Attachment E

Protocol (without Survey)

Protocol: Assessment of occupational injury among fire fighters using a follow-back survey

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Other Project Members: Corey Butler [NIOSH], Steve Miles [NIOSH], Audrey Reichard [NIOSH], Rita Fahy [National Fire Protection Association], William Troup [U.S. Fire Administration]

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PROJECT OVERVIEW

Protocol Summary: The purpose of this project is to describe nonfatal occupational injuries and exposures incurred by fire fighters and treated in a nationally stratified sample of emergency departments (EDs). This will be accomplished via follow-back telephone interviews of the injured and exposed fire fighters. The National Institute for Occupational Safety and Health's (NIOSH) occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work) will be used to identify potential respondents for the interviews. Data collection will be done via a questionnaire containing questions about the respondent's injury or exposure that sent them to the ED, their specific activity at the time of their injury or exposure, work experience and competencies, and recovery experience. The results from the data collected through this project will provide a deeper insight into the prevalence and characteristics of nonfatal occupational injuries and exposures among English-speaking fire fighters 18 years of age and older who sought treatment at an ED for an occupational injury or exposure during the four year study period (2018 through 2021).

Investigators/Collaborators

Suzanne Marsh, MPA, ***principal investigator,*** is a statistician at NIOSH in the Division of Safety Research (DSR) Surveillance and Field Investigations Branch (SFIB), Special Studies Team (SST). She has worked with fatal and nonfatal occupational injury data for almost 28 years. She has managed a project conducting telephone interviews of injured/ill workers, including questionnaire development, administration, and analysis. She has also worked on several projects focused on injuries and fatalities among fire fighters and emergency medical services (EMS) workers.

Corey Butler, MS, REHS is an Occupational Safety and Health Specialist at NIOSH in the Western States Division (WSD), Denver Office. Corey came to NIOSH in 2010. She is Project Officer for the WSD Wildland Fire Fighting Program and was a co-coordinator of the NIOSH National Occupational Research Agenda Public Safety Sector, which includes fire service, corrections, emergency medical service, law enforcement and wildland fire service. Corey also participates in the NIOSH Fire Fighter Fatality Investigations and Prevention Program (FFFIPP).

Steve Miles is a Fire Fighter Fatality Investigator at NIOSH in the DSR, SFIB, FFFIPP. Steve came to NIOSH in 2008. He investigates fire fighter fatalities and produces investigation reports. Prior to NIOSH, Mr. Miles was at the Virginia Beach Fire Department (VB FD) for 31 years where he served as fire fighter and officer in the suppression and training divisions, as a Captain (Shift Safety Officer) in the fire marshal's office and safety division, and as Battalion Chief of Health and Safety. In the safety roles, he was responsible for accident and injury investigations. Steve has served on the National Fire Protection Association (NFPA) Respiratory Protective Equipment Committee as a user since 2003 and as a FFFIPP representative since 2008.

Audrey Reichard, MPH, OTR is an epidemiologist at NIOSH in the DSR, SFIB, SST. She is project officer responsible for updating and maintaining the occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work) and has authored and co-authored several NEISS-Work manuscripts, including one comparing nonfatal injuries among emergency responder occupations. Audrey managed a project conducting telephone interviews of injured ill EMS workers, including questionnaire development, administration, and analysis. Through this effort, she developed a good knowledge base of emergency responder nonfatal injuries.

Rita Fahy, PhD is a Manager of Fire Data Bases and Systems in the Fire Analysis and Research Division of the NFPA. She is involved in statistical analysis and computer modeling work, mainly in the areas of fire fighter deaths and human behavior in fire. She has authored NFPA's annual study of on-duty fire fighter fatalities since 1981.

William Troup, MBA has served at the U.S. Fire Administration (USFA) for 25 years. He manages research programs in Fire Fighter and Emergency Responder Health and Safety. He holds many fire and EMS professional certifications and is an active fire fighter and EMS responder. In 2008, he received the EMS 10: Innovators in EMS award by the Journal of Emergency Medical Services Magazine for contributions to emergency vehicle safety. He works with the U.S. Department of Justice/National Institute of Justice (NIJ), supporting health and safety programs for Law Enforcement and serves on the Department of Homeland Security Science and Technology First Responders Group. Bill is a veteran of the U.S. Air Force.

Funding Source

Funds for this project are primarily provided by NIOSH through the National Occupational Research Agenda (NORA). These funds will be used for staff time to complete administrative tasks and data collection. The funds will also be used to pay the Consumer Product Safety Commission (CPSC) for the collection of telephone interview survey data. Supplemental funding will come from NIOSH DSR, as DSR consistently funds the routine collection of NEISS-Work data.

INTRODUCTION

Literature Review/Current State of Knowledge about Project Topic

Fire fighters play a vital role in community safety. With over 1 million workers at almost 27,000 fire departments in the U.S. [NFPA, 2016], this workforce undertakes many critical public safety activities including fighting structure and wildland fires, responding to motor vehicle incidents, operating at hazardous material incidents, and assisting EMS workers during medical calls. During these activities, fire fighters regularly face hazards for occupational injuries and exposures, including exposure to immediately dangerous to life or health atmospheres, other atmospheric contaminants that may negatively impact health, heat or high-temperature steam, excessive cold, and infectious disease. Fire fighters are also at risk of being struck by motor vehicles during traffic incidents, falling from heights, and sustaining electrical shock. Resulting injuries and exposures can negatively impact the mental, physical, and financial well-being of the workforce, the fire departments, and their communities. Furthermore, several studies suggest that numbers and rates of nonfatal injuries among fire fighters are high compared to many other occupations. A study of data from 2000 to 2001 estimated nonfatal injury rates for all fire fighters to be 3.5 per 100 full-time equivalent (FTE) workers and rates for career fire fighters to be as high as 9.2 per 100 FTE [Reichard and Jackson, 2010]. Data from the 2015 Bureau of Labor Statistics (BLS) Survey of Occupational Injuries and Illnesses (SOII) indicated that the rate of nonfatal occupational injuries and illnesses for fire fighters was 397.5 per 10,000 FTE, almost four times higher than the rate of 104 for all workers [BLS, 2016]. In 2015, NFPA fire fighter survey results indicated there were 68,085 fire fighter injuries, 27,250 exposures to hazardous conditions, and 8,350 exposures to infectious diseases [Haynes and Molis, 2016]. Annual costs of fire fighter injuries have been estimated to be $2.8 to $7.8 billion [NIST, 2004].

Justification for Study

Severity, frequency, and costs of injuries and exposures to fire fighters indicate that prevention should be a priority. While several studies have investigated conditions and causes of fire fighter injuries and exposures [Britton et al., 2013; Frost et al., 2016; Jahnke et al., 2013; Poplin et al., 2012; Walton et al., 2003], these studies are limited by inclusion criteria and coverage. These studies included a limited number of departments, only a portion of the workforce (e.g., Federal wildland fire fighters), or generally excluded volunteers. It is also recognized that there is not a single injury surveillance system for the U.S. fire service [Widman et al., 2017]. While attempting to address some of these limitations, this study offers another piece to this complex puzzle by using data from an ongoing collection of occupational injuries and exposures from a stratified national sample of U.S. EDs. Results will provide an up-to-date picture of nonfatal injuries and exposures to fire fighters treated in EDs and a deeper insight into events that lead to the largest number of nonfatal injuries and exposures among fire fighters.

Intended/Potential Use of Study Findings

Study results will be used to determine common injuries and exposures among fire fighters treated in EDs. The results will assist in identifying subsets of this fire fighting population who are at most risk for occupational injuries and exposures, and identify circumstances and activities that put these fire fighters at risk. These results will be used to provide justification and direction for further research and for the development and improvement of injury prevention efforts for this critical workforce.

DESIGN

Objectives/Study Design/Locations

The primary objective of the proposed research is to identify priority areas for intervention-based research by identifying and characterizing common injury scenarios for fire fighters. Specific aims of this study include:

Aim 1: Identify the study population (fire fighters who received medical treatment at an ED from 2018 to 2021 for job-related injuries or exposures) using an existing surveillance system (NEISS-Work) that provides a national stratified sample of individuals who sought care at EDs in the U.S.

Aim 2: Administer a follow-back survey to the study population identified from NEISS-Work. This fully-vetted follow-back survey was developed and tested on fire fighters during FY 2016 through a DSR-funded pilot.

Aim 3: Following statistical methodology used in previous NEISS-Work follow-back studies, weight the interview data to calculate national estimates of fire fighters treated for occupational injuries and exposures in U.S. EDs.

Aim 4: Apply standardized codes to the study population data to identify and characterize common injury/exposure scenarios for fire fighters. The final data set will be used to conduct data analyses the year after funding ends.

The objective and aims will be accomplished using two inter-related data sources: (1) routinely collected NEISS-Work data which is an occupational supplement to the broader NEISS and (2) follow-back telephone interviews of fire fighters identified from NEISS-Work. Data for NEISS and NEISS-Work, including the telephone interviews, are collected by CPSC. The collection of NEISS-Work data is funded by NIOSH, who monitors data quality, stores the data, and oversees use of the data. NEISS-Work is a nationally representative, stratified probability sample of approximately 67 U.S. hospital EDs

based on hospital size determined by the annual number of ED visits. NEISS-Work includes civilian, non-institutionalized individuals who present to urban and rural hospital EDs with work-related injuries, illnesses, or exposures throughout the U.S. CPSC captures all work-related injuries treated in EDs by abstracting standardized information from the emergency medical record.

Injured/exposed fire fighters will be identified from NEISS-Work. Once cases are identified, CPSC will request contact information for all identified cases from the hospitals. At least ten business days prior to calling a fire fighter identified in the NEISS-Work data, the fire fighter will be sent a letter of consent describing the study and measures that will be taken to protect confidentiality if they choose to participate (Appendix A). The letter provides instructions on how to opt out of the telephone interview study by calling a toll-free number. For fire fighters who do not opt out initially, CPSC will conduct interviews through contracts with trained interviewers. The interview script will ask each fire fighter to provide verbal consent prior to proceeding. Once consent is given, the interview will proceed. Data will be collected on the fire fighters themselves, their injury or exposure, and injury or exposure outcomes. NIOSH will not receive contact information or request any personal identifiers during the interview.

Hypotheses or Questions

Results of the survey will assist us in answering the following questions:

1. What types of nonfatal occupational injuries and exposures do fire fighters incur?
2. What are the characteristics of fire fighters injured or exposed?
3. What are the circumstances and exposures surrounding and contributing to nonfatal occupational injuries incurred by fire fighters?
4. What are the long-term outcomes and impacts of nonfatal occupational injuries on fire fighters?

General Approach

This project consists of follow-back telephone interviews using cases identified from NEISS-Work. The study will be descriptive in nature. It is our aim to collect enough data via the interviews to meet established NEISS-Work reporting requirements and present the data as national estimates. Alternatively, if reporting requirements are not met, the data will be presented as a case series.

How Study Design Addresses Hypotheses and Meets Objectives

The proposed follow-back interview study will use national surveillance data (i.e., NEISS-Work) to identify fire fighters eligible for participation in the telephone interviews. Weighted results will detail estimates of injuries and exposures occurring to fire fighters nationwide. The proposed descriptive analyses of the data collected through the telephone interviews should provide answers to all of the research questions specified in this protocol. The extent to which those details are reportable will be dependent on the number of completed questionnaires.

Audience and Stakeholder Participation

There are several partners and stakeholders that have interest in this area, including the NFPA, USFA, National Fallen Fire Fighters Foundation (NFFF), the National Volunteer Fire Council (NVFC), and the U.S. Department of Interior. Along with comments from the multi-agency project team and NIOSH survey experts, subject-matter experts from the International Association of Fire Chiefs (IAFC), the International Association of Fire Fighters (IAFF), and NVFC provided comments on the content of the questionnaire during the development phase of the survey. Letters of support for the current project were

received from IAFC, IAFF, NFPA, NVFC, as well as CPSC. During the project described in this proposal, it is expected that NIOSH staff will continue to maintain close contact with these same organizations. We will actively seek out assistance from these organizations in interpreting results as well as assistance in disseminating results throughout the fire fighting community to increase awareness of the need to implement prevention efforts to better protect fire fighter safety and health.

Other audiences for this study are researchers working in fire fighter safety and health and safety personnel specifically concerned about fire fighter safety. This study will also likely inform other standard and technology organizations like the National Institute of Standards and Technology.

Study Timeline

The following table provides the proposed project timeline. While funding is only expected through fiscal year 2021, the timeline includes wrap up activities that will occur in fiscal year 2022.

Fiscal Year	Primary Tasks	Specific Activities
2018	**Study Approvals & Data Collection**	• Receive NIOSH Institutional Review Board (IRB) approval[1] • Receive Office of Management and Budget (OMB) approval[1] • Enter telephone interview questionnaire into the computer assisted telephone interviewing system • Conduct interviewer training • Initiate data collection[2] • Perform periodic quality assurance reviews of incoming data
2019	**Data Collection**	• Continue data collection • Perform periodic quality assurance reviews of incoming data • Complete annual IRB renewal
2020	**Data Collection**	• Continue data collection • Perform periodic quality assurance reviews of incoming data • Complete annual IRB renewal
2021	**Data Collection & Initial Data Analysis**	• Continue data collection (expected through 1st quarter of FY 2022 to complete four full years of data collection) • Perform periodic quality assurance reviews of incoming data • Let contract to reweight preliminary interview data • Develop analysis plan and conduct preliminary analysis • Draft outline for peer reviewed manuscript • Complete annual IRB renewal • Complete OMB renewal if required
2022	**Final Data Analysis & Report Writing**	• Complete data collection • Perform final quality assurance reviews and create final data set • Conduct final analysis • Prepare draft manuscript detailing occupational injuries to fire fighters for submission to peer-reviewed journal[3] • Develop non-per reviewed documents (e.g., trade journal article, fact sheet)

[1]Assumes that both IRB and OMB packages are completed and submitted sometime during the 4th quarter of FY 2017.
[2]Timing of IRB and OMB approval and funding availability will determine the ability to initiate data collection during the 2nd quarter of FY 2018.
[3]Publication of peer-reviewed manuscript will be dependent upon the length of time it takes to finalize the data set and conduct the final analyses.

Expedited Protocol Review

This research will result in a summary of injuries and exposures involving fire fighters. This summary will be based on aggregate data output collected during telephone interviews. Potential respondents for these interviews will be fire fighters identified from the NEISS-Work data. Reasonable and appropriate protections will be implemented for data storage and data analysis so that risks related to confidentiality will be no more than minimal. No identifiers or individual results will be incorporated in the products produced for dissemination. Hence, the risk to human subjects is minimal.

STUDY POPULATION

Description and Source of Study Population

Potential respondents will be fire fighters identified from the routinely collected NEISS-Work surveillance case data on an ongoing basis over the four year study period. NEISS-Work includes civilian, non-institutionalized workers treated in a hospital ED for an apparent occupational injury, illness, or exposure.

Case Definitions/Inclusion Criteria/Justification of Exclusion of Sub-segment of Population

Selection of cases for this study will be restricted to injured or exposed fire fighters who are 18 years of age or older. Due to the added complication of obtaining parental or guardian consent, interviews will not be completed with those younger than 18. Less than 1% of the fire fighter workforce from NEISS-Work fall below this threshold. Given that almost 70% of the fire fighters in the U.S. are volunteer, this study will seek to include both paid (or career) and volunteer fire fighters. Since there are no formal plans to translate the questionnaire into a language other than English, non-English speaking fire fighters will be excluded from the study population if they are reached and unable to communicate with the interviewer. Prescreening using the basic NEISS-Work data elements will be used to restrict the potential respondents to those individuals most likely to meet the respondent definition.

Estimated Number of Participants

Based on a detailed review of 12 years of NEISS-Work data, we estimate that we will be able to successfully identify an annual average of 600 unweighted fire fighters 18 years of age or older from the NEISS-Work data. The response rate for a similar follow-back study on emergency medical services (EMS) workers was between 30 and 40%. Therefore, it is estimated that we will complete approximately 240 telephone interviews per year. It is estimated that four years of data collection will be needed to produce large enough numbers to allow detailed reporting of results.

Sampling

Fire fighters participating in the interviews will be identified from NEISS-Work. NIOSH and CPSC collaborate to collect NEISS-Work data through an existing national stratified probability sample of approximately 67 U.S. hospital EDs. NEISS-Work data are captured via review of medical records for all ED-treated patients at each sample hospital. Records are abstracted for patients with work-related injuries, illnesses, and exposures. NEISS-Work data will be used by CPSC and DSR in a joint effort to identify all fire fighters treated in the sampled hospitals during the four year study (2018 through 2021).

The preferred analysis plan for the follow-back telephone interview data is to weight the data and report national estimates. However, a large number of completed interviews and aggregation of response categories are required to provide reliable results that meet general national estimate reporting

requirements. A case series study will be considered if the number of completed telephone interviews is not large enough to permit estimates that meet reporting requirements. There is not a specific number of interviews or completion rate that is required to produce a reasonable study. However, the larger the number of interviews and the greater the overall response rate, the greater chance of being able to produce reliable estimates.

Enrollment

Once injured/exposed fire fighters are identified from NEISS-Work, CPSC will contact participating hospitals and request patient contact information. Potential respondents with viable contact information will be sent a pre-interview letter notifying them of the study and giving them an opportunity to opt out of the study by calling a toll-free number within 10 days of receiving the letter (Appendix A). The letter describes the study and measures that will be taken to protect their confidentiality should they choose to participate in the study. The letter will also contain all of the elements required in an informed consent although we are requesting a waiver of written informed consent. Attempting to collect written informed consent would likely be detrimental to the response rate of the study and would also increase the study cost and the time lapse between treatment and interview date. Persons who do not opt out per the instructions in the letter will have their names included in a list of potential participants to call. CPSC will send this list to the third-party contractor who will conduct the interviews. Contact information will be provided to the contractor approximately three weeks after the date of treatment. NIOSH will not receive individual identifiers or contact information for any of the potential respondents at any point during the life of the study.

Interviewers will be instructed to attempt to contact potential respondents at least ten times. Contact attempts will be made at varying, but reasonable, hours of the day and on varying days of the week. When no personal contact is made after a number of attempts, the interview will be set aside and contact attempts will be made at a later date as time permits to maximize response rate while minimizing recall bias issues. Interviewers are trained to be considerate of respondents and their families, leaving a minimal number of messages or speaking with the respondent or another individual of the residence to arrange a convenient interview time. Messages will include a toll-free response number so that the respondent may call at their convenience. When no personal contact is made, no message system is available, and there is no indicator of an incorrect number, the interviewer will typically spread their call attempts over a longer time period and will commonly make more than 10 contacts. The interviewers will make no more calls than is necessary to complete the desired interviews. Due to privacy concerns, the questionnaire will only be administered to the individual treated in the ED. Interviewers will comply with CPSC contract requirements as approved by OMB.

Upon reaching the injured/exposed fire fighter, the interviewer will read the participant a statement summarizing the elements of informed consent, including a reminder that all information the respondent shares will be protected by the Privacy Act (Appendix B). If the respondent does not opt out, the telephone script will confirm their willingness to participate by asking, “Would you please help us by answering some questions?” A positive response to this question will be deemed to serve as the respondent’s verbal consent to participate. Once a person agrees to participate and meets the inclusion criteria, the interviewer will continue with the questionnaire. If a potential participant opts out by calling in advance or at the time of initial contact by telephone, their contact information will be destroyed.

VARIABLES/INTERVENTIONS

Variables

Data collected through the interviews will include detailed information in the following topical areas: nature, causes, and contributing factors of occupational injuries and exposures to fire fighters; injury and exposure events and factors related to the events (including use of personal protective equipment); characteristics and work backgrounds of injured and exposed fire fighters; and outcomes and impacts of fire fighter injuries and exposures.

Study Instruments, Including Questionnaires, Laboratory Instruments, and Analytic Tests

The primary data collection component of this study involves fire fighter follow-back telephone interviews using the fully vetted follow-back instrument found in Appendix B. Similar mechanisms have been successfully used by NIOSH to provide detailed data on populations such as EMS workers and older workers as well as injury events such as exposure to bloodborne pathogens and workplace violence. The survey instrument that will be used to capture detailed information from injured and exposed fire fighters was developed in fiscal year (FY 2016). The survey was reviewed by the project team as well as scientific and subject matter experts for both content and structure. It was pilot tested on nine injured fire fighters. Final revisions were made based on the pilot test results.

Training for All Study Personnel

Routinely collected NEISS-Work data are gathered by trained abstractors who participate in regular refresher courses and receive materials to supplement training. As part of the larger NEISS data collection efforts, abstractor training is directly overseen by CPSC. NEISS-Work abstractors receive training on the confidential nature of the data and rules they must follow to maintain that confidentiality. In addition, all CPSC-contracted telephone interviewers must have human research protection training and adhere to CPSC-established rules to maintain data confidentiality including annual training on the protection of personal identifiable information. Additional details regarding the steps taken to insure data confidentiality during the telephone interview data collection process can be found in Appendix C.

NEISS-Work telephone interviews are administered by experienced telephone interviewers under contract to CPSC. Prior to initiating the study, NIOSH will provide the telephone interviewers with training specific to this study. This training will involve reviewing the questionnaire and clarification of any questions the interviewers have. Additionally, all CPSC-contracted telephone interviewers are trained on the confidential nature of the specific data that they will be collecting and will be required to adhere to CPSC established rules to maintain data confidentiality. The telephone interviewers will use a Computer Assisted Telephone Interviewing (CATI) system to collect and input the data. Use of this computerized method of data collection helps ensure that the correct logic and skip patterns are being followed during survey administration. The software used will also be programmed to alert interviewers of inaccurate data input.

DATA HANDLING AND ANALYSIS

Data Analysis Plan

Data analysis for this study will include quantitative and qualitative data analysis. Quantitative analysis will involve computing weighted results to describe nonfatal injuries and exposures among fire fighters treated in EDs. To assess the stability of the results, coefficients of variation and confidence intervals will be calculated. Quantitative results will be presented in frequency tables for important outcomes such as demographics, diagnoses, affected body parts, events, outcomes, and training.

Qualitative data analysis will involve identifying themes within the data based on the narrative information collected during the interviews. National estimates will be calculated where feasible. However, if it is not possible to calculate national estimates, qualitative results will be reported using non-numerical quantifiers such as typically used in qualitative research (e.g., many, most, some, few).

The weighting process will involve calculation of a patient base weight, nonresponse adjustment to account for patient interview nonresponse, and post stratification to NEISS-Work frame totals. It is important that weights be used in the analysis of the data to account for variations in selection probability. Weights are critical for producing national estimates and for reducing biases due to nonresponse and undercoverage.

Standard errors for weighted estimates will be calculated using Taylor series linearization in SAS. With Taylor series linearization, the hospital stratum, PSU, and final patient weight are specified to the software. A two-stage stratified "with replacement" design can be assumed for variance estimation, with hospitals sampled at the first stage and ED patients within hospitals at the second stage. Variances will correctly reflect the stratification, unequal probabilities of selection, and clustering in the sample design.

Data Collection

The follow-back questionnaire (Appendix B) that will be used was developed by the study team and pilot tested on nine fire fighters. The NIOSH study team also developed fire fighter case criteria to identify fire fighter injuries and exposures from the routinely collected NEISS-Work data. To select fire fighter cases, CPSC will complete an automated keyword search for indicators of fire fighters by using customized SAS programs. Fire fighter cases identified will be provided to the CPSC contracted telephone interviewers. Data from the interviews will be captured in the CATI system.

Information Management and Analysis Software

The CATI software used by CPSC is The Survey System. This system will be used for designing the electronic data collection screens, including automated skip patterns, and collection of the data itself. Data collected through the CATI software will be exported to SAS for data analysis purposes.

Data Entry, Editing and Management, Including Handling of Data Collection Forms, Different Versions of Data Storage and Dispositions

CPSC will upload contact information for potential respondents to a secured file transfer location. The contract interviewer will download the contact information to a CPSC encrypted laptop. Once the telephone interview data are collected using The Survey System, electronic files will be uploaded to a secured file transfer location for CPSC. CPSC will remove all patient contact information and subsequently transfer the data to NIOSH via a secured electronic file transfer. All transfers will be done on a schedule to be determined at a later date. Once received by NIOSH, the data will be stored in secured network directories that will only be accessible through password-protected computers. The interview data will be maintained as a restricted data set in compliance with the CDC, NIOSH, and DSR sensitive data handling policies. Because of the inherent cost of these data and their intrinsic value to researchers, upon completion of the intended research, IST will maintain the data as "active" files for up to five years. Subsequently, the data will be maintained as archived protected data files for up to 15 years. Final disposition will be handled in accordance with federal recordkeeping requirements.

Quality Control Assurance

There will be three aspects to monitoring and ensuring the quality of the telephone interview data. The first involves The Survey System software that will be used for data entry. The electronic collection tool developed in the software will only allow acceptable response parameters and will include automated skip patterns. The second will be to confirm that all fire fighters captured in NEISS-Work who meet the study criteria described on page 9 are offered the opportunity to participate in the survey. This will be assessed by systematically monitoring incoming NEISS-Work cases. The third aspect is performing quality assurance checks on the data. An automated program will be designed to conduct standardized checks for inconsistencies in the quantitative data. Routine data checks will also be performed for individual case records to confirm the qualitative data.

Bias in Data Collection

It is acknowledged that this study population contains only injuries and exposures treated in EDs. Thus, the population survey is not equally representative of all occupational injuries requiring medical treatment. This population bias will be acknowledged in all publications and presentations.

The national estimates produced by this study have the potential to be biased for occupations or industries that are not geographically distributed throughout the U.S. due to the small sample size and the hospital selection method. However, because the distribution of fire fighters generally follows the same population trends as used for the sample design, no a priori biases because of the hospital sample are expected for fire fighter injury estimates for larger areas that are more likely to have paid fire fighters. Conversely, for smaller areas more likely to have volunteer fire fighters, the medical record for these workers may not reflect their volunteer work that produced the injury or exposure as their usual occupation or industry may be identified.

There is a possibility that national estimates could be overrepresentative or underrepresentative of fire fighter injuries and exposures due to the nature of their work. Fire fighters may be present in EDs when they are involved in patient transports. Thus, it follows that the ED would be a convenient place for fire fighters to seek treatment for injuries and exposures that would commonly be seen in other medical venues. This would result in a larger proportion of ED-treated fire fighters compared to some other occupations. Conversely, fire fighters could easily be underrepresented as they may receive treatment in the field by their fire fighter or EMS colleagues. As the extent of these biases is unknown, there are no methods for adjusting for them. Thus, it will be necessary to describe these possible biases in general terms when reporting results.

There is potential that study results may be affected by a social desirability bias leading to participants responding to questions in a way that they perceive will be viewed favorably by others. This bias will be minimized by not asking the respondent for the name of their employer or other obvious identifying information and reassuring them of the confidential nature of their responses.

Recall bias will potentially affect the study results as the data are being collected retrospectively. However, much effort will be put into minimizing this bias by interviewing the fire fighters soon after the ED treatment for their injury or exposure. It is expected that the length of elapsed time between the time of treatment and interview will average approximately 45 days.

Intermediate Reviews and Analysis

NIOSH will be responsible for tracking all data and conducting regular quality assurance checks.

Limitations of the Study

Coverage of NEISS-Work and of this study is limited to persons treated in EDs for injuries and exposures. Thus, the resulting data will not describe all of the injuries and exposures occurring to fire fighters. However, at the present time, this surveillance system offers the best potential for capturing details regarding fire fighter injuries and exposures from a national perspective and from a source that is inclusive of both career and volunteer fire fighters. All products from this project will explicitly acknowledge that the scope is limited to ED-treated injuries and exposures.

Additional limitations are related to the potential of lower than expected case counts. This may be due to a low telephone interview response rate and/or lack of anticipated funding. In both cases, it is likely that there would be insufficient cases collected to report data or calculate national estimates. Should either situations occur, NIOSH will consider the possibility of presenting the results in a case series format.

HUMAN SUBJECTS CONSIDERATIONS

Participants

This is a descriptive analysis of data collected following the injury or exposure and treatment of fire fighters. Potential participants for this study are described in detail in sections above titled ‘Description and Source of Study Population’ and ‘Case Definitions/Inclusion Criteria/Justification of Exclusion of Sub-Segment of Population’ on page 9.

Potential Risks

While we do not anticipate any potential risks from any part of this study, the largest potential for risk would be related to a breach in confidentiality from either NIOSH or project staff or the CPSC contracted telephone interviewers. We have conducted at least seven similar NEISS-Work follow-back studies, none of which resulted in adverse effects on respondents from an accidental disclosure of confidential information. Use of this trusted methodology, combined with the implementation of multiple safeguards described within this protocol, indicate that a breach of confidential information is very unlikely to occur at any point in this study.

Identifying, Managing, and Reporting Potential Risks

The NIOSH project staff will notify CDC and CPSC immediately upon: (1) discovering any breach or suspected breach of security; (2) discovering any unauthorized disclosure of the confidential information; or (3) receipt of any legal, investigatory, or other demand for access to the confidential information in any form. Should any of these issues occur, project progress will be halted until approval is received from CDC and CPSC to resume project activities. In addition, the IRB will be informally notified within two working days of an incident and formally notified within two weeks of an incident. Proven violation of release of confidential information related to or obtained from the data is cause for immediate termination of data access.

Protection against Risks

We have many safeguards in place to minimize the risk of a breach of confidential information. Based on past successful NEISS-Work follow-back studies, NIOSH and CPSC will identify potential cases for interview, CPSC will contact hospitals to obtain patient contact information, and contact information will be provided by CPSC to their contract telephone interviewers. Upon completion of the interview study, all contact information will be destroyed. Data transfers between CPSC and CPSC contract interviewers and between CPSC and NIOSH will occur using a secured data file transfer location. CPSC

will remove all patient contact information from the data received by NIOSH. While NIOSH will not collect personally identifiable information in the interview, information collected in the routine NIESS-Work surveillance data and the interviews has potential for indirect identification of individuals. Interview data received by NIOSH will be stored in a secure network directory only accessible through password-protected computers. Interview data will be maintained as a restricted data set in compliance with the CDC, NIOSH, and DSR sensitive data handling policies. Data will only be handled by those authorized to view the data and will be protected to prohibit overt and inadvertent release of individual patient or hospital information. Manuscripts or other releases will undergo confidentiality reviews prior to release to unauthorized individuals (internal or external to NIOSH). NIOSH and CPSC have long and established histories of human subject protection. CPSC protections and the NIOSH DSR data confidentiality requirements and procedures in conjunction with applicable federal laws will ensure strong protection against the risks noted above.

Risks/Benefit Ratio

As noted above, the largest potential for risk would be related to a breach in confidentiality from either NIOSH project staff or the CPSC contracted telephone interviewers. Reasonable and appropriate protections as described in this protocol will be implemented for data storage and data analysis so that risks related to confidentiality will be no more than minimal. Furthermore, identifiers and individual results will not be incorporated in the products produced for dissemination. Hence, the risk to human subjects is minimal. There is no direct benefit for participating in this study. However, the knowledge gained from the data collected from the study participants will be invaluable in improving the health and safety of this workforce. Thus, on the basis of regulation 21 CFR 56.111(a)(2) & 45 CFR 46.111(a)(2), the "risks to subjects are reasonable in relation to anticipated benefits….and the importance of the knowledge that may reasonably be expected to result."

Informed Consent

We are requesting a waiver of the need for signed informed consent on the basis of regulation 45 CFR 46.11(c)(2) that states "(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." The research could not be easily carried out with the requirement of a written consent as this would require additional work and follow-through on the part of the respondent because there will be no in-person contact during the study.

Participation in this study has no more than minimal risk to participants as extensive precautions are taken to protect the confidentiality of the participants. The largest risk is an inadvertent release of the data that could lead to a loss of privacy and, consequently, lead to mental stress of the respondent. However, given this has never occurred during multiple follow-back studies that we have conducted using the same methodology, we anticipate that it is very unlikely to occur at any point during this study. Additionally, we will implement many safeguards, as described in this protocol, to prevent such an occurrence.

A waiver of signed informed consent will not adversely affect the rights and welfare of the participants, as they will still receive all required elements of informed consent in print and verbally at the time of interview. Upon being selected for the study, CPSC will mail each potential respondent a letter that contains the required elements of informed consent (Appendix A). The letter will further provide the potential participant instructions on opting out of the telephone interview study by calling a toll-free

number. At the time of the interview, a verbal informed consent will be read to participants. Participants will be told that they should have received a letter explaining the research study and how their privacy will be protected (Appendix B). They will then be informed that there are four key elements of informed consent that must be reviewed with them. During the opening script of the interview, potential respondents will be informed of their rights and any possible effects of the study on their welfare. The telephone script then confirms their willingness to participate by asking, "Would you please help us by answering some questions?" A positive response to this question will be deemed the subject's verbal consent to participate. Both the letter and verbal consent script emphasize that it is the choice of the potential participant to participate.

There will be no additional pertinent information to provide to participants when their role in the study is over. Data will not be shared with persons outside of the CPSC and NIOSH study team. The procedures involved in data collection for this study (telephone interviews) would not normally require written consent outside of the research context. Currently, the OMB-approved interview studies conducted by CPSC on a regular basis do not require written consent.

The readability of the letter being mailed to potential participants is at the 9th grade level on the Flesch-Kincaid scale. For potential participants who have difficulty reading this letter, the elements of informed consent will be reemphasized prior to beginning the interview.

Records Management

This project is expected to generate data. As required, there will be several provisions in place to manage and protect the data collected and obtained through this project. First, NEISS-Work data are protected under the Consumer Product Safety Act and the Privacy Act and are not customarily released to the public, to other government agencies, to non-NIOSH researchers, or to unauthorized NIOSH staff because of potential indirect identification of injured/exposed workers. To become an authorized NEISS-Work data user, interested individuals must follow certain steps. Data users must have a demonstrated need for NEISS-Work data access, receive appropriate supervisory approvals, sign a data use agreement, participate in annual confidentiality training, and submit all NEISS-Work draft publications and presentations to the NEISS-Work project officer for a confidentiality review prior to product release. Security and confidentiality of the NEISS-Work data are also protected by multi-layered CDC firewall and server protections with user authentication.

Data collected via telephone interviews will be protected throughout the life of the project. NIOSH and CPSC will identify potential cases for interview, CPSC will contact hospitals to attain patient contact information, and contact information will be provided by CPSC to their contract telephone interviewers. Data transfers between CPSC and CPSC telephone interview contractors and between CPSC and NIOSH will occur using secure file transfer protocol locations. Once received by NIOSH, data will be stored in restricted-access directories that will only be accessible using password-protected computers. The interview survey data will be maintained as a restricted access data set in compliance with the CDC, NIOSH, DSR sensitive data handling policies and in accordance with federal recordkeeping requirements. The interview contact information, maintained by CPSC and never shared with NIOSH, will be destroyed at the completion of the interview study. Once all products are completed, all resulting datasets will be archived for potential future use. As required, a data management plan will be developed.

Due to the highly confidential nature of the telephone interview data and the need to maintain the data under the control of NIOSH, the interview dataset will only be shared with restrictions through a special-use agreement. Should the telephone interview dataset be of interest to an individual external to NIOSH, a data sharing agreement specific to the dataset and the proposed use will be developed. The agreement would address all specifications as listed in the CDC/ATSDR Policy on Releasing and Sharing Data in the sub-section titled "Data shared with restrictions" as well as any additional specifications prescribed by DSR confidentiality requirements. Data shared with an individual external to NIOSH will be de-identified to the extent possible to further insure confidentiality protections.

DISSEMINATION, NOTIFICATION, AND REPORTING OF RESULTS

Notifying Participants of Their Individual Results

Since the data are collected from information reported by participants, participants are aware of the content of their individual data. Thus, there is no need to provide individual data reports.

Notifying Participants of Study Findings

Project products will be disseminated to the USFA, the NFPA, other fire fighter organizations, researchers interested in fire fighter injury and exposure research, and health and safety personnel whose domain includes fire fighters. Methods of dissemination may include a peer-reviewed publication, a trade journal article, and/or fact sheets. While the participants will not be contacted individually, if they have continued to be active in the fire fighter community since their injury or exposure, they will likely have access to the products produced as a result of this project.

Anticipated Products or Interventions Resulting from the Study and Their Use/Disseminating Results to Public

It is anticipated that project results will be disseminated through the use of a peer-reviewed publication, a trade journal article, and/or fact sheets. These products will describe injuries and exposures to the fire fighters and suggest areas in need of further research and/or prevention activities.

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