Memorandum

Date: February 20, 2004

From: Susan B. Board, Program Official
Office of Extramural Programs, NIOSH, E-74

Subject: Final Report Submitted for Entry into NTIS for Grant 5R01OH003943-03.

To: William D. Bennett
Data Systems Team, Information Resources Branch, EID, NIOSH, P03/C18

The attached final report has been received from the principal investigator on the subject NIOSH grant. If this document is forwarded to the National Technical Information Service, please let us know when a document number is known so that we can inform anyone who inquires about this final report.

Any publications that are included with this report are highlighted on the list below.

Attachment
cc: Sherri Diana, EID, P03/C13

List of Publications

Todd A, Larson C, Brown, M. Professional Update: Occupational Health: Tracking serious injury: Surveillance of work-related trauma. Minnesota Physician; 2001;XV(5): 36, 38.

Title: Niosh Surveillance Research Methodology
Investigator: David L. Parker
Affiliation: International Species Inventory System (isis)
City & State: Minneapolis, MN
Telephone: (612) 676-5220
Award Number: R01OH3943
Start & End Date: 9/30/1999-9/29/2003
Total Project Cost: 443112
Program Area:
Key Words: injuries, surveillance

Final Report Abstract:

Occupational injury is a major public health problem resulting in significant morbidity and mortality and a heavy economic burden. The goal of this grant was to address serious non-fatal work-related trauma by developing a surveillance system, which might provide ongoing information of adequate quality and completeness to provide a basis for preventive efforts.

Objectives

The original objectives or aims of the Surveillance of Serious Work -Related Trauma grant were to:

I. Develop, test, and refine a definition for serious work-related trauma;

2. Determine the feasibility of establishing a surveillance system for serious work-related trauma by linking existing sources of information, such as workers' compensation data, the existing Minnesota Department of Health (MDH) Trauma Registry, and hospital discharge records;

3. Determine reporting biases found in data compiled from different reporting sources; and

4. Determine the magnitude, distribution, etiology, and outcome of serious work-related trauma.

Aims 2,3,4 were revised and submitted to NIOSH on June 21,2002 after the CDC Site Visit on June 18-19,2002.

Methods

The Advisory Work Group reviewed a variety of methods for developing an operational definition of "Serious Work-Related Injury" and also a sampling frame of hospital and trauma centers throughout Minnesota for a population-based study of serious injury .However, the final source of cases was 20 hospitals and medical centers that yielded more than 80 % of cases meeting study criteria during a previous calendar year . The final case definition included Minnesota residents age ? 14 to ~ 65 years who were admitted for a non-fatal serious injury from January 1 through December 31, 2000 who had: a length of stay in the hospital or trauma center ? I day or a UB-92 code identifying anesthesia (for outpatients); no V code as a primary diagnosis; and specific ICD-9 Codes and lCD-9 E Codes for inclusion criteria. The Association of Vital Records and Health Statistics (A VRHS) definition of work-relatedness was used.

Hospital and trauma center staff of participating institutions identified subjects meeting study eligibility criteria and transferred two separate datasets of eligible cases to the MDH, one from the hospital administrative database and the other from the trauma

center registry .Then a random sample of subjects from the hospital database was drawn, and subjects were contacted to determine if the injuries were work-related. Cases with work-related injuries were interviewed by telephone to determine the type of work, nature of injuries and injury event and any change in work and daily living due to the injury .Trauma center data were collected for use as a comparison dataset to assess whether data collection from trauma centers alone could provide a representative sample of serious work-related trauma in Minnesota.. The study required IRB approval from all separate institutions participating in this effort, often with variations in the protocol for data collection and contact of study subjects.

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Todd A, Larson C, Brown, M. Professional Update: Occupational Health: Tracking serious injury: Surveillance of work-related trauma. Minnesota Physician; 2001;XV(5): 36, 38.

Surveillance of Serious Work-Related Trauma

Final Progress Report
FY 1999-2000 through FY 2002-2003
September 29, 2003
RO1 OH03943

RFA OH-99-002
NORA Priority Area:
Surveillance Research Methodology

Technical Report
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Final Progress Report
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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
HCMC	Hennepin County Medical Center
IRB	Institutional Review Board
MDH	Minnesota Department of Health
NIOSH	National Institute for Occupational Safety and Health

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ABSTRACT

Importance

Occupational injury is a major public health problem resulting in significant morbidity and mortality and a heavy economic burden. The goal of this grant was to address serious non-fatal work-related trauma by developing a surveillance system, which might provide ongoing information of adequate quality and completeness to provide a basis for preventive efforts.

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The original objectives or aims of the Surveillance of Serious Work-Related Trauma grant were to:

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3. Determine reporting biases found in data compiled from different reporting sources; and
4. Determine the magnitude, distribution, etiology, and outcome of serious work-related trauma.

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Methods

The Advisory Work Group reviewed a variety of methods for developing an operational definition of "Serious Work-Related Injury" and also a sampling frame of hospital and trauma centers throughout Minnesota for a population-based study of serious injury. However, the final source of cases was 20 hospitals and medical centers that yielded more than 80 % of cases meeting study criteria during a previous calendar year. The final case definition included Minnesota residents age $\geq$ 14 to $\leq$ 65 years who were admitted for a non-fatal serious injury from January 1 through December 31, 2000 who had: a length of stay in the hospital or trauma center $\geq$ 1 day or a UB-92 code identifying anesthesia (for outpatients); no V code as a primary diagnosis; and specific ICD-9 Codes and ICD-9 E Codes for inclusion criteria. The Association of Vital Records and Health Statistics (AVRHS) definition of work-relatedness was used.

Hospital and trauma center staff of participating institutions identified subjects meeting study eligibility criteria and transferred two separate datasets of eligible cases to the MDH, one from the hospital administrative database and the other from the trauma center registry. Then a random sample of subjects from the hospital database was drawn, and subjects were contacted to determine if the injuries were work-related. Cases with work-related injuries were interviewed by telephone to determine the type of work, nature of injuries and injury event and any change in work and daily living due to the injury. Trauma center data were collected for use as a comparison dataset to assess whether data collection from trauma centers alone could provide a representative sample of serious work-related trauma in Minnesota. The study required IRB approval from all separate institutions participating in this effort, often with variations in the protocol for data collection and contact of study subjects.

Results

Conduct of this study was hindered, redirected and completely stopped by a series of events. By December of the study's final year, the Co-Principal Investigator had assumed other responsibilities within the MDH, and the Principal Investigator had absented himself from the study, ultimately resigning from the MDH. NIOSH directed the MDH to stop all study activities in February of the final year, and total study cessation occurred in May at the most critical time of data collection. A CDC Site Visit occurred in June, and approval for both study continuation and the new Principal Investigator did not occur until late August. Without IRB approval, the study could not start again until September. Although a one-year no-cost extension was obtained, no additional funding was secured and key analytic staff reduced effort in the winter and left in the spring.

At the time of study cessation, participating institutions had reported 12,501 inpatient, 3,015 outpatient, and 3,889 trauma center cases meeting the study criteria. Of these cases, a random sample of 7,498 was drawn to contact for determining if injuries were work-related. Although a total of 231 interviews had been completed, the 1682 study subjects remaining could not be contacted according to IRB stipulations, therefore, interviewers were dismissed. When the study restarted four months later all outstanding data were entered and cleaned. Available interview data were double coded and entered.

Due to the incomplete set of interviews designed to address the nature and outcomes of serious work-related trauma, and the loss of key personnel to complete the analysis of existing questionnaire data, hospital and trauma center data, and other study data, the results focus on basic distributions and issues speaking to the adequacy of the proposed methods and suggestions for future studies of serious work-related injury.

Hospital and trauma center cases known to have work-related trauma from interview data, were screened for possible data elements consistently identifying those with serious work-related trauma. Although this effort did not produce algorithms for identifying work injuries without labor intensive interviewing, information on payer (e.g. Workers' Compensation) in hospital databases, work for income in trauma registry databases, and specific E Codes relating to workplace occurrence of injury in both hospital and trauma center data appeared useful. In addition, combining information on cases appearing in both the hospital and trauma center databases of the same institution added further information. These sources produced work-related estimates of 6.8% for the hospital database and 9.0% for the trauma center of one major medical center.

Conclusions

In spite of the disappointment of not being able to take full advantage of the incredible amount of work represented by this effort, methodologic information of use for future research was obtained. The case definition of work-related injury or some variation would seem useful for future efforts. Obtaining outpatient data was too labor intensive for a surveillance system. Also, the demands of separate IRBs from several medical centers were time consuming and unduly complex due to institutional variations in the protocol for contacting study subjects. Based on our experience, a validation study is being discussed with the MDH's Trauma Data Bank, which has ongoing access to data from all trauma centers in Minnesota. The effort would assess the accuracy of using existing data elements such as E codes, "work for income", and Workers' Compensation and other payer information to identify work-related serious trauma.

SIGNIFICANT FINDINGS

Accomplishment of Specific Aims & Revised Specific Aims

Based on knowledge gained from the Serious Work-Related Trauma study and input from the CDC/NIOSH Site Visit team (June 18, 19, 2002) some aims were revised.

Specific Aim 1: To develop, test, and refine a definition for serious work-related trauma.

The development of an operational definition of serious work-related trauma involved extensive discussions and refinements. The eligibility requirement age ≥12 to ≤ 85 years provided the opportunity to assess older and younger workers. However, the case definition actually used was non-fatal injuries for subjects ≥ 14 to ≤ 65 which provided access to the working population of most interest. The inclusion criteria were specific ICD-9 Codes (such as codes for fractures and crushing injuries) and ICD-9 E Codes (such as codes for vehicular accidents and falls) in any of the ICD-9 fields. No V Codes as a primary diagnosis were used. (V Codes are supplementary codes for conditions identified by screening or other contacts with a health care system.) Length of stay (LOS) of one day or more worked well. UB-92 billing data, used to identify outpatients, proved more difficult to obtain from institutions because it is a data source separate from hospital and trauma center databases (see Specific Aim 2 below). Work-relatedness was determined by guidelines developed jointly by the Association of Vital Records and Health Statistics, the National Institute for Occupational Safety and Health, the National Center for Health Statistics, and the National Center for Environmental Health and Injury Control (AVRHS, NIOSH, NCHS, and NCEHIC). At the time of study cessation, 12,501 hospital inpatients, 3015 outpatients, and Trauma Center Data for 3889 cases had been reported to MDH.

Specific Aim 2: To determine the feasibility of establishing a surveillance system for serious work-related trauma by linking existing sources of information, such as Workers' Compensation data, the existing Minnesota Department of Health (MDH) Trauma Registry, and hospital discharge records.

Specific Aim 2 has been modified throughout the project as more information became available about the various data sources proposed in the original grant. The Minnesota Trauma Data Bank at the beginning of grant activities did not include all trauma centers in Minnesota. Also, there was concern that some patients meeting study criteria in the primary medical record database of hospitals (administrative data) might be missed in the trauma center databases (trauma registries). It was decided by the Advisory Group to collect data directly from hospital databases and trauma center databases for institutions with both (and initially from UB-92 billing databases for collection of outpatient data). Workers' Compensation claims (First Reports of Injury, and particularly Physician Reports dealing with the final injury assessment) were not considered for a primary data source. They were considered for comparison purposes only. Workers' Compensation data do not include information on the self-employed, and claims are subject to substantial time delays.

Due to the decision to collect data directly from each hospital and trauma center, IRB approval was needed. This required developing an extensive and detailed IRB packet, completing specific institutional applications and guidelines, meeting with the separate IRBs, and periodically updating each IRB on study progress. This process provided access to the necessary data for surveillance, but raises questions about meeting the CDC's requirement of simplicity in terms of an ongoing surveillance system.

Specific Aim 3: To determine the reporting biases found in data compiled from different reporting sources.

Changing the primary data source to hospital administrative data emphasized the differences between hospital and trauma center data. These differences have been known and reported in the literature, and perhaps can be complimentary in providing additional information on work-related serious trauma. In trauma center and hospital data analyzed for this study, there was substantial overlap in the data sets, with cases appearing in both data sets, but with substantial proportions of cases appearing in only the hospital or the trauma center database. Combining administrative data from the hospital database with additional information in the trauma center registry for the same case appeared useful in identifying more possible cases of work-related serious trauma.

Specific Aim 4: To determine the magnitude, distribution, etiology, and outcome of serious work-related trauma.

As the methodology of this study evolved, it became apparent that the grand scope of this aim was not appropriate. In spite of exploring different approaches with different data sources, a true population-based system was not feasible at the time. In order to determine the magnitude of serious work-related trauma, it is necessary to obtain both measures of incidence and the proportion of the working population affected. Although determining incidence was not possible, the system developed did include the hospitals and trauma centers that treat the majority of serious trauma within the state. As such, this system was adequate to address the spectrum of serious trauma, including work-related trauma, although the system was not as representative as one might hope. If full data collection had occurred, the system should have been adequate to provide good descriptive data for serious work-related trauma and to better address possible risk factors. The study did not develop the methodology that was consistent with an etiologic study, controlling, for example, for personal variables such as training and number of hours worked. Instead, the study was a surveillance effort for work-related trauma that might have been useful for generating hypotheses about etiology of some serious work-related injuries that could have led to etiologic studies. Outcome issues were addressed only briefly in the study questionnaire and not in a manner that yields much insight into the issues addressed. Also, with nearly 1700 study subjects to be contacted at the study's cessation, the sample of questionnaires obtained is inadequate for more than hypothesis generation.

USEFULNESS OF FINDINGS

Due to the unusual circumstances facing the Surveillance of Serious Work-Related Trauma study, the usefulness of the findings center around a number of methodological issues addressed by this effort. The sample of 20 hospitals and medical centers with trauma centers that agreed to participate in this study treat the majority of serious trauma in Minnesota (based on study criteria). So, potentially the serious injuries detected by this system, although not truly population-based, should be representative of the range of serious trauma, including serious work-related trauma. However, the IRB requirements necessary for the participation of individual institutions at this time, are probably too labor intensive for an ongoing surveillance system. Also, the difficulty of obtaining separate UB-92 billing data for outpatients and amount of time for contacting outpatients to ascertain whether injuries were work-related would be too complex for an ongoing system.

Trauma registries focus on the nature, care, and outcome of trauma, and based on our experience, often have more information for identifying injury that is work-related. However, at least in one major medical center, we found that additional information on work-related injuries could be obtained for cases appearing in both hospital administrative databases and trauma registries.

In Minnesota it would seem that the best opportunity for a surveillance system addressing serious work-related injury rests with the Minnesota Trauma Data Bank that now collects data from most trauma centers in the state with arrangements for gathering further information from bordering states. The Trauma Data Bank was not adequately representative of trauma centers when this effort was first considered, but now has statutory language to collect trauma center data on an ongoing basis. Preliminary analyses with data collected for this study were not able to match individuals with data from the same time period obtained by the Trauma Data Bank. We are now discussing studies to match data with the Trauma Data Bank to determine if the same data are obtained and whether this system and its information on injuries due to work might allow access for contacting those whose serious injuries appear work-related. We want to explore if this would permit surveillance of work-related injuries or at least provide the data necessary for focused studies of work-related injuries.

SCIENTIFIC REPORT

BACKGROUND

Occupational injury is a major public health problem resulting in significant morbidity and mortality and a resulting heavy economic burden (Jenkins et al., 1993; Leigh et al., 1997). A 10-year study from 1980-89 estimated that 16 workers are killed and thousands of workers are injured during a typical workday (Jenkins et al., 1993). A study of work-related injuries and fatalities during 1992 suggested there were 6500 work-related fatalities and over 13,000,000 nonfatal injuries in that year (Leigh et al., 1997). The total direct and indirect costs for injuries during that single year were estimated to be $145 billion. A recent NIOSH study for the 16-year period from 1980 through 1995, estimated that more than 93,000 work-related fatalities occurred during this period, with 1093 fatalities in Minnesota (NIOSH, 2001). Mining, agriculture/forestry/fishing, construction, and transportation, long considered among the most dangerous industries, were the leading causes of death. Also, younger workers are at greater risk of injury, due to lack of training, experience, and skill. It is estimated that each year 77,000 teenage workers require emergency room treatment (NORA, 2003).

In 1996 NIOSH laid out a research agenda with some 500 partners in the public and private sector. This agenda, the National Occupational Research Agenda (NORA), was to provide a framework for occupational safety and health efforts. Traumatic occupational injuries were identified as a major priority area. For setting priorities the criteria were to include: problem magnitude, rate of injury, severity, likelihood of effecting prevention, efficiency of intervention, and whether or not the prevention would be adopted (NIOSH, 1998).

In setting priorities, a public health model was to be used for activities ranging from identifying and prioritizing problems, i.e., injury surveillance through analytic research which assesses risk factors, to prevention and control efforts, dissemination and evaluation of prevention efforts.

This research effort is in response to PA-99-143 for Occupational Safety and Health Research directed at developing "knowledge that can be used in preventing occupational diseases and injuries and to better understand their underlying pathophysiology". This grant focused on two of the broad NORA areas, "Disease and Injury", specifically Traumatic Injury and "Research Tools and Approaches", specifically, Surveillance Research Methods. The research aims for this study focused on issues related to the problem of serious work-related trauma.

METHODS

Overview

The initial task of this study effort was assembling an Advisory Work Group with a broad range of expertise in research and treating trauma (**Appendix A**). The Advisory Work Group focused on developing an operational definition of work-related serious trauma, and then identifying a source of cases that would include a broad spectrum of serious work-related trauma. The Minnesota Hospital and Healthcare Partnership (MHHP)—now the Minnesota Hospital Association—was selected. MHHP has hospital inpatient and outpatient claims data based on Uniform Bill, 1992 version (UB-92) for nearly all Minnesota hospitals (MHA, 2003).

Definition of serious work-related trauma, eligibility, sources of cases, and sampling procedures for selecting cases:

Source of Cases

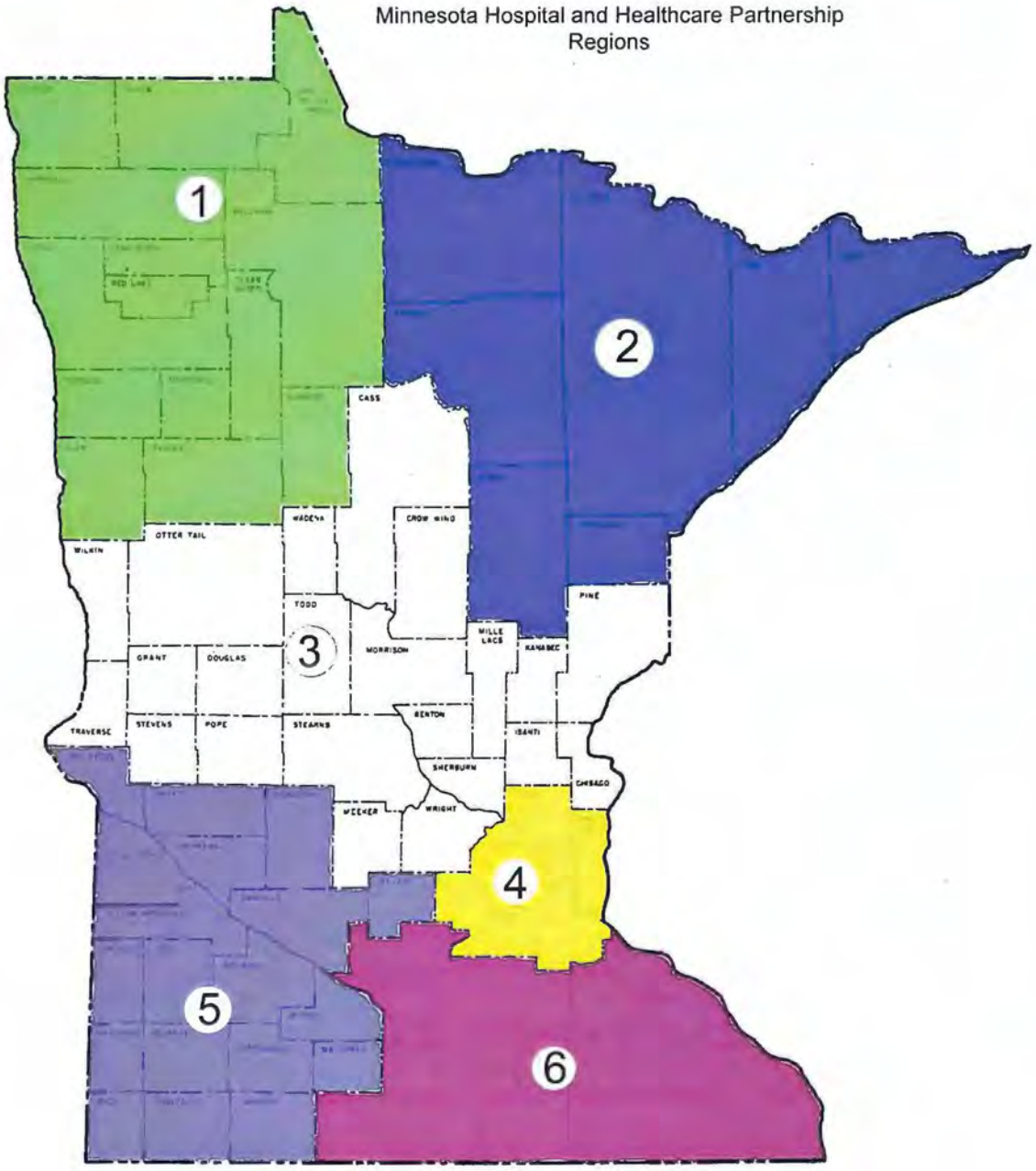
Hospitals reporting to MHHP

The sample frame for the study included all hospitals reporting to the Minnesota Hospital and Healthcare Partnership (MHHP). Hospitals included are 20 of 22 hospitals and medical centers agreeing to participate in the Study (see Table 1, Figure 1). These hospitals provided >80 % of cases meeting study criteria in 1998.

Table 1. Participating Hospitals and Medical Centers by MHHP Region

Institutions with Trauma Centers		Institutions without Trauma Centers	
Institution	Region	Institution	Region
Hennepin County Medical Center	4	Abbot-Northwestern Hospital	4
Immanuel St. Joseph's Hospital	6	Fairview	
		Fairview Ridges Hospital	4
Mayo Clinic		Fairview-University Medical Center	4
Rochester Methodist Hospital	6	Fairview Southdale Hospital	4
Saint Marys Hospital, Rochester	6		
		HealthEast	
Allina Hospitals and Clinics		HealthEast St. John's Hospital	4
Mercy Hospital	4	HealthEast St. Joseph's Hospital	4
Unity Hospital	4		
		Park Nicollet Minnesota	
North Memorial Medical Center	4	Methodist Hospital	4
Regions Hospital	4	Rice Memorial Hospital	5
St. Cloud Hospital	3	Allina Hospitals and Clinics	
		United Hospital	4
St. Luke's Hospital, Duluth	2		
		Refused	
St. Mary's Medical Center, Duluth	2	St. Joseph's Medical Center, Brainerd	3
		Ridgeview Medical Center, Waconia	4

Figure 1


Minnesota Hospital and Healthcare Partnership
Regions
1
2
3
4
5
6
CASS
WADENA
CROW WING
OTTER TAIL
WILKIN
TODD
PINE
MILLE LACS
KANABEC
MORRISON
GRANT
DOUGLAS
STEVENS
POPE
STEARNS
BENTON
ISANTI
TRAVERSE
SHERBURN
CHISAGO
MEEKER
WRIGHT

Eligibility

Minnesota residents from ≥ 12 to ≤ 85 who were Inpatients or Outpatients in the year 2000 (date of admission from January 1, 2000 through December 31, 2000) with non-fatal injuries.

Case definition

For the final case selection, eligible study subjects were ≥ 14 to ≤ 65 years of age with the following specific ICD-9 codes and ICD-9 E codes and no V code as a primary diagnosis (Table 2). Inpatients with a length of stay (LOS) ≥ 1 day and outpatients with a UB-92 Form Locator 42 Revenue Code of 370 or 379 (anesthesia, subcategories "0-General Classification" and "9-Other Anesthesia") were included. (Based on the difficulty of obtaining UB-92 data for obtaining outpatients, it was decided to include only study subjects who were inpatients [study meeting 2/14/02]).

Table 2. Inclusion and Exclusion and Criteria for Study Subjects: ICD-9 Codes and ICD-9 E Codes

ICD-9 Codes	ICD-9 E Codes
Inclusion criteria	Inclusion criteria
800-829 Fractures	E800-E848 Vehicular accidents
830-839 Dislocations	E849 Place of occurrence (home excluded)
850-859 Intracranial injury (concussion)	E860-E869 Accidental poisoning
860-869 Internal injuries (chest, abdomen)	E880-E888 Accidental falls
870-899 Open wounds of head, neck, trunk	E890-E899 Accidents caused by fire
900-904 Injury to blood vessels	E900-E903 Accidents due to heat, cold
925-929 Crushing injury	E905-E909 Accidents due to venom, storms
930-939 Effects of foreign body	E910.3 Accidents due to work in water
940-949 Burns	E912-E913 Suffocation
959-957 Injury to nerves & spinal cord	E914-E915 Foreign body in eye, orifice
959 Injury, other and unspecified	E916-E926 Other accidents
980-989 Toxic effects of substances	E928 Other and unspecified accidents
990-994 Other effects of external causes	E960-E968 Purposely inflicted injury
	E970-E976 Injury due to legal intervention
	No E Codes (field blank)
	Exclusion criteria
	E850-E858 Accidental poisoning
	E870-E879 Misadventures to patients during care
	E904 Hunger, thirst, exposure, and neglect
	E910.0-E910.2 Accidental drowning-recreational
	E910.4 Accidental drowning-bathtub
	E929 Late effects of accidental injury
	E930-E949 Adverse effects of drugs-therapeutic use
	E950-E959 Suicide and self inflicted injury
	E969 Late effects of intentional injury by others
	E977 Late effects of injuries due to legal intervention
	E978 Legal execution
	E980-E989 Injury undetermined if accidental/intentional
	E990-E999 Injury resulting from operations of war

Work-Related Definition

Operational Guidelines for Determination of Injury at Work

Table 3 presents guidelines for defining work-related injuries developed jointly by the Association of Vital Records and Health Statistics (AVRHS), the National Institute for Occupational Safety and Health (NIOSH), the National Center for Health Statistics (NCHS), and The National Center for Environmental Health and Injury Control (NCEHIC) were used to assess whether injuries were work-related.

Table 3. Operational Guidelines for Determination of Injury at Work (Reformatted from AVRHS)

Criteria	Injury at Work	
	Yes	No
On Employer Premises		
Engaged in work activity, apprentice, vocational training	X	
On break, in hallways, rest room, cafeteria, storage area	X	
In employer parking lots while working, arriving or leaving	X	
Engaged in recreational activities on employer controlled facilities (games, etc.) for personal enjoyment		X
As a visitor for non-work purposes, not on official business		X
Off Employer Premises		
Working for pay or compensation, including at home	X	
Working as a volunteer EMS, firefighter, or law enforcement	X	
Working in a family business, including family farm. Activity should be clearly related to a profit-oriented business	X	
Traveling on business, including to and from customer/business contacts	X	
Engaged in work activity where vehicle is considered the work environment (e.g., taxi driver, truck driver, etc.)	X	
Homemaker working at homemaking activities		X
Working for self—non profit, i.e., mowing lawn, repairing own roof, hobby, or recreational activities		X
Student engaged in school activities		X
Operating vehicle (personal or commercial) for non-work		X
Commuting to or from work site		X

Study Questionnaire

The study survey instrument was an interview conducted by telephone. The interview served both as a screening tool to determine if the serious traumatic injuries were work-related, and if work-related, served to collect descriptive information about the injury, workplace, consequences of the injury, as well as basic demographic and lifestyle information. For those choosing not to complete the full questionnaire, a Short Interview was used to determine if the injury occurred at work, name of company or employer, type of industry and type of job (**Appendix B**).

Initial items dealt with the type of work, place of employment, job type and duties. Study subjects were then asked to describe how the injury occurred, the nature of the injury, part(s) of body injured, source of the injury, and environmental conditions around the event. Additional information was obtained on place of injury and if the injury occurred during regular working hours.

The next series of items explored issues relating to return to work including possible changes in time spent at work, work responsibilities or accommodations since returning to work, and/or the effect of injury on ability to do work activities. Information on financial consequences of work-related injury, including workers' compensation, social security disability or other assistance programs was collected.

Additional items on activities of daily living, mobility, and social and emotional functioning explore other outcomes possibly due to the injury. The interview collects basic demographic information and standard information on alcohol and tobacco use. Interviews lasted approximately 20-45 minutes.

Informed Consent

Informed consent/assent (for those under 18 years of age) was obtained from all study subjects before interviews were undertaken. Before study subjects received a telephone call about the study, a letter and study packet, including a consent form had been sent to their residence, informing them of the study and of the upcoming telephone contact (see Study Procedures and Data Collection Protocol). Study subjects were required to give a verbal consent before interviews started, even if consent forms had already been signed. Parents or guardians were contacted for study subjects less than 18 years of age.

Institutional Review Board (IRB) Stipulations by Hospital

The final collection of 18 hospitals and trauma centers included in this study, were from 13 different health care systems. This necessitated working with 13 different institutional review boards with distinct requirements and requests for carrying out the study protocol in their institution or institutions. (**Appendix C**). As a result, procedures for mailing study material to possible study subjects varied from institution to institution. The introductory letter varied by institution. The consent/assent forms and procedures varied, and some other requirements were also institution-specific. All of the hospitals required annual IRB renewals that were substantially different. Some institutions required only a project summary for the previous year, while others requested a formal presentation before the IRB board. This type of labor-intensive institutional contact resulted in

continual telephone, written, email, and personal communication and record keeping for meeting individual IRB requirements.

Study Procedures and Data Collection Protocols

An overview of data collection is presented in Figure 2. Database managers at participating hospitals and trauma centers were contacted to determine the most efficient method of electronically transferring data for all injured inpatients in hospitals and trauma centers meeting eligibility criteria and the case definition who were admitted from January 1, 2000 through December 31, 2000. The preferred method of data transfer involved database managers at institutions running the study selection criteria for year 2000 and electronically transferring data for the identified study subjects to the MDH. That is, data for patients who were Minnesota residents from ≥12 to ≤ 85 years of age with specific ICD-9 codes and ICD-9 E codes were transferred to the study center at the MDH. Possible data from hospitals and trauma centers appear in Table 4.

FIGURE 2
DATA COLLECTION PROTOCOL

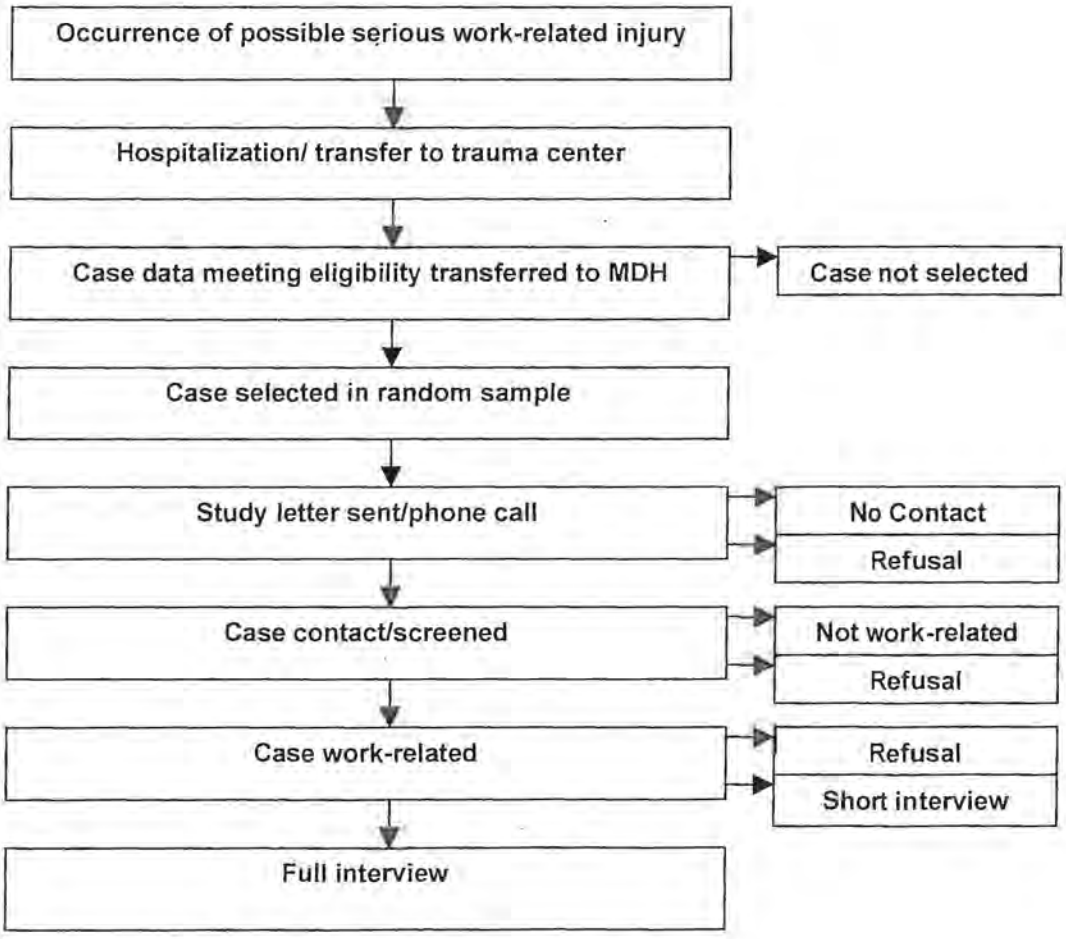


Table 4. Data Elements Obtained from Hospitals and Trauma Centers*

Category	Data Element
Administrative	
	Medical record number/chart number
	Study subject: names
	Last name
	First name
	Middle name
	Study subjects < 18 years of age
	Parent's last name
	Parent's first name
	Parent's middle name
	Address information
	House number
	Street/Avenue/direction
	City
	State
	Zip code
	Second address if applicable
	Telephone number (other phone numbers)
	Social Security Number
Demographic	
	Date of birth
	Age
	Race
	Sex
	Marital status
Injury data	
	Date of injury
	Date of admission
	Patient type (Inpatient/Outpatient)
	All ICD-9 Codes
	All E codes
	All injury severity scores
	An injury description
	Length of stay in hospital

*Not all data elements common across institutions

Selection of Cases

Each participating institution electronically transferred data to MDH for all cases meeting the eligibility criteria for serious trauma during the prescribed study period. Random samples were taken of study subjects ≥ 14 to ≤ 65 years of age from the database provided by each institution. A sample fraction of .41 was used for the random samples.

Contacting Study Subjects

Study subjects selected from the eligible cases at each institution were contacted to solicit their participation for a telephone interview to determine if the injury was work-related. Study subjects contacted were sent a packet containing an introductory letter describing the purpose of the project, consent/assent forms, a medical release form and a self-addressed stamped refusal postcard. If the MDH did not receive a refusal postcard, study subjects typically were contacted by telephone two weeks after the initial mailing to request consent for the study interview. The timing of the contact of study subjects from different institutions varied somewhat depending on institutional preferences (**Appendix D**).

Specific variations in contacting patients included mailing procedures and the language in the introductory letters and consent forms. Most institutions followed the procedure of having MDH send the patient invitation packet, followed by a 14-day waiting period before attempting contact. Two hospitals required two mailings from their institutions, and a 60-day waiting period. Six hospitals required two mailings from their institutions with a 14-day wait following the second mailing. Some study introductory letters were different, for example, being signed by both the MDH principal investigator and the corresponding hospital co-investigator. Some institutions required additional statements in the consent forms such as institutional consent/assent stipulations.

Although there was some variation in the telephone "calling protocol," due to some institutions requiring two, rather than one mailing, a standard calling protocol was followed. There were nine attempts to make contact with a study subject. The calls were made Monday through Saturday at specific times. An operational definition of a call was developed to assure consistency of reporting efforts to contact study subjects and call attempts were recorded on standard forms. A variety of contingencies for unexpected calling situations were outlined, and a standard protocol for leaving telephone messages was followed.

Study Interviews

Study interviewers were trained in basic techniques of interviewing including: establishing rapport, manner of asking questions, probing, answering typical questions (about the study, how the information will be used, how study subjects were identified), keeping subjects focused on the interview, and dealing with difficult subjects and situations. Interviewers also were trained in the background and significance of the study and individual items making up the questionnaire or study instrument (**Appendix E**).

Upon contacting possible study subjects, interviewers obtained informed consent (called the "Tennessen" warning in Minnesota) before conducting the interview. The Tennessen warning describes the purpose of the study, states that information collected is confidential, and that participation is voluntary and will in no way affect their health care, and explains that they can ask any questions during the course of their participation in the study. All study subjects were required to give verbal consent, even if their signed consent form had been received. Some participating institutions required possession of consent forms before the interview could take place.

The first item on the study questionnaire was for screening out those potential study subjects who had not been injured at work. For those who had not been injured at work, the interview was terminated at this point, and they were thanked for their time. Those eligible for the study then continued through all appropriate parts of the study instrument. Study subjects refusing to do the entire interview were asked to do a short interview consisting of five items. Study interviewers recorded answers to interviews on paper copies of the questionnaire.

Coding and Data Entry

Two independent coders, following coding manual directions, coded questionnaires. Discrepancies in coding were resolved by a consensus reaching procedure. If consensus was not possible, the Project Director assisted with the final decision. The Project Director also assisted with coding questionnaire items with apparent insufficient information.

The industry of injured workers was coded using the Alphabetic Index of Industries and Occupations and the Standard Industrial Classification (SIC) manual. Job activities were coded using the Alphabetic Index of Industries and the Standard Occupational Classification (SOC). The circumstances existing pertaining to the injury, event type, source of injury and underlying event, were coded according to the Occupational Injury and Illness Classification (OIIC) Manual.

Data from questionnaires were double entered into a FoxPro database, and any discrepancies in the dual entries were resolved. The data were then transferred to a SPSS file.

RESULTS

The progress for this study was substantially limited by the premature departure of the Principal Investigator, appointment of an interim Principal Investigator, cessation of study activities at the direction of CDC, preparation for a required CDC site visit to approve study continuation, a delayed response to site visit by CDC, inability to secure additional funding to compensate for the interruption of the study, and ultimately, the departure of key staff due to lack of continued funding. This chronology appears in Table 5 with further documentation in **Appendices F and G**.

At the time of study cessation, participating institutions had reported over 15,000 study subjects meeting the criteria for serious trauma (Table 6). These subjects included inpatients, outpatients, and patients seen in trauma centers. For institutions with trauma centers, differing proportions of patients appeared in both the administrative (hospital) databases, as well as the trauma registries. For example, in Hennepin County Medical Center (HCMC), 1914 hospitalized study subjects met the study criteria for serious trauma, while 1585 of those in the trauma registry met criteria; 1227 of these subjects appeared in both databases. However, only three institutions, HCMC, St. Luke's and St. Mary's/Duluth Clinic in Duluth had provided hospital and useful trauma center data at this point. Arrangements with Mayo Clinic for reporting data on serious trauma were in progress at the time study activities were halted, and it was not possible to obtain data from the hospitals at Mayo Clinic after study activities were restarted in September 2002.

A total of 231 interviews, including 11 short interviews, had been completed by May 10, 2002 when interviewing was stopped (Tables 6, 7). At this time there were almost 1700 possible subjects to be contacted or to have interviews completed (Table 7). Most of the nearly 4900 non-participants were study subjects with non-work-related serious trauma (thought to be from 91-97 % of serious trauma based on this study). Other reasons for non-participation included: refusals, possible subjects who could not be contacted, those now deceased, and those with languages that did not permit interviews. The sample interviews obtained were distributed across 13 of the 18 institutions reporting serious trauma. Only 6 participating institutions were represented by 20 or more interviews (Table 7).

Hospital and/or trauma center data for interviewed cases known to have work-related serious trauma, were reviewed for data elements that indicated the injuries were work injuries. There did not appear to be a consistent pattern of data elements for those known to have serious work-related trauma.

Data elements appearing in HCMC hospital and trauma center databases possibly indicating work-related serious trauma are presented in Table 8. Hospital administrative data had information on payments made by Workers' Compensation and other payers and minimal records having E Codes describing the injury work place. The HCMC Trauma Center data had E Codes describing work place where the injury occurred and an item 'Typework' which included the response 'income' that identified cases working for income at the time of the injury.

Table 5. Chronology of Serious Work-Related Trauma Study Interruptions

Date	Event
June 12, 2001	Co-Principal Investigator leaves project, assumes other responsibilities within the MHD on September 4, 2001
November 21, 2001	Dr. David Parker, the original Principal Investigator, begins absence from MDH
February 22, 2002	MDH receives letter from CDC directing suspension of study activities; MDH continues study activities, requesting clarification
March-May 2002	MDH continues to attempt dialogue with CDC
May 3, 2002	After receiving a copy of the February 22, 2002 CDC letter (above) from the original Principal Investigator, Park Nicollet Institute, the overall institutional IRB, directs the MDH to stop all study activities
May 10, 2002	All interviewing for study stops; study interviewers leave study team
May 13, 2002	Park Nicollet IRB acknowledges that data already collected can be used during the period of study cessation to prepare for the CDC site visit
May 29, 2002	Park Nicollet IRB acknowledges CDC's approval of Interim Principal Investigator, but stresses that official CDC lifting of suspension is necessary before Park Nicollet IRB will reconsider reinstating study
June 7, 2002	MDH receives letter from CDC formally announcing CDC Site Visit
June 18-19, 2002	CDC Site Visit at the MDH; CDC to provide review within one month
June 21, 2002	At request of CDC, a list of Revised Aims and Dates for Completing Remaining Objectives sent by email to CDC
August 28, 2002	CDC provides documentation approving the permanent status of Principal Investigators for Serious Work-Related Trauma and other MDH studies
September 9, 2002	Study activities re-start after receipt of Site Visit Report and subsequent lifting of study suspension by Park Nicollet IRB
September 13, 2002	Applied for a no-cost extension due to lost of staff and four months of work
September 18, 2002	Notified of approval of no-cost extension by CDC
November 9, 2002	Applied for cost extension to complete study activities and a waiver for supplemental funds till the end of calendar year 2003; funds not obtained
April 15, 2003	Project Director leaves due to uncertain future funding
May 23, 2003	Key research analyst leaves study; only Principal Investigator and 1 part-time staff member remain
June 2, 2003	Principal Investigator on 6 week medical leave

Table 6. Distribution of Cases of Serious Trauma Reported, Sampled, and Interviewed by Institution and Administrative Database (Inpatient/ Outpatient/Trauma Center)

Hospital/Medical Center	Reported			Sampled	Interviewed
	IP[1]	OP[2]	TC[3]		
Allina Hospitals					
Abbott Northwestern	311	NR[4]	N/A[5]	156	4
Mercy	723	NR	NR	380	13
Unity	829	NR	NR	263	7
United	263	NR	N/A	91	1
Fairview Health Services					
Fairview Ridges	194	603	N/A	230	suspended
Fairview Southdale	449	641	N/A	871	43
Fairview University	291	290	N/A	170	suspended
Health East Hospitals					
Health East-St. John's	358	NR	N/A	84	suspended
Health East-St. Joseph's	514	NR	N/A	98	suspended
Hennepin County (HCMC)	1719	195	1585	1500	42
Immanuel St. Joseph's	378	128	N/A	504	24
Mayo Clinic					
Mayo-St. Mary's	NR	NR	NR	N/A	N/A
Mayo-Methodist	NR	NR	NR	N/A	N/A
North Memorial (NMMC)	397	94	NR	300	23
Park Nicollet	560	4	NR	218	13
Regions	1542	552	NR	915	7
Rice Memorial	194	80	N/A	110	11
St. Cloud	3021	NK[6]	NR	1119	23
St. Luke's	354	361	1579	323	20
St. Mary's Duluth	404	67	725	166	0
TOTALS	12501	3015	3889	7498	231

[1]Inpatient
[2]Outpatient
[3]Trauma Center
[4]Not Reported
[5]Not Applicable
[6]Not Known

Table 7. Status of Interview Data Collection at Time of Cessation of Study Activities due to Preparation for CDC Site Visit (May 22, 2002)[1]

Hospital/Medical Center	Sample	Interviewed	Subjects to be contacted	Non-participants[2]
Allina Hospitals				
Abbott Northwestern	156	4	2	136
Mercy	380	13	3	355
Unity	263	7	2	250
United	91	1	47	33
Fairview Health Services				
Fairview Ridges	230	0	169	61
Fairview Southdale	871	43	54	392
Fairview University	170	0	151	19
Health East Hospitals				
Health East-St. John's	84	0	84	0
Health East-St. Joseph's	98	0	98	0
Hennepin County (HCMC)	1500	42	0	1355
Immanuel St. Joseph's	504	24	6	297
Mayo Clinic				
Mayo-St. Mary's	N/A	N/A	N/A	N/A
Mayo-Methodist	N/A	N/A	N/A	N/A
North Memorial (NMMC)	300	23	1	275
Park Nicollet	218	13	0	204
Regions	915	7	547	361
Rice Memorial	110	11	0	98
St. Cloud	1119	23	400	696
St. Luke's	323	20	0	297
St. Mary's Duluth	166	0	118	48
TOTALS	7498	231	1682	4877

[1]Some row columns do not sum to sample size due to missing cover pages for interviews in circulation

[2]Missing data includes the following categories:

-refusals received by returned postcard
-non-work-related serious trauma (thought to be 91 to 97 % of serious trauma based on this study)
-refusals with work-related trauma
-language difficulties not permitting interview
-study subject deceased
-study material not deliverable
-interviews for study subjects found to be ineligible during review

All of the 57 cases at the HCMC Trauma Center identified by 'Typework' = income had E Codes for E 849 Place of Occurrence. However, these E Codes included all E Code fields and not just the Primary E Code (Table 9). Nearly 80 % of the injury occurrences were classified as having occurred at the "Industrial place and premises".

Table 8. Possible Data Elements for Identifying Work-related Serious Trauma at Hennepin County Medical Center, Minneapolis (HCMC; 2000)

Data element	Hospital	Trauma Center
E Code 849 Place of Occurrence		
E 849.1 Farm	0	7
E 849.2 Mine and quarry	0	1
E 849.3 Industrial place and premises	3	111
Equipment involved[1]	NA[2]	5
Injury description[3]	0	0
Payer[4]	78	NA
Typework = income	NA	57
Occu-Code	NA	NA
Inj-activity	NA	NA
Total number of cases	1573	1585

[1]Farm equipment for 3 cases; industrial equipment for 2 cases
[2]Not available
[3]Data field includes term "work"
[4]Workers' Compensation

Table 9. ICD-9 E-Codes for Subjects with Possible Work-Related Serious Injury Identified by Trauma Center Data Element "Working for Income"* (HCMC; 2000)

ICD-9 E-Code	Study Subjects (n = 57)	
	No.	%
E 849 Place of Occurrence		
E 849.0 Home	2	3.5
E 849.1 Farm	1	1.8
E849.2 Mine and quarry	0	0.0
E 849.3 Industrial place and premises	45	78.8
E 849.4 Place for recreation and sport	0	0.0
E 849.5 Street and highway	2	3.5
E849.6 Public building	3	5.3
E 849.7 Residential institution	1	1.8
E 849.8 Other specified places *e.g. Beach NOS, Dock, Railway line*	3	5.3
E 849.9 Unspecified place	0	0.0
		100.0

*"Working for Income" refers to data element 'Typework' = income

Further review of data from both the hospital and Trauma Center for HCMC showed that additional information on possible work-related serious trauma could be obtained by combining information for cases appearing in databases for both the hospital and Trauma Center (Tables 10, 11). For cases meeting study criteria for year 2000 at HCMC, 1914 cases of serious trauma were in the hospital database and 1585 were in the Trauma Registry (Table 10). Of those cases, 1227 cases appeared in both databases. If only data from the hospital database were used to estimate possible work-related trauma, 90 hospitalized cases or 4.7 % of the cases would be assumed to have work-related serious trauma based on having at least one of the criteria for work association (Table 11). An additional 41 cases, or 131 (6.8 %) of the cases would be assumed work-related using additional information from the Trauma Registry for cases also appearing in the hospital database. Using data from the hospital database would increase the estimates of work-related serious trauma in the Trauma Registry from 8.2 % (130 cases) to 9.0 % (143 cases).

Table 10. Overlap of Cases with Serious Trauma Appearing in Hospital and Trauma Center Databases at the Same Medical Center (HCMC; 2000)

Hospital and/or Trauma Center Databases	No. of cases
Cases in hospital database	1914
Cases in Trauma Center registry	1585
Cases appearing in both hospital and Trauma Center	1227
Cases only in hospital	687
Cases only in Trauma Center	358

Table 11. Possible Work-Related Serious Trauma Cases Identified from Information in Administrative (Hospital) and Trauma Registry Data (HCMC; 2000)

Source of information	Possible work-related cases	
	In hospital database	In trauma registry
	No.	No.
Administrative (hospital) data		
Payer (Workers' Compensation)	90	
At least one of following E Codes:	3	
E 849.1 Farm		
E 849.2 Mine and quarry		
E 849.3 Industrial place and premises		
Cases with at least one of criteria	90	
Trauma Registry data		
Typework = income		57
Equipment involved		5
At least one of following E Codes:		119
E 849.1 Farm		
E 849.2 Mine and quarry		
E 849.3 Industrial place and premises		
Cases with at least one of criteria		130
Hospital and trauma registry data		
Additional cases identified	41	13
Total	131	143

Demographic characteristics of hospitalized and Trauma Center cases of serious trauma at HCMC were similar in terms of age distribution and gender with approximately 75 % of cases being male (Table 12). Injury severity scores were not available for hospitalized cases at HCMC, and injury severity scores were missing for over 15 % of the Trauma Center cases (Table 13). The nature of injuries for hospitalized and Trauma Center cases based on Principal ICD-9 Code appear similar, but the comparison is limited by the "Other" category for hospital cases and the "Unknown" principal ICD-9 Code for Trauma Center (Table 14).

Table 12. Demographic Characteristics of Cases of Serious Trauma in Hospital and Trauma Center Patients in a Major Medical Center (HCMC; 2000)

Characteristic	Hospital cases		Trauma Center Cases	
	No.	%	No.	%
Gender (% male)	1416	74.0	1205	76.0
Age				
14 - 19	214	11.2	205	12.9
20 – 29	502	26.2	422	26.6
30 – 39	479	25.0	394	24.9
40 – 49	417	21.8	339	21.4
50-59	223	11.7	164	10.3
60 – 65	79	4.1	61	3.9
Total	1914	100.0	1585	100.0

Table 13. Measures of Injury Severity for Cases of Serious Trauma in the Trauma Registry of a Major Medical Center (HCMC; 2000)

Measure of severity	Trauma registry cases	
	No.	%
Length of stay (LOS in days)		
≤ 5	1113	70.2
6 – 10	251	15.9
11 – 20	151	9.5
21 – 50	59	3.7
> 50	11	0.7
Total	1585	100.0
Injury Severity Score (ISS)		
0 – 8	569	35.9
9 – 75	752	47.4
Not available	264	16.7
Total	1585	100.0

Table 14. Nature of Injuries for Cases of Serious Trauma in Hospital and Trauma Center Databases of a Major Medical Center Based on Principal ICD-9 Code (HCMC; 2000)

ICD-9 Codes/Nature of injury	Hospital cases		Trauma center cases	
	No.	%	No.	%
800-829 Fractures	732	38.2	620	39.1
830-839 Dislocations	35	1.8	10	0.6
840-848 Sprains and strains of joints/muscles	1	0.1	20	1.3
850-854 Intracranial injury--without skull fracture	154	8.0	177	11.1
860-869 Internal injury of chest/abdomen/pelvis	153	8.0	165	10.4
870-879 Open wound of head, neck and trunk	88		59	
880-887 Open wound of upper limb	70		42	
890-897 Open wound of lower limb	21		22	
	179	9.4	123	7.8
900-904 Injury to blood vessels	25	1.3	24	1.5
905-909 Late effects—injuries, poison, toxic effects	--	--	9	0.6
910-919 Superficial injury	--	--	11	0.7
920-924 Contusion with intact skin surface	6	0.3	20	1.3
925-929 Crushing injury	3	0.2	--	--
930-939 Effects of foreign body entering orifice	6	0.3	--	--
940-949 Burns	94	4.9	100	6.3
950-957 Injury to nerves and spinal cord	13	0.7	12	0.8
958-959 Certain traumatic complications	7	0.4	18	1.1
960-979 Poisoning by drugs, medicinals, biologics	39	2.0	--	--
980-989 Toxic effects of nonmedicinal substances	69	3.6	8	0.5
990-995 Other/unspecified effects of external causes	19	1.0	9	0.6
996-999 Complications of surgical medical care--NEC	30	1.6	--	--
000-799 Other	349	18.2	--	--
Unknown	--	--	259	16.3
Total	1914	100.0	1585	100.0

Tables 15-20 present results for the 231 interviews (220 full interviews) collected before study activities were halted. These telephone interviews were conducted with cases of serious work-related trauma at 13 of the participating institutions (Table 7). The great majority of those injured were male and white (Table 15). Most injured workers (91.8 %) had worked since the injury and most (65.0 %) had received payment for lost income from sources such as Workers' Compensation, Social Security Disability or other assistance programs. More than 40 % of those injured reported using special equipment such as canes or wheelchairs since the injury.

Table 15. Demographic and Selected Outcome Characteristics from Interviews of Cases of Serious Work-Related Trauma Identified at Hospitals and Trauma Centers of Participating Institutions (Year 2000)

Demographic and outcome characteristics	Cases* (n = 220)	
	No.	%
Gender (% male)	182	82.7
Race/ethnic background		
White (Caucasian)	202	91.8
Black (African American)	5	2.3
Other Race	10	4.5
Unknown	1	0.5
Refusal	2	0.9
Worked since injury		
Yes	202	91.8
No	16	7.3
Unknown	2	0.9
Payment received for lost income (e.g. Workers' Compensation)		
Yes	143	65.0
No	71	32.2
Not applicable	2	0.9
Unsure	1	0.5
Unknown	3	1.4
Used special equipment since injury (e.g. cane, wheelchair, special phone)		
Yes	96	43.6
No	120	54.6
Unknown	4	1.8
Only short interview completed	11	

*Of the 231 cases interview, 11 completed only the short interview

Nearly 86 % of the work-related serious trauma occurred in agriculture, construction, manufacturing, transportation, and service industrial categories of the Standard Industrial Classification System (SIC) (Table 16). The SIC category of Services includes a variety of major groups including work in motels and hotels, personal services including laundry and commercial cleaning, automobile repair, miscellaneous repair services, amusement and recreational services and health care services. In terms of occupational classifications of the Standard Occupational Classification (SOC) System, nearly 75 % of serious work–related trauma occurred in: Farming, fishing and forestry occupations; Construction and extraction occupations; Installation and repair occupations; Production occupations; and Transportation and material moving occupations (Table 17).

Table 16. Distribution of Interviewed Cases of Work-Related Serious Trauma by Industry According to the Standard Industrial Classification (SIC)

Major Industrial Divisions (SIC)	Interviewed cases (n =231)	
	No.	%
A Agriculture, forestry, and fishing	25	10.8
B Mining	2	0.9
C Construction	65	28.1
D Manufacturing	39	16.9
E Transportation, communications, electric, gas and sanitary services	27	11.8
F Wholesale trade	4	1.7
G Retail trade	13	5.6
H Finance, insurance, and real estate	6	2.6
I Services	42	18.2
J Public administration	7	3.0
K Non-classifiable establishments	1	0.4
Total	231	100.0

Table 17. Distribution of Interviewed Cases of Work-Related Serious Trauma by the Standard Occupational Classification (SOC)

Major Occupational Groups	Interviewed cases	
	No.	%
11-0000 Management occupations	7	3.0
13-0000 Business and financial operations occupations	6	2.6
17-0000 Architecture and engineering occupations	1	0.4
19-0000 Life, physical, and social science occupations	1	0.4
21-0000 Community and social services occupations	2	0.9
29-0000 Healthcare practitioners and technical occupations	8	3.5
31-0000 Healthcare support occupations	1	0.4
33-0000 Protective service occupations	5	2.1
35-0000 Food preparation and serving related occupations	4	1.7
37-0000 Building and grounds cleaning and maintenance occupations	6	2.6
39-0000 Personal care and service occupations	4	1.7
41-0000 Sales and related occupations	6	2.6
43-0000 Office and administrative support occupations	6	2.6
45-0000 Farming, fishing and forestry occupations	27	11.7
47-0000 Construction and extraction occupations	55	23.9
49-0000 Installation and repair occupations	24	10.4
51-0000 Production occupations	38	16.5
53-0000 Transportation and material moving occupations	28	12.1
Unknown	2	0.9
	231	100.0

Work-related serious trauma reported in interviews was analyzed by the nature of the injury, source of the injury, and the event or exposure that resulted in injury by the Occupational Injury and Illness Classification System (OIICS). Often there were multiple injuries, and as many as five injuries were reported on the questionnaire. The first item reported was considered the primary injury for the analysis. The categories 01 "Traumatic injuries to bones, nerves, spinal cord", 03 "Open wounds" and 08 "Multiple traumatic injuries" accounted for 78.7 % of the injuries (Table 18). Category 01 includes fractures which accounted for nearly 40 % of injuries for all cases of serious trauma in the hospital and Trauma Center at HCMC that were coded by principal ICD-9 code. OIICS injury source refers to the exposure, object, substance or body motion resulting in the injury. The categories of Machinery, Parts and materials, Structures and surfaces, Tools, instruments and equipment, and Vehicles directly resulted in the reported injuries (Table 19). Three categories of events or exposures accounted for over 75 % the injuries reported: Contact with objects or equipment, Falls, and Transportation accidents (Table 20).

Table 18. Primary Nature of Injury of Interviewed Cases with Serious Work-Related Trauma according to the Bureau of Labor Statistics' (BLS) Occupational Injury and Illness Classification System (OIICS)

OIICS Division 0: Traumatic Injuries and Disorders: Injury Nature	Interviewed cases = 231	
	No.	%
00 Traumatic injuries and disorders, unspecified	1	0.4
01 Traumatic injuries to bones, nerves, spinal cord	57	24.6
02 Traumatic injuries to muscles, tendons, ligaments, joints, etc.	10	4.3
03 Open wounds	40	17.3
04 Surface wounds	5	2.2
05 Burns	8	3.5
06 Intracranial injuries	6	2.6
07 Effects of environmental conditions	2	0.9
08 Multiple traumatic injuries	85	36.8
09 Other traumatic injuries and disorders	5	2.2
Unknown	12	5.2
Total	231	100.0

Table 19. Primary Source of Injury of Interviewed Cases with Serious Work-Related Trauma according to the Bureau of Labor Statistics' (BLS) Occupational Injury and Illness Classification System (OIICS)

OIICS Division 0: Traumatic Injuries and Disorders: Injury Source	Interviewed cases = 231	
	No.	%
0 Chemicals and chemical products	4	1.7
1 Containers	3	1.3
2 Furniture and fixtures	2	0.9
3 Machinery	31	13.4
4 Parts and materials	23	10.0
5 Persons, plants, animals and minerals	16	6.8
6 Structures and surfaces	75	32.5
7 Tools, instruments, and equipment	23	10.0
8 Vehicles	28	12.1
9 Other sources	12	5.2
9999 Nonclassifiable	14	6.1
Total	231	100.0

Table 20. Event or Exposure Resulting in Injury to Interviewed Cases with Serious Work-Related Injury by the Bureau of Labor Statistics' (BLS) Occupational Injury and Illness Classification System (OIICS)

OIICS Division: Traumatic Injuries and Disorders: Event/Exposure	Interviewed cases = 231	
	No.	%
0 Contact with objects or equipment	85	36.8
1 Falls	68	29.4
2 Bodily reaction and exertion	22	9.5
3 Exposure to harmful substances or environments	10	4.3
4 Transportation accidents	25	10.9
5 Fires and explosions	2	0.9
6 Assaults and violent acts	5	2.2
9 Other events or exposures	1	0.4
9999 Non-classifiable	13	5.6
Total	231	100.0

DISCUSSION

Initial efforts in this study focused on developing an Advisory Work Group with a broad range of expertise in injury research and epidemiology, experience in treating trauma, and knowledge of the workings of hospitals and trauma centers in dealing with serious trauma. Extensive discussion followed concerning hospitals within Minnesota and bordering Minnesota which might treat Minnesota residents with serious trauma, and whether possible regional sampling frames of institutions could be developed which would permit population-based study of serious work-related trauma. Also, a major effort was directed at developing an operational definition of serious work-related trauma that could adequately represent the complexity of injuries occurring in current workplaces and yet be precise enough to permit efficient data collection.

It had been hoped that the Minnesota Trauma Data Bank that has statutory authority for collecting "severe trauma" from trauma centers in the state would be the data source for the study. Unfortunately, at that time the Trauma Data Bank was collecting data from less than half of the Minnesota trauma centers. In addition, there was concern about common definitions of "serious trauma" across the trauma centers, and whether hospital cases meeting study criteria would actually enter trauma center databases, and ultimately, the Trauma Data Bank. Also, the effect of different software systems used at trauma centers on data collected was not clear (TraumaBase or Cales, or unique software systems developed for specific trauma centers).

Due to concerns about obtaining cases meeting our criteria for serious trauma from participating medical centers, a decision was made to obtain both hospital and trauma center data. One concern was the possibility that medical centers with trauma registries might miss cases meeting study criteria entering their own hospital. Secondly, it would be necessary to address the comparability of data from medical centers with and without trauma centers. Based on the sampling work done with staff at the University of Minnesota and an assessment of state hospitals treating the most patients meeting study criteria with staff at the Minnesota Hospital and Healthcare Partnership (MHHP), it was decided to concentrate on hospitals within the state, and not to stratify hospitals for purposes of sampling. MHHP has hospital inpatient and outpatient claims data based on Uniform Bill, 1992 version (UB-92). Analyses of the 1998 claims data suggested 22 hospitals saw approximately 85 % of the cases meeting study criteria. Those twenty-two institutions were invited to participate in the study, and 20 of the 22 hospitals participated although 2 of the hospitals never provided data.

The case definition of serious trauma based on non-fatal injuries, specific ICD-9 Codes, E Codes, no V Codes, age ≥ 14 to ≤ 65 (eligibility ≥ 12 to ≤ 85) and length of stay ≥ 1 day worked well for inpatients. Database staff at the separate institutions usually applied these criteria without difficulty, doing the necessary data runs to identify cases meeting the serious trauma criteria. One institution did not apply proper inclusion criteria, and an inappropriate phone contact was made before screening criteria were corrected. One trauma center provided a very low number of trauma center patients. After review of data sent, it appears that additional screening filters had been applied—this situation was not reassessed due to staff attrition. Obtaining data for outpatients using UB-92 often proved

difficult. In addition, the number of outpatients seen and the great mobility of outpatients from major urban medical centers could make data collection from this group more labor intensive, which would be undesirable for a surveillance effort.

Since work-related serious trauma is only a small proportion of all serious trauma, all cases needed to be contacted. At HCMC, 1719 inpatients, 195 outpatients, and 1585 trauma registry patients met study criteria (with 1227 patients appearing in both hospital and trauma registry databases). Contacts were attempted for all 1500 study subjects sampled, and 42 interviews with cases with work-related injuries were obtained, i.e. 2.8 % of the serious trauma was work-related. Thus, a great deal of effort was required in contacting study subjects to determine that trauma was work-related. Protocols for contacting study subjects varied from institution to institution (See Methodology; **Appendix D**). The differences were not trivial, and required additional record keeping, and sometimes, substantially more effort. For example, one major institution required that study contact letters be sent from the their institution instead of the MDH. Due to resource limitations at this institution, it was necessary to have MDH staff travel to the institution with a computer and printer to print and mail hundreds of letters. These variations in protocol were not unreasonable requests, considering the cooperation and extra effort requested of participating centers. It does, however, raise issues concerning the suitability of such effort for surveillance.

Due to the cessation of study activities, on May 10, 2002, only an incomplete set of interviews and information about work-related serious trauma are available. With nearly 1700 study subjects to be contacted at the time of the study's cessation, study subjects at some participating institutions were not interviewed or are represented by very few interviews. Analysis of both the data on serious trauma from the participating institutions and interview data is very limited due to the departure of key staff responsible for analysis. Additional funds were unable to be obtained to compensate for the nearly four months of lost time until study reinstatement in September 2002.

Before addressing available data, possible bias in the study design needs to be assessed. All research efforts have the potential for bias, even though the study design attempts to limit the effects. Ascertainment bias and recall bias are possible sources of bias for the Surveillance of Serious Work-Related Trauma study. Although much time was spent trying to develop a comprehensive set of medical centers likely to treat serious trauma, it was not feasible, logistically and politically, to include all hospitals and trauma centers. Ascertainment bias would be possible from two perspectives: institutions within Minnesota, and institutions in bordering states that are more convenient for Minnesota residents. The 20 hospitals and/or trauma centers agreeing to participate in this study provide most of the care for serious trauma in Minnesota. Even without obtaining data from the hospitals of Mayo Clinic, it would be expected that the range of injuries occurring in these institutions would be generally representative of serious trauma in the State. However, it remains unclear whether there might be differences in cases seen at Mayo Clinic or, also, at some of the smaller regional hospitals, that might result in underreporting of certain important categories of serious trauma. Also, it is unclear how many and what kind of injuries are treated at hospitals bordering Minnesota. Year 2000 case data were selected to avoid issues that may affect survey information for questions

on return to work, for example, cases may be in work assistance programs the first couple years after their injury; therefore, following this time period, it was to be determined whether the cases were able to keep their jobs without assistance. Because of this length of time, up to two years, from the time the injury event occurred to the time the injury information was collected, recall bias may exist. This is a matter of concern, since accuracy of reporting injuries has been shown to decrease after 6 months (Gerberich et al., 2001; Gerberich et al., 1991). Of course, some of the information could be validated by comparison with hospital/trauma center data.

Reviewing existing data from Hennepin County Medical Center (HCMC) shows similar demographic characteristic for hospital and trauma registry cases in terms of age and predominance of males, 74 % and 76 %, respectively. These results mirror findings comparing administrative (hospital) and trauma registry data in another large urban medical center (Wynn et al., 2001). Like Wynn et al., this study showed both substantial overlap of those cases appearing in both hospital and trauma center databases, and separate subsets of cases appearing only in hospital or trauma center databases. In HCMC, this was particularly interesting, because it appeared that combining information for these different databases might provide more information on whether injuries were work-related.

Interview data on only work-related serious trauma is difficult to assess with the limited sample completed. Available results show a somewhat greater predominance of male workers (than seen among all cases of serious trauma in the medical centers), racial proportions consistent with Minnesota's current population, and a greater proportion of injuries in industries (Standard Industrial Classification System) and occupations (Standard Occupational Classification) known for greater injury and fatality rates.

The system as designed, even with the incomplete data collection from study interruptions and distractions, would seem inappropriate for surveillance of serious work-related trauma. The system does not appear to meet the current performance guidelines for evaluating public health surveillance systems (CDC, 2001). The system does not meet the criterion of simplicity in terms "methods of collecting data, number of organizations involved in receiving case reports", "methods of managing data....", and "time spent on maintaining the system". For example, for HCMC, a great deal of effort was expended to identify 2.8 % of the cases with work-related serious trauma. Also, the criteria of flexibility, in terms of the number of institutions involved, in terms of continual IRB stipulations as opposed to statutory arrangements, is probably not adequate in the current environment for privacy issues. The surveillance criterion of data quality addresses completeness and validity. The current system probably misses on the criterion of completeness, or it is at least unclear whether it is representative of the full spectrum of work-related serious trauma.

There are concerns about the basic data sources for this study. Trauma registry data are collected to evaluate treatment and outcomes, and administrative data (hospital data) have been reported to have limitations in accuracy for outcome data, as well as diagnostic and procedural data for trauma (Wynn et al., 2001). Others have suggested that trauma registry data needs to be assessed for completeness, as well as for accuracy in coding and

abstracting (Owen et al., 1999; Rosenberg, 1996). Acceptability of this system by hospitals and trauma centers on an ongoing basis for surveillance would be questionable. The sensitivity and predictive value positive cannot be assessed. The timeliness of entry of data on serious work-related trauma into this system and stability of this system, considering its complexity would both be matters of concern.

The key issue for this effort is whether or not the methodologic issues identified and the collaborative arrangements established take advantage of what has been learned from this complex but ill-fated study. There would seem to be definite opportunities to explore. When the original proposal was submitted for the Surveillance of Serious Work-Related Trauma grant there were plans to work with the Center for Health Promotion at the MDH which had a registry for brain and spinal cord injuries and was starting to expand data collection at trauma centers to include serious trauma (Trauma Data Bank). Since that time the Injury and Violence Prevention Unit within the Center for Health Promotion has developed good coverage of the trauma centers in Minnesota and working relationships with trauma centers in most of the states bordering Minnesota where Minnesota residents may be treated. Before the loss of the analytic staff from the Surveillance of Serious Trauma grant, data for year 2000 from the Trauma Data Bank in the Injury and Violence Prevention Unit had been shared with our staff to ascertain if the routinely collected data under statute by the Trauma Data Bank included the data elements used for this study. Unfortunately, in the brief exploration of Trauma Data Bank data, we did not find the same variables for linking records from the datasets obtained by the Serious Work-Related Trauma grant and the Trauma Data Bank from the same trauma registry.

The head of the Trauma Data Bank has expressed willingness to further explore the comparability of the data obtained from trauma centers by these two sections of the MDH. Organizationally, these two sections are now within the same division of Health Promotion and Chronic Disease. Several issues need to be addressed in exploring if routinely collected data by the Trauma Data Bank might be used to assess serious work-related trauma according to the criteria developed by this grant. For example, would it be necessary to also collect hospital data, because in the Serious Work-Related Trauma grant, combining data for cases of serious trauma appearing in both hospital and trauma center databases detected more information about serious trauma that was work-related. Also, the Advisory Group for the Trauma Data Bank that includes broad representation from key trauma associations could be approached about collecting additional or more complete information on work association with injuries. If information in hospital and trauma center data on which serious injuries were work-related were found to be reliably collected and valid, this would obviate the labor-intensive work of tracking all those with serious trauma to determine work-relatedness. The ongoing data collection by the Trauma Data Bank would then permit further exploration of suitability of this method for surveillance and assessment of representativeness of the data. Our association with the Trauma Data Bank will hopefully permit some of the methodology of this study to still be put to use.

CONCLUSIONS

In-spite of the disappointment of not being able to take full advantage of the incredible amount of work represented by this effort, methodologic information of use for future research was obtained. The case definition of work-related injury or some variation would seem useful for future efforts. UB-92 data for identifying outpatients was difficult to obtain at the time this study was conducted and follow-up of outpatients was often too labor intensive for a surveillance system. Also, the demands of separate IRBs from several medical centers was time consuming and unduly complex due to variations in the protocol for contacting study subjects. Based on our experience, a validation study is being discussed with the MDH's Trauma Data Bank, which has ongoing access to data from all trauma centers in Minnesota. The effort would assess the accuracy of using existing data elements such as E codes, "working for income", and Workers' Compensation and other payer information to identify work-related serious trauma.

PUBLICATIONS

Unfortunately, no scientific articles were published from this effort. (An informational article on the study by staff appeared in Minnesota Physician.) The original Principal Investigator of the Surveillance of Serious Work-Related Trauma grant absented himself from the MDH on November 21, 2001 and ultimately resigned from the MDH. This departure occurred during the final scheduled year of the project during data collection. All data collection for the study stopped on May 10, 2002 at direction of the Park Nicollet Institute, the overall institutional IRB (Table 5). Study activities ceased during a crucial period of interviewing. Study activities restarted on September 9, 2002, shortly before the official end of the project on September 29, 2002. Data collection was never completed, and without additional funding for the one-year no-cost extension, key study staff departed.

Publication:

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Surveillance of Serious Work Related Trauma
Final Progress Report
Appendices

Appendix A: Advisory Work Group

Appendix B: Questionnaire

Appendix C: IRB Stipulations/Summary

Appendix D: Protocol and Contacting Study Subjects

Appendix E: Interviewer Training Manual

Appendix F: CDC Site Visit

Appendix G: Study Correspondence

Appendix A

Advisory Work Group

Advisory Work Group

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Appendix B

Questionnaire

Surveillance of Serious Work-Related Trauma Questionnaire

SHORT INTERVIEW

Screening Question:
Could you please tell me if you suffered an injury that occurred at work on <<date>> OR Could you tell me if you were admitted to the hospital due to an injury that occurred at work on <<date>>?

Yes ☐ [Continue with questionnaire]
(If yes and only have admission date) **What date did the injury occur?**
_____/_____/_____

No ☐ [End the interview and thank them for their time]

The first few questions that follow will be about the work you were doing at the time of your injury that happened on <date>. You are welcome to provide comments and ask questions anytime. Please note that you are not obligated to answer any question that may make you feel uncomfortable.

1. At the time you suffered this injury at work, were you employed by a temporary agency?

Yes ☐ **What is the name and address of the company/employer the temporary agency had you assigned to be working with at the time of the injury?** *(Not the temporary agency.)*

Name _____ Unsure ☐ Refusal ☐

Address _____ Unsure ☐ Refusal ☐

_____ **(Skip to 3)**

No ☐ **(Continue to 2)**
Unsure ☐ **(Continue to 2)**
Refusal ☐ **(Continue to 2)**

2. What was the name and address of the company/employer you worked for at the time of the injury?*(If they will not disclose the name of the company, please go onto asking about the type of industry below.)*

Name Unsure ☐ Refusal ☐

_____

Address Unsure ☐ Refusal ☐

_____ (Self-Employed ○ Self-Employed Farmer ○)

_____

3. What kind of work did this company or employer do? (For example, did it manufacture machinery, build apartment complexes, farm row crops, etc.)

Industry Unsure ☐ Refusal ☐

_____

_____

4. What was your job title with this company/employer? What were your duties?

Job Title Unsure ☐ Refusal ☐

_____

Duties Unsure ☐ Refusal ☐

_____

_____

[Completion of Short Interview. Thank you and good-bye.]

Screening Question:
Could you please tell me if you suffered an injury that occurred at work on <<date>> OR Could you tell me if you were admitted to the hospital due to an injury that occurred at work on <<date>>?

Yes ☐ [Continue with questionnaire]
(If yes and only have admission date) **What date did the injury occur?**
_____/_____/_____

No ☐ [End the interview and thank them for their time]

The first few questions that follow will be about the work you were doing at the time of your injury that happened on <date>. You are welcome to provide comments and ask questions anytime. Please note that you are not obligated to answer any question that may make you feel uncomfortable.

1. **At the time you suffered this injury at work, were you employed by a temporary agency?**

Yes ☐ **What is the name and address of the company/employer the temporary agency had you assigned to be working with at the time of the injury?** *(Not the temporary agency.)*

Name _____ Unsure ☐ Refusal ☐

Address _____ Unsure ☐ Refusal ☐

_____ **(Skip to 3)**

No ☐ **(Continue to 2)**
Unsure ☐ **(Continue to 2)**
Refusal ☐ **(Continue to 2)**

2. **What was the name and address of the company/employer you worked for at the time of the injury?***(If they will not disclose the name of the company, please go onto asking about the type of industry below.)*

Name Unsure ☐ Refusal ☐

_____

Address Unsure ☐ Refusal ☐

_____ (Self-Employed ○ / Self-Employed Farmer ○)

_____

3. What kind of work did this company or employer do? (For example, did it manufacture machinery, build apartment complexes, farm row crops, etc.)

Industry Unsure ☐ Refusal ☐

_____

_____

4. What was your job title with this company/employer? What were your duties?

Job Title Unsure ☐ Refusal ☐

_____

Duties Unsure ☐ Refusal ☐

_____

_____

5. Could you please tell me how the accident happened? Refusal ☐

Narrative_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Nature$_1$ _____ **POB$_1$** _____
Nature$_2$ _____ **POB$_2$** _____
Nature$_3$ _____ **POB$_3$** _____
Nature$_4$ _____ **POB$_4$** _____
Nature$_5$ _____ **POB$_5$** _____

Source _____ **Event** _____

Environment _____

(If patient does not provide nature of injury(s), please ask the following question…)

5a. What type of injury(s) did you suffer as a result of this incident?

_____

_____

_____

(If patient does not provide part(s) of body injured, please ask the following…)

5b. Could you please identify the part(s) of your body that were injured during this incident?

_____

_____

_____

(If patient does not provide the source of injury(s), please ask the following…)

5c. What object or motion caused your injury(s) to occur? For example, "If you were hit by moving vehicle, the vehicle would have caused your injury." or "If you strained your shoulder by making a sudden move, your bodily motion would have caused your injury."

_____

_____

_____

(If patient does not provide the event that led to the injury(s), ask the following…)

5d. What type of event led to the injury(s)? For example, "Did you fall from a ladder?"

_____

_____

_____

(If patient does not provide the environment that may have contributed to the injury(s), ask the following…)

5e. Were there conditions at work, such as a wet floor or bad weather, which may have contributed to your injury(s)?

Yes ☐ No ☐ Unsure ☐ Refusal ☐

(If yes) **Explanation:**

_____

_____

_____

6. Did your injury(s) occur on or off of the company's/employer's property?

On-site ☐ Off-site ☐ Unsure ☐ Refusal ☐

7. At the time of your injury(s), were you working indoors or outdoors?

Indoors ☐ Outdoors ☐ Refusal ☐

8. Did the injury(s) occur during your regular working hours?

Yes ☐ No ☐ Unsure ☐ Refusal ☐

Return to Work

9. Have you worked at all since your injury happened on <<date>>?

Yes ☐ **(Skip to 10)**
No ☐ **(Continue to 9a.)**
Refusal ☐ **(Skip to 16)**

9a. What has prevented you from returning to work? *(Can answer both injury and other)*

Injury → Yes ☐ No ☐ **(Continue to 9b.)**
Other → Yes ☐ No ☐ _____

_____

_____

(Continue to 9b.)

Unknown ☐ **(Continue to 9b.)**
Refusal ☐ **(Skip to 16)**

9b. Do you think you will be able to return to work?

Yes ☐ **When do you think you will be able to return?**

_____

_____

Date, if known ___/___/___

No ☐ **Please explain why you do not think you will be able to return to work:**

_____

_____

_____

_____

Too much pain ○
Unable to do job ○
Unable to get to work ○
Fired or laid off ○
Physical limitations ○
Other ○

Unsure ☐ **Please explain why you may not be able to return to work:**

_____

_____

Refusal ☐

(Skip to question 16)

10. On approximately what date did you first return to work?

____/____/____ (month/day/year)

Unsure ☐ Refusal ☐ Never left work ☐

11. Did you return to work at about the same percent time (number of hours/day/week/month) that you were working at the time of your injury?

Yes ☐
No ☐ **Have your hours increased or decreased after your injury?**
Increased ☐ Decreased ☐
Unsure ☐ **Explain:** _____ Seasonal ○ Temporary ○ On Call ○
_____
_____
Refusal ☐

12. Did you return to work with the same employer you were working with when you were hurt on <date>?

Yes ☐ **[Continue to 12a.)**
No ☐ **Why didn't you return to work with the same employer?**

_____

_____

_____ **(Skip to 13)**

Unsure ☐ **(Skip to 13)**
Refusal ☐ **(Skip to 13)**

12a. *(If yes)* **Is this the same job, by job we mean the same job responsibilities and activities, as the one you worked in at the time of your injury?**

Yes ☐ **(Continue to 12b.)**
No ☐ **(Skip to 12c)**
Refusal ☐ **(Skip to 12c.)**

12b. Did your employer modify your job to accommodate you because of your injury?

Yes ☐
No ☐
N/A ☐
Refusal ☐

(Skip to Question 14)

12c. Did your employer give you a new job to accommodate you because of your injury?

Yes ☐ **What is your new job?**

_____

_____

_____

No ☐ **Explanation:**

_____

_____

_____

Unsure ☐

Refusal ☐

(Skip to question 14)

13. Do you currently do the same type of work as you were doing at the time of your injury but with a new employer?

Yes ☐

No ☐ **Why don't you do the same type of work?** _____

_____

_____

Refusal ☐

14. Since returning to work, have you missed any work time due to your injury?

Yes ☐

(If yes) **How much total time have you missed since your return to work?** *(not adding in the time missed from the date of injury to the first date he/she returned to work)*

_____

_____

For what reason(s)? _____

_____

_____

Dr.'s Appointments ○
Too much pain to work ○
Unable to get to work ○
Other ○

Will you continue to miss work due to your injury?

Yes ☐ No ☐ Unsure ☐ Refusal ☐

No ☐

Refusal ☐

Activities of Daily Work

15. At this time does your injury affect your ability to do any activities relating to your work or job?

Yes ☐ **Explain** *(have them tell all things, not only one)*:

_____ Work entire scheduled shift ○
_____ Use tools/equipment ○
_____ Lift/Carry/Move objects ○
_____ Bend/Twist/Reach ○
_____ Communicate ○
_____ Other ○

No ☐
N/A ☐
Refusal ☐

Financial Impact

16. As a result of your injury, have you experienced any financial difficulties?

Yes ☐ No ☐ N/A ☐ Refusal ☐ Unsure ☐

*(If yes)***Explanation** *(have them tell all things, not only one)*:

_____ Had problems paying bills ○
_____ Dipped into savings account ○
_____ Unable to pay mortgage/rent ○
Accumulated credit card debt ○
Lost health insurance ○
Other ○

17. Have you received payments for lost income from worker's compensation, social security disability, or any other assistance program?

Yes ☐ No ☐ **(Continue to 18)** N/A ☐ Refusal ☐ Unsure ☐

(If yes) **Explanation:** _____

_____

_____

_____

Are you still receiving these benefits?

Yes ☐ No ☐ N/A ☐ Refusal ☐ Unsure ☐

Activities of daily living

18. As a result of your injury, are you limited in any way in any activities relating to your daily life, such as walking, dressing, or eating?

Yes ☐ **(Continue)** No ☐ **(Skip to 20)** Refusal ☐ **(Skip to 20)** Unsure ☐ **(Continue)**
(Interviewee may want to explain…)

_____

_____

_____

(If yes or unsure)
During a typical day are you able to… *(1=Without difficulty, 2=With moderate difficulty, 3=Cannot do alone)*

a. Climb up or down at least one flight of stairs..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

b. Walk 1 to 2 blocks..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

c. Maintain or clean your home..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

d. Dress or undress yourself..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

e. Eat your meals..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

f. Bathe yourself..... 1 ☐ 2 ☐ 3 ☐ N/A ☐ Refusal ☐ Unsure ☐

19. Who assists you with daily activities with which you have difficulty?

_____

_____

Spouse/partner ○
Other family member ○
Nurse/Attendant ○
Other ○

Mobility

As a result of your injury…
20. Have you had to use special equipment, such as a cane, wheelchair, special bed, or special telephone?

Yes ☐ No ☐ Unsure ☐ Refusal ☐

(If yes) **What types of assistance have you used?**

_____

_____

_____

Cane ○
Wheelchair ○
Crutches ○
Special Bed ○
Special Phone ○
Other ○

21. Is it more difficult for you to move about the community?

Yes ☐

(If yes) **For what reasons?** _____

_____

_____

- Difficult getting in and out of vehicle ☐
- Unable or difficult to drive a car ☐
- Difficulty with public transportation ☐
- Other ☐

No ☐
Unsure ☐
Refusal ☐

Social & Emotional Functioning

22. Do you feel isolated from your friends, family, and community?

Yes ☐ No ☐ **(Skip to 23)** Unsure ☐ **(Skip to 23)** Refusal ☐ **(Skip to 23)**

(If yes) **Do you feel this isolation is a result of your injury?**

Yes ☐ No ☐ **(Skip to 23)** Unsure ☐ **(Skip to 23)** Refusal ☐ **(Skip to 23)**

(If yes) **Explanation:** _____

_____

_____

- Friends ☐
- Family ☐
- Community ☐

23. Are you having trouble with emotional problems such as feeling depressed or anxious?

Yes ☐ No ☐ (Skip to 24) Unsure ☐ (Skip to 24) Refusal ☐ (Skip to 24)

(If yes) **Do you feel these emotional problems are a result of your injury?**

Yes ☐ No ☐ Unsure ☐ Refusal ☐

24. At this time, would you say your overall outlook for the future is...

Very Good ☐
Good ☐
Fair ☐
Poor ☐
Unsure ☐
Refusal ☐

(If fair or poor) **Do you believe this outlook is a result of your injury?**

Yes ☐ No ☐ Unsure ☐ Refusal ☐

Alcohol Consumption and Tobacco Use

We are interested in the effect your injury may have had on your alcohol consumption and tobacco use. We would like to ask you a few questions about these substances. As noted earlier, your responses are strictly confidential.

25. Before your injury occurred...

a. Did you smoke cigarettes every day, some days, or not at all?

Every Day ☐
Some Days ☐
Not at All ☐
Refusal ☐ Unsure ☐

(If Not At All) **As a result of your injury have you begun smoking?** ***(Do not ask 26a.)***

Yes ☐ No ☐ Unsure☐ Refusal ☐

b. Did you consume alcohol every day, some days, or not at all?

Every Day ☐
Some Days ☐
Not at All ☐
Refusal ☐
Unsure ☐

(If Not At All) **As a result of your injury have you begun consuming alcohol?** ***(Do not ask 26b.)***

Yes ☐ No ☐ Unsure☐ Refusal ☐

26. As a result of your injury,

a. has your smoking...

Increased ☐ Decreased ☐ Stayed the Same ☐ Refusal ☐ Unsure ☐ N/A ☐

b. has your alcohol intake...

Increased ☐ Decreased ☐ Stayed the Same ☐ Refusal ☐ Unsure ☐ N/A ☐

Personal Information

The following section is the last and asks you about personal information.

27. What is your date of birth?

_____/_____/_____
month day year

Refusal ☐

28. What is your gender?

Male ☐
Female ☐
Refusal ☐

29. What country were you born in?

_____

Unsure ☐
Refusal ☐

30. What is your race/ethnic background?

Some Other Race_____ ☐

White (Caucasian) ☐ Black, African American, Negro ☐

American Indian or Alaska Native ☐

Asian Indian ☐ Japanese ☐

Chinese ☐ Korean ☐

Filipino ☐ Vietnamese ☐

Other Asian_____ ☐

Pacific Islander_____ ☐
(*Circle if specific*: Hawaiin Guamanian, Chimarro, Samoan)

Spanish/Hispanic/Latino ☐

Mexican, Mexican American, Chicano ☐ Puerto Rican ☐

Cuban ☐ Other Spanish/Hispanic/Latino ☐

Unsure ☐
Refusal ☐

31. What is the highest level of schooling you have completed?

Less than high school education	☐
Completed high school education or equivalent (GED)	☐
Some technical school training	☐
Completed technical school training	☐
Some college	☐
Completed college (2 year or 4 year)	☐
Graduate or professional school after college	☐
Unsure	☐
Refusal	☐

32. What is your current marital or living status?

Married	☐				
Living with Partner	☐				
Single	☐				
Separated	☐				
Divorced	☐	Widowed	☐	Refusal	☐

33. *(If separated or divorced)* **Did your work-related injury contribute to your separation or divorce?**

Yes ☐ No ☐ Unsure ☐ Refusal ☐

Conclusion

Thank you for your participation. We hope that the information you provided helps to stop this from happening to other workers like yourself. If you have requested we send you a mailing packet, please sign the consent/assent form and the medical release form that are included in the packet and return it to us in the enclosed envelope. Thank you very much for your time.

Interview/Interviewee Quality

(To be completed following the interview)

Subject's cooperation was:

- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

The overall quality of the interview is:

- Unsatisfactory ☐
- Questionable ☐
- Generally reliable ☐
- High quality ☐

If *unsatisfactory* or *questionable*, what was the main reason for the quality:

- Could not remember information regarding the topic ☐
- Did not want to be more specific ☐
- Was emotionally unstable ☐
- Was physically ill ☐
- Hostile ☐
- Other reason_____ ☐

_____

_____

N/A ☐

Who answered the questionnaire?

- Injured person ☐
- Mother of injured ☐
- Father of injured ☐
- Male head of the household ☐
- Female head of the household ☐
- Other_____ ☐

Appendix C

IRB Stipulations/Summary

IRB Stipulations by Hospital

Hospital	Mailing Procedure	Introductory Letter Procedure	Consent Form Procedure	Other Requirements
Allina Hospitals – Mercy/Unity Hosptials United Hospital Abbott Northwestern	•Patient invitation packets will be sent through Dr. Buss' office. • 2 mailings required with 14 day waiting period after date of second letter.	• Sent out on Allina letterhead in Allina envelopes.	• Add Allina/Mercy unity IRB contact info to consent/assent form.	
Fairview Hospitals – Ridges University Southdale	• Patient information packets will be sent through MDH. • 1 mailings required with a 14 day waiting period after date of second letter.	• Include statement in intro letter stating the interviewers are trained to in interviewing people with traumatic injuries.	• Note that participants can call collect • State participation will not affect relationship with subjects' employer. • Researchers and their affiliation be identified by name in the introductory paragraphs of the consent form. • Included statement that interviewers are training in interviewing people with traumatic injuries.	
HCMC	• 1 mailing will be sent through the MDH required with14 day waiting period after date of letter.	• None	• None	
HealthEast Hospitals – St. Joseph's St. John's	• 1 mailing will be sent through the MDH.	• None	• None	
Immanuel St. Joe's	• 1 mailing will be sent through the MDH required with14 day waiting period after date of letter.	• Include a brief explanation that the MDH can legally request information from hospitals on serious work-related incidences.	• Reference the MDH working with the hospital on the study.	

IRB Stipulations by Hospital

Hospital	Mailing Procedure	Introductory Letter Procedure	Consent Form Procedure	Other Requirements
Mayo – St. Mary's Rochester Methodist Rochester	• Patient invitation packets will be sent through Mayo. • 1 mailing required.	• Introductory letter sent out through Mayo.	• None	• Mayo to conduct interviewing.
Park Nicollet Health System	• 1 mailing sent out by the MDH required with a 14-day waiting period after date of letter.	• None	• None	
NMMC	• 1 mailing sent out by the MDH required with a 14-day waiting period after date of letter	• Add explanation on how the subjects' name was obtained.	• Add statement explaining any additional cost to the subject that might result from participation. • Add statement that new findings developed during the research, which may relate to the participant's willingness, will be provided to the subject.	• Add statement on telephone consent asking if they had read the accompanying consent form. • Add the number of projected number of participants.
Regions	• Regions will send out participant packets. • 2 mailings, 14-days apart and a 60-day wait after the second letter is being required by the hospital with letters returning to the MDH. • No patient identifiable data will be given to MDH without prior patient consent.	• Intro letter to be signed by David and Dr. McGonigal. • Introductory letters on HelathPartners letterhead. • Use word "along" in replacement of "conjunction."	• See Regions IRB Protocol for numerous consent/assent stipulations.	• Regions PI involvement outlined in letter by Dr. McGonigal.
Rice Memorial Hospital	• 1 mailing sent out by the MDH required with a 14-day waiting period after date of letter	• None	• None	
St. Cloud Hospital	• 1 mailing sent out through the MDH required with a 14-day waiting period.	• None	• Add Linda Chmielewski's name to the contact info on consent form.	

IRB Stipulations by Hospital

Hospital	Mailing Procedure	Introductory Letter Procedure	Consent Form Procedure	Other Requirements
St. Luke's	• 1 mailing sent outthrough MDH rwith a 14-day waiting period after date of letter.	• Add statement to 3rd pp in intro letter – see St. Luke's IRB Protocol for statement.	•	
St. Mary's Duluth	• SMD will sent out invitation packets according to statute. • 2 mailings and 60-day wait is being required by the hospital. • No patient identifiable data will be given to MDH without prior patient consent.	•	•	

IRB Protocol Summary

Hospital	IRB Renewal Date	Mailing Procedure	Introductory Letter Procedure	Consent/Assent Form Procedure	Other Requirements
Allina Hospitals – Mercy/Unity Hospitals United Hospital Abbott Norhtwestern Hospital	7.20.01	Yes	Yes	Yes	Yes
Fairview Hospitals - Southdale University Ridges	10.3.01	No	Yes	Yes	Yes
HCMC	5.17.01	No	No	Yes	No
HealthEast Hospitals – St. Joseph's St. John's		No	No	No	No
Immanuel St. Joseph's	6.1.01	No	Yes	Yes	No
Mayo		Yes	Yes	Yes	Yes
NMMC		No	Yes	Yes	No
Park Nicollet Health System	10.3.01	No	No	No	No
Regions	11.16.01	Yes	Yes	Yes	Yes
Rice Memorial Hospital		No	No	No	No
St. Cloud Hospital	7.19.01	No	No	Yes	No
St. Luke's Hospital	10.25.01	Yes	Yes	No	No
St. Mary's Duluth	10.5.01	Yes	No	No	No

- "Yes" indicates a request from the hospital to alter the specified form to their stipulation. "No" indicates no specific request was made.

Appendix D

Protocol and Contacting Study Subjects

Calling Sequence

• We will call an individual for a **total** of 9 calls.

⇒ Calls will be made Monday through Saturday from 9 am to 8:30 pm.
⇒ Calls will be divided up by the time of day. The time of day periods for Monday thru Friday will be:

9 am-1pm Morning
1-5 pm Afternoon
5-8:30 pm Evening

The time of day periods for Saturday will be:

9 am-1pm Morning
1 pm-5 pm Afternoon

⇒ The 9 calls will be divided up between the time of day periods as follows: 3 times in the morning, 3 times in the afternoon and 3 times in the evening. Of these calls, at least 2 are to be placed on a Saturday.

⇒ The Saturday call requirements are at least two Saturday calls, but there is no maximum. So even after a subject has been called twice on Saturdays, they will still be eligible for subsequent calls on Saturday until we extend the calling protocol or until a refusal or acceptance is given.

⇒ The program will keep count of how many calls the interviewer makes to the subject and the date and time of those calls. Thus, the computer will only bring up those face sheets that are eligible to be called during the time in which the interviewer has signed-in.

• The subject will be considered a refusal by extension of the protocol, if they indicate to us they do not wish to participate (either by mail, message, or while on the phone), they are not reached before the 9 calls are made or if they are deceased.

• A call is considered a call if the call falls under the following definition:

⇒ If the tennison is read requesting to speak with the subject.
⇒ If the subject answers the phone but no interview is given.
⇒ If the interviewer leaves a message on an answering system.
⇒ If an answering system picks up the call.
⇒ The telephone rings indefinitely.

It is ***not*** considered a call when:

⇒ The wrong number was called

• If the interviewer discovers the subject we are trying to reach is deceased; therefore the face sheet will be a refusal.

• If subject is be considered a refusal by extension of the protocol. The face sheet and the information it contains will then be sent to a database collecting records that are refusals by extension of the calling protocol.

⇒ In the event the calling protocol is extended and a majority of the calls were just no answer or answered by an answering system the database that keeps the refusal by extension of the calling protocol can be reviewed to see if calling should resume because of lack of contact.

• If the interviewer calls for any amount of time before extending the protocol, then discovers the subject is to be reached at a number other than what has been called i.e. they have moved, the calling protocol will cleared and started from the beginning the new number.

⇒The program will reset the protocol once the interviewer enters in the new number into the alternate information field in the new number option on the face sheet. The previous calling record that has now been discarded will go into a abandoned subject database, where the number of rejected face sheets and its calling protocol will be recorded.

• If a day and/or time has been suggested, a preferred calling time screen will be used to record up to 3 suggested times. The interviewer is encouraged to obtain 3 different day/time suggestions to contact the subject. By marking a call a priority, that subject's face sheet will be brought up by the program first on the list of calling to be done for the time period the interviewer is calling during. The calling protocol to be followed in instances of "priority calls":

⇒ The subject will be called 3 times for each day/time suggestion.

⇒The priority call protocol is followed until the subject has been reached or when they have been called three times for each day/time suggestion given (note that priority calls will not follow the typical 9-call protocol as with other subjects). So if only two day/time suggestions are given, 3 calls for each time and day will be made, for a total of 6 calls at which time the priority calling protocol will be extended. After which, the subject will be considered a refusal and the case will be thrown out of the eligibility list.

• The subjects also have the opportunity to call in to the 800 phone number and refuse participation, make an appointment for an interview or in some cases ask to conduct an interview in real time. 3/4 staff will man the 800 phone lines and check the voice mailbox for the 800 line. They will be responsible for calling back and entering preferred calling times onto the program. If the interview is tot take place in real time, the interviewer will need a "search" option to pull up a face sheet by name or address.

⇒ In the case of a real time interview, if phone line transfer is possible, the interviewer is to record the subject's name and phone number prior to transferring the call to an interview room in case the line gets cut-off in the transfer. Otherwise the interview can be done from the 3/4 staff computer.

⇒ The interviewer is to verify name, address, and phone for the subject prior to obtaining consent or conducting the interview.

⇒ We will also have to secure the process for transferring a call into an interview room.

⇒ A paper form questionnaire back up will be available if phone line transfers are not possible.

• The calling protocol will be affected by the mailing procedure of the patient information packets for each hospital. Some subjects will receive 1 mailing prior to calling, while others will receive 2 mailings prior to calling for interviews. How the mailings contribute to the calling protocol is as follows:

Subjects receiving 1 mailing

⇒ Those subjects who receive one mailing will be eligible for calling approximately 7 days after the date of the first letter. These subjects who will receive only one mailing will be identified by the hospital.

⇒ Currently the hospitals requiring one mailing are:

HCMC
Immanuel St. Joseph's
North Memorial Medical Center
Park Nicollet Health System/Methodist
Rice Memorial Hospital
St. Cloud Hospital
HealthEast St. Joseph's and Health East St. John's

Subjects receiving 2 mailings

⇒ Those subjects who receive two mailings will be eligible for calling approximately 7 days after the date of the second letter.

⇒ Currently the hospitals requiring two mailings are:
St. Mary's Duluth

• The "completed" button is selected on the face sheet when call transactions prevent the subject to be called again during the present time of day increment.

Message Protocol

• When a subject is not available, and either an answering system or another person answers the phone, the following protocol apples:

• If a person other than the subject answers the phone, ask them when is a good day and time to get a hold of the subject (as is written on the telephone consent form) and select the preferred calling time button on the face sheet to record up to three day and times that the subject can be reached.

• A total of 2 messages will be left. The program will keep a record of the number of messages left as the interviewer selects the "messages left" button on the face sheet. The program will then record the date and time the message is left and the interviewer will record if the message was left with an answering system ("VM") or someone other than the subject ("MO").

• If possible, a message will be left on the first call with either an answering system or a person.

• The 1st message will be:

"Hello, this is <<your name>> I'm calling from the Minnesota Department of Health. We are conducting a study to evaluate the causes of serious work-related trauma and would like to speak to <<name of subject>> about this study. We will try contacting <<name of subject>> later on in the week, but in the meantime we can be reached at our toll free number 877-925-4189 any time between 9 A.M. and 9 P.M. Monday through Saturday. Thank you for your time."

• If the subject is under 18 the first message will be:

"Hello, this is <<your name>> I'm calling from the Minnesota Department of Health. We are conducting a study to evaluate the causes of serious work related trauma and would like to speak to legal guardian of <<name of subject>> about this study. We will try you later on in the week, but in the meantime we can be reached at 612-676-5074. Or if you live outside the Metro area, you can call our toll free number at 877-925-4189 at any time between 9 A.M. and 9 P.M. Monday through Saturday. Thank you for your time."

- The second message if to be left a week after the first message. Once the first message is left and the program records the date and time of the first message, the program will automatically display the date one week from the first message indicating when it is possible to leave a second.

- The script for the second message will be the same as the first.

- Then once the message is left the interviewer will select the "completed" button on the face sheet indicating the program the face sheet is ineligible for calling until a new day/time of day increment is begun.

Calling Protocol

Calling Sequence

- We will call an individual for a **total** of 9 calls.

⇒ Calls will be made Monday through Saturday from 9 am to 8:30 pm.
⇒ Calls will be divided up by the time of day. The time of day periods for Monday thru Friday will be:

9 am-1pm Morning
1-5 pm Afternoon
5-8:30 pm Evening

The time of day periods for Saturday will be:

9 am-1pm Morning
1 pm-5 pm Afternoon

⇒ The 9 calls will be divided up between the time of day periods as follows: 3 times in the morning, 3 times in the afternoon and 3 times in the evening. Of these calls, at least 2 are to be placed on a Saturday.

⇒ The Saturday call requirements are at least two Saturday calls, but there is no maximum. So even after a subject has been called twice on Saturdays, they will still be eligible for subsequent calls on Saturday until we extend the calling protocol or until a refusal or acceptance is given.

⇒ The program will keep count of how many calls the interviewer makes to the subject and the date and time of those calls. Thus, the computer will only bring up those face sheets that are eligible to be called during the time in which the interviewer has signed-in.

- The subject will be considered a refusal by extension of the protocol, if they indicate to us they do not wish to participate (either by mail, message, or while on the phone), they are not reached before the 9 calls are made or if they are deceased.

- A call is considered a call if the call falls under the following definition:

⇒ If the tennison is read requesting to speak with the subject.
⇒ If the subject answers the phone but no interview is given.
⇒ If the interviewer leaves a message on an answering system.
⇒ If an answering system picks up the call.

It is ***not*** considered a call when:

⇒ The wrong number was called.
⇒ The telephone rings indefinitely.

- If the interviewer discovers the subject we are trying to reach is deceased the face sheet will be a refusal.

- If subject is be considered a refusal by extension of the protocol. The face sheet and the information it contains will then be sent to a database collecting records that are refusals by extension of the calling protocol.

⇒ In the event the calling protocol is extended and a majority of the calls were just no answer or answered by an answering system the database that keeps the refusal by extension of the calling protocol can be reviewed to see if calling should resume because of lack of contact.

• If the interviewer calls for any amount of time before extending the protocol, then discovers the subject is to be reached at a number other than what has been called i.e. they have moved, the calling protocol will cleared and started from the beginning the new number.

• If a day and/or time has been suggested, a preferred calling time will be used to record up to 3 suggested times. The interviewer is encouraged to obtain 3 different day/time suggestions to contact the subject. By marking a call a priority, that subject's face sheet will be brought up by the program first on the list of calling to be done for the time period the interviewer is calling during. The calling protocol to be followed in instances of "priority calls":

⇒ The subject will be called only during the preferred calling time until otherwise noted or until extension of the protocol.

• The subjects also have the opportunity to call in to the 800 phone number and refuse participation, make an appointment for an interview or in some cases ask to conduct an interview in real time.

⇒ The interviewer is to verify name, address, and phone for the subject prior to obtaining consent or conducting the interview.

• The calling protocol will be affected by the mailing procedure of the patient information packets for each hospital. Some subjects will receive 1 mailing prior to calling, while others will receive 2 mailings prior to calling for interviews. How the mailings contribute to the calling protocol is as follows:

Subjects receiving 1 mailing

• Those subjects who receive one mailing will be eligible for calling approximately 7 da the date of the first letter. These subjects who will receive only one mailing will be iden the hospital.

• Currently the hospitals requiring one mailing are:
HCMC
Immanuel St. Joseph's
North Memorial Medical Center
Park Nicollet Health System/Methodist
Rice Memorial Hospital
St. Cloud Hospital
HealthEast St. Joseph's and Health East St. John's

Subjects receiving 2 mailings

• Those subjects who receive two mailings will be eligible for calling approximately 7 days after the date of the second letter.

• Currently the hospitals requiring two mailings are:
St. Mary's Duluth
Regions
All Allina Hospitals

Message Protocol

When a subject is not available, and either an answering system or another person answers the phone, the following protocol apples:

- If a person other than the subject answers the phone, ask them when is a good day and time to get a hold of the subject (as is written on the telephone consent form) and ask for a preferred calling time the subject can be reached.

- A total of 2 messages will be left.

- The 1st message will be:

Hello, this is <<YOUR NAME>> and I'm calling from the Minnesota Department of Health. We would like to speak to <<SUBJECT"S NAME>> regarding a study we are conducting. We'll try contacting <<SUBJECT"S NAME>> later on in the week, otherwise we can be reached at 612-676-5074 (outside the Metro area, 1-877-925-4189). Thank you for your time.

- If the subject is under 18 the first message will be:

"Hello, this is << YOUR NAME>> and I'm calling from the Minnesota Department of Health. We would like to speak to the legal guardian of <<SUBJECT"S NAME>> regarding a study we are conducting. We'll try contacting you later on in the week, otherwise we can be reached at 612-676-5074 (outside the Metro area, 1-877-925-4189). Thank you for your time. Goodbye.

- The second message if to be left a week after the first message.

- The script for the second message will be the same as the first.

Calling Protocol Addendum:

The time and effort spent on phone searches have become exhaustive. Hopefully this addendum will address the problems with the current phone search process without compromising the methods and consistency of the interviewing phase.

I. Currently

If a face sheet is called and found to have a disconnected or incorrect telephone number, the phone number is marked as incorrect then the face sheet is placed in "Phone Search" folder in Rm. 338.

A search is conducted to find possible correct telephone numbers, a maximum of 3, for the subject. They are record on the back of the face sheet then put back into the calling rotation.

When the new phone numbers have all been called and if found to be incorrect, are placed back into the "Phone Search" folder.

I. Proposed

The change implemented here is once the face sheet with the new telephone numbers has been called and found to incorrect, the face sheet is marked as a refusal by reason of extension of calling protocol then placed in the refusals folder. This expedites the phone search process.

II. Currently

The face sheets that have phone numbers found to be incorrect and a phone search has been conducted, are placed in circulation with face sheets that have correct phone numbers on them.

II. Proposed

All face sheets that have had phone searches conducted on them will now be placed in their own folder. This will allow more attention to those face sheets that do have correct numbers.

III. Currently

There is no protocol for subjects whose calls are not answered.

III. Proposed

The "No Answer" subjects need have the same protocol as those of which we do get a hold. The difference here is that the "No Answer" calls are not differentiated as non-qualifying or qualifying. If there are 9 no answer calls – three in morning, three in afternoon, three in evening of which two are on Saturdays, they are considered a refusal by extension of protocol. This will not change the qualifying vs. non-qualifying calls for those people of which we are able to get a hold.

Additional Changes in Protocol:
1. No phone searches that result in first initial, last name.

Calling Protocol Addendum 2:
PCT

Staying consistent with the 9 calling attempts, it is important that this limit being imposed on the subjects that have been marked for calling during a specific time period i.e. mornings, afternoons, evenings.

I. Currently

If a face sheet in placed into one of the four PCT folders (mornings, afternoons, evenings, Saturdays) it is called indefinitely.

I. Proposed

The subject will be called 9 times during the time period requested. Of these 9 calls two should be done on Saturdays.

In the event the face sheet switches out of one PCT folder and into another (formerly was requested to be called during afternoons, then instructed us to call during the evenings), the 9 calls carries forward with the face sheet. IT DOES NOT reset with a new time period.

Mailing Protocol

Procedures for *hospitals* that are mailing out patient information materials and require:

2 letters and a 60-day wait prior to calling[1]

- *For the first mailing,*
  ⇒The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒ The MDH will deliver mailing packets and aid the hospital administration in the labeling and mailing process if the hospital so desires.

- *For the second mailing,*
  ⇒ All refusals or acceptances from the first mailing will be reported to the hospital (electronically and by hard copy) so that these patients do not receive a second mailing[2].
  ⇒The MDH will again print up all materials including, second mailing information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒The MDH will deliver mailing packets and aid the hospital administration in the labeling and mailing process if the hospital so desires.

- *After the 60 day waiting period has passed*
  ⇒ Dated from the second information letter, all refusals and acceptances from the second mailing will be recorded (by either the MDH or the hospital in instances the hospital requires the information be sent back to them).
  ⇒ A list of remaining potential participants will be electronically received from the institution with or without identifiers.
  ⇒ If without identifiers, there will need to be some sort of list with id number and corresponding name/address for calling purposes. These patients will then be called according to the calling protocol in order to obtain consent/assent for participation in the study. This will affect the face sheet as it would be displayed by id # only; no name would be displayed on the face sheet or inserted into the tennsion.

2 letters prior to calling

[1] Some hospitals require they conduct the screening and/or calling process, in the case of Mayo, therefore we will not receive a list of potential subjects to call.
[2] Except in the case where the hospital's request the response materials be mailed back to the hospital. In this case the response postcard and self-addressed stamped envelope will have the hospitals address.

- *For the first mailing*,
  ⇒ The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒The MDH will deliver mailing packets and aid the hospital administration in the labeling and mailing process if the hospital so desires.

- *For the second mailing*,
  ⇒ All refusals or acceptances from the first mailing will be reported to the hospital (electronically and by hard copy) so that these patients do not receive a second mailing[3].
  ⇒ The MDH will again print up all materials including, second mailing information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒ The MDH will deliver mailing packets and aid the hospital administration in the labeling and mailing process if the hospital so desires.

- Calling will begin 2 weeks after the date on the second information letter. The list of potential participants, minus the refusals or acceptances from the second mailing, will then be received electronically from the hospital and called according to the calling protocol.

1 letter prior to calling

- The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail. The MDH will deliver mailing packets and aid the hospital administration in the labeling and mailing process if the hospital so desires.

- Calling will begin 2 weeks after the date on the information letter. The list of potential participants, minus the refusals from the mailing, will then be received electronically from the hospital (except in cases where the materials are returned to the hospital) and contacted for consent/assent.

[3] Except in the case where the hospital's request the response materials be mailed back to the hospital. In this case the response postcard and self-addressed stamped envelope will have the hospitals address.

Procedures for *MDH* mailing out patient information materials and hospitals requiring:

2 letters and a 60-day wait prior to calling[4]

- *For the first mailing*,
  ⇒ The MDH will receive a list of potential participants from the institution electronically and will run mailing labels from this list.
  ⇒The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, labels and envelopes. These materials will be collated into packets ready to mail.
  ⇒ HPR and support staff will prepare the packets and mail them out in volumes deemed acceptable in terms of processing responses.

- *For the second mailing*,
  ⇒ All refusals or acceptances from the first mailing will be recorded (electronically and by hard copy) so that these patients do not receive a second mailing.
  ⇒ The MDH will run mailing labels for a second mailing from the edited list of potential participants.
  ⇒The MDH will again print up all materials including, second mailing information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒ HPR and support staff will prepare the packets and mail them out in volumes deemed acceptable in terms of processing responses.

- *After the 60 day waiting period has passed*
  ⇒ Dated from the second mailing information letter, and all refusals and acceptances from the second mailing have been recorded (by either the MDH or the hospital in instances the hospital requires the information be sent back to them), a list of remaining potential participants will be generated. These patients will be called in order to obtain consent/assent for participation in the study and the calling protocol will then be applied.

2 letters prior to calling

- *For the first mailing*,
  ⇒ The MDH will receive a list of potential participants from the institution electronically and will run mailing labels from this list.
  ⇒ The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital

[4] Some hospitals require they conduct the screening and/or calling process, therefore we will not receive a list of potential subjects to call.

requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
⇒HPR and support staff will prepare the packets and mail them out in volumes deemed acceptable in terms of processing responses.

- *For the second mailing*,
  ⇒ All refusals or acceptances from the first mailing will be recorded (electronically and by hard copy) so that these patients do not receive a second mailing.
  ⇒ The MDH will run mailing labels for a second mailing from the edited list of potential participants.
  ⇒The MDH will again print up all materials including, second mailing information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail.
  ⇒HPR and support staff will prepare the packets and mail them out in volumes deemed acceptable in terms of processing responses.

- Calling will begin 2 weeks after the date on the second information letter. The list of potential participants, minus the refusals or acceptances from the second mailing, will then be contacted for consent/assent.

1 letter prior to calling

- The MDH will receive a list of potential participants from the institution electronically and will run mailing labels from this list. The MDH will print up all mailing materials including, information letter (on MDH letterhead unless otherwise requested from hospital), consent/assent forms, refusal postcard, physician letter (if hospital requires), medical release form, and envelopes. These materials will be collated into packets ready to mail. HPR and support staff will prepare the packets and mail them out in volumes deemed acceptable in terms of processing responses.

- Calling will begin 2 weeks after the date on the information letter. The list of potential participants, minus the refusals from the mailing, will then be contacted for consent/assent.

Mailing Protocol Chart

Hospitals Requiring 1 mailing via MDH
HealthEast Hospitals – St. Joseph's St. John's
Fairview Hospitals - Southdale University Ridges
Hennepin County Medical Center
Immanuel St. Joseph's
North Memorial Medical Center
Park Nicollet Health System
Rice Memorial Hospital
St. Luke's Hospital
St. Cloud Hospital
Hospitals Requiring 1 mailing via their institution
Mayo – Methodist Rochester St. Mary's Rochester
St. Luke's Hospital
Hospitals Requiring 2 mailings via their institution
Allina Hospitals – Mercy/Unity Hospitals United Hospital Abbott Norhtwestern Hospital
Regions
St. Mary's - Duluth

10.09.01

CALLING SCHEDULE

NAME:_____

PHONE:_____

NA-No Answer B-Busy
NN-New Number R-Refusal
AM-Answering Machine CB-Call Back

* For each call attempt, write the date, response code, and your initials

Times	Trys	Mon	Tues	Wed	Thur	Fri	Callback Info
4:00 - 6:30 PM	2						
6:30 - 9:00 PM	3						
7:30 - 12 Noon	1						
Noon - 4 PM	1						
SAT 9-N	1						
SAT N-2 PM	1						

Appendix E

Interviewer Training Manual

Surveillance of Serious Work-Related Trauma

Interviewer Training Manual

Minnesota Department of Health
Chronic Disease and Environmental Epidemiology

Table of Contents

Background Information on Work-Related Injury in Minnesota

The latest Minnesota Department of Labor and Industry (DLI) figures show that about 450 Minnesotans are hurt at work or become ill from a job-related cause each day, amounting to approximately 165,000 cases a year. Compensation for these cases came to an estimated $1.0 billion in Minnesota in 1998. However, this estimate is conservative as it ignores costs associated with delayed production, hiring and training of replacement workers, underreporting of work-related injury, and the economic losses due to pain, suffering and home care provided by families. Overall, workplace injury occurrence over the past decade has dropped, possibly because in the 1990's, the largest employment sector increase occurred in the services industry and professional specialty occupations such as computer engineering and computer systems analysts. These occupations have lower injury rates, which might coincide with the decreasing workplace injury rate. But it cannot be proven if the decrease is due to a shift in the job market away from the industrial labor professions and towards skilled professional careers.

Minnesota's occupational injury rates have been above the national average since 1993. The U.S. incidence rate of occupational injury is 6.7 injured workers per 100 full-time workers (Full Time Equivalent), while Minnesota's occupational injury rate is slightly higher at 7.7 injured workers per 100 FTE. The Department of Labor and Industry also tracks the number of "lost work days" (LWD) an employee is not on the job. Minnesota's LWD rate of 3.4 lost workdays per 100 full-time workers is higher than the national LWD case rate of 3.1 lost workdays per 100 FTE since 1995 (see Appendix D, Figure 2).

According to the DLI, the incidence rate of workplace injury by industry and establishment where total cases are concerned, reveal that state government construction has the highest rate of workplace injury at 13.3 cases a year per full-time employee. This is followed by private sector construction, manufacturing, agriculture, forestry and fishing, finance, insurance and real estate (see Appendix D, Figure 4). The most frequently occurring types of injuries are sprains, strains, and tears of muscles, tendons and joints with 46% of the cases falling under this category (see Appendix D, Figure 16). Other injury types seen are open wounds (8% of cases), surface wounds and bruises (8% of cases), fractures and dislocations (7% of cases) and burns (2% of cases). The remaining cases were systemic diseases (a disease that affects the whole body) and disorders such as musculoskeletal or nervous system disorders, which are not included in this study's case definition. A majority of injuries (42% of cases) take place in the trunk of the body, mostly the back. Other parts of the body include the upper extremities, i.e. the fingers, hands, wrists, and lower extremities, i.e. the knees, ankles, and feet (see Appendix D, Figure 17). Six percent of the work-related injuries involve the head, including the eyes, neck and throat. The cause of such injuries tend to be overexertion while lifting, reaching, or bending. The next most frequent cause was contact with objects or equipment. For example, being struck by an object or being caught or compressed by equipment. The remaining causes are a result of falls, exposure to harmful substances, or transportation incidents.

A major source of non-fatal, work-related injury in Minnesota we will encounter during this study will result from farming accidents. These accidents vary in degree and source of injury. Nineteen percent of farming injuries in 1993 resulted from handling livestock, while other injuries were from hand tools, tractors, or working surfaces (i.e. falling, slipping). In a similar Wisconsin agricultural region, one out of 31 farm residents was

treated every year for farm work-related injuries. The demographics of those injured are mostly men, but injuries to children and women account for a respectable percentage of farm injuries. Agricultural employees age 16 and older totaled 3.2 million in the year 1993. A National Institute of Occupational Safety and Health survey also looked at race in farming revealing an overwhelming majority (92%) of farm injuries occurred in Caucasians. Hispanics made up 6.3% while American Indians made up 1.5% of farm injuries.

Of course, agriculture is not the only occupation in which adults or children are employed. The Bureau of Labor Statistics analyzed worker's compensation claims for adolescents and found that 72% of the claims were males age 16 and 17. Lacerations and punctures were the most frequent types of injury followed by sprains and strains. The more serious injuries, such as fractures, dislocations and amputations, were the least likely to occur with 6% of the claims being these types of injuries. The most frequently listed occupations of these claims were service workers (e.g. a fast food cook) and laborers.

Project Purpose

Each day an estimated 36,000 employees are injured while on the job in the United States. Current occupational safety and health surveillance efforts show us that a total of 5.7 million work-related injuries were recorded in 1997. The economic and medical costs associated with these injuries are as much as cancer and heart disease combined. These figures represent various types of injuries including serious traumatic injuries.

Although existing data is limited, there are indications that serious work-related traumatic injury is a major, yet largely undefined problem both nationally and within Minnesota. For that reason, the National Institute for Occupational Safety and Health (NIOSH), requested proposals for developing and evaluating methods to describe workplace hazards, exposures, and risk factors to promote the early recognition and prevention of workplace illness or injury. The MDH's Center for Occupational Health and Safety was awarded a NIOSH grant titled "*Surveillance of Serious Work-Related Trauma*" in October of 1999 to investigate issues surrounding occupational injuries.

One major goal of this project is to establish a surveillance system that accurately measures the occurrence of serious traumatic injuries and establish preventative measures to avoid serious occupational injuries. Such a system would enable us to better understand the magnitude, distribution, cause, outcomes and trends of these serious injuries. To reach this goal, we will determine a statewide incidence rate of serious work-related trauma, look at disability as an outcome of the injury, and ascertain how disability varies within type of industry, occupation and injury. In order to determine a statewide incidence rate, data on serious traumatic injuries from the year 2000 will be collected from a sample of Minnesota hospitals. The number of serious occupational injuries found in this database will be compared to the 2000 data collected from the nine Minnesota trauma centers. The comparison will then be able to tell us if it the trauma center database alone can be used to represent the type of serious work-related traumatic injuries admitted to both the hospitals and the trauma centers.

At present, there are several different definitions for occupational injury but there is no standardized definition for a serious work-related traumatic injury. Because of this, it is difficult to monitor occurrences of injuries as not everyone agrees to what constitutes the severity of an injury. A second goal of this study is to determine an inclusive definition for serious traumatic injuries – one that all parties interested in occupational injuries (workplaces, government, insurance, medical care, etc.) can use when evaluating traumatic injuries. In order to establish a uniform definition we must investigate the cases of serious work-related trauma. Approximately 6000 patients with occupational injuries will be interviewed to learn more about their work-related injury and the issues surrounding it. To identify candidates for interviewing, we have established a set of criteria that needs to be met in order to be a subject in the study. This set of criteria uses many different types of ailments and circumstances in which the injury occurred to delineate who is a candidate for inclusion in our study. The set of selection criteria we will use to identify potential study participants is discussed below.

Preventing occupational injuries depends on our ability to quantify and track them. Surveillance helps target prevention activities to the industries and occupations that have the greatest needs. Surveillance also expands our knowledge about which prevention programs are effective. The ability to survey and assess the status of occupational health and safety has improved over time, yet surveillance data remain fragmented – collected for different purposes by different organizations using different definitions for work-related injuries. These gaps in data make it difficult to quantify the incidence of work-related injury as well as characterize the overall health of working Americans.

Selection Criteria

We selected twenty hospitals and trauma centers around the State of Minnesota to participate in this study. These hospitals reported to us the number of injuries that met our study's selection criteria. We received about 25,000 names of patients from which we will randomly select 6000 names to participate in our study.

There are two primary criteria that must be met in order for patients to be eligible for this study: 1) the injury must have taken place at or because of work, and 2) the type of injury sustained be one of the study's selected injuries. The injuries and ailments that could result from an occupational injury are taken from the International Classification of Diseases (ICD-9) reference book. Hospitals use this reference book to code the diagnosis a physician gives a patient. When a doctor examines a patient and determines a diagnosis, the diagnosis is then assigned a corresponding code from the ICD-9 book. These codes are numbered and each number sequence pertains to a certain injury or ailment. For example, the code sequences used in our selection criteria are:

Fractures – 800-829
Dislocations – 830-839
Concussions – 850-859
Internal Injury – 860-869
Open wounds – 870-899
Vascular injury – 900-904
Burns – 940-949
Crush injury – 925-929
Foreign body – 930-939
External causes – 990-994

E-codes are another way of classifying injuries and illnesses. These codes are also part of the ICD- 9 reference book but refer to the environmental events, conditions and circumstances as a cause of the injury. E-codes are also included in our selection criteria as a way to determine whether or not to include an injured person in our study. For example, some of the E codes we are using in our selection criteria for work-related injury are:

Vehicles – E800-E848
Workplaces (excluding homes) – E849
Falls – E880-E888
Fires – E890-E899
Work drowning – E910.3
Suffocation – E912-E913
Accidents (excluding drugs, self-inflicted incidents) – E916-E926
Assaults – E960-E968
Toxic exposures – E860-E869

These ICD-9 and E codes are used with the additional criteria listed below to establish the set of selection criteria identifying eligible participants:

- Minnesota residents only
- Non-fatal injuries only
- Work-related injuries only
- Patients age 14 and 65 years at the time of injury
- One or more of the following types of treatment or care received: minimum length of stay (LOS) within a hospital = 1 day **AND/OR** been given anesthesia

If a patient qualifies for each of the selection criteria components, he or she is an eligible case to be interviewed. If at any time the patient fails to qualify for one of the requirements, they will be dropped from the potential pool of participants. The flowchart in Appendix B diagrams the process a patient goes through in order to be eligible for interviewing.

Participant Knowledge About the Study

A duplicate packet of the letters and forms sent to potential participants is located in Appendix E. Every hospital has an Institutional Review Board (IRB) that determines how a study will affect their patients and how they can legally protect their patients from being exploited or violated in any way. As each hospital is acting under its own legal guidelines, it is important to note that each hospital has slightly different requirements for Tennessen[1], mailing procedures, and waiting periods between mailing and calling participants. Every form and contact that reaches the patient has been reviewed and approved by the IRB's. Because of this, we must follow every mailing, calling, and contacting protocol the hospitals decided on. If we do not follow what is dictated by a hospital, they have the right to pull all their patients from the study and/or pursue legal action. All of the protocols will be made clear so that there will be no confusion during the study.

[1] Minnesota statute 13.04 is commonly referred to as the "Tennessen" warning or notification. It states the purpose and intended use of the data collected in the study, whether the individual may refuse, any consequence of participating or not participating may have for the subject, and who will have access to the data.

Making Contact

With our participant pool, we will conduct telephone calls in an attempt to contact the patient for interviewing. Prior to a telephone call, the MDH and/or participating hospitals will have sent out a mailing packet to the subject. This packet will include a letter of introduction to the serious trauma study, refusal card allowing subjects to decline or accept participation, consent forms and assent forms (for those patients under 18) and medical release forms in the event we need to have access to their medical records. Once the mailing packets are sent we will wait the required period of time, determined by the patient's hospital, before contacting the potential participants by phone. Some hospitals require a 14-day waiting period before contact; others require a 60-day wait.

Some of the patients may send back the consent form agreeing to participate, some may send back the refusal card letting us know they are not interested, and yet others might not respond at all. **It is important to remember that participation is voluntary**. We will do our best to track those who wish to participate and those who do not in order to avoid calling someone who has requested to be eliminated from the study. Any participant who does not want to be involved in the study at any time may decline to be interviewed. The subject will be called according to a *calling protocol* which is discussed in detail later in the manual. It states how many times a subject should be called before he or she is considered a refusal. We hope most of the calls made will result in reaching the subject who agrees to participate. Those who agree need to be handled with courtesy and professionalism to assure the quality of the interview.

Study participants usually respond more to the interviewer than to the content of the questions they are asked. The interviewer's tone of voice, style of asking questions, and patience in explaining the study or answering questions will determine the cooperation you receive. The respondent will probably remember more about the interviewer and how the interview was conducted than he or she will about the interview content. Thus, it is important for the interviewer to be professional, capable, courteous, and non-judgmental. The intent of the interviews is to collect information regarding work-related injury, not to evaluate the participant.

Some factors that will increase the participant's receptiveness are:

- **The participant and the interviewer need to establish a good rapport.**

  "Rapport" describes the personal relationship between the interviewer and the participant. Rapport provides the foundation for a good interview. The participant's impression of the interviewer during the introduction and early remarks will determine the rapport that will develop. The interviewer needs to impress the respondent as being someone who is understanding, accepting, sincere and courteous.

- **The participant needs to see the study as being important and worthwhile.**

  The extent to which an interviewer might have to explain the study will vary considerably from participant to participant. All participants should have received a letter explaining the study prior to contact, but many might not have read through the materials they were sent or never received it due to an incorrect address. Even if they are familiar with the study, they still may have several questions. Therefore, be prepared that they might not cooperate completely at this point. Take the time needed to assure the participant as to the importance of the study and that their participation is meaningful and appreciated.

- **Any barriers the participant feels about the interview need to be overcome.**

  Usually the participant will be polite enough to let the interviewer talk. The interviewer must use this opportunity to his or her advantage and be alert to doubts the participant may have even if they do not express them directly.

Asking the Questions

The interviewer's goal is to collect information through the use of the questionnaire. Data from the study participants must be collected in a uniform manner. Thus, all people selected for the study must be asked each question in the same way.

The following principles and techniques must be employed when using the questionnaire.

- Always remain neutral in your tone of voice when asking a question. Nothing in your words or manner can imply criticism, surprise, approval or disapproval to the question or to the respondent's answer. Put simply, another interviewer when asking the same question should solicit the same response from the respondent.

Ask yourself or a partner the following question with different inflections of your voice implying criticism, surprise or approval. See how the tone of your voice can change the message conveyed:

> ***"How long were you out of work due to your injury?"***

- Ask all the questions as worded! Many times changing just one word from what is printed can affect the whole meaning of the question. Simply repeat the question when the need arises. If you repeat the question, read all the words in the question as written even if you feel the question could be worded more simply. Do not improvise on the method of asking questions or further explaining the question.

Ask the following question as is, then try to change a word or two to see how it affects the direction or overall meaning of the question:

> ***"Do you feel your injury has caused you to be isolated from your friends or family?"***

- Attempt to keep the interviewee focused on the questionnaire without being dismissive, abrupt or disinterested in their concern or question.

How would you treat a participant who went on and on about their financial stress when the question you asked them pertained to the pain they have from their work-related injury?

Probing

Probing is the technique used by the interviewer to stimulate discussion and obtain more information in order to meet the needs of a question. A question may have been asked in the uniform manner as described above, but more data is required to fully answer the question. Probing can collect further information. Probing is applicable when the answer may be inadequate in meeting the goals of the question. Thus, you the interviewer must know the goal of each question (there is a section in this manual that explains the goal of each question on the survey). Probing has three major functions:

1. To motivate the participant to expand upon, clarify, or explain his/her answers.
2. To focus the participant's answers so that irrelevant and unnecessary information can be eliminated.
3. To pinpoint objective information, such as dates and names as accurately as possible.

This must be done without influencing the response or antagonizing the participant. The potential for introducing bias during probing is great. Under the pressure of the interview, the interviewer may unintentionally imply that some answers are more acceptable than others or hint that a participant might want to consider this or include that when giving a response. Do not lead a participant into a response. You must fully understand the objective behind each question. Once you understand the purpose of a question, you will find it much easier to decide if you have a satisfactory answer or whether you should probe for a clearer, more complete answer.

Kinds of Probes

A number of different neutral probes, which appear as a part of normal conversation, can be used to stimulate a fuller, complete response. These neutral probes can be accomplished by:

1. Providing an expression of interest and understanding
2. Providing an expectant pause
3. Repeating the question
4. Repeating the participant's reply
5. Providing a neutral question or comment

Types of Probes

Probes to clarify:

- What do you mean exactly?
- What do you mean by...?
- Could you please explain that a little more?
- I don't think I understand.
- So what you're telling me is...

Probes for specificity:

- What in particular do you have in mind?
- Would you be more specific about that?
- Tell me about that.

Probes for data specificity:

- Were you working at that time?

Probes for relevance:

- Could you explain to me exactly what you mean?

Probes for completeness:

- Are there any other ____ you can think of?

One way to ask these questions without offending the participant's answer is to give the participant some power in the interview by taking the blame of not understanding his/her response yourself. Know when to stop probing by evaluating if you have enough information as possible from the participant and you know exactly what the participant has in mind. If at any time the participant becomes irritated or annoyed, discontinue probing.

Answering Questions

As previously mentioned, the subject may or may not be familiar with the study when we call them. Therefore, he or she might have some questions pertaining to the study or the questionnaire. Some typical questions are listed below. These questions are likely to be asked by the participant when you make the initial phone contact, so be prepared to answer them. They include:

- Why are you interviewing me?
- Who gave you my name?
- Why are you doing this study?
- Who will see the information I give you?
- How will the information be used?

Again, you must have ready and convincing answers to these questions. Examples of what to say are listed below.

Why are you interviewing me?

"We are calling thousands of people who may have been injured while at work in order to collect information that will help us to learn more about work-related injuries so we can help prevent them from happening in the future."

Who gave you my name?

"We received your name and address from <<name of hospital>> hospital which is one of many hospitals we are working with to collect information on serious work-related trauma cases. As the state agency for health, the Minnesota Department of Health is authorized to collect information about diseases and injuries that occurred as a result of employment."

Why are you doing this study?

"Minnesota has more lost days of work compared to the national average. We are trying to determine the extent of who is injured and in what industry they worked in, i.e. agriculture, manufacturing etc. This information will help us to define what steps we can take to prevent these injuries in the future."

Who will have access to the information I give?

"All the information you give is kept confidential and is not shared by the Health Department with anyone. Any names or identifying material such as your address and phone will be kept in password protected files in locked offices. Only project employees assigned to the database will have access to the information you give. These employees have also signed data privacy and confidentiality agreements."

How will the information be used?

"The information will be summarized into statistics. The summaries produced will then be analyzed in a report, distributed to the CDC (Centers for Disease Control), and submitted to medical and industrial health journals. No names or other identifying materials will be used in these reports and as a participant you may request a copy of any publications which result from this study."

Why didn't the hospital ask me first before giving you my name?

YES was marked in their medical record about participating in medical research:

> "You marked YES on your medical record to a question that asked if you would be willing to participate in medical research. This allows the hospital to release medical information on patients to research projects that the hospital determines to be safe and ethical."

NO was marked in their medical record about participating in medical research:

> "The Minnesota Department Health as the governing agency on health is authorized to collect certain types of health information. The hospitals are also responsible for reporting this information to the Department of Health. Any personal identifying information is confidential and will not be used in any reports resulting from this study."

Will my employer get information from this?

"No. None of your personal information will be passed on to your employer, nor will they know of your participation in the study."

Can I refuse to give you the name of my employer or any other information I don't want to give out?

"Yes. At any time you can refuse to answer any question or reveal any information with which you do not feel comfortable. But just to reassure you again, if you decide to release this information to us, please understand that it will be kept private and your employer will not find out."

Why do you want to know....?

This question is very broad and can be about almost anything. One of the variables asked about may be the address. An employer's address is requested because a company might have several different addresses that have different job responsibilities. For example, 3M has several locations; some of which are research labs, while others are administrative.

Question Clarification

As previously mentioned, it is important to be careful when the subject asks for clarification after hearing an interview question. Instinct propels us to re-word the question into our own words to make understanding quick and efficient. Unfortunately, this challenges the approved format of the questionnaire. To have a reliable study with data that has been consistently collected, each subject must be asked the same question in the same manner. The proper thing to do in this situation is to read the same question again, with the same words, slowly and clearly. If they ask the definition of a certain word or concept, it is okay to give it to them. The questions are all fairly clear and straightforward however, so hopefully you won't run into this situation often.

Getting the Subject Back on Track

Often when an interviewer asks a question, the subject begins to answer then veers off on a tangent that might be interesting but is not useful in answering the question. In cases like this, lead the subject back to the question very tactfully in order to prevent him or her from feeling insulted. An offended subject is an uncooperative subject.

First, you must identify to yourself what part of the question is not being answered. Second, focus on where the misunderstanding is taking place and try to identify this area for the subject. If this is narrowed down and asked of the subject, the subject does not need to repeatedly ask for clarification. This is why it is so important for every interviewer to understand the "point" of every question. Most of the questions are very straightforward (e.g. "what is your name"), but a few get a little more complex. If you ask a question about whether pain is preventing the subject from getting back to his or her job, you may get many different answers and interpretations of this question. The interviewee could ask you to define 'pain'; he or she could be vague about what work is affected; he or she could have several injuries and describe each one without ever helping you understand what it is they do at work and why they can't do it anymore.

For example, you ask the subject about pain and the subject launches into all the different kinds of pain she has had in her life. How her arthritis is horrible, have you ever had arthritis, what her doctor thinks about arthritis, how she has to take a million pills a day and do you have any idea how useful those little plastic packets with the lids labeled every day of the week are. This would be the time where you listen as patiently as you can and then respond with something like, "that sounds horrible, Mrs. Crutches; how has that affected the way you are able to function at work?" Lots of "uh-mm's" and such let her know you are listening. Then ask something that differentiates between her other kinds of pain and the serious trauma related pain. Her arthritis, however awful, cannot be the factor that is listed as pain that keeps her from work unless it is *DIRECTLY* related to her work-related injury. Just keep gently guiding her back to what you know needs to be answered. Questions to help guide her are things like, "so is it just too painful to stand for eight hours at a time now?" or "were you able to do this job without pain before the accident?" or even just " does your pain keep you from doing your work?"

Challenging Subjects

Unfortunately you will run into "difficult" callers and they will make you want to hand in your room key, MDH ID and not come back. So, how should they be handled? They

seem to fall into two major types: harried and harassed, and hostile. Here are some examples of each and ideas on how to react to them.

Harried and Harassed

You call a subject and once he hears your request, he starts complaining: "I don't have any time. Why are you calling me? This is a really bad time. We're laying carpet and the house is a mess. I have six kids over here and everything is chaos. Oh, and my plumbing exploded..."

> ➢One could label these the "harried and harassed" subjects. They are often straddling the line of refusing the interview or needing to vent. Usually the best thing to do is listen to their frustrations and comfort them. Say things like "that's awful", or "that sounds exhausting", or "how very frustrating!" Most people calm down a bit when they have a chance to unload a bit on a lent ear. Once they return to pacified levels, assure them that they do not need to complete the interview now and ask them when the best time would be to call. Suggest times that feel distant, like three or four days away. **We would rather put off the interview a little than have them refuse.** They usually begin to even laugh a little bit (probably in relief) once they know that you are not just one more person demanding something from them.

Hostile

Another type is the "hostile" subject. These subjects can respond in many different ways, ranging from hanging up on you, being "short" or rude, swearing and yelling insults, or making other horrible statements. These types of interviews are very rare and are somewhat out of your hands.

> ➢ Try your best and, at all times, remember that you are representing the MDH. Obviously, if the subject treats you with little respect and hangs up on you after your first question, you cannot call them back and give them a piece of your mind. Instead, they are to be recorded as a refusal. If the hostile person does not seem to be the subject you wish to reach (for example, you are trying to reach Dick Smith and a woman hangs up on you), write this down in the comments portion of the face sheet and call back a few days later. There are also some people who remain nasty the whole time but are still willing to have an interview coaxed out of them. Do your best, and remember: you do not have to take abuse. If someone is being extremely rude or hurtful and you don't feel up to handling the call, please spare yourself and follow difficult caller protocol explained below. We want to avoid this as much as possible, but we trust your ability to judge the situation. If a situation like this happens, please let someone know so that we can track the occurrences.
>
> Do everything you can to get through the phone call. Make every attempt to complete the phone call before handing it off to your supervisor (another study in our section made 650 phone contacts without ever having to hand it off to someone else). Hostile calls aren't seen as common occurrences, if they happen at all, but in the event it does happen you should be prepared. The best indication that you should hand off the phone call to the supervisor is when the quality of the interview has degraded to a point that the information gathered would no longer be reliable. Reasons for this are hostility, failure to cooperate, and mental instability.

Protocol for Handling Difficult Calls:

1. Take a deep breath and remember that you are representing the MDH. Be polite. The calls are not personal and should not to be taken in such a way. These people don't know you from Adam and are only reacting because of their feelings due to an invasion of privacy; they're busy, etc.

2. Determine if fear may be causing them to be hostile or hesitant with you. These fears may result from fear of us shutting down their business or work environment, causing them to lose their job, causing problems for them at work, what the purpose of the interview is, what the interview will be used for, fear of legal action, medical privacy, etc. All these topics are covered in the *Answering Questions* section so that you will know how to answer these concerns. Take information that they present you as reasons they are uncomfortable or upset in order to be able to reassure them.

3. If the subject remains uncooperative, tactfully ask if we could call them back at a later time. The supervisor will be the one to place that phone call, although it is best if the subject is unaware the or she is being classified as a difficult caller and that a supervisor will be calling back. Follow the protocol for setting up the best time to call back. Be sure to make comments on the memo field that prepare the next caller for making the call. A polite way to exit the conversation is: "Sir/Ma'am, maybe I caught you at a bad time. Would it be all right if someone called you back at a later time?"

4. If they refuse to be called again and do not wish to continue the interview, thank them for their time, wish them a wonderful day, hang up, and make note of your experience with the caller in the notes field.

5. Inform your supervisor about the results of the interview.

Self-Care

Handling unpleasant callers is a good time to talk about self-care as an interviewer. This job ranges from being very challenging and interesting to somewhat monotonous. If you notice yourself getting unfulfilled, please do something about it. The more unmotivated an interviewer is, the less the quality of the interview. Most people cannot do more than two or three hours of calling at a time. Sometimes it is possible to section your time interviewing so it is only done an hour or two at a time. In between interviewing periods, do something like read an interesting book, go on a walk, or do some other diverting activity. While this time is not paid, it is useful to take your mind off interviewing and help you be relaxed and motivated the next time you call subjects.

Self-care also is important when you have just handled a difficult caller. Although such calls happen rarely, it is essential to know how to react to them. Dealing with an unpleasant person usually results in unpleasant feelings for the interviewer, which is completely understandable. After the phone call, please take the time you need to calm down. If you need to, find someone to talk to in our group or take a walk. This is time that is again unpaid, but is invaluable in doing your job well.

Privacy Statements

All personal information obtained from the participants is confidential. Do not discuss it with those who are not involved in the study. All information is kept in locked offices at the Department of Health. The only people with access to these records are employees on the Serious Trauma study. As an employee of the MDH you are held responsible for maintaining data confidentiality. Breaches of privacy will have consequences as outlined in the sections of data privacy agreements signed by all employees on this project. If you have any questions about data privacy, please talk to your supervisor. All of this information is disclosed to potential participants in the mailing packet they received, and also in the consent/assent forms they will sign if they agree to participate.

Calling Protocol

Calling Sequence

- We will call an individual for a **total** of 9 calls.

  ⇒ Calls will be made Monday through Saturday from 9 am to 8:30 pm.
  ⇒ Calls will be divided up by the time of day. The time of day periods for Monday thru Friday will be:

  9 am-1pm Morning
  1-5 pm Afternoon
  5-8:30 pm Evening

  The time of day periods for Saturday will be:

  9 am-1pm Morning
  1 pm-5 pm Afternoon

  ⇒ The 9 calls will be divided up between the time of day periods as follows: 3 times in the morning, 3 times in the afternoon and 3 times in the evening. Of these calls, at least 2 are to be placed on a Saturday.

  ⇒ The Saturday call requirements are at least two Saturday calls, but there is no maximum. So even after a subject has been called twice on Saturdays, they will still be eligible for subsequent calls on Saturday until we extend the calling protocol or until a refusal or acceptance is given.

  ⇒ The program will keep count of how many calls the interviewer makes to the subject and the date and time of those calls. Thus, the computer will only bring up those face sheets that are eligible to be called during the time in which the interviewer has signed-in.

- The subject will be considered a refusal by extension of the protocol, if they indicate to us they do not wish to participate (either by mail, message, or while on the phone), they are not reached before the 9 calls are made or if they are deceased.

- A call is considered a call if the call falls under the following definition:

  ⇒ If the tennison is read requesting to speak with the subject.
  ⇒ If the subject answers the phone but no interview is given.
  ⇒ If the interviewer leaves a message on an answering system.
  ⇒ If an answering system picks up the call.

It is ***not*** considered a call when:

  ⇒ The wrong number was called.
  ⇒ The telephone rings indefinitely.

- If the interviewer discovers the subject we are trying to reach is deceased the face sheet will be a refusal.

• If subject is be considered a refusal by extension of the protocol. The face sheet and the information it contains will then be sent to a database collecting records that are refusals by extension of the calling protocol.

⇒ In the event the calling protocol is extended and a majority of the calls were just no answer or answered by an answering system the database that keeps the refusal by extension of the calling protocol can be reviewed to see if calling should resume because of lack of contact.

• If the interviewer calls for any amount of time before extending the protocol, then discovers the subject is to be reached at a number other than what has been called i.e. they have moved, the calling protocol will cleared and started from the beginning the new number.

• If a day and/or time has been suggested, a preferred calling time will be used to record up to 3 suggested times. The interviewer is encouraged to obtain 3 different day/time suggestions to contact the subject. By marking a call a priority, that subject's face sheet will be brought up by the program first on the list of calling to be done for the time period the interviewer is calling during. The calling protocol to be followed in instances of "priority calls":

⇒ The subject will be called only during the preferred calling time until otherwise noted or until extension of the protocol.

• The subjects also have the opportunity to call in to the 800 phone number and refuse participation, make an appointment for an interview or in some cases ask to conduct an interview in real time.

⇒ The interviewer is to verify name, address, and phone for the subject prior to obtaining consent or conducting the interview.

• The calling protocol will be affected by the mailing procedure of the patient information packets for each hospital. Some subjects will receive 1 mailing prior to calling, while others will receive 2 mailings prior to calling for interviews. How the mailings contribute to the calling protocol is as follows:

Subjects receiving 1 mailing

• Those subjects who receive one mailing will be eligible for calling approximately 7 days after the date of the first letter. These subjects who will receive only one mailing will be identified by the hospital.

• Currently the hospitals requiring one mailing are:

HCMC
Immanuel St. Joseph's
North Memorial Medical Center
Park Nicollet Health System/Methodist
Rice Memorial Hospital
St. Cloud Hospital
HealthEast St. Joseph's and Health East St. John's

Subjects receiving 2 mailings

• Those subjects who receive two mailings will be eligible for calling approximately 7 days after the date of the second letter.

- Currently the hospitals requiring two mailings are:
  St. Mary's Duluth
  Regions
  All Allina Hospitals

Message Protocol

When a subject is not available, and either an answering system or another person answers the phone, the following protocol apples:

- If a person other than the subject answers the phone, ask them when is a good day and time to get a hold of the subject (as is written on the telephone consent form) and ask for a preferred calling time the subject can be reached.

- A total of 2 messages will be left.

- The 1st message will be:

  "Hello, this is <<YOUR NAME>> and I'm calling from the Minnesota Department of Health. We would like to speak to <<SUBJECT"S NAME>> regarding a study we are conducting. We'll try contacting <<SUBJECT"S NAME>> later on in the week, otherwise we can be reached at 612-676-5074 (outside the Metro area, 1-877-925-4189). Thank you for your time. Goodbye."

- If the subject is under 18 the first message will be:

  "Hello, this is << YOUR NAME>> and I'm calling from the Minnesota Department of Health. We would like to speak to the legal guardian of <<SUBJECT"S NAME>> regarding a study we are conducting. We'll try contacting you later on in the week, otherwise we can be reached at 612-676-5074 (outside the Metro area, 1-877-925-4189). Thank you for your time. Goodbye."

- The second message if to be left a week after the first message.

- The script for the second message will be the same as the first.

Program Screens

The interviews will be conducted by paper and pencil rather than using the CATI system. In the event interviewers have time for data entry, the form used to entering data will be done on the computer using the CATI screen for the questionnaire.

Obtaining Informed Consents

To obtain permission of the subject for his or her participation in this study, we read information pertaining to the study known as the "Tennessen." The Tennessen is extremely important and should not be taken lightly as the MDH is required to inform potential subjects about the details of the study and any risks their involvement might cause. Generally, this study offers little or no risk to the subject aside from any emotional stress the participant would go through by having to recount his or her injury. However, we are legally bound to fully inform the participant as to the risks of the study.

Many subjects will have had the opportunity to sign a consent form they may have received in the patient mailing packet we sent prior to calling. Some participants might not have signed the consent form, read the consent form or received the mailing at all. Consequently, all potential participants are to be read the Tennessen and asked their permission to participate in the study. Even if a patient has sent back a response card indicating that he or she will participate in the study, you still need to receive telephone permission to interview them. Some hospitals participating in the study, require us to have the signed informed consent in addition to the telephone consent. In these cases, if we do not have the subject's informed consent on file, we will ask them to mail the consent if they still have a copy or we will to mail one to them to be returned to us.

The Tennessen

The Tennessen, or permission of the participant to be interviewed, is an integral component of the study. Again, without the completion of the Tennessen, no interview can take place. Even if the subject wants to get directly to the interview, you must lead the subject through the Tennessen before you start the questionnaire. The Tennessen begins from the moment someone answers the telephone with a request to speak with the potential participant.

> ➢ **Hello, I am calling from the Minnesota Department of Health. We are working with (hospital name) in a study to evaluate the causes of work-related traumatic injuries. May I please speak with (name of injured)?**

If the subject is a minor, you should request to speak with the injured minor's legal guardian. Something to note here is that each hospital will have a slightly different Tennessen. A few of the words in any paragraph might be different in Region's Tennessen than in North Memorial's Tennessen. These differences for the most part are minor and the program will bring up the correct Tennessen for each patient. However, it is helpful to keep this fact in mind and refrain from repeating the Tennessen from memory as each patient might be from a different hospital with different Tennessen requirements.

The next portion of the Tennessen identifies you, the caller, and asks if they received the patient information packet in the mail.

> ➢ **Hello, Mr. (Ms.) (name of the injured / legal guardian) we are calling from the Minnesota Department of Health. We received your / your son (daughter's) name from (hospital name) where you / they were recently treated. You should have received a letter and an informed consent form from us sometime during the last few days. Do you recall receiving these?**

Depending on their answer, you can reply in a couple different ways. Move on to the next logical question according to the subject response to the previous question. For example,

If Yes: ➢ **"Have you read through the letter and informed consent form?" (if not give them time to do so). Do you have any questions?**

If No: ➢ **We would be happy to send you another copy.**

Some subjects will not have received the packet or will have lost it. If this is the case, follow the protocol for re-sending them the materials. Other subjects will have the information packet handy by the phone and will read through it while the interviewer waits patiently, ready to answer any questions. It is most likely that the information packet sent to them is not directly in front of them. If the subject has not reviewed the materials, the interviewer can suggest the subject read the letter and consent forms without ordering them to do so. A suggestions such as:

➢ **"Well, if you like, I can hold while you read through it."**
Some subjects have no idea where it is and say so. Interviewer response should be polite and not rush the subject.

➢ **"If you would like to look around for it I can hold."**

If the subject wants the interviewer to call back at a later time after he or she has reviewed the materials, simply ask when is a better time to call back. Once a day is established, ask for a time. If a time isn't given, suggest general times that fall in line with the calling protocol.

After reviewing the introductory letter and consent form, the interviewer explains the purpose of the study and asks if the subject is willing to participate:

➢ **We are evaluating work-related traumatic injuries. The purpose of this study is to evaluate the causes of and ways to prevent injuries such as yours from taking place. Any information you give us will be held strictly confidential. Participation is entirely voluntary and will in no way affect your health care. You are one of an estimated 6000 subjects being asked to participate in this study. Please feel free to ask us any questions you may have about the study at this time or during the interview.**

Would you be willing to participate in this study?

Once the subject either refuses or consents to participation, the interviewer records the subject's consent by selecting the appropriate answer to each question. The subject may not agree to the long interview, rather consent only to the short interview. The short interview is a questionnaire consisting of five questions. It is present because some people may take the time to participate in the shorter form instead of completely refusing the interview. The Tennessen in its entirety is also below.

Telephone Interview Consent Form

Telephone consent: Adults / Children

If age 18 or older:
Hello, I am calling from the Minnesota Department of Health. We are working with (hospital name) in a study to evaluate the causes of serious work-related trauma. May I please speak with (name of injured)?

else,
Hello, I am calling from the Minnesota Department of Health. We are working with (hospital name) in a study to evaluate the causes of work-related traumatic injuries. May I please speak with (name of injured) legal guardian?

If no, → What would be a convenient time to contact him/her?

If yes:
Hello, Mr. (Ms.) (name of the injured / legal guardian) we are calling from the Minnesota Department of Health. We received your / your son (daughter's) name from (hospital name) where you / they were recently treated. You should have received a letter and an informed consent form from us sometime during the last few days. Do you recall receiving these?

If yes,→ Have you read through the letter and informed consent form (if no, please give them time to do so)? Do you have any questions or comments?

If no, → We would be happy to send you another copy.

We are evaluating work-related traumatic injuries. The purpose of this study is to evaluate the causes of and ways to prevent injuries such as yours from taking place. Any information you give us will be held strictly confidential. Participation is entirely voluntary and will in no way affect your health care. You are one of an estimated 6000 subjects being asked to participate in this study. Please feel free to ask us any questions you may have about the study at this time or during the interview.

Would you be willing to participate in this study?

yes **no**

If no, → Could I possibly ask you a few questions pertaining to work-related injuries?

If yes → Go on to the short interview.

If no → Thank you and goodbye.

Is this a convenient time to talk to you?

yes **no**

If yes, → Proceed with the questionnaire.

If no, → Could we arrange a time to call back that would be convenient for you?

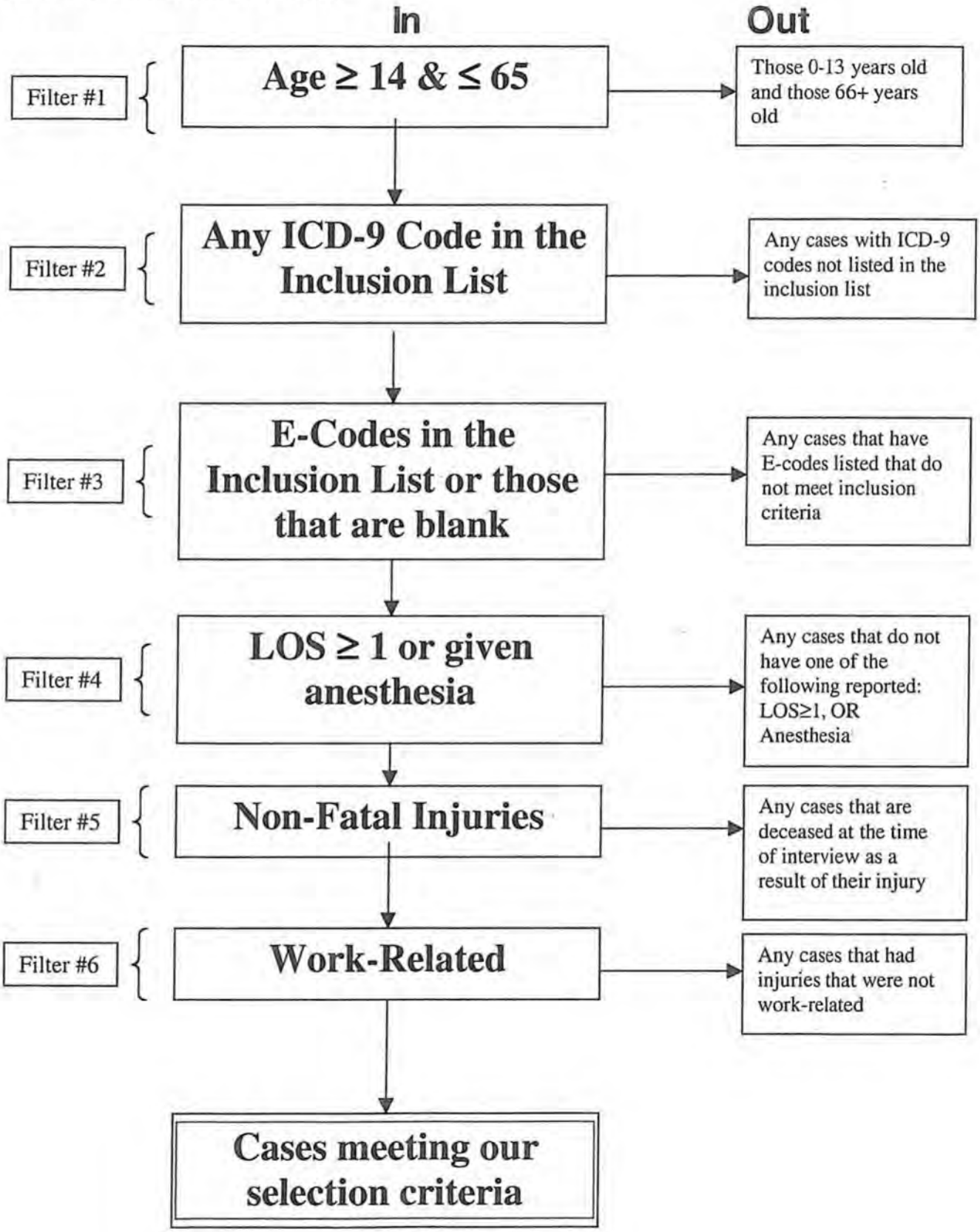
Appendix A

Project Staff

L. Ronald French Interim Principal Investigator	612.676.5239
Allan Williams Epidemiologist Principal	612.676.5105
Christina Larson, MPH Project Director	612.676.5746
Andrea Todd, MS Interviewer Coordinator	612.676.5049
Margee Brown, MPH IRB Coordinator	612.676.5427
Shailly Dham, MPH Data Coordinator	612.676.5647
Karina Debner Health Program Representative	612.676.5074
Damian DiLuzio Health Program Representative	612.676.5716
David Parker, MD, MPH Principal Investigator (Currently on leave)	612.676.5220

Appendix B

Selection Criteria Flowchart



Appendix C

Abrasions ⇒ The wearing away of a substance or structure such as the skin or teeth through some unusual or abnormal mechanical process.

Burn ⇒ A lesion caused by the contact of heat.

1st Degree ⇒ shows redness

2nd Degree ⇒ blistering

3rd Degree ⇒ necrosis through the entire skin i.e. death of the skin cells

4th Degree ⇒ more or less charring

Concussion ⇒ A violent jar or shock, or the condition which results from such an injury. Loss of consciousness, nausea, weak pulse and slow respiration as the result of a brain injury caused by violent blows to the head.

Contusions ⇒ A bruise.

Crush Injury ⇒ A wound or maiming inflicted by extreme pressure being exerted to the body.

Dislocation ⇒ The displacement of any body part, more especially the bone.

Fractures ⇒ A break in the bone.

Comminuted ⇒ a shattering of the bone.

Compound ⇒ a break in the bone open up in the air.

Hematoma ⇒ A tumor containing effused blood.

Internal Injury ⇒ A wound or maiming situated or occurring in the inside of the body; usually applied to damage inflicted to the body by an external force.

Laceration ⇒ A wound made by tearing of the skin.

Nerve Injury ⇒ A wound or maiming to the nerve; a cord-like structure that conveys impulses between a region of the body and the central nervous system.

Open Wound ⇒ A physical injury to the body which is exposed to the air or not covered by broken skin.

Poisoning's (mostly allergy and drug) ⇒ The morbid condition caused by poisoning. Poison is any substance which when ingested, inhaled, absorbed, injected or developed within the body, by its chemical action may cause damage to structure or disturbance of function.

Punctures ⇒ A wound made by a pointed instrument.

Sprains ⇒ A joint injury in which some of the fibers of a supporting ligament are ruptured but the continuity of the ligament remains intact.

Strain ⇒ to overexercise; to use to an extreme or harmful degree. An overstretching or overexerting of some part of the musculature.

Superficial Injury ⇒ a wound or maiming pertaining to or situated near the surface.

Tendinitis ⇒ Inflammation of the tendons and of the tendon-muscle attachments due to strain or wrenching and causing great tenderness and lameness.

Toxic Effects ⇒ Pertaining to, due to, or of the nature of poison.

Vascular Injury ⇒ A wound or maiming pertaining to the blood vessels.

Appendix D

Figure 2
BLS Survey Case Incidence
for Minnesota and the United States, Private Sector, 1984-1998 [1]

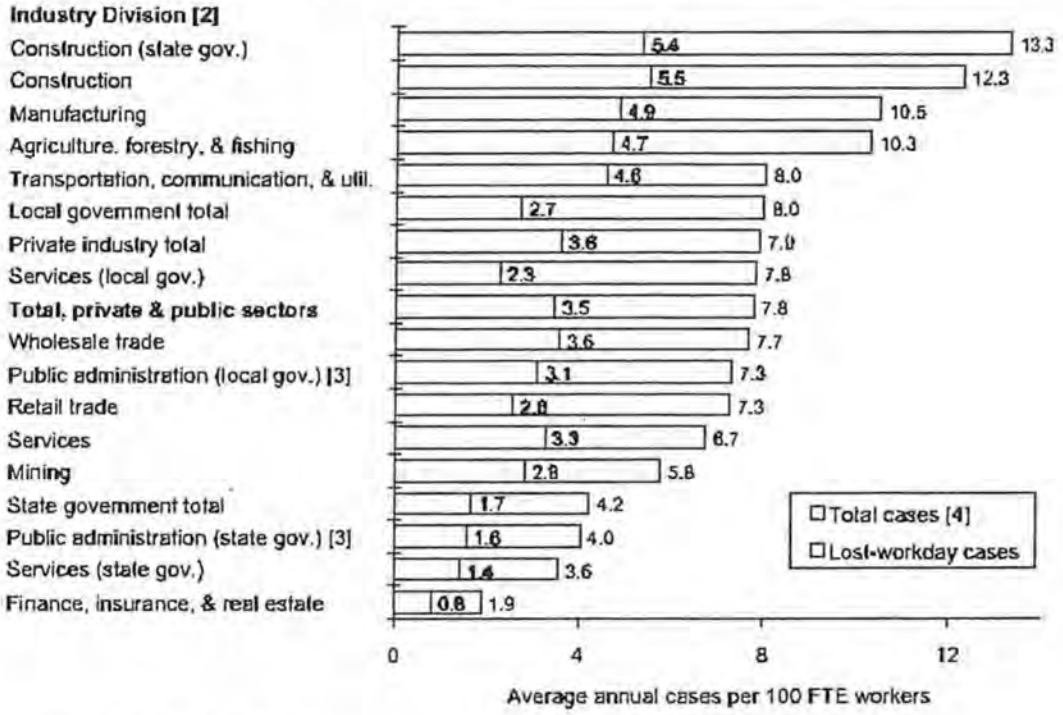
	Cases per 100 Full-Time-Equivalent Workers					
	Total Cases		Lost-Workday Cases		Days-Away-From-Work Cases	
	Minnesota	U.S.	Minnesota	U.S.	Minnesota	U.S.
1984	7.7	8.0	3.4	3.7	3.2	3.4
1985	7.6	7.9	3.4	3.6	3.1	3.3
1986	7.3	7.9	3.3	3.6	2.9	3.3
1987	7.8	8.3	3.5	3.8	3.0	3.4
1988	8.1	8.6	3.7	4.0	3.1	3.5
1989	8.3	8.6	3.9	4.0	3.1	3.4
1990	8.0	8.8	3.8	4.1	2.9	3.4
1991	8.1	8.4	3.8	3.9	2.8	3.2
1992	8.6	8.9	3.9	3.9	2.7	3.0
1993	8.7	8.5	3.7	3.8	2.5	2.9
1994	8.7	8.4	3.8	3.8	2.4	2.8
1995	8.5	8.1	3.9	3.6	2.3	2.5
1996	8.4	7.4	3.7	3.4	2.2	2.2
1997	7.6	7.1	3.6	3.3	2.0	2.1
1998	7.7	6.7	3.5	3.1	1.9	2.0

1. Includes injuries and illnesses.

Source: Survey of Occupational Injuries and Illnesses (U.S. Bureau of Labor Statistics).

Appendix D

Figure 4
Incidence of Total Cases and Lost-Workday Cases (BLS Survey) by Industry Division, Minnesota, 1996-1998 Average [1]



1. Includes injuries and illnesses.
2. Industry divisions are in the private sector unless otherwise noted. Only some industries within state and local government are shown separately (others do not have estimates available).
3. The public administration division is limited to public employees not classifiable under other industry divisions (e.g. construction, services).
4. The bar for total cases starts at zero and lies partly behind the bar for lost-workday cases.

Source: Survey of Occupational Injuries and Illnesses (U.S. Bureau of Labor Statistics).

Appendix D

Figure 16
Nature of Injury or Illness
for Days-Away-From-Work Cases, Minnesota, 1996-1998 Average

Nature of Injury or Illness	Percentage of Cases [1]	Nature of Injury or Illness	Percentage of Cases [1]
Traumatic injuries & disorders	**89.2%**	Other traumatic injuries & disorders	11.3%
		Nonspecified injuries & disorders	10.9
Traumatic injuries to muscles, tendons, joints, etc.	46.5	Back pain, hurt back	3.8
		Soreness, pain, hurt, except back	3.8
Strains, sprains, & tears	46.4	Crushing injuries	0.9
		Multiple nonspec. injuries & disorders	0.4
Open wounds	8.3	Nonspec. injuries & disorders, n.e.c.	2.0
Cuts & lacerations	5.6	Electrocutions, electric shocks	0.2
Punctures, except bites	1.5	Other poisonings & toxic effects	0.1
Amputations	0.8		
Amputations, fingertip	0.3	**Systemic diseases & disorders**	**9.7**
Surface wounds & bruises	8.3	Musculoskeletal system diseases & disorders	3.0
Bruises & contusions	6.0		
Foreign bodies (superf. splinters, chips)	1.5	Rheumatism, except the back	1.6
Abrasions & scratches	0.7	Tendinitis	0.9
		Dorsopathies	1.3
Traumatic injuries to bones, nerves, & spinal cord	6.8	Nervous system & sense organs diseases	3.4
		Disorders of peripheral nervous system	2.8
Fractures	5.7	Carpal tunnel syndrome	2.1
Dislocations	1.1	Disorders of the eye, adnexa, vision	0.5
Burns	1.9		
Heat burns, scalds	1.1	Digestive system diseases & disorders	2.3
Chemical burns	0.6	Hernia	2.3
Intracranial injuries	0.4	Disorders of skin & subcutaneous tissue	0.5
Concussions	0.3		
		Respiratory system diseases	0.3
Multiple traumatic injuries & disorders	4.3		
Sprains & bruises	1.3	**Symptoms, signs, & ill-defined conditions**	**0.8**
Fractures & other injuries	1.3		
Cuts, abrasions, & bruises	1.0	**Infectious & parasitic diseases**	**0.0**

1. Percentages are relative to the number of classifiable cases. Nonclassifiable cases were 8.0% of the total.

Source: Survey of Occupational Injuries and Illnesses (U.S. Bureau of Labor Statistics). Figures computed from published data by DLI Research and Statistics.

Appendix E

Participant Information Packets

This appendix includes a duplication of the packet of informational materials mailed to potential subjects. Bear in mind that some of the potential participants might not have read the materials or received any materials at all. For this reason, it is imperative you are familiar with them in the event the subject has any questions. These materials along with a bound copy of this manual will be posted in each of the interview rooms so that you can refer to them at any time during interviewing.

Appendix E – Introductory Letter

(date)

Dear (injured) :

The Minnesota Department of Health, in conjunction with Methodist Hospital, is studying serious work-related traumatic injuries; this program is called the *Surveillance of Serious Work-related Trauma.* Telephone interviews are being conducted to learn more about factors contributing to these injuries. This information is important for preventing future work-related injuries.

We are asking you to participate in a short telephone interview that covers questions about your traumatic injury. Your participation is voluntary, but it is important that we collect information from as many people as possible who have experienced such work-related injuries. Only then can we hope to reduce occupational traumatic injuries. All your answers are private. The information you provide will be used only by the Minnesota Department of Health study staff. No names or information that can be used to identify you are ever used in reports.

We appreciate your participation and cooperation. Within the next two weeks you will be contacted by the Minnesota Department of Health Surveillance of Serious Work-related Trauma staff. This interview will take approximately 20 minutes to complete.

If you have any questions, please do not hesitate to call us collect at (612) 676-5746. Thank you for your consideration.

Sincerely,

Christina L. Larson
Epidemiologist/Project Coordinator

CLL/ey
enclosures

Appendix E – Consent Form

Consent to Participate in the Minnesota Surveillance of Serious Work-related Trauma

Introduction

You are invited to be in a research study concerned with evaluating the causes of serious work-related traumatic injuries. This study is being conducted by the Minnesota Department of Health (MDH). We ask that you read this form and ask any questions you may have before agreeing to participate.

Purpose

The purpose of this study is to evaluate the causes of serious work-related trauma. The information from this study will help us to better understand in what ways and how often people may be seriously injured at work.

Procedures

If you agree to participate in this study, you will be asked to complete an interview either in person or by telephone. The interview will take between 20 and 45 minutes depending on the severity of your injury. We will not contact your employer without your permission. Significant findings developed during the course of this research will be made available to all interested participants.

Risks and Benefits

Completing this survey may cause you some stress due to remembering the event more clearly. There are no other risks or costs to participation. All participation is voluntary and will in no way affect your health care or work status at this time or in the future. There is no financial compensation or any other immediate benefits for your participation in this study; however, it is our hope that this may lead to preventing these events in the future.

Confidentiality

The record of this study will be kept private. Published reports will not include any information that will make it possible to identify you or your place of employment. Records will be kept in a locked file; only the researchers and the Institutional Review Board (IRB) will have access to the records. The IRB is a committee that reviews research to help ensure that the rights and welfare of all participants are protected and that the study is carried out in an ethical manner.

Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with the Minnesota Department of Health or your health care provider. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

MDH Contact Information

The researcher conducting this study is Dr. David Parker at the Minnesota Department of Health. If you have any questions later, you may contact Dr. Parker at (612) 676-5220. You will be given a copy of this form to keep with your records.

IRB Contact Information

If you have any questions regarding your rights as a research participant, you may call Christine Pedersen with the Park Nicollet Health Services Institutional Review Board at (952) 993-3525.

Statement of Consent

I have read the above information. I have asked questions and received appropriate answers. I consent to participate in the study.

Signature of the Participant:_____ Date:_____

THIS COPY IS YOURS TO KEEP IN YOUR RECORDS

Appendix E – Consent Form

Consent to Participate in the Minnesota Surveillance of Serious Work-related Trauma

Introduction

You are invited to be in a research study concerned with evaluating the causes of serious work-related traumatic injuries. This study is being conducted by the Minnesota Department of Health (MDH). We ask that you read this form and ask any questions you may have before agreeing to participate.

Purpose

The purpose of this study is to evaluate the causes of serious work-related trauma. The information from this study will help us to better understand in what ways and how often people may be seriously injured at work.

Procedures

If you agree to participate in this study, you will be asked to complete an interview either in person or by telephone. The interview will take between 20 and 45 minutes depending on the severity of your injury. We will not contact your employer without your permission.

Risks and Benefits

Completing this survey may cause you some stress due to remembering the event more clearly. There are no other risks to participation. All participation is voluntary and will in no way affect your health care or work status at this time or in the future. There are no immediate benefits to you; however, it is our hope that this may lead to preventing these events in the future.

Confidentiality

The record of this study will be kept private. Published reports will not include any information that will make it possible to identify you or your place of employment. Records will be kept in a locked file; only the researchers and the Institutional Review Board (IRB) will have access to the records. The IRB is a committee that reviews research to help ensure that the rights and welfare of all participants are protected and that the study is carried out in an ethical manner.

Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with the Minnesota Department of Health or your health care provider. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

MDH Contact Information

The researcher conducting this study is Dr. David Parker at the Minnesota Department of Health. If you have any questions later, you may contact Dr. Parker at (612) 676-5220. You will be given a copy of this form to keep with your records.

IRB Contact Information

If you have any questions regarding your rights as a research participant, you may Christine Pedersen with the Park Nicollet Health Services Institutional Review Board at (952) 993-3525.

Statement of Consent

I have read the above information. I have asked questions and received appropriate answers. I consent to participate in the study.

Signature of the Participant:_____ Date:_____

PLEASE RETURN THIS COPY TO THE MN DEPARTMENT OF HEALTH

Appendix E – Assent Form

Assent to Participate in the Minnesota Surveillance of Serious Work-related Trauma

Introduction

You are invited to be in a research study that looks at reasons why serious injuries occur at work. The Minnesota Department of Health is doing this study. We ask you to read this form and ask any questions you may have before agreeing to participate.

Purpose

The purpose of this study is to look at why serious traumatic injuries happen at work. The questions we ask will help us to understand how and why people get seriously hurt at work.

Procedures

If you agree to take part in this study, you will be asked to answer questions from our questionnaire either in person or on the telephone. This will take between 20 and 45 minutes, depending how bad your injury was. We will not contact your employer without you agreeing that we can.

Risks and Benefits

Answering the questions in the survey may make you remember the injury much better, which may make you feel a little uncomfortable. There are no other risks to answering these questions. It is your choice to take part in this study. Completing the survey will not affect your medical care or your job. Answering the questions may help us to prevent this type of injury from happening to other people in the future.

Confidentiality

What you say will be kept private. Printed reports will not include information that will make it possible to find out who you are or where you worked. The survey and any other information about you and your injury will be kept in a locked file. Only the Institutional Review Board (IRB) and the people doing this study will be able to look at these records. The IRB is a group of people that looks at the questions and information we get from you to make sure that your rights are protected and that the study would not harm you in any way.

Voluntary Nature of the Study

Whether you complete the questionnaire or not, your decision will not affect your relationship with the Minnesota Department of Health or your health care provider at this time or in the future. If you decide to take part in the study but then change your mind, you can take yourself out of the study at any time without hurting those relationships.

MDH Contact Information

Dr. David Parker from the Minnesota Department of Health is doing this study. If you have any questions about the study, you can call him at (612) 676-5220. We will give you a copy of this sheet to keep with you at home.

IRB Contact Information

If you have any questions about the study that deal with your rights as a study participant, you can call Christine Pedersen with the Park Nicollet Health Services Institutional Review Board at (952) 993-3525.

Statement of Consent (Please read below and sign if you agree with the statements)

I have read the above form. I have asked questions and have been told appropriate answers. I give my consent to take part in the study.

Signature of the Participant:_____ Date:_____

THIS COPY IS YOURS TO KEEP IN YOUR RECORDS

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Voluntary Nature of the Study

Whether you complete the questionnaire or not, your decision will not affect your relationship with the Minnesota Department of Health or your health care provider at this time or in the future. If you decide to take part in the study but then change your mind, you can take yourself out of the study at any time without hurting those relationships.

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Statement of Consent (Please read below and sign if you agree with the statements)

I have read the above form. I have asked questions and have been told appropriate answers. I give my consent to take part in the study.

Signature of the Participant:_____ Date:_____

THIS COPY IS YOURS TO KEEP IN YOUR RECORDS

Appendix E – Medical Release Form

Surveillance of Serious Work-related Trauma

Verification of Medical Diagnosis and Treatment of Injury Release Form

I give my consent to representatives of the Minnesota Department of Health Surveillance of Serious Work-related Trauma program to obtain information from my physician(s) about: (1) the parts of body associated with the injury; (2) the date of the injury; and (3) whether the injury was work-related. All of my questions regarding this study have been answered to my satisfaction. I may withdraw my consent at any time, and I will have an opportunity to ask any questions at any time during the study.

Please sign your name.

Name:_____

Please print the name(s) and address(es) of the physician(s) who have provided medical care for the work-related injury.

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

THIS COPY IS YOURS TO KEEP IN YOUR RECORDS

Appendix E – Medical Release Form

Surveillance of Serious Work-related Trauma

Verification of Medical Diagnosis and Treatment of Injury Release Form

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Please sign your name.

Name:_____

Please print the name(s) and address(es) of the physician(s) who have provided medical care for the work-related injury.

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

Physician's Name:_____

Address:_____

_____

Telephone Number:_____

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Appendix F

The Questionnaire

Appendix G

Explanations by Question

This section looks at the purpose behind the questions asked in the telephone survey. Not all questions that will be asked are included in this section, as some of the questions are obvious and do not need further explanation, i.e. name and address. The questions are in **bold** and the explanations of the question are located directly after the question in *italics.* The entire questionnaire consists of three parts: consents (Tennessen), screening questions, and the Serious Trauma questionnaire (short or long forms).

The screening questions follow the Tennessen asking the participant if his or her injury was work-related and if so some information pertaining to their employer. Completing this section is necessary, as the participant's injury must be work-related in order to move on with the survey. If the subject qualifies as a work-related injury, the next step is to move on to the short or long form questionnaire depending on which one the subject consented to. If the participant states the injury was not work-related, he or she is not eligible for the study and should be thanked for his or her time and marked as a refusal. The Serious Trauma questionnaire is the third and final section of the survey.

Screening Page

Could you tell me if you suffered a work-related injury on <<day/month/year>>?

The important component of this question is identifying if the participant qualifies for our study. A good thing to have ready is a definition of work-related trauma in the event that the participant does not know if their injury was work-related. The definition work-related injury for the purposes of this study is included in the selection criteria. If the subject meets all of the requirements of the selection criteria, they are eligible for a work-related injury for this study.

1. At the time of your injury were you employed by a temporary agency?

The definition of what a temporary agency is might be asked in this question A temporary agency is defined as someone who is "contracted out" by a company from another company. For example, if you were an accountant for Account Temps and were injured while on the job at 3M, your employer was a temp agency.

2. What was the name and address of the company/employer you worked for at the time of your injury?

A simple name and address of the company is sufficient for this question. However, if they would rather not give out this information, that is more than acceptable and you can move on to the question.

3. What kind of work did this company or employer do?

Here we are looking for a description of the industry they worked in. For example, agriculture, mining, plastics manufacturing etc. This will basically allows us to establish an incidence rate by industry type.

4. What was your job title at the company? What were your duties?

Similar to the above, we are interested in the job title and describing its duties. Finding out the duties involved in the job title will allow us to see what kind of activities the individual was performing at the time of the accident.

! Be aware of the questionnaire response options that nee to be filled in or answered in addition to the original response to the question. For example, the option to mark "self-employed" when asking question number 2.

Questionnaire

5. Could you please tell me how the accident happened?

The interviewer can record the participant's narrative by hand. Upon completing the interview, the interviewer can come back to this question and code the Source, Event, and Environment in which the injury took place using the OIIC book as a guide for codes.

5a. – 5e. Prompt questions

These questions are here in the event the subject does not include enough information in their narrative. Having these questions down by memory will help you know if the subject is covering all the information we want as they tell their injury story

6. Did the injury or injuries occur on or off-site of the company/employer you worked for?

*Remember the delineation of temporary agency here. We want to know if the injury occurred on the grounds of the **hiring** company or on one of its work sites.*

8. Did the injury or injuries occur during regular working hours?

*This question can solicit a lot of clarification. The subject might ask what regular working hours are considered to be. We are only concerned with **their** regular working hours. If a subject normally works from 11 pm until 3 am, that is considered their regular working hours.*

9. Have you worked at all since your injury happened on <<date>>?

We want to know if they have worked at all, not just at the employer at which they were working when they were hurt, but at either a new employer or an old employer but in a new position, etc.. If they have

worked since the accident, you do not need to specify where they have worked since this question will be asked later in the questionnaire.

9a. What has prevented you from returning to work?

Be certain they understand it is the work-related injury, and not any other injury that has prevented them from returning to work.

9b. Do you think you will be able to return to work?

Although this is a subjective question, we are asking if the subject thinks they will ever return to work. This question has several prompts or follow-up questions for the interviewer when given an answer by the subject. They are there to remind the interviewer of what details of the question may be asked.

10. On approximately what date did you first return to work?

The format option in the questionnaire is month/day/year. Be prepared to record the response in this format in the event the participant answers with "12 days ago." If they respond they do not recall, then a few prompts such as "was it months ago, weeks ago or days ago" will help them along in recalling when they did return to work. If they do not remember and give an estimate record the date the estimate would be.

11. Did you return to work about the same percent time that you were working at the time of your injury.

This ironically enough can be tricky for the subjects. What we want to know is if they returned to work the same amount of time at the job they were injured. If they worked two jobs, and one had the time they worked decrease, this can be noted on the questionnaire but they did not decrease their time at the job in which they were injured. It is a fine line between disability in life as a result of an injury and the result the injury had on their job.

12a. Is this the same job, by job we mean the same job responsibilities and activities, as the one you worked in at the time of your injury?

Many subjects will answer yes to this question as they may have returned to the same job title and duties for example if they are a line working postal employee, and they have returned to working on the line, they might answer they returned to the same job, but in the same breathe say they no longer lift heavy items off the conveyor belt. Technically, their job responsibilities did change, but please record their answer as they gave it but record a note on the side of the question that they no longer lift heavy items. The answer to this question can affect the next question 12b as far as the two having different responses than would seem logical.

12b. Did your employer modify your job to accommodate you because of your injury?

If the participant inquires as to what is meant by "modify," we want to know if they were given any assistance to complete their job. For example, after an injury occurred, a worker who at one time lifted 50 pound bags of flour, now was given a dolly or forklift to accomplish this task because of the injured back they sustained lifting the bags manually. We are not interested in modification of job responsibilities, as that is an earlier question.

15. At this time does your injury affect your ability to do any activities relating to your work or job?

Many participants will have answered question 12a. in a way that it should really be recorded here. 12a. asks if they returned to work with the same responsibilities and activities. They might respond, "Yes, but I no longer lift heavy items." In actuality, the response they gave is what we are looking for in this question.

16. As a result of your injury, have you experienced any financial difficulties?

After asking this question be aware that if the subject isn't sure what sort of financial difficulties we are looking for, reference the prompts to the right of the explanation section of this question. As with all questions that require the subjects to list out their thoughts in response to a question be thorough and allow them to answer the question completely or use prompts to inquire, "Is that all?" to help them along to completing the answer.

20. As a result of your injury... Have you had to use special equipment, such as a cane, wheelchair, special, or special telephone?

Again be aware here of using prompts to help the subject give a complete answer.

21. As a result of your injury... Is it more difficult for you to move about the community?

Many people may answer "no" to this question, because they claim they can still drive or get around. However, they may also mention that it takes them an extra hour to get in and out of the car, or that because their shoulder was hurt they shift with the "wrong" hand while driving. Because the question asks if they can get around at all, technically their answer of "no" is correct, but we also want to know if getting around is more difficult since their injury. If there is any increase of hassle for them since their accident, mark their answer as a "yes" and write down an explanation.

22. Do you feel isolated from your friends, family and community?

This question is soliciting more emotional information, so be considerate and patient. We want to know if the overall level of communication and activity with friends and family has suffered because of the accident. Some patients may scoff a little at this question, but sometimes if you remind them of things they are missing that they may have mentioned earlier, they will consider the question a little more seriously and may change their answer.

!Questions 22-26 include many skips according to the subject's answers, be careful in where their answer brings you next.

References

American Journal of Industrial Medicine, "Work-related injuries in minors" Vol. 14, No. 5, pages 585-595, 1998

National Farm Medicine Center, Agricultural Injury Fact Sheet - 1996

National Institute for Occupational Safety and Health Special Hazard Review, Identifying high risk small business industries: Basis for preventing occupational injury, illness and fatality.

National Institute for Occupational Safety and Health, Worker Health Chartbook – 2000.

National Occupational Research Agenda, Traumatic Occupational Injury Research Needs and Priorities.

Minnesota Department of Labor and Industry, Workplace Safety Report – 1998.

Appendix F

CDC Site Visit

MINNESOTA MDH DEPARTMENT of HEALTH

Surveillance of Serious Work-Related Trauma

5 RO1 OH03943-02

Overview and Progress to Date

Center for Occupational Health & Safety

Specific Aims

1)Develop, test, and refine a definition for serious work-related trauma;

2)Determine the feasibility of establishing a surveillance system for serious work-related trauma;

3)Determine the reporting biases found in data compiled from different reporting sources; and,

4)Determine the magnitude, distribution, etiology, and outcome of serious work-related trauma.

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Major Activities

- Establish an advisory group
- Develop case definitions and selection criteria
- Develop a surveillance reporting network
- Determine sampling frame
- Recruit hospitals for participation
- Apply for Institutional Review Board approvals from all participating hospitals
- Data collection
- Conduct case interviews
- Code data
- Analyze data
- Develop and distribute reports and papers

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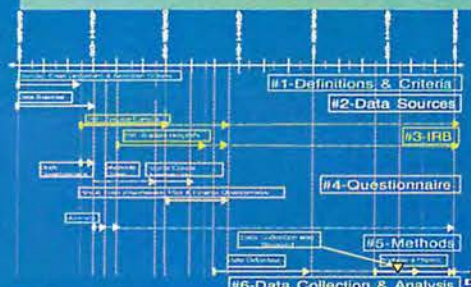
Project Timeline



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Advisory Group

- Members
- Role

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MDH

Definitions & Eligibility Criteria

- Work-Related Definition
- Criteria/Definition for a Serious Traumatic Injury
- Other eligibility criteria

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Trauma Surveillance Network

- Minnesota Trauma Registry Alliance (MTRA)
- Minnesota Department of Labor & Industry
- MN Trauma Data Bank Advisory Committee
- MN Hospital & Healthcare Partnership
- University of MN - School of Public Health

Sampling Frame & Recruitment

- 1998 MN Hospital and Healthcare Partnership reporting hospitals
- Recruited
  - Twenty-two hospitals that treated nearly 80% of the claims that met our study criteria in 1998*
  - All MN trauma centers
  - MN Department of Labor & Industry (MNDLI)

* Based on MN Hospital and Healthcare Partership data

Facilities Agreeing to Participate

Facilities Agreeing to Participate

- Hennepin County Medical Center
- North Memorial Medical Center
- Regions Hospital
- St. Cloud Hospital
- St. Mary's Medical Center - Duluth
- St. Luke's Medical Center - Duluth
- Mercy Hospital
- Unity Hospital
- Mayo Health System - St. Mary's Hospital & Methodist Hospital
- Immanuel St. Joseph's Hospital
- United Hospital
- Abbott-Northwestern Hospital
- Rice Memorial Hospital
- Fairview Southdale Hospital
- Fairview-University Hospital
- Fairview Ridges Hospital
- HealthEast St. Joseph's Hospital
- HealthEast St. John's Hospital
- Park Nicollet - Methodist Hospital

Institutional Review Board Approvals

- National Institute for Occupational Safety and Health (NIOSH) requirements:
  - Overall Institutional Review Board (IRB) approval for project
  - Single Project Assurances (SPAs) and/or Federal Wide Assurances (FWAs) or Multiple Project Assurance (MPA) numbers from each participating facility
- Participating facility requirements:
  - Hospital IRB approval for project

IRB Issues

- No MDH IRB
- External IRB required to act as the overall project IRB
- Number of IRBs required to go through due to the number of participating facilities
- Release of federal funds was dependent on IRB approvals
- Inconsistent process among facilities
- Length of time required to apply and receive IRB approval
- Immense amount of people time and resources necessary
- Differing stipulations and changes required from each facility
- Personal data requests were difficult despite MDH statutory authority
- OHRP requirements for SPAs, MPAs, and FWAs was a new process for staff
- Internal PIs required by some facility IRBs
- Lack of internal IRBs in some facilities

Case Selection & Collection

- Eligible hospital cases reported to MDH
- Random case selection from hospital cases
- Eligible cases reported to MDH from MN Trauma Centers and MNDLI

Outpatient Hospital Data

- Data collection difficulties
- Inconsistent data between facilities
- Length of time to obtain

Cases Reported by Participating Facilities

Hospital	Inpatient Cases Reported	Outpatient Cases Reported	E.C. Data Reported
Abbott-NW	311	Did not report	N/A
Fairview Ridges	194	603	N/A
Fairview Southdale	449	641	N/A
Fairview University	291	290	N/A
HCMC	1719	195	1345
HealthEast St Joe's	514	Did not report	N/A
HealthEast St John's	350	Did not report	N/A
ISJ	378	128	N/A
Mercy	723	Did not report	Has not reported
Unity	829	Did not report	Has not reported
Methodist	260	4	N/A
NMMC	397	94	Has not reported
Regions	1542	552	Has not reported
Rice	194	80	N/A
St. Cloud	3021	Unknown*	Has not reported
St. Luke's	254	361	1379
St. Mary's Duluth	404	67	725
United	263	Did not report	N/A
Mayo St. Mary's	Has not reported	Has not reported	Has not reported
Mayo Methodist	Has not reported	Has not reported	Has not reported
TOTAL	12501	3012	3849

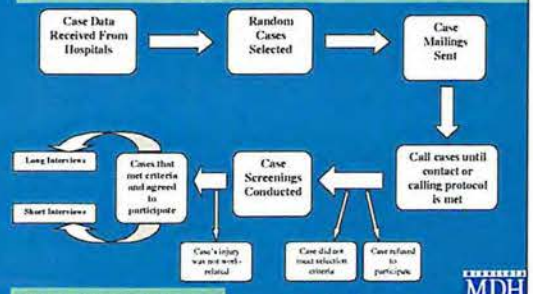
Questionnaire Development

- Industry & Occupation
- Injury information
- Return to work information
- Activities of daily work and living
- Financial impact
- Mobility
- Social & emotional functioning
- Alcohol & tobacco consumption
- Personal information

Case Interview Process & Protocol

- Project packets mailed
- Attempt to contact by telephone
  - Calling protocol
- Interview
  - Consent
  - Screening
  - Survey

Collection of Data and Process of Interview



Status of Data Collection

Hospital	Interviewing Start Date	Interviewing Completion Date	Sample #	# Completed Surveys	# Non-Participants	In Circulation
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	Jul 01	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Allina Hospitals						
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	Aug 01	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]						
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Totals			7498	271	4977	1582

[illegible]

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Consequences of the Cease of Data Collection

- Incomplete data collection from both hospitals & trauma centers
- Incomplete screenings and interviews
- Loss of staff due to loss of work
- IRB consequences
- Formal NIOSH approval required to restart

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Survey Assessment

Hospital	Interviewing Start Date	Interviewing Status at 2/22	Sample #	# Completed Surveys Prior to 2/22	# Completed Surveys After 2/22
Park Nicollet	Jun 01	Completed	[illegible]	[illegible]	[illegible]
[illegible]	Jun 01	Completed	[illegible]	[illegible]	[illegible]
[illegible]	Aug 01	Completed	[illegible]	[illegible]	[illegible]
[illegible]	Sep 01	Completed	[illegible]	4	[illegible]
[illegible]	Sep 01	Completed	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	Completed	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	Completed	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	Completed	[illegible]	[illegible]	[illegible]
HCMC	Dec 01	Ongoing	[illegible]	[illegible]	4
Fairview Southdale	Feb 02	Ongoing	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	Ceased*	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	Ceased*	[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	Ceased*	[illegible]	[illegible]	[illegible]
Fairview University	Suspended	Suspended	170	[illegible]	[illegible]
[illegible]	Suspended	Suspended	[illegible]	[illegible]	
[illegible]	Suspended	Suspended	[illegible]	[illegible]	[illegible]
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[illegible]	Suspended	Suspended	[illegible]	[illegible]	[illegible]
TOTALS			[illegible]	[illegible]	[illegible]

*[illegible]

Center for Occupational Health & Safety

MDH

Data Management & Quality Control

- 100% Interview Evaluation
- Data Entry (Dual Entry)
- Coding (Dual Coding and Consensus)

Center for Occupational Health & Safety

MDH

Data Analysis & Reporting

- Descriptive statistics
- Injury occurrence
- Data source evaluation and comparison
  - Example: Hennepin County Medical Center
- Data dissemination and reports

Center for Occupational Health & Safety

MDH

Sample Comparison

Cases in Hospital = 1914

Cases in trauma center registry = 1585

Cases exclusively in hospital = 687

Cases exclusively in trauma center = 358

Overlapping cases = 1227

Center for Occupational Health & Safety

MDH

Lessons Learned

- Issues surrounding IRBs
- Difficulties associated with data collection
  - Data privacy
  - The data you missed is unknown
  - IP/OP
  - Data inconsistencies both within and between facilities
  - Immense data clean-up required
- Time and resources necessary to determine work-relatedness
- Time saved if able to utilize a CATI system for interviewing
- Project data sources need to be further explored and evaluated

Center for Occupational Health & Safety

MDH

"Serious Trauma" Needs

- A project extension allowing the completion of analysis and the report of data
- The carry-over of project funds not expended
- Official NIOSH letter withdrawing the cease in data collection, supporting our present PI and project activities, and stating we can utilize data collected after Feb. 22
- IRB re-approvals from all participating facilities

Center for Occupational Health & Safety

MDH

Appendix G

Study Correspondence

Surveillance of Serious Work-Related Trauma Study:
(5 RO1 OH03943)

Revised Aims/Objectives
Accomplishments by 9/30/02 & 4/30/03
Budget Projections for 9/30/02 & 4/30/03

Revised Aims/Objectives

Aims	Status	Date
1. Definition of Serious Work-Related Trauma	Completed	
2. Determine Surveillance System Feasibility	Revised	
Lessons learned:		
•Outpatient data		
Variable		
Too labor intensive for surveillance effort		
•IRB Issues (if many institutions involved)		
Labor intensive		
Results in variable data collection protocols		
Objectives:		
•Complete data cleanup		Sept
Study (hospital) data		
Trauma center data		
Interview data		
•Complete data entry and coding of interview data		Sept
•Complete linking tests for study (hospital) data and		March
First Report of Injury (DLI)		
Trauma center data		
3. Determine reporting biases	Revised	
Objectives:		
•Initial comparisons		March
Hospital and Trauma center data		
First Report of Injury/hospital/trauma center data		
Agreement between hospital and interview data		
ICD-9 and E codes		
4. Determine magnitude/distribution/etiology/outcome	Revised	
Lessons learned:		
•Not a population-based system		
Magnitude i.e. incidence not appropriate		
•Not an etiologic study		
Perhaps, some hypothesis generation		
•Outcome		
Due to ceasing data collection ceasing		
Inadequate sample size for interviews		
Perhaps, some hypothesis generation		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

FEB 22 2002

Mary Manning
Acting Division Director
Chronic Disease Prevention and Control
State Of Minnesota Department of Health
717 Delaware Street
Minneapolis, MN 55440-9441

Re: Grant Awards R01 OH03884-01; R01 OH03943-02; R01 OH04550-02; U01 OH07304-01; U60 CCU507283-12

Dear Ms. Manning:

This is in reply to your memorandum of December 12, 2001, that provided a summary of organizational changes that impact the Center for Occupational Safety and Health. It was noted that Dr. David Parker, Principal Investigator (PI), for the subject awards, would no longer be responsible for supervision and direction of the project activities. These responsibilities would defer to the Acting Director. Although you indicated that Dr. Parker would continue in his Principle Investigator role, in reality the Principle Investigator responsibilities now resides with Center Director. The CDC accepted definition of Principal Investigator is:

> **"An officer, director, owner, partner, key employee, or other person within a recipient organization with primary management or supervisory responsibilities; or a person who has critical influence on or substantive control over a covered transaction, whether or not employed by the recipient organization. "**

In accordance with 45 CFR Part 74.25, prior approval by the recipients from the awarding office is required for change in the Principal Investigator. Specifically prior approval is required if:

> **"Change in the principal investigator or other key persons specified in the application, or the absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved principal investigator requires prior approval from the HHS awarding agency."**

This office has not received, nor approved any prior approval request from you concerning this matter. The request for approval should include a justification for the change, the curriculum vitae of the individual proposed, and any budgetary changes resulting from the proposed change.

As a result of your *proposed* organizational changes, changes of responsibility for the Principal Investigator listed in the application, and the absence of any prior approval authorization from the awarding office, all activities and the incurring of costs on subject grant awards are immediately suspended. Suspension actions are not appealable. Upon receipt of the requested documentation and acceptance of the proposed candidate (including those acting in a temporary capacity as Principal Investigator), the suspension will be reviewed by this office. Please note that incurring cost after the receipt of this letter and prior to approval by the awarding office of your replacement, candidate will result in the disallowance of those costs and may jeopardize other current awards made to your organization by this agency.

We trust this issue will be resolved in a timely manner. Should you have any concerns, please contact me at (770) 488-2656.

Sincerely,

Robert L. Williams, Chief
Acquisitions and Assistance Branch
Procurement and Grants Office

Cc: Michael Galvin, Ph.D./MS-E74
Lee Sanderson, Ph.D./MS-E74
Sheryl Heard, MS-E13

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May 3, 2002

Dr. David Parker
2808 River Parkway West
Minneapolis, MN 55406

Re: *Surveillance of Serious Work Related Trauma* (#1398-99-C)
RO1 OH03943-02

Dear Dr. Parker:

This office is in receipt of correspondence, provided by you, from the Centers for Disease Control. Date stamped February 22, 2002, this correspondence effectively suspends the grant supporting the above referenced study.

As a result, this letter serves as notification of corresponding suspension of this study by the Park Nicollet Institute Institutional Review Board (IRB). All study-related activity must cease immediately. The suspension may not be lifted, and study activity resume, without prior approval from this IRB and supporting documentation from the CDC.

It should be noted that any data collected during the suspension period may not be used.

Please address the following concerns:

- You have indicated that you were made aware of this suspension in mid-March. This IRB was not advised of the suspension until May 2, 2002. Please justify this lapse in required reporting.

- It is our understanding, based on a separate memo from you, dated May 2, 2002 and addressed to me, that activity on this study has continued despite the suspension. Please provide a detailed accounting of what activities you believe have occurred in the interim since the suspension and what your role in those activities has been.

- You have indicated that as many as 15 individual facilities are involved in this project. Our study file indicates that only two additional facilities – St. Cloud and Mercy/Unity Hospitals – were

added to this protocol. Please provide a complete listing of all involved facilities, as well as justification as to why this IRB was not informed of their involvement.

- As principal investigator, you are required to keep all participating IRBs informed of the status of this research. Please provide assurance of expeditious reporting of this suspension to all other participating IRBs.

- Please provide a higher-quality copy of the letter received from the CDC, as well as hard copies of your memos, dated May 2, 2002, that were included with this facsimile transmission.

Given the history of the file and under the current circumstances, a new application and full Committee review will be required when requesting approval to lift the suspension imposed by this IRB, as well as appropriate documentation indicating the CDC's resolution of this matter.

The Park Nicollet Institute IRB, Committee C, will be informed of this suspension at their next meeting on May 7, 2002. A copy of this letter will also be forwarded to the CDC and, per regulatory reporting requirements, to the Office for Human Research Protections.

Your prompt attention to this matter is expected. Should you have any questions or concerns, please feel free to contact me at 952.993.3015.

Regards,

Tamara J. O'Black
Institutional Review Board Administrator

Cc: Dr. Alan Bender; Mary Manning; Office of Human Research protections (OHRP); Centers for Disease Control (CDC)

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May 10, 2002

Dr. David Parker
2808 River Parkway West
Minneapolis, MN 55406

Re: #1398-99-C *Surveillance of Serious Work-Related Trauma*

Dear Dr. Parker:

The Park Nicollet Institute Institutional Review Board (IRB) met on May 7, 2002 and reviewed the current circumstances surrounding the above referenced study, including correspondence to date.

The IRB moved to uphold the Centers for Disease Control and Prevention's (CDC) suspension of this study as outlined in correspondence date stamped February 22, 2002. In addition, the Board echoed concerns reflected in my correspondence of May 3, 2202.

Your response to those concerns will be reviewed by the full IRB as soon as is feasible. Further, should the suspension be lifted by the CDC, you must still satisfy the concerns of this IRB before our lifting of the suspension may be addressed. In addition, should those concerns be satisfied, you will be required to submit a new application for approval in support of this research.

Please feel free to contact me directly at 952.993.3015 should you have any questions or concerns. Your prompt attention to this mater is expected.

Regards,

Tamara J. O'Black
Park Nicollet Institute
IRB Administrator

MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

Tamara O'Black
Park Nicollet Institute
Health Research Center
3800 Park Nicollet Blvd.
Minneapolis, MN 55416-2699

RE: "Surveillance of Serious Work-Related Trauma": 1398-99-C

Dear Ms. O'Black,

This letter is in response to your communication with Dr. Alan Bender on Wednesday, May 15, 2002, and to your letter of May 3, 2002 to the previous Principal Investigator, who has been absent from the Minnesota Department of Health since November 21, 2001.

As you requested, no further data are being collected for this study, including interviews and interview data. However, based on your discussion with Dr. Bender, we will continue to pull data and information together in preparation for the site visit from CDC. In addition, we will notify other institutions that are a part of this grant that no further data will be collected, but that data are being organized for the CDC site visit.

Also, in a letter dated May 14, 2002, the CDC has approved my appointment as interim Principal Investigator. U.S. Public Health Service regulations required the Minnesota Department of Health to propose a substitute Principal Investigator when the previous Principal Investigator had been absent for three months or more. We submitted the request on February 22, 2002, and we were pleased to receive approval last week.

Please do not hesitate to contact me if there are any questions. (612-676-5239).

Sincerely,

L. Ronald French

L. Ronald French, MPH, PhD
Epidemiologist

received 5/24/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

May 22, 2002

Mary Manning
Acting Division Director
Chronic Disease Prevention and Control
Minnesota Department of Health (MDH)
717 Delaware Street
Minneapolis, MN 55440-9441

Re: NIOSH awards R01 OH04265, U01 OH07304, U60 CCU507283, R01 OH003943, R01 OH04320

Dear Ms. Manning,

This letter is in response to your five letters dated February 25, 2002, in which you requested to change the Principal Investigator (PI) on each of the above referenced awards. Based on the material provided to CDC, final decisions about the acceptability of the proposed PIs cannot be made at this time. A site visit is necessary to obtain the additional material. Therefore, CDC approves these nominees listed below as interim PIs for a period of time not to exceed 30 days after the completion of a proposed site visit, unless otherwise amended by CDC:

Dr. Alan Bender - R01 OH04320, U60 CC507283
Dr. L. Ronald French - U01 OH07304, R01 OH003943
Dr. Alan Williams - R01 OH04220

If you have any questions regarding this matter, please do not hesitate to contact Mildred Garner at 770-488-2745 or Lee M. Sanderson at 404-498-4682.

Sincerely,

Lee M. Sanderson, Ph.D.
Program Administrator
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)

for

Robert L. Williams, Chief
Chief, Acquisition and Assistance Branch B
Procurement and Grants Office (PGO)
Centers for Disease Control and Prevention (CDC)

cc: R. Williams
A. Berry

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May 29, 2002

Dr. L. Ronald French
Chronic Disease and Environmental Epidemiology
Minnesota Department of Health
717 Delaware Street SE
Minneapolis, MN 55414

Re: *Surveillance of Serious Work Related Trauma* (#1398-99-C)
RO1 OH03943-02

Dear Dr. French:

This office is in receipt of correspondence from you, undated, indicating CDC approval of your appointment as principal investigator for the above referenced study. I also received brief emails from Dr. David Parker indicating that it was his understanding, via a conversation with Mary Manning, that the CDC had granted provisional approval for this appointment..

As previously requested both in writing and in conversation with Dr. Alan Bender, this office requires a copy of official correspondence from the CDC approving this appointment. To date, no such documentation has been provided. Neither has documentation been provided, as discussed with Dr. Bender, which indicates CDC rescinding of the suspension or their acknowledgement that they "responded inappropriately."

In addition, please understand that once this IRB is able to confirm your role as principal investigator, you are responsible for answering all concerns previously raised in correspondence to Dr. David Parker regarding this study. Until all such concerns are satisfactorily addressed, and a new application submitted, approval for this study remains suspended.

In addition to providing the requested documentation concerning your appointment, please address the following:

- Official documentation from the CDC indicating their lifting of the suspension must be provided before local approval can be reconsidered.

- It is our understanding that personnel in your office were aware of the CDC suspension of this study possibly as early as February of 2002. This IRB was not advised of the suspension until May 2, 2002. Justify this lapse in required reporting.

- It is our understanding that activity on this study continued during this period, despite the suspension. Provide a detailed accounting of what activities occurred in the interim and on what date personnel were informed to halt all study-related activities. Be advised that all data collected during the suspension may not be used.

- It is our understanding that as many as 15 individual facilities are involved in this project. Our study file indicates that only two additional facilities – St. Cloud and Mercy/Unity Hospitals – were added to this protocol. Provide a complete listing of all involved facilities, as well as justification as to why this IRB was not informed of their involvement.

- As principal investigator, you are required to keep all participating IRBs informed of the status of this research. Provide dates as to when this suspension was conveyed to all other participating IRBs.

- Given the history of the file and under the current circumstances, a new application and full Committee review will be required when requesting approval to lift the suspension imposed by this IRB, in addition to the requested documentation indicating CDC resolution of this matter.

Your prompt attention to this matter is expected. If a complete and timely response is not received regarding this matter, this inattention may be considered serious non-compliance and will be reported as such to the Office for Human Research Protections (OHRP).

Should you have any questions or concerns, please feel free to contact me at 952.993.3015.

Regards,

Tamara J. O'Black
Institutional Review Board Administrator

Cc: Alan Bender; Mary Manning; David Parker

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Memorandum

Date: June 7, 2002

From: Tamara J. O'Black
Administrator, Park Nicollet Institute IRB

faxed 6/7

To: Dr. Alan Bender, Minnesota Department of Health

Re: *Surveillance of Serious Work- Related Trauma*

Per our previous telephone conversation on May 13, 2002, and as reiterated in our discussion today, this IRB acknowledges that data collected during the time this study was suspended will and should be made available to regulatory officials during your scheduled NIOSH site visit on June 18-19, 2002.

Further, it is understood per your voice mail message of this morning that immediately following this site visit you and your personnel will be addressing concerns regarding this study as outlined in correspondence of May 3, 2002 (addressed to Dr. David Parker and copied to you) and May 29, 2002 (addressed to Dr. L. Ronald French and copied to you).

It is expected that your response be received by this office no later than Friday, June 28, 2002. Additional delays in providing requested information will be viewed as serious, continuing non-compliance and may be reported as such to the Office for Human Research Protections (OHRP).

I look forward to resolution of these issues. Feel free to contact me at 952.993.3015 should you have any additional questions or concerns.

MINNESOTA
MDH
DEPARTMENT OF HEALTH

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June 20, 2002

Ms. Tamara J. O'Black
Administrator
Park Nicollet Institute IRB
Park Nicollet Institute
Health Research Center
3800 Park Nicollet Boulevard
Minneapolis, Minnesota 55416-2699

Dear Ms. O'Black:

This letter is to confirm our telephone conversation of today relative to the grant activity referenced as Surveillance of Serious Work-Related Trauma. The NIOSH site visit was concluded yesterday. It went very well. NIOSH will require at least two weeks before providing us documentation on the permanent status of the Principal Investigator for this initiative. I have enclosed a letter from NIOSH that documents Dr. L. Ronald French as the interim PI (R01 0H003943).

I am also of the understanding that the Minnesota Department of Health may continue to use data under the auspices of your IRB to respond to any requests from NIOSH.

If you have any questions or if my understanding is not correct, please contact me at (612) 676-5229. Thank you.

Sincerely,

Alan Bender

Alan Bender, D.V.M., Ph.D., Section Chief
Chronic Disease and Environmental Epidemiology
P. O. Box 9441
717 Delaware Street Southeast
Minneapolis, Minnesota 55440-9441

AB:dr
Enclosure
cc: Ron French
Allan Williams
Mary Manning

received 6/24/02 TO

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June 24, 2002

Dr. L. Ronald French & Dr. Alan Bender
Chronic Disease and Environmental Epidemiology
Minnesota Department of Health
717 Delaware Street SE
Minneapolis, MN 55414

Re: *Surveillance of Serious Work Related Trauma* (#1398-99-C)
RO1 OH03943-02

Dear Drs. French and Bender:

This office is in receipt of correspondence from Dr. Alan Bender, dated June 20, 2002, concerning the recent NIOSH site visit auditing the above referenced study. As previously requested, and as promised by Dr. Bender in conversation the morning of June 20, 2002, this correspondence does include documentation of Dr. French's appointment as interim principal investigator.

It does not include information addressing other concerns as noted in correspondence to Dr. French (and copied to Dr. Bender) dated May 29, 2002 and as previously conveyed to Dr. David Parker in correspondence dated May 3, 2002. While it is understood that NIOSH will be providing you with documentation concerning their site visit findings, this in no way negates responsibility for fully addressing the concerns of this IRB.

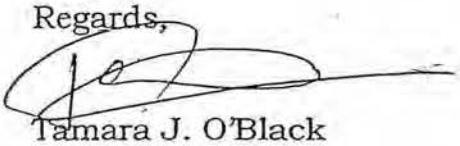
In conversation with Dr. Bender on June 7, 2002, and documented in a memo to him on the same date, I granted an extension for the Department of Health's response to IRB concerns in light of the upcoming site visit. That memo clearly stated the expectation that all concerns regarding this study were to be addressed no later than June 28, 2002. It also reiterated that should such correspondence not be received by that date, such a delay would be viewed as serious and continuing non-compliance and reported as such to the proper regulatory authorities.

Be advised that your complete response to the IRB concerns previously voiced must be received by this office no later than 4:00 pm on Friday, June 28, 2002. No extension will be granted. Failure to provide this information will be reported to the Office for Human Research

Protections (OHRP), the CDC, and NIOSH. A copy of the May 29, 2002 correspondence is enclosed for your convenience.

Please contact me at 952.993.3015 should you require additional clarification. Your prompt attention to this matter is expected.

Regards,



Tamara J. O'Black
IRB Administrator
Park Nicollet Institute

MINNESOTA
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DEPARTMENT OF HEALTH

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June 26, 2002

Ms. Tamara J. O'Black
Administrator
Park Nicollet Institute IRB
Park Nicollet Institute
Health Research Center
3800 Park Nicollet Boulevard
Minneapolis, Minnesota 55416-2699

Dear Ms. O'Black:

I am in receipt of your correspondence dated June 24, 2002, relative to the Surveillance of Serious Work Related Trauma (#1398-99-C).

On Thursday, June 20, 2002, I conveyed to you the information that we would not be able to address point one of the May 29, 2002 letter for about two weeks. I asked and thought I received your verbal approval to delay our response until the NIOSH documentation arrived. In fact, we even discussed the possibility that if the MDH received a retroactive lifting of the suspension to February 22, 2002, the requirement of a complete IRB review might also be waived. Apparently, I was wrong.

We have opted to respond to your questions with full and complete details. One of the points may require interaction with Dr. David Parker who has been absent from work since November, 2001. Mary Manning, who had several communications besides mine with NIOSH is unavailable until next week. Also, we are expecting additional correspondence from NIOSH that will document that the Minnesota Department of Health acted in good faith to fulfill its obligation to NIOSH during the suspension period, and conducted these activities funded by NIOSH in accordance with the protocols that were previously approved by them. Finally, there may be legal issues that will require consultation with the Attorney General's office before we can provide you a detailed response.

received
6/27/02

Since it is apparent that the ethical conduct of the Minnesota Department of Health during this study is being called into question, I believe that a fragmented, incomplete and undocumented response to your request does not serve your IRB or the MDH. In order to fully satisfy your request, I again respectfully ask for the time necessary to obtain the forth coming NIOSH documentation, to address questions generated by the conduct of the previous PI, and to insure that all federal and state legal obligations are satisfied. In any event, we will not be able to provide you the details that you have requested by June 28, 2002, for all the reasons given, it is simply not in our control to do so.

Sincerely,

Alan Bender

Alan Bender, D.V.M., Ph.D., Section Chief
Chronic Disease and Environmental Epidemiology
P. O. Box 9441
717 Delaware Street Southeast
Minneapolis, Minnesota 55440-9441

AB:dr
Enclosure
cc: Mary Manning, Acting Division Director
Ron French, M.P.H., Ph.D.
Aggie Leitheiser, Assistant Commissioner of Health
Julie Brunner, Deputy Commissioner

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June 26, 2002

Dr. L. Ronald French & Dr. Alan Bender
Chronic Disease and Environmental Epidemiology
Minnesota Department of Health
717 Delaware Street SE
Minneapolis, MN 55414

Re: *Surveillance of Serious Work Related Trauma* (#1398-99-C)
RO1 OH03943-02

Dear Drs. French and Bender:

This office is in receipt of faxed correspondence from Dr. Alan Bender, dated June 26, 2002, regarding your response to IRB concerns related to the above referenced study.

It is understood that you will not be able to fully respond to the issue of the CDC suspension and possible retroactive lifting of the suspension until resolution of the NIOSH site visit. Once documentation is received from NIOSH, it is expected that this aspect be addressed.

With respect to the remaining concerns outlined in my letter of May 29, 2002, these are local concerns. Their resolution is not dependent upon receipt of additional information from NIOSH, CDC or other outside entities. While the IRB acknowledges and appreciates the logistical challenges of this situation as outlined in your letter, we have been consistent in our request that these concerns be addressed in a timely manner. Correspondence from this office to Dr. David Parker, dated May 3, 2002 and copied to you, originally laid out these concerns and the expectations of the IRB in writing. This was further clarified in my conversation with you on May 9, 2002.

Those concerns, excerpted from the May 29, 2002 letter, are as follows:

- It is our understanding that personnel in your office were aware of the CDC suspension of this study possibly as early as February of 2002. This IRB was not advised of the suspension until May 2, 2002. Justify this lapse in required reporting.

- It is our understanding that activity on this study continued during this period, despite the suspension. Provide a detailed accounting of what activities occurred in the interim and on what date personnel were informed to halt all study-related activities. Be advised that all data collected during the suspension may not be used.

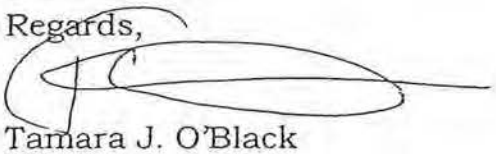
- It is our understanding that as many as 15 individual facilities are involved in this project. Our study file indicates that only two additional facilities – St. Cloud and Mercy/Unity Hospitals – were added to this protocol. Provide a complete listing of all involved facilities, as well as justification as to why this IRB was not informed of their involvement.

- As principal investigator, you are required to keep all participating IRBs informed of the status of this research. Provide dates as to when this suspension was conveyed to all other participating IRBs.

Again, we appreciate the difficulties of navigating this situation and are willing to grant reasonable accommodation as regards documentation of the suspension and pending resolution with CDC/NIOSH; however, our expectation regarding your responsibility to resolve the remaining issues is quite clear. Please provide a complete response to the concerns noted above no later than 4:00 pm on Friday, June 28, 2002.

Please contact me at 952.993.3015 should you require additional clarification. Your prompt attention to this matter is expected.

Regards,



Tamara J. O'Black
IRB Administrator
Park Nicollet Institute

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DEPARTMENT OF HEALTH

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June 28, 2002

Ms. Tamara J. O'Black
IRB Administrator
Park Nicollet Institute
Health Research Center
3800 Park Nicollet Boulevard
Minneapolis, Minnesota 55416-2699

Dear Ms. O'Black:

Thank you very much for your quick response to my letter of June 26, 2002. I understand the importance of the work conducted by your IRB. I also understand that there are strict guidelines that you must adhere to and I understand the reasons for them. I want to assure you that with time we will be able to address your questions completely. This is our intent and has been from the beginning.

As I indicated in my last letter, there are many factors outside our control that preclude a complete response by your deadline. I have conferred with our Executive Office and we simply cannot address points 1, 2, and 4 of your latest letter without the NIOSH correspondence and documentation that is forth coming. NIOSH staff is working hard to move through their channels, yet their responses are at least a week away. We will need additional time after receipt of this material to provide complete responses to your questions. I mentioned in my last letter that Dr. David Parker has not been at work at the Department of Health since November, 2001. Accordingly, we cannot completely respond to point three of your letter either. However, I can transmit what we know at this time.

The complete listing of all facilities involved in the Surveillance of Serious Work-Related Trauma study:

Hennepin County Medical Center
Regions Hospital
St. Mary's Hospital - Rochester
Methodist Hospital - St. Louis Park
Unity Hospital
St. Cloud Hospital
HealthEast St. John's Hospital
Fairview Ridges Hospital
Fairview Southdale Hospital
Abbott-Northwestern Hospital
North Memorial Medical Center
St. Mary's Medical Center - Duluth
Methodist Hospital - Rochester
Mercy Hospital
St. Luke's Hospital - Duluth
Rice Memorial Hospital
HealthEast St. Joseph's Hospital
Fairview University Hospital
Immanuel St. Joseph's Hospital
United Hospital

IRB approval was obtained from each of these facilities prior to initiation of the study.

received 7/2/02 tv

We can find no documentation from the previous principal investigator (Dr. Parker) to Park Nicollet concerning the inclusion and participation of the above facilities in the study. However, in the original Institutional Review Board application, dated 09/20/99, it was stated that "patients would be recruited from the 11 regional trauma centers, Minnesota Department of Labor and Industry, and hospitals that are yet to be defined." In both annual progress reports sent 09/19/00 and 09/17/01, all questions were answered, including those asking for total number of participants screened, enrolled and completed with the study.

Letters from the MDH went to the IRBs of all other participating facilities informing them of the upcoming site visit and explaining that until pending study issues were resolved, no further study data were to be collected. As you can see from this information, we have very different perspectives on this issue and we hope to be able to resolve them soon.

Finally, you state in your letter that all data collected during the suspension may not be used. I am assuming that our agreement that the MDH may still use these data for purposes of responding to NIOSH requests is still valid.

I hope that this letter further clarifies the situation. Thank you very much for your time and attention.

Sincerely,

Alan Bender

Alan Bender, D.V.M., Ph.D., Section Chief
Chronic Disease and Environmental Epidemiology
P. O. Box 9441
717 Delaware Street Southeast
Minneapolis, Minnesota 55440-9441

AB:dr
Enclosure
cc: Mary Manning, Acting Division Director
Ron French, M.P.H., Ph.D.
Aggie Leitheiser, Assistant Commissioner of Health
Julie Brunner, Deputy Commissioner

Park Nicollet

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July 9, 2002

Michael Carome, Director of Compliance Oversight
Office for Human Research Protections (OHRP)
Department of Health and Human Services (DHHS)
The Tower Building
1101 Wootton Parkway – Suite 200
Rockville, MD 20852

Re: RO1 OH003943 *Surveillance of Serious Work-Related Trauma*
Original Principal Investigator: Dr. David Parker
Current Interim Principal Investigator: Dr. L. Ronald French
Granting Agency: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)

Dear Mr. Carome:

Pursuant to 45 CFR 46.103(b)(5), we are notifying OHRP of serious, continuing non-compliance with regard to the above referenced protocol.

This study was originally approved by the Institutional Review Board (IRB) for Park Nicollet Institute in November of 1999 with Dr. David Parker as principal investigator. At that time, the Minnesota Department of Health "agree(d) to abide by all decisions and requests" made by this IRB. A Single Project Assurance, approved April 19, 2000, was filed by the MN Department of Health with DHHS. Since that time, we have considered the Park Nicollet Institute IRB as the IRB of record for this study.

What follows is a timeline of recent events:

Early/Mid-March 2002 Dr. David Parker approached me on two occasions expressing concern over what he referred to as the Minnesota Department of Health's ongoing efforts to have him removed as principal investigator on the above grant. I indicated that it was the jurisdiction of the granting agency to have him removed, that the MN Dept. of Health would presumably have to show cause for his removal, and that until documentation of NIOSH approval for his removal was received by this IRB, Dr. Parker was still considered the principal investigator (PI) of record.

March 25, 2002 Correspondence was received from Margee Brown, MN Dept. of Health IRB Coordinator, indicating that Dr. David Parker was being replaced as PI on this grant by Dr. L. Ronald French. No supporting documentation was attached.

March 27, 2002	I spoke with Ms. Brown and indicated that this IRB cannot approve the change in PI until documentation approving the change is received from NIOSH.
Undated letter	Correspondence was received from Dr. Alan Bender, Section Chief of Chronic Disease and Environmental Epidemiology at the MN Dept. of Health repeating the request that Dr. Parker be replaced by Dr. French as PI on this grant. No supporting documentation was attached.
April 15, 2002	Sent correspondence to Dr. Bender again expressing the need for documentation of NIOSH approval of this transfer of PI, indicating that Dr. Parker will remain the PI of record until such correspondence is received, and requesting that a curriculum vitae and letter of intent from Dr. French accompany the documentation when forwarded.
May 2, 2002	At his request, Dr. Parker met with Dr. Margaret Healey, Director of Clinical Research for Park Nicollet Institute, and myself regarding what he termed serious ethical concerns regarding the conduct of this study. During the course of that conversation he revealed that 1) this study had been suspended by CDC due to ongoing difficulties in properly designating a PI; 2) study-related activity was ongoing; and 3) there were as many as 15 institutions participating in the study where the original application proposed 11. In response to this meeting, Dr. Parker provided a brief memo outlining his understanding of the related events to date, a separate memo indicating that he would begin compiling a list of the participating institutions, and a poor, facsimile copy, date stamped February 22, 2002, of the CDC suspension letter. *A copy of this letter is attached.*
May 3, 2002	Sent formal correspondence to Dr. Parker reflecting the IRB for Park Nicollet Institute's understanding of the situation, effectively suspending the study immediately in conjunction with the CDC suspension, indicating that all study-related activities must cease immediately and that data collected during the suspension period could not be used, and requesting that he address the following: • Lapse in required reporting of the NIOSH suspension to this IRB; and the • Nature of and justification for study-related activities that occurred following his knowledge of the suspension. Dr. Parker was also asked to provide a complete list of participating facilities and assurance that the suspension had been appropriately reported to those institutions/IRBs. This letter was copied to Dr. Bender, Mary Manning at the MN Dept. of Health, OHRP, and CDC. *A copy of this letter is attached.*

May 7, 2002 — The IRB for Park Nicollet Institute met, reaffirmed suspension of this study, and deferred consideration of renewed approval until complete resolution of all IRB concerns and submission of a new application is received. *A copy of this letter (dated 5/10/02) is attached.*

May 9, 2002 — I received a telephone call from Dr. Bender expressing concern over what he termed the lack of trust reflected in my letter. He indicated that Dr. Parker had "vacated his role as PI. Regarding the suspension, he indicated that NIOSH had since rescinded the suspension and acknowledged that it (NIOSH) had responded inappropriately to the situation. He also implied that study-related activity was ongoing and would continue as such, and expressed concern over how long this situation would take to resolve. He said that documentation reflecting the mistaken suspension would be forwarded within the next week.

I explained to Dr. Bender that this IRB must act on information presented to it, that until concerns were addressed the study remained under Dr. Parker as PI and remained suspended, and that I could make no promises about the time to resolution.

May 13, 2002 — Dr. Bender left a voice mail indicating that staff were now complying with conditions outlined in the IRB suspension letter, and that NIOSH would be conducting a site visit and he had a question regarding use of data for that purpose.

When I returned his call, he reiterated that they are following through on curtailment activity. He also indicated that NIOSH had accepted the PI transfer. I clarified that the understanding of this IRB with regard to the use of data collected during the suspension did not preclude complete compliance with NIOSH requests in conjunction with their site visit.

Dr. Parker copied me on an email to Dr. Bender and Ms. Manning requesting a list of institutions involved in the study in order to respond to IRB concerns.

May 19, 2002 — Dr. Parker indicated in separate emails to me that he had been informed via phone that NIOSH had approved the transfer of the grant and change in PI.

May 24, 2002 — Dr. Parker indicated in an email that the MN Dept. of Health had declined to provide him with a list of institutional contacts for this grant, and that Ms. Manning stated to him that she would be in contact with our office.

May 24, 2002

Correspondence was received from Dr. French confirming his status as interim PI, acknowledging the IRB letter of May 3, and providing assurance that no data was being collected for the study at that time. Previously conveyed IRB concerns were not addressed. *A copy of this letter is attached.*

May 29, 2002

Sent correspondence to Dr. French acknowledging the general understanding of his new role as PI but again requesting that documentation be provided, as promised, of both NIOSH approval of the transfer and their alleged rescinding of the suspension. The letter reiterated all previously outlined IRB concerns, indicated that prompt attention to these concerns was expected, and that continuing inattention may be considered serious non-compliance and reported as such to OHRP. The letter was copied to Dr. Bender and Ms. Manning. *A copy of this letter is attached.*

June 7, 2002

Spoke with Dr. Bender who again requested, and was provided with, clarification regarding use of data collected for the NIOSH site visit on June 18-19. He requested an extension of their time to respond given the need to prepare for the site visit but assured me that they would address all concerns immediately following the visit. I agreed to the extension with the clear understanding that all issues must be dealt with immediately following the site visit.

I provided a memo via fax and mail indicating our understanding regarding use of the data, providing a June 28 deadline for receipt of their response to IRB concerns, and clearly indicating that additional delays would be considered serious, continuing non-compliance and be reported as such to OHRP. *A copy of this memo is attached.*

June 20, 2002

Dr. Bender called and requested another extension to respond to IRB concerns. He indicated that the site visit had just concluded and that he expected to receive correspondence within two weeks effectively rescinding the NIOSH suspension. I asked if this was the same documentation he had promised to provide more than a month ago. I was not given an answer. He then indicated that he had no documentation pertaining to this study. When I question him he clarified that he did have documentation approving the appointment of Dr. French as interim PI. I requested that this information be forwarded immediately, along with their response to local IRB concerns. It was emphasized that an extension was not being granted. He indicated that he would get that information out the same day. Again, he raised the issue of use of collected data in conjunction with the NIOSH site visit and our understanding was again clarified.

June 24, 2002	Documentation was received from Dr. Bender regarding CDC/NIOSH approval of Dr. French as Interim PI. No other IRB concerns were addressed. *A copy of this letter is attached.*
June 24, 2002	Sent correspondence via same-day courier service to Drs. Bender and French again requesting that IRB concerns be addressed. The letter clearly indicated that the deadline remained June 28, that no additional extensions would be granted, and that failure to provide the requested information would be reported to OHRP. *A copy of this letter is attached.*
	Confirmation of the reported suspension was received from OHRP.
June 25, 2002	Dr. Bender left a voice mail indicating that he had received a request from one of his staff regarding renewal of this study. I returned his call and left a voice mail indicating that 1) the study was currently suspended and thus renewal was not a concern at this point; and 2) the last approval date was November 6, 2001 and thus even under normal circumstances the study would not be due for renewal until November 5, 2002.
June 26, 2002	Faxed copy of correspondence was received from Dr. Bender (hard copy received 6/27/02). The first full paragraph of this letter clearly misrepresented the contents of my conversation of June 20 with Dr. Bender. No extension was granted, no waiver of complete IRB review was discussed. Dr. Bender offered a number of reasons why he believed the Dept. of Health could not respond in a timely manner to the IRB concerns noted. He implied that further additional time is needed in order to provide a complete and documented response. *A copy of this letter is attached.*
June 26, 2002	Sent correspondence via same-day courier service to Drs. Bender and French acknowledging that, as concerned CDC suspension of the study, it was understood that they might not be able to fully respond until additional information was received documenting the NIOSH site visit; however, the letter again requested that the remaining IRB concerns be addressed immediately as these were local concerns and response was not dependent upon input from NIOSH. The deadline was again clearly stated. *A copy of this letter is attached.*
June 28, 2002	Facsimile copy of correspondence was received from Dr. Bender (hard copy received 7/02/02) again stating that they could not, for various reasons, fully respond to the concerns of this IRB as had been requested. Dr. Bender did provide a list of 20 participating institutions, but no additional details were provided and he did not address any other IRB concerns. *A copy of this letter is attached.*

July 1, 2002

In an effort to clarify the situation, I contacted NIOSH directly and spoke with Dr. Lee Sanderson, Program Administrator. Dr. Sanderson conveyed the following information:

- According to NIOSH, the study was no longer suspended and remained so only during the period from the initial notification through their letter of May 22 approving appointment of the interim PI;
- The site visit was conducted with the primary purpose of gathering additional information on the qualifications of the new PI and checking on the general status of the study. It was not conducted to explore any human subjects or regulatory compliance related concerns. The CDC Procurement and Grants Office conducted a concurrent assessment of the financial status of the grant;
- Dr. Sanderson was unaware that the study was and remained suspended by the Park Nicollet IRB, the IRB of record for the study; and
- He agreed that it would not appear as if the pending report from NIOSH would address any of the concerns promulgated by this IRB with regard to local conduct of the study.

July 2, 2002

The IRB for Park Nicollet Institute met and, upon review of the information available, moved to report the situation as serious, continuing non-compliance to OHRP.

Where noted, copies of correspondence have been attached. A compete set of file correspondence, including logs of telephone conversations, is available upon request.

This office, on behalf of the Park Nicollet Institute IRB, has made a continuing effort to work with Drs. Bender and French to resolve these issues. Despite repeated assurance of their intent to provide complete information, the Minnesota Department of Health has yet to fully respond to serious local concerns, originally conveyed May 3, 2002, regarding conduct of this study. This failure to comply with minimal IRB reporting obligations and expectations demonstrates a lack of respect and understanding for the role this IRB is federally mandated to play in the protection of humans subjects and compliance with pertinent federal, state, and local regulations and policies.

In order to resume the study at this site, the MN Department of Health must fully address all outstanding IRB concerns, identify a new local investigator or liaison, and submit a new application for consideration of approval. If this matter is not resolved within 30 days of the date of this letter, this study will be permanently terminated.

While this IRB considers this matter serious, it should be noted that at this time we have no reason to suspect that any human subjects have been harmed as a result of this non-compliance.

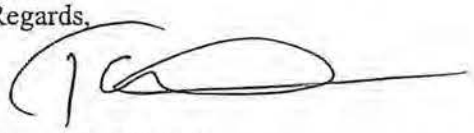
Investigators are reminded in routine correspondence to inform the IRB of any changes in the study that may potentially affect human subjects. As part of ongoing quality assurance and

improvement efforts, we will be taking a closer look at the educational materials provided to our investigators in order to ensure that reporting obligations are indeed clearly delineated.

We will inform the Office for Human Research Protections of any additional formal action taken to resolve this situation. Please advise us if any additional supporting documentation or information is desired.

Should you have any immediate questions or concerns, please feel free to contact me directly at 952.993.3015.

Regards,



Tamara J. O'Black
Institutional Review Board Administrator
Park Nicollet Institute

Cc: Dr. L. Ronald French, MN Department of Health
Dr. Alan Bender, MN Department of Health
Dr. Lee Sanderson, National Institute for Occupational Safety and Health
Robert L. Williams, Centers for Disease Control and Prevention
James V. Toscano, Institutional Official, Park Nicollet Institute

To: 'Ronald French'
From: "O'Black, Tamara J." <oblact@parknicollet.com>
Subject: RE: CDC Site Visit to MDH
CC: Alan Bender; Mary Manning
Date Sent: Friday, September 6, 2002 2:43 PM

Dr. French:

Attached, please find an electronic version of the letter that went out. All involved parties should be receiving their respective copes shortly. In addition, I've attached the letter of final resolution sent to OHRP regarding our report of non-compliance.

Please feel free to contact me at 952.993.3015 should you have any additional questions or concerns.

Warmest Regards,
Tamara

-----Original Message-----
From: Ronald French [mailto:Ronald.French@state.mn.us]
Sent: Friday, September 06, 2002 2:18 PM
To: oblact@parknicollet.com
Cc: Alan Bender; Mary Manning
Subject: CDC Site Visit to MDH

Tamara,

Mary Manning mentioned that you have had a chance to review the report of the CDC/NIOSH Site Visit to the Minnesota Department of Health (June 18, 19, 2002). It is my understanding that the findings and recommendations of the Site Visit team have resolved the remaining concerns of the Park Nicolett IRB.

I understand that a letter will be sent to the MDH confirming the lifting of the suspension by Park Nicollet. However, I would appreciate an email confirmation, so that we than get our staff back to work on the Surveillance of Serious Work-Related Trauma project (#1398-99C) as soon as possible.

Thank you in advance for you help, and also we appreciate your offering to help us find a local Park Nicollet liaison if necessary.

Sincerely,

Ron French

September 3, 2002

Dr. L. Ronald French
Chronic Disease and Environmental Epidemiology
Minnesota Department of Health
717 Delaware Street SE
Minneapolis, MN 55414

Re: *Surveillance of Serious Work Related Trauma* (#1398-99-C)
RO1 OH03943-02

Dear Dr. French:

The Institutional Review Board (IRB) for Park Nicollet Institute met on September 3, 2002 and reviewed correspondence from the Centers for Disease Control and Prevention (CDC), date stamped August 28, 2002, as forwarded by Mary Manning regarding the above referenced study.

Upon review, the Committee finds that all outstanding concerns regarding the conduct of this study have been satisfied. The suspension of this study imposed by this IRB is hereby lifted with following understanding:

You are free to conduct continued data analysis of study information already collected from subjects contacted via Park Nicollet. Should you wish to access new/additional information via Park Nicollet, you will need to identify a local liaison and submit an updated application form.

We appreciate your cooperation in resolving this matter and look forward to future collaborative efforts with the Minnesota Department of Health.

Should have any questions or concerns, or desire assistance in identifying a local liaison, please feel free to contact me at 952.993.3015.

Warmest Regards,

Tamara J. O'Black
Regulatory Affairs Manager
Park Nicollet Institute

Cc: Dr. Alan Bender, MN Department of Health
Mary Manning, MN Department of Health
Dr. Lee Sanderson, National Institute for Occupational Safety and Health
Robert L. Williams, Centers for Disease Control and Prevention
Michael Carome, Office for Human Research Protections (OHRP)
Jim Toscano, Institutional Official

September 3, 2002

Michael Carome, Director of Compliance Oversight
Office for Human Research Protections (OHRP)
Department of Health and Human Services (DHHS)
The Tower Building
1101 Wootton Parkway – Suite 200
Rockville, MD 20852

Re: RO1 OH003943 *Surveillance of Serious Work-Related Trauma*
Original Principal Investigator: Dr. David Parker
Newly Confirmed Principal Investigator: Dr. L. Ronald French
Granting Agency: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)

Dear Mr. Carome:

Pursuant to 45 CFR 46.103(b)(5), we are providing final documentation on the resolution of previously reported concerns of serious, continuing non-compliance with regard to the above referenced protocol.

As of this date, all outstanding concerns have been satisfactorily resolved and the suspension of the study by this IRB has been lifted (please see attached letter).

Internally, we are reassessing the educational materials provided to our investigators in order to ensure that reporting obligations are indeed clearly delineated.

We appreciate the support of the Office for Human Research Protections in oversight of this matter. Please advise us if any additional supporting documentation or information is desired.

Should you have any questions or concerns, please feel free to contact me directly at 952.993.3015.

Warmest Regards,

Tamara J. O'Black
Institutional Review Board Administrator
Park Nicollet Institute

Cc: Dr. L. Ronald French, MN Department of Health
Dr. Alan Bender, MN Department of Health
Mary Manning, MN Department of Health
Dr. Lee Sanderson, National Institute for Occupational Safety and Health
Robert L. Williams, Centers for Disease Control and Prevention
James V. Toscano, Institutional Official, Park Nicollet Institute