

**Date:** November 10, 2014

**Project Title:** Preventing Blood and Body Fluid Exposures during Surgical Procedures

**Grant Number:** K01 OH 00 9657

**Project Period:** 9/1/09 – 8/31/14 (including NCEs)

**Principal Investigator:** Douglas J. Myers, ScD, MA,<sup>a</sup>

**Co-Investigators:** Hester J. Lipscomb, PhD<sup>b</sup>, John M. Dement, PhD<sup>b</sup>, Lynn Smith-Lovin, PhD<sup>c</sup> (Mentors) and Carol Epling, MD<sup>b</sup>, Debra Hunt, DrPH<sup>d</sup> and William Richardson, MD<sup>b</sup> (Contributors)

**Affiliations:** <sup>a</sup>Department of Occupational and Environmental Health Sciences, West Virginia University, <sup>b</sup>Occupational and Environmental Medicine, Duke University, <sup>c</sup>Department of Sociology, Duke University, <sup>d</sup>Biological Safety, Duke University, <sup>e</sup>Department of Orthopedic Surgery, Duke University.

**Contact Information:** Douglas Myers, ScD, MA  
Assistant Professor  
Department of Occupational and Environmental Health Sciences  
West Virginia University  
P.O. Box 9190, Morgantown, WV 26506  
Phone: 304-581-1152  
Email: [djmyers@hsc.wvu.edu](mailto:djmyers@hsc.wvu.edu)

**Institution Receiving Award:** West Virginia University Research Corporation, 886 Chestnut Ridge Road  
P.O. Box 6845, Morgantown, WV 26506-6845

## Table of Contents

	Page #
List of Terms and Abbreviations	2
Abstract	3
Section 1	
Significant (Key) Findings	4
Translation of Findings	4
Outcomes/Impact	5
Section 2	
Scientific Report	6
Inclusion Enrollment Form	52
Publications	53

## **LIST OF TERMS AND ABBREVIATIONS**

BBF	Blood and Body Fluid
BBFE	Blood and Body Fluid Exposure
CI	Confidence Interval
OR	Operating Room
PI	Principal Investigator
RR	Rate Ratio
SD	Standard Deviation

## ABSTRACT

**Title:** Preventing Blood and Body Fluid Exposures during Surgical Procedures

**Investigator:** Douglas J. Myers, ScD, MA, Department of Occupational and Environmental Health Sciences, West Virginia University School of Public Health, Morgantown, WV, 26506

**Affiliation:** West Virginia University School of Public Health

**State:** WV

**Phone:** 304-581-1152

**Award Number:** K01 OH 00 9657

**Start & End Dates:** 9/1/09 – 8/31/14 (including NCEs)

**Program Area:** Occupational Safety and Health

The rate of percutaneous blood and body fluid (BBF) exposures in the operating room (OR) remains high despite various attempts to reduce the rate of these outcomes. This study included an assessment of surgical procedure characteristics that modify the risk of BBF exposures and evaluation of efforts to reduce the risk of BBF exposures in the OR. The intervention included an institutional policy requiring the implementation of a hands-free neutral passing zone to avoid hand to hand passing of surgical instruments during procedures, the promotion of blunt suture needles use for certain suturing tasks, and the promotion of double gloving. All intervention measures were implemented between July 2005 and January 2007.

We explored the role of teamwork as it relates to safety in the operating theater. We used a social network measure of “past collaboration” found in the sociological literature, but never before used to study safety in the operating room, to produce a quantitative score for each team assembled for each surgical procedure. We explored whether teams who have worked together more in the past experienced lower rates of BBF exposures, possibly through greater familiarity among team members.

To achieve these aims, we gathered several administrative datasets spanning a ten year period (2001-2010) at a single large teaching hospital. Individual-level data were linked via employee identifiers; patient identifiers were used to link injury events to surgical procedures during which they occurred. These data included 2,113 BBF exposure events and 333,073 surgical procedures. Poisson regression was used to analyze the data. Separate models were produced for BBF exposures due to suture needles and those due to all other surgical instruments.

The overall rate of reported BBF exposures was 6.3 per 1,000 surgical procedures (2.9 per 1,000 surgical hours). BBF exposure rates increased with estimated patient blood loss, number of personnel working in the surgical field during the procedure, and procedure duration. Regression results showed associations were generally stronger for suture needle-related exposures. There was no detectable effect of the intervention measures; rates of BBF exposures rose steadily across the entire study period.

Results show a small but statistically significant ( $\alpha < 0.05$ ) reduction in risk of BBF exposures for teams that had higher past collaboration index scores. This association was also strongest for BBF exposures involving devices other than suture needles.

The main conclusions of this study are 1) more intense efforts or different measures and strategies than those used at this study site will likely be required to improve safety in the OR, 2) future studies should explore why risk factors for suture needles and other devices may differ and 3) additional research should be done to verify the novel findings that suggest greater familiarity among surgical team members improves safety in the OR. The measure of past collaboration used here may be used to explore the role of team stability for other outcomes, such as patient safety outcomes, or in other work settings where teamwork may conceivably affect safety, such as among firefighters or miners.

## **SECTION 1**

### **Significant (Key) Findings**

The key findings of this study are:

- 1) Results show the overall rate of reported BBF exposures for the ten year period was 6.3 per 1,000 surgical procedures (2.9 per 1,000 surgical hours). This is consistent with the pilot study conducted prior to this larger investigation.
- 2) BBF exposure rates increased with estimated patient blood loss, number of personnel working in the surgical field during the procedure, and procedure duration. These three variables may imply greater risk in procedures of greater complexity. Regression results showed associations were generally stronger for suture needle-related exposures.
- 3) There was no detectable effect of the intervention measures. The rate of BBF exposures continued to rise steadily, year by year, after the interventions had been conducted. There was no detectable change in the slope of the increase in the rate of BBF exposures in the post-intervention period. The rate simply continued to increase, unabated, across the entire study period. This was true for crude rates and for rates which were adjusted for all procedure characteristics available in the administrative records.
- 4) Results show a moderate but statistically significant ( $\alpha < 0.05$ ) reduction in risk of BBF exposures for teams that had higher past collaboration index scores (i.e., teams that had worked together more in the previous six month period). This association was strongest for BBF exposures involving devices other than suture needles. This stronger effect among these other devices was expected as BBF exposures due to suture needles are more likely to be done to oneself, while those involving other devices are more likely to occur in situations where team members are coordinating their actions and where, therefore, teamwork has a greater opportunity to be relevant for safety.

### **Translation of Findings**

- 1) These findings suggest that future studies of BBF exposures in the OR should consider analyzing exposures due to suture needle separately from exposures due to other devices. Future epidemiologic studies may use these result to develop hypotheses to explain the differences in risk factors for different device types. It is recommended that future studies gather original data rather than administrative records as administrative data are not likely suited for testing hypotheses about these different risk factor patterns.
- 2) The measures applied at the study site included 1) a policy to implement a hands free neutral passing zone which would prohibit the direct hand to hand passing of surgical instruments contaminated by blood and body fluids, 2) the promotion of blunt suture needle use for certain procedures and 3) the promotion of double gloving. The results demonstrating the lack of impact of the intervention measures suggest that either greater effort to implement these measures is required, or that alternative measures to reducing risk must be identified and implemented. Our device stratified results might suggest that current intervention efforts are not adequately targeting BBFE that are due to devices other than suture needles. Perhaps new intervention measures focusing on new and possibly riskier technologies being used in the OR are needed. More research is needed to explore this possibility.

3) The findings pertaining to protective effects of team stability are, to our knowledge, completely novel. We believe this measure has never before been used to explore safety and teamwork in the operating theater, nor in any other setting. Therefore, additional research must be done to replicate these findings to determine their generalizability before policy recommendations may be generated. However, we believe the evidence generated in this study is sufficient to lead us to recommend the further application and testing of this method of quantifying the stability of social relations in other studies of workplace safety. We recommend this be done in other operating room settings and in other work settings in which teamwork may conceivably affect safety of team members (for example among fire fighters or miners). Future studies will determine whether these findings hold in operating rooms in other hospitals and how various contexts may modify the role of team stability as it pertains to safety. Similarly, this measure may be used again in the operating room but to look at other outcomes such as those involving patient safety, or in other hospital settings to examine the importance of teamwork for effective patient handoffs.

Should other studies using this measure to investigate the risk of BBF exposures during surgical procedures show similar results, the implications would be that teams should be assembled to reduce turnover and increase familiarity among members so that safety be increased. This may be most important in high risk cases where the patient is known to have bloodborne pathogens, such as Hepatitis or HIV. Future work may find that teamwork matters more in certain situations, such as during very urgent procedures, for particularly long and complicated procedures, those occurring unexpectedly at night, etc.

## **Outcomes/Impact**

### ***Potential Outcomes***

This study may lead to improvements in occupational safety and health at the study site. These findings demonstrated that the intervention efforts implemented at the study site were not effective. Presenting results of the intervention measures to members of the Department of Surgery and the Department of Biological Safety at the study site should generate discussion among them regarding ways that they may either 1) improve the enforcement of these measures or 2) develop alternative ways to improve safety in the OR with regard to percutaneous blood and body fluid exposures. This study is therefore a contribution to safety at the site in that it demonstrates that further actions are required.

In addition, while these findings must be replicated in other studies, should other studies produce similar findings the implications would be that surgical departments should be aware that reducing turnover on surgical teams could improve safety with regard to some outcomes, in particular, those BBF exposures due to surgical instruments other than suture needles. It might be particularly relevant for surgical departments to consider assigning hazardous surgical cases, such as those involving patients known to have bloodborne pathogens, to surgical teams that have been more stable in their recent histories, or at least not allow such cases to be performed by teams who have members not rather familiar to the team.

This study may impact future research in several ways. First, it is not common that BBF exposures involving suture needles are examined separately from those involving other surgical instruments. This study demonstrates that some risk factors are likely different

for exposures due to these different device categories. Future studies that examine these outcomes separately might lead to a better understanding of the processes patterning the outcomes and more specific and effective intervention efforts. This difference in risk factors by device type includes not just properties of procedures identified in the administrative data, but also the role of teamwork as measured by the index of past collaboration. Second, the variables obtained from administrative records that are associated with increased risk of BBF exposure (estimated patient blood loss, number of personnel working in the surgical field during the procedure, and procedure duration) seem to combine to represent a crude measure of complexity of the procedure. Future studies of BBF exposures during surgical procedures might try to measure complexity directly.

Finally, the findings that teams that have worked together more extensively in the past have lower risk of BBF exposures involving surgical instruments other than suture needles must be replicated as this is the first study to make such an observation (in fact this is possibly the first study to even attempt a quantitative assessment of this association). Therefore, future investigations of this sort are needed. These findings warrant the use of this measure to quantify the social stability of work teams in the OR as well as in other settings, and to explore the role of team stability with regard to other outcomes, such as patient safety outcomes occurring during surgical procedures.

#### ***Intermediate Outcomes***

There are no intermediate outcomes to report at this time.

#### ***End Outcomes***

There are no end outcomes to report at this time.



## SCIENTIFIC REPORT

### **Background**

**Blood and Body Fluid Exposures: Persistence of the Hazard, Risk Factors and Prevention** – It is widely known that blood and body fluid exposures (BBFE) are common among healthcare workers employed in a variety of settings and occupations. Among hospital-based healthcare workers alone the annual number of percutaneous injuries in the US has been estimated to be 384,325 (Panlilio et al., 2004). Surgical team members are known to have more frequent exposure to blood and higher rates of percutaneous injuries than those working in other healthcare settings and occupations (Bi, Tully, Pearce, & Hiller, 2006; J. Jagger, Bentley, & Tereskerz, 1998; Makary et al., 2007; McCormick, Meisch, Ircink, & Maki, 1991; Radecki, Abbott, & Eloi, 2000; White & Lynch, 1997). Although overall rates of percutaneous injuries have declined (Beekmann & Henderson, 2005), recent research suggests that surgical personnel remain among those most at risk of BBFE (Babcock & Fraser, 2003; Bakaeen et al., 2006; Dement, Epling, Ostbye, Pompeii, & Hunt, 2004; Doebbeling et al., 2003).

A number of studies assessing the risk of BBFE among surgical staff have been conducted (Gerberding, Littell, Tarkington, Brown, & Schechter, 1990; Panlilio et al., 1991; Popejoy & Fry, 1991; Quebbeman et al., 1991; Tokars et al., 1992; White & Lynch, 1993). However, many of these studies of BBFE have been descriptive, focusing mainly on the distribution of events by categories such as type of BBFE, surgical department, occupation and type of device involved (Bakaeen et al., 2006; Bi et al., 2006; Goob, Yamada, Newman, & Cashman, 1999; J. Jagger et al., 1998; Monge, Mato, Mariano, Fernandez, & Fereres, 2001; Venier et al., 2007; White & Lynch, 1997). Relatively few studies have been done in which characteristics of the surgical procedures were analyzed (Gerberding et al., 1990; Panlilio et al., 1991; Popejoy & Fry, 1991; White & Lynch, 1993).

Our previous investigation of BBFE in the OR (Myers, Epling, Dement, & Hunt, 2008) revealed several findings consistent with other published research. The overall rate of reported BBFE in our study was similar to that observed in a French study (Tarantola et al., 2006) and the fraction of events incurred by surgeons and residents was quite comparable to that found in another study (J. Jagger et al., 1998). In addition, characteristics of procedures associated with BBFE risk including procedure duration, patient blood loss, number of personnel in the field, and surgical specialty, were found to be associated with risk of BBFE in our study and in other studies as well (Gerberding et al., 1990; Panlilio et al., 1991; Popejoy & Fry, 1991; Quebbeman et al., 1991). A novel finding of our work was that risk factor patterns differed by device type. Most other studies have either restricted outcomes to suture needle-related BBFE or have examined all BBFEs combined, thereby preventing a comparison of risk factors by device type.

Several studies have examined the efficacy of precautionary measures for OR personnel, particularly the use of double-gloving (Laine & Aarnio, 2001) and blunt suture needles (Centers for Disease Control and Prevention, 1997; Doebbeling et al., 2003; Florman et al., 2005; Sohn, Eagan, Sepkowitz, & Zuccotti, 2004; Stafford, 1994; Vaughn et al., 2004). In addition, the efficacy of these preventive measures is recognized and promoted by a variety of national agencies and organizations. The American College of Surgeons has recommended hands-free instrument passing zones, the use of blunt suture needles and double-gloving (American College of Surgeons, 2005; Berguer & Heller, 2004). The use of blunt suture needles has also been advocated by the

Association of Perioperative Registered Nurses (2005) and the National Institute of Occupational Safety and Health (2007).

While the efficacy of these techniques has been demonstrated, the persistent high rate of BBFE among surgical staff suggests that their implementation may be limited, thus impinging on their success in reducing risk (Babcock & Fraser, 2003; Bakaeen et al., 2006; Dement, Epling, et al., 2004; Doebbeling et al., 2003). Therefore, while a reduction in the rate is the ultimate goal of epidemiologic research on BBFE, and an outcome to be assessed in this study, the adoption of safe practices and the reasons for non-compliance with their use will be investigated as well. One of the perspectives explored in this study suggests the adoption of these measures occurs mainly on a unit-level, rather than individual-level, basis. That is, the adoption of recommended safety practices is expected to differ by organizational structures, namely surgical departments.

**Social Factors, BBFE Risk and Compliance with Safety Measures** – With the rise of social epidemiology as a sub-discipline, social factors are increasingly the focus of epidemiologic studies. Social factors refer to the relationships among individuals and properties of social aggregates larger than individuals (i.e., groups) (Diez-Roux, 1998). In this study, two social factors will be examined: 1) the degree to which surgical team members have become familiar with each other by virtue of having worked together on surgical procedures in the past, and 2) the social norms held by members of surgical departments. The first of these factors will be examined as a potential modifier of BBFE risk in the OR; the second will be explored as a factor affecting compliance with recommended safety measures.

**Communication, Past Collaborations, and Safety in the OR** – Several studies have suggested that a major contributor to medical errors and BBFE in ORs is the breakdown in communication among surgical team members (Davies, 2005; Gawande, Studdert, Orav, Brennan, & Zinner, 2003; Gawande, Zinner, Studdert, & Brennan, 2003; Lingard et al., 2004; Risser et al., 1999; Sutcliffe, Lewton, & Rosenthal, 2004). In addition, the Joint Commission on the Accreditation of Healthcare Organizations cite communication failures as a root cause of a variety of sentinel events (Joint Commission on Accreditation of Healthcare Organizations, 1998). As individuals spend more time together, they are likely to become more familiar with each other's routines and behavior patterns (Undre, Sevdalis, Healey, Darzi, & Vincent, 2006). Greater familiarity with the routines and habits of others in the procedure may facilitate communication, including the willingness of team members to make interruptions in order to alert one another about safety risks, and make the actions of team members more predictable (DiConsiglio, 2003; Edmondson, 2003). It is believed that familiarity improves safety for the surgical team members. A greater degree of past collaboration among surgical team members is therefore expected to lead to better communication, more highly coordinated actions and a reduced risk of BBFE in the OR.

**Summary and Significance** – The effect of surgical team members repeatedly working together on risk of BBFE in the OR has never before been studied. Understanding the effect of past collaborations and the familiarity among team members it produces has both practical and theoretical implications. A protective effect of past collaborations may suggest that surgical teams be assembled to include members who have previously worked together to some minimum degree, and when this is not possible, to make team members aware that working with others unfamiliar to them raises their risk of BBFE. This may also have implications for training surgical teams as units. The proposed analysis of the role of past collaborations may improve the current understanding of the effect of job tenure on risk of injury outcomes in a variety of settings. That is, working

with the same coworkers repeatedly over time may be a social phenomenon that partly explains a protective effect of “experience,” which is commonly conceived of as the property of an individual.

Producing change in the behaviors of individuals may depend on an understanding of the properties of the groups in which they work. Efforts to promote change at the individual level may be hampered by group-level factors including social norms. Exploring the effect of norms of surgical units, as will be done in this study, may suggest strategies for health promotion that address structural barriers to the adoption of safety measures and the compliance with these practices by the groups’ members.

Exploring the role of the familiarity among team members in the risk of BBFE represents the further development of approaches to occupational health and safety risks that stem from properties of groups rather than properties of individuals. Further developing this group-oriented perspective is an important aspect of occupational health that may help develop new approaches to the etiology of BBFE and other injuries in other industries, and strategies for improving health and safety in the OR and in many other work environments.

In sum, the epidemiologic significance of this study lies in 1) a highly detailed and precise analytic structure for examining risk factors for BBFE in the OR made possible by the availability of several linkable data sources, 2) the statistical power presented by this large longitudinal dataset, 3) the analysis of changes in BBFE rates post-intervention and 4) the innovative exploration of social factors not previously examined as potential risk factors for BBFE in the OR.

## **Specific Aims**

The specific aims of this study were as follows:

### **1. Enhance the understanding of BBFE risk factors for individuals and surgical procedures by:**

- a. Enumerating all surgical procedures that took place at DUH from 2001 through 2010 and identifying the cohort of attending surgical staff via administrative records; identifying all reported BBFE that occurred during the surgical procedures performed in the study period; and linking BBFE to the individuals and procedures.
- b. Identifying procedure-level risk factors for BBFE such as duration, case urgency and the frequency of past collaborations among surgical team members; identifying individual-level risk factors such as surgical specialty, occupation and tenure; and conducting analyses stratified by categories of surgical department, occupation and device type.

### **2. Evaluate the effectiveness of intervention efforts in reducing risk of BBFE in the OR by:**

- a. Establishing longitudinal quantitative measures of the burden of BBFEs (e.g., annual frequencies and rates) among the surgical staff in the pre- and post-intervention periods.
- b. Analyzing the secular trends in BBFE rates for the entire surgical staff and stratified by subgroups such as surgical units and occupations; and assessing the impact of the intervention on high risk groups.

### **3. Measure the adoption of NIOSH-recommended practices for reducing BBFE risk among surgical staff by:**

- a. Conducting focus groups and interviews to determine changes in the surgical staff members' use of recommended practices before and after the intervention and reasons for non-compliance.
- b. Exploring how the social norms of surgical units may affect the adoption of safer practices.

## **Methodology**

### **1. Enhance the understanding of BBFE risk factors for individuals and surgical procedures by:**

- a. Enumerating all surgical procedures that took place at DUH from 2001 through 2010 and identifying the cohort of attending surgical staff via administrative records; identifying all reported BBFE that occurred during the surgical procedures performed in the study period; and linking BBFE to the individuals and procedures.
- b. Identifying procedure-level risk factors for BBFE such as duration, case urgency and the frequency of past collaborations among surgical team members; identifying individual-level risk factors such as surgical specialty, occupation and tenure; and conducting analyses stratified by categories of surgical department, occupation and device type.

## **Materials and Methods**

Data were derived from the Duke Health and Safety Surveillance System (DHSSS) developed in 2001 and updated annually throughout the study period. This dataset is the product of several ongoing programs that gather data from sources including human resources, employee health benefits, industrial hygiene, radiological hygiene, hazardous waste management, emergency preparedness, occupational medicine, workers' compensation, and employee health promotion. (Dement, Pompeii, et al., 2004) The system provides for comprehensive surveillance of occupational injuries and diseases, as well as occupational exposure hazards, and makes use of existing data sources for variables such as departments, jobs, and work locations. Linkage of data across datasets permits individual level data analyses; data are de-identified after linkages are made. For the current study, BBF exposure events which occurred during the 2001-2010 study period in the operating rooms at Duke University Medical Center were obtained via the DHSSS. Information about the BBF exposure events were also extracted from the DHSSS.

Perioperative data sources providing characteristics of all surgical cases occurring in the Duke North OR, Ambulatory Surgery Center and Duke Eye Center during 2001–2010 were gathered and merged to supplement the DHSSS data. BBF exposure events occurring in these surgical suites during 2001–2010 and gathered in the DHSSS were matched to the surgical cases in which they occurred. The BBF events were restricted to percutaneous exposures; splashes were excluded. The additional information obtained from the perioperative data included the following variables which were considered in our analyses:

- Estimated patient blood loss
- Urgency of surgical case
- Date of the surgical procedure
- Surgical procedure start and stop times (used to determine duration)
- Department or service responsible for surgery
- Number and job classifications of personnel in the operating room

Estimated patient blood loss for each surgical case was grouped into three categories: none, 1-500 cc, 501-1,000 cc and >1,000 cc. Urgency of the surgical procedure, which

describes the maximum allowed time between posting of the case and start of the procedure, was categorized according to Duke Medical Center's criteria as follows:

- Elective
- Emergency Level 1 ("stat" – within 1 hour)
- Emergency Level 2 (within 4 hours)
- Emergency Level 3 (within 12 hours)
- Emergency Level 4 (within 24 hours)
- Emergency Level 5 (non-elective cases not deemed as of urgency Levels I-IV; organ harvesting and transplant procedures included).

For each surgical procedure, the surgical services performing the procedure were grouped as follows: Dental Surgery, General Surgery, Obstetrics/Gynecology, Cardiac Surgery, Neurosurgery, Otolaryngology, Orthopedics, Ophthalmology, Plastic Surgery, Pediatric Surgery, Thoracic Surgery, and Urology. The time procedures began was used to categorize surgical cases into three shifts as follows: 7:00 am – 3:00 pm (1<sup>st</sup> shift), 3:00 pm - 11:00 pm (2<sup>nd</sup> shift) and 11:00 pm - 07:00 am (3<sup>rd</sup> shift). Total procedure duration, calculated using start and end times, was grouped into intervals of: <2 hours, 2-<4 hours, 4-<6 hours, >=6 hours, and unknown.

Operating room workers were classified according to whether his/her job involved potential BBF exposure, referred to as working in the surgical field. Occupations defined as working in the surgical field included: Attending Surgeon, Anesthesiologist, Certified Nurse Anesthetist, Scrub Nurse, Circulator Nurse, Fellow/Resident/Student, OR/Surgical Technician, and Other Technician.

Finally, calendar year of procedures was identified. Trends by year are reported descriptively; trends are also controlled for in multivariate modeling.

The data analyzed in this study were gathered retrospectively and from sources which were not originally intended to conduct an epidemiologic investigation. Therefore, some measures which might have been useful for a detailed and theoretically guided assessment of BBF exposure etiology, and potential preventive strategies, were not consistently available.

*Surgical Team Stability* – A variable unique to this BBFE study was a measure of the extent to which individuals have worked together on surgical procedures in the past. At the team level, this indicated the "team stability" of those assembled to perform each procedure. The extent to which a surgical team is stable over time reflects the opportunity its members have had to develop familiarity among its members. That is, working together over time implies a greater potential for the members present during any given procedure to function as a cohesive unit. It has long been known that as surgical team members come to know what is expected of them they may perform tasks during operations without even being asked ahead of time (Wilson, 1954).

A measure of "past collaborations" developed by Borgatti and Jones (1996) was adapted to quantify the stability of each surgical team present at each surgical procedure in the study sample. To produce their measure of collaboration they first created a measure of non-collaboration and then took its additive inverse. The measure of non-collaboration reflects the degree to which members of a team have worked on *different* procedures,

without other team members present in the given procedure. This is expressed as follows:

$$\eta_p = \frac{|A \cup B \cup C \cup \dots|}{|A| + |B| + |C| + \dots}$$

Where A, B and C represent three team members of procedure, p. The notation |X| represents the size of the set, in this case, the number of procedures. The numerator is the number of *different* surgical procedures all team members have worked on and the denominator is the total number of procedures worked. To obtain the measure of collaboration, they subtract this measure,  $\eta$ , which ranges from zero to one, from one.

$$\zeta_p = 1 - \eta_p$$

When none of the team members has ever worked with the others,  $\eta$  reaches its maximum value of 1.0 and  $\zeta$  reaches its minimum of  $1-1=0.0$ , reflecting no prior collaboration among any team members. If all the team members have always and only worked with each other in the past, then  $\zeta$  reaches its maximum of 1.0 reflecting perfect collaboration among team members. This method of counting different procedures worked on avoids the double-counting that happens when more than one pair of present individuals have collaborated in the past. In addition, Borgatti and Jones (1996) explicitly state that this formulation of past collaborations may be more appropriate than other group level measures when it is hypothesized that the more team members work together, the better their performance, which is precisely the argument presented here.

This measure was slightly modified to meet the needs of this study. Since the presentation of the index is not contextualized, Borgatti and Jones (1996) make no reference to the length of the period over which the past collaborations are to be measured. In this longitudinal study spanning ten years, the index included a moving window within which past collaborations were measured. The window required to attain a level of familiarity with team members that may improve safety in the OR is not clear. Given the exploratory nature of this part of the study, a six-month was used to generate these indices. The choice of six months for a window was arbitrary. Some published literature have suggested that it may take up to two years for relationships between attending surgeons and scrub nurses to reach a level of trust and proficiency where they form bonds viewed to be akin to spouses (Wilson, 1954). However, a window of two years would eliminate 20% of the BBF exposure data from this study and may be too long for other relationships to reach a level sufficient for coordination improvements sufficient to increase safety.

Perioperative data were used to produce the past collaborations measure. These records include the identifiers of the surgical staff who attended each procedure. For each person on each procedure, the team members taking part in the present procedure were identified. All procedures the given team member worked in the window were identified and the past collaborations with the team members present were enumerated. This measurement was made for every team performing each procedure in the data, excluding those done in the first six months, as the window of six months does not allow for computation of the measures in the first six months of the study period.

## **Data Analysis**

The numbers and proportions of surgical procedures, as well as BBF exposure events, stratified by potential risk factors were calculated and presented as descriptive statistics. Rates of BBF exposures (per 1,000 surgical cases) were also calculated for these same risk factor variable categories. Bivariate associations between BBF exposures and these categorical variables were tested via chi-square statistics. Surgical procedures were treated equally regardless of their duration for this descriptive part of the analysis.

Since the information needed to calculate the duration of procedures was available, Poisson regression models were used to examine associations between BBF exposure rates and the aforementioned risk factors. We applied an approach to Poisson regression developed by Loomis, et al (Loomis, Richardson, & Elliott, 2005) which allowed for the analysis of "ungrouped" data to assess properties of cases while still providing unbiased incidence rates. Procedure duration was used as the offset variable and relative rate ratios were the measure of association obtained.

In these analyses, Poisson regression models were used to analyze "ungrouped" data in which individual surgical procedures and their associated procedure durations are the unit of analysis. This approach was demonstrated to yield unbiased incidence rates by Loomis, et al (Loomis et al., 2005). Poisson regression models included only percutaneous BBF events. Events were stratified by device type (suture needles and all other types) resulting in two models being generated to analyze risk of BBF exposure. Results were reported as adjusted incidence rate ratios (RR) and 95% confidence intervals (95% CI). In addition, likelihood ratio tests were conducted to determine the statistical significance of variables modeled as classes of indicator variables. All statistical analyses were conducted using the Stata statistical software package, Version 11 (StataCorp, 2009).

Since the surgical team stability score was measured as a continuous index which ranges from 0 to 1, the score was transformed into studentized values to model the association as a continuous variable. In these models, the coefficient represents the change in the rate of BBFE for a one standard deviation change in the index score. The index was also modeled as a class of indicator variables representing quartiles of the distribution of scores.

### **Aim 2. Evaluate the effectiveness of intervention efforts in reducing risk of BBFE in the OR by:**

- a. Establishing longitudinal quantitative measures of the burden of BBFEs (e.g., annual frequencies and rates) among the surgical staff in the pre- and post-intervention periods.
- b. Analyzing the secular trends in BBFE rates for the entire surgical staff and stratified by subgroups such as surgical units and occupations; and assessing the impact of the intervention on high risk groups.

Much of the data, methods and analytic techniques described for Aim 1 were also employed for Aim 2. However, the focus of Aim 2 was modeling of the trend in rates of BBFE by year. In these analyses, Poisson regression models were used to analyze "ungrouped" data in which individual surgical procedures and their associated procedure durations are the unit of analysis. This approach was demonstrated to yield unbiased



incidence rates by Loomis, et al (Loomis et al., 2005). Also, the use of Poisson regression to examine trends over time has been demonstrated to be a valid approach by Kuhn, et al (1994). Poisson regression models included only percutaneous BBF events. Events were stratified by device type (suture needles and all other types) resulting in two models being generated to analyze risk of BBF exposure. Results were reported as adjusted incidence rate ratios (RR) and 95% confidence intervals (95% CI). In addition, likelihood ratio tests were conducted to determine the statistical significance of variables modeled as classes of indicator variables. All statistical analyses were conducted using the Stata statistical software package, Version 11 (StataCorp, 2009).

One additional technique employed to examine the trend in BBFE rates is that of piecewise regression (Schwarz, 2014). This technique examines a trend as an ordinal variable (year) and an additional variable that represents the time in years since the intervention and zero for years previous to the intervention. This is sometimes referred to as a “hockey stick” model as it allows for a trend to change direction at one point, sometimes resembling the shape of a hockey stick. This modeling approach was used to test whether the slope of the increase in the rate of BBF exposures changed after the intervention period. We used 2007 and 2008 (representing no lag and a one year lag respectively) to explore the possibility that the rate of the increase over time had changed (i.e., slowed) in the post-intervention period.

The variables described under Aim 1 were included in various regression models to control for potential confounding and provide adjusted rates for the time variables.

**Aim 3. Measure the adoption of NIOSH-recommended practices for reducing BBFE risk among surgical staff by:**

- a. Conducting focus groups and interviews to determine changes in the surgical staff members' use of recommended practices before and after the intervention and reasons for non-compliance.
- b. Exploring how the social norms of surgical units may affect the adoption of safer practices.

This aim proved to be exceptionally difficult. Though the PI took a class in qualitative research methods at the University of North Carolina as part of this project, the process of gathering data – of getting surgical staff to take part in interviews – was unfortunately not accomplished to a degree sufficient for scientific inquiry. Despite enlisting assistance from the orthopedic surgeon on board this project, only four interviews from surgical staff were granted. The PI did take part in monthly meetings with the Sharps Injury Reduction Team, and heard several stories of experiences in the OR. However, the sum of the data gathered from these sources is not sufficient for a proper qualitative analysis and amounts merely to anecdotal information. This was, nonetheless, a great learning experience for the PI. This experience demonstrated the tremendous difficulty in getting access to medical professionals, at least in the fields of surgery (nurses and physicians) and anesthesiology (anesthesiologists, nurse anesthetists and technicians). Several individuals (physicians, nurses, anesthesiologists, etc.) tentatively agreed to participate in interviews yet failed to respond to several attempts to secure a meeting time. Many repeatedly urged the PI to keep asking them to participate, indicating they supported the study. Many were intrigued by the matter of teamwork explored in this project. Yet surgical staff members are exceptionally busy and had trouble finding the time despite repeated attempts to meet with them at their convenience. In addition, after

being encouraged to talk to medical students about their various rotations through several surgical specialties to hear the contrasting ways work might be done, I was informed that after the second year of medical school, students were scattered across not just the institution but the region and beyond. Apparently many do research in the years after they've rotated through the surgical services. The PI also learned there are also greater restrictions on approaching students for participation. The PI could only present the study and invite participation at various talks and classes and leave contact information for students to follow up on their own. None did. Also, some nurses who were invited to participate responded via email and copied several nurse administrators on the response. One asked whether permission from supervisors was required to speak to the PI. When informed that they did not require supervisor permission to provide a confidential interview for this federally funded research, the nurse was not heard from again. This may reflect a very hierarchical social and cultural order of the surgical department at the study site.

Finally, the anecdotal data gathered did provide some interesting insights which will be used to shape hypotheses about the social contexts of the OR which will be explored in future studies of safety during surgical procedures. This aim taught the PI the value of qualitative research in epidemiologic studies might often be 1) to assist in interpretation of findings and 2) to develop hypotheses for future testing. This lesson is extremely important to the PI and will be heeded, and some of these notions possibly examined, in future work on this population.

## **Results & Discussion**

### **Aim 1. Enhance the understanding of BBFE risk factors for individuals and surgical procedures by:**

- a. Enumerating all surgical procedures that took place at DUH from 2001 through 2010 and identifying the cohort of attending surgical staff via administrative records; identifying all reported BBFE that occurred during the surgical procedures performed in the study period; and linking BBFE to the individuals and procedures.
- b. Identifying procedure-level risk factors for BBFE such as duration, case urgency and the frequency of past collaborations among surgical team members; identifying individual-level risk factors such as surgical specialty, occupation and tenure; and conducting analyses stratified by categories of surgical department, occupation and device type.

In total, 333,073 surgical cases were included in the analysis (Table 1). The overwhelming majority of surgical cases were Elective (89.2%); a similar majority of procedures occurred during the 1<sup>st</sup> Shift (88.5%). Half (52.2%) were under two hours in duration. Orthopedics was the predominant surgical service represented (20.8%), followed by General Surgery (17.2%). A majority of cases (70.9%) involved between 8-14 personnel working in the surgical field during the procedure.

Table 2 contains characteristics of the 2,113 reported percutaneous BBF exposure events observed in this study. Suture needles accounted for approximately half (49.0%) of the devices associated with exposures. A range of workers reported exposures, with Fellow/Resident/Student being the predominant group (40.0%), followed by Attending Physician (27.5%). The type of body fluids or tissues associated with BBF exposures were mostly body tissue (48.1%) followed by blood or blood products (38.0%). The

majority of exposures occurred during elective operations (86.4%) and during the 1<sup>st</sup> shift (86.12%). BBF exposures occurred most often during procedures lasting 2 to 4 hours in total duration (43.6%). Orthopedics had the highest proportion of BBF exposures (21.1%), followed by General Surgery (18.3%). Finally, BBF exposures occurred most frequently with 8-14 workers present in the surgical field over the duration of the procedure (82.3%).

A BBF exposure rate was calculated as number of exposure events per 1,000 surgical procedures, stratified by potential risk factors (Table 3). Overall, OR employees reported 2,113 BBF exposure events (6.3 events per 1,000 procedures) during 2001-2010. The BBF exposure rate increased monotonically with increasing blood loss, number of surgical field personnel, shift of procedure start and duration of surgical procedures. The rate varied by urgency of procedure, with Emergency Level 1 ("stat") cases having a rate nearly twice as high as elective procedures. The rates among cases of Emergency Level 5 (non-elective cases not deemed as of urgency Levels I-IV; organ harvesting and transplant procedures included) were also elevated. In addition, the rate of BBF exposures varied among surgical services with increased exposure rates observed for Obstetrics/Gynecology, Cardiac Surgery, and Plastic Surgery. Chi-square p-values for each of the above associations were well below the 0.05 significance level.

Poisson regression model results are presented in Tables 4a-b. Crude incidence density rates (events per 1,000 procedure *hours*) are also shown. Both models reported below include adjustment for calendar year which, in both models, was statistically significant at the  $\alpha = 0.05$  level (data not shown).

Table 4a provides Poisson regression results for percutaneous BBF exposures involving suture needles only (n = 1036). Statistically significant (at the  $\alpha = 0.05$  level) increasing rate ratios were observed with blood loss and number of personnel in the surgical field. The rate varied significantly by procedure duration, but the rate did not increase monotonically across categories. Rates did not significantly vary across categories of procedure urgency (p = 0.15), but risk of BBF exposures was elevated among the Emergency – level 1 ("stat") category compared to elective procedures. When urgency was recoded to a single variable indicating "stat" procedures vs. all other levels of urgency, the rate ratio was 1.48 (95% CI 1.07, 2.06) (not shown). The rate also varied significantly among surgical services and three of the eleven surgical services showed elevated risks compared to the General Surgery referent category. Risk of suture needle related exposures did not vary across shift.

Table 4b shows Poisson regression results that included percutaneous BBF exposures involving all other device types other than suture needles (n = 1077). Blood loss, number of personnel in the field and surgical service were associated with risk of exposure involving these other device types. All levels of case urgency had rate ratios higher than the Elective referent category, but the pattern differed from that found with suture needle related exposures and the likelihood ratio test p-value for the class of variables did not achieve statistical significance at the traditional level (p = 0.09). Recoding urgency to a single variable indicating all non-elective procedures (regardless of level) vs. elective procedures produced a rate ratio of 1.26 (95% CI = 1.04, 1.53). Rate ratios for non-suture percutaneous BBF exposures varied by surgical service; Ophthalmology, Cardiac, Otolaryngology, Orthopedics and Plastic Surgery all had rate ratios higher than the comparison category (General Surgery). Blood loss, number of personnel in field and surgical service were all below the traditional significance level in this model. As with suture needle related events, risk of suture needle related exposures did not vary across shift in the adjusted model.

*Past Collaboration* – The past collaboration scores ranged from 0 to 1 by design of the index. The overall mean score for all procedures was 0.35 (SD = 0.13). The distribution of the index across all procedures is provided in Figure 1. Table 5 contains scores by various properties of surgical procedures. Differences across all values of each procedure properties are mostly small, but strongly significant with such a large sample (N=317,395). The distributions of the values for each surgical service are provided in Figure 2. The means differ across services, as do the shapes of the distributions.

Regression models stratified by device type showed the effect of team stability on risk of BBFE due to suture needles was protective and significant (RR = 0.88, 95% CI = 0.83-0.94). However, adjusting for surgical service resulted in a non-significant association with these outcomes (RR = 0.95, 95% CI = 0.88, 1.03). Additional adjustment for characteristics of procedures did not change this association. Models that broke the index into quartiles showed a non-linear association between the index and risk of BBFE due to suture needles (Table 6).

Results were stronger with regard to BBFE due to devices other than suture needles (Table 7). These findings show a non-significant crude association, but a significant protective effect of greater team stability after adjustment for surgical service (RR= 0.90, 95% CI = 0.84, 0.99). These results indicate a ten percent reduction in risk for a one standard deviation increase in the index score. This effect weakened slightly but remained statistically significant after adjusting for several properties of the procedures. When modeled as categorical variables for quartiles, the results show a significant dose-response association across categories when adjusting for surgical service alone. The dose-response association remains but becomes slightly weaker and non-significant when as the properties of procedures are included to adjust for potential confounding.

**Table 1: Characteristics of Surgical Procedures, 2001-2010**

Surgical Procedure Characteristics	Surgical Procedures (N=333,073)	
	N	% Procedures
<b>Estimated Patient Blood Loss</b>		
Not reported	1,057	0.3
None	214,359	64.4
1-500 cc	99,288	29.8
501-1,000 cc	12,170	3.7
>1,000 cc	5,953	1.8
<b>Urgency of Surgical Case<sup>a</sup></b>		
Not reported	354	0.1
Elective	297,206	89.2
Emergency – Level 1	6,354	1.9
Emergency – Level 2	10,905	3.3
Emergency – Level 3	9,367	2.8
Emergency – Level 4	2,712	0.8
Emergency – Level 5	6,201	1.9
<b>Shift of Procedure Start</b>		
Not reported	276	0.1
1 <sup>st</sup> Shift: 07:00-15:00	294,676	88.5

2 <sup>nd</sup> Shift: 15:00-23:00	28,117	8.4
3 <sup>rd</sup> Shift: 23:00-07:00	10,030	3.0
<b>Procedure Duration</b>		
Not reported	276	0.1
<2 hours	174,011	52.2
2-<4 hours	115,518	34.7
4-<6 hours	32,903	9.9
≥6 hours	10,391	3.1
<b>Surgical Service</b>		
Not reported	30	0.01
Dental Surgery	1,705	0.5
General Surgery	57,328	17.2
Obstetrics/Gynecology	23,890	7.2
Cardiac Surgery	17,811	5.4
Neurosurgery	26,867	8.1
Ear/Nose/Throat	17,711	5.3
Orthopedics	69,074	20.8
Ophthalmology	54,540	16.4
Plastic Surgery	15,951	4.8
Pediatrics and Subspecialties	11,458	3.4
Thoracic Surgery	14,487	4.4
Urology	21,975	6.6

<b>Number of Personnel Ever in Surgical Field</b>		
1-7	93,194	28.0
8-14	236,127	70.9
≥ 15	3,777	1.1
<b>Blood and Body Fluid Exposures (BBF)</b>		
<b>Number with Reported BBF Exposures<sup>b</sup></b>	2,087	0.6
<b>Number without Reported BBF Exposures</b>	330,740	99.4

<sup>a</sup> See the text for a description of case urgency

<sup>b</sup> 26 surgical procedures resulted in more two BBF exposures

**Table 2. Characteristics of BBF Exposure Events and Associated Surgical Procedures**

BBF Exposure Event and Procedure Characteristics	BBF Exposures (N=2,113)	
	N	% Events
<b>Device Associated with BBF Exposure</b>		
Suture needle	1,036	49.0
Scalpel blade	155	7.3
Other sharp object	266	12.6
Hypodermic needle w disposable syringe	110	5.2
Wire	80	3.8
Bovie electrocautery device	42	2.0
Other medical device	184	8.7
Missing or Unknown	240	11.4
<b>Type of Fluid Associated with BBF Exposure</b>		
Blood, blood products	803	38.0
Blood/body fluid	20	1.0
Bloody solution	9	0.4
Body tissue	1,016	48.1
Other	6	0.3
Unknown	18	0.9



Missing	241	11.4
<b>Occupational Group of BBF Exposed</b>		
Attending physician	580	27.5
Anesthesiologist	37	1.8
CRNA	136	6.4
Fellow/Resident/Student	846	40.0
Scrub Nurse (replace RN)	263	12.3
Circulator Nurse	84	4.0
OR/Surgical Tech	160	7.6
Other Tech	7	0.3
Missing	0	0.0
<b>Estimated Patient Blood Loss</b>		
None Reported	971	46.0
1-500 cc	763	36.1
501-1,000 cc	215	10.2
>1,000 cc	157	7.4
Missing	7	0.3
<b>Urgency of Surgical Case</b>		
Elective	1,826	86.4
Emergency – Level 1	75	3.6
Emergency – Levels 2-4	155	7.3

Emergency – Level 5	55	2.6
Missing	2	0.1
<b>Shift of Procedure Start</b>		
1 <sup>st</sup> shift: 07:00-15:00	1,820	86.1
2 <sup>nd</sup> shift: 15:00-23:00	185	8.8
3 <sup>rd</sup> shift: 23:00-07:00	108	5.1
Missing	0	0.0
<b>Procedure Duration</b>		
<2 hours	441	20.9
2-<4 hours	921	43.6
4-<6 hours	469	22.2
≥ 6 hours	282	13.4
Missing	0	0.0
<b>Surgical Service</b>		
Dental Surgery	6	0.3
General Surgery	386	18.3
Obstetrics/Gynecology	210	9.9
Cardiac Surgery	273	12.9
Neurosurgery	153	7.2
Ear/Nose/Throat	107	5.1
Orthopedics	445	21.1

Ophthalmology	154	7.3
Plastic Surgery	124	5.9
Pediatrics and subspecialties	44	2.1
Thoracic Surgery	66	3.1
Urology	145	6.9
Missing	0	0.0
<b>Number of Personnel Ever in Surgical Field</b>		
1-7	245	11.6
8-14	1,738	82.3
≥ 15	130	6.2
Missing	0	0.0

**Table 3: BBF Exposure Rates Associated with Surgical Procedure Characteristics**

Procedure Characteristics	Surgical Cases and BBF Exposures Events			Chi-square P –value for Association
	# of Surgical Procedures	# of BBF Exposure Events	BBF Exposures per 1,000 Surgical Procedures	
Estimated Patient Blood Loss <sup>a</sup>				
None	214,616	971	4.5	< 0.001
1-500 cc	99,294	763	7.7	
501-1,000 cc	12,175	215	17.7	
>1,000 cc	5,956	157	26.4	
Urgency of Surgical Case <sup>b</sup>				
Elective	297,214	1,826	6.1	< 0.001
Emergency – Level 1	6,347	75	11.8	
Emergency – Levels 2-4	22,982	155	6.7	
Emergency – Level 5	6,201	55	8.9	
Shift of Procedure Start <sup>c</sup>				
1 <sup>st</sup> shift: 07:00-14:59	294,678	1,820	6.2	< 0.001
2 <sup>nd</sup> shift: 15:00-22:59	28,116	185	6.6	

3 <sup>rd</sup> shift: 23:00-06:59	10,028	108	10.8	
Number of Personnel Ever in Surgical Field <sup>d</sup>				
1-7	93,194	245	2.6	< 0.001
8-14	236,127	1,738	7.4	
≥15	3,777	130	34.4	
Procedure Duration <sup>e</sup>				
<2 hours	174,022	441	2.5	< 0.001
2-<4 hours	115,515	921	8.0	
4-<6 hours	32,898	469	14.3	
≥ 6 hours	10,387	282	27.1	
Surgical Service <sup>f</sup>				
Dental Surgery	1,706	6	3.5	< 0.001
General Surgery	57,337	385	6.7	
Obstetrics/Gynecology	23,891	210	8.8	
Cardiac Surgery	17,817	273	15.3	
Neurosurgery	26,874	153	5.7	
Ear/Nose/Throat	17,713	107	6.0	
Orthopedics	69,080	445	6.4	
Ophthalmology	54,767	154	2.8	
Plastic Surgery	15,954	124	7.8	
Pediatrics and Subspecialties	11,461	44	3.8	
Thoracic Surgery	14,489	66	4.6	
Urology	21,979	145	6.6	

<sup>a</sup> with 1,057 missing data

<sup>b</sup> with 351 missing data

<sup>c</sup> with 276 missing data

<sup>d</sup> with 0 missing data

<sup>e</sup> with 276 missing data

<sup>f</sup> with 30 missing data

**Table 4a: Poisson Regression Model Results for Percutaneous BBF Exposures:  
Suture Needle-Related BBF Exposure Events Only**

<b>Risk Factor</b>	<b>Number BBF Events (Crude Rate)*</b>	<b>Adjusted Rate Ratio**</b>	<b>95% CI for Adjusted Rate Ratio</b>	<b>LR Test <sup>†</sup></b>
<b>Shift of Procedure Start</b>				0.323
1 <sup>st</sup> shift: 07:00-14:59	897 (1.40)	1.0	(reference)	
2 <sup>nd</sup> shift: 15:00-22:59	91 (1.59)	1.07	(0.84, 1.36)	
3 <sup>rd</sup> shift: 23:00-06:59	48 (1.31)	0.82	(0.59, 1.12)	
<b>Estimated Patient Blood Loss</b>				<0.001
None Reported	426 (1.06)	1	(reference)	
1-500 cc	406 (1.59)	1.28	(1.09, 1.51)	
501-1,000cc	110 (2.30)	1.86	(1.48, 2.36)	
>1,000cc	91 (3.13)	2.58	(1.97, 3.36)	
<b>Urgency of Surgical Case†</b>				0.146
Elective	904 (1.39)	1	(reference)	
Emergency – level 1	43 (2.39)	1.48	(1.06, 2.06)	
Emergency – levels 2-4	64 (1.34)	0.96	(0.73, 1.26)	
Emergency – level 5	24 (1.44)	1.00	(0.66, 1.52)	

<b>Procedure Duration</b>				0.002
<2 hours	180 (0.90)	1	(reference)	
2-<4 hours	476 (1.58)	1.41	(1.17, 1.71)	
4-<6 hours	235 (1.51)	1.21	(0.95, 1.53)	
>=6 hours	145 (1.91)	1.22	(0.93, 1.60)	
<b>Number of Personnel Ever in Surgical Field</b>				<0.001
1-7	94 (0.73)	1	(reference)	
8-14	878 (1.50)	1.49	(1.19, 1.86)	
>=15	64 (3.04)	2.31	(1.61, 3.29)	
<b>Surgical Service</b>				<0.001
General surgery	226 (1.67)	1	(reference)	
Ophthalmology	55 (0.75)	0.74	(0.54, 1.03)	
Dental	2 (0.43)	0.36	(0.08, 1.46)	
Obstetrics/Gynecology	156 (3.36)	2.06	(1.67, 2.54)	
Cardiac Surgery	135 (1.62)	1.21	(0.93, 1.56)	
Neurosurgery	63 (0.89)	0.53	(0.40, 0.70)	
Ear/Nose/Throat	55 (1.98)	1.39	(1.03, 1.87)	
Orthopedics	163 (1.04)	0.61	(0.50, 0.75)	
Plastic Surgery	51 (1.40)	0.92	(0.67, 1.25)	
Pediatrics and Subspecialties	30 (1.98)	1.55	(1.05, 2.28)	
Thoracic surgery	25 (0.79)	0.54	0.36, 0.82)	



Urology	75 (1.39)	0.80	(0.61, 1.04)	
---------	-----------	------	--------------	--

\* ( ) Incidence density - BBF events per 1,000 surgical procedure duration hours

\*\* Model is also adjusted for calendar year (not shown)

¶ Likelihood ratio test for class of indicator variables

†To model the effect of urgency of the surgical case, Levels 2, 3 and 4 were grouped together since statistical power did not allow for analysis of these levels separately.

**Table 4b: Poisson Regression Model Results for Percutaneous BBF Exposures:**

**Non-suture Needle-Related BBF Exposure Events Only**

<b>Risk Factor</b>	<b>Number BBF Events (Crude Rate)*</b>	<b>Adjusted Rate Ratio**</b>	<b>95% CI for Adjusted Rate Ratio</b>	<b>LR Test <sup>†</sup></b>
<b>Shift of Procedure Start</b>				0.953
1 <sup>st</sup> shift: 07:00-14:59	923 (1.44)	1	(reference)	
2 <sup>nd</sup> shift: 15:00-22:59	94 (1.65)	0.98	(0.76, 1.24)	
3 <sup>rd</sup> shift: 23:00-06:59	59 (1.61)	0.96	(0.72, 1.28)	
<b>Estimated Patient Blood Loss</b>				<0.001
None	544 (1.36)	1	(reference)	
1-500 cc	357 (1.39)	0.98	(0.83, 1.14)	
501-1,000cc	105 (2.20)	1.56	(1.23, 1.98)	
>1,000cc	66 (2.27)	1.64	(1.22, 2.20)	
<b>Urgency of Surgical Case†</b>				0.034
Elective	921 (1.41)	1	(reference)	
Emergency – level 1	32 (1.78)	1.26	(0.86, 1.83)	
Emergency – levels 2-4	91 (1.91)	1.39	(1.10, 1.76)	
Emergency – level 5	31 (1.86)	1.28	(0.89, 1.84)	

<b>Procedure Duration</b>				0.253
<2 hours	258 (1.28)	1	(reference)	
2-<4 hours	448 (1.48)	1.14	(0.96, 1.35)	
4-<6 hours	233 (1.50)	1.06	(0.85, 1.32)	
>=6 hours	137 (1.80)	0.95	(0.73, 1.23)	
<b>Number of Personnel Ever in Surgical Field</b>				0.034
1-7	151 (1.77)	1	(reference)	
8-14	859 (1.47)	1.07	(0.89, 1.29)	
>=15	66 (3.13)	1.56	(1.11, 2.20)	
<b>Surgical Service</b>				<0.001
General surgery	160 (1.19)	1	(reference)	
Ophthalmology	98 (1.34)	1.34	(1.02, 1.77)	
Dental	4 (0.86)	0.81	(0.30, 2.21)	
Obstetrics/Gynecology	54 (1.16)	1.04	(0.76, 1.41)	
Cardiac Surgery	138 (1.66)	1.53	(1.16, 1.99)	
Neurosurgery	90 (1.28)	1.10	(0.85, 1.42)	
Ear/Nose/Throat	52 (1.87)	1.71	(1.25, 2.48)	
Orthopedics	282 (1.80)	1.49	(1.22, 1.82)	
Plastic Surgery	73 (2.00)	1.87	(1.41, 2.48)	
Pediatrics and Subspecialties	14 (0.92)	0.85	(0.49, 1.47)	

Thoracic surgery	41 (1.29)	1.15	(0.82, 1.63)	
Urology	70 (1.30)	1.09	(0.81, 1.45)	

\* ( ) Incidence density - BBF events per 1,000 surgical procedure duration hours

\*\* Model is also adjusted for calendar year (not shown)

¶ Likelihood ratio test for class of indicator variable

†To model the effect of urgency of the surgical case, Levels 2, 3 and 4 were grouped together since statistical power did not allow for analysis of these levels separately.

Figure 1. Distribution of Past Collaboration Index – All Surgical Procedures

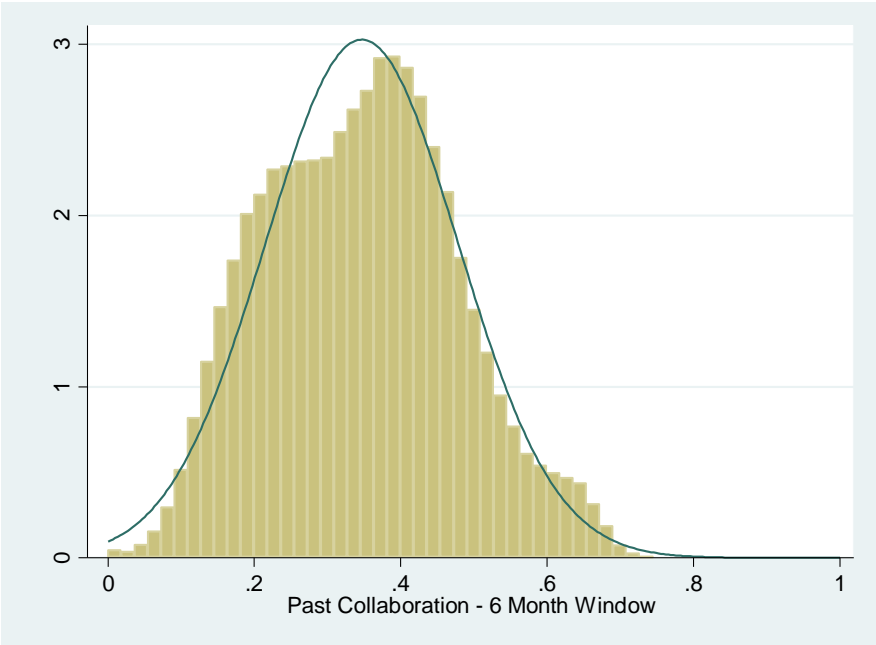
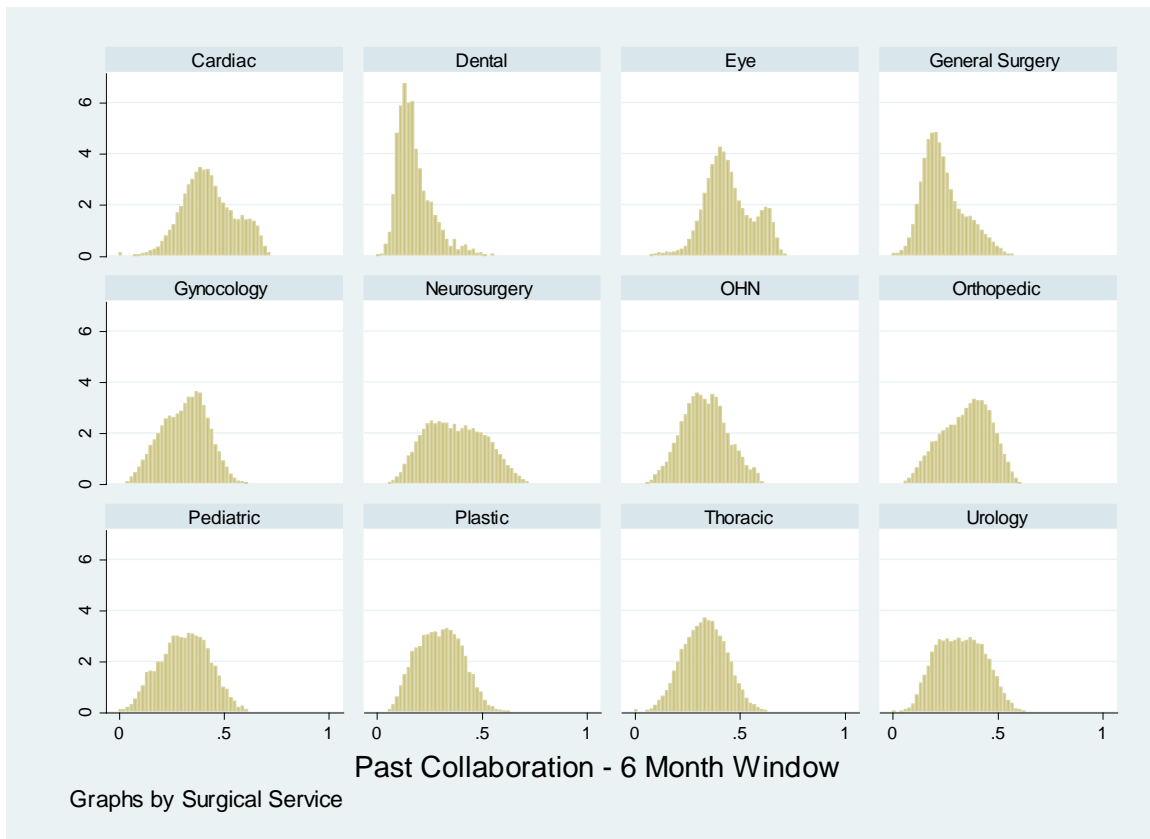


Figure 2. Distribution of Past Collaboration Index by Surgical Service



**Table 5: Past Collaboration Index Scores by Surgical Procedure Properties**

	Mean	SD	N	F-statistic P-Value
<b>Shift</b>				<0.0001
1st shift: 07:00-14:59	0.36	0.13	280852	
2nd shift: 15:00-22:59	0.26	0.13	26817	
3rd shift: 23:00-06:59	0.33	0.16	9521	
<b>Blood Loss</b>				<0.0001
None	0.37	0.13	198943	
1-500 cc	0.31	0.12	99288	
501-1,000 cc	0.32	0.11	12172	
>1,000 cc	0.31	0.10	5956	
<b>Urgency</b>				<0.0001
Elective	0.36	0.13	283294	
Emergency – Level 1	0.25	0.12	6010	
Emergency – Levels 2-4	0.22	0.11	21723	
Emergency – Level 5	0.26	0.10	6085	
<b>Duration</b>				<0.0001
<2 hours	0.36	0.13	166775	
2-<4 hours	0.33	0.13	109267	
4-<6 hours	0.36	0.12	31115	
≥ 6 hours	0.37	0.14	10033	
<b>Personnel in Field</b>				<0.0001
1 - 7	0.33	0.14	86525	
8 - 14	0.35	0.13	227203	
≥15	0.34	0.12	3688	
<b>Surgical Service</b>				<0.0001
Cardiac	0.43	0.12	16696	
Dental	0.18	0.08	1657	
Eye	0.45	0.11	52769	
General Surgery	0.25	0.10	54138	
Gynecology	0.32	0.11	22719	
Neurosurgery	0.38	0.14	25596	
Otolaryngology	0.34	0.11	16861	
Orthopedics	0.35	0.12	66636	
Pediatric	0.32	0.12	10897	
Plastic	0.30	0.11	15065	
Thoracic	0.34	0.10	13358	
Urology	0.33	0.11	21003	
<b>Total</b>	<b>0.35</b>	<b>0.13</b>	<b>317395</b>	

Table 6. Poisson Regression Models – Index of Past Collaboration and BBFE Rates – Suture Needle Events

Suture Needle Events		Model										
		1a		2b		3c		4d		5e		
Past Collaboration		RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI	
Continuous Measure <sup>f</sup>		0.88	(0.83, 0.94)	0.95	(0.88, 1.03)	0.96	(0.88, 1.04)	0.96	(0.89, 1.05)	0.96	(0.88, 1.04)	
Quartile	1 <sup>g</sup>	6a		7b		8c		9d		10e		
		RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI	RR	95% CI	
	1	1.0	--	1.0	--	1.0	--	1.0	--	1.0	--	
	2	1.13	(0.96, 1.32)	1.17	(0.99, 1.39)	1.10	(0.93, 1.31)	1.11	(0.94, 1.32)	1.11	(0.94, 1.32)	
	3	0.77	(0.64, 0.93)	0.87	(0.71, 1.05)	0.87	(0.71, 1.07)	0.88	(0.72, 1.08)	0.88	(0.72, 1.08)	
	4	0.82	(0.69, 0.98)	1.01	(0.83, 1.24)	1.05	(0.85, 1.30)	1.07	(0.87, 1.33)	1.06	(0.85, 1.31)	
Likelihood Ratio Test			<0.0001		0.0091		0.0672		0.0649		0.066	
Number of Procedures			316944		316293		315564		315564		315564	

a Unadjusted

b Adjusted for surgical service

c Adjusted for surgical service, blood loss, urgency, duration, in field personnel and shift

d Adjusted for surgical service, blood loss, urgency, duration, in field personnel, shift and month

e Adjusted for surgical service, blood loss, urgency, duration, in field personnel, shift, month and year

f Studentized continuous measure

g Referent group



Table 7. Poisson Regression Models – Index of Past Collaboration and BBFE Rates – Non-Suture Needle Events

<b>Non-Suture Needle Events</b>		<b>Model</b>									
<b>Past Collaboration</b>		<b>1a</b>		<b>2b</b>		<b>3c</b>		<b>4d</b>		<b>5e</b>	
		<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>
Continuous Measure <sup>f</sup>		0.96	(0.91, 1.02)	0.90	(0.84, 0.97)	0.91	(0.84, 0.99)	0.92	(0.85, 0.99)	0.92	(0.85, 0.99)
<b>Quartile</b>		<b>6a</b>		<b>7b</b>		<b>8c</b>		<b>9d</b>		<b>10e</b>	
		<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>	<b>RR</b>	<b>95% CI</b>
1 <sup>g</sup>		1.0	--	1.0	--	1.0	--	1.0	--	1.0	--
2		0.97	(0.82, 1.15)	0.87	(0.73, 1.04)	0.86	(0.72, 1.03)	0.87	(0.73, 1.04)	0.87	(0.73, 1.04)
3		0.98	(0.82, 1.16)	0.83	(0.69, 1.00)	0.85	(0.70, 1.03)	0.86	(0.71, 1.04)	0.85	(0.70, 1.04)
4		0.90	(0.76, 1.07)	0.75	(0.62, 0.92)	0.78	(0.64, 0.97)	0.79	(0.65, 0.98)	0.80	(0.65, 0.99)
Likelihood Ratio Test g		0.6501		0.0401		0.1416		0.1851		0.2133	
Number of Procedures		316944		316293		315564		315564		315564	

a Unadjusted

b Adjusted for surgical service

c Adjusted for surgical service, blood loss, urgency, duration, in field personnel and shift

d Adjusted for surgical service, blood loss, urgency, duration, in field personnel, shift and month

e Adjusted for surgical service, blood loss, urgency, duration, in field personnel, shift, month and year

f Studentized continuous measure

g Referent group

## Discussion

During the 2001–2010 study period approximately 49% of BBF exposures that happened during surgical procedures in the OR were associated with the use of suture needles. Another report done at a teaching hospital showed nearly identical results, reporting that 50% of OR BBF exposures involved suture needles (Tarantola et al., 2006). Approximately 28% of all BBF exposures in our study occurred to Attending Physicians/Surgeons. This is similar to results reported by Jagger which showed that Residents and Attending Physicians accounted for 36% and 28% of exposures respectively, (J. Jagger et al., 1998) and a French study that observed approximately 35% of BBF exposures occurred among surgeons (Tarantola et al., 2006).

The overall patterns of risk factors observed in this study were consistent with those found in the literature. Previous studies have shown procedure duration and estimated blood loss to be risk factors, (Gerberding et al., 1990; Panlilio et al., 1991; Popejoy & Fry, 1991; Quebbeman et al., 1991; White & Lynch, 1993) and at least one prior study found an association with number of personnel in the surgical field (Quebbeman et al., 1991). Variation in rates of BBF exposures across surgical service types has also been previously observed (Popejoy & Fry, 1991; Tokars et al., 1995).

Although the lack of association between shift and BBF exposures may be surprising, this finding is consistent with one study that examined all BBF exposures at a university hospital and found no association with time of day, although in that study exposures were not limited to percutaneous exposures and the setting was not restricted to the operating room (Macias, Hafner, Brillman, & Tandberg, 1996).

The device-stratified results show that the importance of procedure duration differed between these device categories. The procedure duration was found to be associated with exposures involving suture needles but not for those involving all other device types. As length of procedure may be correlated with complexity and the greater opportunity for using various devices, this was a rather unexpected finding. Regarding suture needles, the association does not show a steady rise in risk with procedure duration. Rather, in the adjusted model, the highest risk appears in procedures lasting 2 to 4 hours in duration. It is possible that this unexpected pattern is due to the inclusion of estimated blood loss and number of personnel in the surgical field which may indicate some measure of procedure complexity, the amount of suturing required, as well as duration. Greater complexity has previously been noted to be a risk factor (Puro, De Carli, Petrosillo, & Ippolito, 2001).

It is possible that blood loss is correlated with the degree of suturing required during a procedure and that this association represents exposure to the suturing task. Risk of suture needle-related exposures also trended upward across the number of personnel in the surgical field. This could represent greater procedure complexity or it may suggest that the physical crowding of surgical field increases the risk of exposures involving suture needles.

“Stat” level urgency of the procedure was expected to be associated with elevated risk of BBF exposure compared to planned elective procedures and other procedures of lesser urgency, as one study found that emergency procedures had greater risk of exposure than scheduled operations (White & Lynch, 1993). This was found in the data for suture needle events only. When case urgency was grouped by elective vs. non-elective cases, non-elective cases showed an elevated risk of BBF exposure involving devices other than suture needles. These observations call for additional research.

Risk of BBF exposures varied significantly among surgical services. This was true of both suture needle-related events and for risk associated with other device types. However there were differences in the pattern of risk among specialties by device type. Obstetrics/Gynecology and Pediatrics and Subspecialties and Ophthalmology all had significantly elevated rates of suture needle related events compared to the General Surgery referent group. These results may reflect more suturing performed in these services. However, Obstetrics/Gynecology and Pediatrics and Subspecialties and Ophthalmology again had significantly elevated rates of non-suture needle related events as well as rates of events associated with suture needles. While there are other possible explanations, the elevated risk of both kinds of events in these three surgical specialties suggests the possibility of better reporting in these groups. The Cardiac and Orthopedic specialties were also found to have elevated risk of non-suture needle related events. The elevated risk observed for these specialties may be due to the more frequent use of certain devices.

Results show a moderate reduction in risk of BBF exposures for teams that had higher past collaboration index scores (i.e., teams that had worked together more in the previous six month period). This association was strongest for BBF exposures involving devices other than suture needles. This stronger effect among these other devices was expected as BBF exposures due to suture needles are more likely to be done to oneself, while those involving other devices are more likely to occur in situations where team members are coordinating their actions and where, therefore, teamwork has a greater opportunity to be relevant for safety.

A meta-analysis of group cohesiveness and performance noted effects of cohesiveness on a variety of performance measures were often statistically significant but small in magnitude (Mullen & Copper, 1994). The same study indicated that several contextual factors may modify the effects of cohesiveness. These observations are consistent with the findings of this study. These past studies suggest that commitment to the task may be driving the effect of cohesiveness on performance, though it is not known whether this is the case in our findings.

Our study has several strengths and limitations. A major strength was the availability of a fairly large number of surgical procedures for study, despite being restricted to percutaneous events occurring during surgical procedures. The low rate of missing values with regard to covariates of interest as well as the time and duration of surgical procedures is also a strength of this study. Finally, the ability to match BBF exposures events to surgical procedures for enabled an analysis of procedure characteristics.

Though the incidence rate of reported BBF exposure events was low, the number of procedures gathered over ten years was quite high, resulting in 2,113 events on which to conduct analyses. Even when stratifying by device type we had considerable power. Some important associations were observed which have implications for future studies and the further development of prevention strategies.

A limitation of this study is its reliance on surgery department personnel to report their BBF exposures to Employee Health staff; the actual number of exposures occurring in this workplace is certainly higher than reported here. Some of the findings reported here may be due in part to differential reporting among occupations (Doebbeling et al., 2003; Voide et al., 2012) and surgical services (Au, Gossage, & Bailey, 2008). However, one study recently suggested the importance of setting, noting that dermatologists working in academic settings may report exposures at higher rates than those working in solo or

group practice contexts (Donnelly, Chang, & Nemeth-Ochoa, 2013). Reporting at this academic institution, therefore, might be better than in other settings.

The analysis stratified by device type demonstrated commonalities and differences in the effect of the risk factors examined in this study. It may be important to examine risk of BBF exposures separately for suture needle and non-suture needle related percutaneous exposures. However, as this study took place in a single institution, future research is needed to confirm whether such differences exist in other settings to understand how risk factors might influence BBF exposures involving different devices. Future studies, if large enough, should also consider conducting analyses stratified by surgical specialty.

The six month window chosen to assess the role of teamwork on safety is arbitrary. It is not known how long it might take for team members to operate more safely together. In addition, the length of this time may vary by job title. The surgical teams are dynamic. Some members may come and go from the OR. As team members do not swipe in or out of procedures, and the time of the events might not be reported with great accuracy, we cannot be positive who was actually in the room at the instant the event occurred. Finally, other unmeasured and unidentified confounders might be driving results. Studies overcoming these limitations will likely require large amounts of primary data collection rather than additional analysis of administrative records.

**Aim 2. Evaluate the effectiveness of intervention efforts in reducing risk of BBFE in the OR by:**

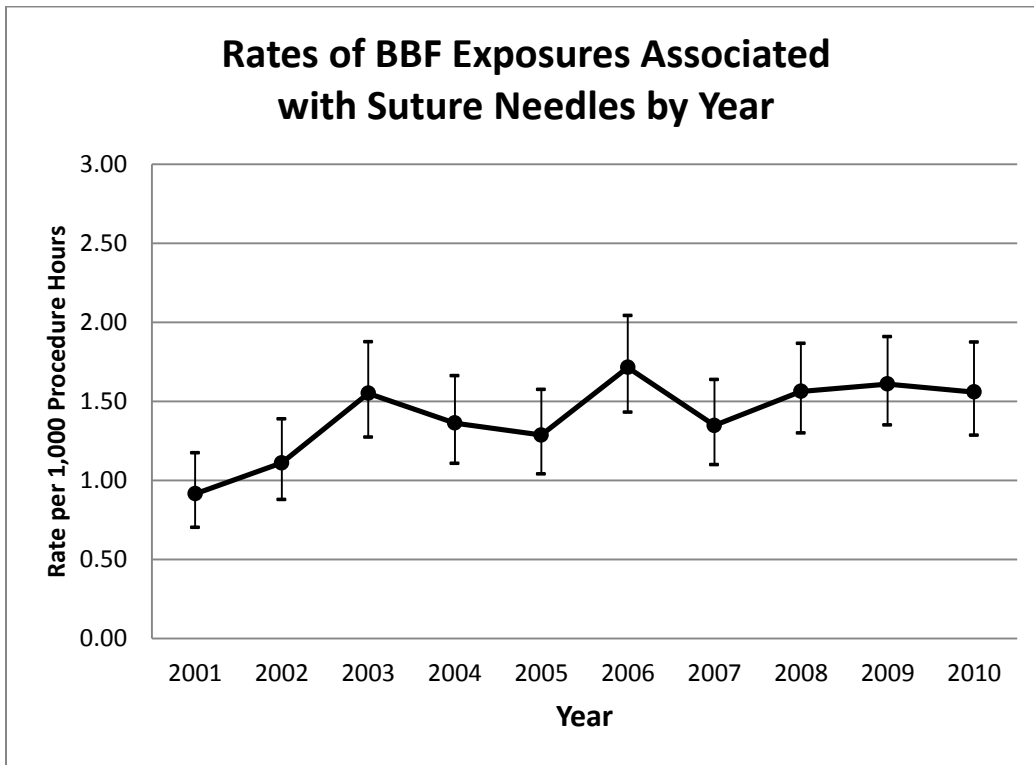
- a. Establishing longitudinal quantitative measures of the burden of BBFEs (e.g., annual frequencies and rates) among the surgical staff in the pre- and post-intervention periods.
- b. Analyzing the secular trends in BBFE rates for the entire surgical staff and stratified by subgroups such as surgical units and occupations; and assessing the impact of the intervention on high risk groups.

Trends of rates of BBF exposures by year, stratified by device type, are reported in Figures 1a and 1b. For each device category, the rate per 1,000 procedure hours is shown (with 95% confidence interval error bars). Suture needle events show a modest increase over the study period. The rate of non-suture needles increased more sharply, particularly after 2006.

Poisson regression models showed that rates of BBF exposures increased across the study period, for both suture needles and all other surgical devices (Table 8)s. Examination of the trend using piecewise regression techniques show that the rate of BBF exposures due to suture needles increased about 5% per year, on average, across the entire study period (RR = 1.05, 95% CI = 1.01, 1.09). The results of the post-intervention period variable show a non-significant flattening of the increase after the intervention period (RR = 0.96, 95% CI = 0.87, 1.06). This was the case whether the intervention period was modeled as beginning in 2007 or 2008. For BBFE due to other surgical instruments, the trend was even stronger. Across the study period, the rate of BBFE for non-suture needle devices increased about 8% per year, on average (RR 1.08, 95% CI = 1.04, 1.12). The post-intervention period actually saw an increase in the rate of BBFE due to non-suture needles, though this result was of marginal statistical significance (RR 1.09, 95% CI = 0.99, 1.20). Again, this finding was observed whether the intervention period was modeled as beginning in 2007 or 2008. Models included were adjusted for all available properties of the surgical procedures.

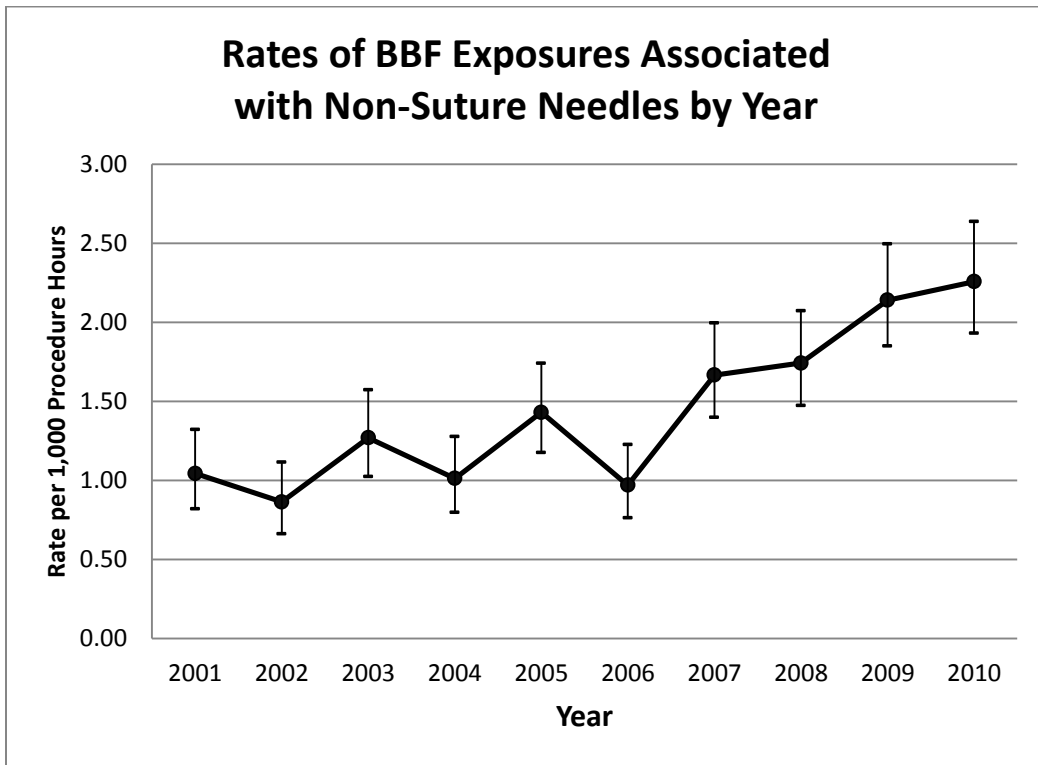
The increase in rates of BBF exposures over time was statistically significant for each device strata. However, the meaning of these findings is not clear. It is possible that procedures are becoming more dangerous, and that new and more dangerous instruments are being used. It is also possible that efforts to promote safety interventions and to encourage reporting of events may be contributing to this observed increase across the study period. However, we cannot explain why this would not apply to exposures due to suture needles as well.

Figure 3.a. Rates of BBF Exposures Associated with Suture Needles by Year



\*Per 1,000 Surgical Procedure Hours

Figure 3.b. Rates\* of BBF Exposures Associated with Non-Suture Needles by Year



\*Per 1,000 Surgical Procedure Hours

**Table 8. Poisson Regression - Trend and Post Intervention Analysis**

	<b>Suture Needles</b>		<b>Non-Suture Needles</b>	
	<b>RR*</b>	<b>95% CI</b>	<b>RR*</b>	<b>95% CI</b>
Year	1.05	(1.01, 1.09)	1.08	(1.04, 1.12)
Post-Intervention Years (2007)	0.96	(0.87, 1.06)	1.09	(0.99, 1.20)
Year	1.05	(1.01, 1.08)	1.08	(1.06, 1.13)
Post-Intervention Years (2008)	0.96	(0.83, 1.07)	1.09	(0.97, 1.22)

\*Adjusted for shift, estimated blood loss, urgency, duration, personnel in field, service and month



**Aim 3. Measure the adoption of NIOSH-recommended practices for reducing BBFE risk among surgical staff by:**

- a. Conducting focus groups and interviews to determine changes in the surgical staff members' use of recommended practices before and after the intervention and reasons for non-compliance.
- b. Exploring how the social norms of surgical units may affect the adoption of safer practices.

As noted earlier, four formal interviews were conducted. This data are not sufficient to achieve the stated Aim. Anecdotes regarding the relationships among surgical staff, the adherence to intervention measures, and the issues individuals considered with regard to the decision to report or not report BBFE were noted and will be used to generate hypotheses for future studies.

## **Conclusions**

**Aim 1. Enhance the understanding of BBFE risk factors for individuals and surgical procedures by:**

- a. Enumerating all surgical procedures that took place at DUH from 2001 through 2010 and identifying the cohort of attending surgical staff via administrative records; identifying all reported BBFE that occurred during the surgical procedures performed in the study period; and linking BBFE to the individuals and procedures.
- b. Identifying procedure-level risk factors for BBFE such as duration, case urgency and the frequency of past collaborations among surgical team members; identifying individual-level risk factors such as surgical specialty, occupation and tenure; and conducting analyses stratified by categories of surgical department, occupation and device type.

These findings suggest that future studies of BBF exposures in the OR should consider analyzing exposures due to suture needle separately from exposures due to other devices. Future epidemiologic studies may use these result to develop hypotheses to explain the differences in risk factors for different device types. It is recommended that future studies gather original data rather than administrative records as administrative data are not likely suited for testing hypotheses about these different risk factor patterns.

Our findings support the need for additional prevention programs. Exposure rates of both suture needle and non-suture needle related BBF exposures increased steadily over the decade-long study period. It is not clear whether this increase is due to a greater frequency of BBF exposure events or an increase in reporting, as the reporting of events at the study site has been repeatedly encouraged. However, this increase observed in the surgical theater is consistent with the findings reported by Jagger, et al (Janine Jagger, Berguer, Phillips, Parker, & Gomaa, 2011).

The variation in rates by surgical service suggests that future studies of BBF exposure risks by surgical service could reveal differences among different types of procedures. Understanding service specific risk factors might identify tailored intervention measures as well as incentives for occupational groups to adopt them. In addition, interventions targeted at mitigating risks for BBF exposures posed by substantial blood loss may be particularly important and beneficial. Stringer, et al (2002), found that use of a neutral or safe zone for passing sharps during surgery was most effective during procedures with more than 100 cc of blood loss. Finally, in their evaluation of glove integrity, Laine and Aarnio (Laine & Aarnio, 2001) showed a higher likelihood of glove perforation with longer duration of surgery. Thus, double-gloving to defend against perforation during lengthy surgical cases is strongly encouraged but adherence with this policy has not been evaluated.

In a recent literature review, DeGirolamo, et al, found double-gloving, blunt suture needles and hands-free transfer of sharps to be the most proven measures of prevention (DeGirolamo, Courtemanche, Hill, Kennedy, & Skarsgard, 2013). Similar recommendations for preventive measures have come from a variety of national agencies and organizations. The American College of Surgeons (ACS) has recommended hands-free instrument passing zones, the use of blunt suture needles and double-gloving (Berguer & Heller, 2004). The use of blunt suture needles has also been recommended by the Association of Perioperative Registered Nurses (AORN) (2005) as well as the National Institute for Occupational Safety and Health (NIOSH) (2007).

While the common realities of surgical procedures may limit the possibility for surgical team members to implement these measures, their use is recommended whenever circumstances allow.

Results suggest that greater team stability may improve safety during surgical procedures, particularly for exposures involving devices other than suture needles. However, these new findings must be interpreted cautiously. The findings pertaining to protective effects of team stability are, to our knowledge, completely novel. We believe this measure has never before been used to explore safety and teamwork in the operating theater, nor in any other setting. Therefore, additional research must be done to replicate these findings to determine their generalizability before policy recommendations may be generated. It is possible that the complexity of the surgical procedures leads to lowered team stability as more and less frequently encountered colleagues take part in procedures. However, adjusted models included the number of personnel in the surgical field as well as duration and estimated blood loss which may be correlated with complexity. Including these variables slightly weakened the observed dose response relationship across quartiles of the index, and led to the lack of statistical significance of the group of indicator variables. However, results of the continuously measured index were not altered by including personnel in the field, duration and estimated blood loss.

We believe the evidence generated in this study is sufficient to lead us to recommend the further application and testing of this method of quantifying the stability of social relations in other studies of workplace safety. We recommend this be done in other operating room settings and in other work settings in which teamwork may conceivably affect safety of team members (for example among fire fighters or miners). Future studies will determine whether these findings hold in operating rooms in other hospitals and how various contexts may modify the role of team stability as it pertains to safety. Similarly, this measure may be used again in the operating room but to look at other outcomes such as those involving patient safety, or in other hospital settings to examine the importance of teamwork for effective patient handoffs.

Should other studies using this measure to investigate the risk of BBF exposures during surgical procedures show similar results, the implications would be that teams should be assembled to reduce turnover and increase familiarity among members so that safety be increased. This may be most important in high risk cases where the patient is known to have bloodborne pathogens, such as Hepatitis or HIV. Future work may find that teamwork matters more in certain situations, such as during very urgent procedures, for particularly long and complicated procedures, those occurring unexpectedly at night, etc.

## **Aim 2. Evaluate the effectiveness of intervention efforts in reducing risk of BBFE in the OR by:**

- a. Establishing longitudinal quantitative measures of the burden of BBFEs (e.g., annual frequencies and rates) among the surgical staff in the pre- and post-intervention periods.
- b. Analyzing the secular trends in BBFE rates for the entire surgical staff and stratified by subgroups such as surgical units and occupations; and assessing the impact of the intervention on high risk groups.

There was no detectable effect of the intervention measures. Not only was there no reduction in the rate after the three intervention measures had been implemented, but the rate of BBF exposures actually continued to rise steadily after the interventions had been conducted. There was no significant change in the slope of the rising rates of BBF exposures in the post-intervention period. The measures applied at the study site included those which, as noted above, have been found to be effective, at least under certain conditions and for some surgical procedures. It is surprising, therefore, that a decrease in risk was not observed. However, the study by Jagger, et al (2011), reports an increase in the rate of BBF exposures in the OR consistent with these findings. Our device stratified results might suggest that it is not necessarily that intervention efforts are not working, but that perhaps they are not keeping up with new and perhaps riskier technologies being used in the OR. More research is needed to explore this possibility and to identify new strategies for improving safety in the OR.

**Aim 3. Measure the adoption of NIOSH-recommended practices for reducing BBFE risk among surgical staff by:**

- a. Conducting focus groups and interviews to determine changes in the surgical staff members' use of recommended practices before and after the intervention and reasons for non-compliance.
- b. Exploring how the social norms of surgical units may affect the adoption of safer practices.

No conclusions made for this aim.

## Inclusion Enrollment Report

**Study Title:** Preventing Blood and Body Fluid Exposures during Surgical Procedures

**Total Enrollment:** 3,184 **Protocol Number:**
**Grant Number:** K01 OH 00 9657

<b>PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race</b>				
<b>Ethnic Category</b>	<b>Females</b>	<b>Males</b>	<b>Sex/Gender Unknown or Not Reported</b>	<b>Total</b>
Hispanic or Latino	14	44	0	58 **
Not Hispanic or Latino	1209	1516	0	2,725
Unknown (individuals not reporting ethnicity)	5	4	392	401
<b>Ethnic Category: Total of All Subjects*</b>	1,228	1,564	392	3,184 *
<b>Racial Categories</b>				
American Indian/Alaska Native	4	3	0	7
Asian	133	186	0	319
Native Hawaiian or Other Pacific Islander	0	2	0	2
Black or African American	183	141	0	324
White	903	1228	0	2,131
More Than One Race	0	0	0	0
Unknown or Not Reported	5	4	392	401
<b>Racial Categories: Total of All Subjects*</b>	1,228	1,564	392	3,184 *
<b>PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)</b>				
<b>Racial Categories</b>	<b>Females</b>	<b>Males</b>	<b>Sex/Gender Unknown or Not Reported</b>	<b>Total</b>
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported	1214	1520	392	3,126
<b>Racial Categories: Total of Hispanics or Latinos**</b>	14	44	0	58 **

\* These totals must agree.

\*\* These totals must agree.

**Publications***In preparation:*

Myers, DJ, Dement, JM, Lipscomb, HJ, Epling, C., Richardson W, and Smith-Lovin, L. Surgical Procedure Characteristics and Risk of Sharps-Related Blood and Body Fluid Exposure. To be submitted to *Infection Control and Hospital Epidemiology*

\*Myers, DJ, Dement, JM, Lipscomb, HJ, Epling, C., Richardson W, and Smith-Lovin, L. Surgical Team Stability and Risk of Sharps-Related Blood and Body Fluid Exposures during Surgical Procedures. To be submitted to *Social Science and Medicine*.

Two manuscripts are in progress. The first, "Risk of Sharps-Related Percutaneous Blood and Body Fluid Exposure in Operating Rooms" will be reviewed next week by administrators at Duke University prior to submission for publication. This manuscript is otherwise complete and ready for submission. The second, "Surgical Team Stability and Risk of Sharps-Related Blood and Body Fluid Exposures during Surgical Procedures" is still being written. All data analyses are complete and tables are made. The study team mentors are working on this with the PI and we will submit it for review by team the other members as soon as this is done. This second paper, as with the first, will be reviewed by Duke University administrators then submitted for publication. The NIOSH Scientific Program will be notified of the publication of these manuscripts.

\*The findings of this study were presented at the Annual Meeting of the American Public Health Association, November 2014, New Orleans, LA.

**Materials**

No data or research materials are available for sharing with other investigators.

## References

- American College of Surgeons. (2005). Statement on blunt suture needles. from [http://www.facs.org/fellows\\_info/statements/st-52.html](http://www.facs.org/fellows_info/statements/st-52.html)
- Association of Perioperative Registered Nurses (AORN). (2005). AORN guidance statement: sharps injury prevention in the perioperative setting. *Aorn J*, 81(3), 662, 665-666, 669-671.
- Association of Perioperative Registered Nurses(AORN). (2005). AORN guidance statement: sharps injury prevention in the perioperative setting. *2005 Standards, Recommended Practices, and Guidelines*. 2005
- Au, E., Gossage, J. A., & Bailey, S. R. (2008). The reporting of needlestick injuries sustained in theatre by surgeons: are we under-reporting? *Journal of Hospital Infection*, 70(1), 66-70. doi: 10.1016/j.jhin.2008.04.025
- Babcock, H. M., & Fraser, V. (2003). Differences in percutaneous injury patterns in a multi-hospital system. *Infect Control Hosp Epidemiol*, 24(10), 731-736.
- Bakaeen, F., Awad, S., Albo, D., Bellows, C. F., Huh, J., Kistner, C., . . . Berger, D. H. (2006). Epidemiology of exposure to blood borne pathogens on a surgical service. *Am J Surg*, 192(5), e18-21.
- Beekmann, S. E., & Henderson, D. K. (2005). Protection of healthcare workers from bloodborne pathogens. *Curr Opin Infect Dis*, 18(4), 331-336.
- Berguer, R., & Heller, P. J. (2004). Preventing sharps injuries in the operating room. *J Am Coll Surg*, 199(3), 462-467.
- Bi, P., Tully, P. J., Pearce, S., & Hiller, J. E. (2006). Occupational blood and body fluid exposure in an Australian teaching hospital. *Epidemiol Infect*, 134(3), 465-471.
- Borgatti, S. P., & Jones, C. (1996). A measure of past collaboration. *Connections*, 19(1), 58-60.
- Centers for Disease Control and Prevention. (1997). Evaluation of blunt suture needles in preventing percutaneous injuries among health-care workers during gynecologic surgical procedures--New York City, March 1993-June 1994. *MMWR Morb Mortal Wkly Rep*, 46(2), 25-29.
- Davies, J. M. (2005). Team communication in the operating room. *Acta Anaesthesiol Scand*, 49(7), 898-901.
- DeGirolamo, K. M., Courtemanche, D. J., Hill, W. D., Kennedy, A., & Skarsgard, E. D. (2013). Use of safety scalpels and other safety practices to reduce sharps injury in the operating room: what is the evidence? *Can J Surg*, 56(4), 263-269.
- Dement, J. M., Epling, C., Ostbye, T., Pompeii, L. A., & Hunt, D. L. (2004). Blood and body fluid exposure risks among health care workers: results from the Duke Health and Safety Surveillance System. *Am J Ind Med*, 46(6), 637-648.
- Dement, J. M., Pompeii, L. A., Ostbye, T., Epling, C., Lipscomb, H. J., James, T., . . . Thomann, W. (2004). An integrated comprehensive occupational surveillance system for health care workers. *Am J Ind Med*, 45(6), 528-538.
- DiConsiglio, J. (2003). Listen closely. Communication helps collaboration with the O.R. *Mater Manag Health Care*, 12(1), 18-21.
- Diez-Roux, A. V. (1998). Bringing context back into epidemiology: variables and fallacies in multilevel analysis. *Am J Public Health*, 88(2), 216-222.
- Doebbeling, B. N., Vaughn, T. E., McCoy, K. D., Beekmann, S. E., Woolson, R. F., Ferguson, K. J., & Torner, J. C. (2003). Percutaneous injury, blood exposure, and adherence to standard precautions: are hospital-based health care providers still at risk? *Clin Infect Dis*, 37(8), 1006-1013.
- Donnelly, A. F., Chang, Y. H., & Nemeth-Ochoa, S. A. (2013). Sharps injuries and reporting practices of U.S. dermatologists. *Dermatol Surg*, 39(12), 1813-1821. doi: 10.1111/dsu.12352
- Edmondson, A. C. (2003). Speaking Up in the Operating Room: How Team Leaders Promote Learning in Interdisciplinary Action Teams. *Journal of Management Studies*, 40(6), 1419-1452.
- Florman, S., Burgdorf, M., Finigan, K., Slakey, D., Hewitt, R., & Nichols, R. L. (2005). Efficacy of double gloving with an intrinsic indicator system. *Surg Infect (Larchmt)*, 6(4), 385-395.
- Gawande, A. A., Studdert, D. M., Orav, E. J., Brennan, T. A., & Zinner, M. J. (2003). Risk factors for retained instruments and sponges after surgery. *N Engl J Med*, 348(3), 229-235.
- Gawande, A. A., Zinner, M. J., Studdert, D. M., & Brennan, T. A. (2003). Analysis of errors reported by surgeons at three teaching hospitals. *Surgery*, 133(6), 614-621.

- Gerberding, J. L., Littell, C., Tarkington, A., Brown, A., & Schecter, W. P. (1990). Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General Hospital. *N Engl J Med*, 322(25), 1788-1793.
- Goob, T. C., Yamada, S. M., Newman, R. E., & Cashman, T. M. (1999). Bloodborne exposures at a United States Army Medical Center. *Appl Occup Environ Hyg*, 14(1), 20-25.
- Jagger, J., Bentley, M., & Tereskerz, P. (1998). A study of patterns and prevention of blood exposures in OR personnel. *Aorn J*, 67(5), 979-981, 983-974, 986-977 passim.
- Jagger, J., Berguer, R., Phillips, E. K., Parker, G., & Gomaa, A. E. (2011). Increase in Sharps Injuries in Surgical Settings Versus Nonsurgical Settings After Passage of National Needlestick Legislation. *AORN*, 93(3), 322-330. doi: 10.1016/j.aorn.2011.01.001
- Joint Commission on Accreditation of Healthcare Organizations. (1998). *Senitnel Events: Evaluating Cause and Planning Improvment* (2nd ed.). Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations.
- Kuhn, L., Davidson, L. L., & Durkin, M. S. (1994). Use of Poisson regression and time series analysis for detecting changes over time in rates of child injury following a prevention program. *Am J Epidemiol*, 140(10), 943-955.
- Laine, T., & Aarnio, P. (2001). How often does glove perforation occur in surgery? Comparison between single gloves and a double-gloving system. *Am J Surg*, 181(6), 564-566.
- Lingard, L., Espin, S., Whyte, S., Regehr, G., Baker, G. R., Reznick, R., . . . Grober, E. (2004). Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care*, 13(5), 330-334.
- Loomis, D., Richardson, D. B., & Elliott, L. (2005). Poisson regression analysis of ungrouped data. *Occup Environ Med*, 62(5), 325-329.
- Macias, D. J., Hafner, J., Brillman, J. C., & Tandberg, D. (1996). Effect of time of day and duration into shift on hazardous exposures to biological fluids. *Academic Emergency Medicine*, 3(6), 605-610.
- Makary, M. A., Al-Attar, A., Holzmueeller, C. G., Sexton, J. B., Syin, D., Gilson, M. M., . . . Pronovost, P. J. (2007). Needlestick injuries among surgeons in training. *N Engl J Med*, 356(26), 2693-2699.
- McCormick, R. D., Meisch, M. G., Ircink, F. G., & Maki, D. G. (1991). Epidemiology of hospital sharps injuries: a 14-year prospective study in the pre-AIDS and AIDS eras. *Am J Med*, 91(3B), 301S-307S.
- Monge, V., Mato, G., Mariano, A., Fernandez, C., & Fereres, J. (2001). Epidemiology of biological-exposure incidents among Spanish healthcare workers. *Infect Control Hosp Epidemiol*, 22(12), 776-780.
- Mullen, B., & Copper, C. (1994). The Relation between Group Cohesiveness and Performance - an Integration. *Psychological Bulletin*, 115(2), 210-227. doi: Doi 10.1037//0033-2909.115.2.210
- Myers, D. J., Epling, C., Dement, J., & Hunt, D. (2008). Risk of sharp device-related blood and body fluid exposure in operating rooms. *Infect Control Hosp Epidemiol*, 29(12), 1139-1148. doi: 10.1086/592091
- National Institute for Occupational Safety and Health. (2007). *Use of Blunt-Tip Suture Needles to Decrease Percutaneous Injuries to Surgical Personnel*. (Publication No. 2008-101). DHHS (NIOSH) Retrieved from <http://www.cdc.gov/niosh/docs/2007-132/pdfs/2007-132.pdf>.
- Panlilio, A. L., Foy, D. R., Edwards, J. R., Bell, D. M., Welch, B. A., Parrish, C. M., . . . Perlino, C. A. (1991). Blood contacts during surgical procedures. *Jama*, 265(12), 1533-1537.
- Panlilio, A. L., Orelie, J. G., Srivastava, P. U., Jagger, J., Cohn, R. D., & Cardo, D. M. (2004). Estimate of the annual number of percutaneous injuries among hospital-based healthcare workers in the United States, 1997-1998. *Infect Control Hosp Epidemiol*, 25(7), 556-562.
- Popejoy, S. L., & Fry, D. E. (1991). Blood contact and exposure in the operating room. *Surg Gynecol Obstet*, 172(6), 480-483.
- Puro, V., De Carli, G., Petrosillo, N., & Ippolito, G. (2001). Risk of exposure to bloodborne infection for Italian healthcare workers, by job category and work area. Studio Italiano Rischio Occupazionale da HIV Group. *Infect Control Hosp Epidemiol*, 22(4), 206-210.
- Quebbeman, E. J., Telford, G. L., Hubbard, S., Wadsworth, K., Hardman, B., Goodman, H., & Gottlieb, M. S. (1991). Risk of blood contamination and injury to operating room personnel. *Ann Surg*, 214(5), 614-620.
- Radecki, S., Abbott, A., & Eloi, L. (2000). Occupational human immunodeficiency virus exposure among residents and medical students: an analysis of 5-year follow-up data. *Arch Intern Med*, 160(20), 3107-3111.



- Risser, D. T., Rice, M. M., Salisbury, M. L., Simon, R., Jay, G. D., & Berns, S. D. (1999). The potential for improved teamwork to reduce medical errors in the emergency department. The MedTeams Research Consortium. *Ann Emerg Med*, 34(3), 373-383.
- Schwarz, C. J. (2014). *Regression - hockey sticks, broken sticks, piecewise, change points*. Course Notes for Beginning and Intermediate Statistics. Retrieved from <http://www.stat.sfu.ca/~cschwarz/CourseNotes>
- Sohn, S., Eagan, J., Sepkowitz, K. A., & Zuccotti, G. (2004). Effect of implementing safety-engineered devices on percutaneous injury epidemiology. *Infect Control Hosp Epidemiol*, 25(7), 536-542.
- Stafford, M., S Uthayakumar, S Falder, P Thomas, M Jolly, JR Smith. (1994). Techniques for reducing needlestick injury in surgical practice. *Infect Control Hosp Epidemiol*, 15(5), 350.
- StataCorp. (2009). Stata Statistical Software: Release 11. College Station, TX: StataCorp LP.
- Stringer, B., Infante-Rivard, C., & Hanley, J. A. (2002). Effectiveness of the hands-free technique in reducing operating theatre injuries. *Occup Environ Med*, 59(10), 703-707.
- Sutcliffe, K. M., Lewton, E., & Rosenthal, M. M. (2004). Communication failures: an insidious contributor to medical mishaps. *Acad Med*, 79(2), 186-194.
- Tarantola, A., Golliot, F., L'Heriteau, F., Lebasacle, K., Ha, C., Farret, D., . . . Bouvet, E. (2006). Assessment of preventive measures for accidental blood exposure in operating theaters: a survey of 20 hospitals in Northern France. *Am J Infect Control*, 34(6), 376-382.
- Tokars, J. I., Bell, D. M., Culver, D. H., Marcus, R., Mendelson, M. H., Sloan, E. P., . . . et al. (1992). Percutaneous injuries during surgical procedures. *Jama*, 267(21), 2899-2904.
- Tokars, J. I., Culver, D. H., Mendelson, M. H., Sloan, E. P., Farber, B. F., Fligner, D. J., . . . Bell, D. M. (1995). Skin and mucous membrane contacts with blood during surgical procedures: risk and prevention. *Infect Control Hosp Epidemiol*, 16(12), 703-711.
- Undre, S., Sevdalis, N., Healey, A. N., Darzi, S. A., & Vincent, C. A. (2006). Teamwork in the operating theatre: cohesion or confusion? *Journal of Evaluation in Clinical Practice*, 12(2), 182-189.
- Vaughn, T. E., McCoy, K. D., Beekmann, S. E., Woolson, R. E., Torner, J. C., & Doebbeling, B. N. (2004). Factors promoting consistent adherence to safe needle precautions among hospital workers. *Infect Control Hosp Epidemiol*, 25(7), 548-555.
- Venier, A. G., Vincent, A., L'Heriteau, F., Floret, N., Senechal, H., Abiteboul, D., . . . Parneix, P. (2007). Surveillance of occupational blood and body fluid exposures among French healthcare workers in 2004. *Infect Control Hosp Epidemiol*, 28(10), 1196-1201.
- Voide, C., Darling, K. E., Kenfak-Foguena, A., Erard, V., Cavassini, M., & Lazor-Blanchet, C. (2012). Underreporting of needlestick and sharps injuries among healthcare workers in a Swiss University Hospital. *Swiss Med Wkly*, 142, w13523. doi: 10.4414/smw.2012.13523
- White, M. C., & Lynch, P. (1993). Blood contact and exposures among operating room personnel: a multicenter study. *Am J Infect Control*, 21(5), 243-248.
- White, M. C., & Lynch, P. (1997). Blood contacts in the operating room after hospital-specific data analysis and action. *Am J Infect Control*, 25(3), 209-214.
- Wilson, R. N. (1954). Teamwork in the Operating Room. *Human Organization*, 12((winter 1954)), 9-14.



Department of Health and Human Services  
**Final Invention Statement and Certification**

(For Grant or Award)

DHHS Grant or Award No.

K01 OH009657

- A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

through

original effective date

date of termination

- B. **Inventions** (Note: If no inventions have been made under the grant or award, insert the word "NONE" under Title below.)

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS
NULL		
(Use continuation sheet if necessary)		

- C. **Signature** — This block *must* be signed by an official authorized to sign on behalf of the institution.

Title		Name and Mailing Address of Institution West Virginia University Research Corporation 886 Chestnut Ridge Road P.O. Box 6845 Morgantown, WV 26506-6845
Assistant Secretary		
Typed Name		
Mary Jane Buckland		
Signature	Date	
Mary Jane Buckland	11/17/14	

# TANGIBLE PERSONAL PROPERTY REPORT

## Final Report SF-428- B

Federal Grant or Other Identifying Number Assigned by Federal Agency (Block 2 on SF-428).

K01 OH009657

D. Myers, PI

**1. Report** (Select all that apply)

a. ☐ Federally-owned Property (List on Supplemental Sheet SF-428S or recipient equivalent and complete Section 2a below.)

b. ☐ Acquired Equipment with acquisition cost of \$5,000 or more for which the awarding agency has reserved the right to transfer title (List on Supplemental Sheet SF-428S or recipient equivalent and complete Section 2b below.)

c. ☐ Residual Unused Supplies with total aggregate fair market value exceeding \$5,000 not needed for any other Federally sponsored programs or projects. (Complete Section 2c below)

d. ☐ None of the above

**2. Complete relevant section(s)**

**For Agency Use Only**

**2a. Federally-owned Property**  
(Select one or more.)

Agency response to requested disposition of Federally owned property:

- (i) ☐ Request transfer to Award \_\_\_\_\_  
 (ii) ☐ Request Federal Agency disposition instructions  
 (iii) ☐ Other (Provide detail in Block 3 or attach request)

- (i) Recipient request approved \_\_\_\_\_ denied \_\_\_\_\_  
 (ii) Dispose in accordance with attached instructions \_\_\_\_\_

**2b. Acquired Equipment** (Select one or more.)

Agency response to requested disposition of acquired equipment:

- (i) ☐ Request unconditional transfer of title with no further obligation to the Federal Government.  
 (ii) ☐ Request Federal Agency disposition instructions

- (i) Recipient request approved \_\_\_\_\_ denied \_\_\_\_\_  
 (ii) Dispose in accordance with attached instructions \_\_\_\_\_

Authorized Awarding Agency Official

Signature:

Date:

Name:

Phone:

Title:

Email:

Note: If the awarding agency does not provide disposition instructions within 120 days the recipient may continue to use the equipment for Federally supported projects or dispose in accordance with the applicable property standards.

**2c. Reportable Residual Unused Supplies**

- (i) ☐ Sale proceeds or ☐ Estimate of current fair market value ..... \$ \_\_\_\_\_  
 (ii) Percentage of Federal participation ..... %  
 (iii) Federal share ..... \$ \_\_\_\_\_  
 (iv) Selling and handling allowance ..... \$ \_\_\_\_\_  
 (v) Amount remitted to the Federal Government..... \$ \_\_\_\_\_

**3. Comments**

NULL

FINAL REPORT ATTACHMENT TO SF-428

Agency use only





November 28, 2014

Mary Pat Shanahan  
Grants Management Specialist  
Centers for Disease Control and Prevention  
Procurement and Grants Office  
OD, Environmental, Occupational Health and Injury  
Prevention Services Branch/Team 2  
P.O. Box 18070  
626 Cochrans Mill Road  
Pittsburgh, PA 15236-0070

RE: Close out Documents for Grant K01 OH 00 9657

Dear Ms. Shanahan:

Enclosed please find the Final Progress Report, Tangible Personal Property form, and the Final Invention Statement relative to the above referenced grant. The Federal Financial Report has been submitted by our business office via eraCommons.

If you have any questions, please do not hesitate to contact me at 304-581-1152.

Sincerely,

A handwritten signature in black ink, appearing to read 'Douglas J. Myers'.

Douglas Myers, MA, ScD  
(Principal Investigator)  
Assistant Professor  
Department of Occupational and Environmental Health Sciences  
West Virginia University