

A Longitudinal Examination of Mental and Physical Health among Police Associated with COVID-19

Supporting Statement Section B

New

Request for Office of Management and Budget (OMB) Review and Approval for a Federally Sponsored Data Collection

Project Officer:

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1. Respondent Universe and Sampling Methods

This aim of this project is to evaluate the longitudinal mental and physical health effects of COVID-19 in police officers.

The target population for “A Longitudinal Examination of Mental and Physical Health among Police Associated with COVID-19” questionnaires and clinic exam are police officers. The officers that will be eligible for this study are officers who worked during COVID-19 and who previously participated in a Buffalo Cardio-Metabolic Occupational Police Stress (BCOPS) study. For safety reasons, women officers who are pregnant at the time of examination will be excluded. The BCOPS studies were conducted by the University of Buffalo at New York (UB) in collaboration with NIOSH to evaluate the psychological, physiological, and subclinical measures of mental and physical health in Buffalo, NY police officers. For this study, NIOSH has contracted with the UB to collect mental and physical health data on approximately 200 police officers. Recruitment for this study will initially focus on recruiting the police officers who participated in the last BCOPS study (n=240). Based on previous participation, the police officers who participate in this study will be mostly male, Caucasian, and approximately 49 years old.

The funding for this study fixes the sample size at 200 police officers. NIOSH expects to get at least 85% participation rate. Because this study will utilize the BCOPS participant pool, it is likely that the response rate for the current study will be similar to the participation rate observed in BCOPS. The participation rate in the first BCOPS study was 62%. However, since then the average participation rate has been approximately 85%. The lowest participation rate was the first visit (62%), while the highest was visit 5 at 100%. UB will focus on recruiting officers who participated in the last visit, which showed a 100% participation rate, 240/240 officers participated. It is possible that at least 40 of the officers will decline to participate or have retired. In that case, UB will recruit any officer who has previously participated in BCOPS, but who also worked during COVID. This recruitment strategy should increase the chance that 200 officers can be recruited.

2. Procedures for the Collection of Information

The sample for this study will consist of 200 police officers who previously participated in the BCOPS study. Although we expect, based on previous participation rates to have at least 90% participation (n=180), sample size calculations indicate that we will have the power to show an effect if at least 162 officers participate. If 10% of the eligible officers choose not to participate in the first round then again in the second round, we will have a sample size of 162 officers. Based on this assumption, we can estimate effect sizes using the given sample size, an alpha level of 0.05, and power level of at least 0.8. Minimum detectable effects are given below for each type of analysis that will be used in this study.

- 1) In a multiple regression model relating a continuous dependent variable to a continuous exposure variable, we will be able to detect statistically significant partial correlations as low as 0.23, adjusting for six potential confounders each with single degrees of freedom (power = 83%). Thus, we can detect significant association with any exposure variable that explains as little as 5.3% of the variation in the outcome, after covariate adjustment.
- 2) For ANCOVA, given that all relevant covariates have been adjusted for in the model, we can detect an effect size of 0.22 or larger, with up to three levels of the main effect with 81% power. For example, this translates as having statistical power to detect differences between two groups, among three, when the group difference is 0.22 standard deviations or greater.
- 3) Cumulative incidence ratios (IRs), often-called risk ratios (RRs), for dichotomous health outcome variables ($Y=0/1$), in relation to either continuous or categorical exposure variables (X), will be estimated using log binomial regression. The IR is the ratio of cumulative incidence of the outcome (Y) at two different levels of the continuous exposure variable ($IR=(Pr(Y=1/X=a))/(Pr(Y=1/X=b))$). For example, Table 1 presents the required power

to detect a minimum detectable risk ratio at various levels of the incidence of the outcome (ranging from 5% incidence to 50% incidence) based on sample of $n = 162$; the estimates represent the risk ratio associated with 1SD increase in standardized continuous exposure variable with normal distribution. For example, for outcome with incidence proportion of 10%, we can detect a risk ratio of 2.2 with 85% power; this calculation assumes that there are no prevalent cases to be excluded at baseline. We have presented minimum effect sizes that can be detected with 0.8 power for different analytical approaches. Using the most powerful analytical approach presented here we can detect a correlation coefficient of 0.23 or higher.

Table 1. Effect size for continuous exposure and dichotomous outcome, given $n=162$, $\alpha=0.05$ and power=0.8.

	Minimum detectable risk ratio			
Outcome incidence proportion (probability of outcome)	2.5	2.2	2.0	1.75
0.05	0.77	0.62	0.50	0.34
0.10	0.94	0.85	0.74	0.54
0.15	0.98	0.93	0.86	0.68
0.20	0.99	0.96	0.91	0.76
0.25	0.99	0.98	0.94	0.82
0.30	0.99	0.99	0.96	0.85
0.35	0.99	0.99	0.97	0.87
0.40	0.99	0.99	0.97	0.89
0.45	0.99	0.99	0.97	0.89
0.50	0.99	0.99	0.98	0.90

These results indicate that we will have the power to address the aims of this project even if all the officers do not participate.

UB has conducted numerous epidemiologic studies. The staff are well trained in health data collection procedures. Quality control of data includes use of a detailed manual-of-operation for all procedures, systemic training of the staff, monitoring of the lab internal control with internal standards, and periodic testing and maintenance of instruments.

Round One

This study will consist of two rounds. During the first round the officers will be asked to come to clinic where they will complete the demographic, medical history, work stress, mental health, and COVID questionnaires, physical exam and blood draw. As previously mentioned, the funding for this study fixes the sample size at 200 officers. UB will initially focus on recruiting all of the police officers who participated in the last BCOPS study. The study protocol is outlined below.

- Participants will be sent a letter explaining the study and requesting participation (Appendix G). If the participant agrees to participate in this research, a letter of introduction will then be mailed (Appendix H). Participants will then call the UB clinic and verify that she/he can participate. Participants will be informed that they must fast for a minimum of 10 hours prior to coming into clinic at UB in order to take

a blood test. Scheduling will be flexible and will be coordinated with the police department. If two letters have been sent without a response, UB will phone the officer and invite them to participate in the study. If they decline, they will no longer be contacted. If they agree, the letter of introduction will be sent.

- Participants will be scheduled by clinic staff over the phone. All procedures will be in the same room. Rooms will be sanitized before and after each participant. Procedures will be face-to-face with clinic staff at a six foot distance. Staff and participants must wear face masks throughout the study. The entire visit is estimated to take two hours.
- When participants arrive at the clinic, the COVID-19 screening form will be reviewed. Participant's temperature will be taken and they will be advised that they must maintain a six foot distance between them and clinic staff and wear a mask.
- Participants will have already received the consent form via mail (Appendix E). They will review it again and sign the consent form if desired and asked if they have any questions.
- A blood sample will be drawn by a trained phlebotomist after consent - a small amount of blood (approximately 4 tablespoons) will be drawn as part of this study. An additional amount of blood (approximately 1 ½ tablespoons) to check the accuracy (quality control) of our measurements may be taken randomly. To meet the aims of this study, blood will be analyzed for selected inflammatory, hemostasis, and metabolic markers that have been associated with stress, obesity, CVD, or metabolic syndrome will be measured. These biomarkers include C-reactive protein (CRP), interleukin 6 (IL-6), fibrinogen, D-dimer, adiponectin, insulin, leptine and telomere length analysis.
- Participants will be provided a light breakfast consisting of cereal, orange juice and coffee if desired.
- After breakfast, participants will have blood pressure taken while comfortably seated. The technician will place a cuff that is appropriate for the size of the right arm and will measure blood pressure three times. With the forearm resting comfortably on the table, staff will count radial pulse for 30 seconds. This procedure will take approximately 15 minutes. _
- Participants' height, weight, abdominal height, waist circumference and neck circumference will be measured and recorded. This procedure will take approximately 10 minutes to complete.
- Participants will be asked to complete several surveys including a survey about how COVID-19 has affected their feelings and well-being, and the effects of the civil unrest (Appendix D17). Nothing in the surveys is designed to diagnose or treat any health condition. They will be informed that they may skip any questions that they do not want to answer or feel uncomfortable with at any time without any consequence.
- Cortisol saliva testing will be done outside of the clinic at the participant's residence by the participant. Participants will be provided with Salivettes (Sarstedt, USA), a commercially available collection device consisting of dental rolls and centrifuge tubes, to take with them when they leave the clinic for the collection of saliva samples. Participants will be given instructions on how to collect the samples to be taken the day after they leave the clinic- four samples in the morning when they awaken, one at lunchtime, one at dinner, and one when they go to sleep. UB will ask the participant to return the saliva samples to the clinic when completed either in person or via paid postage.
- This ends the clinic visit. UB will advise the participant upon departing that they would like to contact them again in about 6-8 months to complete the same surveys they did in the clinic. If agreed, UB will mail the surveys at that time with a return stamped envelope for participants to return the surveys.

UB will conduct a follow-up survey approximately 6-8 months after the clinic visit. Each officer who participated in the first round will be sent the same set of psychological surveys, the medical history questionnaire, and a follow-up COVID questionnaire (Appendix D15). The psychological surveys will be the same surveys they did during the first round, while the COVID questionnaire asks additional questions related to their experience with COVID since the clinic visit. They will not be asked to complete the personal history questionnaire the second time. This second set of questionnaires allows us to meet the study aims.

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

If officers do not respond after two letters inviting them to participate in the study have been sent, UB staff will contact the officers by phone to invite them to participate in the study. If they say they are not interested in participating they will not be contacted further. Recruitment will continue until either 200 police officers have been recruited or there are no more eligible officers to recruit (i.e. they did not work during COVID-19 and did not participate in one of the BCOPS studies).

As described in Section A9, as a token of appreciation respondents will receive \$100 for participating in the first round of the study and \$50 for completing round two of the study. Previous experience indicates that this is an extremely difficult population to recruit and that without this token of appreciation the participation rate will likely be very low.

4. Test of Procedures or Methods to be Undertaken

With the exception of the COVID questionnaire the surveys being used in this study have all been previously validated and are extensively used to evaluate psychosocial outcomes in both the clinical or research environment [1-10]. Furthermore, these surveys have been used as part of the BCOPS study since 2000. To meet the aims of this study it is imperative that we use the exact same surveys that were administered as part of the BCOPS study. The overarching aim of this study is to longitudinally measure changes in psychological stress and physical health markers of police officers during COVID-19 and mental health measures approximately one year later. This can only be accomplished if NIOSH can compare the officers' responses on the surveys obtained when they participated in at least one BCOPS study to the responses obtained during COVID and one year later as part of the current study.

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

NIOSH will contract with the UB to collect the data for this study. Specifically, UB will recruit the police officers, collect the biological and psychological markers of disease during round one and the psychological surveys and follow-up COVID survey during round two. UB will clean and enter the data into a database. They will then send NIOSH de-linked and de-identified data for statistical analysis.

NIOSH and contractor contacts are listed below.

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