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Bloodborne Exposure Management
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List of Abbreviations:

1. Guidelines: U.S. Public Health Service Guidelines
2. EMS: Emergency Medical Service
3. BBP: Bloodborne Pathogens
4. HIV: Human Immunodeficiency Virus
5. HBV: Hepatitis B
6. HCV: Hepatitis C
7. UP/SP: Universal Precautions/Standard Precautions
8. PEP: Post Exposure Prophylaxis

Abstract

The purpose of this study was to identify factors related to compliance with the 1996 US Public Health Service Guidelines for the management of occupational exposures to blood or other body fluids possibly contaminated with the human immunodeficiency virus (HIV).[1]

The Guidelines call for rapid exposure reporting with evaluation of the exposure risk, counseling and prophylactic treatment with anti-retroviral medications and follow-up care as needed. With an estimated 300,000 to 500,000 bloodborne exposures in occupational settings each year, these Guidelines potentially affect a large number of employees.[2-3] The Guidelines are designed to reduce the risk not only for employees at acute care health facilities, but also for employees across a broad range of occupations, including non-hospital based health care workers and public safety workers. The extent to which these Guidelines are followed, and equally important, the identification of problems with compliance and follow-through, remains largely unknown. Our previous research emphasized the identification of barriers to compliance with universal precautions in both hospital- based and non-hospital based health care workers, as well as exposure risk in public safety workers, including law enforcement employees (including prison workers). This line of research led to successful intervention research and the implementation of strategies for risk reduction in health care worker populations. While the methods and findings from this line of earlier work have been demonstrated to help reduce exposures, the 1996 Guidelines are directed at activities to perform following an exposure, and the problems and barriers here may be quite different from the barriers to compliance with universal precautions. Thus this study was specifically designed to identify barriers to implementation of the 1996 Guidelines.

To address this issue we surveyed a sample of emergency medical service (EMS) workers recruited from first responder facilities located in Baltimore County, Maryland. The survey instrument was informed by extensive qualitative processes and extensive pre and pilot testing. Anonymous questionnaires were self-administered by a convenience sample of EMS workers employed throughout the county at a variety of facilities and locations (e.g., urban, rural, suburban). The response rate was nearly 50%. The major goals of the study were:

1. To assess and evaluate the infection control programs for minimizing risk of bloodborne pathogens in EMS.
2. To assess and characterize adherence to the US Public Health Service Guidelines at both the employee and employer levels.
3. To determine the characteristics that distinguish exposed workers who experienced full versus incomplete compliance with the US Public Health Service Guidelines. Characteristics include worker-centered variables (e.g., sociodemographics, exposure history, employee reporting practices, and organizational variables (e.g., adequacy of resources to implement the Guidelines, safety climate, training and education).
4. To identify data-driven strategies to improve implementation and compliance with the Guidelines among a population of health care workers at potential risk of exposure.

Significant Findings

Demographics: The sample of 244 EMS was predominantly male (81.1%), with a median age of 40 years. More than half (60%) worked in primarily urban areas, most of the remaining EMS worked in suburban areas (30%) or rural (10%). Respondents were predominantly educated at the Associate Degree or Diploma level (80%) about 20% had

college degrees. Respondents had various professional certificates; over 50% (52.9%) had an EMT-B certificate, with the remainder reporting advanced certificates, such as CRT (7.4%) and EMT-P (35.2%). Most responders had worked as EMS professionals for approximately 15 years. Roughly half worked on an EMS transport vehicle, with the other half working on a Fire Department First-Response vehicle. Most (92.3%) worked four 12 hour shifts per week.

Exposure History: 3.6% (n= 9) of the respondents reported a total of 11 needlesticks in the 12 month period prior to the study. Of these, only 6 were reported (54.5%) to their employer; an underreporting rate of 45.5%. There were other types of potentially serious exposures reported on the questionnaires, including splashes to the eyes/mouth (n=11), open wound contact with blood/body fluids (n=3), and cuts with sharps (n=12). The underreporting rate for these other types of exposures ranged from a low of 20% (splashes) to a high of 70% (cuts).

Reports of exposures which occurred over their lifetime EMS careers were high; 42% reported at least one needlestick during their career, with about half of these occurring during their present employment. Overall 26% of respondents reported at least one needlestick in their present job.

HBV Vaccination History: The respondents reported high rates of vaccination, with 97.1% reporting that they had received a primary series of all three doses of HBV vaccine, with 93% reported that they were tested for titers following their series.

Risk Factors for Recent Exposures: Respondents were asked to report the type of instrument or equipment they were using during their most recent exposure. The most frequently cited was IV needle (41%) and glucometer lancet (41%), followed by syringe and needle (7.7%). Safety devices were often in use in a high percentage (66%) of these exposure incidents, including: retractable needles (35.4%), or other type of safety needle (22.7%).

Infection Control: A new 10-item employee health-specific safety climate scale was developed for this study. The scale has an alpha of .69, mean = 7.7, median = 8.0, mode = 8.0, SD plus/minus 1.3, range = 1-10. While the overall climate was high, low scores were noted on some specific items. For instance, 73.7% of respondents reported that they did not have access to an employee health professional at their organization. And while a high level of training was reported, 91.4% reported that they received annual bloodborne pathogen training, with, nearly 51% provided with 3 or more training hours per year, and 32% receiving 2 hours per year, a substantial proportion (17%) received 1 hour or less per year.

Compliance with Universal Precautions/Standard Precautions (UP/SP): A 12-item well-characterized UP scale was included on the questionnaire. The alpha was .69, the mean = 51.6, median = 52, mode = 53, SD plus/minus 4.7 and range = 32-60. While compliance was generally reportedly high, scores for some specific items were suboptimal. For instance, 13% reported often/always recapping contaminated needles and 60% never/rarely wore protective outer garments when needed.

Reporting Practices: There were four items on the questionnaire addressing reporting of exposures. The results were as follows:

- Percent reporting that they are encouraged by employer to report near misses: 17.2%
- Percent reporting that they are encouraged by employer to report all exposures: 91.3%
- Percent reporting that they are encouraged by employer to report only significant exposures: 29.7%
- Percent reporting reluctance to report exposures: 16.9%

The most common reasons cited for reluctance to report included: (1) reporting is too time consuming (9.4%), (2) fear of getting into trouble (8.2.%), and (3) uncertainty about what to do (form to use, etc.) (3.2%). Open ended responses to this question included: "(female) gender," "fear of lack of confidentiality," "lack of supervisor support," "fear of taking anti-retrovirals."

Safety Climate: An 18-item safety climate scale was included, which targeted bloodborne pathogen related aspects of safety climate. The alpha was .90, the mean = 69.9, median = 70, SD plus/minus X, range = 18-90. The responses indicated, in general, the respondents scored the safety climate reasonably positive.

Post-Exposure Care: Thirteen questions addressed the issue of post-exposure follow-up. Some of the responses here were of concern. For example, only 39.5% of respondents reported that they completed an incident/accident report, although, more than half (58%) reported receiving information on how to report during their initial on-the-job training. Another problem noted was the high rate of exposed workers reporting a delay in their post-exposure care; 36.7% were seen by a healthcare professional within 2 hours or less, 16.7% were seen more than 2 hours after their exposure, and 46.7% were never seen at all. For those reporting a greater than 2 hour delay, commonly cited reasons included: (1) "did not think it was medically necessary" (50%), (2) "did not know I should go" (31.3%), and (3) "could not get a replacement" (12.5%). Post exposure care that included psychological counseling was reported by only 22%.

There were 14 respondents that reported that they were offered post-exposure prophylaxis (PEP) for HIV. Of these, only 2 (14%) actually accepted the PEP; reasons for non-acceptance included: fear of side effects, and perceived low risk of patient. No one reported a referral to an HIV specialist to manage their post-exposure care, although 86% reported that they were provided with written information about post-exposure treatment. Overall, 29% of respondents with exposures ranked their post-exposure experience as excellent/good, and 71% ranked it as fair or poor. Three percent of respondents reported that they had left a job because of a needlestick injury.

Correlates of Exposure: Only two variables were significantly associated with exposure. The first was work setting (EMS transport vs. fire department first responder vehicle); EMS transport workers were twice as likely to experience a percutaneous injury compared to fire department first responders (OR= 2.0, $CI_{95\%}$ 1.02-3.91). The other variable was distraction/stress, a composite question that included the following variables: distracted, overworked, rushed, stressed about work, stressed about personal matters, and, tired. Workers with a high score on this scale were nearly 4 times as likely to also report a percutaneous exposure (OR= 3.70, $CI_{95\%}$ 1.74-7.89). In this group, safety climate was not significantly associated with exposure, which may have been a function of either low variability and/or small number of exposures.

Translation of Findings: These findings were discussed at a recent NIOSH-sponsored EMS working group meeting of experts in EMS, front-line workers (or representatives of front-line practitioners, safety experts, etc.) and found to be commonly reported by other EMS populations nationally. The problem of rapid post-exposure follow-up is an issue for many agencies, especially those located in sparsely populated or rural areas. As show by our data, post-exposure care, as proscribed by the Guidelines, appears to be less than universally adopted across settings and agencies. Key recommendations, such as provision of referral to HIV specialists, do not appear to be implemented. This is worrisome, because even when recommended, many exposed EMS workers chose not to receive anti-retrovirals due to concerns regarding their side effects and efficacy. Consulting with a specialist might be especially helpful here. The frequent lack of psychological counseling was also troubling, given that there are many

well characterized adverse mental health affects associated with needlestick injuries, including spill-over to the healthcare worker's family.

These findings indicate a need to well-publicize the Guidelines to both employees and employers, and to encourage employers to implement strategies that have been found effective in other non-hospital settings where rapid access to PEP may be difficult (e.g., prisons), such as readily available starter kits of anti-retrovirals until such time as the worker can be appropriately evaluated. This is essential for the health and wellbeing of the nation's more than 150,000 career EMS workers, with a much greater number in volunteer services. While important strides in risk reduction have been noted in other recent healthcare worker studies regarding exposure, especially since the introduction of safer needle devices, there are still reports of problems with these devices as we also noted in this study. Until these newer devices are perfected or until such time as training or education in the use of these devices is fairly widespread and adopted, exposures may continue to occur. This further intensifies the need for adherence to all aspects of the Guidelines.

Another important finding was the relatively high proportion of EMS workers who were reluctant to report near misses or exposures in general. There should be no barriers to reporting, as this is key to providing access to preventative healthcare to exposed workers. Again, education of both employers and EMS employees is essential to prevent any reluctance to report. These findings suggest the need for a NIOSH Alert that addresses the PHS recommendations. This can be generic or tailored to EMS or to all non-hospital based healthcare workers. The Alert should be widely broadcast so that as many potentially affected employers and employees are reached.

Background

In 1996, the U.S. Public Health Service published new Guidelines for the management of Health Care Workers (HCWs) occupationally exposed to HIV[1]. The Guidelines were designed to limit the risk of HIV infection, and health care organizations were recommended to make key elements of the Guidelines, including easy accessibility to post-exposure prophylaxis, available to their employees. The Guidelines, while specifically addressing health care workers, also included any employee whose activities involve contact with patients or patients' blood or body fluids; therefore, public safety workers, such as Emergency Medical Services employees (EMS), were also included. A key component of the Guidelines is the recommendation for employers to ensure the rapid availability of anti-retrovirals, which has been shown to be highly effective in reducing the risk of HIV seroconversion.[4-6] Yet there have been reports of poor compliance with the implementation of the Guidelines, including low exposure reporting rates among health care workers, although it is unclear why this may be so, especially when there is clear evidence of the efficacy of post-exposure management care. We can hypothesize, for example, that in non-hospital health care settings, there may be organizational barriers to compliance with the Guidelines related to poor accessibility to rapid treatment, and in the hospital setting, the barriers may possibly be related to a lack of employee awareness regarding the advantages of post-exposure prophylaxis. In either case, the employee may be at increased risk because compliance with the Guidelines is lacking or incomplete. Conversely, there are also reports of HCWs who inappropriately request chemopropylaxis, even though their exposure risk does not warrant this. It is therefore equally important for us to identify any barriers to the appropriate implementation of the Guidelines because of the potential seriousness of medical outcomes related to non-compliance, such as occupationally acquired HIV and other bloodborne pathogen infections and also because of the medical and cost effectiveness considerations of inappropriate treatment. Furthermore, even when

exposures are reported, employees may have difficulty complying with the recommended post-exposure follow-up care, because of a combination of independent and interdependent factors. This also may have serious consequences for both the employee and the employer/organization. In this section, information on the risk to employees, as well as information on the Guidelines, is briefly presented.

Occupational risk of exposure and infection to bloodborne pathogens

Occupational exposure to blood and body fluids is well documented among health care workers, with annual exposure prevalence rates ranging from less than 10% to as high as 40% depending on the occupational group.[7-9] Risk factors associated with exposure have been identified and these include: urgency of the procedure, the amount of blood loss (>200 mLs), blind procedures (e.g., obstetrical suturing), the duration of the procedure, use of sharps such as needles or scalpels, and the lack of compliance with safe work practices, such as universal precautions.[9] Most exposures that are reported involve percutaneous injuries (e.g., needlesticks or other sharps injury), mucocutanous exposure, (e.g., spray or splashes to the eyes or mouth) or direct contact with non-intact skin.[9] It has been estimated that as many as 1/100 exposures involve HIV contaminated blood.[9]

As of the Centers for Disease Control and Prevention (CDC) reported 57 HCWs with documented HIV seroconversion following occupational exposure and an additional 138 cases of HIV infection in HCWs that most likely resulted from occupational exposure.[10] Reports of HIV infection in non-hospital HCWs, including home healthcare providers, lab technicians, embalmers, and others have been documented.[11] The risk of contracting HIV and other bloodborne pathogen infections by health care workers, given a contaminated needlestick exposure has been estimated at 0.3% to 0.4% for HIV, 10% to 35% for hepatitis B virus (HBV) (in non-vaccinated persons), and 1.2% to 10% for hepatitis C virus (HCV).[6,11-16] The risk factors commonly associated with HIV infection include percutaneous injuries with hollow-bore needles, deep wounds, devices with visible blood drawn from a vein or artery, and source patients with terminal AIDS.[17-20] Occupational transmission to HIV and HBV has also occurred, albeit rarely, from unusual routes of transmission including contact with bloody saliva, human bites, contact with human remains (e.g., embalming procedures), and stab wounds from contaminated needles.[21-23]

Hepatitis B virus infection, while dramatically reduced in HCWs since the introduction of the HBV vaccine, is still reported by approximately 400 HCWs each year.[4,24] And HBV has been occupationally transmitted through blood contact and through contact with saliva and human bites a potential risk for EMS.[21] Several studies have shown that HCV may be transmitted both percutaneously as well as through mucutaneous routes. Rarely, HIV and HCV have been transmitted simultaneously through needlestick injuries, with unusually rapid and fatal results.[25]

Risk for emergency medical service employees

Several studies have documented the risk of bloodborne exposure in emergency medical service employees. For example, a study by Reed *et al.* in 1993, found an incidence rate of reported exposures of 4.4/1000 calls, with roughly 75% involving blood/body fluids.[26] In their study, 75% of the exposed EMS employees who experienced a needlestick injury elected to seek treatment and of those that did, about 90% had previously been vaccinated against HBV. And in an earlier study we conducted involving Baltimore County EMS employees, 12.7% reported at least one needlestick injury in the previous six months of our survey.[27] We also documented significant barriers to their adoption of safe work practices, such as the unavailability of sharps

containers. Under-reporting of exposures has been a problem in the past for EMS employees as a whole, but it is not known to what extent this is still a problem or how readily they can avail themselves of necessary post-exposure care.[27]

Risk Management Strategies

The health care community has nearly two decades of experience with managing the risk of bloodborne pathogen exposure in the occupational setting. Early on in the AIDS epidemic, safe work practices were identified and encouraged, first through the publication of numerous CDC Guidelines, which were then followed by the promulgation of the OSHA Bloodborne Pathogen Standard.[6,7,28,29,30] Not long after, several studies noted widespread lack of compliance with even the most basic elements of the standard, and this was noted for both hospital-based and non-hospital based health care workers.[31-35] Lack of compliance has been shown by Gershon, *et al.* to be associated with both worker-centered variables (e.g., lack of knowledge, inaccurate perception of risk, maladaptive fear response, negative influence of subjective norms, risk-taking personality profile, and sociodemographic factors, such as male gender and occupation [physician]), as well as organizational variables (e.g., lack of resources, poor safety climate, and inadequate training and educational programs).[36-45] Importantly, exposure has been repeatedly found to be related to a lack of compliance. However, even if adherence to universal precautions and standard precautions were optimal, they are not really designed to protect HCWs from the most serious type of exposures, namely percutaneous injuries. Needles and other sharps devices are simply inherently a risky, and thus more recent risk reduction strategies have appropriately emphasized safer needled devices and other engineering controls. This has resulted in sustained decreases in certain types of injuries, most notably in intravenous catheter-related needlesticks. Jagger and co-workers documented decreases in needlestick injuries related to the introduction of a needleless system ranging from 4% to 88%.[46] A needlestick surveillance study we recently conducted noted a 91% decline in needlesticks following the introduction of needleless intravenous systems.[47] However, many other types of injuries and exposures, including wounds associated with hollow-bore needles, have remained a considerable threat. For example, in our recent study, hollow bore injuries still accounted for 68% of all exposures in a mid-sized hospital. Fortunately, new devices designed to safely inject or withdraw blood are rapidly entering the health care field and should have a significant impact on these types of injuries, although cost and availability remain obstacles to their wide-spread use, especially in certain settings, such as the correctional health care setting, where budgets may be severely constrained.

Other risk management strategies have focused on administrative factors, such as involving front-line workers in the management of the bloodborne pathogens program. This has been shown to have an important effect in several ways. First, because this is a highly efficient method for identifying risk reduction measures and second, employee involvement in the safety process leads to more positive perceptions of organizational safety climate, which in turn has been found to lead to higher rates of adoption of safe work practices.[42,45] This has led, in at least one study, to reduced exposure rates; as we noted in our recent total quality management study, bloodborne pathogen team participation was associated with a 30% reduction in exposures.[48] All of these strategies are considered primary prevention strategies, and this approach is clearly the most beneficial and cost-effective since it can prevent exposures from ever occurring. However, when primary prevention fails, secondary prevention strategies can still effectively prevent further adverse outcomes, such as infection. The secondary

prevention strategy for bloodborne exposures is to implement effective post-exposure management plans as soon as possible. These are briefly described below.

Public health service guidelines for the management of health-care worker exposures to HIV and recommendations for post-exposure prophylaxis.

There have been a number of published guidelines and recommendations addressing the management of bloodborne exposure including protection from hepatitis viruses as well as HIV.[4-8] The PHS Guidelines, updated as recently as June, 2001, are based upon recommendations made by leading experts from several agencies and institutions.[49] The recommendation to administer post-exposure prophylaxis drugs following a known or suspected HIV exposure was in response to significant case control data first published in 1995 which indicated that an 80% reduction in the risk of infection could be achieved with the rapid administration of zidovudine.[9] The PHS recommendations, while technically *Guidelines* and not *regulations* are, however, considered a requirement under OSHA's Bloodborne Pathogen Standard, and as such, are required to be provided by employers.[6,10] It should be remembered that even though these are required, both employees and employers can readily circumvent them. Employees, similarly, are required to report exposures and to follow recommended post-exposure protocols. The Guidelines include the following five key elements: 1) exposure reporting, 2) evaluation (assessment of exposure risk), 3) counseling, 4) treatment (including source testing, baseline testing and repeat testing) as well as drug prophylaxis and 5) follow-up care as necessary (including treatment for drug reactions).[49] In addition, employers are required to establish written exposure-control plans, and to comply with incident reporting requirements as mandated by the Occupational Safety and Health Administration. The Guidelines also require that employers provide access to clinicians who can provide treatment during all working hours, including nights and weekends. Anti-retroviral medications for post-exposure prophylaxis must be readily available, either on-site or through links with other facilities, such as local hospital emergency rooms. The Guidelines also stipulate that HCWs should receive education regarding the need to report exposures as soon as feasible, and to be taught the basic principles of post-exposure management. The education should be provided at new employee orientation and through regularly scheduled on-going educational programs. The management of exposures requires a good deal of diligence and commitment on the part of employers as the protocols and the decision-making process in terms of determining the drug requirements are complex. Post-exposure treatment includes anti-hepatitis virus modalities as well, and HCV testing protocols are extremely complicated. Thus, management of a sound post-exposure program, which includes all of the recommended key elements, can be challenging, especially for agencies or facilities without access to high-level infection control and employee health programs.[50,51]

Significance of the problem

Employee exposure to blood and other body fluids potentially contaminated with bloodborne pathogens remains a major public health problem. The annual cost associated with exposure is estimated to be well over $100 million each year. Post-exposure prevention costs are estimated at $2,000/exposure while the life time cost of care for HIV infection is now $200,000 per patient.[22] Additionally, infected employees who file lawsuits against their employers typically are rewarded multimillion-dollar settlements. A recent study by Marin *et al.* noted that post-exposure chemoprophylaxis would prevent 53 HIV seroconversions per 100,000 exposures at a societal cost of $2.0 million per case of HIV prevented.[53] In one large tertiary care 1000 + bed hospital, the annual post-exposure care in 1998, was in excess of $850,000.[54] Additional cost, in

terms of human suffering among those workers exposed and infected, is incalculable.[55,56] In addition, exposures adversely affect the delivery of care and the effective operation of health systems.[57] Given that exposures continue to occur among the nation's 5.5 million health care workers with patient or patient specimen contact, and among an additional 1.5 to 2.0 million other employees at risk in a wide variety of jobs, including public safety, it is important to identify barriers to compliance with post-exposure management programs in order to assure their successful and appropriate implementation.

Methodology

Overview

The two year, five phase study involved approximately 250 emergency medical services employees recruited from Baltimore, Maryland agencies. For convenience and also to eliminate the concern employees may have had about being "singled out" for participation, the entire work populations of a random selection of agencies, stratified by location, was chosen.

A new study questionnaire was developed to examine both worker-centered and organizational barriers to the effective implementation of the PHS guidelines. Focus groups were organized in order to identify potential barriers specific to the Guidelines. Confidential questionnaires were administered, in an addressed sealed envelope packet distributed directly to the EMS employees. Analysis of data was directed towards the identification of barriers to the effective implementation of the Public Health Service Guidelines. The researchers prepared summaries of the results for members of participatory action research teams. The teams, comprised of representatives of the study population, worked in collaboration with the study researchers, and guided by the data, identified strategies to improve compliance with the Guidelines. The study plan is outlined in Figure 1.

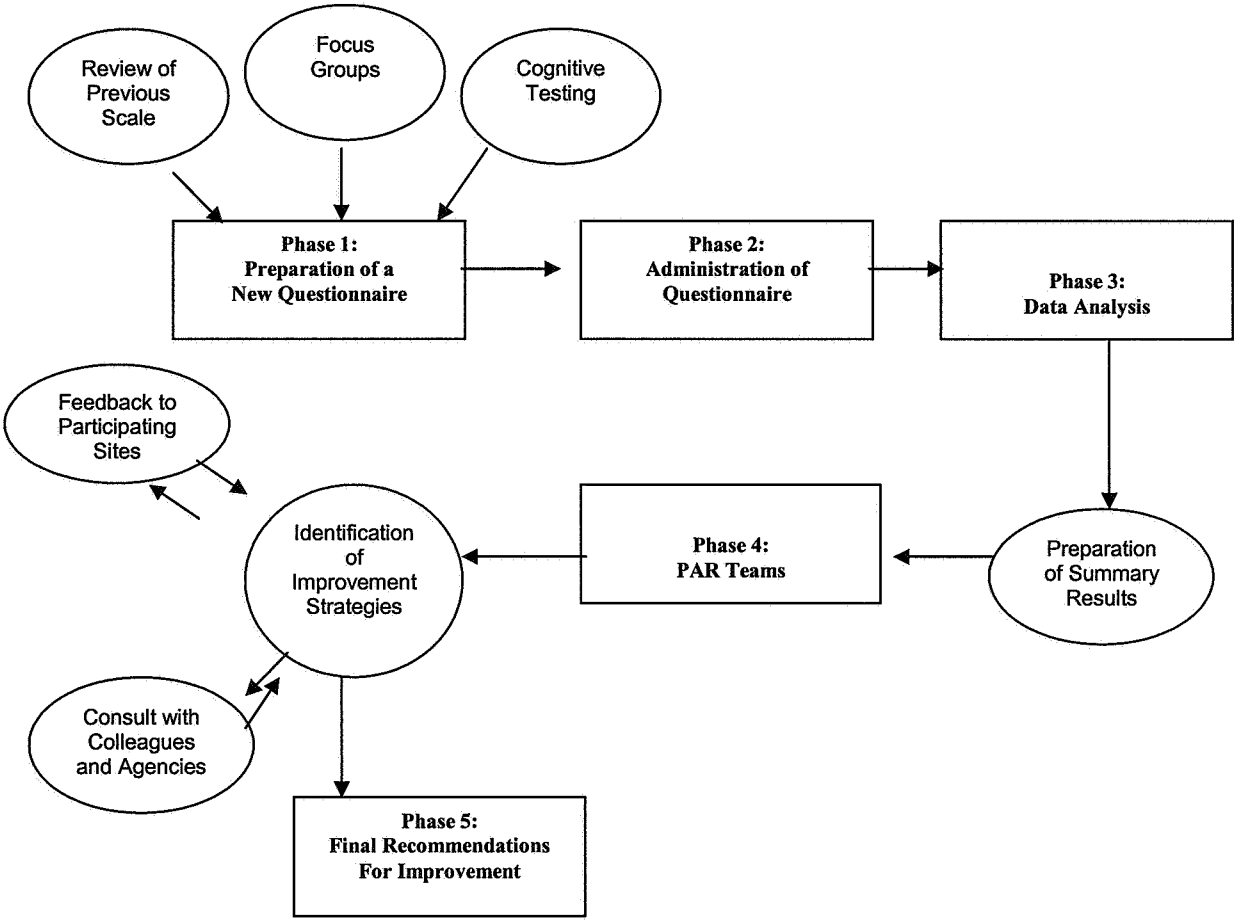

Figure 1. Study Design Overview

Study Support

Support for the study was provided in several ways. First, letters of cooperation supporting our access to their members and facilitating our visits were obtained from participating agencies. Second, the principal investigator and/or study coordinator visited informally with study participants in order to familiarize them with key aspects of the study.

Study Hypotheses

The theoretical model for the study (Figure 2) was an adaptation of DeJoy's Behavioral Diagnostic Model which itself is based upon the PRECEDE framework of Green.[58,59] This model was particularly suitable in guiding the development of the study questionnaire because it integrates both the worker-centered determinants as well as organizational determinants of self-protective safety behaviors, thus emphasizing the inter-connectedness between the individual and the work environment. This model indicates that both worker-centered and organizational factors exist which relate to both the exposure and the exposure reporting process. Once this step has taken place, there may be additional and unique factors which preclude the exposed employee from receiving appropriate treatment. For example, even if the employer has a fully developed post-exposure management plan, but the employee is not made aware of it, the program

has failed. Or if the employee drops out of the treatment protocol due to untreated side effects, again the program has failed.

Worker-center variables included items related to employees' reporting behaviors, i.e., regarding their decision to report a bloodborne exposure promptly and to follow through on the recommended elements of the post-exposure management plan. This decision is also affected by outside influences including their co-workers' attitudes (subjective norm), how easily the reporting mechanism is facilitated by their supervisors, and their accessibility to follow-up care. Employees need to have time-off provided so that they can report to employee health or the nearest hospital, and then once enrolled in the post-exposure management program, they will periodically have to report back to employee health for follow-up care. Many employees who go through the treatment become quite ill from the anti-retroviral drug side effects. Often they require extended time off; in some cases they need sick leave for the full four weeks of treatment. Throughout the follow-up period, which may last 6-12 months, supportive organizational policies and procedures can facilitate the employees' efforts, and the converse is also true. Thus organizational factors can either serve as barriers or facilitators, and may drive the entire process to a considerable extent. The theoretical model is shown below.

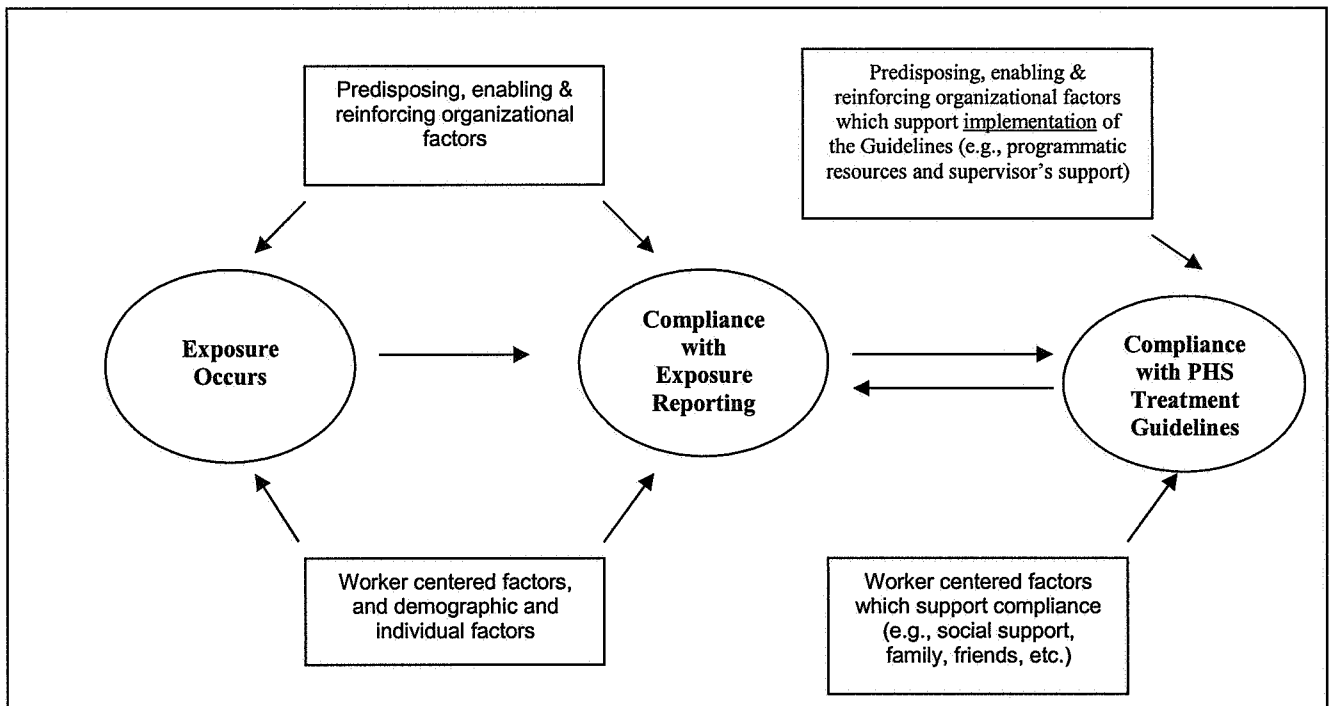

Figure 2. Theoretical Model

Based on preliminary data from our earlier studies, including our recent pilot survey of exposed employees, we hypothesized that both worker-centered barriers and organizational barriers may exist which prevent both exposure reporting as well as the complete implementation of the Guidelines.

Accordingly, the study hypotheses were:

1. Worker centered variables, such as level of knowledge about the risk of exposure, perception of risk, belief regarding efficacy of post-exposure prophylaxis, and attitudes about post-exposure follow-up, will be associated with

compliance with both intentions regarding reporting exposures and follow-up behaviors.

2. Organizational variables, such as availability of post-exposure resources (program staff, written protocols, supplies, medications, etc.), safety climate, supervisory support, and employee training and communication programs, will be associated with both employees' intentions and past behaviors with respect to reporting exposures and compliance with recommended management plan.

Certain worker-centered and organizational variables, when combined, will be associated with the lowest levels of compliance (i.e., inter-dependence).

Study Sites and Study Populations

Emergency medical service personnel

The Baltimore County Fire Department serves an area 610 square miles with a population of nearly 700,000 people. There are ten advanced life support companies and nine heavy rescue squads. There are 41 advanced life support units with approximately 500 career and volunteer EMS employees. Fifty-five percent are career employees. Approximately 80% are cardiac rescue technicians (CRTs), and 20% are emergency medicine technicians-paramedics (EMT-P), all of whom are accessible for the purposes of the study. Of the total population of all EMS, the median age is 36 years, and 75% are male and approximately 60% are Caucasian. All EMS must attend quarterly infection control training at headquarters.

Study Overview

The study was divided into five distinct phases over a period of two years in order to simplify the study management. Phase One provided for ample time to develop the sample frame and the study questionnaire. In Phase Two, the questionnaire was provided in person in a questionnaire packet in a sealed envelop with a return pre paid, pre addressed return mailer. Data were double entered directly into the study database (using dBASE software). In Phase Three, the analysis was conducted. In Phase Four, we developed recommendations for implementation. And finally, in Phase Five, the final reports to the funding agency and scientific papers and presentations was prepared. An overview of the study design is presented in Table 1.

Table 1. Outline of Study Management Plan

Year One			Year Two	
Risk Assessment Stages				
Phase One (1-6 Months)	Phase Two (7-10 months)	Phase Three (11-17 months)	Phase Four (18-21months)	Phase Five (22-24 months)
Sample Frame Determination, Volunteer Recruitment, Questionnaire Development (Focus Group, Cognitive Testing, Pilot Testing, Psychometric Analyses)	Questionnaire Administration, Data Entry, Data Cleaning	Data Analysis Summary, Process Evaluation (ongoing through all 5 phases)	Development of Recommendations Consultation with Collaborators/Agencies	Final Reports Presentation of Results at National Meetings

Phase 1:

Sample frame determination

In this aspect of phase one, the principal investigator, the study coordinator, and research assistant contacted the site contacts and finalized plans for the recruitment of volunteers in the final sample for recruitment.

Inclusion of women, ethnic and racial groups

Because this application recognized the importance of the inclusion of women and as wide a range as possible of various ethnic and racial groups in the study, the sampling strategy was designed to include adequate representation of women and various ethnic/racial groups. We expected that approximately 20% of the EMS would be female and that minority groups would represent at least 50% of the overall sample as this is the current demographic make-up of the study population. Every effort to encourage the full participation of all minority groups was made.

Questionnaire development

A five-page questionnaire was developed in order to assess two major study constructs and to meet the specific aims of the study. The questionnaire was written at an 11th grade reading level and took about twenty minutes to complete. It was presented in an extremely user-friendly format. Survey Pro software (Apian Software, Inc., Menlo Park, CA) was used to format the questionnaire. The questionnaire was based, whenever possible, on well-defined scales. In addition, several procedures were applied in order to generate qualitative data and to contribute to the overall instrument content. These procedures were: focus group sessions, cognitive testing and pilot testing. Each of these aspects of the questionnaire development is briefly described below.

- **Review of existing instruments and measures**

Several potentially useful scales have been previously developed, and these scales were obtained and reviewed for their usefulness on this proposed study. Whenever possible, pre-existing and well-characterized valid and reliable measures were used. Most questionnaire items had a four or five-point Likert scale responses.[60]

- **Focus group sessions**

Five separate, group specific focus groups were organized in order to learn more about the study populations with respect to this problem and to obtain qualitative data that informed the study questionnaire. Topics included exposure reporting, difficulties in reporting, exposure Guidelines, barriers to appropriate follow-up care, knowledge regarding exposure follow-up care, factors that serve to facilitate or act as barriers to follow-up care, organizational constraints to follow-up care, etc. Group participant were recruited through the Baltimore County Emergency Medical Services bulletin board. Focus groups followed a defined protocol, which included the following elements:

- Each group was led by an experienced facilitator.
- Each group had at least one research assistant who will take notes.
- Each group had 6-8 attendees.
- Each session was two hours long.
- Each session was held in a convenient location
- Consent procedures were be followed.
- All meetings were held at convenient times.

A meal was served at each meeting, and each participant received a small remunerators. Facilitators used a prepared moderator's guide. The guide included the research objectives.

- **Cognitive testing**

This technique is used to evaluate draft survey questionnaires by performing intensive interviews of volunteers, including the "talk aloud" method. For this phase of development, five volunteers were interviewed, each representative of the study population. These interviews focused on the cognitive processes that participants use when answering the survey questions. Understanding the nature of the response process helped us to redesign the questions so that survey questions are clear. This allows for precise interpretation of the questions, thereby leading to more accurate responses. Volunteers for both focus groups and cognitive interviews were recruited by announcement flyers, as previously described. Cognitive sessions took approximately two to two-and-a-half hours each and were held at a convenient time for participants.

- **Pilot testing**

Working drafts of the questionnaires were prepared. The questionnaire was pre-tested on a sample of EMS.

- **Constructs and items**

Based upon the literature and our preliminary studies, and guided by the theoretical model, the following topics were included in the final instrument. These are described below and the major constructs are outlined in Table 2.

Self reported compliance (or intentions to comply) with exposure reporting guidelines. Employees were asked to self-report their practices with respect exposures experienced in the previous 12 months and during their careers in EMS. They were asked about any barriers to reporting (i.e., reluctance to report).

Perception of organizational factors. Employees were asked about management's commitment to safety (safety climate), management's availability of resources to manage exposures and comply with Guidelines (e.g., employee health personnel, arrangement for off-site treatment, ability to receive treatment in 2 hours, ability to obtain clinical advice whenever they are on duty, ability to provide follow-up care, pre + post-test counseling, etc.). Also, we included items related to managements' training and educational programs with respect to bloodborne pathogen exposure management, managements' (supervisors and senior level management) support of exposed employees, group norms and group expectations (regarding post-exposure management practices such as reporting).

Exposure history. Employees were asked to recall past exposures (past 6 months and ever during their tenure), routes of transmission, detailed post-exposure management care, including post-exposure prophylaxis, compliance with care protocols, their satisfaction with care, etc.

Sociodemographics. Continuous variables such as age, number of years of work experience, and categorical variables such as gender, race/ethnicity job category and others were included.

Table 2. Study constructs

Major Constructs	Sample Items/Scales
1. Worker-centered Factors	Demographic characteristics (e.g., age, gender, race/ethnicity, occupation, marital status, education, job tenure, etc.) attitudes towards exposure reporting and follow-up care
	Injury/exposure history
	Distress
	Shift work, hrs worked per week
	Experience with guidelines (previous 12 months), including all key elements
	Post-exposure attitudes towards treatment
2. Compliance	Self-reported compliance with reporting of exposures or intentions to report exposures
	Self-reported compliance (or intentions to comply) with appropriate Adherence to Guideline recommendations, including follow-up care
3. Organizational Factors	Employees' perceptions of organizational factors
	Safety climate (management's commitment to safety)
	Availability of resources for implementing guidelines (e.g., staff, policies and protocols in place)
	Supervisory support for reporting and/or follow-up care
	Training and education on post-exposure Guidelines

Phase 2: Questionnaire administration

All procedures involving study volunteers (e.g., questionnaire administration, focus groups, unstructured interviews, cognitive interviews and pre-testing) were reviewed and

approved by the Columbia University's Institutional Review Board. Details of the administration of the questionnaire are described below.

- **Questionnaire management**

Each questionnaire was assigned (by the study coordinator) a unique study number (i.e., a code number). A list of code numbers and mailing addresses for the sample of EMS constituted the "Master Code Book." The hand delivered questionnaire packets were distributed by station captains, (anonymous).
The questionnaire packet consisted of the following:

- . Cover letter of introduction signed by the Principal Investigator and Agency Representative
- . Questionnaire (with envelope for privacy)
- . Consent form
- . Pre-addressed, pre-stamped return envelope
- . Declination post card

The master code book was kept under lock and key and only the study Principal Investigator and study coordinator had access to this book. Only the study Principal Investigator or study coordinator had access to any unblinded computer files, which were accessible only by code.

The Principal Investigator's name and office phone number was included on the questionnaire, the cover letter, and consent form in case the employee has any questions or comments regarding any aspect of the study.

- **Data collection and management: Qualitative Data**

Focus group and cognitive interviews data were collected and managed as follows:

- . No identifiers were used.
- . Summary reports were prepared using a standardized format as soon as possible after the event. Original notes and reports were kept under lock and key for the duration of the study. Summary of findings were periodically presented to the research team members.
- . All original notes and records will be destroyed at the conclusion of the study.

- **Quantitative Data**

All questionnaires returned to the study office were inspected for legibility and completeness. Mailed questionnaires that had a substantial number of questions unanswered or illegible were discarded. Data from the completed questionnaires were then entered directly onto a data-base. Data was backed up using cds. Data were protected by pass codes. The original questionnaires and disks were all kept under lock and key in the study office. At the conclusion of the questionnaire phase of the study, the master code book was destroyed. All computer files will be maintained indefinitely.

- **Phase 3: Analysis of data**

After checks for internal reliability and validity of responses and other data editing procedures were completed, we performed an array of descriptive statistics (e.g., frequencies, histograms, and measures of central tendency and dispersion) and graphical techniques to characterize the distribution of variables, starting at the most refined level of measurements. This strategy provided familiarity with the data and allowed us to determine if the data met assumptions required by the intended statistical testing procedures. Factor analysis was applied to all new scales, and all scales

underwent correlation procedures. Exploratory factor analyses were conducted after the questionnaire is piloted. Frequency rates for exposure and appropriate post-exposure care were calculated (Specific aims 1 and 2) both by occupational group and overall. Overall levels of individual and organizational risk factors associated with compliance and compliance intentions were determined by cross-classifying independent variables with the outcome variable (compliance intentions and behaviors) appropriate to the level of measurement. Analyses were accomplished using logistic regression methods for dichotomous outcome variables, such as compliance vs. incomplete compliance, to control for demographic variables, such as age, gender, occupation, etc, in order to evaluate the effects of other variables of interest, such as knowledge, perception of organizational variable, etc. The outcome (dependent) variable was both *intentions to comply* (i.e., to report an exposure) as well as actual reporting (over the past 12 months) since intentions are known to strongly predict behaviors. This also allowed us to examine the entire sample, and not just the exposed employees, thus increasing our power. Also, since the window of opportunity for obtaining anti-retrovirals is so short, it is important to evaluate employee intentions since they will have to act quickly. The relationship between risk factors and intentions to seek post-exposure management care was also determined using simple statistical tests, including chi-squares statistics, ANOVA and ANCOVA techniques and bivariate and multivariate regression techniques (Specific aim 3). Risk factors were determined for the sample as a whole and by occupational group, as we anticipate group differences. The new theoretical model was also be tested using structural equation modeling techniques.

- **Process evaluation**

It is important to periodically determine how well a program is operating, i.e., to determine how effective it is in terms of meeting the expected project goals in a timely and cost-effective manner. The evaluation component was also important for resolving identified problems or for filling identified needs. The evaluation improved our understanding of how well the project was being conducted and documents the organizational and operational procedures of the project. Both outcome evaluations, which emphasize the effectiveness of the program, as well as process evaluations which characterize the program, were periodically conducted (at the end of each study phase). For example, we were able to evaluate the development of the survey, insuring adequate pre-testing and maximizing validity of responses, as well as monitor the dissemination of reports. This is a modification of the standard process evaluation approach developed by researchers at the Office of Substance Abuse Prevention (United States Department of Health and Human Services). We addressed each aspect of the evaluation procedures through audits, observation, and a review of records and data. Our consultant, Dr. David DeJoy helped provide for the objective evaluation process. Based on the evaluation results, we made adjustments as needed. Particular attention was focused on the participants' reaction to ensure that we have made all aspects of participation as simple, convenient and enjoyable as possible. Any risks to participants could be discovered quickly through the evaluation process and immediately managed to avoid untoward effects on study participants. No adverse impact on participants was noted.

Phase 5: Dissemination of Data

The agency will receive a copy of this report, with an additional executive summary. Also, we propose to submit a summary of recommendations to national organizations representing the study populations. We also plan to submit abstracts for

presentations to national meetings as well. All intramural dissemination to EMS will be handled by the Agency and we will assist them in any way possible.

Extramural dissemination

In order to inform the broadest possible audience with potential interest in this area of study, several approaches are needed. All extramural information will be presented to the Baltimore County Emergency Medical Service first as a courtesy. The Principal Investigator and other investigators will work closely with our National Institute of Occupational Safety and Health (NIOSH) colleagues to help publicize our findings as widely as possible. Using a variety of media (e.g., print, video, computer), we intend to make two tangible products available: (1) a synopsis of study results, (2) detailed questionnaires, constructs and coding information, (3) in addition, if NIOSH indicates that this is necessary, we will assist in the preparation of a NIOSH Alert for employers regarding exposed workers. In addition, oral presentations, articles, posters, etc. will be prepared and presented to reach as wide an audience as possible (e.g., organizational psychologists, nurse researchers, safety specialists and health experts, etc.). Some examples of possible journals for publication include: American *Journal of Infection Control, Journal of Occupational and Environmental Medicine, Infection Control and Hospital Epidemiology, American Journal of Public Health*. Where indicated, media releases of our findings will be prepared by the Columbia University Department of Public Affairs. Study investigators also expect to present research findings at a variety of conferences intended to reach the target audience (e.g., ANA Conference), etc.

Study Limitations

We considered a number of potential biases and study limitations as discussed below.

Selection bias

Several aspects of the study design could potentially have led to selection bias. For example, we may have inadvertently selected employees who were different from the non-participants. If non-participation was related to either the risk factors for not reporting, or the outcome status (e.g., compliance) or both, we would have threats to external validity and/or strength of association. We countered this problem in several ways; first, we tried to obtain a high response rate from all potential participants through the methods we previously described. Second, we compared the EMS group demographics to available demographics for the State and found they are very similar. Based on our examination of sociodemographic data comparing the Maryland sample to National statistics, there is also no reason to suspect that any of the Maryland employees differ significantly from other similarly employed workers in other states. Using single agencies to look at organizational factors is important because employees' perceptions regarding the organizational program can greatly influence their behaviors, regardless of the size and scope of the actual program. The lessons we learned here will thus be useful to other agencies in other states. We also have a validated tool which other agencies can use to measure their own post-exposure management programs.

Non-responder bias

Non-responder bias may have been a problem if large numbers of employees failed to complete the questionnaires. We tried to maximize the follow-up response rate by following the recruitment measures as previously described. We estimated non-responder bias and use statistical procedures to estimate effect.

Validity of self-reports

Since employees were asked to provide self-reports on their exposure history, exposure reporting practices, and their perception of safety climate and other variables, their responses may not have been accurate because the respondents may have wanted to provide socially desirable responses. This is a concern in most studies that seek to measure sensitive issues and non-normative behaviors. We were fortunate in that we had pre-existing data that affirms accurate responses e.g., the recent HBV vaccine correlation rate, (self-reports vs. serological evidence). Also, the anonymous nature of the study may have helped to mitigate this effect. Recall bias was also not a serious problem, as we asked respondents to recall events that occurred, for the most part, within the previous twelve months. Exposure events are so stressful for most employees-that they are unlikely to forget it.

Confounder bias

There may be confounding variables affecting both the risk factors and the outcome variable, which are caused by secular changes over the course of the study. For example, changes in the field of EMS that have nothing to do with our study may have occurred and may have important effects on this study. An example of this might be a death of an EMS worker from a workplace exposure. There may be changes in policies, exposure protocols, senior management, health insurance union leadership, etc., which may affect the way that employees think about their exposure. There may be new incentives to report exposures. All of these factors must be considered during the course of the study. This is always a potential problem for non-experimental studies, and we tried to address them as best we can. However, the potential significance of this study supercedes this concern, and we tried to address this artifactual problem by measuring a multitude of variables and by testing for trends.

Cross-sectional design

This study was cross-sectional and thus it precluded the determination of causality, therefore only associations can be made. However, the cross-sectional design was a useful and efficient design to glean information in a timely manner. This design was also a cost effective first step used to identify potential risk factors, which later can be expanded upon in future longitudinal, and experimental research designs.

Generalizability of findings

Since we only sampled employees from one state, our results may not be generalizable to all employees. There is no reason, however, to suspect that Maryland EMS workers varied significantly from non-Maryland EMS workers. We compared responders' demographics of Maryland agencies with other national samples to ensure we had sound representation. Further, this study expands previous work by generating information on at-risk personnel in several important ways: 1) data were collected from both men and women of all races and ethnicities and (2) analyses were directed at determinants using relative (i.e., we are examining relationships between variables) rather than absolute measures, thereby enhancing generalizations of observed associations.

HUMAN SUBJECTS

An application was filed with the Columbia University School of Public Health Institutional Review Board (IRB) regarding the use of study volunteers. The committee provides oversight and guidance to all research projects involving human volunteers.

The research project involved human subject participation in several different aspects of the study as follows:

Procedure	Number of Employees	Consent Form Required	Disclosure Statement Provided
a) Focus Groups	25	X	X
b) Cognitive Testing	5	X	X
c) Questionnaire Administration	25	X	X

The subjects in all cases were Emergency Medical Service employees who are all 18 years of age or older. We anticipated between 150-500 employees would participate in the questionnaire aspect of the study. Both male and female employees were recruited for participation. Their health status should have been generally good.

The data generated by the various qualitative and quantitative phases of the study was collected from living subjects who will be asked to consent to participate in the various aspects of the study.

Subjects were recruited as follows:

a) Qualitative data generation: Notices requesting volunteers for each qualitative procedure (e.g., focus groups, cognitive testing, etc.) were placed on the Emergency Medical Service bulletin boards. The study office phone number was provided so that the employees could contact us directly and confidentially. Consent forms were provided to each potential participant for their review prior to agreeing to participate. Each participant was requested to sign his or her consent form. We did not seek any wavers of the consent procedure.

b) Quantitative data generation: Packets were delivered to all stations, captains were asked to distribute them to all EMS workers.

c) A consent form and disclosure statement, enclosed with each questionnaire that was presented or mailed to employees, described the study and participants' role, including why the consent form is necessary.

The potential risks to the subjects were mainly psychological, since we asked them potentially sensitive questions (i.e., about their exposures). Employees might get upset when they are asked to think about their exposure, especially if they did not receive satisfactory treatment. We did not have any reports of adverse events.

Several steps were taken in order to minimize any risk to study participants and are as follows:

a) Qualitative data generation:

During focus groups, all employees were reminded to refrain from discussing highly sensitive issues in the group. Groups were facilitated by trained moderators. No identifiers of any sort were linked to qualitative data; only summaries of the employees' conversations were made available to the research team. No individual information was provided to Maryland EMS. Trained facilitators will led the groups.

b) Quantitative data generation:

All questionnaires were coded using a unique identifier. Only the study's Principal Investigator and study coordinator had access to the master code book, which linked the employees' names to this code number. During the study, the master code book was kept under lock and key. At the conclusion of the study, the master code book was destroyed.

No one from the Emergency Medical Service had access to individual data or individual (coded) questionnaires. Only group data was distributed in published reports (other than unidentified individual quotes).

The risks to subjects were reasonable in that the potential benefits to subjects out-weighed any potential risks. Subjects benefited in several ways: through increased understanding of employers on the methods that will improve post-exposure management and through increased awareness and sensitivity of the employees regarding their risk of exposure.

Publications

Gershon RR. Blood/body fluid exposures in Maryland EMS workers: preliminary findings. Presented at: WESTAT, Rockville Maryland, February 12, 2004.

Gershon RRM. EMS exposure data. Presented at NIOSH, Cincinnati, Ohio, March 22, 2004.

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