Reducing Fatigue Among Taxi/Rideshare Drivers

New Information Collection Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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B.1. Respondent Universe and Sampling Methods

According to the US Bureau of Labor Statistics, California has the largest number of taxi drivers compared to all other states (https://www.bls.gov/oes/current/oes533041.htm#st). The study will be conducted virtually with no in person interaction in a large metropolitan area (e.g., San Francisco) that has a diverse population of several thousand taxi/rideshare drivers. A sample of 180 drivers will be recruited to participate in this study and randomly assigned to one of three study groups: 1. Online Training Only (T), 2. Online Training plus fatigue score feedback (T+FB), and 3. Control (C).

The expected response rate for data collection overall is approximately 36%. There are a total of 5 observation periods, one week per observation period. Three fatigue scores will be generated a day, for a total of 105 observations (21 x 5 periods) per subject. The difference to be detected is set as follows: the control group has a coefficient of zero, the training only group (T) is set at a level about 3% higher than the control group and the training + feedback group (T+FB) is set at a level almost 5% higher than the control group. The results indicate that 84.8% power is achieved with a total sample size of 120 (40 in each of the three treatment groups). This is based on 1,000 simulations at each sample size where the number of subjects ranges from 30 per group to 100 per group. To both increase power and account for loss to follow up, we have increased the sample size needed for each study group to 60 from 40, a realistic and necessary but still affordable and manageable number for the study.

Flywheel, a large company based in California, serves San Francisco. Flywheel has partnered with not only traditional taxi companies physically located in San Francisco but hosts an app where drivers driving for other companies (such as Uber and Lyft) can also pick up shifts through Flywheel. When reaching out to the San Francisco Municipal Transportation Agency, which was already prioritizing mitigating fatigued driving among transportation workers, the administrator recommended Flywheel as a company to partner with. Flywheel has offered strong support for the study and is proactive in prioritizing fatigue awareness and mitigation as an important role in safety and productivity.

Inclusion criteria are: drivers who are licensed in the city for at least 12 months and drive at least 30 hours per week. Drivers who do not plan to drive in San Francisco for at least 5-6 months will be excluded. All drivers from various backgrounds, women drivers, pregnant drivers, drivers of various ages will be included to the extent they are represented in the company's driving population and want to participate.

Sample Size and Statistical Methods

A study size of 180 participants, 60 in each study group, will be the target for study enrollment. Specifically, there are a total of 5 observation periods, one week per observation period. Three fatigue scores will be generated a day, for a total of 105 observations (21 x 5 periods) per

subject. The difference to be detected is set as follows: Given that the control group (CO) has a coefficient of zero, the fatigue intervention training only group (IT) is set at a level about 3% higher than the control group and the fatigue intervention training + fatigue score feedback group (IT+FS) is set at a level almost 5% higher than the control group. The results indicate that 84.8% power is achieved with a total sample size of 120 (40 in each of the three treatment groups). This is based on 1,000 simulations at each sample size where the number of subjects ranges from 30 per group to 100 per group. To maximize power and account for loss to follow up, we have increased the sample size needed for each study group to 60 from 40, a realistic and necessary but still affordable and manageable number for the study (see Figure 1).
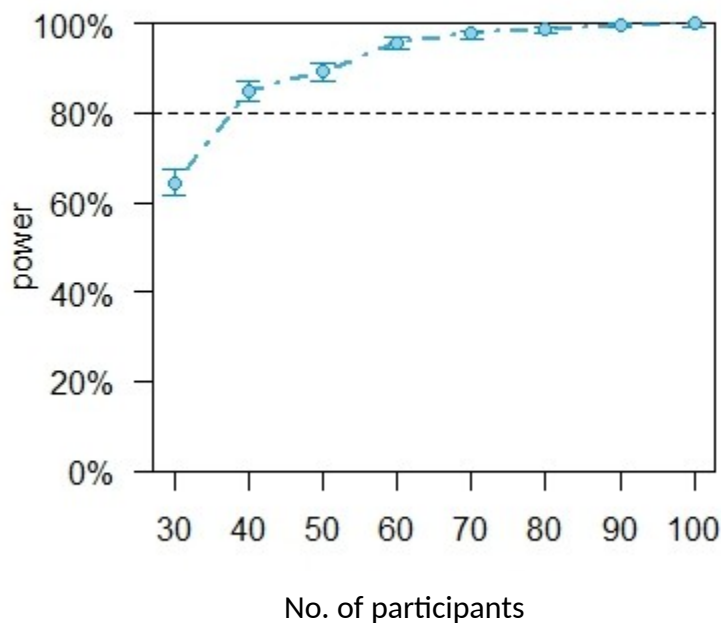

Figure 1 – Graph of the number of participants (sample size) required to achieve the estimated power.

B.2. Procedures for the Collection of Information

Overview

Data collection for each participant will occur over a roughly 4-month period spread across five 7-day data collection periods. There will be 2 pre-intervention data collection periods two weeks apart and 3 post-intervention data collection periods at 1, 4, and 12-week post intervention. The data collection contract has been awarded and contractors may propose staggering data collection periods across the 180 participants (rather than measuring them all

in one week) to focus time and resources on smaller groups of participants at a time, thus making the data collection time roughly 4 months.

Here is a brief description of the data collection activities:

1) The sleep researchers with expertise in driving performance awarded the contract and trained by the NIOSH project officers recruit San Francisco drivers through texts and flyers. The flyer is used to recruit drivers while providing a brief overview of the study. During information sessions, interested drivers will have access to a presentation conveying the study activities using plain language. Interested drivers meeting inclusion criteria will provide their informed consent. Inclusion criteria are: (a) being a licensed taxi driver for that city for at least 12 months, (b) planning to stay with the company for at least 4 months (the length of the study), and (c) working at least 30 hours on average per week.

2) The drivers will sign the consent form, provide contact information for texting and come up with their own 6-digit study id that they memorize based on an algorithm provided to them for ease of remembering. The signed consent form, contact text, and self-generated study ID will belong to NIOSH personnel and used for tracking and matching study instruments with the driver over the 4 months. Drivers will be trained to record their number on their sleep and activities diaries, it will be affixed on the actigraph, and it will be used with the training and evaluation completion.

3) The contractor will not have access to the matched list of study IDs, text information, and participant names.

4) The contractor will text the participant to schedule a time to provide the actigraph (labeled A + study ID by study participant) 72 hours in advance to start generating estimated fatigue scores for Day 1, administer the surveys (Work and Health Survey, Sleep Health Knowledge Assessment) and drop off the Sleep and Activities Diaries on Day 1 and answer any questions about the actigraph or any other part of the study. On Day 7 at the company lot the contractors will collect the actigraph and sleep and activities diaries (labeled D + study ID), answer any questions, and provide the driver with the completion bonus for their time. A time and date will be set for two weeks to begin data collection period 2. The actigraph data and the survey data automatically upload to a secure cloud storage area that is accessible by study staff only. Raw data for this study period will be transferred to the NIOSH project officer through channels set up by NIOSH through ODIT for data security.

5) The contractor will schedule a time to provide the actigraph 72 hours in advance of Day 1 of the 2nd data collection period, confirming it is labelled by the participant. The contractor will check in with the participant on Day 1 of the 2nd data collection period, administer the abbreviated Work and Health Survey, the Sleep Health Knowledge Assessment and drop off the Sleep and Activities Diaries. On Day 7 at the company the

contractors will collect the actigraph and Sleep and Activities Diaries, answer any questions, and provide the driver with the completion bonus for their time. The actigraph data and the survey data automatically upload to a secure cloud storage area that is accessible by study staff only. Raw data for this study period will be transferred to the NIOSH project officer through channels set up by NIOSH through ODIT for data security.

6) After the 2nd data collection period has occurred, 120 drivers will be randomly assigned to take and complete the online training and evaluation within a week after finishing the 2nd data collection period. The drivers will be provided a completion bonus for 3 hours' time for taking the training and completing the Training Evaluation.

7) The contractor will schedule a time to provide actigraph 72 hours in advance of Day 1 of the 3rd data collection period 2 weeks after the training was administered, confirming it is labelled by the participant. The contractor will check in with the participant on Day 1 of the 3rd data collection period, administer the abbreviated Work and Health Survey, the Sleep Health Knowledge Assessment and drop off the Sleep and Activities Diaries. On Day 7 at the company the contractors will collect the actigraph and Sleep and Activities Diaries, answer any questions, and provide the driver with the completion bonus for their time. The actigraph data and the survey data automatically upload to a secure cloud storage area that is accessible by study staff only. Raw data for this study period will be transferred to the NIOSH project officer channels set up by NIOSH through ODIT for data security.

8) The contractor will schedule a time to provide actigraph 72 hours in advance of Day 1 of the 4th data collection period 4 weeks after the training was administered, confirming it is labelled by the participant. The contractor will check in with the participant on Day 1 of the 4th data collection period, administer the abbreviated Work and Health Survey, the Sleep Health Knowledge Assessment and drop off the Sleep and Activities Diaries. On Day 7 at the company the contractors will collect the actigraph and Sleep and Activities Diaries, answer any questions, and provide the driver with the completion bonus for their time. The actigraph data and the survey data automatically upload to a secure cloud storage area that is accessible by study staff only. Raw data for this study period will be transferred to the NIOSH project officer through channels set up by NIOSH through ODIT for data security.

The contractor will schedule a time to provide the actigraph 72 hours in advance of Day 1 of the 5th data collection period 12 weeks after the training was administered, confirming it is labelled by the participant. The contractor will check in with the participant on Day 1 of the 5th data collection period, administer the abbreviated Work and Health Survey, the Sleep Health Knowledge Assessment and drop off the Sleep and Activities Diaries. On Day 7 at the company the contractors will collect the actigraph and Sleep and Activities Diaries, answer any questions, and provide the driver with the completion bonus for their time. The actigraph data and the

survey data automatically upload to a secure cloud storage area that is accessible by study staff only. Raw data for this study period will be transferred to the NIOSH project officer through channels set up by NIOSH through ODIT for data security. Study staff will perform data management and reduction activities and will transfer the final data files through an FTP located on the CDC server.

The research team members will be established by an external competitive contract, awarded to Washington State University, Sleep and Performance Research Center. The research team will create online versions of the survey instruments using an online survey tool (e.g, RedCap). The respondents will complete a self-administered questionnaire using this online survey tool. The research team will assist in recruiting activities and enroll 180 drivers contracted with Washington State University, Sleep and Performance Research Lab.

The research team will manage enrollment logs that will document whether the respondents meet inclusion/exclusion criteria, obtain informed consent, and self-generated 6-digit identification numbers that anonymously link the participant to their study information.

Electronic equipment used for data collection (surveys, PVTs, uploading of actigraph and other instrumentation data) will be dedicated solely to the project and kept in a secure location. The research team will transfer de-identified study participant enrollment data to the project officer after enrollment is completed and before data collection period 1 has started in a process approved by the CDC/NIOSH HSRB protocol.

Training

All contractor staff will receive mandatory training, including any subcontractor, including Information Security Awareness, privacy, records management before performing any work under this contract. Thereafter, the contract employees shall complete CDC Security Awareness Training (SAT), Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.

All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training (RBT) within 60 days of assuming their new responsibilities. Thereafter, they shall complete RBT at least annually in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities (SSR) Memorandum. All HHS employees and contractors with SSR who have not completed the required training within the mandated timeframes shall have their user accounts disabled until they have met their RBT requirement.

 The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

Respondents will be enrolled based on their interest and eligibility to participate in the study as previously described. Respondents will receive an outline of the study activities in an introductory PowerPoint Presentation during the informed consent.

B.3. Methods to Maximize Response Rates and Deal with No Response

The research team will use staff experienced in fatigue research that are representative of the driver population (e.g., men from ethnically diverse backgrounds) to carry out data collection tasks to the extent feasible. These include further clarifying information provided to the drivers, coordinating and clarifying device fitting, and tracking retention through the enrollment logs.

To identify participants not filling out the diary and surveys, the research team will monitor the surveys and diaries completed in the online survey tool during the data collection.

B.4. Test of Procedures or Methods to be Undertaken

Similar methods for measuring and improving knowledge of fatigue among workers have been used in several other studies involving other worker populations. The following list includes each instrument used in the study with an accompanying key reference.

The Work and Health Survey was adapted from a recent study among Taxi Drivers in two metropolitan U.S. cities: Chaumont Menendez C et al [2019]. Individual, business-related, and work environment factors associated with driving tired among taxi drivers in two metropolitan U.S. cities. J Safety Res 70:71-77. This survey includes sections to assess fatigue including the following:

The Epworth Sleepiness Scale measures excessive daytime sleepiness and has been previously validated: Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep, 14, 540-545.

The Pittsburgh Sleep Quality Index measures sleep quality and disturbances over the previous month: Buysse, D. J., Reynolds, C. F., III, Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res, 28, 193-213.

The sleep and activity diary was adapted from a study among police officers: Carney, Colleen E., et al. "The consensus sleep diary: standardizing prospective sleep self-monitoring." Sleep 35.2 (2012): 287-302.

Actigraphy will be used in the context of the sleep and activity diary to assess behavior changes. Actigraphy has been validated for use in clinical and research settings: Ancoli-Israel S, Martin JL, Blackwell T et al. [2015]. The SBSM Guide to Actigraphy Monitoring: Clinical and Research Applications. Behavioral Sleep Medicine, 13:supl 1, S4-S38.

The Fatigue Knowledge Survey will measure the knowledge of sleep health and strategies to reduce sleepiness and evidenced-based ways to promote alertness as related to work and health. The Fatigue Knowledge Survey was adapted from previous NIOSH studies and products. These items are part of the test to measure knowledge retained from an online training program for police officers: NIOSH, Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH training for nurses on shift work and long work hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. [www.cdc.gov/niosh/docs/2015-115/]

The intervention will be an approximately 3-hour web-based interactive course on fatigue as developed in this study using previously validated training among nurses: Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH Training Program for Nurses on Shift Work and Long Work Hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention,

National Institute for Occupational Safety and Health. www.cdc.gov/niosh/work-hour-training-for-nurses.

Additionally, a similar study has just completed data collection among Law Enforcement Officers by NIOSH project officer C. Caruso and colleagues (OMB Control Number 0920-1278) that has different goals, a different homogenous workforce that does not drive for a living and is not as comprehensive as the current study design presented.

A multilevel statistical model is designed to test the two hypotheses: (1) study participants in Study Group 1, after completing the online fatigue training and receiving thrice daily feedback on their fatigue score derived from their actigraph, will experience less fatigue as indicated by changes in their fatigue scores compared to the control group (Study Group 3), and (2) study participants in Study Group 2, after completing the online fatigue training only, will experience less fatigue, as indicated by changes in their fatigue scores, compared to the control group.

Testing these two hypotheses with the proposed statistical model requires the following variables: one dummy variable for the first intervention group (I_{T+FS}) (control group is the referent), one dummy variable for the second intervention group (I_T) (control group is the referent), one variable indicating study phase (0=pre-intervention, 1=post-intervention), one variable indicating time of shift (0=beginning, 1=middle, 2=end), and one variable indicating time of work week (1-7 for each day of 7-day workweek). Interaction terms will be created and added to the model to describe fatigue changes for a specific intervention group for a specific time of shift or time of work week. The variables indicating time of shift and time of work week will be tested early in the analysis process to see if they are significantly associated with fatigue. Time of work week may not follow any pattern in describing fatigue, but time of shift is expected to follow a U-shaped curve. If either variable is found to be significantly associated with fatigue, it will be incorporated into the interaction terms. For example, if time of shift is significant with fatigue changes, a three-way interaction term comprised of the intervention group dummy variable, study phase and time of shift variable would describe fatigue changes throughout the day for the online fatigue training with fatigue score feedback group post-intervention compared to the control group.

The working statistical model is described as:

Fatigue$_{ij}$ = β$_{0ij}$constant + β$_{1ij}$covariates + β$_{2j}$T+FS + β$_{3j}$T + β$_{4ij}$Study Phase + β$_{5ij}$T+FS*Study Phase + β$_{6ij}$T*Study Phase where Level 1 (within-person variable) is designated by i, Level 2 (between-person variable) is designated by j, the constant term is 1, and $β_{1j}$covariates refers to a vector of covariates that are selected in a process described a $priori$ (as follows). Every variable included in the Work and Health survey will comprise the list of potential covariates for the final model and will be included in model-building processes. Covariates will be included in the final model if they meet a set of criteria: they must be significantly associated with the outcome, fatigue, they must not be strongly correlated with another covariate also selected for the model, and if they were not evenly distributed between the study groups. All covariates meeting these criteria will be added to the model and a stepwise backwards selection procedure would be

followed where those not statistically significant at p>0.20 will be removed. The difference in the -2ln(likelihoods) comparing the full model with the model missing only the two interaction terms will be used to test the study hypotheses. To test differences in fatigue levels throughout the day or work week the distance between predicted levels for the intervention group and control groups pre- and post-intervention will be compared. They will be calculated as linear combinations of the standardized estimated coefficients present in the final model (additional interaction terms will be added to reflect the within day or throughout workweek trends if significant). Wald tests will be used to assess their significance. The final model variables and their parameters (including standard errors) for both models will be presented in a table, along with the difference in -2ln(likelihoods) that describes significance of interventions. The findings of the fatigue scores pre- and post-intervention will also be presented in a figure, with average fatigue scores designated by study group for each study phase. If there are within-day changes or within-work week changes that were significant, those will be in a figure as well to visually depict the fatigue changes in as straightforward a manner as possible. To test the difference in effect of the two intervention groups, specifically, the effectiveness of the contribution of receiving feedback on fatigue scores, the differences between the interaction effects will be tested. All analyses will be done using the latest version of SAS.

Finally, using the statistical models separate figures depicting fatigue levels (Fatigue Score) and alertness levels (recorded on diaries) throughout the day before and after the training intervention will be graphed by intervention group and study phase (pre- vs post-intervention).

The knowledge scores will also be graphed pre and post intervention by intervention group to depict differences and sustained knowledge through each post-intervention period, which will be tested using a series of paired t-tests.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Personnel Consulted on Statistical Design
Terry Wassell, PhD, Associate Director for Biostatistics, NIOSH/CDC, 304-285-5946, jtw2@cdc.gov

Personnel Responsible for Collection and/or Analysis of Information
Cammie Chaumont Menéndez, PhD, MPH, MS, Research Epidemiologist, NIOSH/CDC, 304-285-6233, fxf8@cdc.gov. Dr. Chaumont Menéndez is the NIOSH Project Officer responsible for organizing and supervising the project activities, receiving and approving contract deliverables, and responsible for analyses of the survey data.

Steve James, PhD, Assistant Professor, and Lois James, PhD, Assistant Dean for Research, Associate Professor, of the Washington State University Sleep and Performance Center. Steve James: 509-385-9385, stevejames@wsu.edu. Lois James: 509-385-9386, lois_james@wsu.edu. They will be procuring, calibrating and providing the data collection tools.

References

Ancoli-Israel S, Martin JL, Blackwell T et al. [2015]. The SBSM Guide to Actigraphy Monitoring: Clinical and Research Applications. Behavioral Sleep Medicine, 13:supl 1, S4-S38.

Buysse, D. J., Reynolds, C. F., III, Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res, 28, 193-213.

Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH Training Program for Nurses on Shift Work and Long Work Hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. www.cdc.gov/niosh/work-hour-training-for-nurses

Chaumont Menendez C et al [2019]. Individual, business-related, and work environment factors associated with driving tired among taxi drivers in two metropolitan U.S. cities. J Safety Res 70:71-77.

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep, 14, 540-545.

NIOSH, Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH training for nurses on shift work and long work hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. [www.cdc.gov/niosh/docs/2015-115/]