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USE OF THE HANDS-FREE TECHNIQUE IN HOSPITAL OPERATING ROOMS

A STUDY OF THE EFFECTIVENESS OF A RECOMMENDED WORK PRACTICE

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements of the degree of Ph.D.

Dedicated to the memory of Bev Holmwood, an operating room nurse who contracted Hepatitis C due to a work injury and died two months later in December, 1991.

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1. ACKNOWLEDGMENTS

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2. ABSTRACT

The hands-free technique is the indirect transfer of surgical instruments between surgeon(s) and other scrubbed personnel as well as circulating personnel, during which only one person touches the same sharp item at the same time. Items are usually placed in a designated neutral zone, which can be a section of the surgical field or a container, from where they can be retrieved.

Use of the hands-free technique for passing sharp instruments during surgery has been recommended as a work practice by many professional organizations in order to reduce accidents, but its effectiveness has not been adequately studied. This study was designed to determine whether use of the hands-free technique resulted in a decrease in injuries, contaminations and glove tears.

A prospective approach was used. All surgeries performed from the end of October, 1995 to mid-April 1996 at The Providence Medical Center in Seattle, Washington were elible for inclusion in the study.

In 3,765 of 5,388 (70%) eligible surgeries performed during that five and one/half month period, circulating nurses filled out forms in the operating rooms right after a surgical case, assessing the proportion of passes done where no more than one person touched a sharp instrument at the same time.

For the purposes of the study, the hands-free technique was considered used, when it was judged that 75% or more of the passes in a surgery were done in this manner and not used, when it was judged that 50% or less were done in this manner.

In addition to use of the hands-free technique during surgery,

type of surgery, length of surgery, bloodloss during surgery, noise levels, emergency status, number of personnel present and time of day, were also recorded.

All injuries, contaminations and glove tears were considered to be the primary outcomes of interest, although a secondary analysis with only injuries and contaminations more directly related to handling and passing sharp instruments, plus all glove tears, was also carried out.

RESULTS: The hands-free technique was used, as defined, in about 42% of the surgeries. In another 50% of the surgeries it was used half the time or almost never. It was not used at all in 8% of surgeries. An overall injury, contamination and glove tear rate of 3.9% was measured during the study period.

After adjusting for confounding factors, use of the hands-free technique was associated with a reduction in the likelihood of an injury, contamination and glove tear depending on the amount of bloodloss. In surgeries with greater than 100 cc bloodloss, use of the hands-free technique was associated with a 59% [OR 0.41 (95% CI 0.23-0.72], reduction in injuries, contaminations and glove tears, while in surgeries with less than 100 cc bloodloss, that association was not seen [OR 0.99 (95% CI 0.49-1.98)]

When only injuries and contaminations more directly related to handling and passing sharp instruments, plus all glove tears, were used in the analysis, again use of the hands-free technique was associated with a reduction in the likelihood of an injury, contamination and glove tear depending on the amount of bloodloss. In surgeries with greater than 100 cc bloodloss use of the hands-free

technique was associated with a 57% [OR 0.43 (95% CI 0.21-0.86], reduction in injuries, contaminations and glove tears, while in surgeries with less than 100 cc bloodloss, that association was not seen [OR 1.49 (95% CI 0.68-3.31)]

CONCLUSION: Use of the hands-free technique at The Providence Medical Center during the study period was associated with a reduction in injuries, contaminations and glove tears, in surgeries with more than 100cc blood loss but a similar reduction was not observed when blood loss was less than 100 cc.

Use of the hands-free technique in surgeries with more than 100cc blood loss is associated with a reduction in risk. This lends some support to those organizations which have recommended use of the hands-free technique during surgery in order to reduce the risk of transmission of blood-borne diseases among operating room personnel.

Résumé

Dans la technique dite «mains libres», le transfert d'instrument chirurgicaux entre le (ou les) chirurgiens, les personnes aseptisées, et le personnel de passage, est fait de telle manière qu'une seule personne à la fois manipule un instrument coupant et tranchant. Les instruments sont habituellement placés dans une zone neutre réservée à cet effet et à partir de laquelle ils peuvent être repris. Cette zone peut être une partie du champ opératoire ou un récipient.

L'usage de la technique dites des «mains libres» pour le passage d'instruments coupants et tranchants pendant une intervention chirurgicale a été recommandée par de nombreuses organisations professionnelles afin de réduire les accidents, mais son efficacité n'a pas été étudiée de manière satisfaisante. Cette étude a été conçue pour documenter la fréquence avec laquelle cette technique était utilisée au Providence Medical Center de Seattle, dans l'état de Washington, aux États-Unis, la manière dont elle était appliquée et dans quelle mesure son usage résultait en une réduction du nombre des blessures, contaminations et déchirures de gants.

Une approche prospective a été utilisée. Toutes les interventions chirurgicales effectuées entre la fin du mois d'octobre 1995 et la mi-avril 1996 au Providence Medical Center de Seattle ont été prises en compte pour cette étude. Pour 70% (3,765 sur 5,388) des interventions retenues, les infirmières concernées ont rempli des formulaires qui permettent d'estimer le nombre de passes effectuées alors qu'une seule personne à la fois touchait l'instrument coupant et tranchant.

Dans le cadre de cette étude, on a considéré que la méthode des «mains libres» avait été utilisée si les instruments avaient été passés de cette manière au moins 75% du temps, et qu'elle n'avait pas été utilisée lorsque les instruments avaient été passés de cette manière moins de 50% du temps.

En plus de l'usage de la méthode «mains libres», pour chaque observation nous avons mesurée d'autres paramètres tels que le type et la durée de l'intervention, le bruit, le degré d'urgence de l'opération, le nombre de personnes présentes au même moment dans la salle d'opération et le moment de la journée où s'est déroulée l'intervention.

Toutes les blessures, les contaminations, les déchirures de gants ont été considérées comme des événements dignes d'intérêt au cours de la première analyse. Une seconde analyse portant seulement sur les blessures, les contaminations directement imputables à la manipulation d'instruments coupants et tranchants et toutes les déchirures de gants a été conduite par la suite.

RÉSULTATS: La technique des «mains libres», telle que définie dans cette étude, a été utilisée dans environ 42% des interventions. Dans 50% des interventions, cette méthode fut utilisée dans moins de la moitié des manipulations ou presque jamais; elle n'a pas du tout été utilisée dans 8% des interventions. Le taux global de blessures, de contaminations, ou de déchirures de gants fut de 3,9% pour l'ensemble de la période étudiée.

Après ajustement pour les facteurs confondants, on a trouvé que l'usage de la méthode des «mains libres» réduisait la probabilité de blessure, de contamination, ou de déchirure de gants de 59% dans les interventions chirurgicales au cours desquelles l'épanchement sanguin avait excédé 100 cc (OR = 0.41, I.C. = 0.23-0.72). Cette réduction n'existait plus durant les interventions avec épanchement de sang inférieur a 100 cc (OR=1.00, I.C.= 0.49-1.98). Lorsqu'on ne prend en compte que des blessures, des contaminations directement liées à la manipulation et au passage d'instruments coupants et tranchants et des déchirures de gants, l'effet protecteur de la méthode dites «mains libres» passe à 57% (O.R.=0.43, IC= 0.21-0.86) au cours desquelles l'épanchement sanguin avait excédé 100 cc. Cette réduction n'existait plus durant les interventions avec épanchement de sang inférieur a 100 cc (OR=1.49, I.C.= 0.68-3.31).

CONCLUSION: L'usage de la méthode dites «mains libres» au cours de la période étudiée était positivement corrélée avec une réduction des blessures, des contaminations et des déchirures de gants dans les interventions chirurgicales au cours desquelles l'épanchement sanguin dépassait 100 cc. Cette étude tend à donner raison aux organisations qui ont recommandé son usage afin de réduire le risque de transmission de maladies par le sang contaminé, au personnel des salles d'opérations.

4. PREFACE

As a former registered nurse I have a long-standing interest in hospital work practices that are believed to reduce the risk of transmitting infectious diseases.

As a result of working as an infection control nurse at Vancouver General Hospital I was familiar with the recommended operating room work practice called the hands-free technique, which was supposed to reduce the number of percutaneous injuries, as well as blood and body fluid contaminations. The definition of the hands-free technique by the American Association of Operating Room Nurses is "The hands-free technique is carried out by placing a sharp in an established neutral zone on the surgical field, placing a sharp in a basin or other means of ensuring that only one scrubbed or circulating surgical member touches this sharp at the same time".[1]

Despite the intuitive appeal of the technique, its use or its effectiveness had never been evaluated. Thus it seemed ripe for an evaluation and I undertook this for my doctoral dissertation.

Finding a suitable hospital in which to conduct the study was difficult. My first choice was the Royal Victoria Hospital in Montreal where I received all necessary approvals by the summer of 1994. After about one month of data collection (during which there was a problem of a low response rate) a dispute between unionized operating room personnel and management made completion of the study impossible. A search throughout Canada, including a letter to the editor of the Canadian Medical Association Journal[2] (Appendix 1) found no other hospital willing or able (the technique was simply not used enough), so the search widened to include the United States. It

was not until September 1995 that one was found.

After minor revisions of the questionnaire, the Institutional Review Committee at The Providence Medical Center, in Seattle, Washington, gave permission (Appendix 2) for the study of the effectiveness of the hands-free technique.

This thesis is based upon a prospective study that I carried out there from October 30th 1995 to April 15th, 1996.

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[1] AORN Journal. Recommended practices: Universal precautions in the perioperative practice setting. 1993;57:554-558.

[2] Stringer B. Hospital needed for research on hands-free technique. CMAJ 1995;153:139.

5. DEFINITIONS

Hands-free technique is the indirect transfer of instruments between the surgeon(s) and other scrubbed personnel such that only one person touches the same sharp item at any time. Items are usually placed in a designated neutral zone, which can be a section of the surgical field or a container, from where they can be retrieved.

Events consist of injuries, contaminations and glove tears as defined below.

Sharp instruments consist of scalpels, loaded needle holders, rakes, gelp retractors, sharp pointed electrocautery tips, skin hooks [1], all needles including suture needles, needles attached to syringes, needles attached to tubing, glass, wires and pins. [2]

Passing directly means passing hand-to-hand, in the absence of the hands-free technique.

A percutaneous injury is a puncture or laceration of the skin by a sharp (needle or other pointed instrument or object). Self-reporting of the percutaneous injury by the injured party is required. An apparent wound would be a confirmation as would a pricking/stabbing sensation, not necessarily confirmed visually. Blood does not have to be present at the injury site.

A cutaneous contamination occurs when blood or body fluid comes into contact with skin (intact or non-intact). [3] A cutaneous contamination due to the handling/passing of sharps, will most often be seen on the hand.

A mucous membrane contamination occurs when blood or body fluid comes into contact with mucous membrane, usually that lining the eyes, nose or mouth. It may be felt or seen.

A glove tear is a perforation of a glove, which is usually but not always visible. It may be felt or seen.

Body fluid is any liquid arising from a patient's body, whether it is visibly bloody or not.

Seroconversion occurs when specific antibodies are detected in the blood after infection or immunization.

Main circulating nurse is present during each surgical procedure. Her primary responsibility is for maintaining the non-sterile component of perioperative care of the patient. [4]

A case surgery is a surgery during which at least one percutaneous injury, glove tear or contamination of the skin or mucous membrane has occurred.

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[1] AORN Journal. Passing surgical sharps without injury. 1992;55:264-266.

[2] Jagger J. (Data Collection Form) Uniform blood and body fluid exposure report: Operating room personnel. October 1993.

[3] Manian FA. Universal precautions 'clarified'. Infect Control Hosp Epidemiol 1988;9:343-344.

[4] Gerberding JL et al. Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General hospital. N Engl J Med 1990;322:1788-93.

6. BACKGROUND AND LITERATURE REVIEW

In a 1993 editorial in the *American Journal of Infection Control* an associate editor wrote: "The uniqueness of the surgical environment has created a need for us to accurately characterize the risk (of percutaneous injuries and contaminations) if we are to adopt specific strategies to reduce the risk of occupational exposure to blood-borne pathogens in this setting. Moreover, reducing risks of occupational exposure for health care workers, specifically risks of percutaneous injuries, will ultimately benefit the patient.....

"The challenges of reducing risk of occupational exposure to blood in the surgical setting will require a commitment to changing the perception of occupational risk, characterizing the nature and type of exposures, and adopting specific strategies to reduce the risk of exposure during surgical procedures in an environment that already has high standards for maintaining a safe, aseptic environment to control infection risks in patients." [1]

The following chapter contains a description of the occupational setting in which surgery takes place; it outlines how health outcomes associated with occupational exposure to blood in the surgical setting are a product of: 1) the prevalence of blood-borne pathogens among surgical cases; 2) the disease organisms' ability to be transmitted; 3) the operating room personnel's likelihood of exposure to blood or bloody fluids; 4) the existence of post-exposure treatment; 5) the consequences of acquiring the diseases; and, it contains a review of the literature on risk of occupational exposure to blood in the surgical setting.

6.1 The surgical setting

POPULATION: In Canada, approximately two million surgical procedures were performed by 7,500 surgeons, 2,100 residents, and an unknown number of nurses and other operating room personnel in hospitals in 1993-94. [2] [3] [4] Approximately 145,000 surgeons and 113,000 registered and licensed practical nurses working in operating rooms in the United States performed 24 million surgical procedures in 1995. [5]

THE OPERATING ROOM: The operating room is the hospital environment with the greatest concentration of sharp instruments. It is also an area where workers are exposed to large quantities of free flowing, undiluted blood, to splashes with bloody body fluid (during irrigation for example) and to other types of contact with tissue from procedures such as drilling into bone. In the surgical setting there are well established protocols and specialized surgical teams.

COMMUNICATION PROBLEMS: The surgical environment is unusual in that required personal protective equipment such as caps, surgical masks, face shields or goggles, and surgical gowns can make it difficult to communicate. Words may be muffled. Students come and go during surgical training. Often, a variety of accents must be understood. Gestures that may enhance the meaning of words in everyday life may not be possible in an operating room because of protective equipment. As well, the need at times to hold instruments in place without moving, or even blindly, has required the development of work practices and routines to overcome communication problems. These difficulties are sometimes made worse by understaffing, noise and other distractions. Work in the

operating room has an assembly line aspect to it that sometimes leads to boredom. There is considerable pressure for maximum patient turnover.

6.2 Prevalence of pathogens among surgical cases

There are numerous pathogens that can be transmitted by exposure to blood and body fluids. Of most current concern, because of fatal outcomes, are the hepatitis B (HBV), hepatitis C (HCV) and human immunodefiency (HIV) viruses.

PREVALENCE OF HEPATITIS B: From 1980 to 1989, the reported incidence of HBV in Canada increased by a factor of 2.5, with Québec and British Columbia discovering the greatest number of new infections during the latter part of the decade. [6] In 1981 in B.C. the rate of HBV infection was 0.98/100,000 and in 1991 this rate had increased to 26.1/100,000. [7] Reported cases Canada-wide were 2,463 in 1991, and 2,622 by November 30th, 1992, but increased to 3,078 in 1994 and 3,326 in 1995. [8] The reported number of cases of hepatitis B may only represent 10% to 20% of the actual number that occur in all of Canada.[9] The prevalence of HBV markers in the U.S. and Canada is thought to be approximately 4-6% [10] while the number of Canadians with HBV infection is thought to approximate 0.3-0.6%.[11]

PREVALENCE OF HEPATITIS C: Persons with household contact, sexual contact, and percutaneous exposure (especially hemophiliacs who have been heavily transfused for more than 10 years, organ transplant patients and those sharing IV needles with drug users known to be HCV infected) account for 60% of all cases. There is still a large number of cases that are not accounted for, although low socioeconomic status is associated with many of these.[12]

In the U.S., prevalence of infection among hospitalized patients is 2-18%. [13] The CDC considers HCV to be the most poorly reported of

all types of viral hepatitis in the U.S. and believes that there have been 150,000 cases of HCV annually over the past 10 years. [14]

The Canadian data indicate the prevalence to be 0.3-0.6% (the same as HBV) but this may not be an accurate estimate. [15] In fact, in 1994 there were 2,856 cases of Hepatitis C reported while in 1995 there were 10,868 reported. [16] In British Columbia alone there were 5,137 new cases from January to December 1995. [17]

PREVALENCE OF HIV: The risk of HIV infection to health care workers continues to grow despite a lower overall rate of transmission, due to the continuing absolute increase in numbers of HIV infected and their relatively longer period of survival. In Canada it was estimated that 1.5/1000 adults were infected with HIV. [18] In the U.S. it is estimated that more than double this number of adults are infected. [19]

Health Canada estimated that there were approximately 35,000 persons infected with HIV in Canada [20] in a population that now approximates 29 million. [21] Four provinces, British Columbia, Ontario, Québec and Alberta, accounted for 95% of the AIDS cases in Canada.[22] It is assumed, as with the hepatitis infections, that not all cases are reported.

6.3 Disease transmission

TYPE OF EXPOSURE: An organism's infectivity (inherent capacity to infect) and the type of exposure (across the skin or mucous membrane versus on intact skin) as well as the dose of organisms received, are the primary determinants of infection. [23] Occupational exposure to infected blood and body fluids falls within the following categories:

a) Cutaneous -- contamination of intact and non-intact skin;

b) Mucous membrane -- contamination of the lining of the mouth, nostrils, eyes and genital mucosa;

c) Percutaneous (sometimes called transcutaneous or parenteral) -- injuries that penetrate through the skin.

TRANSMISSION RISK THROUGH INTACT AND NON-INTACT SKIN: Intact skin is considered to be an effective barrier against microorganisms, [24] although most occupational transmission of hepatitis B may in fact occur because of minute unobservable breaks in the skin. [25] Many health care workers, especially operating room personnel, develop breaks in their skin. It has been shown that suture tying leads to paper-cut like lesions on the fingers. [26] Breaks in the skin are also thought to be due to repeated scrubbing and hand washing and to dermatitis linked to latex glove exposure. [27] The prevalence of latex sensitivity was reported to be 3% in hospital workers as a whole and 6% in surgical units. [28] While approximately 1% of the general population is thought to have latex allergy, in one study as many as 15% of health care workers had developed it. [29] The number of health care workers who will develop latex allergy is thought to be increasing.

Transmission of HIV, HBV and HCV through non-intact skin has been reported. [30]

TRANSMISSION RISK THROUGH MUCOUS MEMBRANES: The mucous membrane is more vulnerable to penetration by disease organisms than intact skin. The risk of HIV transmission from a mucous membrane contamination has been estimated to be .09%. [31] There have been at least four documented cases of U.S. workers who sero-converted after being exposed to HIV-infected blood [32] through contact with mucous membranes. One case in Italy is also documented. [33] There are many examples of HBV infection after mucous membrane exposure [34] and HCV infection after a similar exposure has occurred at least once. [35]

TRANSMISSION RISK FROM PERCUTANEOUS INJURIES: Percutaneous injuries with contaminated sharp objects are considered the most likely means of blood-borne disease transmission. [36] These may be caused by a variety of means including: sharp instruments, such as hollow-bore needles and scalpels, and even rigid tissues such as bone and teeth. The overall risk of seroconverting has been estimated at approximately 0.3% after a percutaneous injury (needlestick or cut) with an HIV-contaminated instrument; [37] 30% after an HBV-contaminated percutaneous injury if the carrier is HBeAg (Hepatis B-e antigen) positive and approximately 6% if HBeAg negative; [38] and between 3%-10% for an HCV-contaminated percutaneous injury. [39] [40] Risk can be greater depending on the quantity of virus present in the blood of the source patient at the time of the injury. [41] [42] The risk of infection also depends on the depth of the injury and on the volume of blood

and bloody body fluid breaching the cutaneous barrier. For example, hollow-bore needles deliver much greater numbers of organisms than solid-core needles or sharps. [43] [44] But the risk of infection from solid-bore needles can be reduced by a glove. It has been shown that if a solid-core suture needle passes through a glove, the needle may lose half its blood volume on the glove surface. [45] No HIV seroconversions have been documented following suture needle injuries, [46] although there has been a case of transmission of HIV to a surgeon through a cut caused by a scalpel blade. [47]

SEROCONVERSION: The rate of seroconversion after needlestick injuries for HBV has been estimated to be between 6% and 30%, depending on whether or not the HBeAg is present in the reservoirs' blood. [48] For HCV it is estimated at 3-10 %. The risk of transmission after a percutaneous injury from an HIV contaminated sharp instrument is considered to be approximately 0.3%. [49]

HEPATITIS B

MODE OF TRANSMISSION: Transmission of HBV occurs through the exchange of all types of body fluids, with bloody body fluids being most infectious. Presence of HBeAg in the blood is thought to be an indicator of infectivity, [50] although there is some recent controversy about this, since some transmission from surgeons to patients has not been associated with detectable HBeAg. [51] HBV is more easily transmitted than HIV or HCV.

HEPATITIS C

MODE OF TRANSMISSION: The risk of HCV transmission is not as well quantified as it is for HBV and HIV, although its mode of transmission seems to mainly resemble that of the HBV. The main

route of transmission of HCV is through exposure to blood products.[52]

There is a report of an occupational transmission leading to the death of a nurse two months after a hollow-bore needlestick injury in 1991 in a British Columbia operating room. [53] There is also a report of transmission of HCV after a blood splash to the eye. [54]

HIV

MODE OF TRANSMISSION: HIV is transmitted sexually, via blood and in utero, but much less easily than HBV and HCV.

Only 52 'documented' occupationally acquired U.S. cases of HIV were listed, while more than twice as many (111) were 'possible' occupationally acquired HIV cases. [55] Because occupational transmission documentation depends on two factors, reporting an incident and documenting worker baseline seronegativity and then subsequent seroconversion, both the U.S. and Canadian documented figures are likely to be an underestimate. It has recently been found that on occasion, seronegativity persists beyond the "window" period, because of an atypical host response. [56]

In Canada, there is one definite documented case of occupationally acquired HIV, which occurred in a British Columbia physician in 1995, and two probable occupational transmissions, one in an Ontario laboratory worker, and one in a Québec laboratory worker. [57]

The B.C. Centre for Excellence in HIV/AIDS has noted that the occupational exposure case was the first seroconversion among 1,000 needlesticks reported in B.C. over the last 5 years. [58] As well, Canada's voluntary National Surveillance of Occupational Exposure to the Human Immunodeficiency Virus Program, in existence since

1985, had enrolled a total of 626 health care personnel by January 1996, none of whom has seroconverted. [59]

A retrospective U.S./English/French/Italian case-control study [60] has added to the growing information on health care workers' risk of contracting HIV after a documented skin perforation from an HIV-contaminated sharp. Thirty-three cases from four participating countries were assessed along with 665 U.S. controls. Controls and cases all sustained a percutaneous contaminated injury that fit the criteria as high risk.

This study has identified factors significantly associated with seroconversion: 1) having a deep injury or/and the device causing the injury being visibly contaminated with the patient's blood or/and the procedure involving placement of a needle directly in a patient's vein or artery; 2) sustaining an exposure from a patient who died within two months of the injury; 3) non-use of zidovudine in the injured worker post-exposure. When zidovudine was used, the risk of contracting HIV was estimated to be reduced by approximately 81% (OR=0.19 (95% CI 0.06-0.52).

This study has been criticized because of the small number of cases who came from France, England, Italy and the U.S., while all controls originated from the U.S; Because information from cases was obtained long after transmission occurred whereas controls who were exposed, provided information soon after the injury; And, because the efficacy of zidovudine should be evaluated through clinical trials.

Nevertheless, this evaluation, within a case-control study has found that cases were significantly less likely than controls to have

taken zidovudine prophylactically and as a result of this study there is increased confidence about the definition of a 'high risk' exposure and zidovudine treatment post-exposure has become the standard in North America.

SUMMARY: The risk of blood-borne disease transmission to operating room workers from an event appears most related to the level of the organism in the contaminating fluid, its infectivity, whether a hollow-bore sharp instrument is being used and the effects of the transmitted organism.

6.4 Operating room personnel's likelihood of exposure to blood or bloody body fluids

INTRODUCTION: From the operating room studies reviewed in detail, researchers have found a percutaneous injury rate of between 1.7% and 15%, over periods ranging from 1 to 10 months depending on type of surgery and other factors. As well, blood and body fluid contaminations have been found to occur at rates between 6.2% and 50%.[61 62 63 64 65 66]

LITERATURE: A review of the literature found 21 studies that examined risk factors for injuries and contaminations in the operating room.

Two studies did not provide sufficient information on methods to determine how the study had been carried out[67 68] and another was very small (total of 67 open heart cases) and was primarily concerned with glove use, although some data on percutaneous injuries was provided.[69]

Five studies used survey questionnaires mailed to operating room personnel, asking them to recall past injuries and/or contaminations during surgeries.[70 71 72 73 74]

Five prospective studies either asked operating room personnel to fill out questionnaires[75 76 77] or to participate in interviews,[78 79] each time an injury occurred. Two additional prospective studies required that a circulating nurse fill out a questionnaire when an injury or contamination was observed or reported.[80 81]

The remaining six studies were prospective cohort studies that collected data on consecutive surgeries to assess risk factors for percutaneous injuries alone[82] and for both percutaneous injuries and

contaminations. [83] [84] [85] [86] [87] Only one of these studies looked at the effect of using the hands-free technique during surgery. [88]

6.5 Comments on the design of operating room studies

Retrospective operating room studies, sometimes asking surgeons to recall many years in the past, suffer from potentially serious recall bias. In other studies, one or more of the following problems were present: collecting only the details of surgeries in which an event occurred thus not permitting comparison to incident-free surgeries; not collecting details essential to the evaluation of the studies such as status and training of observers, definition of exposures and outcomes, protocol for case identification. Poor methodology or lack of ability to evaluate methods because they were not outlined in study reports, rendered study results unreliable for most operating room studies found in the literature.

The six more robust studies (Table 6.1) have used similar methods to measure and collect information. In these studies, the surgery was the unit of observation. Each surgery was considered a member of the cohort and exposures and outcomes assessed from start of the surgery to the end of the surgery. In all studies, an observer was designated to assess exposure and outcome. Sometimes the observer was a working member of the surgical team while in others the observer had no other tasks. The risk factors measured in these studies were: type of surgery, length of surgery, shift during which the surgery occurred, blood loss, emergency/non-emergency status of the surgery, community or university affiliated status of the hospital, as well as certain work practices such as holding tissues with fingers or instruments. When an injury or contamination occurred during a surgery, the surgery became a case surgery and the circumstances of the injury or contamination were recorded. All

studies provided risk estimates and all studies controlled for confounding factors.

Table 6.1 Prospective Cohort Studies in the Operating Room
Risk estimates for factors found to be associated with injuries/contaminations are given.

STUDY	FINDINGS
1. Gerberding et al, 1990; 1,307 consecutive surgeries; Working circulating nurses observing.	Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations in 6.4% of surgeries ; Percutaneous injuries only in 1.7%; Surgery 3 hr. or > (OR 1.60 [95% CI 1.24-2.06]; > 300 ml blood loss (OR 1.63 [95% CI 1.27-2.11]; Vascular surgery (OR 3.19 [95% CI 1.95-5.21]); Intraabdominal gyne surgery (OR 1.82 [95% CI 1.18-2.08]); Residents suffered most of the Percutaneous injuries. Glove perforation rates for the outer glove in double gloved personnel, was 17.5% compared to 5.5% of the inner glove, during a validation study of gloves.
2. Panlilio et al. 1991; 206 selected surgeries; Infection control nurses with no other OR duties observing.	Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations in 30.1% of surgeries; Percutaneous injuries only in 4.9%; Surgery 1 hr or > (OR 3.32 [95% CI 1.56-7.09]); > 250 ml blood loss (OR 2.12 [95%CI 1.21-3.72]); Emergency (OR 2.4 [95% CI 1.5-3.8]). Surgeons had the most total number of Percutaneous, Cutaneous & Mucous Membrane exposures, although scrub nurses had as many Percutaneous injuries as surgeons.
3. Popejoy and Fry 1991; 684 consecutive surgeries; Working circulating nurses observing.	Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations in 28% of surgeries; Percutaneous injuries only in 3%; 14% surgeries < 1 hr long had Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations; those > 1 to < 3 hr had 26%; those > 3 - < 5 hr had 48%; > 5 hr. had 58%; 58% of cardiothoracic surgeries had Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations (P=0.001), 49% of trauma had Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations (P=0.003), 48% of c-section had Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations (P=0.021). Circulating nurses had the most total number of Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations, although surgeons had the most Percutaneous injuries.
4. Quebbeman et al. 1991; 232 selected surgeries; OR nurses with no other OR duties observing.	Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations in 50% of surgeries ; Percutaneous injuries only in 15%; For each 1.5 hours of surgery, the RR for risk of contamination was 1.44 (p=0.004); 250 ml blood loss (RR 1.16 (P=0.0006)); 700 ml irrigation fluid used (RR 1.11, (P= 0.004)); 75% gyne (most) had Percutaneous, Cutaneous &Mucous Membrane injuries/contaminations compared to the least in 38% of general surgeries; Surgeons and Residents had the most total number of had Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations.
5. Tokars et al. 1992; 1,382 selected surgeries; Nurses/techs with no other duties observing.	Percutaneous injuries only in 6.9 % of surgeries; Surgery of 2.7 hrs (OR 2.3 [1.5-3.4]); Holding tissue with fingers (OR 2.4 [1.5-3.]); Day shift surgeries(OR 3.1 [1.6-5.9]); Vaginal hysterectomy (OR 3.5 [1.6-7.5]); Surgeons and Residents had the most total number of Perc injuries although 4th year Residents had the greatest risk. 67/99 injuries caused by suture needles; In 29/99 injuries potential exposure of the patient to the body fluid of personnel occurred.
6. Lynch/White 1993; 8,502 consecutive surgeries; Working circulating nurses observing.	Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations in 10.2% of surgeries; Surgery of 2 hr. (OR 1.51 [1.46-1.56]); Emergency surgeries (OR 1.44 [1.21-1.66]); Thoracic surgery (OR 2.08 [1.74-2.43]); Burn, trauma, organ transplant (OR 1.76 [1.23-2.29]); Neurosurgery (OR 1.40 [1.10-1.69]); orthopedic (OR 1.32 [1.13-1.52]); University hospital Vs community hospital(OR 2.2 [1.89-2.63]). Surgeons had the most total number of Percutaneous, Cutaneous & Mucous Membrane injuries/contaminations.

6.6 Risk Factors in Prospective Cohort Operating Room Studies

TYPE OF SURGERY: Certain types of surgery have been associated with an increased risk of contamination by blood and body fluids. These are vascular [89] various gynecological procedures [90 91 92 93], cardio-thoracic [94], burn and organ transplant, neurological and orthopedic. [95]

Because hospitals' surgical case mix varies, the interpretation of the data on type of surgery is problematic. In four studies [96 97 98 99] cardiac surgeries were observed, but in two [100 101] they were not. Cardiac surgery was found to be significantly associated with an increased rate of percutaneous injury in only one study. [102]

EMERGENCY VERSUS ELECTIVE SURGERY: Gerberding et al. [103] found that a surgery carried out on an emergency basis was not predictive of a higher risk for intra-operative exposure; Tokars et al. [104] found that an emergency designation was not predictive of percutaneous injury risk in a univariate analysis; Panlilio et al. [105] found an emergency designation to be predictive of risk for all surgeons' contaminations and/or injuries (RR 2.4 [95% CI 1.5-3.8]). Lynch and White [106] found that an emergency designation was predictive of risk, when the outcome was defined as 'any type of contamination or injury' (OR 1.44 [95% CI 1.21-1.66]), but not predictive when contamination of intact skin was removed from the definition, meaning that emergency surgery was not predictive for 'contamination of non-intact skin and percutaneous injury'.

Overall, the emergency designation of a surgery does not appear to be predictive of risk. Emergency designation may be correlated with type of surgery (neurological, orthopedic to name two) or with higher than average blood loss.

DAY VERSUS NIGHT SURGERY: Lynch and White [107] found that surgeries carried out from 23:00-07:00 hours were significantly associated with a higher frequency of injuries and/or contaminations in univariate analysis but not when other factors (surgical service, community vs. university hospital, length of surgery, and emergency status) were accounted for. Tokars et al. [108] found that surgery carried out during the day, not during the evening or night, carried the highest risk (OR 3.1 [95% CI 1.6-5.9].

It is more likely that surgery carried out at night is emergency surgery and emergency status is probably correlated with other risk factors such as type of surgery, blood loss during surgery etc.

LENGTH OF SURGERY: Panlilio et al. [109] found that an operation lasting more than 1 hour was related to the rate of injuries and/or contaminations among surgeons (OR 3.32 [95% CI 1.56-7.09]). Lynch and White [110] found that surgery lasting 2 or more hours was a risk factor for all injuries and contaminations (OR 1.51 [95% CI 1.46-1.56]) as well as when intact skin contamination was removed from the definition of the outcome (1.39 [95% CI 1.31-1.47]). Tokars et al. [111] found that for general surgery, gynecology, orthopedics, and trauma, there was a significantly higher risk of a percutaneous injury during a surgery of 2.7 hours or more compared to a surgery lasting one hour or less (OR 2.3 (95% CI 1.5-3.4). Gerberding et al. [112] found that a surgery of more than 3 hours was independently associated with

higher rates of contaminations and injuries (OR 1.63 [95% CI 1.27-2.11]), but did not find that length of surgery was related to percutaneous injury alone. Popejoy and Fry [113] did not find an association between length of surgery and percutaneous injury, but they did find that every 1.5 hours of surgery increased the risk of contamination by 44% (P<0.01).

An increase in the number of injuries and/or contaminations with increased length of surgery was found in all studies, although the numbers of injuries and/or contaminations for each duration category was not reported except by Popejoy and Fry. [114]

GLOVES AND OTHER BARRIERS: The effectiveness of double gloving was evaluated in two studies. It was found to have reduced perforation of the inner glove and some cutaneous contamination of the hand. [115] [116] Three studies found that circulating nurses and anesthesiology personnel did not wear gloves consistently. [117] [118] [119] Lynch and White [120] reported that anesthesia personnel and circulating nurses still wear short sleeves and experience regular contamination of their arms and that other team members can have their faces and necks splattered and their feet soaked with blood and bloody fluid when it drains off the operating table. Similar experiences were noted in other studies as well. [121] [122] [123]

Gerberding et al. [124] reported that 2% of gloves were found to be perforated prior to the start of surgery.

NUMBER OF PERSONNEL PRESENT: Only Quebbeman et al. [125] assessed the effect of the number of personnel present during surgery and found that every additional person increased the risk of contamination and/or injury by 86% (RR 1.86, [P< 0.01]). This

variable is likely to be correlated with other risk factors such as severity/complexity of an operation, for example.

OCCUPATIONAL GROUPS: Panlilio et al. [126] found that although surgeons and scrub personnel were equally at risk for percutaneous injuries (1.2/100 worker procedures), surgeons had the greatest number of contaminations and/or injuries (18.6/100 procedures). Lynch and White [127] found that 21% of surgeons versus 11% of non-surgeons had percutaneous injuries/non-intact skin/mucous membrane contaminations. In five [128 129 130 131 132] of six studies, surgeons were at higher risk than others working in operating rooms for percutaneous injury. Tokars et al. [133] identified resident surgeons with 4 or more years of training as the highest risk group with 2.6% of their procedures resulting in percutaneous injury. Gerberding et al. [134] also found residents at highest risk.

It appears that surgeons and residents, who are the ones most often using sharp instruments and who are usually closest to blood and body fluid, are at greatest risk of injury and all types of contamination.

TYPE OF HOSPITAL: Lynch and White [135] were the only investigators to consider a difference in risk associated with type of hospital. Of the nine hospitals participating in their study, two were university affiliated and seven were community hospitals. When the outcome excluded intact skin contamination, the risk of sustaining a percutaneous injury/non-intact skin/mucous membrane contamination was twice as high in surgeries performed in university affiliated hospitals [2.2 (95% CI 1.89-2.63)] in comparison with community hospitals.

Again this variable could be correlated with factors such as type and duration of surgery.

KNOWLEDGE OF PATIENT'S INFECTIOUS STATUS: Two studies assessed whether operating room workers' knowledge of patient's HIV or HBV infectious status was related to injury and/or contamination rates and did not find a link. [136] [137] Operating room personnel were found to have assessed correctly the patient's infectious status approximately 70% of the time in one study. [138]

DESCRIPTION OF INJURIES AND CONTAMINATIONS: From 36% to 91% of injuries and contaminations in these studies were caused by suture needles. [139] [140] [141] [142] [143] [144] Tokars et al. [145] report that 63% of injuries were on the lower side of the fingers and 50% were due to blindly locating the suture needle tip with the fingertips of the non-dominant hand. As well, using fingers instead of an instrument to hold tissue while suturing, was associated with percutaneous injury (OR 1.9 [95% CI 1.2-2.9]).

NOISE: Noise is an additional potential risk factor for injury and contamination but it was not considered in the six prospective cohort studies reviewed in detail. Nevertheless noise, as a risk factor, has been considered in other medical studies and will be briefly reviewed here.

In a study of changes in mental efficiency and short-term memory, 20 anesthesia residents were exposed to pre-recorded operating room noise levels of 77.32 dB(A) (the average noise level measured in their hospitals' noisiest operating rooms during a pilot study) for 90 minutes. The residents' scores on tests evaluating short term memory, cognitive function and mental efficiency, carried out

while exposed to the noise, were significantly decreased ($p<0.05$) compared to scores achieved while they were not exposed. [146]

Noise levels in the operating room have also been known to approximate the 90 dBA OSHA standard of maximum permissible noise exposures (over eight hours) permitted in workplaces in 1972.[147]

Another study [148] found a range of intermittent noises from 52 dB(A) to 108 dB(A) during one surgery. The highest measurement in one study of orthopedic surgery was 104.9 dB(A) for plaster saws. [149]

In a group of 150 male and 38 female anesthesiologists, 66% per cent tested had an abnormal audiogram. [150]

Kjellberg [151] has argued that it may be that the dB(D) noise scale gives a better prediction of noise that is annoying than the dB(A) scale, especially for noise containing strong low-frequency components. Yet all the studies on operating room noise found in the literature have used the dB(A) scale to measure noise.

SUMMARY: Investigators have studied various risk factors regarding operating room personnel's likelihood of exposure to blood or bloody body fluids. These include: type of surgery, bloodloss, number of personnel present during the surgery, shift when a surgery was carried out, emergency status, length of surgery, occupational group most affected and type of hospital. Although how exposure to operating room noise affects personnel, was not considered in the six studies reviewed in detail, noise has been evaluated to some extent, albeit not with regards to injuries and contaminations sustained during surgery.

6.7 Hands-free technique in operating room studies

Tokars et al. [152] evaluated hand-to-hand transfer and a number of other surgical techniques (i.e. tying suture knots with needles attached) to assess risk of percutaneous injury.

Of the 1,382 surgeries in Tokar et al.'s study, 957 involved less than 1/3 hand-to-hand transfer by surgeons, and 21 involved less than 1/3 hand-to-hand transfer by nurses. When looking at individuals not surgeries, surgeons were much more likely to transfer sharp instruments using the hands-free technique than nurses.

Neither the nurses' handling of sharp instruments directly most of the time nor the surgeons' handling instruments using the hands-free technique (although this was always referred to as handling sharps indirectly) were significantly associated with a decrease or increase in risk of injury.

Although use of hand-to-hand transfers and the hands-free technique were evaluated in a prospective cohort operating room study, the study did not demonstrate a significant increase or decrease in injuries as a result of use of either technique.

6.8 Under-Reporting

The under-reporting of injuries and contaminations by hospital workers is the subject of numerous studies. A representative sample of the studies on under-reporting reviewed for this thesis, estimates the amount of under-reporting to range from 33% to 96%. [153] [154] [155] [156] [157] [158] [159] [160] [161] [162] [163] Table 6.2 presents these findings.

Under-reporting of incidents that could lead to transmission of blood-borne diseases affects our understanding of the magnitude of the risk to both operating room personnel and patients. Under-reporting also hinders efforts to characterize the risk factors leading to injuries and contaminations. For example, there may be differential under-reporting. Certain events may not be reported because perceived risk is minimal or more of certain kinds of injuries may be reported because perceived risk is greater.

Under-reporting has certainly resulted in a lack of post-exposure care, possibly leading to the transmission of blood-borne diseases, especially HBV.

Studies on under-reporting have almost all been retrospective surveys in which participants have been asked to remember their incidents, in some cases as far back as 'ever in the past', and some response rates have been low. The reasons why individuals have chosen to participate in surveys, as well as the level of accuracy associated with remembering details of events that occurred far in the past, could certainly have affected study conclusions.

SUMMARY: Based upon studies on under-reporting, the injury and contamination rates cited in this study may be underestimates. The "true" rates could be much higher.

Table 6.2 Studies of Under-Reporting

AUTHORS	STUDY	POPULATION	RESPONSE RATE	FINDINGS
1. Rattner et al. 1994	Survey	Nurses and house staff	78%	33% of contaminated percutaneous injuries not reported by nurses; 59% not reported by house staff.
2. O'neill et al. 1992	Survey	Medical students and residents	64%	96% of injuries by residents not reported; 79% not reported by medical students.
3. Donnelly and Evans 1991	Survey	Physicians	82%	Over 95% of hollow-bore needle injuries not reported.
4. Tandenberg et al. 1991	Survey	Emergency physicians, nurses, technicians	74%	64.5% of contaminated percutaneous injuries not reported
5. Mangione et al. 1991	Survey	Internal medicine house staff	72%	70% of the most recent needlestick injuries not reported.
6. Heald and Ranohoff, 1990	Survey	Residents	57%	81% of sharps injuries not reported.
7. McGeer at al, 1990	Survey	Internal medicine and general surgery house officers	100%	95.7% of injuries not reported.
8. Hamory, 1983	Survey	Medical personnel	50.8%	40-75% of injuries not reported.
9. Popejoy and Fry, 1991	Cohort study	Operating room personnel		97% of surgeon's blood exposures not reported.
10. McCormick and Maki, 1981 and 1991	Incident analysis	All staff		In 1981-injury rate was 60.4/1000 HCWs; no operating room injuries reported; only 1/500 staff and house physicians reported an injury. In 1991 injury rate was 187.8/1000 HCWs; 16% of injuries occurred in operating rooms; no surgeons reported injuries.

6.9 Post-exposure treatment

Since 1982, vaccines, which can be administered before or after HBV exposure, have been available, but protection resulting from vaccination is incomplete for two reasons: although effective, 5-10% of health care workers do not develop the protective hepatitis B surface antibody after vaccination; [164] although health care workers have been actively encouraged to accept the vaccine, the rate of vaccination among those at risk has varied. It may be that approximately 50% of practicing surgeons are not immune to hepatitis B. [165] A pilot study conducted between 1991-1992, in a large Montréal hospital found that only approximately 50% of the staff at risk had been vaccinated. [166]

There is no HCV vaccine, and because HCV is so heterogeneous, it is unlikely that a vaccine will be developed. [167] [168]

Although a low efficacy HIV vaccine is near readiness, it has been put on hold in one study. [169] It is thought that due to its low efficacy, it could do more harm than good because individuals who are vaccinated may increase their high risk activities, yet remain unprotected.

Both Hepatitis B immune globulin and the HBV vaccine can be given to prevent the transmission of HBV post-exposure, while zidovudine and other drugs given in combination are offered to prevent the transmission of HIV.

6.10 Consequences of acquiring the diseases

As cited previously the literature reveals 52 documented cases of medical personnel who contracted HIV because of needlestick or other exposures in the U.S. as well as one case in Canada. The estimate for numbers of medical personnel who have contracted and are likely still contracting HBV at work is many times greater. [170] Because of the course of the HBV disease, yearly deaths among U.S. (and Canadian) medical personnel are still occurring that could be attributed to past HBV infection. [171] There has been at least one death of a Canadian operating room nurse due to HCV acquired during surgery. [172]

HEPATITIS B: Under 1% of acute Hepatitis B infections die from fulminant liver failure; between 6-10% of persons who contract the virus as adults develop chronic infection and remain infectious for their lifetimes. [173] Of those who become chronically infected it is estimated that 20% to 30% have a lifetime risk of dying of cirrhosis of the liver and 50% of these may go on to die from hepatocellular carcinoma, [174] although a Montréal study following HBV carriers did not find such an elevated risk of death from cirrhosis and/or hepatocellular carcinoma. [175]

The U.S. CDC estimated that 1,012 health care workers were infected with HBV in 1994, which would result in 22 deaths from acute and chronic HBV infection. [176] Because of the HBV vaccines and better work practices such as universal precautions, this is an improvement from 1989 when the CDC estimated that on a yearly basis 12,000 health care workers contracted HBV occupationally, of which 250 health care workers would die as a consequence. These

deaths would have resulted from fulminant hepatitis with acute liver failure (12-15 cases/year), or from cirrhosis and its sequelae (170-200 cases/year), and hepatocellular carcinoma (40-50 cases/year) as a result of the chronic form of the disease. [177]

HEPATITIS C: Approximately 70% of those with acute HCV infection go on to develop chronic HCV infection and more than 85% have persistent viremia. [178] The number of those with chronic infection who will die or develop liver cancer has not been estimated as yet, [179] although in Japan 60% of cases of hepatocellular carcinoma are infected with HCV. [180]

Prior infection with HCV does not provide protection from subsequent episodes of infection with other forms of HCV because of the heterogeneous nature of HCV and its ability to undergo rapid mutation, permitting it to escape immune detection by the host. This characteristic of HCV is also what will make development of a vaccine unlikely. [181] [182]

HIV: Although HIV infection is less easily transmitted than HBV, it is still considered likely that anyone who becomes HIV positive will eventually develop AIDS and die as a result. Reports at the 1993 International Conference on AIDS in Berlin presented several U.S. cohorts of sero-positive homosexual men that indicate many have remained AIDS-free longer than expected. In one study: 1% developed AIDS within 2 years; 11% after 5 years; 51% after 10 years; 65% after 13 years; while the remainder did not yet have the disease and continued to be followed. [183] Reports that risky behaviour continues in subgroups of those who are sero-positive for HIV, contribute to concern about just how well the epidemic is being

controlled. [184]

OTHER DISEASES: Diseases other than HBV, HCV, HIV have also been transmitted through occupational percutaneous injury. For example, diphtheria, was transmitted from a knife cut occurring during the removal of tissue from the neck of a fatal case and staphylococcus aureus leading to endocarditis resulted from a needlestick injury. [185]

6.11 Risk to patients

The operating room is also a place where patients are vulnerable to infection generally and from operating room personnel specifically. In Canada in 1992 there was a report of two cases of HBV transmission to two orthopedic patients operated on in 1989 and 1990 by a surgeon who was known to have been HBeAg positive as of September 1986. [186]

A review of English-language journals found that 21 HBV infected health care workers transmitted infection to approximately 400 patients. [187] Seventeen of these workers carried out surgery or dentistry. The remaining four gave intra-muscular injections, obtained blood gases, performed venipunctures or operated a cardiac pump. By 1994 the U.S. CDC had found 42 infected health care workers linked to clusters of HBV transmission. [188]

Seroprevalence studies of surgeons have shown that past or present HBV infection has ranged from 10-28%. [189] [190]

Contact with the patient's wound following a worker sustaining a percutaneous injury, was reported in two of the six operating room studies reviewed in detail: in one study there was contact with the patient's wound 32% of the time; [191] contact occurred 11% of the time in the other. [192]

Two reports of hepatitis transmission to patients [193] [194] illustrate the possibility of nosocomial transmission of blood-borne infection by operating room personnel.

AN EXAMPLE OF HBV TRANSMISSION FROM SURGEON TO PATIENTS: There is a report [195] about a surgeon who was HBV negative in 1989 before completing a general residency in surgery.

He was offered the hepatitis B vaccine, but never received it. In July, 1991, he began to carry out surgery in two hospitals. In January, 1992, he became fatigued and was found to be positive for HBsAg and was off work until March of the same year. He returned to work until a patient, without other risk factors for HBV, became acutely ill with HBV four months after having thoracic surgery. The surgeon was found to be HBsAg and HBeAg positive at that time and stopped carrying out surgery.

A retrospective evaluation of all patients the infected surgeon had operated on since contracting HBV was carried out and 19 were found to be infected with HBV. Of these patients, 13 had the same HBsAg subtype as the surgeon.

The surgeon remembered one or two needlesticks during the period under investigation and no injuries from other sharp objects. His co-workers believed that his surgical technique was good. Nevertheless several of his practices went counter to what is recommended: he did not routinely double glove; he applied hemostatic materials to the sternal wound with gloved hands as opposed to using a sponge between his gloved hand and the wound.

All surgical staff involved in this case of transmission, including the surgeon, reported that it was routine at the end of surgery to find blood on one's hands whether or not visible glove tears were present in the gloves and regardless of the type of glove used.

The surgeon complained about pain over the index fingers when prolonged suture tying was required. The surgeon was asked to participate in a one-hour simulation suture tying exercise, and after that hour it was noted that he had acquired paper-cut-like lesions on

his gloved fingers; washings of his hands, after the simulation, contained HBsAg and HBV DNA particles.

AN EXAMPLE OF HCV TRANSMISSION FROM SURGEON TO PATIENTS: There is a reported transmission of HCV from a chronically infected cardiac surgeon to five of his patients over a period of six years. [196]

Because the Barcelona Post-Transfusion Hepatitis Study followed cardiac patients to see if they developed HCV as a result of transfusion post-operatively, it was discovered that two patients who developed HCV had been operated on by a cardiac surgeon known to have chronic HCV infection. As a result, some former patients of this surgeon were identified. Of the 222 patients who were part of the Barcelona Post-Transfusion Hepatitis Study population, 19 patients had developed HCV. Of these, 13 had received blood from a donor with HCV, leaving six who had HCV unrelated to transfusion. Five of the 6 shared the same HCV genotype as the surgeon.

It appears that the surgeon acquired HCV after a 1984 percutaneous injury with a scalpel while operating on a patient found to have chronic HBV. Because the surgeon was found to be negative for HBV at the time of the injury he received appropriate post-exposure prophylaxis. Six months later, although HBV negative, his serum alanine aminotransferase level was high and in 1991 he was found positive for HCV antibodies. From 1991 until 1994, he continued to perform surgery.

This surgeon recalled percutaneous injuries that occurred most often during the tying of sternal wires at the end of the surgery. Usually he did not notice the injury until after the procedure was

completed. The surgeon and his co-workers reported changing gloves and contaminated equipment if injuries were noticed. Two fellow surgeons also reported frequent percutaneous injuries while closing the sternum with wires.

HIV TRANSMISSION TO PATIENTS: HIV transmission between caregiver and patients is reported in two cases. A Florida dentist transmitted HIV to five patients who all had HIV strains closely related to each other and to the strain infecting the dentist. [197] [198] How transmission between this health care worker and patients occurred, is still unknown.

A French orthopedic surgeon, who is believed to have become HIV infected in 1983 when he carried out a femoral prothesis operation, was diagnosed with AIDS in 1993. In 1995, the French ministry of health informed his former patients and offerrd testing for HIV. Of 3,000 former patients, 986 had blood tests and one was found to be HIV positive. She had been tested and found to be HIV seronegative shortly before the two surgeries carried out by the surgeon with AIDS. During the second operation, which he reported as having been lengthy and difficult, the surgeon pierced his gloves and injured his hands. [199]

SUMMARY: When accidents happen in operating rooms, not only workers, but patients as well, are at risk of blood-borne disease.

6.12 Glove tears

Until recently, gloves have been worn primarily to maintain sterility of the surgical wound. Glove use for protection of operating room workers is often an extension of that practice. For the protection of personnel, gloves are worn while touching blood and body fluids; while touching mucous membranes and non-intact skin; while handling contaminated instruments; while performing venipuncture or other vascular and arterial access procedures. [200] As well, as the length of a surgical procedure increases, with the aid of heat and humidity, the natural skin flora of the hands re-establishes itself and as a result a perforated glove is a source of contamination to the patient and must be replaced immediately. [201] Unfortunately, faulty surgical gloves have been all too common, [202 203 204 205 206] although it is believed that the quality of gloves is improving. In one of the operating room studies detailed previously, 2% of gloves were not intact at the start of surgery. [207] The problem of perforated gloves has also been recognized because of latex allergy reactions in patients during surgery. [208]

One study [209] found a glove tear rate of 10.9% during 2,292 surgical procedures over a three month period at a tertiary care teaching hospital. The mechanism causing the glove tear could not be indentified in 67% of the tears. "Known mechanism" was defined as the tear being witnessed. "Unknown mechanism" was defined as the tear being noticed incidentally during or at the end of the surgery. The presence of blood on the hand was reported in 63% of the glove tears. The presence of blood on the hand was more common (76%) after glove tears where the mechanism causing it was unknown.

When the mechanism causing the tear was known the presence of blood on the hand was noted 35% of the time.

As indicated before, there have been examples of transmission of HBV and HCV to patients without a clear indication that it was related to either an injury or an obvious contamination. The most likely route of transmission was through a glove tear and the perforated skin of the surgeon's hand. Glove tears are also thought to be routes by which cutaneous exposures to surgeons and other health care workers occur.

6.13 Strategies to reduce risk during surgery

UNIVERSAL PRECAUTIONS: The most widely used strategy to reduce risk in the hospital operating room is called the system of universal precautions. This is a hospital-wide system that recommends that all patients' body fluids, especially those that are blood tinged, be treated as potentially infectious. While there are no precautions specific to surgical procedures in the system of universal precautions, its introduction has meant an increased used of protective barriers in operating rooms.

INDUSTRIAL HYGIENE MODEL: It has been argued [210] that just using universal precautions is an insufficient strategy for the operating rooms and that instead, an industrial hygiene model would be more useful. In fact, this approach is the basis for the U.S. Occupational Safety and Health Administration (OSHA) Blood-borne Pathogen Standard. The model emphasizes a hierarchy of controls that should be applied in the operating rooms. The first level of control is the use of engineering controls that modify the environment in which work is performed rather than attempting to change human behaviour. In the case of an operating room this could mean bloodless surgery (using ultrasound to reduce kidney stones, for example), as well as redesigned devices and equipment such as scalpel blades, saws, and other sharps. The second level in the hierarchy is controls on work practice, that is, changing the way in which the work is performed. This involves standardized procedures and techniques that are designed to reduce risk of exposure. The hands-free technique is an example of such a work practice control, as are universal precautions and tying suture knots with

instruments. The third level of control in the hierarchy is personal protective equipment and other forms of personal protection. This third level is meant to supplement the first two, so that if the first two controls cannot eliminate the problem, the third can mitigate its effects. In the operating room, gloves, gowns, masks and protective eye wear, as well as the hepatitis B vaccine and post-exposure prophylaxis to HBV or HIV are examples of this mitigating, third level of control.

SUMMARY: Reducing or eliminating operating room blood and body fluid exposures can be addressed by using three levels of control.

6.14 The hands-free technique

The definition of the hands-free technique as provided by the American Association of Operating Room Nurses is "Instrument transfer between the scrubbed person and the surgeon that ensures that the surgeon and the scrubbed person never touch the same sharp instrument at the same time. Instruments can be placed in a neutral zone between the scrub person and the surgeon." [211]

LITERATURE REVIEW: A review of the literature consisted of a computerized search using MEDLINE, [212] for the last 15 years (1982-1997) using the following key words for the exposure of primary interest, as well as words used to describe events occurring during surgery that could lead to contracting an occupational infection: hands-free technique, no-touch technique, occupational diseases, operating room, surgery, percutaneous injury, contaminations, blood-borne diseases, Hepatitis B, Hepatitis C, HIV and Human Immunodeficiency Virus. The list of references from articles themselves and relevant journals (Advances in Exposure Prevention, Hospital Infection Control, Infection Control and Hospital Epidemiology, Journal of Hospital Infection, CCDR, MMWR etc.) were systematically reviewed for pertinent articles. As well, attendance at a Centres For Disease Control and American Medical Association conference in Atlanta in 1994 on Prevention of Transmission of Blood-borne Pathogens During Surgery and Obstetrics enabled the researcher to review all relevant literature.

STUDIES ON USE OF THE HANDS-FREE TECHNIQUE: Only one operating room study evaluated use of the hands-free technique and other work practices used in surgery and their association with

percutaneous injury.[213]

In addition, a survey was carried out in Toronto [214] to determine surgeons' compliance with practices promoted as safe, such as the hands-free technique. For this, all surgical staff and some surgical residents affiliated with the University of Toronto were asked about the types of work practices they used (such as use of the "no-touch technique") to prevent transmission of blood-borne diseases. The study's response rate was 93.3% (503/539) with an almost equal response from residents as surgeons. Only 3.8% of surgeons reported that they passed sharps back in kidney basins and/or 3.2% said they used the "no-touch" technique.

6.15 Summary

The literature reveals a significant risk of contracting blood-borne diseases in the operating room. Several risk factors and means of diminishing risk, have been identified. Some risk factors have not been adequately studied. A work practice control, the hands-free technique, has been suggested as a means to reduce the risk of blood-borne disease transmission. To date, no study has adequately assessed its use or its effectiveness.

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7. STUDY RATIONALE AND OBJECTIVES

Making recommendations regarding safe procedures requires that one think like a choreographer -- what effect will changes in movement and use of equipment have on the final production? [1] The surgery as a whole must be divided into distinct parts that can be altered with its effect on safety in mind.

Recommendations for risk reduction strategies primarily come from organizations like the Association of Operating Room Nurses (AORN), the Academy of Orthopedic Surgeons (AAOS), the Royal College of Surgeons of England, the U.S. Centers for Disease Control, and OSHA. OSHA has enacted a standard, Part 1910.1030 of Title 29 of the Code of Federal Regulations, effective March 6, 1992, titled "Occupational Exposure to Blood-borne Pathogens". These organizations advocate changes in equipment, technique and practices, such as: use of the hands-free technique for passing sharps; verbal warnings when sharps must be passed directly; double and triple gloving; complete barrier protection; redesign of instruments; tying suture knots without the needle in hand; identifying exposure-prone procedures, avoiding haste while carrying out procedures and many others.

To effectively evaluate injury reduction strategies of this type, one must assess their use and then compare accident levels when used and not used.

7.1 Gaps in knowledge

The studies to determine the use and effectiveness of the hands-free technique have not been done. In fact, there are gaps in knowledge in most areas of accident prevention in the operating room. The literature review reveals no study where the primary hypothesis or target was an operating room work practice. This may in part be because of the difficulties presented in studying injury control methods.

One injury epidemiologist [2] has suggested succinct criteria for judging injury control measures. "Measures designed to prevent injuries depend for their effectiveness on three things: they must work when properly used, that is, they must be efficacious; second, they must be used; and third they must be used properly." To reframe this advice, a study assessing control measures should determine frequency of use, frequency of appropriate use and measure the risk of injury and/or contamination associated with absence of its use.

The hands-free technique was selected as a topic for study to fill in a gap in our knowledge of the effectiveness of a recommended work practice. It is an essential part of safety recommendations made for some time by professional organizations and is officially part of many hospitals' operating room policies, including The Providence Medical Center in Seattle, where the study was carried out. Although the hands-free technique was being used at The Providence Medical Centers, operating room personnel reported it was not being used all of the time. The extent and appropriateness of its use, in fact, had not been evaluated. Studying the hands-free-

technique allowed findings to build on one previous study. [3]

INJURIES, CONTAMINATONS AND GLOVE TEARS: In order to evaluate the hands-free technique, outcomes had to be chosen that could be used to compare surgeries in which the hands-free technique was used, and not used. Again, since the hands-free technique has not been previously looked at, there is a gap in the knowledge of what outcomes are best studied to determine its effectiveness.

Based upon the six operating room studies discussed extensively above, injuries and contaminations were two obvious outcomes to be looked at. A third outcome, glove tears, was also chosen, as a near miss injury. One previous study [4] did look at injuries, glove tears and gown leaks. Glove tears, as noted in the literature review, have been cited as possible routes for transmission of blood-borne pathogens.

One could argue that only injuries, glove tears and contaminations directly related to the handling and passing of sharp instruments would be of interest in a study of the use of the hands-free technique. This would be the proper methodology if the sole interest was in handling and passing sharp instruments. That is, if one wished to only study whether or not it was safer to pass instruments directly or indirectly. The previous study which did consider the hands-free technique amongst other risk factors only assessed injuries and only injuries when sharps were passed.

This study presumes to look at more by making the assumption that the hands-free technique goes beyond simply passing sharps indirectly. It is, in fact, part of a system of regularizing operating room work practices. It is a way of establishing a common routine

among a diverse group of skilled workers who may or may not regularly work together. Thus, to judge whether use of the hands-free technique makes the surgical operating room work environment safer, one must look at overall safety of handling sharp instruments.

Injuries, glove tears and contaminations are best seen as parts of an accident continuum, with all being indicators of the overall safety level of handling sharp instruments in the operating room work environment. All are certainly means by which blood-borne diseases can be transmitted. Thus, to look at changes in the rate of injuries, glove tears and contaminations is to look at changes in levels of safety. Other researchers have incorporated the same thinking. [5,6]

A study in a Finnish shipyard demonstrated that improved housekeeping reduced all sorts of accidents, not just those caused by deficiencies in housekeeping. [7] The researchers suggest that improved housekeeping could allow room for individuals to process information about other hazards in the environment. That is, if workers do not need to worry about housekeeping hazards they can focus on other safety concerns.

In a similar fashion, the mechanism by which the hands-free technique improves the overall safety of handling sharp instruments could be that it allows surgical personnel to focus more on hazards other than the passing of sharp instruments.

Therefore the events listed above were considered most appropriate to include in the main analysis and interpreted in the final results. Nevertheless, the results of a secondary analysis using only injuries/contaminations directly due to handling and passing and all glove tears was also included.

7.2 Primary and secondary objectives

The main objective of this study was to assess the risk of injuries, contaminations and glove tears during surgical operations when the hands-free technique was and was not used.

In particular, the study compared the reported number of percutaneous injuries, contaminations and glove tears during surgeries when approximately 75% or more of sharp instrument passes were carried out using the hands-free technique, to surgeries where approximately 50% or less of sharp instrument passes were carried out using the hands-free technique.

As a secondary objective, the study assessed the risk of injuries, contaminations and glove tears with the following potential risk factors: noise during surgery, time of day when the surgery occurred and number of people present for at least 75% of the surgery.

Additional variables, previously found to be risk factors, were also measured: bloodloss, type of surgery, length of surgery and emergency/non-emergency status.

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8. SUBJECTS AND METHODS

8.1 The hospital and its operating rooms

The Providence Medical Center is a 300-bed private teaching hospital near the commercial centre of Seattle, Washington, opened in 1906 and owned by the Sisters of Providence. The hospital primarily serves the neighborhood's lower income population.

Eleven rooms in the main operating rooms were opened in 1964 and four rooms dedicated to open heart surgery were added in 1978. As well there are four same-day surgery operating rooms that opened in 1992.

All types of surgery are carried out in the main operating rooms and the same-day surgery operating rooms. Patients in the main operating rooms usually undergo more complex surgery and are frequently admitted overnight or are in-patients, while patients in the same-day surgery are rarely admitted overnight and are out-patients. Surgical cases may be moved from same-day surgery to the main operating rooms depending on the patient's status.

Same-day surgery operating rooms are open weekdays, from approximately 0800 to 1600 hours, while the main operating rooms have staff on-call 24 hours per day, seven days a week. Scheduled surgery in the main operating rooms usually ends in the late evening, but emergency surgery is carried out whenever necessary.

8.2 Operating room personnel

Salaried operating room personnel are assigned to either the main operating rooms or the same-day surgery operating rooms, but many nurses and technicians work in both areas, depending on need. Personnel in the main operating rooms are usually trained to work in multiple areas, such as cardiac surgery, orthopedic or general surgery. Staff from both the same-day surgery unit and the main operating rooms receive weekly in-service training together and both areas have the same nursing director. Surgeons, residents and anesthetists work in both units.

Approximately 40% of surgeons who perform surgery at the Providence Medical Centers work primarily at that institution, while 60% do not work there regularly. Open-heart surgeons and orthopedic surgeons frequently employ their own assistants: doctors, physician assistants, registered nurses or registered nurse assistants.

8.3 Study Design

This prospective cohort study consisted of data collected on consecutive surgeries in the Providence Medical Centers' main and same-day surgery operating rooms from October 30th, 1995, to April 15th, 1996.

Each surgical operation was the unit of observation and analysis. Therefore, a range of sample sizes were calculated after specifying a value of 5% for the type 1 (alpha) error and a value of 20% for the type 2 (beta), to detect a 50% risk reduction. The rate of injuries, contaminations and glove tears for which sample sizes were calculated were: 4%, 5% and 6%; and non-use (exposed) of the hands-free technique was estimated at 50% and 80%. [1]

Table 8.1
Sample Size Required

		Percentage of surgeries when there was non-use of the hands-free technique	
		50%	80%
Proportion of surgeries with events	6%	749	1996
	5%	906	2416
	4%	1,141	3,048

All operations with a full-time circulating nurse were eligible for inclusion (a circulating nurse is not present in some minor surgeries). Excluded were cystoscopies in the main operating room's cystoscopy room because the sharp part of the instrument used for biopsy remained covered until the scope was inside the patient's bladder, so there was no exposure to sharp instruments.

All physicians, nurses, technicians, physicians' assistants, residents and students who provided direct surgical care to the

patient and who could sustain an injury, a contamination, or a glove tear during the surgeries were included in this study. The only operating room personnel who were not included were anesthetists or others providing anesthesia care, orderlies, and other assistants who were not handling sharp instruments used during surgery.

8.4 Hospital participation

Although the study had been reviewed by the McGill University Faculty of Medicine's scientific review committee, which included an ethicist, and the Royal Victoria ethics committee, the Providence Medical Centers' Institutional Review Committee reviewed it for both legal and ethical purposes and authorized the study. A copy of the letter of assent is in Appendix 2.

8.5 Data Collection

A questionnaire (Appendix 3) was developed for this study based on one by Dr. Janine Jagger. [2] Jagger's original questionnaire had been used to collect data on hospital-wide injuries and contaminations.

The questionnaire was divided into four sections on two sides of a single 8 1/2 X 11 inch sheet of paper.

Section A consisted of questions on when surgery began and ended, whether the patient was an in-patient or out-patient, whether the case was an emergency or a non-emergency, the type of surgery, total blood loss during surgery, number of personnel present at least 75% of the time and an assessment by the circulating nurse of noise levels. In addition, the circulating nurse (who consulted with scrub personnel at the end of each surgery) was asked to assess the proportion of passes of sharps in which the hands-free technique (procedures to ensure that surgeons and nurses/technicians never touched the same sharp instrument at the same time) was used. Circulating nurses recorded the proportion in one of the following categories: none of the time, approximately 25%, 50%, 75% or 100% of the time. This section was filled out by the circulating nurse at the end of each surgical operation.

Section B was used to elicit information on any event: whether information about the event was obtained from the affected person or from a co-worker; whether an injury, contamination or glove tear occurred; who was responsible for the event (not to lay blame but rather to help establish causality of the event); the job category of the person who experienced the event; and the type of protective

apparel worn by the affected person at the time of the event. It was completed by the circulating nurse for every surgery in which an event (defined as an injury, blood or body fluid contamination or glove tear) took place.

Section C was filled out if a percutaneous injury occurred. Questions included whether the injury was self-inflicted; if the injured worker was right-handed or left-handed; if the sharp causing the injury was contaminated with blood or body fluid and how deeply the sharp penetrated the skin; the purpose for which the sharp was used and the point during surgery when the injury occurred (before use of the sharp, during use of the sharp, during disposal of the sharp etc.).

Section D was completed if a skin or mucous membrane or other blood or body fluid contamination occurred. Questions about the type of body fluid in contact with intact or non-intact skin, how much of it and for how long contact with body fluid lasted, and details about how and why the contamination occurred, were asked.

The questionnaire was designed so that it could be completed quickly. When Section A alone was filled out it took approximately 15 seconds; when Section B was also filled out it took approximately 10 more seconds, if Section B with either Section C or D were filled out, it usually took approximately 60 seconds in total.

8.6 Pre-testing the questionnaire, accuracy of secondary data and reliability of the hands-free data

The questionnaire was first tested by 25 operating room nurses at the Royal Victoria Hospital, in Montréal, over three to four weeks and then two weeks prior to the start of the study, by operating room nurses at The Providence Medical Center.

Questionnaire training was given to everyone who was involved with the study, with special emphasis on scrub and circulating personnel, who were being asked to complete the questionnaires.

Quality control during the study was carried out on an ongoing basis by the researcher checking the accuracy of responses on the questionnaire compared to the OR sheets where much of the information was also recorded. The accuracy of responses to questions like time of day when the surgery occurred, length of surgery and patient status was well over 95%. This indicated that circulating nurses were accurate when abstracting data from OR documents.

A reliability study comparing the level of hands-free use recorded by circulating nurses and scrub personnel in conjunction to that of the researcher, was also performed (see below).

8.7 Measures taken to ensure a high response rate

To ensure that surgeons, residents and medical students reported all injuries, contaminations and glove tears, a memo was prepared, in collaboration with the surgeon in charge of medical education in the operating room, which was sent to all surgeons who carried out surgery in The Providence Medical Center operating rooms. This memo explained what was expected of them with regards to reporting percutaneous injuries, contaminations and/or glove tears to the circulating nurses, approximately how long the study would last, and that the investigator would be available in the operating rooms for three to four days each week throughout the study, if they wished additional information. All medical students and residents were also told by the surgeon in charge of medical education about the study's objectives and the nature of their roles in the study.

Although the operating room nurse clinician(s) at The Providence Medical Centers had been collaborating in the study for several months prior to the start, scrub and circulating personnel were only approached two weeks prior to commencement of the study to determine if they were willing to participate and to review the questionnaire prior to printing.

For each surgery, a packet with all necessary forms was usually prepared in advance and the study questionnaire became one of the components of this packet. Therefore questionnaires were brought into the operating room for each surgery with the rest of the regular paperwork that needed completing. In case the questionnaire had not been added to the packet (in the very early stage of the study

this occasionally happened), or in case more than one questionnaire was required during a surgery because several events took place during that surgery, additional questionnaires were placed in a Plexiglass wall holder present in every operating room.

To ensure a high level of compliance, incentives for the technicians and nurses were introduced at the outset. After each surgery in which a questionnaire was completed, all scrubbed technicians and nurses and the circulating nurse(s) who collaborated in the filling of the form, were asked to place their names in envelopes to make them eligible for a weekly draw and for a final draw that took place at the end of the study. The weekly prizes consisted of items such as bottles of wine and movie tickets while the final draw consisted of a paid weekend in Vancouver. As well, baked goods and candy were provided weekly to operating room personnel to thank them for their participation.

Regular messages about the progress of the study and reminders about documenting events such as glove tears were included in the operating rooms' weekly newsletter (Appendix 4).

Finally, the investigator spent 3-4 days each week reviewing questionnaires for completeness, coding questionnaires and observing surgery. It was very important to try to understand 'the operating room culture' because it is unique within the hospital and the candidate learned to be creative in her approach to ensuring a high response rate over the six months as a result of these regular weekly observations. For example, when a request was made by operating room staff for information on other issues pertinent to health and safety in the operating room (anesthetic gas exposure as

an example) it was obtained. As well, the most popular baked goods and candies were repeated.

8.8 Data collection problems

It became apparent about 5 weeks into the study, when on approximately 50% of the reports information on blood loss was missing and after several discussions during the weekly in-service sessions, that circulating nurses were often too busy at the end of a case to make the extra effort of asking the anesthetist for an estimate of blood loss during the procedure. Consulting anesthesia records to find the missing blood loss data did not work because those records were also frequently incomplete. Therefore, after consulting with the operating room nurse clinician, a list of all procedures being carried out was compiled and the average blood loss was estimated for each procedure. This estimate was used when the 'total blood loss' question had not been answered. The researcher observed during the remainder of the study that these estimates corresponded closely to completed answers for similar surgeries.

8.9 Revised data instrument

The questionnaire was modified approximately 6 weeks after the study was initiated in order to clarify two questions and to relocate a diagram to make it more accessible, so that staff would fill it out for all events, including glove tears. The modifications were as follows:

Question 5 in Section A originally asked, "Were procedures followed to ensure that surgeons and nurses/technicians never touched the same sharp instrument at the same time? yes/no." This wording was changed to "Was the hands-free technique used? (procedures to ensure surgeons and nurses/technicians never touched the same sharp instrument at the same time) yes/no.".

Question 2, Section B, originally asked: "Incident type, injury, contamination, both"; this was changed to "Incident type, injury, contamination, glove tear"

In the first questionnaire the hand diagram was placed in the centre on the back page. In the modified questionnaire, the diagram was placed at the very top of the back page. (Appendix 3)

8.10 Definition of the main exposure variable, the hands-free technique

AS A BINARY VARIABLE A dichotomized hands-free variable (exposed vs. non-exposed) was developed. After the first weeks of observing surgeries, it became clear that there were significant problems with the definition of the hands-free technique provided by the AORN: "Instrument transfer between the scrubbed person and the surgeon that ensures that the surgeon and the scrubbed person never touch the same sharp instrument at the same time. Instruments can be placed in a neutral zone between the scrub person and the surgeon." [3]

The intent of this definition is clearly that there be no direct passes of sharp instruments. In the real world of the operating room, there were many passes with many variations of practice. Sometimes the nursing staff passed sharp instruments into a neutral zone but the surgeon didn't. Sometimes only one of three surgeons present in a complex operation passed sharp instruments into a neutral zone but the other two passed directly. Given the definition, could the hands-free technique be said to have been used in these situations? Could there be partial use of the hands-free technique or is using the hands-free technique an either/or definition?

The circulating nurse, in consultation with scrub personnel, was asked to judge what proportion of passes in a particular surgery were performed so that no more than one person touched a sharp instrument at the same time. To answer the question, the questionnaire provided five choices: approximately 100% of the time, 75% of the time, 50% of the time, 25% of the time or 0% (none) of the

time.

It was obvious that when the proportion of passes judged to be hands-free was approximately 100%, then the hands-free technique could confidently be said to have been used. But what about when the proportion of passes judged hands-free was approximately 75% or 50% or 25%?

Ongoing observation of surgeries by the candidate revealed that when approximately 75% of passes were judged to be hands-free, this usually meant that most persons passing sharps passed them to a neutral zone most of the time.

When approximately 50% of the passes were judged to be hands-free, one of two situations was usually occurring. In most situations surgeons received instruments directly into their hand from a nurse or technician, but then dropped or lay down or even threw the sharps into a neutral zone when finished with them. Thus 50% of the passes between the nurse, OR technician and surgeon were judged hands-free. In the other situation, about half of the personnel working during a surgery would always pass instruments using a neutral zone, while half did not.

When approximately 25% of the passes were judged to be hands-free, typically some passes were done via a neutral zone, but not consistently or one of four or five personnel always used a neutral zone to pick-up the sharp and always returned it by laying it down in a neutral zone.

Based upon these observations, it was decided for the purposes of the study, to define use of the hands-free technique in a binary manner, as those surgeries when the proportion of passes was judged

to be approximately 75% or greater. This seemed to correspond most with the intent of the definition provided above, which is that no two people handle a sharp instrument at the same time. What seemed evident from observation was that only in those surgeries where percentage of passes was judged to be 75% or greater were all personnel making a consistent effort to use the hands-free technique.

For these reasons, the binary variable was selected as most appropriate for interpretation in this study.

AS A CATEGORICAL VARIABLE: Hands-free use was also categorized as a five-point categorical variable.

Recognising that it is difficult to precisely quantify complex behaviour carried out by several operators; and, also knowing that risk would not necessarily decrease with the recorded levels of use of the hands-free technique, it was nevertheless hypothesized that a monotonic decrease in the frequency of events, with each category of increasing use of the hands-free technique, might be observed.

8.11 Construction of confounder and other risk factor variables for use in the analyses

The strategy used to carry out data analysis was the following: All risk factor variables were defined as categorical. Once data collection was complete, and the number of surgeries under each variable was determined, then cut-off points were decided upon. The decision to collapse categories was made in order to equalize the size of the groups used in the analysis.

- Surgical types, were collapsed from nine categories to four (orthopedic surgeries, 'other' surgeries, general surgeries, cardio-thoracic and cerebro-vascular (CVT) surgeries) leaving three specific categories and combining all other surgeries under the 'other' category. These four categories were used in all further analyses.
- Length of surgery, was divided into three categories: 1 hour or less, 1-2 hours and greater than 2 hours.
- Noise, which was originally categorized into three levels, was dichotomized. Quiet surgery became one category and normal and loud surgeries were collapsed into the other.
- Shift, was dichotomized with day shift becoming one category and evening and night shift merged to form the other.
- Number of personnel present at least 75% of the time was divided into 1-5 personnel in one category and more than 5 personnel in the other.
- Bloodloss was divided into categories of 100ccs or less and greater than 100ccs.
- Emergency and non-emergency were kept the same.

8.12 Definition of the event variable

Events in this study were injuries, contaminations and glove tears.

DEFINITION OF OUTCOMES: For surgeries resulting in one or more injury, contamination or/and glove tear, there was the opportunity to collect additional information, dependent upon the event. Information that could only be collected because an event was identified and for which the questionnaire contained specialized questions.

To decide which events were prevented by use of the hands-free technique some would argue that all events would be affected because use of the hands-free technique could be viewed as a part of a system of regularizing operating room work practices (i.e. having a common routine among diverse groups of skilled workers). Others would argue that only those injuries, contaminations and glove tears directly related to handling and passing sharp instruments would be appropriately included as events that could be prevented.

This study looks at both. Two definitions of events were included, each corresponding to one of the arguments above. However, more weight is given to the analysis using all events.

Work practices in an operating room vary because of the nature of the work and because the mix of personnel frequently changes. The mix of dangerous instruments and materials, irregular procedures and a changing mix of personnel increases the likelihood of accidents. Introducing a standard work practice such as the hands-free technique is not just an attempt to increase the safety of passing and handling sharp instruments, but is also a means of regularizing

procedures to improve overall safety. When one dangerous activity is made safer, people can pay more attention to other dangers.

As well, this theory corresponded to experience in the data collection phase of the study. Glove tears, injuries and contaminations seemed to occur together. That is, when there was more or less of one there was correspondingly more or less of the others. When the hands-free technique was used, there were 0.8% injuries, 1.4% tears and 1.8% contaminations reported. When the hands-free technique was not used, there 4% injuries, 4.9% tears and 4.5% contaminations reported (This corresponds to results found in Table 9.4).

However, to assess the more direct effect of the use of the hands-free technique on passing and handling sharp instruments a restricted category of events (a subset of all events) was also constructed. All glove tears were included in this restricted category because most often operating room personnel do not report when a glove tear occurs, [+] but rather when it is noticed. Often tears are so small that they do not get noticed until a surgery is over. Also included in the restricted events category were injuries and contaminations directly related to handling or passing sharp instruments.

So, to conclude, two definitions of events were elaborated, but the broader definition of events was selected as most appropriate.

8.13 Statistical analysis

TECHNIQUES: Simple univariate descriptions such as means and proportions of the hands-free technique variable and other determinants were carried out first. Descriptive statistics of the outcomes were also calculated.

The crude association between hands-free use and the outcomes was also calculated. This was done with hands-free use as a binary variable and the association displayed in a 2x2 table with the associated crude rate, then as a categorical variable, which was displayed in 2x5 table with the associated crude rates.

The distorting effects of potential confounding variables were first assessed one by one by constructing a table showing the association between use of the hands-free technique and the outcomes for each level of each potential confounder. Mantel-Haenszel summary ORs were calculated for 1 variable at a time, with hands-free use as a binary variable and as a 5-point categorical variable. This step allows readers to see the 'raw data' and the potential for, and directions, of possible distortions.

Logistic regression was carried out to adjust for confounders simultaneously and to check for effect modification, using SPSS 6.1 (SPSS Inc. 444 N. Michigan Ave., Chicago, Illinois 60611). Odds Ratios (OR) were estimated, and confidence intervals (CI) were calculated. The hands-free variable for logistic regression was defined as a binary variable.

A full model with the exposure of primary interest, use of the hands-free technique, all measured risk factors -- whether previously recognized confounders a priori or potential confounders

in this study data, was first constructed. Then, a full model plus all effect modification terms, was considered. Based on the literature review- bloodloss, length of surgery and types of surgery were considered previously recognized confounders.

Effect modification terms were created with previously recognized confounders and the exposure variable. Potential effect modication between the main exposure variable, use of the hands-free technique and events by blood loss, could exist. For example, use of the hands-free technique may result in risk reduction when larger amounts of blood are lost; Potential effect modification between use of the hands-free technique and events by certain types of surgery may occur. Some operations require large, heavy, sharp tools such as saws and drills, while others use very small delicate sharps. As well, some surgeries result in sharps being placed deeper into body cavities, while in others, sharps are used near the skin surface. There is the potential therefore, for the hands-free technique to have a different effect in one type of surgery compared to another; this may also be the case for increased length of surgery. In later hours of surgery the hands-free technique may be more protective than during the first hour of surgery.

To check for interaction, the likelihood ratio [5] was used; the effect modification term was only retained if the maximum likelihood chi-square statistic was below 10% (statistically signifcant at $p<0.10$).

After effect modification (hands-free variable *bloodloss) was found, the two other previously recognized confounders were kept in the model, as were the other four potential confounders, to create the

best unconfounded model.

8.14 Reliability of measured data on use and non-use of the hands-free technique

Each of 68 surgeries of almost every type of surgery was rated independently by the investigator as to the proportion of hands-free passes used in order to test the reliability of the observations made by the circulating nurses. The sample was chosen to include some of every type of surgery over 8 weeks (October 30, 1995-January 30, 1996), although most surgeries were observed in December and January.

The crude agreement was calculated as 68% (46/68) when using the full 5 categories. The Kappa index for inter-rater reliability using the hands-free technique as a variable with 5 categories was calculated and found to be 0.54 (95% CI 0.16-0.70) (Table 8.2) when a variety of circulating nurses and the researcher's assessments were classified into level of hands-free technique used (judging the proportion of passes to equal 0% to 100% in 5 categories). This level of concordance is considered 'moderate'. [6]

Table 8.2
Kappa Test for Inter-rater reliability using the variable with 5 categories
Circulating nurses

Researcher	0%	25%	50%	75%	100%
0%	1	0	0	0	0
25%	3	9	7	0	0
50%	0	1	23	6	2
75%	0	0	0	8	2
100%	0	0	0	1	5
Total	4	10	30	15	9

Kappa 0.54 (95% CI 0.16-0.70) Based on SE=.078

Inter-rater agreement is greater when hands-free use was defined as a binary variable.

Table 8.3
Kappa Test for Inter-rater reliability using binary variable
Circulating nurses

Researcher	No HF	Yes HF	Total
No HF	44	8	52
HF	0	16	16
Total	44	23	68

Kappa 0.72 (95% CI 0.54-0.90) Based on SE=.09

Greater concordance would be expected to be seen when the variable is binary (Table 8.3) compared to when it is divided into 5 categories.

Looking at Table 8.2, it can be seen that only twice was the proportion that the circulating nurse estimated, compared to that of the researcher, different by two categories. In all other comparisons the difference was approximately 25% (one category). The circulating nurses over-estimated the amount relative to the researcher 17

times and underestimated the amount relative to the researcher once.

It should be noted that while the researcher recorded proportion of use of the hands-free technique based on her observations from different locations around the operating room table, the circulating nurses based the proportion after consulting scrub personnel who were much closer to the surgical site.

8.15 Ethics

Anonymity of staff and patients was ensured. Although it was determined that individual consents did not have to be signed by operating room personnel, individuals could choose whether or not to actively participate in the study by providing information when an event occurred. If the person(s) involved did not provide the details of an event, other personnel, particularly the circulating nurses did ask others about the event. In most cases when personnel involved in an event did not provide the details of the event, it was because they were occupied but not unwilling to describe the event. No names of personnel present were recorded on the questionnaires, although the operating room number was listed. Completed questionnaires were always kept under lock and key while at the hospital.

During the study a few staff were not willing to actively participate in filling out questionnaires (if circulating) or assessing the use of the hands-free technique (if scrubbed). Besides attempting to determine why this was occurring, the researcher did not insist on their participation.

Each time an event occurred the researcher determined whether or not the hospital's incident report form had been completed. As a result of a discrepancy between the number of events recorded for the study and the number of forms sent to the employee health department, the researcher emphasized the need for post-exposure assessment and prophylaxis, during weekly (Tuesday morning) in-service sessions. No additional effort was made to encourage reporting and follow-up.

[1] Dupont WD, Olummer WD Jr. Power and sample size calculations; a review and computer program. Controlled Clinical Trials 1990; 11: 116-128.

[2] Jagger J. (Data Collection Form) Uniform blood and body fluid exposure report: Operating room personnel. October 1993.

[3] AORN Journal. Recommended practices: Universal precautions in the perioperative practice setting. 1993; 57: 554-558

[4] Wright JG. Mechanisms of glove tears and sharp injuries among surgical personnel. JAMA 1991; 266: 1668-1671.

[5] Kleinbaum DG. Logistic Regression: A self-learning text. Springer-Verlag Publ. 1994: 134-149.

[6] Kramer MS, Feinstein MD. The biostatistics of concordance. Clin Pharmacol. Ther 1981; 29: 111-123.

9. RESULTS

9.1 Participation rate

To be included in this study a questionnaire had to have an answer to the question "Was the hands-free technique used?" Missing data were allowed for the question about the proportion of use of the hands-free technique and other questions. Of the eligible 5,388 surgeries during the study period, 3,765 questionnaires had an answer to this question, for a 70% response rate.

As shown in Table 9.1, the data completion rates were lowest for emergency surgeries and non-day shift surgeries. Forms were filled in for only 51% of emergency operations and for only 60.4% of operations performed on non-day shifts. It should be noted that 61.7% of all emergency surgeries during the study period at the study hospital occurred in non-day shifts. The lower percentage of forms filled for operations performed during the evening shift and on an emergency basis are thus linked and also correspond to periods when fewer personnel were present. There was also a low response rate for urology (59.7%) and CVT (61.0%) surgeries, although that meant that only 31/77 urology surgeries did not have questionnaires completed. However for CVT surgery, 409/1048 questionnaires were not completed. Response rates were also lower in December and in the last month of the study. The researcher was absent for two weeks after November 30th, 1995, due to a death in the family and data was collected through the Christmas and New Year periods. The decrease in April likely occurred because personnel knew that the study had to be terminated by mid-April

due to a hospital management decision.

Table 9.1 PARTICIPATION RATE

	SURGERIES INCLUDED	TOTAL SURGERIES
OVERALL	3765 (69.9%)	5388
BY MONTH OF STUDY		
November	810 (73.9%)	1096
December #	584 (61.9%)	943
January	713 (70.5%)	1011
February	686 (74.0%)	927
March	696 (73.0%)	953
April *	276 (61.3%)	458
# Investigator absent for 1/2 month		
* collection for 1/2 month only		
EMERGENCY/NON-EMERGENCY		
Emergency	362 (51.0%)	710
Non-emergency	3334 (72.7%)	4587
Unknown	69 (75.8%)	91
SHIFT		
Days+ (0700-1459)	2989 (73.0%)	4092
Evening/nights	776 (60.4%)	1285
Unknown	0 (0%)	11
+Started between 0700 and 1459		
TYPE OF SURGERY		
General	992 (73.3%)	1354
Orthopedic	1156 (69.6%)	1662
CVT	639 (61.0%)	1048
Plastic	104 (71.2%)	146
Urology	46 (59.7%)	77
ENT	219 (82.3%)	266
Gynecological	252 (66.5%)	379
Eye	190 (88.0%)	216
Other	164 (81.6%)	201
Unknown	3 (7.7%)	39

9.2 Description of numerator data only

There were 136 surgeries in which 144 events occurred.

Of the 144 surgeries with events, 143 had answers to the question on the proportion of use of the hands-free technique.

The events were 40 injuries, 51 contaminations and 52 glove tears recorded. And this produced an event rate of 144/3764=3.9%.

After an event occurred, extra information for that surgery was collected to define how and to whom the event occurred and the protective clothing used by those involved. This information was not available for the non-event surgeries included in this study.

About 44% of events were incurred by surgeons; 16% by scrub nurses; 9% by operating room technicians; 8.% by residents; 8% by physician's assistants.

Only 46% explained what had occurred to them, while for 50%, the information came from a co-worker. Where the information came from was not specified for the other six events. When personnel did not agree to participate the circulating nurses sometimes went ahead and filled in the questionnaire themselves or they asked a co-worker close to the injured person (usually another scrubbed personnel) for details of the event.

About 67% of the incidents were self-inflicted, 15% were inflicted by a co-worker, while 8% were included within the 'other' category, which included reasons such as 'spontaneous' 'glove tear' etc., while 10% were not placed in any category.

INJURIES: The sharp was contaminated for 68% of the 40 injuries, while for 25% it was not yet contaminated with blood or body fluids and the rest were not classified. About 48% of injuries

were superficial, 40% were moderately deep, and 5% very deep. Forty-five per cent of the injuries occurred during suturing of skin, 20% occurred during the suturing of muscle, 18% during cutting, 5% while using a tool but not on the patient, and 2.5% each during electrocautery, during wiring/fixing, during an injection, and for 'other' reasons. Fifty per cent of injuries occurred during use of the item, 23% before use of the item, 8% while manually retracting surgical tissue, 5% while passing hand-to-hand, 5% while disassembling a device or equipment, 3% while recapping a used needle, and 3% after use while cleaning up item after use on or near disposal container.

CONTAMINATIONS: Fifty-three per cent of the contaminations were due to handling a sharp instrument; 16% were due to an unspecified circumstance; 14% were due to a spurt; 8% were due to direct patient contact; 6% were due to touching contaminated equipment; and in 2% each a container was over filled and an IV tubing bag or pump leaked. Ninety-two per cent of the 51 blood or body fluid contaminations were on visibly intact skin, 4% were on the eyes/nose or mouth, 2% were on non-intact skin and another was at another site. There was less than 5cc of contaminated fluid in 92% of contaminations, while in 6% there was less than 50cc contaminated fluid and in only 2% there was more than 50cc contaminated fluid. The contaminating substance was in place less than 5 minutes in 77% of incidents, 5-14 minutes in 6%, 15 minutes to one hour in 4%, and more than one hour in 6%. Ninety-six per cent of contaminations were with blood and 2% were with peritoneal fluid. Eighteen per cent of contaminations were on unprotected skin; 2% occurred because of

a gap in the garment; 4% were contaminations due to soaking through a protective garment; and 75% were contaminations as a result of a glove tear.

GLOVE TEARS: About 50% of the 52 glove tears occurred among surgeons, 21% among operating room technicians, 14% among scrub nurses and 10% among personal assistants. The tears were described as self-inflicted 62% of the time and inflicted by a co-worker 17% of the time. Personnel were wearing single gloves in 92% of the tear incidents and double gloves in 6%.

SURGERIES IN WHICH MORE THAN ONE EVENT OCCURRED: There was more than one event in five plastic surgeries and three CVT surgeries. In one CVT surgery there were three events, while in two CVT surgeries and five plastic surgeries there were two events.

There were two surgeries during which two events occurred at the same time (in one CVT surgery there were two injuries and in another two glove tears) and six surgeries in which more than one event occurred at different times.

In the CVT surgery when two injuries occurred at the same time, they were caused by a suture needle and surgeons were affected. The sharp was described as 'held by another' and 'held by the injured person', the injuries were superficial and penetrated the anterior side of the hand of one surgeon and the dorsal side of the hand, of the other. In the CVT surgery when two glove tears occurred at the same time, one was the glove of a surgeon and one was the glove of a scrub nurse.

The three glove tears in one CVT surgery all occurred at different times, to two surgeons and one operating room technician.

When only those events in which an injury or contamination directly due to handling or passing sharp instruments plus all glove tears are included, five surgeries with more than one event occurred. Only glove tears occurred during these surgeries, and none occurred at the same time.

9.3 Protective effect of hands-free technique

In the 3,765 surgeries included in this study, 136 surgeries had additional data collected because of an event.

In all 3,698 (of the 3,765 surgeries data was complete for a reduced number) the proportion of passes judged to be performed so that no more than one person touched a sharp instrument at the same time, occurred all of the time in 18.5% of surgeries (695). In 22.6% of surgeries (850), the hands-free technique was used almost always. In 37.0% of surgeries (1,392) it was judged used half of the time. In 12.6% of surgeries (476) it was judged used some of the time. In 7.6% of surgeries (285), it was judged not used.

The hands-free variable is presented as either a binary variable for which hands-free was used (75% and 100%) and hands-free was not used (0-50%); or as a variable with 5 categories ranging in use of the hands-free technique from 0%, 25%, 50%, 75% and 100%.

The overall rate of events is 3.9%.

The rate of events when the hands-free technique was used, was 33/1545= 2.1%; while the rate of events when the hands-free technique was not used, was 110/2153= 5.1%, for a rate ratio (RR) of 2.1/5.1= 0.41. The odds ratio (OR) is derived from (2.1/97.9)/(5.1/94.9)= 0.40

When disease (or event) is rare over the study period the odds ratio and the rate ratio estimates are approximately similar. [1] Logistic regression will thus be used in this analysis because the software is more readily available.

This OR is a measure of effect (possibly confounded) of the relationship between the two categories of hands-free use (75%,

100%) versus non-use (0%, 25% and 50%) and all events.

Table 9.2
All events by use of hands-free (HF) technique

	Event	No Event	Total
HF Used	33 (2.1%)	1512 (97.9%)	1545
HF Not-used	110 (5.1%)	2043 (94.9%)	2153
Total	143 (4.0%)	3555 (96.1%)	3698

The crude OR=0.41 (95% CI 0.30-0.60) was calculated.

Crude ORs for increasing use of the hands-free technique and events were also calculated at each level. Although the overall trend appears to be a decrease in risk for each increasing category of use of the hands-free technique, this is not seen for the OR associated with 50% use of the hands-free technique:

Table 9.3
All events by use of hands-free (HF) technique (categorical)

HF use	No Event	Event	OR
0%	274	11	
25%	458	18	0.98 (0.46-2.11)*
50%	1311	81	1.53 (0.80-2.09)
75%	825	25	0.76 (0.37-1.57)
100%	687	8	0.29 (0.12-0.73)

*Approximate 95% confidence limits were calculated for the ORs using Woolf's method. [2]

9.4 Event rates in relation to various risk factors

To provide an initial view of risk during surgery, the overall event rate of 3.9% in this study, was compared to the event rate according to risk factors.

The event rate during CVT surgeries was 12.1% (Table 9.4). The incident rate during the day shift was 4.2%, while on evenings and nights it was 2.3%. Surgeries where bloodloss was greater than 100cc had an event rate of 7.8% while surgeries where the bloodloss was 100cc or less had an event rate of 1.4%. Increase in bloodloss is associated with longer surgeries and with certain types of surgeries.

When six or more personnel were in the operating room the event rate was 6.5% while when five or less workers were present the rate was 2.1%. All types of events showed an increase with more than six personnel present.

Table 9.4 All event rates in relation to percentage of passes judged hands-free and other aspects of the operation

	Injury	Tear	Contamination	Total*
Overall	40	52	51	144 **(3.9%)**
By Hands free				
No HF	3 (1.1%)	4 (1.4%)	4 (1.4%)	11 (3.9%)
25%	5 (1.1%)	7 (1.5%)	6 (1.3%)	18 (3.8%)
50%	25 (1.8%)	29 (2.%)	27 (1.9%j)	81 (5.8%)
75%	6 (0.7%)	9 (1.1%)	10 (1.2%)	25 (2.9%)
100%	1 (0.1%)	3 (0.3%)	4 (0.6%)	8 (1.2%)
By surgical specialty				
General	9 (0.9%)	10(1.0%)	14 (1.4%)	33 (3.3%)
Orthopedic	3 (0.3%)	5 (0.4%)	6 (0.5%)	14 (1.2%)
CVT	22 (3.4%)	30 (4.7%)	25 (3.9%)	77 (12.1%)
Plastics	0	3 (2.9%)	0	3 (2.9%)
Urology	1 (2.2%)	0	1 (2.2%)	2 (4.3%)
ENT	2 (0.9%)	1 (0.5%)	1 (0.5%)	4 (1.8%)
Gynec	2 (0.8%)	2 (0.8 %)	3 (1.2%)	7 (2.8%)
Eye	1 (0.5%)	0	0	1 (0.5%)
Other	0	2 (1.2%)	1 (0.6%)	3 (1.8%)
By emergency/non-emergency status				
Emergency	5 (1.4%)	4 (1.1%)	5 (1.4%)	14 (3.9%)
Non-emerg	34 (1.0%)	48 (1.4%)	45 (1.3%)x	127 (3.8%)
By shift				
Day	30 (1.0%)	49 (1.6%)	47 (1.6%)	126 (4.2%)
Non-day	10 (1.3%)	4 (0.5)	4 (0.5%)	18 (2.3%)
By bloodloss				
100cc or less	8 (0.3%)	12(0.5%)	14 (0.6%)	34 (1.4%)
Over 100cc	31 (2.2%)	41 (2.9%)	37 (2.7%)	109 (7.8%)
By number of personnel in operating room				
Five or less	16 (0.7%)	15(0.7%)	16 (0.7%)	47 (2.1%)
Six or more	24 (1.6%)	38(2.5%)	35 (2.3%)	97 (6.5%)
By noise level judged by circulating nurse				
Quiet	14 (0.9%)	20(1.3%)	24 (1.5%)	58 (3.6%
Noisier	26 (1.3%)	32(1.6%)	25 (1.2%)	83 (4.1%)
By length of surgery				
1 hr or less	3 (0.2%)	1(0.06%)	3 (0.2%)	7 (0.5%)
1-2 hr.	11 (0.9%)	11 (0.9%)	15 (1.2%)	37 (3.0%)
over 2 hr.	26 (2.6%)	41 (4.1%)	33 (3.3%)	100 (10.0%)

*Numbers do not add up to 144 events for each category because of missing data. Although 144 events are included in this study, in one event the hands-free technique was used, but the amount of use was not specified.

9.5 Confounding

To begin the assessment of confounding Table 9.5 was generated.

Of note are CVT surgeries where the hands-free technique was used all and most of the time in only 22.3% of CVT surgeries compared to 41.8% in all surgeries.

The hands-free technique was used less than the overall average during emergency surgery, when blood loss was > than 100cc and during the evening and night shifts and noticeably less when surgeries lasted longer than two hours.

TABLE 9.5
EXTENT OF HANDS-FREE USE IN ALL SURGERIES AND IN SUB-GROUPS OF SURGERIES

OVER-ALL	0%	25%	50%	75%	100 %	Total
Surgeries	285	476	1392	850	695	3765
%	7.6%	12.6%	37.0%	22.6%	18.5%	100%
SURGICAL SPECIALTY						
General	53 (5.5%)	109 (11.2%)	344 (35.4%)	269 (27.7%)	196(20.2%)	971
Ortho	82 (7.2%)	178 (15.6%)	395 (34.7%)	280 (24.6%)	203 (17.8%)	1138
CVT	49 (7.8%)	75 (11.9%)	366 (58.0%)	86 (13.6%)	55 (8.7%)	631
Plastics	5 (5.0%)	9 (8.9%)	28 (27.7%)	22 (21.8%)	37 (36.6%)	101
Urology	5 (11.4%)	3 (6.8%)	17 (38.6%)	11 (25.0%)	8 (18.2%)	44
ENT	22 (10.3%)	27 (12.6%)	56 (26.2%)	41 (19.2%)	68 (31.8%)	214
Gynecology	39 (15.8%)	19 (7.7%)	57 (23.1%)	61 (24.7%)	71 (28.7%)	247
Eye	20 (10.6%)	21 (11.2%)	85 (45.2%)	34 (18.1%)	28 (14.9%)	188
Other	10 (6.2%)	35 (21.7%)	44 (27.3%)	45 (28.0%)	27 (16.8%)	161
EMERGENCY/NON-EMERGENCY						
Emergency	47 (13.0%)	40 (11.1%)	159 (44.0%)	80 (22.2%)	35 (9.7%)	361
Non- emerg	227 (6.9%)	428 (13.1%)	1210 (37.0%)	755 (23.1%)	649 (19.9%)	3269
SHIFT						
Days	180 (6.1%)	379 (12.9%)	1064 (36.3%)	702 (23.9%)	609 (20.8%)	2934
Other	105(13.7%)	97 (12.7%)	328 (42.9%)	148 (19.4%)	86 (11.3%)	764
BLOODLOSS						
100cc or less	180 (7.8%)	323 (14.0%)	756 (32.7%)	538 (23.3%)	513 (22.2%)	2310
Over 100cc	103 (7.5%)	150 (11.0%)	627 (45.9%)	309 (22.6%)	177 (13.0%)	1366
PERSONNEL PRESENT						
1-5	187 (8.4%)	296 (13.3%)	700 (31.5%)	534 (24.0%)	508 (22.8%)	2225
over 5	98 (6.7%)	180 (12.2%)	692 (47.0%)	316 (21.5%)	187 (12.7%)	1473
NOISE						
Quiet	102 (6.5%)	134 (8.5%)	616 (39.1%)	333 (21.1%)	390 (24.8%)	1575
Noisier	140 (7.0%)	330 (16.5%)	732 (36.6%)	498 (24.9%)	298 (14.9%)	1998
LENGTH OF SURGERY						
1 hr or less	139 (9.4%)	167 (11.3%)	482 (32.7%)	315 (21.3%)	373 (25.3%)	1476
1-2 hours	78 (6.3%)	181 (14.6%)	417 (33.7%)	352 (28.4%)	210 (17.0%)	1238
Over 2 hr	67 (6.9%)	127 (13.0%)	489 (50.2%)	183 (18.8%	108 (11.1%)	974

Numbers do not add up to 3,765 surgeries for each category because of missing data.

Table 9.6 shows events rates and use of the hands-free technique. The two categories where the event rate was highest (CVT surgery -- 12% and surgery longer than two hours -- 10%), were also the two categories where hands-free use was lowest. Compared to the average rate, hands-free use was 22% in CVT surgeries, 34% in surgeries where more than five personnel were present, 30% in surgeries that lasted longer than two hours, 32% in emergency surgeries, 31% in non-day shift surgeries and 36% in surgeries where blood loss was greater than 100cc.

Lower than average event rates in combination with higher than average use of the hands-free technique occurred: in general surgeries , other types of surgeries and orthopedic surgeries; when 1-5 personnel were present 75% or more of the time; when the surgery was 1 hour or less and 1-2 hours long; when 100 cc or less of blood was lost; and during quiet surgery. This would tend to exaggerate the protective effect of use of the hands-free technique (OR further away from 1), as would higher than average event rates and lower than average use of the hands-free technique tend to diminish the protective effect of the hands-free technique (OR closer to 1). This combination also existed: during CVT surgeries; when more than 5 personnel were present 75% or more of the time; when the surgery lasted more than 2 hours; and during noisier surgery.

The categories of various risk factors had been collapsed as outlined in Chapter 8. In Table 9.6 with all categories redefined as well as hands-free use defined as a binary variable, the assessment of confounding by risk factors was again carried out.

TABLE 9.6
EVENT RATES AND FREQUENCY OF USE OF HANDS-FREE TECHNIQUE OVERALL AND RISK FACTORS IN REDEFINED CATEGORIES

	Total surgeries	Surgeries with events	Surgeries using hands-free technique
Overall			
Number	3,765	144 (3.9%)	1545 (41.0%)
Surgical specialty			
General	992	33 (3.3%)	465 (47.9%)
Other	975	20 (2.1%)	453 (47.4%)
Orthopedic	1156	14 (1.2%)	483 (42.4%)
CVT	639	77 (12.1%)	141 (22.3%)
Number of personnel present in operating room			
1-5	2271	47 (2.1%)	1042 (46.8%)
More than 5	1494	97 (6.5%)	503 (34.1%)
Length of surgery			
1 hr or less	1499	7 (0.5%)	688 (46.6%)
1-2 hr.	1261	37 (2.9%)	562 (45.4%)
More than 2 hr.	995	100 (10.1%)	291 (29.9%)
Bloodloss			
100cc or less	2350	34 (1.4%)	1051 (45.5%)
Greater than 100cc	1391	109 (7.8%)	486 (35.6%)
Shift			
Days	2989	126 (4.2%)	1311 (44.7%)
Evenings/nights	776	18 (2.3%)	234 (30.6%)
Emergency non-emergency status			
Emergency	352	4 (3.9%)	115 (31.9%)
Non-emergency	3334	127 (3.8%)	1404 (42.9%)
Noise level judged by circulating nurse			
Quiet	1597	58 (3.6%)	723 (45.3%)
Noisier	2032	83 (4.1%)	796 (39.2%)

9.6 Multivariate data analysis for all events to adjust for confounding

MANTEL-HAENSZEL: To assess the magnitude of confounding or potential modification of the hands-free event rate relationship, Mantel-Haenszel summary estimates (Appendix 5) correcting for each risk factor, one at a time, were calculated.

When the hands-free variable was binary the Mantel-Haenszel ORs were all below one. All risk factors resulted in an OR closer to 1 than the crude OR of 0.41, except for bloodloss during surgery and the emergency status of the surgery.

If these ORs were inspected more closely at each factors' levels, an indication of the effect of hands-free use was observed. For 'types of surgery' for example, the OR for the reference surgery (orthopedic surgery) was 1.16 and decreased at each of the next three levels, with an OR of 0.37 for the last level, CVT surgery. Use of the hands-free technique during CVT surgery, which was found to have a greater rate of events than other types of surgery, may have resulted in the greatest protective effect.

Apparent effect modification was also seen for longer surgeries, for bloodier surgeries, for surgeries occurring in the evening and at night and for surgeries in which more than five personnel were present.

When the hands-free variable was categorical, the Mantel-Haenszel ORs were all greater than the crude OR, except when there was 100% use of the hands-free technique. The estimate for each risk factor at 100% use of the hands-free technique, was below 0.41. When using the hands-free technique 50% of the time, on the other

hand, the risk was the highest, ranging from 1.13-1.54. This indicates increased risk when the hands-free technique was used 50% of the time compared to when it was used 0% of the time.

Because Mantel-Haenszel ORs were corrected for variables one at a time and not simultaneously, therefore these results were not fully adjusted.

LOGISTIC REGRESSION: A series of multiple regressions to adjust for confounders simultaneously, as well as to assess effect modification, were next carried out (Appendix 6).

Initially, three previously recognized confounders from previous studies (bloodloss, length of surgery and type of surgery) and all other potential confounders (noise, number of personnel present during surgery, time of day and emergency status), were included in a model. Risk reduction associated with use of the hands-free technique in this model was determined to be about 44% (OR=0.56 [95% CI 0.36-0.87].

Next, three effect modification terms (hands-free*bloodloss, hands-free *length of surgery and hands-free*type of surgery) were included in the full model. The hands-free*bloodloss interaction was found to have $P< 0.05$ by the likelihood ratio test.

The final, most unconfounded model, included all potentially confounding variables and the effect modification term hands-free technique* bloodloss (Appendix 6).

Table 9.7
Odd Ratios for HFT use (all events)

HFT	Bloodloss <100cc		Bloodloss>100cc	
	OR	95% CI	OR	95% CI
Not used (0-50%)	1.00 (reference)		1.00 (reference)	
Used (75-100%)	0.99	0.49-1.98	0.41	0.23-0.72

***Corrected for:**

Type of surgery	Length of surgery	Personnel
Emergency status	Noise	Shift

Full model analysis carried out with 3485 surgeries and 136 events
MH OR HFT N/Y with bloodloss (0)=0.95 and bloodloss (1)=0.34

When blood loss was greater than 100cc, and the hands-free technique was used, risk was reduced by 59%. This finding was statistically significant. According to this, the effect of the hands-free technique is not present when bloodloss is less than 100cc, but when it is higher than 100cc, there is a risk reduction of approximately 60%.

The Mantel-Haenszel odds ratio (0.34) for bloodloss greater than 100cc was more protective (further from 1) than the logistic regression odds ratio indicating effect modification between hands-free use and bloodloss which resulted in an odds ratio of 0.41. Because the Mantel-Haenszel estimate had not been fully adjusted, the difference between the two estimates was expected.

SECONDARY VARIABLES: None of the three variables of secondary interest (noise, time of day and number of personnel), were independently associated with the outcome.

9.7 Protective effect of the Hands-free Technique using a restricted definition of events

To test a more direct effect on passing and handling sharp instruments, analyses were also carried out using only injuries and contaminations associated with handling and passing sharps and all glove tears.

There were 3,647 surgeries in which 94 such events occurred.

Of the surgeries with events, 93 had answers to the question on the proportion of use of the hands-free technique.

Table 9.8
Restricted events by use of hands-free (HF) technique

	Event	No event	Total
HF used	25 (1.6%)	1512 (98.4%)	2110
HF not used	68 (3.2%)	2042 (96.8%)	1537
Total	93 (2.6%)	3554 (97.4%)	3647

The crude OR =0.50 (95% CI 0.31-0.79) associated with a restricted number of events was calculated.

9.8 Multivariate data analysis for a restricted number of events to adjust for confounding

MANTEL-HAENSZEL: To assess the magnitude of potential confounding and effect modification, Mantel-Haenszel summary estimates (Appendix 5), corrected for each risk factor, one at a time, were calculated.

When the hands-free variable was binary the Mantel-Haenszel ORs were all below one. All adjustment with individual risk factors resulted in an OR greater than the crude OR of 0.50, except for shift during surgery and emergency status.

If ORs were inspected at each level of the risk factor, a difference in ORs was seen. For types of surgery for example, the OR for the reference surgery (orthopedic surgery) was 1.02 and there was a decrease at each of the next three levels, with an OR of 0.54 for the last level, CVT surgery. This may have indicated that use of the hands-free technique during CVT surgery, which is known to have a greater rate of events than other types of surgery, resulted in hands-free use having the greatest protective effect.

Apparent effect modification was also seen for other factors that may have modified the hands-free event rate relationship.

LOGISTIC REGRESSION: LOGISTIC REGRESSION: A series of multiple regressions to adjust for confounders simultaneously, as well as to assess effect modification, were next carried out (Appendix 6).

Initially, three previously recognized confounders from previous studies (bloodloss, length of surgery and type of surgery) and all

other potential confounders (noise, number of personnel present during surgery, time of day and emergency status), were included in a model. There was no risk reduction associated with use of the hands-free technique in this model (OR=0.71 [95% CI 0.43-1.18].

Next, three effect modification terms (hands-free*bloodloss, hands-free *length of surgery and hands-free*type of surgery) were included in the full model. The hands-free*bloodloss interaction was found to have P< 0.05 by the likelihood ratio test.

The final, most unconfounded model, included all potentially confounding variables and the effect modification term hands-free technique* bloodloss (Appendix 6).

Table 9.9
Odd Ratios for HFT use (restricted events)

HFT	Bloodloss <100cc		Bloodloss>100cc	
	OR	95% CI	OR	95% CI
Not used (0-50%)	1.00 (reference)		1.00 (reference)	
Used (75-100%)	1.49	0.68-3.31	0.43	0.21-0.86

***Corrected for:**

Type of surgery	Length of surgery	Personnel
Emergency status	Noise	Shift

Full model analysis carried out with 3,439 surgeries and 90 events
MH OR HFT N/Y with bloodloss (0)=1.40 and bloodloss (1)=0.33

When blood loss was greater than 100cc, and the hands-free technique was used, risk was reduced by approximately 60%. According to this, the effect of the hands-free technique is not present when bloodloss is low, but when it is high, there is a statistically significant reduction of risk.

The Mantel-Haenszel odds ratio for bloodloss greater than100cc when the hands-free technique was used, equalled 0.33, which was

more protective (further from1) than the logistic regression effect modification odds ratio of 0.43. Simultaneous adjustment with other variables decreased the OR's distance from one.

SECONDARY VARIABLES: Of the three variables of secondary interest (noise, time of day and number of personnel), time of day may be independently associated with the outcome (OR=0.45 [95% CI 0.20-1.03]. This would indicate a 65% risk reduction for surgery carried out during the evening and night compared to surgery occurring during the day.

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[1] Kramer MS. Clinical epidemiology and bio-statistics. Springer-Verlag Publishers, 1988: 98-102.

[2] Schlesselman JJ. Case-control studies: Design, conduct, analysis. Oxford University Press, 1982: 176.

10. DISCUSSION

The discussion will first focus on two issues of data interpretation, what constitutes use of the hands-free technique and which "events" are relevant, before commenting on the results.

10.1 Definition of hands-free technique

As outlined in Chapter 8, during the study design the researcher envisaged a continuum of hands-free use, from a little, through a lot, to all of the time. But after extended periods spent in the operating room it was noticed that hands-free use was not so simple.

The basic underpinning of the hands-free technique is the idea that no two persons in the operating room handle a sharp instrument at the same time. Therefore, could the hands-free technique be said to have been used when a surgeon receives a sharp directly, hand-to-hand, from a nurse but then places that instrument in a neutral zone or tray for the return pass? This was judged by circulating nurses to have been 50% use of the hands-free technique.

Rethinking the definition of hands-free technique based upon experience in the operating room, led to recoding the data into simple yes/no categories. Only when the proportion of passes done so that no more than one person touched a sharp instrument at the same time was judged 75% or 100%, could it reasonably be said that the hands-free technique was used. In fact, one could argue that only those surgeries where the proportion of passes done so that no more than one person touched a sharp instrument at the same time was judged 100% really met the definition of the hands-free technique. This category had an event rate of only 1.2% compared to a 2.1%

event rate among those judged 75% or 100%, which was used as the "hands-free used" category in the final analysis. However, only 695 of 3,765 operations (18.5%) fell into the 100% category.

10.2 Events

Defining events to include all glove tears, contaminations and injuries is also a point of debate. But, it should be noted that levels of all three rose and fell in concert through the following categories: percentage of passes judged hands-free, surgical specialties, emergency/non-emergency, patient status, bloodloss, personnel present 75% of the time and noise level. Only in the shift category did we see a discrepancy in the results. On non-day shifts the rate of tears and contaminations was lower while the rate of injury did not significantly change (Table 9.4). This is likely explained by a reluctance to report "minor" occurrences on night and evening shifts, when staff numbers were reduced and when staff worked overtime.

This rise and fall in concert suggests behaviours or other mechanisms that caused injuries, contaminations and glove tears may have been related.

10.3 Results

The primary goal of this study was to assess the effect a recommended work practice, the hands-free technique, has on the rate of injuries, contaminations and glove tears, which can lead to transmission of blood-borne diseases between patients and operating room personnel, during surgery.

When surgeries done with the hands-free technique used most of the time, were compared to surgeries where it was not used and a logistic regression model containing all previously recognized confounders and potential confoundersis was constructed, a statistically significant reduction in risk (44%) of all events was found.

But of more interest was the finding that when surgeries done with the hands-free technique used most of the time, were compared to surgeries where it was not used and greater than 100cc of blood was lost, the hands-free technique was approximately 60% protective. This finding was statistically significant. This protective effect was seen after adjustment for all potential confounders included in the study.

When surgeries done with the hands-free technique used most of the time, were compared to surgeries where it was not used and less than 100cc of blood was lost, the hands-free technique was not protective.

The protective effect was approximately the same when only events more directly related to handling and passing sharp instruments and all glove tears, were used in the analysis, but also only when more than 100cc of blood was lost.

There were 1,366 surgeries (Table 9.5) where blood loss was greater than 100cc, and in 486 of these surgeries the hands-free technique was used; in 880 it was not used. The event rate in the surgeries with more than 100cc bloodloss in which the hands-free technique was not used was 10.2%. If this study's findings were correct, instead of 90 events, we might expect (90 x 0.41) to have 36 events or 54 fewer events if the hands-free technique were used during surgeries with greater than 100 cc blood loss.

This study suggests that use of the hands-free technique in surgery, when greater than 100cc of blood is lost, may reduce the risk of injuries, contaminations and glove tears, which could lead to transmission of blood-borne diseases from patients to surgical personnel. It also suggests that when less than 100cc of blood is lost during surgery, the hands-free technique does not reduce the risk of injury, contamination and glove tears.

The other questions about the hands-free technique can be said to have been answered as follows:

If the hands-free technique is used properly it appears to work when 100cc or greater of blood is lost during an operation;

The hands-free technique was used approximately 40% of the time in this study; and

Proper use of the hands-free technique cannot constitute occasional use of the hands-free technique by only one or a few members of the surgical team, it must be used by the majority, during the majority of the time. Only this, meets the AORN definition that was previously cited. Every person working during a surgery must pass instruments using neutral zones all of the time or almost

all of the time.

10.4 Reasons for non-use of hands-free technique

As outlined above, despite recommendations from various professional bodies, the hands-free technique is not widely used. The reasons for this can only be speculated upon, but conversations with nurses and physicians provide some clues.

Surgeons who did not use the hands-free technique at the Providence Medical Centers commented that picking up sharp instruments from a field or basin would make them remove their eyes from the surgical site for brief moments, which they were not used to doing. As well, surgeons were concerned that surgeries would take more time if the hands-free technique was used. They also stated an unwillingness to change practices that satisfied them. In other words, surgeons seemed reluctant to make changes that might reduce the quality of their surgical technique and therefore patient care.

Surgeons who did use the hands-free technique did not perceive any deterioration in patient care. In fact, if use of the hands-free technique does indeed reduce the risk of transmission of disease from medical personnel to patients, then obviously patient care would be improved.

Likely an element in surgeons' resistance to change has been a lack of evidence that use of the hands-free technique does in fact reduce the risk of disease transmission: the results of this study may contribute to increase this evidence and therefore lead to changes in their practice.

Nurses have shown more of an interest in the work practice as demonstrated by their early recommendations and publications on

the subject. This study may also provide the evidence required to improve chances of having the practice implemented by them and further evaluated.

10.5 Study design

Initially a case-control study was considered, especially when it became evident that only one hospital would participate. Because it would have meant interviewing cases and controls retrospectively approximately 24 hours after the event, the potential problem of recall bias seemed significant. Details of an event could be hard to remember when staff may have been involved in many surgeries since the event. Because of this, a prospective design was considered preferable. This design has worked effectively before to study the relationship between certain risk factors and injuries and/or contaminations sustained during surgery. The prospective design permitted a thorough assessment of the main exposure (use of the hands-free technique), exposures of secondary interest, and other risk factors, as well as several outcomes, by the end of each surgery.

The ideal might be an experimental study in which the intervention (hands-free technique) could be assigned to different surgeries or different hospitals, in a random manner.[1] The intervention could be assigned to designated hospitals, while 'normal' work practices would continue in the non-designated hospitals. The difficulty with this type of study would be finding facilities, and especially surgeons, to participate. As Wright[2] found in his survey, surgeons are dissatisfied with the lack of research being carried out to prevent the transmission of blood-borne pathogens, but when asked what they did individually to protect themselves, only 33% double gloved.

10.6 Study limitations and possible biases

MISSING DATA ON PERSONNEL: Because this was an anonymous study, data on operating room personnel such as age, gender, length of time that a surgical team has worked together and years of experience, could not be measured. Number of personnel (and the job they carried out) present in the room 75% of the time or more was collected for each surgery, but additional information on personnel was only collected when an event occurred. Even that information did not consist of personal identifiers or demographic information and other factors that might be thought to be associated with the outcomes of interest.

Although individual characteristics of personnel especially surgeons, such as age or year of graduation from medical school, may also be associated with the exposure (hands-free technique), they could not be measured in this study. Uncontrolled confounding could be an issue, and could lead to over or under-estimation of the protective ability of the hands-free technique.

REFUSAL TO PARTICIPATE: There were three circulating nurses who refused, from the outset, to participate in the study. Their lack of participation may have reduced response rates overall, and may have resulted in fewer questionnaires completed for specific types of surgery, the areas where they primarily worked. Response rates ranged from 60% in urological surgeries to 88% in eye surgeries, with an overall response rate of 70%. In CVT surgery, where 61% of all potential questionnaires were filled out, none of the nurses refused to participate. Non-participation by a few would have likely had little effect on the estimate.

FEWER QUESTIONNAIRES FOR A TYPE OF SURGERY: The hands-free technique was used during CVT surgery approximately 23% of the time compared to 40% in surgeries as a whole, while the event rate in CVT surgeries was approximately 12% compared to 4% in surgeries as a whole. Questionnaires were filled out for approximately 61% of all CVT surgery.

Although the response rate for CVT surgeries was almost 10% less than average, there are problems only if there was a different event rate in non-responders compared to responders.

EXPOSURE CLASSIFICATION POTENTIALLY AFFECTED BY OCCURRENCE OF AN OUTCOME If the event occurred early in the surgery, the proportion of use of the hands-free technique had likely not been selected. As long as the selection of the amount of use of the hands-free technique was not affected by the occurrence of an event, then bias would not have occurred. Ideally though, hands-free classification should have been carried out by someone other than the person recording an event.

If measurement of hands-free use was unaffected (i.e. given a higher or lower proportion), by the occurrence of an event, then the point estimate should not have been affected.

Exposure classification may have been affected by outcome but events were self-reported or reported by a close colleague, while exposure was quantified by the circulating nurse (in consultation with scrub personnel), usually at the very end of the surgery.

REPORTING OF EVENTS: If workers who used the hands-free technique were more likely to report events than those who did not use the hands-free technique, the protective effect of the hands-free

technique may have been altered. This may have lead to a greater number of events reported by those who would have been classified as users of the hands-free technique, thus lowering the protective effect of the hands-free technique.

The problem of under-reporting of events has likely not been a significant problem in this study. It should be noted that during the study period 92 injuries and contaminations, all eligible for follow-up by employee health, were reported. Of these, only 11 were self-reported by operating room personnel to the employee health department (Appendix 7). This is consistent with previous research on under-reporting.

DESCRIPTION OF EVENTS: It was important that the circulating nurse make the required effort to collect information when an event occurred, especially if the person who was injured, contaminated or sustained a glove tear, was not willing to participate. Properly responding to questions such as did the event occur when the instrument was being handled, was being passed and so forth then permitted the event to be classified within the category of handling and passing, and placed in the group of restricted events for example. Inadequate or erroneous information about the details of events could have lead to a decrease in number of restricted events for analysis and an altered risk difference, which would likely have resulted in a decrease in the protective effect of using the hands-free technique.

IMPACT OF EXPOSURE MEASUREMENT ERROR: Seven additional variables besides the variable of primary interest, use of the hands-free technique, were measured in this study. If error in

the measurement of these potential confounders occurred, this would result in inadequate control for confounding. The comparison of the crude OR with the fully adjusted final model indicates that there was some confounding observed, but if there was remaining measurement error it was likely non-differential and it would be difficult to predict what effect this would have on the measurement outcome.

10.7 Comparing results to other studies

The one study [3] that previously evaluated the incidence of percutaneous injuries if instruments were handled hand-to-hand or if instuments were handled using the 'no touch' technique, did not find an association between hand-to-hand transfer and decrease in the rate of injury.

Our study's primary focus was the assessment of the hands-free technique and its' association to the occurrence of events. As a result, measurement of the hands-free technique was divided into five proportions and the decision about use or non-use of the work practice was made by circulating nurses in consultation with personnel, other than surgeons, closest to the surgical site. As well, approximately 2 1/2 times as many surgeries were observed during this study compared to the previous one.

Risk factors of secondary interest in this study were not independently associated with the risk of an event when 'all' events were considered, although when a 'restricted' number of events were analyzed, work during the evening and night shift was protective by about 55%. This finding, although borderline statistically significant and possibly due to chance, was also found by Tokars et al. [4]

Findings regarding all other risk factors were consistent with those found in previous operating room studies.

10.8 Population to whom the findings apply

This study could apply to most hospitals in the U.S. and Canada. Although the hospital in which this study was carried out was privately funded, it is located in the core of a large U.S. city, and accepted uninsured patients.

The majority of surgeons who work in the Providence Medical Centers carry out surgery in more than one facility and are therefore familiar with the routines and practices of other hospital operating rooms.

The Providence Medical Centers frequently trains medical students, residents and nursing students and permits physicians to be accompanied by employees that they have hired and trained. Although training all categories of medical students is also common in Canada, surgeons are not permitted to use their employees as assistants during surgical procedures carried out in hospital.

Types of surgery done at the Providence Medical Centers was highly complicated in some cases and quite routine in others, which is also typical of hospitals in both the U.S. and Canada.

10.9 Risk to patients

Although the main concern of this study was transmission from the patient to the worker, the risk of transmission from the worker to the patient, is also an important consideration.

As described in the literature review, risk to patients from operating room personnel is significant. The operating room is a place where transmission of blood-borne pathogens to patients is always possible.

In the United Kingdom, surgeons who are HBeAg positive (the infectious state known to be most frequently implicated in transmission to patients by staff) are suspended from practice. It is currently mandatory that all surgeons receive the Hepatitis B vaccine in the United Kingdom, and that surgeons provide proof of antibody response to the vaccine.[5] In Canada, surgeons do not have to be vaccinated against the HBV, nor is it mandatory that surgeons prove that they are either protected by the vaccine or if unprotected, HBeAg antibody negative, although a meeting of Canadian and international experts came to a policy consensus that resembles the one in existence in the United Kingdom. [6]

As for HIV, only one province in Canada, Saskatchewan, requires that any known HIV infected physician be reported to the Medical Officer of Health.[7]

The cases of HBV, HCV and HIV transmission between infected health care personnel and their patients is placing pressure on the health care industry to devise personnel policies and practices during surgery that lessens the risk to patients. The use of the hands-free technique, in so far as it reduces the number of operating room

accidents during which a surgeon or other personnel could bleed into a patient, which would in turn lessen the risk.

10.10. Recommendations

In so far as operating room work practices at the Providence Medical Center in Seattle are typical of surgeries in other hospitals, this study lends weight to recommendations made by various professional bodies that the hands-free technique be employed as a safety measure.

To further test the hypothesis it is recommended that a multi-hospital prospective study or/and a randomized control trial on the effectiveness of the hands-free technique, could be carried out.

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[1] Bland MJ, Kerry SM. Trials randomised in clusters. BMJ 1997;315:600.

[2] Wright JG, Young NL, Stephens D. Reported use of strategies by surgeons to prevent transmission of blood-borne diseases. CMAJ 1995;152:1089-1095.

[3] Tokars JI et al. Percutaneous injuries during surgical procedures. JAMA 1992;267:2899-2904.

[4] ibid.

[5] Lancet. Entry to medical school: by examination and vaccination? 1994; 343: 927-928.

[6] Recommendations from the Consensus Conference on Infected Health care Workers: Risk of Transmission of Blood-borne Pathogens. 1996.

[7] Karrel AIG. HIV-infected physicians: How best to protect the public. CMAJ 1995; April 1: 1059-1062.

11. STATEMENT OF ORIGINALITY

I proposed this study and I wrote the protocol for this study under the supervision of Dr. Claire Infante-Rivard and with additional help from other members of my Ph.D. committee. I am solely responsible for all subsequent aspects of this study, including: finding a facility that used the hands-free technique and which would agree to the study; obtaining approval from the Department of Occupational Health's Protocol Review Committee and from both McGill University's Ethics Committee and The Providence Medical Centers' Ethics Committee; designing the data collection instrument; training personnel; spending approximately four days/week on-site for the duration of the study; collecting and reviewing all questionnaires; designing and implementing strategies to ensure that throughout the data collection phase operating room personnel remained aware of the study and motivated to participate; coding all questionnaires and supervising data entry; data analysis; writing this thesis.

There are several aspects of this study that provide an original contribution to scientific research.

First, the effectiveness of the hands-free technique, a work practice recommended by professional associations to decrease the rate of sharps injury among operating room personnel, had not previously been studied. The results of this study suggest the work practice, in at least one context, does in fact reduce event rates.

A second original contribution relates to the methodology of data collection. Although the prospective approach to studying blood and body fluid exposures of operating room personnel has been carried

out previously with circulating nurses responsible for recording risk factors and events, in this study, circulating nurses were required to assess the risk factor of interest, the hands-free technique, in a more precise way than has been done before. The circulating nurses were asked to consult with scrubbed personnel who were closest to the use of the work practice, to determine not only if the hands-free technique was used during a surgery, but to classify its use into five categories ranging from no use, to always used.

In addition, the study attempted to take a multi-disciplinary approach by using criteria established by injury epidemiologists Baker and Haddon and applying them to infection control. To help resolve an infection control problem, the following injury epidemiological questions guided the design and implementation of the study: Is the hands-free technique used? Is the hands-free technique used properly? Does the hands-free technique work when properly used? While the infection control approach has proven useful in designing work practices, it does not provide an easy set of criteria for measuring their effectiveness. Again, this multi-disciplinary approach could prove useful in studying other work practices.

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Appendices

13.1 Stringer's letter to CMAJ

HOSPITAL NEEDED FOR RESEARCH ON HANDS-FREE TECHNIQUE

The article "Reported use of strategies by surgeons to prevent transmission of bloodborne diseases" (*Can Med Assoc J* 1995; 152: 1089–1095), by Dr. James G. Wright, Nancy L. Young and Derek Stephens, and newspaper reports of HIV seroconversion due to a scalpel injury in an Italian surgeon (the first such case documented) illustrate the need for research on ways to prevent transmission of bloodborne diseases during surgery.

In the survey by Wright and colleagues, 92% of respondents reported a willingness to change the way they performed surgery to prevent transmission of bloodborne diseases, and 55% believed that there was too little research into ways of reducing the risk. Yet only 3.2% of respondents used the "no-touch" technique (also called the "hands-free" technique) and only 3.8% passed sharps in a basin.

As a third-year doctoral student in the Department of Occupational Health, Faculty of Medicine, McGill University, Montreal, I have developed a protocol to study the hands-free technique. This technique is defined as the indirect transfer of instruments between the surgeon or surgeons and other scrubbed personnel, during which neither person touches the same sharp item at the same time. This may involve placing sharps in a designated neutral zone — a section of the surgical field or a container — where they can be retrieved.

The hands-free technique has been recommended by the Royal College of Surgery, the Academy of Orthopaedic Surgeons, the Association of Operating Room Nurses and the US Centers for Disease Control and Prevention. Only one previous study assessed the technique, along with several other factors, and the findings were inconclusive.[1]

Hence, although it is recommended, the hands-free technique has not yet been adequately subjected to the questions used to judge injury-control measures: Is the technique used? Is it used properly? Does it reduce injury when properly used?[2]

Although use of the hands-free technique is related to only a portion of high-risk behaviour during surgery, the only way to evaluate injury reduction is to choose a few discrete practices, assess their use and compare accident levels before and after the introduction of the practices.

However, I have encountered difficulty in implementing my study because I cannot find a hospital in which at least 20% of surgical procedures are conducted with the use of the hands-free technique. The study would take 4 to 6 months in a moderately busy hospital and would involve gathering information from approximately 3000 procedures.

If any reader knows of a hospital that may meet the criteria for this study, please contact me through the Department of Occupational Health, Faculty of Medicine, McGill University, fax 514 398-7435.

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Montreal, Que.

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← For prescribing information see page 225

13.2 Letters from The Providence Medical Centre accepting to participate in the study

13.3 Questionnaires 1 and 2

OPERATING ROOM DATA COLLECTION FORM FOR HANDS-FREE TECHNIQUE STUDY (Confidential)

SECTION A: Must be filled out for each surgery by circulating nurse

OR Theatre# _____
Date _____
day/mo./yr.
Incision time_____hr.
Surgery ended_____hr.

1. Case status
(Check one of each following)

i. in-patient [a] out-patient [b]
ii. emergency [c] non-emergency [d]

2. Service (Check one below)

general surgery	a	ENT	f
orthopedic	b	transplant	g
cvt	c	gynecological	h
plastics	d	eye	i
urology	e	other	j

3. Total blood loss _____ml./cc.

4. Personnel present for 75% or more of the time, that the operation lasted? *(Add number after each occupational category)*

a) surgeon (attending/staff)	g) scrub nurse
b) surgeon(intern/resident	h) circulating nurse
c) medical student	i) OR tech
d) anaesthesist (attending/staff)	j) PA
e) anaesthesist (resident/fellow)	k) perfusionist
f) anaesthesia tech.	l) other

5. Were procedures followed to ensure that surgeons and nurses/technicians never touched the same sharp instrument at the same time? Yes [a] No [b]

If this was done, what method was usually used?
Sharp instruments were passed to:
a section of the sterile field.. [c]
a kidney basin..... [d]
onto a mayo stand..... [e]
f) other (please describe)_____
_____
_____

6. What proportion of passes of sharps were done by placing them so no two persons touched a sharp instrument at the same time?

Always..... [a]
about 75% of the time..... [b]
about 50% of the time..... [c]
about 25% of the time..... [d]

7. During the surgery could you easily hear (check one) :

Quiet talking..... [a]
normal talking ..... [b]
loud talking..... [c]

SECTION B: To be filled out ONLY if an INJURY (perforation of the skin) or/and CONTAMINATION (of the skin or mucous membrane with blood or body fluid) OCCUR during the surgery described in Section A

1. Injured/contaminated person:

agrees to participate..... [a]
does not agree to participate..... [b]

2. Incident type:

injury..... [a]
contamination..... [b]
both..... [c]

3. Was this incident:

self inflicted..... [a]
inflicted by a co-worker..... [b]
c) other, explain_____
_____

4. Surgical procedure at time of contamination/injury_____
_____
_____

OR Theatre # _____
Time of event _____hr.

5. Data about the injury or/and contamination is from the:

worker who sustained incident..... [a]
co-worker..... [b]
(Co-worker nearest to incident should provide information if injured/contaminated person leaves for first-aid) If information is from co-worker, fill out Section B by asking the injured/contaminated employee questions when s/he returns)

6. Check job category of person injured/contaminated (check one)

surgeon (attending/staff).....	a	OR tech.....	f
surgeon (intern/resident).....	b	nursing student	g
medical student.....	c	PA	h
scrub nurse.....	d	i) other, describe_____	
circulating nurse	e	_____	

7. What protective apparel was worn by person at the time of the contamination/injury? (check all that apply)

surgical mask.....	a	eyeglasses.....	f
surgical gown, disposable.....	b	eyeglasses & side shields.....	g
surgical gown, reusable.....	c	goggles.....	h
single pair latex/vinyl gloves.....	d	faceshield.....	i
double pair latex/vinyl gloves....	e	j) other_____	

TURN PAGE PLEASE

Section C IF THE EVENT WAS AN INJURY

OR Theatre # _____
Time of event _____hr.

1. Is the person who caused the injury:
right-handed..... a
left-handed..... b

2. Is the injured worker:
right-handed..... a
b

3. Was the sharp instrument/item (check one)
held by another person..... a
held by the injured person..... b
c

4. Was the sharp instrument/item considered:
contaminated..... a
uncontaminated..... b
unknown..... c

5. What device/item caused the injury (scalpel blade etc.)?_____
If you can't name it, please describe it_____

6. Was the injury:
superficial..... a
moderate (some bleeding)..... b
severe (deep/profuse bleeding)..... c

7. For what purpose was item causing injury originally used?

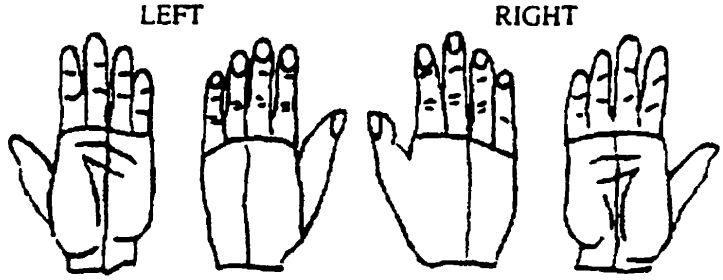
cutting	a	to obtain tissue	i
electrocautery	b	injection (IM, SC, other into tissue)	j
wiring/fixing	c	to contain specimen	k
drilling/sawing	d	using as a tool (not on patient)	l
suturing skin/other tissue	e	m) other _____	
suturing muscle/fascia	f		
retracting tissue/bone	g		
to obtain a body fluid	h		

8. Did the injury occur: (check one)

before use of the item	a	recapping unused needle	j
during use of item	b	after use, while cleaning up	k
while manually retracting surgical tissue	c	item left on or near disposal container	l
passing instruments, hand-to-hand	d	while putting into disposal container	m
passing instruments, hands-free technique	e	after disposal, protruding from container	n
disassembling device or equipment	f	item pierced side of disposal container	o
in preparation for reuse of reusable equipment	g	after disposal item pierced trash bag	p
withdrawing a needle from rubber/other resistant material	h	q) other, describe _____	
recapping used needle	i		

9. Describe circumstances leading to injury/ contamination. Place an X(s) on diagram at right where (if) the employee's hand was injured/contaminated.

_____
_____
_____
_____



Section D IF THE EVENT WAS A CONTAMINATION

OR Theatre # _____
Time of event _____hr.

1. Contact was made on:
intact skin..... a
non-intact skin..... b
eyes/nose/mouth..... c
d) other_____

2. How much fluid was in contact?
small (< 5 cc)..... a
moderate (< 50 cc)..... b
large (> 50 cc) c

3. How long was fluid in contact?
<5 minutes..... a
5-14 minutes..... b
15 minutes - 1 hour..... c
> one hour..... d

4. Which type of body fluids were involved? (Place B in box if bloody.)

blood or blood product	a	sputum	g
vomit/gastric contents	b	saliva	h
CSF	c	peritoneal fluid	i
pleural fluid	d	amniotic fluid	j
urine	e	k) other, describe _____	
pus	f		

5. Did the blood or body fluid:

touch unprotected skin	a	soak through protective garment	c
touch skin through gap in garment	b	touch skin through tear in glove	d
		soak through undergarments	e

6. Was exposure due to:(check one)

handling a sharp item	a	touching contaminated sheets, drapes, gowns	f
a broken specimen container	b	direct patient contact	g
a leaking specimen container	c	a blood/body fluid spurt	h
other container spill/leak	d	an IV tubing/bag/pump leak	i
touching contaminated equipment	e	j) other _____	

OPERATING ROOM DATA COLLECTION FORM FOR HANDS-FREE TECHNIQUE STUDY (Confidential)

SECTION A: Must be filled out for each surgery by circulating nurse

OR Theatre# _____
Date _____
day/mo./yr.
Incision time_____hr.
Surgery ended_____hr.

1. Case status
(Check one of each following)

i. in-patient [a] out-patient [b]
ii. emergency [c] non-emergency [d]

2. Service (Check one below)

general surgery [a] ENT [f]
orthopedic [b] transplant [g]
cvt (i.e. open ht.) [c] gynecological [h]
plastics [d] eye [i]
urology [e] other [j]

3. Total blood loss (best estimate)
_____ml./cc.

4. Personnel present for 75% or more of the time, that the operation lasted? *(Add number after each occupational category)*

a) surgeon (attending/staff)	g) scrub nurse
b) surgeon(intern/resident	h) circulating nurse
c) medical student	i) OR tech
d) anaesthesist (attending/staff)	j) PA
e) anaesthesist (resident/fellow)	k) perfusionist
f) anaesthesia tech.	l) other

5. Was the hands-free technique used? (procedures to ensure surgeons and nurses/technicians never touched the same sharp instrument at the same time)

Yes [a] No [b]
If this was done, what method was usually used?
Sharp instruments were passed to:
a section of the sterile field.. [c]
a kidney basin..... [d]
onto a mayo stand..... [e]
f) other (please describe)_____
_____

6. What proportion of passes of sharps were done so no two persons touched a sharp instrument (hands-free technique) at the same time?

Always..... [a]
about 75% of the time..... [b]
about 50% of the time..... [c]
about 25% of the time..... [d]

7. During the surgery could you easily hear (check one) :

Quiet talking..... [a]
normal talking ..... [b]
loud talking..... [c]

SECTION B : To be filled out ONLY if an INJURY (perforation of the skin) or/and CONTAMINATION (of the skin or mucous membrane with blood or body fluid) or/and GLOVE TEAR occur during the surgery described in Section A

1. Person injured/contaminated or with torn glove:

agrees to participate..... [a]
does not agree to participate..... [b]

2. Incident type:

injury..... [a]
contamination..... [b]
glove tear..... [c]
(Turn page and answer question B8 [hand diagram] for all incident types)

3. Was this incident:

self inflicted..... [a]
inflicted by a co-worker..... [b]
c) other. explain_____
_____

4. Surgical procedure at time of injury/contamination/glove tear

_____

OR Theatre # _____
Time of event _____hr.

5. Data about the injury/contamination/glove tear is from the:

worker who sustained incident..... [a]
co-worker..... [b]
(Co-worker nearest to incident should provide information if injured/contaminated person leaves for first-aid) If information is from co-worker, fill out Section B again by asking the injured/contaminated employee questions when s/he returns)

6. Job category of person injured/contaminated or with torn glove (check one)

surgeon (attending/staff)..... [a]
surgeon (intern/resident)..... [b]
medical student..... [c]
scrub nurse..... [d]
circulating nurse ..... [e]
OR tech..... [f]
nursing student ..... [g]
PA ..... [h]
i) other, describe_____
_____

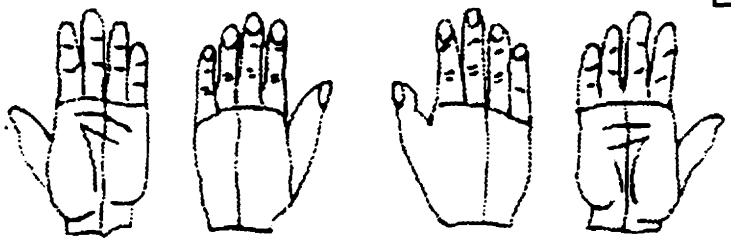
7. What protective apparel was worn by person at the time of the contamination/injury/glove tear? (check all that apply)

surgical mask..... [a]
surgical gown, disposable..... [b]
surgical gown, reusable..... [c]
single pair latex/vinyl gloves..... [d]
double pair latex/vinyl gloves.... [e]
eyeglasses..... [f]
eyeglasses & side shields..... [g]
goggles..... [h]
faceshield..... [i]
j) other_____

TURN PAGE PLEASE

B 8. Describe circumstances leading to injury/ contamination/glove tear. Place an X(s) on diagram at right where (if) the employee's hand was injured/contaminated or glove torn. _____

LEFT RIGHT



a) palm b) back c) back d) palm

Section C IF THE EVENT WAS AN INJURY

OR Theatre # ___Time of event _____hr.

1. Is the person who caused the injury:

right-handed..... a
left-handed..... b

2. Is the injured worker:

right-handed..... a
left-handed..... b

3. Was the sharp instrument/item (check one)

held by another person..... a
held by the injured person..... b
not held by anyone..... c

4. Was the sharp instrument/item considered:

contaminated..... a
uncontaminated..... b
unknown..... c

5. What device/item caused the injury (scalpel blade etc.)?_____
If you can't name it, please describe it_____

6. Was the injury:

superficial..... a
moderate (some bleeding)..... b
severe (deep/profuse bleeding)..... c

7. For what purpose was item causing injury originally used?

cutting..... a
electrocautery..... b
wiring/fixing..... c
drilling/sawing..... d
suturing skin/other tissue..... e
suturing muscle/fascia..... f
retracting tissue/bone..... g
to obtain a body fluid..... h
to obtain tissue..... i
injection (IM, SC, other into tissue)..... j
to contain specimen..... k
using as a tool (not on patient)..... l
m) other _____

8. Did the injury occur: (check one)

before use of the item..... a
during use of item..... b
while manually retracting surgical tissue..... c
passing instruments, hand-to-hand..... d
passing instruments, hands-free technique..... e
disassembling device or equipment..... f
in preparation for reuse of reusable equipment..... g
withdrawing a needle from rubber/other resistant material..... h
recapping **used** needle..... i
recapping **unused** needle..... j
after use, while cleaning up.. k
item left on or near disposal container..... l
while putting into disposal container..... m
after disposal, protruding from container..... n
item pierced side of disposal container..... o
after disposal item pierced trash bag..... p
q) other, describe_____

Section D IF THE EVENT WAS A CONTAMINATION

OR Theatre # _____
Time of event _____hr.

1. Contact was made on:

intact skin..... a
non-intact skin..... b
eyes/nose/mouth..... c
d) other_____

2. How much fluid was in contact?

small (< 5 cc)..... a
moderate (< 50 cc)..... b
large (> 50 cc) c

3. How long was fluid in contact?

<5 minutes..... a
5-14 minutes..... b
15 minutes - 1 hour..... c
> one hour..... d

4. Which type of body fluids were involved? (Place B in box if bloody.)

blood or blood product..... a
vomit/gastric contents..... b
CSF..... c
pleural fluid..... d
urine..... e
pus..... f
sputum..... g
saliva..... h
peritoneal fluid..... i
amniotic fluid..... j
k) other, describe_____

5. Did the blood or body fluid:

touch unprotected skin..... a
touch skin through gap in garment. b
soak through protective garment.... c
touch skin through tear in glove..... d
soak through undergarments..... e

6. Was exposure due to:(check one)

handling a sharp item..... a
a broken specimen container..... b
a leaking specimen container..... c
other container spill/leak..... d
touching contaminated equipment.. e
touching contaminated sheets, drapes, gowns..... f
direct patient contact..... g
a blood/body fluid spurt..... h
an IV tubing/bag/pump leak..... i
j) other_____

13.4 The Providence Medical Center OR Newsletters

INSIDE LINE

CHILLING ORTHO NEWS

Where is the ice machine?

The ice machine has been ***removed*** from PACU. When you need ice for your bone donor styrofoam containers, you will have to obtain it from the ***CV Pump Room***.

Steris Training

We will be scheduling 1 1/2 hour training sessions for everyone to use the new sters. It is mandatory for each of us to take the class and pass a post test in order to use. We will start with "key" people and then eventually everyone will be signed off.

Training starts January 24th & 25th. Can and Pat will coordinate the schedule. Thanks for your attention to this.

Pat Conlon & Cari Jackman

Attention

There are a number of people who have yet to sign up for holiday call in General Surgery, and there are some shifts yet to be covered. Please check this and sign up. February 18th, there appears to be a 12 hour slot not covered. And....this is just "around the corner". Look at the bulletin board list for your name. Thanks.

Pat Conlon

Attention

It is not necessary to complete "Neutral Zone" questionnaires for Cystos. When an incident or contamination occurs please fill out sections B and C or D completely.

Thanks you, Bernadette

SYRINGE NEWS

Reminder

Please do not send syringes with needles on the end to Micro Lab. Any culture in a syringe must be capped. Sterile caps may be found in the blue Anesthesia Carts, if necessary - or in PACU. This is a safety issue for lab personnel. Thank you for your cooperation.

Pat Conlon

New Item

We now have Bard Albumin Grafts (DeBakey) in SAT Dist. They come in assorted sizes of straight and bifurcated. ***Hot Item*** with Dr. Rodriguez.

The Gang in Satellite

Education News

To all the O.R. Staff, Administration, and Physicians: Thank you for your good wishes and congratulations. Please feel free to stop by the Education office and let me know about anything you would like to see or learn about on the Tuesday inservice. I welcome all suggestions. Thank you again.

Cari Jackman

INSIDE LINE

WELCOME:

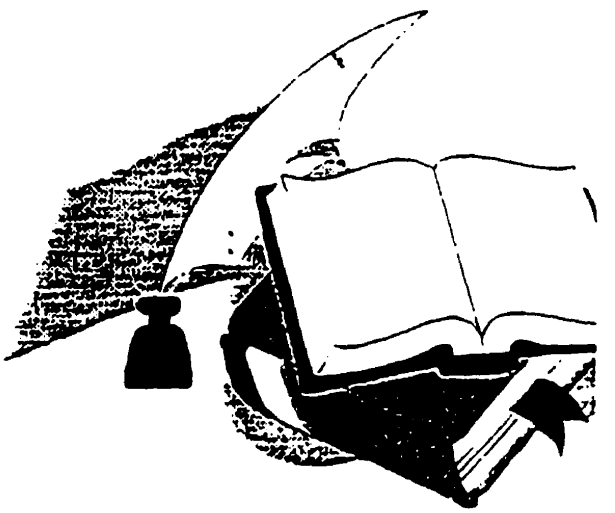
Please join the Anesthesiologist in welcoming Dr. Pascale. He has replaced Dr. Mondzac who is now working in Bellingham.

Education News

Thank you for all your good questions, help, and cooperation during the Steris training. You will soon see some more information on it from Karen Geiger and in the next staff meeting. We will go over who the contact people will be when we start using it in the middle of February. The Same Day Surgery Center will start using the Steris this week.

Thank You

A warm thank you from all the nursing students for all your help during their rotation. They will continue to float through until February 28th. Thanks.
~Cari~



Neutral Zone Questionnaires

As of January 25th approximately 1,800 questionnaires have been completed. You are moving along at a nice, steady pace. Don't forget to place your names in the envelopes for the weekly and final draws.
~Bernadette~

GOSSIPS:

(TRIOLET)

The wheel or the tongue: Which runs the more lightly when spinners are young -
The wheel or the tongue?

The white flax is flung, The white teeth flash brightly; The wheel or the tongue:
Which runs the more lightly?

~George Cumming~

The instrument/equipment wish list will be posted through the end of this week. I will turn in all requests to Lilly on Tuesday, March 5, 1996.

Now... on the cookie request I will be happy to make the first few dozen if you will consider bringing a few to each Tuesday inservice... think about it. ♥

OPEN ENROLLMENT FOR RN'S:

Please pick up your flex select binder in Alicia's office. Karen Crider, Human Resources Benefit Specialist, will have a couple forums thoughout the month of March, to answer questions before she comes on March 26th to talk to our staff and answer our questions regarding the new health care plan. I will post dates as I receive them.

COMMITTEE NEWS:

Needle Count Committee

This committee will meet for the first time on February 28, 1996. They will be looking at ways we can standardize our present needle count policy. Members include: Tanya Bonds, Atsuko Chitose, Patti Eder, Jet Hert, Cari Jackman, Shannon McDill, and Leona Pollack.

CQI:

This group is a continuation of the "8:00 Start Time" project. They will be looking at patient prep and transportation issues. Members are: Katie Amudson, Kim Dotson, Barbara Downward, Linda Gilsdorf, Cindy Kindsvogel, Lilly Nelson, and Zoltan Lengyel.

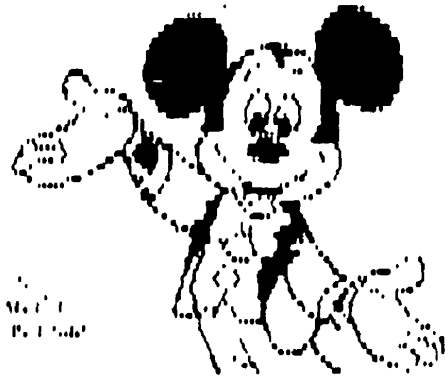
THANK YOU:

I would like to take this opportunity to thank each and everyone of you that has taken the time to help the nursing and medical students rotating through this month, they are very impressed with all of you and thank you very much for all your help.

I also would like to thank the Team Leaders for allowing me to use their office for inservice when multiple discipline needs are to be addressed. I truly appreciate their help and support.

~HAVE A GREAT WEEK~

CARI



SICK LEAVE:

Please note revised Policy & Procedure #667 reporting sick leave. The revised copy has been posted on the bulletin board in the nurses lounge.

HANDS FREE TECHNIQUE STUDY REMINDER:

There are envelopes for your names (with packets of slips of paper) in the:

1. Open Heart area
2. On the glass window surrounding the desk
3. In the Staff Lounge

13.5 Mantel-Haenszel Tables

[Crude OR= 0.41] 144 Events Mantel Haenzel Hands-free No/Yes

	Service	Length	Bloodloss	Shift	Personnel	Noise	Emergency
	Orthopedic	**<1 hr**	**<100cc**	**Days**	**1-5**	**Quiet**	**Emergency**
	648 7	784 4	1240 19	1529 94	1152 31	808 44	233 13
	477 6	685 3	1036 15	1279 32	1026 16	710 13	114 1
OR	**1.16**	**0.86**	**0.95**	**0.41**	**0.58**	**0.34**	**0.16**
	Other	**1-2 hr**	**>100cc**	**Non-days**	**>5**	**Normal/Loud**	**Non**
	490 12	652 24	790 90	514 16	891 79	1138 64	1770 95
	445 8	550 12	468 18	233 1	486 17	777 19	1373 31
OR	**0.73**	**0.59**	**0.34**	**0.14**	**0.40**	**0.44**	**0.42**
	General	**>2 hr**					
	484 22	601 82					
	454 11	273 18					
OR	**0.53**	**0.48**					
	CVT						
	421 69						
	133 8						
OR	**0.37**						
Overall OR	**0.55**	**0.54**	**0.47**	**0.38**	**0.46**	**0.41**	**0.40**

MANTEL-HAENSZEL
BY HANDS-FREE PROPORTION (144 events)

	Service	Length	Blood	Shift	Personnel	Noise	Emergency
25% Hands free							
Level 1	81 1	139 0	177 3	171 9	183 4	99 3	45 2
	176 2	166 1	317 6	364 15	289 7	131 3	38 2
OR	**2.92**	--	**1.12**	**0.78**	**1.11**	**0.76**	**1.18**
Level 2	97 4	76 2	95 8	103 2	97 7	132 8	218 9
	114 0	175 6	139 11	94 3	169 11	315 15	412 16
OR	--	**0.30**	**0.94**	**1.64**	**0.85**	**0.79**	**0.94**
Level 3	52 1	58 9					
	102 7	116 11					
OR	**3.57**	**0.61**					
Level 4	44 5						
	65 9						
OR	**1.20**						
Overall OR	**1.0**	**0.82**	**1.06**	**0.90**	**0.94**	**0.78**	**0.97**
50% Hands free							
Level 1	81 1	139 0	177 3	171 9	183 4	99 3	45 2
	391 4	479 3	746 10	984 70	680 20	578 38	150 9
OR	**0.83**	**?**	**0.79**	**1.34**	**1.35**	**2.17**	**1.35**
Level 2	97 4	76 2	95 8	103 2	91 7	132 8	218 9
	279 8	401 16	556 71	317 11	631 61	691 41	1140 70
OR	**0.70**	**1.52**	**1.52**	**1.79**	**1.26**	**0.98**	**1.49**
Level 3	52 1	58 9					
	330 14	427 62					
OR	**2.21**	**0.94**					
Level 4	44 5						
	311 55						
OR	**1.56**						
Overall OR	**1.25**	**1.13**	**1.31**	**1.41**	**1.29**	**1.42**	**1.54**
75% Hands free							
Level 1	81 1	139 0	177 3	17 9	183 4	99 3	45 2
	276 4	313 2	527 11	678 24	524 10	327 6	79 1
OR	**1.17**	**?**	**1.23**	**0.67**	**0.87**	**0.61**	**0.28**
Level 2	97 4	76 2	95 8	103 2	91 7	132 8	218 9
	209 5	344 8	295 19	142 1	301 15	180 18	731 24
OR	**0.58**	**0.88**	**0.56**	**0.35**	**0.65**	**0.62**	**0.80**
Level 3	52 1	58 9					
	260 9	168 15					
OR	**1.80**	**0.58**					
Level 4	44 5						
	79 7						
OR	**0.78**						
Overall OR	**0.86**	**0.72**	**0.75**	**0.63**	**0.73**	**0.70**	**0.72**
100% Hands free							
Level 1	81 1	139 0	177 3	171 9	183 4	97 3	45 2
	201 2	372 1	509 4	601 8	502 15	383 7	35 0
OR	**0.81**	**?**	**0.46**	**0.25**	**0.55**	**0.60**	**?**
Level 2	97 4	76 2	95 8	103 2	91 7	132 8	218 9
	236 3	206 4	173 4	86 0	185 2	297 1	642 7
OR	**0.31**	**0.74**	**0.28**	**?**	**0.14**	**0.56**	**0.26**
Level 3	52 1	58 9					
	191 2	105 3					
OR	**0.54**	**0.18**					
Level 4	44 5						
	54 1						
OR	**0.16**						
Overall OR	**0.33**	**0.34**	**0.33**	**0.22**	**0.30**	**0.22**	**0.30**

[Crude OR= 0.50] 93 Events Mantel Haenzel Hands-free No/Yes

	Service	Length	Bloodloss	Shift	Personnel	Noise	Emergency
	Orthopedic	**<1 hr**	**<100cc**	**Days**	**1-5**	**Quiet**	**Emergency**
	646 4	784 2	1239 12	1527 62	1151 16	808 25	233 7
	477 3	685 2	1036 14	1279 24	1026 12	710 9	114 1
O R	**1.02**	**1.15**	**1.40**	**0.46**	**0.84**	**0.41**	**0.29**
	Other	**1-2 hr**	**>100cc**	**Non-days**	**>5**	**Normal/Loud**	**Non**
	490 8	650 10	788 56	513 6	889 52	1136 42	1767 60
	445 7	550 11	468 11	233 1	486 13	777 15	1373 24
OR	**0.96**	**1.30**	**0.33**	**0.37**	**0.46**	**0.52**	**0.52**
	General	**>2 hr**					
	484 15	600 56					
	454 8	273 12					
O R	**0.57**	**0.47**					
	CVT						
	420 41						
	133 7						
O R	**0.54**						
Overall OR	**0.66**	**0.67**	**0.59**	**0.46**	**0.57**	**0.50**	**0.49**

MANTEL-HAENSZEL
BY HANDS-FREE PROPORTION (93 events)

	Service	Length	Blood	Shift	Personnel	Noise	Emergency
25% Hands free							
Level 1	81 1	139 0	177 3	170 5	183 3	99 2	45 1
	176 2	166 1	317 5	364 11	289 3	131 2	38 1
OR	**0.46**	**?**	**0.93**	**1.03**	**0.63**	**0.76**	**1.18**
Level 2	97 3	76 1	94 3	103 1	90 3	132 4	217 5
	114 0	175 4	139 7	94 1	169 9	315 10	412 11
OR	**?**	**1.74**	**1.58**	**1.10**	**1.60**	**1.05**	**1.56**
Level 3	52 0	57 5					
	102 6	116 8					
OR	**?**	**0.79**					
Level 4	43 2						
	66 5						
OR	**1.63**						
Overall OR	**1.21**	**0.96**	**1.24**	**1.04**	**1.12**	**0.96**	**1.16**
50% Hands free							
Level 1	81 1	139 0	177 3	170 5	183 3	99 2	45 1
	389 2	479 2	745 4	993 46	679 10	578 2	150 5
OR	**0.42**	**?**	**0.32**	**1.58**	**0.90**	**1.80**	**1.50**
Level 2	97 3	76 1	94 3	103 1	90 3	132 4	217 5
	279 5	399 5	555 46	316 4	630 40	689 28	1138 44
OR	**0.58**	**0.95**	**2.60**	**1.30**	**1.91**	**1.34**	**1.68**
Level 3	52 0	57 5					
	330 9	427 43					
OR	**?**	**1.15**					
Level 4	43 2						
	311 34						
OR	**2.35**						
Overall OR	**1.43**	**1.21**	**1.31**	**1.41**	**1.29**	**1.42**	**1.54**
75% Hands free							
Level 1	81 1	139 0	170 5	17 9	183 3	42 0	45 1
	276 2	313 2	678 19	678 24	524 8	18 1	79 1
OR	**0.59**	**?**	**0.95**	**0.67**	**0.93**	**0.76**	**0.60**
Level 2	97 3	76 1	94 3	103 1	90 3	99 2	217 5
	209 5	344 7	295 10	147 1	301 12	327 5	731 19
OR	**0.77**	**1.55**	**1.06**	**0.70**	**1.20**	**0.96**	**1.13**
Level 3	52 0	57 5					
	260 6	168 11					
OR	**?**	**0.75**					
Level 4	43 2						
	79 7						
OR	1.91						
Overall OR	**1.33**	**1.04**	**1.09**	**0.92**	**1.07**	**1.05**	**1.05**
100% Hands free							
Level 1	81 1	139 0	177 3	170 5	183 3	99 2	45 1
	201 1	372 0	509 4	601 5	502 4	383 4	35 0
OR	**0.40**	**?**	**0.46**	**0.28**	**0.49**	**0.52**	**?**
Level 2	97 3	76 1	94 3	103 1	90 3	132 4	217 5
	236 2	206 4	173 1	86 0	185 1	297 1	642 5
OR	**0.27**	**1.48**	**0.18**	**?**	**0.16**	**0.11**	**0.34**
Level 3	52 0	57 5					
	194 2	105 1					
OR	**?**	**1.19**					
Level 4	43 2						
	54 0						
OR	**?**						
Overall OR	**0.33**	**0.36**	**0.33**	**0.25**	**0.33**	**0.26**	**0.30**

13.6 SPSS Logistic Regression Output (models with and without interactions

14 Mar 98 SPSS 6.1

Total number of cases: 3765 (Unweighted)
Number of selected cases: 3765
Number of unselected cases: 0

Number of selected cases: 3765
Number rejected because of missing data: 280
Number of cases included in the analysis: 3485

Dependent Variable Encoding:

Original Value	Internal Value
0	0
1	1

	Value	Freq	Parameter Coding (1)	(2)	(3)
NUNUSERV					
	0	1086	.000	.000	.000
	1	908	1.000	.000	.000
	2	916	.000	1.000	.000
	3	575	.000	.000	1.000
NULENGTH					
	0	1401	.000	.000	
	1	1182	1.000	.000	
	2	902	.000	1.000	

Interactions:
INT_1 NUBLUDLO by PASSNUNY
Dependent Variable.. EVENTYN 1=event 0=noevent

Beginning Block Number 0. Initial Log Likelihood Function

-2 Log Likelihood 1148.8729

* Constant is included in the model.
Beginning Block Number 1. Method: Enter

Variable(s) Entered on Step Number
1.. CASESTA2 0=non-Emergency 1=Emergency
NOISE 0=quiet 1=normal and loud
NUBLUDLO 0=100cc or less, 1=>100cc
NULENGTH 0=1hr or less, 1=1-2hrs, 2=>2hrs
NUNUSERV 0=ortho, 1=other, 2=general, 3=CVT
NUSHIFT 0=days(0700-1459) 1=non-day shift
NUTHERE 0=1-5 personnel, 1=more than 5

PASSNUNY 1=75%,100% 0=0%, 25%, 50%
NUBLUDLO * PASSNUNY

Estimation terminated at iteration number 7 because
g Likelihood decreased by less than .01 percent.

-2 Log Likelihood	949.167
Goodness of Fit	3145.056

	Chi-Square	df	Significance
Model Chi-Square	199.706	12	.0000
Improvement	199.706	12	.0000

Classification Table for EVENTYN

Observed		Predicted 0	Predicted 1	Percent Correct
0	0	3349	0	100.00%
1	1	136	0	.00%
			Overall	96.10%

---------- Variables in the Equation ----------

Variable	B	S.E.	Wald	df	Sig	R	Exp(B)
CASESTA2	-.0708	.3208	.0486	1	.8255	.0000	.9317
NOISE	.1230	.1889	.4242	1	.5148	.0000	1.1309
NUBLUDLO	.8809	.3037	8.4144	1	.0037	.0747	2.4132
NULENGTH			26.0994	2	.0000	.1387	
NULENGTH(1)	1.8449	.4525	16.6266	1	.0000	.1128	6.3275
NULENGTH(2)	2.4529	.4824	25.8569	1	.0000	.1441	11.6223
NUNUSERV			21.8688	3	.0001	.1175	
NUNUSERV(1)	.7911	.3710	4.5477	1	.0330	.0471	2.2057
NUNUSERV(2)	1.2564	.3456	13.2129	1	.0003	.0988	3.5128
NUNUSERV(3)	1.5729	.3471	20.5325	1	.0000	.1270	4.8207
NUSHIFT	-.3399	.2925	1.3505	1	.2452	.0000	.7118
NUTHERE	-.2839	.2309	1.5111	1	.2190	.0000	.7529
PASSNUNY	-.0101	.3546	.0008	1	.9772	.0000	.9899
INT_1	-.8893	.4545	3.8290	1	.0504	-.0399	.4109
Constant	-6.2399	.5343	136.3917	1	.0000		

14 Mar 98 SPSS 6.1

Total number of cases: 3714 (Unweighted)
Number of selected cases: 3714
Number of unselected cases: 0

Number of selected cases: 3714
Number rejected because of missing data: 275
Number of cases included in the analysis: 3439

Dependent Variable Encoding:

Original Value	Internal Value
0	0
1	1

	Value	Freq	Parameter Coding (1)	(2)	(3)
NUNUSERV					
	0	1080	.000	.000	.000
	1	904	1.000	.000	.000
	2	906	.000	1.000	.000
	3	549	.000	.000	1.000
NULENGTH					
	0	1399	.000	.000	
	1	1167	1.000	.000	
	2	873	.000	1.000	

Interactions:

INT_1 NUBLUDLO by PASSNUNY

Dependent Variable.. EVENTYN 1=event 0=noevent

Beginning Block Number 0. Initial Log Likelihood Function

-2 Log Likelihood 833.38659

* Constant is included in the model.

Beginning Block Number 1. Method: Enter

Variable(s) Entered on Step Number

1.. CASESTA2 0=nonEmergency 1=Emergency
NOISE 0=quiet 1=normal and loud
NUBLUDLO 0=100cc or less, 1=>100cc
NULENGTH 0=1hr or less, 1=1-2hrs, 2=>2hrs
NUNUSERV 0=ortho, 1=other, 2=general, 3=CVT
NUSHIFT 0=days(0700-1459) 1=non-day shift
NUTHERE 0=1-5 personnel, 1=more than 5
PASSNUNY 1=75%,100% 0=0%, 25%, 50%
NUBLUDLO * PASSNUNY

Estimation terminated at iteration number 7 because
Log Likelihood decreased by less than .01 percent.

-2 Log Likelihood	691.349
Goodness of Fit	3333.805

	Chi-Square	df	Significance
Model Chi-Square	142.038	12	.0000
Improvement	142.038	12	.0000

Classification Table for EVENTYN

		Predicted 0	Predicted 1	Percent Correct
		0	1	
Observed 0	0	3349	0	100.00%
1	1	90	0	.00%
			Overall	97.38%

---------------------- Variables in the Equation ------------------------

Variable	B	S.E.	Wald	df	Sig	R	Exp(B)
CASESTA2	.0045	.4061	.0001	1	.9912	.0000	1.0045
NOISE	.2318	.2309	1.0078	1	.3154	.0000	1.2608
NUBLUDLO	.6488	.3784	2.9401	1	.0864	.0336	1.9132
NULENGTH			25.8959	2	.0000	.1621	
NULENGTH(1)	1.8214	.5557	10.7429	1	.0010	.1024	6.1807
NULENGTH(2)	2.8334	.5835	23.5827	1	.0000	.1609	17.0034
NUNUSERV			12.3444	3	.0063	.0873	
NUNUSERV(1)	1.1228	.4691	5.7285	1	.0167	.0669	3.0734
NUNUSERV(2)	1.3948	.4504	9.5912	1	.0020	.0954	4.0340
NUNUSERV(3)	1.5497	.4516	11.7740	1	.0006	.1083	4.7101
NUSHIFT	-.8045	.4231	3.6149	1	.0573	-.0440	.4473
NUTHERE	-.0727	.2866	.0644	1	.7997	.0000	.9299

PASSNUNY	.4041	.4045	.9980	1	.3178	.0000	1.4980
INT_1	-1.2563	.5387	5.4388	1	.0197	-.0642	.2847
Constant	-7.0525	.6815	107.0849	1	.0000		

07 Jul 98 SPSS 6.1 for the Power Macintosh

Total number of cases: 3714 (Unweighted)
Number of selected cases: 3714
Number of unselected cases: 0

Number of selected cases: 3714
Number rejected because of missing data: 275
Number of cases included in the analysis: 3439

Dependent Variable Encoding:

Original Value	Internal Value
0	0
1	1

	Value	Freq	Parameter Coding (1)	(2)	(3)
NUNUSERV					
	0	1080	.000	.000	.000
	1	904	1.000	.000	.000
	2	906	.000	1.000	.000
	3	549	.000	.000	1.000
NULENGTH					
	0	1399	.000	.000	
	1	1167	1.000	.000	
	2	873	.000	1.000	

Dependent Variable.. EVENTYN 1=event 0=noevent

Beginning Block Number 0. Initial Log Likelihood Function

-2 Log Likelihood 833.38659

* Constant is included in the model.
Beginning Block Number 1. Method: Enter

Variable(s) Entered on Step Number
1.. CASESTA2 0=nonEmergency 1=Emergency
NUBLUDLO 0=100cc or less, 1=>100cc
NULENGTH 0=1hr or less, 1=1-2hrs, 2=>2hrs
NUNUSERV 0=ortho, 1=other, 2=general, 3=CVT
NUSHIFT 0=days(0700-1459) 1=non-day shift
NUTHERE 0=1-5 personnel, 1=more than 5
NOISE 0=quiet 1=normal and loud
PASSNUNY 1=75%,100% 0=0%, 25%, 50%

Estimation terminated at iteration number 7 because
Log Likelihood decreased by less than .01 percent.

-2 Log Likelihood	697.010
Goodness of Fit	3265.768

	Chi-Square	df	Significance
Model Chi-Square	136.377	11	.0000
Improvement	136.377	11	.0000

Classification Table for EVENTYN

		Predicted 0	Predicted 1	Percent Correct
Observed				
0	0	3349	0	100.00%
1	1	90	0	.00%
			Overall	97.38%

---------- Variables in the Equation ----------

Variable	B	S.E.	Wald	df	Sig	R	Exp(B)
CASESTA2	.0091	.4057	.0005	1	.9820	.0000	1.0092
NUBLUDLO	.1988	.3047	.4259	1	.5140	.0000	1.2200
NULENGTH			25.1574	2	.0000	.1593	
NULENGTH(1)	1.7699	.5561	10.1294	1	.0015	.0988	5.8702
NULENGTH(2)	2.7579	.5801	22.6041	1	.0000	.1572	15.7675
NUNUSERV			13.9145	3	.0030	.0975	
NUNUSERV(1)	1.1618	.4678	6.1677	1	.0130	.0707	3.1957
NUNUSERV(2)	1.4322	.4494	10.1562	1	.0014	.0989	4.1880
NUNUSERV(3)	1.6540	.4494	13.5463	1	.0002	.1177	5.2277
NUSHIFT	-.8427	.4232	3.9654	1	.0464	-.0486	.4305
NUTHERE	-.0782	.2834	.0761	1	.7826	.0000	.9248
NOISE	.2625	.2304	1.2972	1	.2547	.0000	1.3001
PASSNUNY	-.3378	.2572	1.7239	1	.1892	.0000	.7134
Constant	-6.7229	.6514	106.5241	1	.0000		

Total number of cases: 3765 (Unweighted)
Number of selected cases: 3765
Number of unselected cases: 0

Number of selected cases: 3765
Number rejected because of missing data: 280

Number of cases included in the analysis: 3485

Dependent Variable Encoding:

Original Value	Internal Value
0	0
1	1

	Value	Freq	Parameter Coding (1)	(2)	(3)
NUNUSERV					
	0	1086	.000	.000	.000
	1	908	1.000	.000	.000
	2	916	.000	1.000	.000
	3	575	.000	.000	1.000
NULENGTH					
	0	1401	.000	.000	
	1	1182	1.000	.000	
	2	902	.000	1.000	

Dependent Variable.. EVENTYN 1=event 0=noevent

Beginning Block Number 0. Initial Log Likelihood Function

-2 Log Likelihood 1148.8729

* Constant is included in the model.
Beginning Block Number 1. Method: Enter
Variable(s) Entered on Step Number
1.. CASESTA2 0=non-Emergency 1=Emergency
NUBLUDLO 0=100cc or less, 1=>100cc
NULENGTH 0=1hr or less, 1=1-2hrs, 2=>2hrs
NUNUSERV 0=ortho, 1=other, 2=general, 3=CVT
NUSHIFT 0=days(0700-1459) 1=non-day shift
NUTHERE 0=1-5 personnel, 1=more than 5
NOISE 0=quiet 1=normal and loud
PASSNUNY 1=75%,100% 0=0%, 25%, 50%

Estimation terminated at iteration number 7 because
Log Likelihood decreased by less than .01 percent.

-2 Log Likelihood 953.010
Goodness of Fit 3173.470

	Chi-Square	df	Significance

Model Chi-Square	195.863	11	.0000
Improvement	195.863	11	.0000

Classification Table for EVENTYN

Observed		Predicted 0	Predicted 1	Percent Correct
0	0	3349	0	100.00%
1	1	136	0	.00%
			Overall	96.10%

---------- Variables in the Equation ----------

Variable	B	S.E.	Wald	df	Sig	R	Exp(B)
CASESTA2	-.0669	.3205	.0436	1	.8346	.0000	.9353
NUBLUDLO	.5954	.2551	5.4487	1	.0196	.0548	1.8137
NULENGTH			25.4744	2	.0000	.1367	
NULENGTH(1)	1.8120	.4526	16.0299	1	.0001	.1105	6.1225
NULENGTH(2)	2.4115	.4806	25.1737	1	.0000	.1420	11.1511
NUNUSERV			23.6415	3	.0000	.1239	
NUNUSERV(1)	.8184	.3702	4.8881	1	.0270	.0501	2.2668
NUNUSERV(2)	1.2798	.3449	13.7691	1	.0002	.1012	3.5958
NUNUSERV(3)	1.6332	.3454	22.3575	1	.0000	.1331	5.1205
NUSHIFT	-.3622	.2923	1.5356	1	.2153	.0000	.6962
NUTHERE	-.2819	.2294	1.5107	1	.2190	.0000	.7544
NOISE	.1418	.1885	.5658	1	.4519	.0000	1.1523
PASSNUNY	-.5722	.2208	6.7175	1	.0095	-.0641	.5643
Constant	-6.0324	.5152	137.0974	1	.0000		

13.7 Number of OR injuries/contaminations reported to the Employee Health Department at The Providence Medical Center