Title Page

Sleep-Wake Patterns and Real-Time Fatigue Reduction in EMS Clinicians: Phase II

Brief Title:

The SleepTrackTXT2 Randomized Trial with Air-Medical Personnel

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Project Name: Sleep-Wake Patterns and Real-Time Fatigue Reduction in EMS Clinicians: Phase II

Project Description (2000 character limit):
Fatigue is an "unpleasant symptom incorporating feelings of tiredness to exhaustion creating conditions that interfere with the ability to function in a normal capacity."[1] Recent data show that half of clinicians in ground and air-medical based Emergency Medical Services (EMS) operations suffer from fatigue and are at elevated risk of a negative safety outcome.[1, 2] Existing fatigue risk management programs and systems may not have the intended impact. Experts believe the future of fatigue risk management is real-time assessment and intervention of fatigued workers.[3, 4]

Recently, we completed the first pilot randomized trial that tested real-time assessment of fatigue and sleepiness in EMS clinicians. The SleepTrackTXT pilot randomized trial successfully enrolled 100 paramedics, flight paramedics, flight nurses, emergency room nurses and several emergency physicians to participate over 90-days and use text-messages to report feelings of fatigue and sleepiness during shift work.[5] Participants in the intervention group received strategy messages in real-time if they reported high levels of fatigue, sleepiness, or difficulty concentrating at the beginning or during shift work. The study was a success, and participants answered 88.1% or 36,073 text messages. Participants in the intervention group that worked extended shifts (e.g., 12-hour shifts) reported lower levels of fatigue at the end of shift compared to participants in the control group ($p<0.05$). At the end of the study, participants reported high satisfaction with the SleepTrackTXT tool as the primary means for assessing fatigue in EMS settings.

The overarching goal of this proposal is to address the MedEvac foundation priority of educational techniques and technologies and improve HEMS safety by determining if overall sleep quality and intra-shift fatigue of HEMS clinicians can be improved with real-time assessment and intervention.

Abstract (2500 characters)
It is widely believed that extended shift patterns such as 12-hour and 24-hour shifts lead to fatigue and increase the odds of negative safety outcomes for shift workers.[6] Our recent research shows that greater than half of EMS clinicians

report fatigue while at work, and poor safety outcomes are more common among fatigued EMS clinicians.[2] These data suggest that existing fatigue management programs may not be as effective as hoped, and stress the need to identify and reduce fatigue with new and innovative tools.

Recently, we tested an innovative tool that identifies fatigue in real time and intervenes in real time with fatigue-reduction strategies.[5, 23] The SleepTrackTXT tool uses text-messaging to query EMS clinicians in real-time at the beginning, during, and end of scheduled shifts. From January 2014 to June 2014, we enrolled 100 EMS clinicians in a 90-day research study, including more than a dozen clinicians that work in air-medical operations. Participants randomized to the intervention group were sent strategies via text-messages in real-time during shifts that can help reduce feelings of fatigue and sleepiness. Preliminary findings show use of text-messaging is feasible and attractive to EMS clinicians. Participants documented 2,621 shifts, and nearly half (48.4%) were greater than 12-hours in length. The SleepTrackTXT sent 40,947 text messages asking EMS clinicians about fatigue and sleepiness in real-time. Participants responded to 36,073 text-messages, 88.1%. Results show that our pilot intervention reduced feelings of fatigue by the end of shift work. During follow-up interviews, participants requested additional help with structuring sleep patterns and habits to deal with shift work and improve overall sleep quality.[23]

The overarching goal of this proposal is to address the MedEvac foundation priority of educational techniques and technologies to improve safety, and determine if an enhanced SleepTrackTXT intervention, including a sleep health component, reduces fatigue during shift work and leads to clinically meaningful improvements in sleep quality.

Aim 1: To determine the short-term impact of an enhanced SleepTrackTXT intervention on HEMS clinician fatigue reported in real-time during and at the end of shift work.

Aim 2: To determine the long-term impact of the SleepTrackTXT intervention on sleep quality and sleep health indicators including hours of sleep and recovery between shift work.

Resources and Environment (a standard form downloaded from the MedEvac site)

Study sites include MedCenter Air of Carolinas HealthCare, STAT MedEvac of the University of Pittsburgh Medical Center (UPMC), MedFlight of Ohio, and Mercy Flight of Buffalo. All four sites have demonstrated their capability to fulfill multi-site studies based on successful enrollment and participation in previous

and ongoing research of air-medical clinicians. All sites have the required support staff and on-site, active site-specific co-investigators.

The lead study site for this multi-site study is the Department of Emergency Medicine (DEM) at the University of Pittsburgh, Pittsburgh, PA. The Department has a long history of scientific research involving observational and experimental study designs and focused research on EMS safety. Dr. Patterson has assembled a multi-disciplinary team of experienced investigators and study coordinators. Our team is cohesive and actively engaged in related research involving our four study sites. We are well suited to undertake and complete the study as designed. Our research team has experience conducting research, completing studies on time, and presenting study findings to scientific and other audiences.

Co-investigator Mr. Jack Doman of the University of Pittsburgh is the architect of the original SleepTrackTXT study tool shown effective in our recent randomized trial. Mr. Doman has developed an enhanced version of our novel tool for use in this prospective experimental study funded by the MedEvac Foundation.

Research Protocol, Part One – Introduction, background, significance (3000 characters):

INTRODUCTION: Fatigue has been defined as “a subjective, unpleasant symptom, which incorporates total body feelings ranging from tiredness to exhaustion creating an unrelenting overall condition which interferes with individual’s ability to function to their normal capacity.”[7] There is convincing evidence connecting extended shift patterns, such as 24-hour shifts, to poor sleep health, fatigue, and negative safety outcomes.[8, 9]

BACKGROUND: Emergency Medical Services (EMS) clinicians are a group of workers where extended shifts, inconsistent shift patterns, poor sleep, and fatigue are common.[2, 10-12] There are an estimated 19,000 EMS organizations and 800,000 to 1 million licensed EMS workers in the U.S. today.[13] EMS workers are often the first point of clinical contact for the acutely ill and injured. Many EMS workers are on the job for extended periods (e.g., 24 hours), they often work consecutive shifts, and accumulate many hours of overtime.[2, 10-12] Data show that half of EMS workers sleep less than six hours per sleep period and many report poor sleep quality.[2] One-third of EMS workers report excessive daytime sleepiness[14] and more than half report excessive mental and physical fatigue.[2, 10] Odds of injury are 1.9 times greater among fatigued EMS workers than the non-fatigued – after controlling for confounding.[2] Odds of making an error or experiencing a patient-related adverse event are 2.2 times greater among fatigued EMS workers than the non-fatigued.[2] Fatigue and poor sleep increase the likelihood of risky behaviors. Odds of engaging in behaviors that compromise safety are 3.6 times greater among EMS workers that report fatigue.[2]

SIGNIFICANCE: There is limited real-time fatigue monitoring of EMS clinicians. However, there is growing enthusiasm and preliminary data to support use of real-time fatigue monitoring using mobile technologies such as cell phones and smartphones.[15, 16] Most Americans (90%) own a cell phone and half own a smartphone.[17, 18] Most cell phone owners (80%) send or receive text-messages.[17] A recent systematic review of intervention studies using text-messages or mobile applications showed a positive impact on behaviors, such as smoking cessation, diabetes control, weight loss, asthma self-management.[16] Tailored text-message based interventions may benefit EMS worker sleep habits and behaviors related to fatigue. Text-message interventions are a potentially high-impact, low-cost platform for encouraging positive sleep habits, tracking fatigue, and distributing information to EMS workers at risk of negative safety outcomes related to fatigue. In the first known study using text-messaging to study fatigue in EMS, we have 1) shown it is feasible to use this tool to monitor fatigue in real-time, and 2) produced early evidence that we can reduce perceived fatigue by intervening with tailored fatigue reduction strategies in real-time.

Research Protocol, Part Two – Objectives Hypotheses (3000 characters):

The overarching goal of this proposal is to address the MedEvac foundation priority of educational techniques and technologies to improve safety, and determine if an enhanced SleepTrackTXT intervention, including a sleep health component, reduces fatigue during shift work and leads to clinically meaningful improvements in sleep quality.

Aim 1: To determine the short-term impact of an enhanced SleepTrackTXT intervention on HEMS clinician fatigue reported in real-time during and at the end of shift work.

Rationale Aim 1: In our recent SleepTrackTXT pilot randomized trial, we have successfully shown that real-time assessment of fatigue involving EMS clinicians and text-messages is possible. We have also shown that sending text-messages in real-time to clinicians that report high levels of fatigue leads to reduced fatigue by the end of shift. An enhanced intervention that addresses additional sleep health information (e.g., sleep debt), may have a greater impact.

Hypothesis 1A: We hypothesize that an enhanced version of the SleepTrackTXT tool that includes sleep health and sleep quality components will contribute to significant reductions in intra-shift fatigue.

Aim 2: To determine the impact of the SleepTrackTXT intervention on sleep quality and sleep health indicators including hours of sleep and recovery between shift work.

Rationale Aim 2: Preliminary findings from our pilot randomized trial using an Intent-To-Treat analysis shows a statistically significant improvement in sleep quality among participants in the intervention group. The improvement fell short of a cut point thought to be clinically meaningful. We believe an enhanced intervention focused on sleep debt may have a grater impact on sleep quality.

Hypothesis 2A: We believe an enhanced version of our brief SleepTrackTXT intervention that includes a sleep health and sleep quality component can lead to clinically meaningful improvements in sleep quality over time.

Our power calculation was designed to determine the number of subjects needed to detect a clinically meaningful difference of 3 points on the PSQI from baseline to the study end. We fixed alpha at 0.05 and performed one-sided hypothesis testing. The standard deviation of the difference was estimated as 2.2 using data from our recent randomized trial.[5] Group sample sizes of 27 for the intervention and 27 for the control group achieve 90% power to reject the null hypothesis of equal means with a standard deviation of 2.2 and significance level of 0.05 using a two-sided two-sample equal variance t-test. We estimate a 15% attrition rate based on our prior randomized trial.[23] We estimate 15% of participants in the intervention group will not abide by the intervention protocol. Based on these estimates, we seek to enroll a total of n=100 (50 per group) to account for attrition and non-compliance.

Research Protocol, Part Three – Methods (3000 characters):

STUDY DESIGN: We will use a two-arm parallel, randomized, controlled and single-blinded trial. Our design is similar to the original SleepTrackTXT trial with 100 EMS clinicians.[5, 23]

SETTING AND POPULATION: We will recruit and enroll study participants from four air-medical EMS organizations: 1) Carolina's MedCenter Air; 2) STAT MedEvac; 3) MedFlight of Ohio, and 4) MercyFlight of Buffalo, NY.

Site 1: MedCenter Air (MCA) is a CAMTS accredited critical care transport service offering ground, rotor wing, and fixed wing services. MCA utilizes nurse/nurse or nurse/respiratory therapist crew configuration. Rotor wing services are based at airports surrounding the Charlotte area of North Carolina (Hickory, NC; Concord, NC; Rock Hill, SC). MCA performs approximately 2,200 rotor wing transports yearly. MCA employs 170 clinicians that work 12-hour

shifts.

Site 2: STAT MedEvac site is a CAMTS accredited, regional critical care service with 17 base sites across Eastern Ohio, Pennsylvania, Northern Maryland, and the District of Columbia. STAT MedEvac has an annual patient volume of 10,000. STAT MedEvac employs 160 prehospital flight nurses and paramedics that have a minimum of three years of critical care experience and required certification of CFRN or FP-C. Shift schedules are mostly 24-hours in duration, with some that work 12-hour shifts.

Site 3: MedFlight of Ohio is a CAMTS accredited rotor and ground critical care service operating from 12 bases in Ohio. MedFlight serves primarily central Ohio but also transports patients originating from Pennsylvania and West Virginia. In 2013, MedFlight of Ohio completed approximately 7,000 transports. MedFlight of Ohio employs 150 clinicians certified or licensed as nurses or paramedics. Employees are classified as either full-time or part-time and work shifts of 12-hours and 24-hours in duration.

Site 4: Mercy Flight of Buffalo, NY. Mercy Flight operations are conducted from three bases (Buffalo, Olean and Batavia), 24 hours a day / 7 days a week. The Mercy Flight Team consists of 26 paramedics, 27 nurses,13 pilots, 9 air medical communications specialists, 6 aircraft mechanics and an 11 member administrative, development, finance and facilities management team that provides the necessary support service for flight operations. Each helicopter crew consists of a Pilot, Paramedic and Nurse. Flight Paramedics have at least two years of high volume, critical care EMS experience. Flight Nurses have more than 2 years of critical care experience in an Emergency Room (ER), Intensive Care Unit (ICU) or other critical care field. Over the past 30+ years, Mercy Flight has conducted more than 20,000 patient missions and thousands of Ground Crew Safety Training and Community Education sessions throughout its primary service area of Western New York, Northwest Pennsylvania and Southern Ontario. The dispatch center is staffed 24/7 by Communications Specialists who field, prioritize, dispatch and coordinate incoming flight requests. They are certified by the National Association of Air Medical Communication Specialists (NAACS). Mercy Flight a Part 145, FAA Certified Repair Station and our in-house aircraft mechanics utilize more than 100 years of combined experience to keep the helicopters flight-ready.

PROTOCOL: We will recruit via email and study flyers sent directly to eligible individuals employed at the study sites. We seek to enroll n=100 clinicians. Clinicians with an interest in the study will complete a telephone screening appointment. Inclusion criteria include: 1) 18 years of age and older, 2) working clinically at a study site, 3) currently working in shifts, 4) has a smartphone, and 5) willing to take part in a research study that requires the sending and receiving of multiple text messages daily over 4-months. Eligible clinicians will complete a standard enrollment process with an IRB-approved informed consent procedure.

Randomization into the intervention versus control groups will occur immediately after completion of informed consent. All consented participants will receive a unique login account to access the study website. Participants will use the secure study website to document shift schedules for four months. Participants will receive $100 remuneration.

INTERVENTION GROUP: The intervention and control group participants will use an online sleep diary, a shift scheduling tool to document shift schedules, answer text-message queries about their fatigue and sleep health between shifts (inter-shift) and during shiftwork (intra-shift). The intra-shift text-messages are modeled after the original SleepTrackTXT trial (clinicaltrials.gov identifier: NCT02063737). Participants in the intervention group will receive tailored text-messages ("*Alertness Promoting Messages*") if they report high levels of fatigue, sleepiness, or difficulty with concentration during shiftwork (intra-shift). The inter-shift messages will be sent on days off from work at noon (12:00pm). These messages will include queries about sleep obtained, perceived recovery since last shift, fatigue, sleepiness, and difficulty with concentration. Participants in the intervention group will also receive a Sleep Debt text-message that highlights the participant's calculated sleep debt over the past 7 days, followed by recommendations for obtaining adequate sleep. Finally, the intervention group will also have access to a graphic illustration of reported fatigue levels over time. The Y-axis will be the fatigue score 0=not at all to 5=very much and the X-axis will be over time (the study period). One line will represent the participant's reported fatigue. Other lines will include de-identified aggregated data from other participants in the study. A select group of n=10 intervention participants will wear wrist actigraphy for purposes of validating self-reported sleep diary information. This same select group of 10 participants will be asked to complete psychomotor vigilance tests (PVTs) at the beginning and end of a select number of shifts during the study period.

CONTROL GROUP: The control group participants will use an online sleep diary, a shift scheduling tool to document shift schedules, answer text-message queries about their fatigue and sleep health between shifts (inter-shift) and during shiftwork (intra-shift). The intra-shift text-messages are modeled after the original SleepTrackTXT trial (clinicaltrials.gov identifier: NCT02063737). Control group participants will receive inter-shift messages on days off from work at noon (12:00pm). These inter-shift messages will query the participant's sleep obtained, perceived recovery since last shift, fatigue, sleepiness, and difficulty with concentration. A select group of n=10 control group participants will wear wrist actigraphy for purposes of validating self-reported sleep diary information. This same select group of 10 control group participants will be asked to complete psychomotor vigilance tests (PVTs) at the beginning and end of a select number of shifts during the study period.

Research Protocol, Part Four – Outcome Measures & Data Analysis (3000 characters):

One outcome of interest (linked to Aim 2) is sleep quality, which will be measured with the widely used Pittsburgh Sleep Quality Index (PSQI).[19] A PSQI score of 6 or more on a 21-point scale indicates poor sleep quality. A reduction in PSQI of 3-points suggests a clinically meaningful improvement in sleep quality.[22] We will administer the PSQI at baseline and then again at the end of the 4-month study period.

Our power calculation was designed to determine the number of subjects needed to detect a clinically meaningful difference of 3 points on the PSQI from baseline to the study end. We fixed alpha at 0.05 and performed one-sided hypothesis testing. The standard deviation of the difference was estimated as 2.2 using data from our recent randomized trial.[5] Group sample sizes of 27 for the intervention and 27 for the control group achieve 90% power to reject the null hypothesis of equal means with a standard deviation of 2.2 and significance level of 0.05 using a two-sided two-sample equal variance t-test. We estimate a 15% attrition rate based on our prior randomized trial.[23] We estimate 15% of participants in the intervention group will not abide by the intervention protocol. Based on these estimates, we seek to enroll a total of n=100 (50 per group) to account for attrition and non-compliance.

One outcome measure is linked to Aim 1 and is intra-shift fatigue reported at the beginning, during, and end of scheduled shifts. We will use a single-item measurement of fatigue, which is the preferred approach for research that involves real-time data capture and/or ecological momentary assessment (EMA).[20] This measure was constructed based on prior EMA research of insomnia, it has been tested in our pilot trial and shown to be sensitive to change in fatigue over the course of shift work.[21] We hypothesize that over time and after repeated exposure to the intervention, participants in the intervention group will report lower levels of fatigue at the end of shift than participants in the control group.

We will use linear mixed-model analyses to examine the effectiveness of the intervention on reducing reported fatigue at the end of shift among participants in the intervention group and compare reported values to the control group. We will construct a model where the outcome is the reported fatigue at the end of each shift, a fixed effect of time in study, and a random effect for participants to account for multiple shifts within each person. We will examine the estimated change in fatigue per shift and over multiple shifts throughout the study period. Post-estimation testing will be used to describe the correlation in fatigue scores within the subjects across shifts.

Independent measures of interest include age, sex, health status indicators, and other demographic and person-level variables that address employment status, shift schedule/pattern, general fatigue, co-morbidities/diagnoses, and psycho-social factors that may be associated with sleep and shiftwork. We will use descriptive statistics to examine the distribution of these variables, parametric and non-parametric tests to assess change in values/scores on measures that may change over the course of the 4-month study period.

Research Protocol, Part Five – Limitations (3000 characters):
We recognize that clinicians participating in this study may be different based on demographic factors, including experience-related variables of other HEMS clinicians not participating. We believe that once a participant has enrolled, he/she will most likely demonstrate a high level of adherence with fidelity to the design of the study. We wish to point out that participation in our pilot randomized SleepTrackTXT trial was excellent, and included 12 air-medical clinicians. We also wish to point out success in the recent observational study funded by MedEvac, where we successfully enrolled n=120 individual air-medical clinicians, of which 18 participated twice for a total of n=138 study participations. Based on these data, we believe that once a person has enrolled, compliance with required queries will be high. Based on our prior experience, we are confident we will reach the goal of 100.

Finally, we are limited by the lack of a gold standard in fatigue measurement. The literature is clear that no such standard exist and that most assessments of fatigue in any population must rely on self-reported and subjective assessments of fatigue signs and symptoms. We have completed numerous studies of fatigue involving EMS clinicians. We have demonstrated use of psychometrically sound tools, which is a minimum standard when using measures involving self-report. For purposes of this proposal, we will use single-item measures of fatigue and sleepiness. We have developed these measures based on the best available science, including recent research analogous to our research involving repeated – hourly – queries of symptoms related to insomnia.

We will include a validation component whereby a select sample of 20 participants selected at random (10 from intervention and 10 from control group) will answer additional fatigue questions from previously validated tools over the course of the study period in a repeated fashion. These data will be used to examine construct and predictive validity as well as internal consistency reliability.

Research Protocol, Part Six – Impact on the medical transportation community (3000 characters):

The medical transportation community requires that skilled providers are available and accessibly 24 hours a day, necessitating shifts that diverge from normal circadian sleep cycles. In addition, the cost of readiness in medical transportation often necessitates long shifts due low unit hour utilization and remote locations. In these instances, providers are asked to perform cognitively complex duties with limited sleep and under conditions of poor sleep health. Fatigue in these situations has been associated with medical error, provider injury, and poor patient outcomes.[2]

This study provides a novel mechanism for fatigue risk management through improved real-time surveillance and targeted, individualized, and tailored interventions. This study will have a significant impact on the transportation community. First, the future of fatigue risk management is use of real-time monitoring. Real time knowledge of fatigued providers will allow for improved fatigue and risk management strategies, which may include interventions such as prompting the provider to use caffeine or take a nap. In our recent pilot randomized trial with 100 EMS participants, findings reveal that a simple intervention of prompting EMS clinicians to take a nap or drink caffeine with fatigued leads to reductions in fatigue, sleepiness, and difficulty with concentration.[5, 23] These data support the addition of real-time monitoring and intervention with use of a mobile technology like text-messages. With additional data produced from this study, it may be appropriate for the agency to integrate this type of technology and protocol as part of a larger fatigue risk management system that includes brief rest periods or other strategies. This research may also lead to the technology being used to proactively to identify HEMS clinicians with poor sleep health and offer them resources to mitigate fatigue related risk and improve their quality of life.

Operationally, long shifts (those greater than or equal to 12 hours) provide a convenience to provider and agency alike. In more remote areas of the country, they may be a necessity as it would be impracticable for them to work shorter shifts. As a result, agencies and their employees bear the responsibility to operate safely in this challenging environment. Real time tools for fatigue management hold the promise to be impactful by improving patient and provider safety and simultaneously ensuring round the clock access to this important resource.

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