Workplace Violence Prevention Programs in NJ Healthcare Facilities

Request for Office of Management and Budget Review and Approval for Federally Sponsored Data Collection

Section B

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B1. Respondent Universe and Sampling Methods

Specific Aim 1: *Compare the comprehensiveness of healthcare facility workplace violence prevention programs before and after enactment of the NJ regulations*

> *Working Hypothesis: Enactment of the NJ regulations will improve the comprehensiveness of hospital workplace violence prevention program policies, procedures and training.*

Statistical Power Calculation: Fifty hospitals will be sampled to address this aim. Using 50 hospitals as the target enrollment, statistical power to detect a significant increase in the comprehensiveness of hospital workplace violence prevention programs following enactment of the regulations is provided in Table 1. Final compliance rates ranging from 80% to 95% were selected based on suggested rates found in California hospitals from the previous NIOSH-funded study after enactment of similar legislation. This increase is based on an average baseline comprehensiveness rate of approximately 70% from the California study. Based on the findings from Table 1, we will have sufficient power to detect a meaningful increase in the comprehensiveness of hospital workplace violence prevention programs by enrolling 50 hospitals.

Table 1: Statistical power for varying levels of compliance after enactment.

Final Compliance Rate	Power
95%	100.0%
90%	99.9%
85%	98.3%
80%	79.1%

Statistical Analysis: Two measures of comprehensiveness will be created: (1) baseline measure to represent the degree to which hospitals already have the components of the NJ regulations in place prior to enactment, and (2) compliance measure to represent the degree to which hospitals have the components of the NJ regulations in place following enactment. Both baseline and compliance measures will be scored by category of the regulation. These categories include violence prevention policies, reporting systems for violent events, violence prevention committee, violence risk assessments, post incident response, and violence prevention training. Within each category, hospitals are required to implement specific components. Therefore, baseline comprehensiveness and compliance will be measured using a score for each category. The score will be calculated as the proportion of the total number of regulation components each hospital has in place, where each hospital will be given one point per component. We will not assign weights to the components because there is no precedent for assuming the presence of one component is more important than the presence of another. Baseline component scores, by category of the regulations, are available from the previous NIOSH-funded study for New Jersey hospitals. Compliance component scores will be calculated using data collected in the proposed project.

Baseline comprehensiveness and compliance scores will be compared using paired t-tests. Comparisons by hospital type, as well as categories of operations data (e.g., number of hospital beds, number of patients per year, amount of charity care rendered, and hospital control) will

also be examined. Amount of charity care rendered is defined as care given to persons with modest resources without standard compensation for that care. Hospital control will be defined into categories of for-profit and non-profit.

Specific Aim 2: *Describe the workplace violence prevention training nurses receive following enactment of the NJ regulations*

> *Working Hypothesis: Nurses receive at least 80% of the workplace violence prevention training components mandated in the NJ regulations.*

Statistical Power Calculation: A total of 2000 nurses will be surveyed using a stratified random sampling design. Nurses will be stratified by licensed practical nurses (LPNs) and registered nurses (RNs). The power calculation for this aim is based on an aggregate measure of worker knowledge of the facility's workplace violence prevention training program. The sampling errors for estimated proportions of knowledge based on the nurse's responses are presented in Table 2.

> Table 2. Sampling errors for estimated proportion of nurses who received 80% of training components based on a sample of 1000 (50% response rate) and on a sample of 1500 (75% response rate).

Sample Size of 1000		Sample Size of 1500	
Estimated Proportion	Sampling Error	Estimated Proportion	Sampling Error
10%	±2%	10%	±2%
25%	±3%	25%	±2%
50%	±3%	50%	±3%
75%	±3%	75%	±2%
90%	±2%	90%	±2%

Statistical Analysis: A comprehensiveness score for nurse training in workplace violence prevention will be calculated as the proportion of training components nurses identify as having received by their hospitals, where the denominator is the total number of components mandated in the NJ regulations. This comprehensiveness measure will be calculated post-enactment of the NJ legislation. Weights will not be assigned to the components of the regulations because there is no precedent for assuming one component is more important than another.

Post-enactment comprehensiveness scores will be compared across hospital type and worker characteristic categories (i.e., job title, hospital department, shift) using t-tests and ANOVA. Nonparametric options will be considered if distributions vary from normality. Since there are 50,050 RNs and 1,600 LPNs working in hospitals in NJ, there will be a need to over-sample LPNs so that we can do a comparison between RNs and LPNs. Therefore, a sampling weight for each nurse will also be incorporated into this analysis. Finite corrections to the variance of the estimates will also be calculated in this analysis based on the population totals in the data frame.

Specific Aim 3: *Examine patterns of assault injuries to workers before and after enactment of the regulations*

> *Hypothesis:* The rates of assault injuries to workers will decrease following enactment of the regulations.

Statistical Power Calculation: A stratified random sample will be selected based on the provided sampling frame of hospitals. Five strata will be created based on the five facility types: Trauma I, Trauma II, GAC < 300 beds, GAC >= 300 beds, Psychiatric. A sample of 10 hospitals will be selected in each of the five strata so that a total of 50 hospitals will be selected. Weights will be

calculated for each hospital within a specific stratum by dividing the total number of hospitals in that stratum by the number of hospitals randomly selected within that stratum. Based on assault injury rates (48% decrease in emergency departments and 37% decrease in psychiatric units) from Casteel et al, we anticipate having 87% power to detect a 40% decrease in assault injury rates following enactment of the regulations.

Statistical Analysis: A Poisson regression model will be selected to assess the effectiveness of the regulations in reducing rates of physical assault injury before the regulations were enacted (2008-2011) compared to after the regulations were enacted (2012-2014). The number of physical assault injuries for each hospital will be modeled to identify potential statistical confounders both before and after the regulations by year. The logarithm of employee hours per year at each hospital will be used as an offset variable so that rates are modeled. The weight associated with each hospital will be incorporated in this analysis. Generalized Estimating Equations will be used for the Poisson regression assuming each separate hospital as a cluster.

We will examine patterns of physical assault injury before and after enactment of the regulations by hospital type, hospital control and rates of community crime surrounding the hospital. These variables will be measured as effect-measure modifiers based on findings from the previous NIOSH-funded study. Hospital type and hospital control are defined in previous sections. Community crime will be defined as town-level index and violent crime obtained through Uniform Crime Reports. Community crime rates will be calculated as the number of index and violent crimes per 100,000 town population per year, where population size will be obtained through the U.S. Census Bureau.

The components of a hospital's workplace violence prevention program will also be examined as a potential effect-measure modifier. The total components will be defined as the average score across each regulation category (see Specific Aim 1 for definitions). This average score will be categorized into tertiles of high, medium and low for analysis. Depending on the distribution, we may also categorize program components based on the percentage of components in place (e.g., hospital has at least 50% of the components in place, where the reference category is having less than 50% of the components in place).

B.2 Procedures for the Collection of Information

Data Collection Methods: Data collection in Phase I Facility Survey will include abstraction from the facility's workplace violence prevention policies and procedures and interviews with the facility's violence prevention committee chair (who is the individual responsible for oversight of the program) (Specific Aim 1), and abstraction from the facility's violent event incident reports and administrative records (Specific Aim 3). Data collection in Phase II Nurse Survey will include self-administered survey of nurses (Specific Aim 2).

Phase I: Facility survey

Abstraction from Workplace Violence Prevention Policies and Procedures: These data will be used to measure the compliance of the facility's workplace violence prevention program. At the time of recruitment, Dr. Blando will request a copy of the facility's workplace violence prevention policies, procedures and training materials. Receipt of these documents will be requested via email attachment. If not possible by email, we will provide a pre-paid, pre-addressed mailer to the facility for mailing the documents.

The instrument was developed and piloted (see B.4. Section) by the research team and includes questions that follow the specific elements of the NJ regulations. Dr. Blando will abstract the information prior to the interviews with the violence prevention committee chair. A reliability check of the abstraction will be performed with an additional member of the research team.

Interviews with Violence Prevention Committee Chairs: The purpose of these interviews is to supplement (and clarify, if needed) data abstracted from the policies, procedures and training materials, as well as to obtain qualitative information about the chair's knowledge and attitudes about the NJ regulations. The interviews will utilize a standardized questionnaire designed for administration to the Chair of the Workplace Violence Prevention Committee. At the time of recruitment, Dr. Blando will schedule an interview to be conducted at the facility with the committee chair.

This instrument was also developed and piloted by the California study research team. The interview protocol is primarily open-ended to allow for details about the facility's workplace violence prevention program that may not be documented in the written policies and procedures, as well as information about barriers and facilitators to implementing the regulations. Based on the pilot, we estimate that each interview will take approximately 45-60 minutes to complete.

Violent Event Incident Reports and Administrative Records: These data will be used to measure changes in the incidence rate of employee violence before and after enactment and phased implementation of the NJ regulations. The violent event data will also be used to describe the circumstances surrounding the events. According to the regulations, facilities are required to gather the following information after a violent incident: date, time and location of the incident; job title and job task of the victim; perpetrator's relationship to victim and number of perpetrators; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants; and actions taken by the facility in response to the incident.

In our pilot with 8 facilities in the Fall 2010, violent event data were available electronically for all sites. For data available electronically, we will request a personal de-identified dataset that contains the variables required in the NJ regulations. For facilities where data are not available electronically, we will abstract on-site from hard-copy incident reports. Upon request from a facility, we will develop a standardized data use agreement to access violent event data. Dr. Blando will take primary responsibility for the abstraction from both on-site and electronic files. Ms. Emily O'Hagan R.N. (retired NJ Department of Health and Senior Services), who will work as a consultant on the proposed project, will assist Dr. Blando with data abstraction. Ms. O'Hagan was a key field staff member in the previous NIOSH-funded California legislation study. In addition, her experience in both clinical care and public health will have significant utility in this phase of the project. A reliability check of abstracted violent event data will be performed with an additional member of the research team.

Violent event data will be requested for the three years preceding enactment of the legislation (2009-20111) and three years' post enactment (2012-2014). In keeping with the regulation's definition of a violent event and to standardize data collection across facilities, we will request incident reports that document physical assaults only. Based on our preliminary research in hospitals, workers are more inclined to report physical violence than verbal threats of violence, which gives us a level of confidence that underreporting will be minimal.

The NJ Department of Health and Senior Services (NJDHSS) Division of Health Care Facility Evaluation and Licensing, Office of Health Care Financing maintains financial and operational data on all licensed health care facilities within the state. This information is collected via standard annual data submissions (i.e. Form C data) that healthcare facilities must complete in June as per N.J.A.C. 8:31B. This information is detailed and contains specifics such as employee hours, physician fees, and other cost information. Employee hour data will be used as the denominator values in incidence rate calculations to accomplish Specific Aim 3. The employee hours data are broken down by 50 different departmental cost centers, which include all employee hours for the emergency department, behavioral health, and skilled nursing care units. Therefore, the total number of employee hours charged to a particular cost center will be contained within this form C data if a licensed health care facility has an emergency department, behavioral health care unit, or skilled nursing care. Each of the eligible hospitals for the proposed study fit these criteria.

The study team had abstracted employee hours data for emergency departments and behavioral health units in the previous study for the years 1992 - 2001, at which time the data were maintained via hard copy. However, since 2001 the NJDHSS has maintained the data in electronic formats. These electronic databases are considered public information and can be obtained via Open Public Records Act (OPRA) requests. The study team has already obtained the Form C data for all hospitals in NJ for the years 2005 - 2009 through a previous OPRA request. Data becomes available approximately one year after the data submission. Therefore, 2010 data will become available in June 2011.

Phase II: Nurse survey

Self-Administered Survey: The purpose of this survey is to document the type and frequency of workplace violence prevention training nurses receive. The survey will be mailed with a self-addressed, stamped envelope for return to the third-party contractor. The contractor will track and manage the mailing and response. The contractor will also enter the survey data and send the completed de-identified tracking and survey databases to NIOSH. NIOSH will have direct access to the database of any surveys completed online.

The survey will include questions about nurses' knowledge of the NJ regulations, whether they receive the training components mandated in the regulations and their experience with verbal and physical assaults in the previous year**.** We estimate the survey to take no more than 20 minutes to complete. The survey will be pilot-tested in Summer 2011 prior to full-scale administration.

A letter of introduction with information on consent will be included with the survey questionnaire. Names of nurses will not be recorded on the survey questionnaire and thus, their questionnaires will not be shared with their employers. The survey poses minimal risk to nurses and human subjects review approval is not a problem.

Quality Control and Data Management**:** To ensure inter-rater reliability of data abstracted from the facility's workplace violence prevention policies, procedures and training and from violent event incident reports, a quality control check with six facilities will be conducted at the beginning of the study. Drs. Blando and Casteel will independently abstract, from the same six facilities, data from the facility's workplace violence prevention program and violent event reporting system. The objective is to compare whether completion of the data abstraction forms are consistent among the two raters, both of whom were responsible for similar data collection tasks in the previous NIOSH-funded California study. Two trauma facilities, two general acute

care facilities (one with < 300 beds, one with >= 300 beds), and two psychiatric facilities will be assessed. Key inconsistencies will be identified and resolved.

Each eligible facility in NJ will be assigned a unique study identification number. This number will be used on all abstraction and interview forms. The facility name and address will never be documented on these forms. In addition, violent event data abstraction will contain no personal identifying information on the victims, perpetrators or witnesses of the events. Abstraction and interview data will be collected directly into SAS databases. Any pertinent information from the interview that is not amenable to key stroke entry will be recorded in hard copy, and decisions will be made after the site visit on how best to incorporate this information. However, it is important to note that the database will contain text fields that can allow for respondents to expand on questions asked in the interview. The direct data entry is an efficient process and will also reduce the potential for transcription errors.

A password-protected FTP (File Transfer Protocol) site, available through NIOSH, will be used to transfer SAS databases from Drs. Blando and Casteel to Ms. Ridenour and Dr. Hartley at NIOSH. In addition, employee hour data from the New Jersey Department of Health and Senior Services (NJDHSS) Division of Health Care Facility Evaluation and Licensing, Office of Health Care Financing will be requested electronically and in aggregate - that is, names of workers or other personal identifier, such as social security number, will not be requested or accepted.

Detailed protocols for mailing nurse surveys from the contractor will be developed. These protocols will include procedures for mailing surveys and reminders, for making “automated” calls, for maintenance of a master tracking database, and for two person data entry. Hard-copy survey data will be computer-entered into a SAS database by the contractor for data editing by NIOSH. Data editing will include careful scrutiny of the entered data for errors in accuracy, consistency and completeness that were missed at the time of data entry. In addition, 20% of all entered records will be sampled and checked against hard-copy forms.

A tracking database will be maintained of all eligible health care facilities identified from the NJDHSS, Division of Health Care Facility Evaluation and Licensing. This database will link the facility with the study identification number and will track: status of participation (enrolled, declined, passive withdrawal), and if declined, the reason why; facility-level financial and operation data (e.g. number of hospital beds, number of patients per year, amount of charity care rendered, hospital control); and dates the various sources of data are received at NIOSH. Ms. Ridenour and Dr. Hartley will maintain this database and monitor all field activity.

Data cleaning will be conducted on a quarterly basis. Codebooks will be created for all databases. Back-up copies of databases and codebooks will be regularly archived on secure file servers maintained by NIOSH. All data will be maintained on password-protected computers, accessible only to project staff. All hard-copy forms will be stored in locked filing cabinets in locked project staff offices and shredded once data entry and cleaning are completed.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Potential limitations of the study include: (1) Low response rate of mailed worker surveys, (2) Respondent bias from worker surveys, (3) Hospital nonparticipation, and (4) Quality of hospital-level regulation implementation. *Low response rate of mailed worker surveys:* We plan to maximize survey response using multiple mechanisms. First, the Health Professionals and Allied

Employees (HPAE) will conduct "automated" calls (pre-recorded messages from the HPAE Vice-President requesting participation and support of the membership) to the union members, and the contractor will do the same with non-union members. Second, the contractor will mail the survey out up to 3 times. Third, we have developed the survey to be completely anonymous. Fourth, an online version of the survey will be available. Finally, we have included an "opt-out" option on both the mailed and online surveys. *Respondent bias from worker surveys:* The protocols we have incorporated for maximizing worker response will likely help in minimizing respondent bias. Since our sampling frame does not include worker characteristics, we are unable to measure worker-level differences between respondents and non-respondents. In addition, because our sampling frame does not identify the hospital in which the worker is employed, there is no way to measure differences using hospital-level characteristics, including the prevalence of violence. We developed the survey and sampling frame to protect worker anonymity. *Hospital nonparticipation:* Nonparticipation will be minimized through several means which includes follow-up by letter and phone during the recruitment process. Studies have shown that follow-up letters and multiple phone calls can increase participation rates by up to 10%. In addition, a significant factor that will enhance participation is the pre-existing relationships between the hospital security directors and the research team members. This was evident during the pilot study, where the targeted recruitment goal was met within several weeks. In addition, past experience with site visits in 2005 and 2006 can provide additional assurance about participation because the research team was able to recruit 50 of the 84 hospitals in NJ at that time, for a successful field visit and participation rate of 60%. The previous study also demonstrated that additional hospitals could have been recruited if it were necessary. *Quality of hospital-level regulation implementation:* The proposed analysis plan for measuring baseline comprehensiveness and post-enactment compliance to the NJ regulations is based on the number of components hospitals have in place. In other words, it is a quantitative measure and does not incorporate the quality of implementation of the component. The interview we conduct with the Chair of the Violence Prevention Committee will include qualitative descriptions of implementation. While we do not plan to conduct a formal qualitative analysis, we will use the information anecdotally to help interpret quantitative findings.

B.4 Tests of Procedures of Methods to be Undertaken

Pilot Test: In preparation for the proposed project, we pilot-tested the data collection instrument to be used to interview administrators about the elements of their facility's workplace violence prevention programs. The pilot test was instrumental in improving the interview process and provided assurance that an interview will be an effective way of obtaining detailed information from administrators. The pilot test involved administration of the survey in a direct face-to-face interview at hospitals in an identical manner proposed for this project. The pilot was conducted with eight NJ healthcare facilities in October and November 2010. Facilities were selected to represent various hospital types, specifically acute care (general) and psychiatric hospitals, and sizes. Based on the pilot, we developed two data collection instruments, one as the interview form and the other to abstract data from the facility's written programs. To keep the interview to 45-60 minutes, the abstraction form was developed to obtain information on the facilities workplace violence prevention program, leaving the interview to provide more qualitative input into the barriers and facilitators to interpreting and implementing the NJ regulations.

The nurse survey will be pilot-tested in Summer 2011 prior to full-scale administration.

A NIOSH protocol for the full study was peer-reviewed by a committee of grant proposal reviewers and external peer reviewers. The protocol was submitted for NIOSH HSRB review and was approved on 9/21/2011 (Appendix E). In the event that any changes need to be made to the data collection forms, a change justification will be submitted to OMB.

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

Key personnel providing statistical consulting, data collection, and study design are provided below.
Statistician consulting: Completed the power calculations and developed the sampling methodology:

Scott Hendricks, M.S.
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Data collection: The hospital interviews will be conducted by Dr. Blando. The nurse surveys will be done by contract employees: Contract to be awarded in FY12. OMB will be notified upon contract award.

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Study design, data collection, and analysis: The principle investigators (NIOSH project officers), Carri Casteel and James Blando are responsible for the study design, management of the data collection, management of the system of records, and analysis of the data:

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