the United States (i.e., 12.2 million people) reported using pain relievers non-medically in the past year. Additionally, opioid analgesics are some of the most commonly used drugs leading into illicit drug abuse (Kenan, Mack, & Paulozzi, 2012).

Vulnerable subpopulations at highest risk for opioid abuse include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. In contrast, evidence supports that the rate of prescription opioid drug misuse is higher among veterans than civilians (National

Institute on Drug Abuse, 2013). To elaborate, veterans who served in recent wars often experienced emotional injury resulting in posttraumatic stress disorder (PTSD), often accompanied with physical pain from injuries sustained (Snow et al., 2018). These soldiers are among the thousands of individuals being prescribed opioid pain medication at steadily increasing rates. Therefore, active duty military and veteran populations face unique challenges in controlling the risk factors associated with opioid abuse and dependence. The majority of overdose risks that veterans face during civilian readjustment are vastly grounded in their military experience and exacerbated by additional challenges (Bennett, Elliott, & Golub, (2015).

Target State and Population of Concern for Grant Proposal

West Virginia covers 24,078 square miles, with a 2017 estimated population of 1,815,857 people, with 693,506 people living in rural areas (USDA-ERS). According to 2017 data from the U.S. Census Bureau, 93.6% of the state's population is white, 3.6% is African-American, 0.8% is Asian, 0.2% is American Indian or Alaska Native, and 1.6% is of Hispanic or Latino origin (Rural Health Information Hub. org).

West Virginia Rural Healthcare Facilities

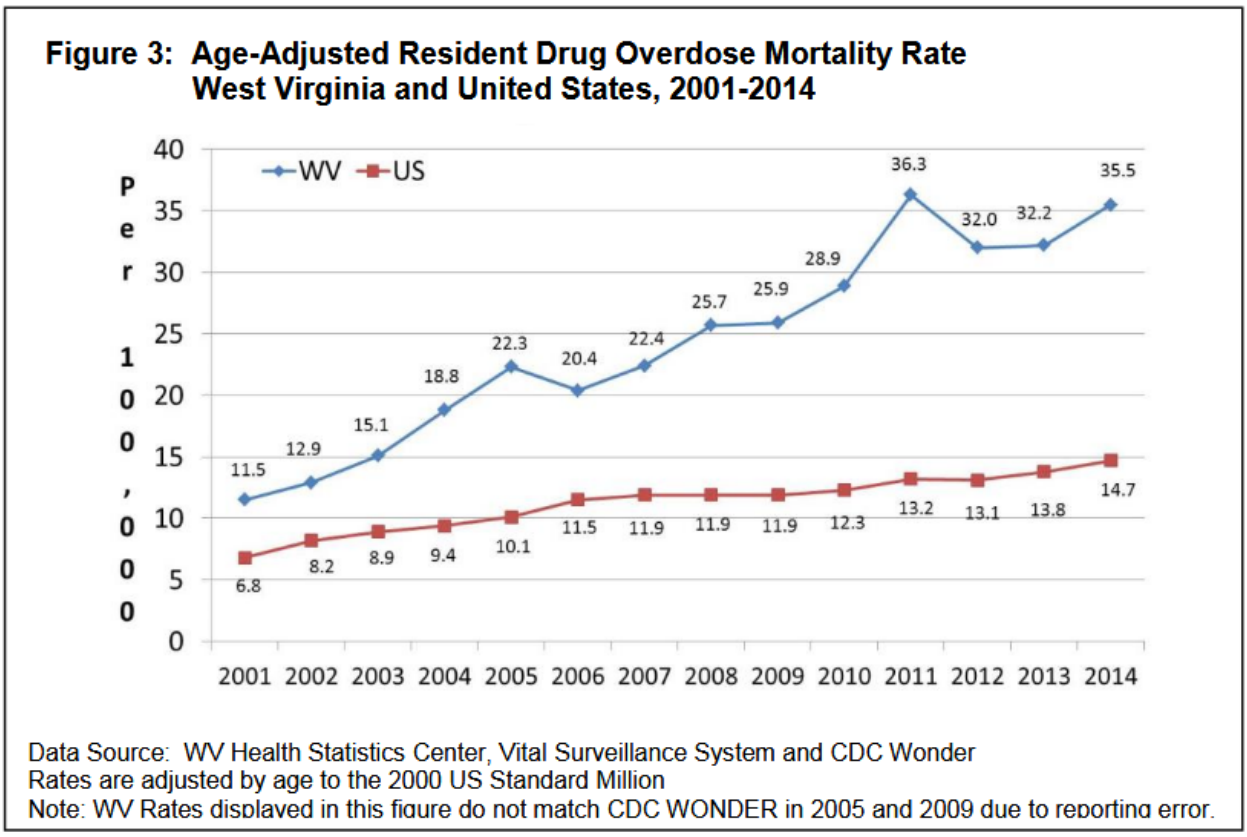
There are 54 hospitals in West Virginia (Kaiser, 2016), 20 of which are identified as Critical Access Hospitals (Flex Team, 7/2018). There are 53 Rural Health Clinics in West Virginia (CMS, 2017) and 27 Federally Qualified Health Centers provide services at 307 sites in the state (NACHC, 2017)(RDIHub.org).

Background: Contributing Factors to West Virginia's High Opioid-related Deaths:

West Virginia has long been known as "coal country." Mining, timbering, and manufacturing played a huge role in West Virginia's economy. These types of jobs require heavy manual labor and often leave workers prone to injury. According to a Bureau of Labor Statistics report, as of March 2016, West Virginia had the second-highest unemployment rate in the US, at 6.5% trailing Alaska.

West Virginia has been experiencing a devastating public health epidemic of drug overdose deaths for over the last 10 years or so. Intentional and unintentional drug overdoses are happening among the more densely populated areas of the state, especially the more rural southern areas. As of 2015, West Virginia drug overdose death rates compared to the United States indicates that West Virginia resident drug overdose mortality rate of 35.5 is more than twice as high as the United States mortality rate of 14.7 per 100,000 (WVDHHR, 2017). West Virginia has the highest age-adjusted mortality rate in the nation and over a third higher than the next highest state, Kentucky as displayed in chart below:

Figure 3. Age-Adjusted Resident Drug Overdose Mortality Rate WV



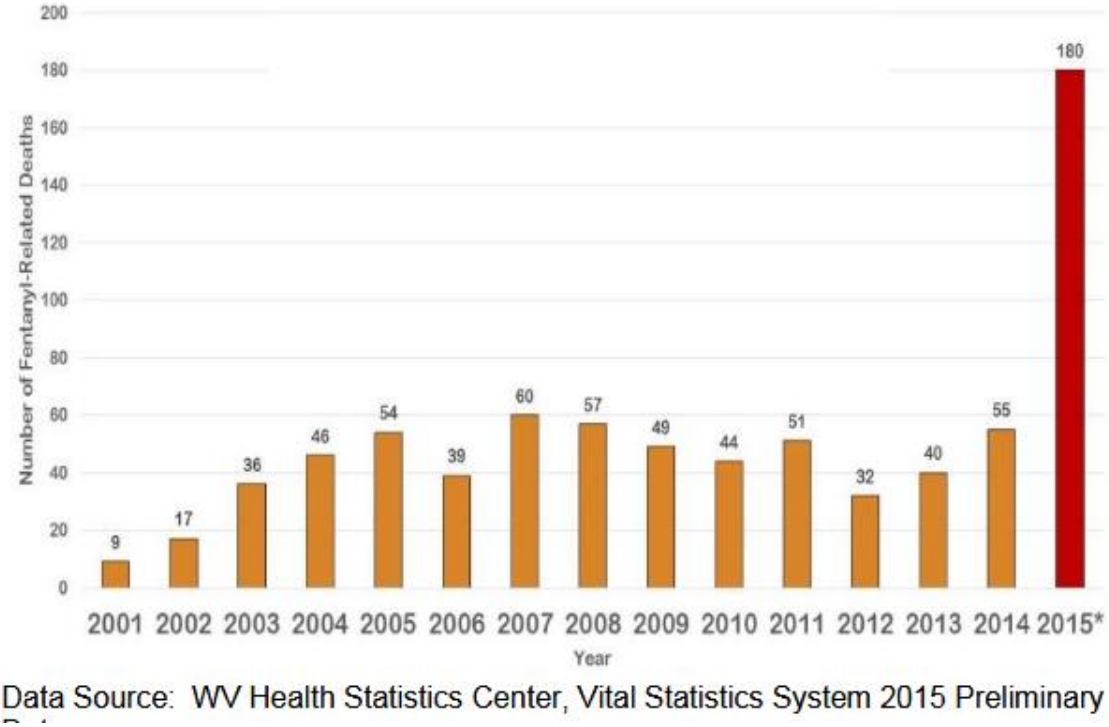
Source: (WVDHHR, 2017)

Opioid-Related Overdose Deaths

In 2016, West Virginia had the highest rate of opioid-related overdose deaths in the United States—a rate of 43.4 deaths per 100,000—and up from a low 1.8 deaths per 100,000 in 1999. The number of overdose deaths peaked at 733 deaths in 2016 with the majority of deaths attributed to synthetic opioids and heroin. Since 2010, deaths related to synthetic opioid deaths quadrupled from 102 to 435 deaths and deaths related to heroin rose from 28 to 235 deaths (National Institutes of Drug Abuse (NIDA), 2018).

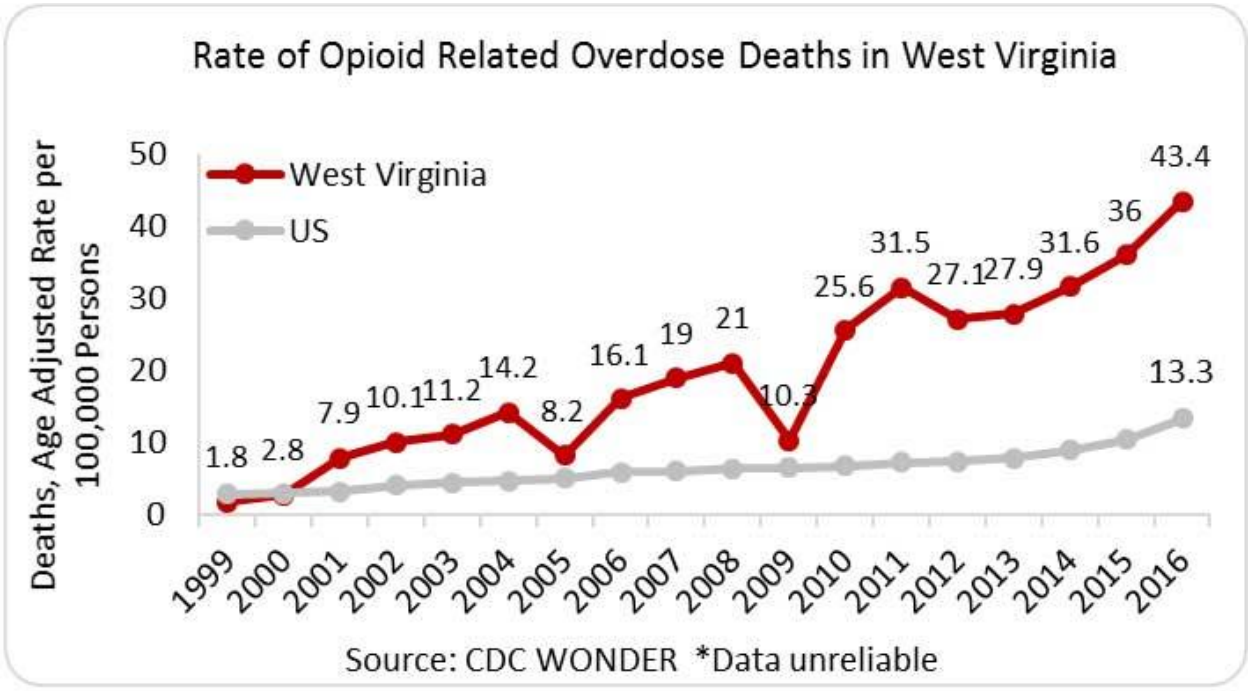
Raleigh, Kanawha, and Cabell accounted for 29.4% of reported deaths from oxycodone from 2001 through 2015, while 819 heroin-related deaths were reported over the last 15 years. In more recent years, 2013 through 2015, heroin has become the second leading opioid contributing to 523 overdose deaths (WVDHHR, 2017).

Figure 4. Fentanyl-Related Overdose Deaths West Virginia Occurrences 2001-2015(N=769)



Source: (WVDHHR, 2017)

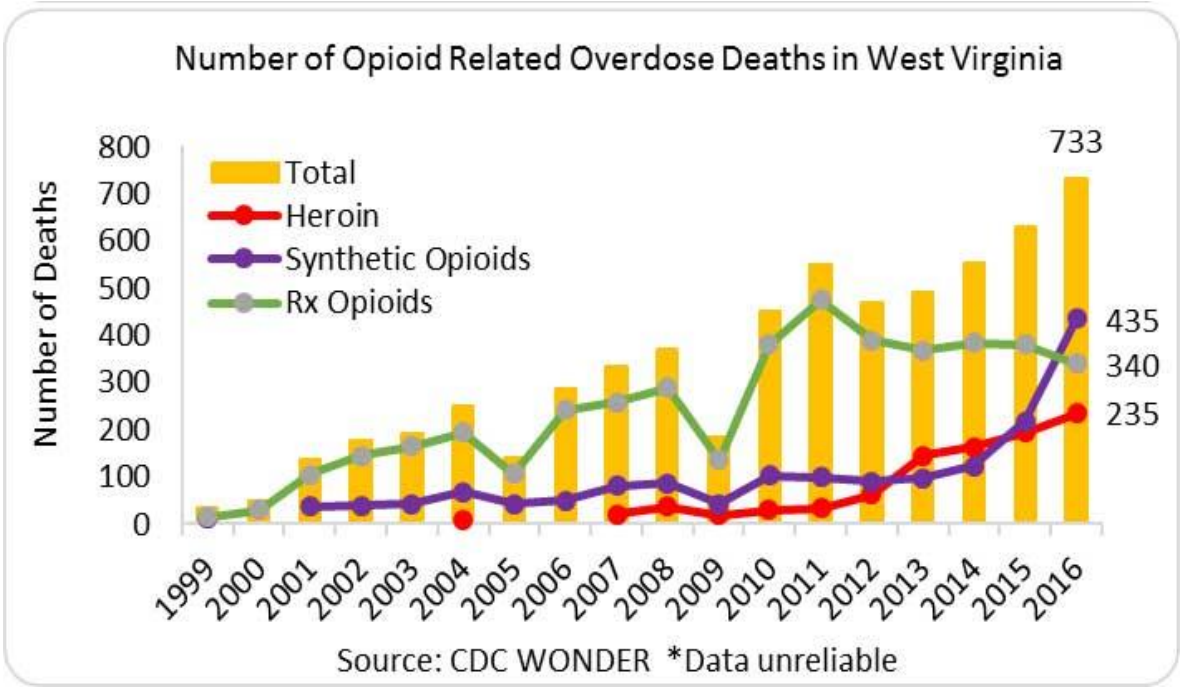
Figure 5. Rate of Opioid Related Overdose Deaths in West Virginia



Source: (NIDA, 2018)

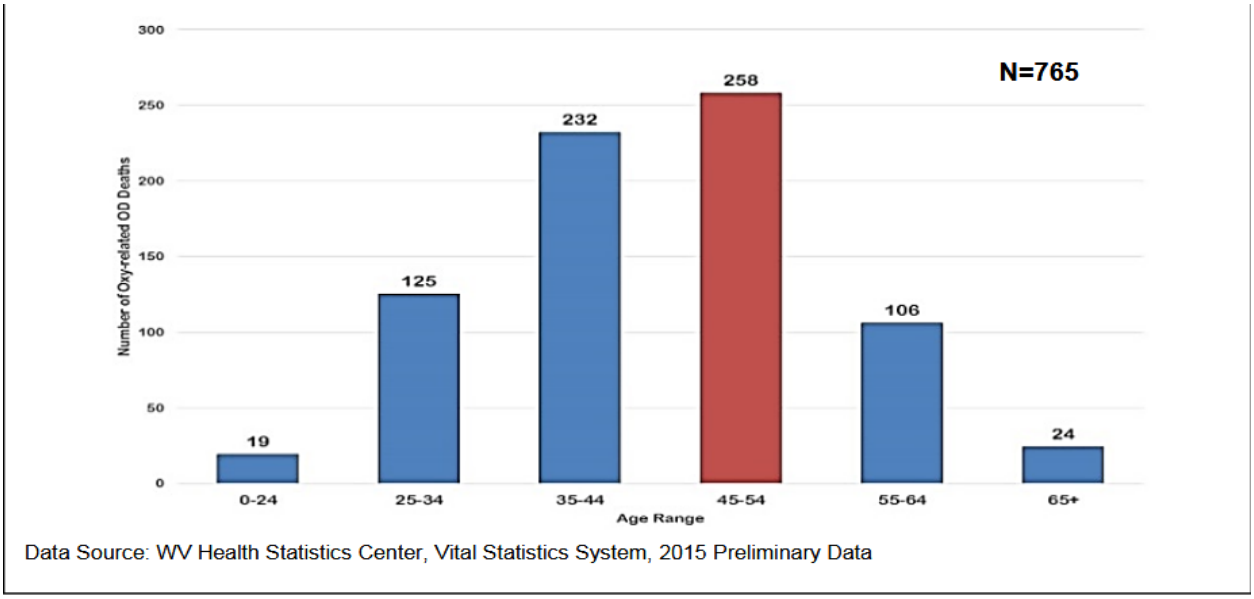
In 2013, West Virginia providers wrote 110 opioid prescriptions per 100 persons (2.08 million prescriptions). In the same year, the average U.S. rate was 70 opioid prescriptions per 100 persons (NIDA, 2018).

Figure 6. Number of Opioid Related Overdose Deaths in West Virginia



Source: (NIDA, 2018)

Figure 7. Oxycodone-Related Overdose Deaths by Age in West Virginia Occurrences, 2012-2015



Source: (WVDHHR, 2017)

Veteran Statistics in United States (OUD)

The rate of prescription opioid drug misuse is higher among Veterans than civilians where evidence supports that opioid drugs are abused approximately seven times more often by veterans as compared to civilians (Snow & Wynn, 2018). According to Bennett et al (2015), the army has reported that among active-duty personnel, drug toxicity deaths more than doubled between 2006 and 2011, and overdose rates were significantly elevated among VA patients as compared with the civilian population. A May 2014 VHA report indicated that 440,000 current patients were prescribed opioids, placing them at potential risk, and 55,000 veteran patients were diagnosed as having a current opioid

use disorder, placing them at even greater risk. The following (Figure 8.) provides a snapshot of Greenbrier County is located in the southern area of West Virginia. According the U.S. Census (2012) Greenbrier County residents constitute 1.9 % of the population of the state. Greenbrier's veteran population is 13.8 % as compared to the overall 11.4% for the state WV as referenced below in Figure 8. (U.S. Census Bureau, 2012).

Figure 8. Greenbrier County Population Statistics

Demographic Data

		Greenbrier	WV
Population		35,820	1,855,413
Race	White	94.8%	94.0%
	Black	2.8%	3.5%
	Other	2.4%	2.5%
Median age		45.0	41.7
Labor force*		53.2%	54.9%
Median household income*		$35,180	$39,550
Income below poverty level*		19.3%	17.5%
High school graduate or higher*		79.4%	82.6%
Civilian veterans*		13.8%	11.4%

Source: US Census Bureau, 2012 population estimates, *American Community Survey (2007-2011)

Veteran Health Administration (VHA)

Intro: Military veterans make up one of the nation's biggest health care systems. It is a complex operation that treats 6.5 million people a year at 151 hospitals and 820 outpatient clinics, with more than 18,000 doctors and an annual budget of more than $57 billion (Veterans Administration.gov).

Opioid Use Disorder (OUD) Interventions: In 2013, a national system-wide effort mandated by Congress, the Department of Veterans Affairs (VA) and the Department of Defense (DoD), developed and implemented the **Opioid Safety Initiative (OSI)**, a multi-faceted, comprehensive effort to improve Veteran quality of life suffering from chronic pain, to assist in decreasing opioid prescribing practices associated with adverse outcomes, and to promote safer opioid-related prescribing for Veterans.

Problems and Concerns: The Veterans Health Administration has a known history of corruption, scandal and many other difficult challenges in serving their Veteran population (Fulton & Brooks, 2018; Krause, 2017; Sisk, 2018). VHA's recent and historical problems with mismanagement, reporting falsification and preventable deaths has created a distrustful image. Problems with veterans' care still continue through 2018 revealing ongoing, systematic problems (Fulton & Brooks, 2018; Krause, 2018; Sisk, 2018). Examples include a July 2014 whistleblower report where many U.S. veterans died while waiting for care at the Phoenix VHA which led to a VA IG investigation in August of 2014 involving 93 VHA facilities accused of manipulating wait times (Fulton & Brooks, 2018). Also, the IG investigation confirmed manipulations of wait time were

prevalent (Fulton & Brooks, 2018). In reference to the Opioid Epidemic, lawsuits are emerging due to years of veterans lodging complaints against their primary care providers for removing veterans from opioids without utilizing appropriate tapering techniques (Krause, 2017). The result of these measures has allegedly forced veterans into the black market to seek alternative treatments for chronic pain including using heroin (Krause, 2017).

Combating the Problem

Given these alarming trends, the time has emerged for urgent, actionable, smart and sustainable responses to prevent opioid abuse and overdose and treat people with opioid use disorder (OUD) (ASPE, 2015). Recent studies confirm that multimodal interventions that have both pharmacological and psychosocial components are the most effective treatment for Opioid Use Disorder (OUD) (Mark et al., 2018). Nationally, experts are pointing to local **opioid coalitions** as a **promising response strategy** (Max, Garrow & Willis, 2017). According to a 2016 innovation report by the Institute for Healthcare Improvement (IHI) that identified new approaches for addressing the prescription opioid crisis, the report concluded that the epidemic will heighten in the absence of a "coordinated and collaborative community-wide approach" (Martin, Laderman, Hyatt, Krueger, 2016). IHI's proposed theory of change necessitates local efforts that scale promising practices, build public awareness, and engage a broad, diverse set of partners beyond public health and health care Innovation (Martin et al., 2016). An example of this theory is the success of Project Lazarus in North Carolina, a multi-stakeholder

community-based model that has seen significant reductions in opioid prescribing and deaths. Also, representing as a leading federal agency in the opioid response, SAMHSA also promotes **coalition-based efforts** and offers web-based resources and technical assistance (Max et al., 2017).

Examples of Effective Working Models

Project Lazarus Model is a public health model based on the twin premises that overdose deaths are preventable and that all communities are responsible for their own health. Established in 2007, as a response to extremely high overdose mortality rates in Wilkes County, NC, Project Lazarus successfully and dramatically decreased Wilkes' overdose mortality rate by devising and implementing this model approach (Albert, Brason, Sanford, Dasgupta, et al, 2011). With dedication to assisting in the fight of the Opioid epidemic, Project Lazarus specializes in helping communities build and establish Coalition groups and/or revive an already existing group. Also, this organization offers unique programs and training to individuals, communities and other specialty groups (law enforcement, military, and tribal populations) (Albert et al., 2011). Presently, some components of Project Lazarus have been implemented in some areas of West Virginia.

The California Health Care Foundation (CHCF) is a statewide network of 16 coalitions operating in 23 counties. The California Prescription Opioid Misuse and Overdose Prevention Workgroup brings together a broad partnership of more than 40 organizations, including the departments of justice, corrections, education, drug enforcement, health care services and others. State efforts focus on broad, cross-sector

efforts in place of siloed interventions. This Opioid Safety Coalitions Network has three priority strategies: Safe opioid prescribing; Use of medication-assisted addiction treatment (MAT); and Access to naloxone to reverse drug overdoses. Based on the Network successes thus far and considering a national overview, the evidence supports moving towards a broader menu of strategies beyond MAT, naloxone and safe prescribing. The recommendation is for strategic planning that expands into complementary interventions. This planning would advance adoption of the core strategies and draw in wider local engagement. Suggested strategic priorities identified by the CHCF coalition leaders include safe medication disposal, behavioral health integration, stigma reduction, prevention strategies, and addiction recovery services (Max et al., 2017).

Team, Red, White & Blue (Team RWB) is a unique and rising veteran and military serving organization. It is a 501(c)(3) nonprofit organization founded in 2010 with the mission of enriching the lives of America's veterans by connecting them to their communities through physical and social activity. Team RWB's operational model strives towards delivering local, consistent, and inclusive activities designed to build a community-of-communities concept. Identifying as an evidence based organization and wellness intervention, Team RWB aims to measure and communicate its programmatic impacts on participating veterans' enrichment (Angel & Armstrong, 2016).

Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO): Uses video-teleconferencing to hold monthly or bi-weekly scheduled

sessions between a multi-disciplinary specialty care team at urban medical centers and PCPs, many of whom are at Community-Based Outpatient Clinics (CBOCs)(VA.gov)

Working models such as: SCAN-ECHO; Patient Aligned Care Team (PACT) and The Opioid Safety Initiative represent an internal collaboration, multimodal platforms unique to the Veterans Administration system. Also, according to SAMHSA recommendations for treatment for substance abuse disorders, non-clinical support services are vital to patient recovery efforts. Recovery support services should include: Transportation to and from treatment and recovery-oriented activities; Employment or educational supports, Specialized living situations, Peer-to-peer services, mentoring, coaching; Spiritual and faith-based support; Parenting education; Self-help and support groups; Outreach and engagement; Staffing drop in centers, clubhouses, respite/crisis services, or warm lines (peer-run listening lines staffed by people in recovery themselves); Education about strategies to promote wellness and recovery. Another working model that is veteran focused is Team Red, White, and Blue (RWB). This Evidence-Based wellness intervention model uses a positive psychology approach. Team RWB assists veterans seeking connection to develop authentic relationships through physical and social activity. It is through these new or strengthened social relationships that Team RWB supports better mental health by mitigating against challenges resulting from a lack of connection (such as depression and suicide) and facilitating newly transitioned veterans into socially supportive communities to prevent social isolation (Angel & Armstrong, 2016). Although many efforts towards collaboration are being made, there is still a

limited, yet growing body of research that supports the effectiveness of several interventions to address opioid use disorder. Hence, it is very important that continued monitoring and evaluation of all programs remain as essential tasks to further strengthen the evidence base and inform program and policy decision making (ASPE, 2015).

Summary of current problem and study relevance

After an extensive literature review, all the facts and evidence reveal that the opioid epidemic has grown into a devastating, complex, multifaceted problem! Navigating through the complicated terrain of the opioid crisis will require a multidimensional and multi-sectoral research effort. Also, it can be concluded that the State of West Virginia, specifically those rural, extremely troubled counties, are in urgent need of strategic collaboration of multimodal services. Evidence supports that, veterans present with a unique scenarios of comorbidities as well as other psycho-social challenges making them a population that can face extreme risks associated with drug abuse and dependency. Also, as mentioned earlier, the entire VHA is under a microscope, transitioning/scrambling to rebuild a long, troubled, history and damaged reputation. Therefore, in reference to this proposal, it can be predicted that the hypothetical military member with an opioid use disorder (OUD) transitioning from active duty life to civilian life and residing in West Virginia, specifically, one of West Virginia's troubled counties, will be highly at risk for an opioid related injury based on the States' opioid-related statistics. This grant proposal is relevant because the pilot-project can provide a platform for seamless continuance of

care, reveal gaps in known research; discover areas in need of improvement; create targeted interventions; and lastly, accelerate effective implementation that drive positive change.

CHAPTER III: METHODOLOGY

Introduction

Chapter III includes a summary of the problem, description of the pilot-project and a review of funding agencies that champion support towards finding solid, comprehensive solutions to decrease the devastating imprint of the opioid epidemic. It also includes a summary of the grant announcement for this proposal.

Summary of Problem

According to (ASPE, 2015), the U.S. Department of Health and Human Services (HHS) has made addressing the opioid abuse problem a high priority and has committed to accelerating its work towards two broad goals: 1) decreasing opioid overdoses and overall overdose mortality and 2) decreasing the prevalence of opioid use disorder.

In October 2017, President Donald J. Trump declared the opioid epidemic a nationwide public health emergency. According to the Fiscal Year (FY) 2019 Budget Fact Sheet, he stated: "Ending the epidemic will require mobilization of government, local communities and private organizations. It will require the resolve of our entire country (FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic)." Under the budget caps agreement, the Trump Administration is seeking nearly $17 billion in opioid-related spending in 2019 to stop the deadly spread. Notably, the Administration proposes $3 billion in new funding in FY 2018 and $10 billion in new funding for FY 2019 in the Department of Health and Human Services (HHS), amounting to a total of $13 billion in new funding.

This new funding will be allocated to combat the opioid epidemic through expanding access to prevention, treatment, and recovery support services, as well as support mental health services and includes investments to help stop the illegal supply of drugs (FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic). Significant to this grant proposal, on 6 June 2018, President Trump signed the VA Maintaining Systems and Strengthening Integrated Outside Networks Act (VA Mission Act of 2018). This act provides a community health program for veterans and extends Veterans Choice coverage until the Mission Act is implemented. Under the VA Mission Acct of 2018, veterans are entitled access to community care if the VHA does not offer the care or services required, it does not operate a full-service medical facility in the veteran's state, the veteran lives more than 40 miles from a VHA facility, the VHA is not able to meet the designated access standards it establishes, or the veteran and clinician agree that community care would be in the veteran's best interest (Fulton & Brooks, 2018).

Description of Pilot-Project: "TEAM Adapt, Conquer & Endure (ACE)"

TEAM ACE will be a pilot-project structured to serve transitioning military members and veterans population dealing with OUD challenges within rural areas of West Virginia. Packaged as a 501(c) (3) nonprofit organization, TEAM ACE will evolve as a mixed-model plan resembling the aforementioned Project Lazarus and Team RWB design models. Projected staff positions will consist of: President/CEO, Program Director, Program Accounts Manager, Prevention and Treatment Coordinator, Championship Advocate, and many other ancillary staff. As referenced in the project's

name, TEAM ACE will motivate and inspire its' members with the motto: "Be Adaptive, Conquer Challenges and Endure with Courage!" Participant incentives (monetary) may be offered based upon prevention and treatment accomplishments. For example, an OUD treatment accomplishment could be allowing tapering of medicines or allowing a combination of alternative pain medicines in conjunction with attending all complementary therapy (mental health, massage, chiropractic, acupuncture, etc.) appointments over a certain time period (3, 4, 6 months), This mixed-model design presents the opportunity to create a unique organization in TEAM ACE. The uniqueness of TEAM ACE will be that it offers its' participants a single connect, one stop hub for bridging all areas associated with OUD treatment and prevention. The project will be champion-driven to foster effective, transparent connections to all available Veteran Health Services (rural vs urban) and other complementary community health services. These collaborations working together will enhance prevention and treatment efforts and improvement in overall quality of life for its members. The focus of the program will be to explore, advocate for and connect those areas, as current research suggests, that can be most beneficial to addressing the Opioid crisis such as: Barriers to access including clinician bias, the lack of resources, transportation issues, insurance restrictions and misunderstanding of coverage, the wide disparity in rural-urban supply of trained substance use treatment providers, increasing education and access to treatment opportunities-particularly in non-traditional treatment settings like complimentary pain treatment options. Data collection and evaluation activities will be obtained and emulated from other successful Opioid Safety Coalition Networks such as: Project

Lazarus, California Opioid Safety Coalition, and SAMHSA toolkits. The end goal will be for TEAM ACE to build towards a strong, duplicable (to any state), brand identity demonstrating a unique, coalition-style network of seamless community service interventions, connections, and organizational activities. Lastly, TEAM ACE will strive to foster an atmosphere of comradeship for its participants (see Appendix C. Figure 9. for a working draft of TEAM ACE Logic Model Processes).

According to the CHCF Opioid Safety Coalition Network, tackling the complexity of the opioid crisis requires a constellation of partners to implement meaningful solutions (Max et al., 2017).

Logic models and strategy maps are tools often used to organize project goals, activities and outcomes. With logic models, each category and component are dependent to the other for effective working processes. An example of OUD activities within a logic model may include some of the following components:

- **Inputs:** Employing the right staff and connecting the right partners based around a community needs; applying an efficient lens framework specific to building strategy; planning for specific programs and consider effective monitoring and evaluation activities.
- **Support Services:** Consider communication resources and strategies that display simplicity and understanding; seek out coaching and mentoring to solidify strong coalition leadership; integrate appropriate data collection tools; plan measurement milestones and an evaluation procedure.

- **Results:** Strategic planning into any project or organization yields strength, clear vision and focus with well-defined goals, creates a pathway to strong management and effective leadership, build brand recognition that fosters broad engagement and membership; builds a successful model of subject matter expertise.
- **Outcomes:** All efforts conclude to positive prevention and treatment activities
- **Goal:** The overall goal is for all activities to lead to a decline in Opioid-related overdoses and deaths.

Review of Funding Agencies

There are several federal, state, public and private organizations joining the fight of this epidemic, however, the following mentioned agencies are considered major players of possible funding streams to support ongoing efforts to curb the opioid epidemic.

U.S. Department of Health & Human Services (HHS) - Mission: To enhance and protect the health and well-being of all Americans. That mission is fulfilled by providing for effective health and human services and fostering advances in medicine, public health, and social services (HHS.gov). The President's Budget request for HHS proposes $95.4 billion in discretionary budget authority and $1,120 billion in mandatory funding to carry out the mission of the Department and to fulfill the promises made by the Administration to the American people (Putting America's Health First, FY 2019 President's Budget for HHS, 2018).

- **National Institutes of Health (NIH) -** A part of the U.S. Department of Health and Human Services, NIH is the largest biomedical research agency in the world.

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH invests nearly $37.3* billion annually in medical research for the American people. More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world (NIH.gov).

- **Centers for Disease Control and Prevention (CDC) - Mission:** CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. The Centers for Disease Control and Prevention's (CDC) Office of Financial Resources (FOR) aids in achieving CDC's mission by quickly and effectively allocating funds to where they are needed. In its *Pledge to the American People*, CDC commits to being a diligent steward of the funds entrusted to the Agency. OFR ensures this pledge remains intact (CDC.gov).

The President's FY 2019 Budget for CDC prioritizes activities that address the opioid epidemic, with a total funding level of $126 million, which is $1 million above the FY 2018 Continuing Resolution. CDC contributes to the Department's five-point strategy to combat the opioid crisis and is committed to an approach that protects the public's health and prevents opioid overdose deaths by improving data, strengthening state and local

efforts, and equipping health care providers(FY 2019 Budget Fact Sheet-Combating the Opioid Epidemic).

- **The Substance Abuse and Mental Health Services Administration (SAMHSA)** is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities (SAMHSA.gov).

According to President Trump's FY 2019 Budget Factsheet, in 2016, roughly 1 in 25 adults in the United States, age 18 and older, battled serious mental illness, such as a psychotic or major depressive disorder. A portion of these individuals may cycle repeatedly among the health, behavioral health, and criminal or juvenile justice systems, with each system insufficiently prepared to meet their needs. A suggested $10 billion dollar investment proposed in the Budget will support activities that address serious mental illness, and help fight the opioid epidemic.

Selected Funding Agency

For this grant proposal, I chose NIH as a potential funding agency due to their vast availability and allocation of financial resources. As specifically mentioned in President Trump's FY 2019 Budget for National Institutes of Health (NIH), the Budget suggest $500 million for NIH to support a public-private partnership with the pharmaceutical industry to develop prevention and treatments for addiction, overdose-reversal, and non-addictive therapies for pain.

Example of a Funding Stream: The NIH Common Fund is a component of the NIH budget which is managed by the Office of Strategic Coordination/Division of Program Coordination, Planning, and Strategic Coordination/Office of the NIH Director. Common Fund programs address emerging scientific opportunities and pressing challenges in biomedical research that no single NIH Institute or Center (IC) can address on its own, but are of high priority for the NIH as a whole. The Common Fund is a unique resource at NIH, functioning as a "venture capital" space where high-risk, innovative endeavors with the potential for extraordinary impact can be supported. Common Fund programs are short-term, goal-driven strategic investments, with deliverables intended to catalyze research across multiple biomedical research disciplines.

Common Fund programs must meet five overarching criteria. Programs must be:

- **Transformative**: Must have high potential to dramatically affect biomedical and/or behavioral research over the next decade
- **Catalytic**: Must achieve a defined set of high impact goals within a defined period of time
- **Synergistic**: Outcomes must synergistically promote and advance individual missions of NIH ICs to benefit health
- **Cross-cutting**: Program areas must cut across missions of multiple NIH ICs, be relevant to multiple diseases or conditions, and be sufficiently complex to require a coordinated, trans-NIH approach
- **Unique**: Must be something no other entity is likely or able to do

Common Fund programs are intended to change paradigms, develop innovative tools and technologies, and/or provide fundamental foundations for research that can be used by the broad biomedical research community.

Description of Research Grant Proposal

Under the application guidelines for NIH Funding Opportunity Announcement (FOA) PAR-18-745, I propose a pilot-project designed around a coalition platform to create an interdisciplinary, community-based (multimodal) collaboration to improve access to complementary care. The project's goal will be to explore challenges with access to treatment, identify knowledge gaps and suggest targeted interventions. This proposal **aims to: a)** understand the dynamics of opioid-related risks behaviors as they develop over time and to track the changing dimensions of veterans' reintegration experiences that impact substance use patterns-predicted specifics and targeted endpoints could be management and prevention activities and strategies **b)** Propose interactive, collaborative interventions designed to aid in transitioning processes, preventing opioid misuse and decreasing opioid-related risk factors; **c)** Highlight the need for maximized community-based multifaceted collaboration that multiplies options for integrative pain management care.

Research Questions this Proposal will attempt to Address: 1) What are the contributing factors affecting physiological, social, and psychological opioid- related risk behaviors in the active duty/veteran populations? **2)** What are the knowledge gaps as it pertains to

awareness of opioid misuse, dependence, and risk factors associated with transitioning processes? **3)** Identify intervention strategies to reduce risks and improve patient care?

Methods: After IRB approval and DOD/VA contractual agreement to access active duty/VA patients, selections of a major military hospital and smaller base clinic system as well as two VA hospital centers (in high risk areas such as: WV) will be prepped to host and champion for the pilot-program "Team ACE". After obtaining written consents, transitioning opioid dependent active duty members (to WV area) and recently released veterans (6 months to 1 year-in WV area) will be recruited for participation. Utilizing a mixed methods approach through pre- and post- surveys and focus groups, the research will explore and capture data from the participants that examines attitudes, knowledge, common experiences/themes, and dynamics surrounding access to multifaceted pain management models, continuity of care and quality of life status. Examples of data to be collected will be two-fold: 1. Building the pilot-project- will consist of performing a community needs assessment to determine needed stakeholders for an effective coalition styled approach. 2. Advocating for the Participants- will consist of gathering information from surveys based on lifestyle-related information including substance use and misuse; Discuss participants access to multimodal care plans; Explore participants barriers (such as transportation issues) and challenges (motivational factors) as it relates to their opioid use disorder; Access ways to improve overall quality of life.

Analysis: Epi-info, IBM SPSS 22.0, and NVivo 11 statistical packages will be used for primary analysis of quantitative and qualitative data collected. Results from data analysis will be used to identify knowledge gaps, improve access and continuity of care, and

improve risk mitigation strategies associated with opioid abuse and dependence in rurally challenged areas. Lessons learned from this project-based study could be used as a catalyst to develop unique, specific, individualized care plans and targeted interventions for controlling and decreasing opioid-related exacerbations and accidental incidences.

Summary of the Grant Announcement

The title of the selected **Funding Opportunity Announcement (FOA) PAR-18-745: Addressing the Challenges of the Opioid Epidemic in Minority Health and Health Disparities Research in the U.S. (R21 Clinical Trial Optional)**

Background: The abuse of prescription and non-prescription opioids is one of the greatest public health threats in the US today. Ninety-one Americans die every day from an opioid overdose. Driven by this alarming rate of opioid abuse and misuse, drug overdose is now the leading cause of accidental death in the U.S. Nearly 2.5 million people in the US are suffering from opioid addiction related to prescription drugs for chronic pain. Opioid use disorders (OUD's) were most common among those who were uninsured or unemployed, were low-income individuals, or had behavioral health problems. Seventy-five to eighty-three percent of those reported starting with a prescription drug. Presently, death rates from opioid overdoses in rural areas exceed urban areas, contributing to 63% of all overdose deaths. Those states with the highest opioid prescriptions per capita also have the highest opioid overdose mortality. These staggering rates are overwhelming families, communities, first responders, and healthcare facilities nationwide, with consequences that could reverberate for generations. The

complexity of the crisis necessitates a multidimensional and multi-sectoral research effort.

A major consequence of OUD is opioid-associated Neonatal Abstinence Syndrome (NAS) and the considerable pressure on the foster care system generated by NAS. Although the immediate consequences of this crisis are well known, knowledge gaps exist on the long-term consequences of NAS on growth and development, behavioral outcomes, as well as the effect of involvement of dysfunctional parents in the care of opioid-dependent newborns or the alternative of foster care. OUD also increases risk of infectious diseases with co-use of illicit substances by injection especially hepatitis viruses and HIV.

The majority (80%) of persons with OUD had another substance use disorder (SUD). Among persons with OUD, 29% had major depressive episode (MDE), 32% had bipolar disorder, 13% had schizophrenia, 53% smoked cigarettes, 41% had alcohol use disorder (AUD), and 43% had 1 other drug use disorder.

Rates of opioid overdose deaths continued to increase for all racial/ethnic groups. Non-Hispanic Whites (hence, Whites) and American Indian/ Alaskan Natives (AI/AN) have experienced the largest rise in opioid-related fatalities. The American Indian/Alaska Native (AI/AN) communities, historically vulnerable to substance use, have an overdose rate comparable to Whites. Overdose rates increased 63% for Black persons and 43% for Latinos from 1999 to 2015. By comparison, the rate of overdose deaths among White persons increased 240% from 1999 to 2015 and similar increases were noted for AI/AN

populations. By 2014, Whites and AI/AN's were dying at double or triple the rates of African Americans and Latinos, respectively. Factors that may contribute to these disparities include preferential opioid prescribing to Whites in specific clinical settings, and possible differences in clinical pharmacogenomics. There may also be undefined social and cultural factors among Latinos and African Americans that contribute to these observed differences. In summary, multiple factors specific to these populations may contribute to racial differences in opioid sensitivity, clinical management and resistance to opioid misuse. Available data indicate that a disproportionate burden of opioid use overdose deaths is borne by persons living in rural areas of less privileged socioeconomic status. There are no data on patterns of opioid use among sexual gender minorities and limited data on Asians, Native Hawaiians, and U.S. Pacific Islanders.

Women of reproductive age (15-44 years) receive more prescription medications than men, which in turn resulted in increased risk of misuse. Presently, a woman reports to the emergency department every three minutes requesting pain medication. The face of the opioid epidemic is increasingly young, White, and female. Among diagnosed OUD in 2015, 0.9 million were men and 1.2 million women, with 3,300 women affected daily. Women who misuse opioids face gender-specific challenges, effectiveness of treatment and outcomes. Unlike men, women commonly report stigma as one of the top reasons they do not seek treatment for substance use disorders. Women seeking treatment report high rates of childhood victimization, histories of sexual abuse, and current danger (47%) from violent partner. In contrast to men, women also tend to enter treatment at a much

later stage of addiction, with more serious health complications due to accelerated physiological damage. More research is needed to address the gender-specific challenges posed by the opioid misuse crisis.

Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to treat and prevent opioid overdose (OUD). MAT has proven effective in combating OUD. The three medications used most in MAT are Methadone, Buprenorphine, and Naltrexone. However, less than 40% of those with OUD have access to treatment. Barriers to access include clinician bias, a lack of resources, insurance restrictions, and a wide disparity in rural-urban supply of trained substance use treatment providers. Efforts to increase education on treatment, particularly in non-traditional treatment settings, would be beneficial to addressing the opioid crisis. Timely population-based data about persons with OUD are needed for improving access to MAT for subpopulations, including underserved racial/ethnic groups, to reduce opioid addiction.

Prescription Drug Monitoring Programs (PDMPs), being statewide databases that gather information from pharmacies on dispensed prescriptions of controlled substances, are associated with significant reductions in opioid prescribing. Prescribing practices for treating pain should be evidence-based, responsive to patients' needs, maintain a "minimize harm" guideline, and implemented carefully by trained professionals in a manner that involves reasonable oversight through pain management regulatory policies. Implementation of the CDC Guidelines on chronic opioid prescribing would include

routine urine testing for prescribed medication and other substances, monitoring statewide database for other controlled substance prescriptions and a harm reduction strategy to reduce the morphine equivalent dose of opioids to 90 mg/day or less. More research is needed to understand the influence of these policies and practices across various regions in the U.S and how that influences OUD.

Prevention in the realm of OUD remains a work-in-progress and requires strategies to ameliorate the current crisis. Evidence-based interventions are needed on the opioid crisis in order to promote drug-free communities.

Current community-level interventions include public education, clinician-patient partnerships, and community-based medication disposal programs. Some States now require information about opioids in the health education and medical school curriculum. There is increasing Clinician-Patient Partnerships where patients reach explicit understanding about goals and expectations of treatment with their clinicians. Future evaluation of Community-Based Medication Disposal Programs for unused prescription opioids awaits. Further research investigations are needed to understand the role of economic upheaval, unemployment, inequality, and other systemic sources of despair in increasing the risk for addiction and decreasing the odds of recovery.

In the criminal justice setting, drug treatment courts have been effective in treating individuals with substance use disorders. These courts are specialized problem-solving courts that divert eligible drug-abusing offenders from the traditional court system into court supervised treatment. More research is needed to reduce drug use relapse through

risk and need assessments, judicial interaction, monitoring and supervision, graduated sanctions and incentives, treatment, and rehabilitation services.

The Grant Review Process:

The NIH grant application and submission process can be accomplished online via grants.nih.gov. NIH grant application guidelines are very complex and detailed. For this grant, the application and submission process can be found in section IV of the FOA. However, for the purpose of completing a thesis for the Emory EMPH program, the student was only required to write the project summary/abstract which has a limit of 30 lines of text and the narrative part of the proposal which has a limit of 3 sentences. The Primary Investigator (PI) was not required to complete any other pieces in the application package such as specific aims, research strategy, commercialization plan, budget, or financial and tax information and biographical sketch.

Proposal Criteria: Detailed review criteria for the full grant proposal can be found in section V. of the FOA. However, since the EMPH grant thesis requires only the narrative portion to be written for grading purposes, the grant reviewers received via email a link to the full FOA and the grant proposal thesis document with an attachment of a short questionnaire (Kasukusa, 2017) of mixed multiple choice and open ended questions to apply their comments.

- How/when did the reviewers get the proposal to review? The Proposal was emailed out on November 1st, 2018.

- How much time did they have to review it? The reviewers had 3 to 5 days to review the proposal.
- What instructions and review criteria were provided to reviewers? The instructions were to read the FOA for understanding; then read thesis proposal and finally, to answer questionnaire and provide comments.
- Were reviews shared among reviewers or provided individually? The reviews were shared individually.
- How was the information returned to the student, analyzed and interpreted? The comments were returned to the student via email.

A Description of the Grant Proposal Reviewers and their Expertise:

The grant reviewers consisted of the EMPH Committee Chair and Field Advisor for the student's Thesis, along with three additional outside reviewers. The reviewers were chosen based on their expertise and background experience with opioid use disorder and addiction, knowledge and interest in the veteran population, and achievements with developing healthcare initiatives and improving patient care outcomes.

Iris Smith, Ph.D., MPH-Committee Chair

Dr. Smith holds a doctorate in Community Psychology from Georgia State University and a Master's Degree in Public Health from Emory University. She is currently an Associate Professor in the Behavioral Sciences and Health Education Department at Emory University's Rollins School of Public Health where she has taught graduate courses in Program Evaluation, Substance Abuse, Social Determinants of Health, and

Mental Health Capstone course. In addition to teaching Dr. Smith serves as the Coordinator for the Center for the Application of Prevention Technologies (CAPT) Southeast Resource Team. In this role, she supervises a team of training and technical assistance specialists, content experts and consultants who provide training and technical assistance to Substance Abuse and Mental Health Services (SAMHSA) state grantees in the 12 states and U.S. territories that comprise the CAPT Southeast Service Area. Prior to coming to Emory, she was the Director of National Evaluation Services for the American Cancer Society, and has also served as a Deputy Commissioner for the Georgia Department of Juvenile Justice. From 1979- 1992, Iris was Principal and Co-Investigator on a number of studies on prenatal drug exposure and intervention for substance abusing women and their children at Emory University's School of Medicine. Her accomplishments include design, implementation and evaluation of outreach, intervention and treatment programs for substance abusing women and their children. She is currently a member of the Scientific Advisory Board for the National Association for Children of Alcoholics and has served on advisory boards for the Atlanta Association for Developmental Disabilities, DeKalb County Center for Torture and Trauma Survivors, Georgia NOFAS and the Marcus Institute. Dr. Smith's expertise includes substance abuse prevention and treatment, juvenile justice and program evaluation.

Keli Edwards, Pharm.D., J.D. - Field Advisor

Dr. Edwards has a diverse background in both inpatient and outpatient treatment settings; she has worked in DOD health systems and supervised pain management care,

counseling and drug distribution for Veterans receiving chronic and short term opioid treatment. She also has a wealth of experience in commercial, retail, and community setting outpatient pharmacies and clinics; finally, she is abreast of Clinical practice guidelines, cutting edge new drug developments, and the investigational drug and research process, having served as a staff pharmacist most recently with the National Institutes of Health. Finally, she previously worked as a Prescription Benefits Manager Pharmacist-- managed Medicaid Pharmacy Benefits, to include pharmacy Lock-in Programs that addressed narcotic utilization, imposed quantity limits, and curtailed, "doctor shopping" for narcotics drugs, and opioids.

Reviewer 1: Cassandra L. Jackson, BSN, RN, CNOR; RN Care Manager, Patient Aligned Care Team, Primary Care Miami VA Healthcare System; Retired Captain, USAF

Captain Jackson served honorably in the USAF before retiring in 2013. She currently serves the veteran population by providing clinical care for a primary care panel which consists of 1200 clients that require ongoing assessment and evaluation of care for veterans with acute and chronic conditions.

Reviewer 2: Tammy A. Cook, BSM; Mission Support Specialist, Department of Homeland Security

Ms. Cook has over 15 years of experience in a solution-oriented working environment. She performs a wide range of complex administrative management issues as well as developing and implementing policy and procedures. Also, Ms. Cook served honorably

for 13 years in the U. S. Army Reserves achieving the rank of Sergeant (E-5).

Reviewer 3: Patricia Sims, R.Ph., Pharm.D.

Dr. Sims is a pharmaceutical Industry professional, who worked as an original clinical liaison for Reckitt Benckiser's buprenorphine (Suboxone) and (Subutex), drugs used for opioid addiction treatment. Also, she has extensive experience in the retail and community pharmacy sector. Her background experience expands over 25+ years of pharmacy expertise.

Protection of Human Subject

According to the NIH FOA, requirements and responsibilities as required by federal regulations (45 C.F.R. 46) and NIH policy, applications that propose to involve human subjects must address: 1. The risk to subjects. 2. The adequacy of protections against risk. 3. Potential benefits of the research to subjects and others. 4. The importance of the knowledge to be gained 5. For clinical trials, data and safety monitoring plan and a data and safety monitoring board for Phase III trials.

CHAPTER IV: INCORPORATION OF REVIEWER'S COMMENTS

This chapter outlines and addresses the reviewers' comments and discusses how changes for the comments were incorporated into the final version of the proposal.

I want to thank the reviewers for their time, willingness and support given in reviewing this proposal. Their combined expertise, background and experiences provided pertinent feedback which allowed positive expansion and strength to the content of this proposal. Also, I really appreciate all help given on content organization and flow, sentence structure and grammatical edits. The combined efforts of the reviewers helped create a more focused and polished thesis proposal.

Reviewer 1 Comments: Iris Smith

Comment 1: Most recent feedback was to walk the reader through the TEAM ACE Coalition Logic model for better understanding of project activities.

Response to Comment 1: This comment is addressed in the Appendices, page 80 Appendix C. To provide more clarity of the logic model, each bullet point briefly describes a proposed utilization of resources to implement certain activities that will drive listed outcomes or results.

Reviewer 2 Comments: Keli Edwards

Comment 1: Please state your level of agreement/disagreement with the following statement: The submission is responsive to the proposal criteria. A. Strongly Agree - The background and literature review were extensive and thoroughly responsive to the

proposal criteria. It was especially clear that targeted population of transitioning veterans in certain West Virginia counties would be at risk of OUD (opioid use disorder). The proposal criteria goals to

"Understand the dynamics of opioid related risks...propose interactive. Interventions, and highlight the need for 'multifaceted collaboration'" are well developed and reasonable considering the dynamic needs of this target population.

Response to Comment 1: No response needed

Comment 2: How could the submission have been more responsive to the proposal criteria?

No suggestions, here. The topic and target population of the proposal fits the grant criteria focus, and, if completed, has the potential to add a wealthy contribution to the developing literature on OUD.

Response to Comment 2: No response needed

Comment 3: Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound. B. Agree -While the hypothetical research group of West Virginia veterans will likely experience OUD and be a good population to survey and research, there are still some unknowns that may not be resolved or discovered until any action is taken. A little more detail to allow for these variables could be discussed.

Response to Comment 3: I concur with this comment. On page 44, line 16, I added in more specific predictable variables (listed in parentheses) that will be explored. "Explore participants' barriers (such as transportation issues) and challenges (motivational factors) as it relates to their opioid use disorder; Access ways to improve overall quality of life." However, because this project is evolving in pilot mode from afar, unknown variables remain as constant.

Comment 4: 4. What improvements could be made to the theory and structure of the proposal?

The structure of the proposal is observational and survey based to identify knowledge gaps concerning OUD, and risk factors. It could be improved by attempting to resolve a more specific endpoint.

Response to Comment 4: I also agree with this comment. However, due to the changing dynamics associated addition risks, predicted target endpoints could be management and prevention activities and strategies which is listed in specific aims of project. This addition is found in Chapter 3, page 50 starting on line 10.

Comment 5: Please state your level of agreement/disagreement with the following statement: The Principal Investigator (PI) makes a compelling case that the proposed research/project/program is necessary. A. Strongly Agree--The PI has provided extensive overview, data collection, and analysis of opioid prescribing and use, the likelihood of veteran populations to be at risk for OUD, as well as the current political and social aspects of OUD as a trending news topic.

Response to Comment 5: No response needed

Comment 6: What would have improved the argument that the proposed activities are necessary? No additional argument needed on this end. The PI has shown, by providing an overview of the abundance of funding and attention to the opioid crisis, that this activity is necessary. She highlights that the Presidential 2019 fiscal budget has allocated over $120 million to activities that address the opioid epidemic. In addition, she points out the issues within the Veterans Administration infrastructure that would likely contribute to veterans' care being mismanaged and disjointed. The PI purports a logical and well developed idea to consider the minority populations of rural West Virginia veterans in the VA system for this proposal.

Response to Comment 6: No Response Needed

Comment 7: What additional comments and suggestions do you have for the PI? Be advised that since this is a dynamic area of research, there will be the need to be flexible and understanding of that characteristic and therefore, some modes of solutions may be on point, while others may need tweaking. Because this proposal is observational and seeking to survey and highlight issues, it may likely provide an opportunity to hone in on more specifics in future research. Overall this area of research is a jewel and attempts to bring attention to groups that are marginalized (rural), isolated (transitioning veterans), and unique.

Response to Comment 7: No Response Needed

Reviewer 3 Comments: Cassandra Jackson

Comment 1: How could the submission have been more responsive to the proposal criteria? The Principal Investigator's submission criterion has been met. It is purposefully well-defined and is distinctly aimed towards the needs of the vulnerable population

Response to Comment 1: No Response Needed

Comment 2: What improvements could be made to the theory and structure of the proposal? None. The PI utilized scholarly research along with evidentiary submission that prepared the reader for a comprehensive review of compelling evidence.

Response to Comment 2: No Response Needed

Comment 3: What would have improved the argument that the proposed activities are necessary? The PI may possibly want to consider researching the following concern: impact of familial co-dependency due to opioid prescription sharing. On many occasions, family members become addicted too. A closer look at the veteran's family system could help to provide a sustainable platform towards improving the opioid crisis.

Response to Comment 3: I agree with this comment. Familial codependency assessment will be an important inclusion and strategy when planning participant's care plan. This activity can fit into the working activities when performing the patient's needs assessment found in TEAM ACE logic Model processes found in appendix C on page 80.

Comment 4: What additional comments and suggestions do you have for the PI? The PI's body of work was informative and scrupulously identified a public health threat with widespread involvement. Grant approval as outlined would help to address these growing concerns.

Response to Comment 3: No Response Needed

Reviewer 4 Comments: Tammy Cook

Comment 1: Please state your level of agreement/disagreement with the following statement: The Principal Investigator (PI) makes a compelling case that the proposed research/project/program is necessary. A. Strongly Agree: The PI makes a strong case which demonstrates a need to support this project in the Veteran community to save lives and restore hope to those who are suffering in this crisis.

Response to Comment 1: No Response Needed

Comment 2: What additional comments and suggestions do you have for the PI? The proposal was well researched and supported with facts and charts that draws in the reader to better understand the Opioid crisis in the veterans community.

Response to Comment 2: No Response Needed

Reviewer 5 Comments: Patricia Sims

Comment 1: How could the submission have been more responsive to the proposal criteria? This is current and vital hot topic that is on the political table; therefore it remains important to observe the future developments in order to address this question.

Response to Comment 1: No Response Needed

Comment 2: What improvements could be made to the theory and structure of the proposal? Outcome goals in more details could be added and developed. The data seems to be generalized and survey based nature, and needs to hone in more on specifics.

Response to Comment 2: I agree. This comment is similar to Reviewer's 2 comment 4 and the same response applies: Due to the changing dynamics associated with addition risks, predicted specifics and targeted endpoints could be management and prevention activities and strategies which are listed in the specific aims of project. This addition is found in Chapter 3 on page 50 starting at line 10.

Comment 3: Please state your level of agreement/disagreement with the following statement: The Principal Investigator (PI) makes a compelling case that the proposed research/project/program is necessary.

Response to Comment 3: No Response Needed

Comment 4: What would have improved the argument that the proposed activities are necessary? The relevant news and media was addressed but would have liked more context as it relates to the targeted groups in West Virginia.

Response to Comment 4: This is a relevant comment. I addressed this comment by adding in a U. S. Bureau graphic in Chapter 2, page 34, see figure 8, discussion is right before the figure. It shows Greenbrier County vs overall WV Civilian veterans 13.8% compared to 11.4% overall. Source: US Census Bureau, 2012 population estimates, *American Community Survey (2007-2011)

Comment 5: What additional comments and suggestions do you have for the PI? This is not an easy fix; it is very political; staying the course is very important for others to follow through. Response to Comment 5: No Response Needed

Questionnaire multiple choice responses:

Comment	**Strongly Agree**	**Agree**	**Neither Agree or Disagree**	**Disagree**	**Strongly Disagree**
The submission is responsive to the proposal criteria.	III	I			
The proposal is well thought out and theoretically sound.	III	I			
The Principle Investigator (PI) makes a compelling case that the proposed project is necessary.	IIII				

*Note: One reviewer did not provide comments via questionnaire but provided comments via google doc (hence only 4 responses recorded to each question).

CHAPTER V: FINAL VERSION OF GRANT PROPOSAL

Project Title

Combating the Opioid Epidemic! A Project-Based Grant Proposal to Assist Transitioning Military Members and Veteran Population Struggling with Opioid Use Disorder

Summary/Abstract

Presently, the opioid epidemic is a critical focal point on the national stage. The escalating opioid-related overdoses and deaths has caused significant, socio-economical challenges and placed heavy burdens upon the society as a whole.

This epidemic is distinctly connected and has been catalytically driven by the treatment of chronic, nonmalignant pain which has also evolved into a substantial public health problem in the United States (Debono, Hoeksema, Hobbs, (2013). Currently, the extent of usage for opioid analgesics in the United States is unprecedented in the country's history and unparalleled to anywhere else in the world. Americans make up 4.6% of the world's population and yet consume approximately 80% of the world's opioid supply (Blozen, 2013).

Researchers have identified that the states suffering the most devastation from this crisis are located along the Appalachian Mountain Region where West Virginia (WV) is glaring with the highest rate of deaths from drug overdoses than any other state. West Virginia classifies as a challenged state due to its makeup of socio-economically, disadvantaged populations and underserved rural populations. Also, vulnerable subpopulations at highest

risk include youth and young adults, older adults, prisoners, military personnel, veterans, and populations with comorbidity of psychiatric disorders. Distinctly, active duty military and veteran populations face unique challenges in controlling the risk factors associated with opioid abuse and dependence.

Researchers suggests that tackling the complexities of the opioid epidemic demands an urgent, multidimensional and multi-sectoral effort (ex. Coalition-Based Model- Max, Garrow, & Willis, 2018). Specific to this grant thesis, a coalition-based project will be proposed to help transitioning military members and other veterans residing in West Virginia explore the many challenges associated with bridging access to multi-modal treatment options.

Narrative Statement (via FOA- 3 sentence limit)

The opioid epidemic in currently a hot topic on the national stage receiving attention from all levels (Federal, State, etc.) of the U. S. government. The devastating aftermath of socio-economic effects has left many scrambling and searching for interventions, strategies and solutions to remedy and diffuse this devastating problem. Targeted States such as West Virginia which has vast rural areas and a variety of underserved populations (ex. veterans) will be the focus of this project-based grant proposal.

Specific Aims

The project's goal will be to explore challenges with access to treatment, identify knowledge gaps and suggest targeted interventions. This proposal **aims to: a)** understand the dynamics of opioid-related risks behaviors as they develop over time and to track the

changing dimensions of veterans' reintegration experiences that impact substance use patterns; **b)** Propose interactive, collaborative interventions designed to aid in transitioning processes, preventing opioid misuse and decreasing opioid-related risk factors-predicted specifics and targeted endpoints could be management and prevention activities and strategies **c)** Highlight the need for maximized community-based multifaceted collaboration that multiplies options for integrative pain management care.

Research Strategy

Under the application guidelines for NIH Funding Opportunity Announcement (FOA) PAR-18-745, I propose a pilot-project designed around a coalition platform to create an interdisciplinary, community-based (multimodal) collaboration to improve access to complementary care. The project's goal will be to explore challenges with access to treatment, identify knowledge gaps and suggest targeted interventions. This proposal **aims to: a)** understand the dynamics of opioid-related risks behaviors as they develop over time and to track the changing dimensions of veterans' reintegration experiences that impact substance use patterns-predicted specifics and targeted endpoints could be management and prevention activities and strategies **b)** Propose interactive, collaborative interventions designed to aid in transitioning processes, preventing opioid misuse and decreasing opioid-related risk factors; **c)** Highlight the need for maximized community-based multifaceted collaboration that multiplies options for integrative pain management care.

Research Questions this Proposal will attempt to Address: 1) What are the contributing factors affecting physiological, social, and psychological opioid- related risk behaviors in the active duty/veteran populations? **2)** What are the knowledge gaps as it pertains to awareness of opioid misuse, dependence, and risk factors associated with transitioning processes? **3)** Identify intervention strategies to reduce risks and improve patient care? **Methods:** After IRB approval and DOD/VA contractual agreement to access active duty/VA patients, selections of a major military hospital and smaller base clinic system as well as two VA hospital centers (in high risk areas such as: WV) will be prepped to host and champion for the pilot-program "Team ACE". After obtaining written consents, transitioning opioid dependent active duty members (to WV area) and recently released veterans (6 months to 1 year-in WV area) will be recruited for participation. Utilizing a mixed methods approach through pre- and post- surveys and focus groups, the research will explore and capture data from the participants that examines attitudes, knowledge, common experiences/themes, and dynamics surrounding access to multifaceted pain management models, continuity of care and quality of life status. Examples of data to be collected will be two-fold: 1. Building the pilot-project- will consist of performing a community needs assessment to determine needed stakeholders for an effective coalition styled approach. 2. Advocating for the Participants- will consist of gathering information from surveys based on lifestyle-related information including substance use and misuse; Discuss participants access to multimodal care plans; Explore participants barriers (such as transportation issues) and challenges (motivational factors) as it relates to their opioid use disorder; Access ways to improve overall quality of life.

Analysis: Epi-info, IBM SPSS 22.0, and NVivo 11 statistical packages will be used for primary analysis of quantitative and qualitative data collected. Results from data analysis will be used to identify knowledge gaps, improve access and continuity of care, and improve risk mitigation strategies associated with opioid abuse and dependence in rurally challenged areas. Lessons learned from this project-based study could be used as a catalyst to develop unique, specific, individualized care plans and targeted interventions for controlling and decreasing opioid-related exacerbations and accidental incidences.

APPENDICES

Appendix A: NIH Suggested Cover Letter Format

The NIH Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) strongly suggests that Principal Investigators use a specific format for cover letters requesting assignment to an Institute or Center (IC) and/or a Scientific Review Group (SRG). Officials believe that a consistent outline for the cover letter will shorten the time from submission to review. Special formatting requested by NIH include the following:

- List one request per line.
- Place IC and SRG review requests (if applicable) on separate lines.
- Place positive and negative requests (if applicable) on separate lines.
- Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.

A sample cover letter is shown below:

Sample Cover Letter Format Suggested by NIH – All items may not be applicable.

Application title.

Funding Opportunity Announcement number:

Please assign this application to the following:

Please note the outline of indentions.

Institutes/Centers

National Cancer Institute – NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].

List of individuals (e.g., competitors) who should not review the application and why.

Disciplines involved, if multidisciplinary.

Statement that required NIH approval documents are included (e.g., budget over $500K/year; approval for conference grant proposal; cooperative agreement, etc.)

For late applications - if applicable, include explanation of the delay as part of the letter.

Note: Program officers in NIH Institutes can be excellent sources of advice on whether and how your proposed research fits with their mission and priorities as well as which SRG is most appropriate. It is advised that before you submit a grant you communicate with an appropriate program officer about your project. Program officers and areas of specialty for the Demographic and Behavioral Sciences Branch of NICHD are listed here. And those for the Division of Behavioral and Social Research at NIA are listed here. If you have questions about which program officer is appropriate please consult with the Director or Associate Director.

[PSTC Template on Next Page]

Population Studies &
Training Center
Box 1836
68 Waterman Street
Providence, RI 02912

Date

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Application for the NIH Research Grant Program (Mechanism Name)

To Whom It May Concern:

I am pleased to submit a grant proposal with the title "**Application Title**" for consideration under the NIH Research Grant Program **(Mechanism Name)** with PA number **PA-XX-XX,** as discussed with **Program Officer**.

Please assign this application to the following:

Institutes/Centers

Eunice Kennedy Shriver National Institute of Child Health and Human Development – NICHD
National Institute on Aging – NIA

Scientific Review Groups

Social Sciences and Population Studies Study Section – SSPS
Health, Behavior and Context Study Section – HBC

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are **[provide a narrative explanation for the request(s)]**.

List of individuals (e.g., competitors) who should not review the application and why.

Disciplines involved, if multidisciplinary.

Statement that required NIH approval documents are included (e.g., budget over $500K/year; approval for conference grant proposal; cooperative agreement, etc.)

For late applications - if applicable, include explanation of the delay as part of the letter.

This project is alignment with the mission of the **[relevant institute]** (e.g., this proposal is on migration and migration is listed as one of DBSB's areas on the Web site).

I have spoken about this project with **[Program Officer].**

Thank you very much for your consideration.

Sincerely,

First and Last Name
Title

Appendix B: Biographical Sketch (example)

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION DEGREE
(if applicable)
Completion Date
MM/YYYY
FIELD OF STUDY

A. Personal Statement

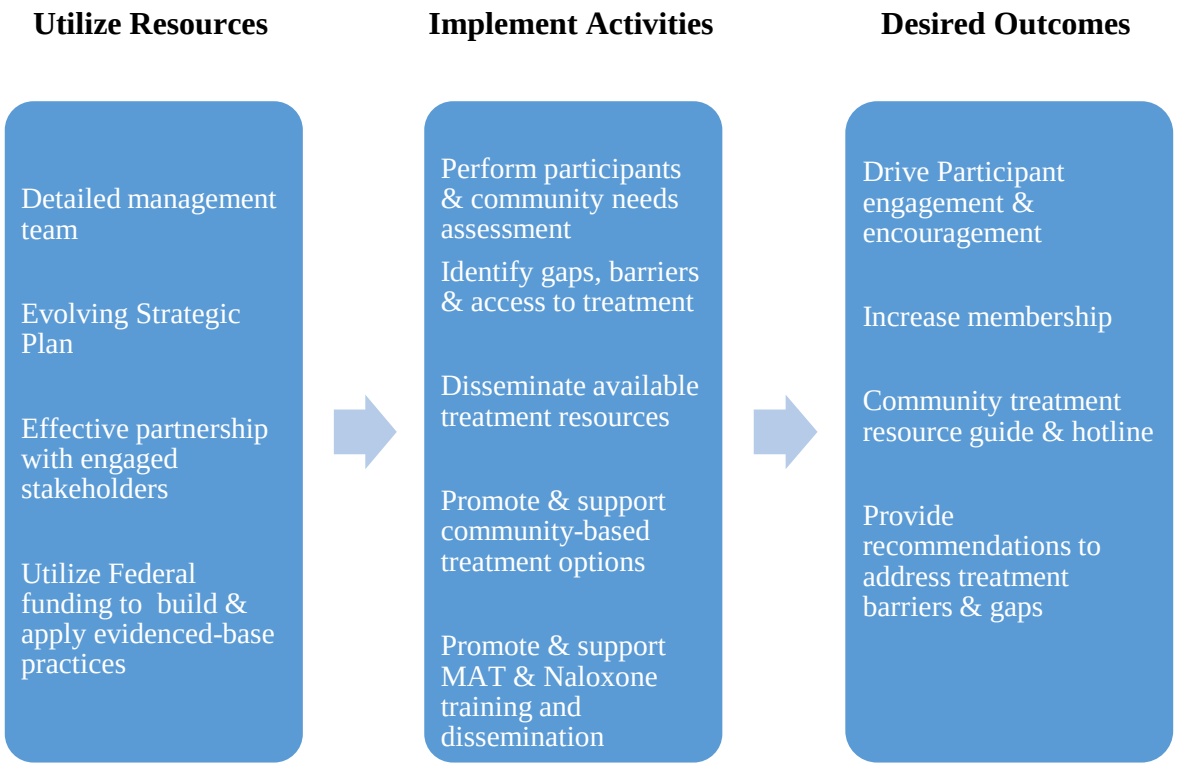
B. Positions and Honors

C. Contributions to Science

D. Additional Information: Research Support and/or Scholastic Performance

Appendix C: Figure 9. Logic Model Processes (working draft):

TEAM ACE Coalition Project



Appendix D: Grant Reviewers Questionnaire (Kasukusa, 2017)

A. Please provide your Name and Title with a brief description of your expertise- Thanks!

1. Please state your level of agreement/disagreement with the following statement: The submission is responsive to the proposal criteria.

A. Strongly Agree
B. Agree
C. Neither Agree nor Disagree
D. Disagree
E. Strongly Disagree

2. How could the submission have been more responsive to the proposal criteria?

3. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

A. Strongly Agree
B. Agree
C. Neither Agree nor Disagree
D. Disagree
E. Strongly Disagree

4. What improvements could be made to the theory and structure of the proposal?

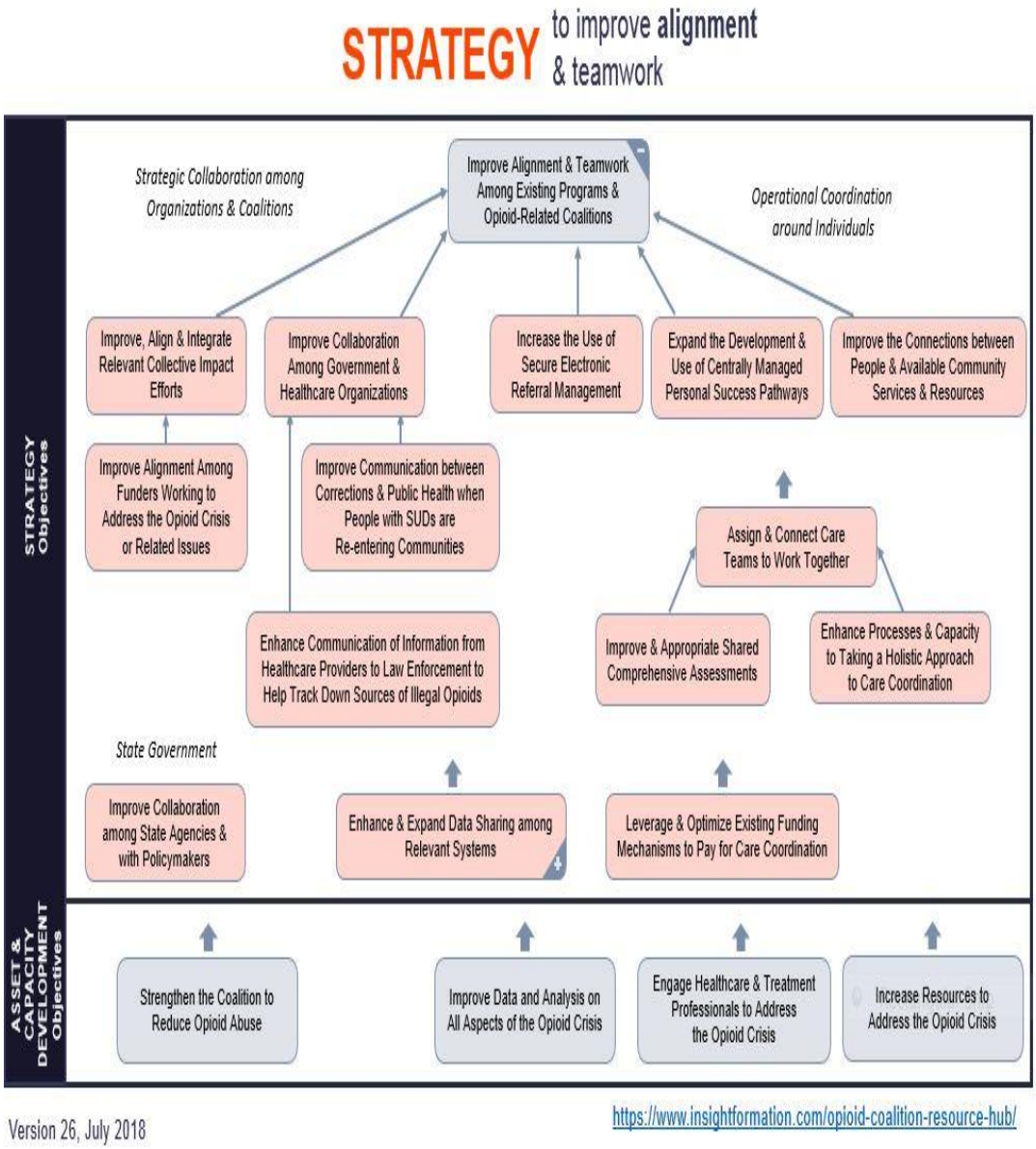
5. Please state your level of agreement/disagreement with the following statement: The Principle Investigator (PI) makes a compelling case that the proposed research/project/program is necessary.

A. Strongly Agree
B. Agree
C. Neither Agree nor Disagree
D. Disagree
E. Strongly Disagree

6. What would have improved the argument that the proposed activities are necessary?

7. What additional comments and suggestions do you have for the PI?

Appendix E: Coalition-based Opioid Use Disorder (OUD) Strategy Map to Approve Alignment and Teamwork



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