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An Evaluation of Needleless Intravenous Therapy Devices

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AN EVALUATION OF NEEDLELESS INTRAVENOUS THERAPY DEVICES

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An Abstract presented to the Faculty of the Graduate School of Lindenwood College in Partial Fulfillment of the Requirements for the Degree of Master of Science Health Care Administration

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ABSTRACT

As the number of persons infected with bloodborne diseases continues to increase, it is paramount that all health care workers exhibit behaviors reflecting unerring compliance with universal precaution.

The majority of occupational exposures to potentially infectious blood and body fluids occur via needlestick injury. The morbidity and mortality from these exposures is significant. A review of research examining work practices mandated by the Bloodborne Pathogen Standard challenges their effectiveness. Principles identified provide insight into why work practice may not prevent needlesticks.

Several industries are developing new products to address this situation, but there are few data on how well these devices will reduce the risk of exposure and whether they will be cost effective. This study was undertaken to evaluate the impact of "needleless" intravenous IV systems on needlestick exposure and to determine if the installation of these new methods could be justified.

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A Culminating Project Presented to the Faculty of the Graduate School of Lindenwood College in Partial Fulfillment of the Requirements for the Degree of Master of Science Health Care Administration

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Prepared For Dr. Betty Lemasters

CHAPTER 1: DESCRIPTION OF THE PROBLEM

Statement of Purpose

Many devices have been recently introduced for the purpose of permitting intravenous injections without the use of needles. Medical suppliers are promoting these as a method of drastically reducing the possibility of disease transmission through Needlestick Injuries. However, there is little data which documents product effectiveness in relation to the overall problem in relation to its cost. This study will evaluate the efficacy of two needleless IV therapy devices in decreasing the overall number of Needlestick Injuries (NSI) in health care workers.

Setting

Health Care Workers (HCWs) are at risk for exposure to many different bloodborne illnesses such as Hepatitis B Virus (HBV). and Human Immuno Deficiency Virus (HIV) in the workplace. The CDC

estimates that 12,000 HCWs will develop occupationally acquired HBV every year and 200-300 of these infected workers will die. To date, forty HCWs have become HIV positive after occupational exposure to HIV with no other HIV risk factors. (Federal Register 2/13/92). While Human Immuno Deficiency Virus (HIV), the biological agent that causes AIDS, is transmitted primarily through sexual contact or intravenous drug use, it poses a threat to anyone with unprotected exposure to blood or body fluids. The Hepatitis B Virus (HBV) has an even greater potential for transmission in the work place setting than HIV (CDC, Recommendations ... HIV, 316).

There is a class of occupational injury within the health care industry called Needlestick Injuries which have recently received a good deal of highly warranted attention. These are accidental skin punctures which usually occur in the process of making injections or recapping needles after use. The Center for Disease Control reported that eighty percent of occupational exposures to the blood and body fluids of an HIV infected individual occurred via a needlestick (Marcus, 1122).

There are many effects and side effects to this phenomenon which manifest themselves in both physical and psychological ways. Lost man-hours within the industry are frequently the result of illness caused by bloodborne diseases. At least some of the nurses who are currently leaving the profession do so because of the fear

of catching a life threatening illness as the result of an occupational accident or exposure. The potential for occupational exposure to bloodborne diseases is an alarming and real threat for all Health Care Workers (HCWs). As the number of persons infected with blood-borne diseases increases, it is critical that all health care workers and institutions do whatever they can to alleviate the problem, but care must be taken that remediation be done in the most cost effective methods possible, or valuable resources will be channeled in the wrong direction.

Background and history

Prior to the advent of HIV/AIDS, Needlestick Injuries received little attention, although they were widely known to contribute to the transmission of diseases such as hepatitis, tetanus, and syphilis, and many of these diseases are more efficiently transmitted than HIV. For example, once contact is made via needlestick with a Hepatitis B virus, a Health Care Worker has a thirty percent risk of contracting the virus (U.S. Department of Health and Human Services, 7). Severe consequences of Hepatitis B include cirrhosis of the liver, liver cancer, and even death (Levin, 1974). Contact with the HIV virus via a needle- stick, in comparison, carries less than a one percent chance of sero conversion - transmission of disease through the injection of enough viral serum to take an illness from one person to

another (Marcus, 1123). Nevertheless, the heightened concern about needlestick injuries has produced more frequent reporting of the incidence of the needlestick phenomenon. In Maki's study, the frequency of needlestick injury (NSI) increased from 69/1,000 employees in 1979 to 180/1,000 in 1988 (Maki, 376 - 377). The more frequent reporting of the incidence magnifies the seriousness of the problem and creates opportunities to develop strategies that prevent occupational exposure to blood and body fluids.

At the center being studied, thirty five percent of hospital related injuries in employees are caused by needlesticks and sharps punctures. There are approximately 800,000 needlestick injuries in the U.S. each year. Up to eighty percent of all exposures of Health Care Workers to HIV are through accidental needle-sticks. The problem may be even larger than this, however. Research examining compliant reporting behavior estimated that thirty percent to sixty percent of nurses failed to report a needlestick injury (AHC 1990; Hamory, 195; Jackson, 5).

Although documented case reports of occupational needlestick transmission do not estimate risk because of lack of a denominator, they indicate the frequency of sero conversion, the transmission of active viral serum from one host to another. As of December 31, 1991, the CDC (Morbidity and Mortality, (40), 359) reported that twenty four Health Care Workers sero converted as a

result of a percutaneous injury from an HIV infected patient. None of the injuries and resulting sero conversions occurred from contact with a solid bore needle. In comparison, four health care workers have converted as a result of HIV exposure via the mucous membrane or non-intact skin.

An additional eighteen cases are attributed to suspected occupational HIV transmission. These health care workers report no other risk factors for HIV infection, but documented sero conversion after exposure was not obtained (CDC, Morbidity and Mortality; (40),359).

The Federal Government has recognized the role which puncture wounds play in the transmission of bloodborne diseases in the Health Care Worker (HCW) environment, and through the Occupational Safety and Health Administration (OSHA) has issued a Bloodborne Pathogens Standard in the attempt to limit health care worker exposure to infection in the workplace.

Two methods to minimize employee exposure are emphasized as primary prevention strategies in the OSHA standard: work practices and engineering controls. Personal protective equipment is recommended as a secondary alternative. These strategies apply in developing a needlestick prevention program.

Engineering controls are devices that "isolate or remove the bloodborne pathogen hazard from the workplace" (Department of

Labor, Federal Register, 1991, 3910). Sharps disposal units are a frequently used device in the health care industry, and provide a barrier between contaminated, disposed needles and workers.

Work practices consist of "altering the manner in which a task is performed" (Department of Labor, Federal Register, 1991, 3910). The effectiveness of work practices relies on compliant behavior. Behaviors that are believed to increase the risk of needlestick injuries are prohibited.

Medical suppliers have seen an opportunity in the heightened awareness of the situation to introduce new technologies intended to reduce the number of exposures to needles in general which health care workers experience, and a wide variety of needleless devices have been brought to the marketplace in recent years to eliminate the danger at its source. These devices are costly, however, and the question arises as to whether the benefit involved in utilizing the new devices is really great enough to justify the cost.

Scope of the project

In November of 1993, eight randomly selected nursing units at the hospital in this study converted to a needleless system for intravenous connections.

The purpose of the project was to evaluate the cross-over needleless heparin lock (NHL) to a conventional heparin lock (CHL)

system and compare complications, sharps injuries (SIs), and cost while complying with the OSHA Bloodborne Pathogen Standards.

Phase I comprised thirteen weeks (Study group: 4 units using NHL, Control group: 4 units using CHL). Phase II, twelve weeks (Study group: CHL. Control group: NHL. At the end of the period the incidence of needle injury in the study group was to be compared to that within the control group and a determination made regarding whether the needleless IV units caused enough of a difference in the needlestick rates to justify the cost of installing and maintaining them.

Significance of the project

So many health and safety issues currently need attention that, without accurate reporting, decision makers may fail to appreciate the magnitude of NSI among health care workers. Without a full appreciation of the problem, decisions may fail to meet health care workers needs in supplying safe and effective products that prevent NSI.

The potential cost or savings from switching to a safety device can be ascertained by adding the actual savings incurred by eliminating needlestick treatment cost to the calculated cost avoidance dollars. According to experts, most safety devices are two to seven

times the cost of the products that they replace. Accidental needlesticks of health care workers occur in hospitals every day. A needlestick injury not resulting in disease transmission may incur medical follow up cost of $200 to $1,000 in addition to the resulting anguish, loss of time, and administrative cost. Current estimates are that the number of accidental needlesticks among health care workers is nearly one million annually, and many more may go unreported. Estimated cost of implementation at the instuitution under study of the needleless cannula system on a hub would be approximately one million dollars yearly. Therefore, it was very important that all areas of concern such as nursing and infectious disease, look extensively at the device itself. There is much literature available in reference to the utilization of safety devices, the attitude and behavior of the health care worker and the training program addressing the attitudes and knowledge. However, because of the lack of clinical evidence on their effectiveness, it was uncertain whether needleless devices decrease the number of percutaneous needlestick injuries sustained by health care workers (HCWs).

CHAPTER 2: LITERATURE REVIEW

A review of the literature indicates just how recently this problem of needlestick injury has been addressed and how novel the technology is. Although the systems have been in various stages of testing for a good many years, the first commercial units were only introduced in March, 1992. There are no published studies which deal with the efficacy of the equipment itself. The research which has been done has focused on three areas: prevention or reduction of needlestick risks and injuries using the new technology; the cost of the safer technology; and user perceptions regarding comfort, ease of use and effect on technique and procedure. A few of these skirt on questions of equipment utility and efficiency, but the author does not feel that any have adequately or definitively addressed the issue.

Jagger, et al, in 1990 presented a paper to the 6th International Aids Conference in which he cited that 67% of injury occurrence happened after use and before disposal. He speculated that as much as 88% of these would be eliminated by the introduction of the new technology and/or better training of personnel in the old methods and techniques (Jagger, et. al., Preventing HIV Transmission, 1990).

Cost has been addressed by two published works, but the statements and conclusions are somewhat contradictory. Chin, in 1990, projected the cost of conversion to the new technology for a typical hospital and suggested that the high prices which were then being quoted would hinder widespread use of the equipment (Chin, Sato and Mann, 6). Once the equipment had been introduced, however, and prices had been finalized, the American Journal of Infection Control was able to report in late 1993 that an overall cost reduction had been effected of $1.85 per IV setup within eight months of the installation of the new devices. The issue of cost has also been addressed by Congress. In a Report to Congress on needle-stick injuries presented to the House of Representatives by Senator Stark (D. CA) in March, 1993, it was noted that the incremental cost of installation of needleless devices varied greatly by device and also by institution. It tended to be around two to five times the cost of standard equipment, but in one case a study device was actually $.04 lower per use than the standard product in use at the institution. This same device was shown to cost $.46 more at a different institution and was found to be not acceptable to the staff. Still another device and differing institution were found to be eighteen times more costly. In this report, factors which influenced the wide variations in incremental costs included base pricing for the existing devices, the need to add additional equipment to make the

safety devices work more effectively, and the choice of products selected from within a product line, where such options were available (Jagger, Hunt , Pearson, 586 - 587.).

More work has indeed been done, regarding ease of use and user perceptions. As early as 1987, Brennan evaluated experimental needleless devices already set up in Great Britain as a method for eliminating those needlestick injuries associated with recapping and found it to be a very effective one (Brennan, et. al., 295)

There have also been many unpublished internal studies done by various hospitals and institutions which document the ease of use issue.

Manufacturer supplied information indicates that at six hospitals injuries declined 16% overall and that Hepatitis B and HIV exposures declined by 30% and 23% respectively in its product efficacy testing. However, the source of the documentation and vested interest of the supplier of the information leave it somewhat suspect, and does not thoroughly investigate or account for the role of the safer devices as opposed to the changes in awareness level among the nursing staffs involved.

At New York University (1993) it was noted that the safety of a device was influenced by whether the safety feature was passive or active, i.e., whether or not the worker had to do something to the device to effect the safety mechanism, such as advance forward a

needle guard versus having one in place throughout the procedure. Passive safety devices, such as needleless systems or recessed needles, provided the greatest amount of worker protection. However, even with some of these systems, in some cases, needles could still be needed to access an IV part; thus safety assurance remained dependent on worker cooperation and understanding of the safety system (Yassi, McGill, 132).

Internal studies at Mercy Hospital and Ellis Hospital have indicated that their nurses reported ease of use to be one of the most highly beneficial aspects of installation of the new systems, with 98% and 89% (respectively) citing the attainment of an acceptable comfort level with the equipment within five uses. They also noted, however, that variations in hospital study designs and the cessation of evaluations in certain cases were limiting a comprehensive determination of the safety impact of all of the devices studied However, they felt it was still possible to assess the safety of IV delivery equipment and that in three out of four hospitals polled in their study, IV related injuries declined between 75% and 93.8% between the first and second half of the year. The fourth hospital reported an increase in reported IV related injuries, but this was believed to be associated with the failure of staff to properly utilize the safety systems on the equipment supplied (Yassi, McGill, 133).

CHAPTER 3: RESEARCH AND DATA COLLECTION

Health care workers have long been aware of the risk of on-the-job exposure to infectious diseases. However, with AIDS, hepatitis B, and drug-resistant tuberculosis increasing, the workplace can be deadly without the proper safeguards. For these caregivers, a split-second prick from a hypodermic needle can mean a year of immeasurable fear while they wait to see if they become infected with a disease which may end in chronic debilitation or death.

The protection of health care workers from the hazard of needlesticks has been tragically neglected. Today alone, more than 2,100 health care workers will have sustained preventable needlesticks, and 44 of them will plunge needlessly into crises and uncertainty as they begin their wait for HIV or hepatitis results (Bell, Feb. 1992, 6).

Current estimates are that 800,000 accidental needlesticks occur each year. Over 50% of these are caused by unnecessary needles., that is, needles used to access intravenous equipment. In a recent report, a University of California at San Francisco professor disclosed that 22 percent of medical students and 15 percent of dental students were accidentally exposed to blood last year. Approximately 15 percent of all nurses receive accidental needlesticks

each year and, in one hospital, eight percent of all employees sustained a needle injury in one year (Jagger, Preventing HIV transmission. Sixth International Conference on AIDS).

Experts estimate that half of the needlestick injuries could be eliminated with the use of improved devices which minimize exposure to contaminated needles. Many new products have been introduced into the market that attempt to make devices with needles safer. Each of these contains a manufacturer's claim of the efficacy of the device.

A device that eliminates the needle hazard altogether is the needleless intravenous (IV) system. This device allows for administering medication or drawing blood, and injection cap system. Either a reflux valve system or a blunt plastic cannula with injection adapter are available but are not yet in widespread use due to a higher price for safer devices as compared to conventional needles.

In a study conducted by the New York State Department of Health in 1991, after implementation of devices using safer technologies, the number of sharps-related injuries decreased 30.8 percent and IV related injuries decreased 75-93 percent. Data gathered by Dr. Janine Jagger, et. al, at the University of Virginia suggest that "88 percent of needlesticks could potentially be eliminated by product redesign or substitution." (Jagger, J, Hunt, E.H., and Pearson, 162)

The cost differential

Many health care facilities have not adopted this equipment due to the cost involved. As an example, for a hospital to transition to a needleless IV system can cost as much as $10,000 for each 100 beds. Currently, IV systems with safety devices can cost as much as 2.5 times to 6.5 times the current market rate for devices without safety features. However, if a hospital converts to a needleless system for IV administration, the total needlestick reduction rate may be as high as 73 percent with a total cost impact of $4,366 in savings (Frummond, Stoddart, Torrance, 198).

What may not be apparent to health care facility administrators is that the cost of one needlestick resulting in HIV infection exceeds the average cost of converting one hospital to a needleless IV system. For example, the estimated average cost of treating just one person with AIDS is $102,000, while the cost of converting an average 300 bed hospital to a safer device is only $31,000.

As to other types of needle devices, which are often referred to as "sharps," much progress can also be made. Presently, the annual cost of producing one safer "sharp" device is approximately ninety cents per needle. However, with mass production, manufacturers estimate the production of this safer needle device to drop to just fourteen cents (Drummond, 197).

This study will evaluate the efficacy of two needleless IV therapy devices' efficacy in decreasing the overall number of needlestick injuries (NSI) in health care workers and the attendant impact on hospital costs.

Research model

The research model selected for this project is the action/applied research model. It was chosen because it is a change-oriented endeavor. The need for an effective intervention for needlestick prevention technology on injury prevention and on hospital cost is clear. Prevention of occupational exposure, especially through needlestick injuries, is therefore an important public health priority. Among the factors that influence injury rates are changes in reporting patterns, equipment, procedures, and patient census, as well as staffing patterns and turnover and educational initiatives. For these reasons, perhaps the most valid and reliable injury rate is one that is device specific, as it is least subject to external influences and affords the opportunity to evaluate the effectiveness of a particular intervention by comparing pre- and post- implementation data.

Objective, Goal, and Intervention

To determine the impact of Needlestick prevention technology on injury prevention, **the goal** is that within a six month period, IV

line related exposures in the study group will decrease from 28 percent of all the sharps exposures in the year prior to implementing the NLS to 7%. Thus, about one quarter of all Health Care Worker exposures to bloodborne pathogens can be eliminated by this new technology.

Proposed: There are several indicators that can be used to assess the impact of safer technology on needlestick injuries. These include: (1) incidence data on total sharps-related injuries; (2) injuries by the category of procedure (i.e., phlebotomy, IV-related) or type of equipment (i.e., IV catheter, needle/syringe); and (3) injury rates that are device-specific (i.e., based on the number of injuries per devices purchased or used. The study was also conducted (4) to determine within the study group the impact of implementing a safer technology on hospital costs, considering both the incremental costs of the change in the technology and the costs avoided in injury reduction pre- and post- intervention.

Within a six month period, the total needlestick reduction rate will be as high has 75%, with a total cost impact of $4,366 in savings.

To assist in this analysis, divisions were requested to provide specific cost, volume, and frequency data related to their experience during the project. This was analyzed using the technique known as cost-effective analysis to determine economic efficiency (Mauskauph., Bradley, and French, 691 - 698).

Intervention

Description: Over 800,000 needlestick injuries occur each year in the United States (Jagger, Preventing HIV transmission, 6th International Conference on AIDS). Such events are an important source of occupational injury and frequently result in exposure to bloodborne pathogens, such as hepatitis B virus (HBV) and human immuno deficiency virus (HIV). Studies have shown infection to occur following 6-30% of HBV exposures and 0.4% of HIV exposures, and can result in disease, disability, and death (Marcus, 1118; Bell, 1992. and Centers for Disease Control, "Recommendations for protection against viral Hepatitis", 34).

Data from this study enabled projection of the volume of reported needlestick injuries in New York State. It is estimated that more than 23,000 such events are reported in hospitals each year, of which almost 2,000 are believed to represent exposure to HIV. These injuries alone conservatively cost $8.6 million (Jagger, Hunt and Pearson 586). These estimates do not account for injuries that occur in other settings where health care is provided or injuries that go unreported. Prevention of occupational exposure, especially through needlestick injuries, is therefore an important public health priority.

Historically, strategies to prevent needlestick injuries have focused on modifying worker behavior and work practice controls.

Such efforts have achieved limited success. More recently, injury prevention has been targeted to controlling the hazard through modification of needled devices. As a result, a plethora of products have emerged. These devices have not been subjected to clinical scrutiny to determine how well they work, their overall acceptability to workers, and the degree to which they impact on safety and on hospital cost. The pilot study presented here is an innovative attempt to examine two issues, product efficacy and both incremental cost to the change in technology and the costs avoided in injury reduction.

This study covers the period from November 1, 1993 through March 31, 1994. It was an offshoot of a longer investigation, whose results provide a basis for comparative analysis.

The following describes the manner in which the pilot study was approached within the Department of Infectious Disease and how each participating nursing division selected its own study population and study device(s). Ultimately, this represents not one individual hospital study, but rather eight individual studies from which common information was aggregated where appropriate and otherwise handled as separate data.

Divisions: All divisions in the hospital were notified about the study by letter and invited to request an application packet. Twenty-

six divisions were subsequently sent application materials, and fifteen submissions were received. Each of the applications was individually read and rated using pre-established criteria. The selection process took into consideration the overall quality of the application and institutional ability to implement the study, as well as divisional size and degree of high risk (Jacobson, Burke, and Conti, 101). Ultimately, a greater proportion of high risk divisions, particularly units, were represented among the selected facilities. Nursing stations with less than thirty beds and intensive care units with less than fifteen beds were not included due to insufficient responses and limited volume of needlestick injuries, which would have made it difficult to observe an impact on injuries during the study period.

Among the criteria for participation was a requirement that each division have a multi-disciplinary committee to guide the study internally. Required membership included nursing, infection control, employee health and safety, administration, materials management, and representation from areas that would be using the study devices. These committees were intended to help study design and provide divisional support. (Fishman, Cathers, and Stamp, 37). The information collected by the divisional support personnel was centrally gathered and evaluated by the researcher. With the selection of the pilot divisions, a study group was formed.

As part of the oversight function, site visits were conducted to assess progress and provide support and technical assistance. These visits were mutually beneficial in that they demonstrated the level of commitment to the project as well as offering insight on the functional issues associated with the study devices.

The selected divisions which participated in this pilot study were entitled to be paid special reimbursement rates, cover reasonable costs incurred for the purchase and use of needlestick preventive and other related devices. Budgets were requested estimating both costs and volumes of anticipated device usage. Other costs, such as administrative support by the divisions, were considered to be "in kind" contributions.

Study Devices: Devices for possible inclusion in the study were identified through contacts with manufacturers and information offered by several organizations. A list of devices was subsequently compiled and distributed to divisions with the application packets. At the discretion of the researcher and the project site contact, devices for study were targeted to: 1) procedures associated with a high volume of needle use and 2) procedures associated with a high frequency of sharps injury. These include delivery of intravenous (IV) medications, administration of injections, withdrawal of blood through phlebotomy, and insertion of IV catheters.

Each division selected a device or devices for study based on its experience with needlestick injuries, presence of existing safety equipment, and interest in a particular safety design. A total of fifteen products were accepted for evaluation; however, one safety syringe with needle guard was never introduced because the manufacturer stopped production of the product. The remaining fourteen devices included: six devices for IV delivery, including two alternatives to the use of needles for accessing IV sites, and four recessed needle devices; two syringes with needle guards; two vacuum tube assemblies; two safety needles, one for injection, the other for phlebotomy; one winged steel needle; and one safety IV catheter (Jagger, Hunt, and Pearson, 584).

Study Design: The broad design for the pilot study consisted of two primary components; 1) a product evaluation which included a brief pilot period to determine general product acceptability of the study device followed by a period of broader implementation, and 2) an impact evaluation consisting of a prospective data collection on all sharps related injuries within the divisions. There are divisional variations in how this basic design was carried out, particularly as it relates to the product evaluation component of the study. Factors contributing to this variation included appropriateness of a particular approach for the study device, and personnel and fiscal

resources to carry out the project. In addition, in cases where the initial pilot evaluation failed a device, the evaluation of that particular device in the division was terminated.

As part of introducing each product, around-the-clock inservice education was provided. This was usually carried out by manufacturers' representatives and/or the researcher.

Data Collection Plan: Instruments for data collection were developed and refined by the co-investigators. Two instruments were utilized; one for product evaluation data, the other for injury data. The product evaluation form (Appendix A) consisted of twenty questions designed to elicit quantitative and qualitative information on the experience with the study devices. Issues focused on included: ease of use; effect on procedural technique; number of times it took to become comfortable using a device; need for education prior to use; impact on waste volume; packaging effectiveness in promoting sterility and providing directions on product use; whether use of a product was affected by the urgency of the procedure performed; and whether the user would recommend the study device over the one it would replace. For greater specificity, space was provided to solicit user comments. A Lickertt scale was used as the basis for establishing the majority of quantitative responses.

The questionnaire on injury incidence (Appendix B) sought to identify: who sustains sharps related injuries; when and where such injuries occur; the specific devices associated with sharps related events; and. when during the use of sharps do injuries take place (i.e., before, during, or after a procedure). Included in the questionnaire is information about "downstream" injuries. These are defined as sharps injuries that occur after use, i.e., those that are related to sharps in the laundry or trash.

Both forms omit any reference to the Department of Infectious Disease or the pilot study in an effort to avoid biasing the respondent. Divisions were free to add information they felt was necessary for institutional purposes.

Product evaluation forms for each device were distributed by contacts in each division towards the end of a study period, either the pilot or the broader evaluation, and completed by staff who were using the study products. Upon completion, they were returned for data entry.

The sharps related injury form was completed by the victim, often with the help of a divisional contact, at the time of a reported injury. This data was also returned to a central point for entry.

Data Management EPI INFO software was utilized to facilitate the collection of study information. Data entry programs were created

staff and distributed to participants. Disks were then sent to the researcher upon conclusion of the study for entry into a common data base.

Cost Analysis: As part of the study mandate, information was required which would enable assessment of the cost-effectiveness of the various study devices. To facilitate this process, divisions were asked for the following: 1) costs associated with the purchase of study devices and the volume of study devices used; 2) detailed costs, and frequency with which they were incurred, associated with the management of blood exposures, including immunobiologics (i.e., vaccines) and medication (i.e., ZDV), laboratory costs, personnel time for source patient and employee evaluation, counseling, testing and time off work for the employee groups known to be at risk for needlestick injuries. This information was aggregated and analyzed according to the most widely recognized methodology (Detsky and Naglie, 147-154).

CHAPTER 4: RESULTS, CONCLUSIONS, AND RECOMMENDATIONS

Needlestick injury continues to be an important, preventable problem in the health care industry. Great expense, time, and effort have been spent on equipment and or education of health care personnel in an attempt to reduce the number of exposures from sharp devices - such as needles, lancets, and scalpels - and the related risk of acquiring bloodborne disease. The fear and risk of exposure to acquired immuno deficiency syndrome and hepatitis B are real (Boland, and Gerbert, Maguire, Badnes and Stone, 266). Although some studies have shown that the actual risk of acquiring AIDS in the health care setting is small (Gerberding, Littell, Tarkington, Brown and Schecter, 1789), the risk of acquiring hepititis B is much greater. The Occupational Safety and Health Administration estimates that about 300 deaths per year occur from hepititis B. A minimal risk of acquiring acquired immuno deficiency syndrome, however, is of little comfort to an employee who suffers an exposure to a contaminated sharp device.

The medical supply industry has been taken to task for failing to develop better devices at a reasonable cost to protect the health care worker (Jagger, Hunt, Brand-Elnaggar, and Pearson, 285). Several

industries are developing new products (Rosenbaum, 6), but there are few data on how well these devices will reduce the risk of exposure and whether they will be cost effective. This study was undertaken to evaluate the impact of a "needleless" intravenous (IV) system on needlestick exposures in our institution and to determine if the increase in cost of the new system could be justified.

Summary of Results

Investigation of the needlestick prevention technology on injury prevention reveals there are several indicators that can be used to assess the impact of safer technology on needlestick injuries. These include (1) incidence data on total sharps-related injuries; (2) injuries by category of procedure (i.e., phlebotomy, IV-related) or type of equipment (i.e., catheter, needle/syringe); and (3) injury rates that are device specific (i.e., based on the number of injuries per devices purchased or used). Among the factors that influence injury rates are changes in reporting patterns, equipment, procedures, and patient census, as well as staffing patterns and turnover. Divisional differences in how injuries are categorized also will influence how data are interpreted in and among divisions. For these reasons, perhaps the most valid and reliable injury rate is one that is device-specific, as it is least subject to external influences and affords the

opportunity to evaluate the effectiveness of a particular intervention by comparing pre- and post-implementation data.

In most divisions, information that would permit calculation of device-specific injury rates is not readily available. All of the participating divisions had sharps-related injury data for three to four years prior to participating in the study, and most could categorize their injuries by type of equipment or procedure. However, the lack of a standardized approach for categorizing such injuries and calculating injury rate resulted in divisional variations which made comparisons difficult. (This is not unique to this experience.) In addition, none of the institutions had detailed information which would allow device-specific rate calculations pre- and post-intervention (i.e., number of needlestick injuries per 100,000 devices purchased or used).

Additional factors limiting this impact analysis were instances of premature cessation of evaluation programs because of product failures, and limited time to assess impact when studies were performed. However, there is a body of information collected through this study that reflects important trends in injury prevention, and serves as a surrogate for a more precise method of analysis. This information is presented as a description of participating divisions' experiences. Because the information is considered sensitive, specific identifiers have been eliminated.

Effect of New Technologies on Division A

Division A implemented a unit-wide needleless IV system during 11/93 - 4/94, and studied syringes with needle guards on selected applications as part of the pilot project. In the two years preceding the introduction of the safer technology, Division A observed a small decline each year in reported sharps-related injuries; 4.5% during 1991 and 3.0% in 1993. During 1992, this division's number of sharps-related injuries dropped 28.6% (See APPENDIX C).

When reported needlesticks during 11/93 were categorized by type of device, and the first and second halves of this study period were compared, the actual number of injuries increased in the second half (Figure 1.1). This increase was limited to three injury categories; injection procedures, phlebotomy, and "other." The number of injuries related to IV delivery remained relatively constant during the six months and were a small proportion of the sharps-related injuries (9.3%) This is presumably the effect of the safer IV system implemented. The number of injuries related to IV stylets was also small.

It is possible that two things happened in this division which may be reflected in conflicting trends. First, the decline in the number of sharps-related injuries between 1992 and 1993 is likely to be a direct result of the safer IV delivery system. This is supported by

Effect of New Technologies on Division A

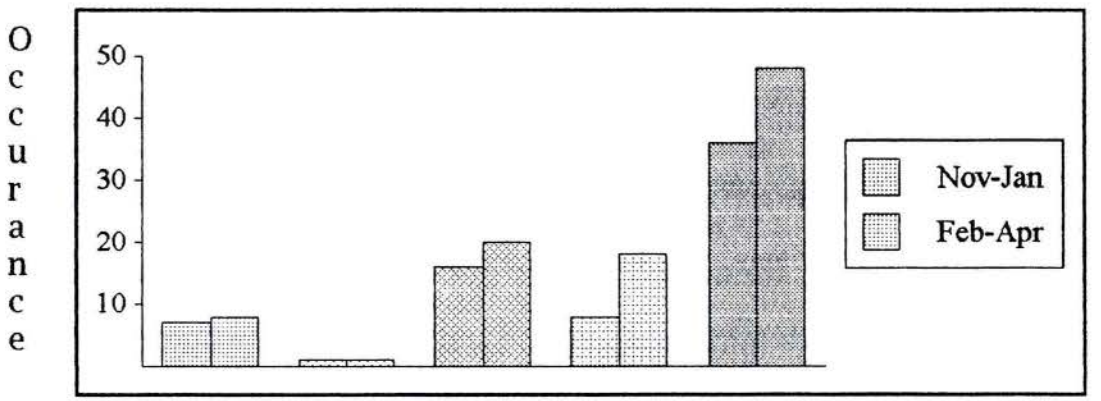
Division A implemented a unit-wide needleless IV system during 11/93 - 4/94, and studied syringes with needle guards on selected applications as part of the pilot project. In the two years preceding the introduction of the safer technology, Division A observed a small decline each year in reported sharps-related injuries; 4.5% during 1991 and 3.0% in 1993. During 1992, this division's number of sharps-related injuries dropped 28.6% (See APPENDIX C).

When reported needlesticks during 11/93 were categorized by type of device, and the first and second halves of this study period were compared, the actual number of injuries increased in the second half (Figure 1.1). This increase was limited to three injury categories; injection procedures, phlebotomy, and "other." The number of injuries related to IV delivery remained relatively constant during the six months and were a small proportion of the sharps-related injuries (9.3%) This is presumably the effect of the safer IV system implemented. The number of injuries related to IV stylets was also small.

It is possible that two things happened in this division which may be reflected in conflicting trends. First, the decline in the number of sharps-related injuries between 1992 and 1993 is likely to be a direct result of the safer IV delivery system. This is supported by

evidence that the proportion of IV related injuries in this category was small when compared to averages reported in the literature. Secondly, it can be speculated that the attention given to needlestick prevention in general, and to the need for injury reporting in particular, resulted in an increased reporting trend in the second half, creating the increase in specific injury categories. Without additional detail, it is not possible to identify the factors that influenced this outcome.

Figure 1.1: **Procedure Related Injuries for Division A**



IV Delivery/IV Insertion/Phlebotomy/Injection/Othery

Effect of New Technologies on Division B

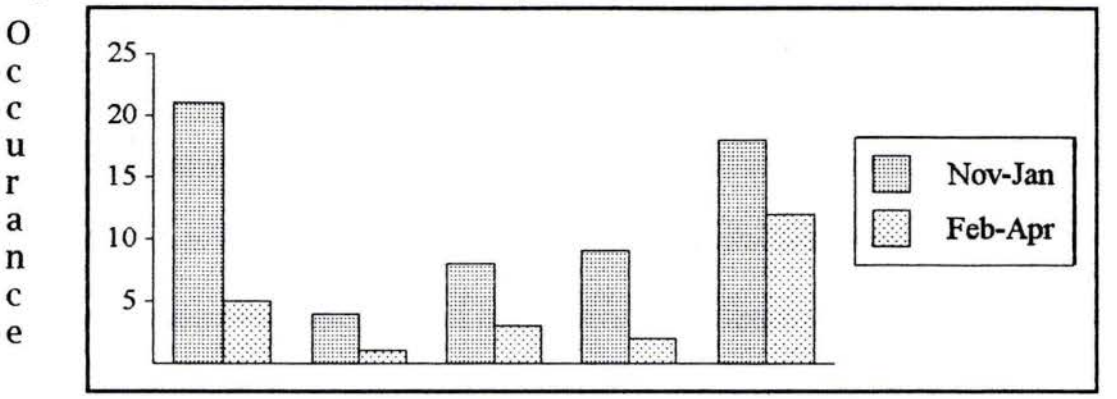
The trend in the number of sharps-related injuries from 1991 to 1993 for division B is similar to that of division A. The number of injury reports declined 5.3% in 1993 and 3.0% in 1994. With the introduction of a recessed needle for IV piggybacks early in November, 1993, followed by implementation of a needleless system for

heparin locks in November, 1993, the number of sharps related injuries declined 29.7% (See APPENDIX C).

When injury data for the first and second half were compared, declines in all procedure related categories were observed (figure 1.2). In particular, a decrease of 77.3% in IV related injuries is believed to be directly related to the introduction of the safer IV system. Had the division also assured that "flushes" and administration of medication were handled through a needleless approach, four additional injuries could have been prevented and the decline would have reached 86.4%.

The reason for decreases in the other procedure categories in the absence of a specific intervention is unclear. It can be speculated that the Hawthorne effect was operative and that heightened awareness of injury prevention brought about by the study may have contributed to the staff being more careful. It is also possible that the availability of the safer IV delivery system resulted in less access with other needled devices, although this is unlikely since needles attached to syringes continued to be used for "flushes" and most likely for other procedures as well.

Figure 1.2: **Procedure Related Injuries for Division B**



Effect of New Technologies on Division C

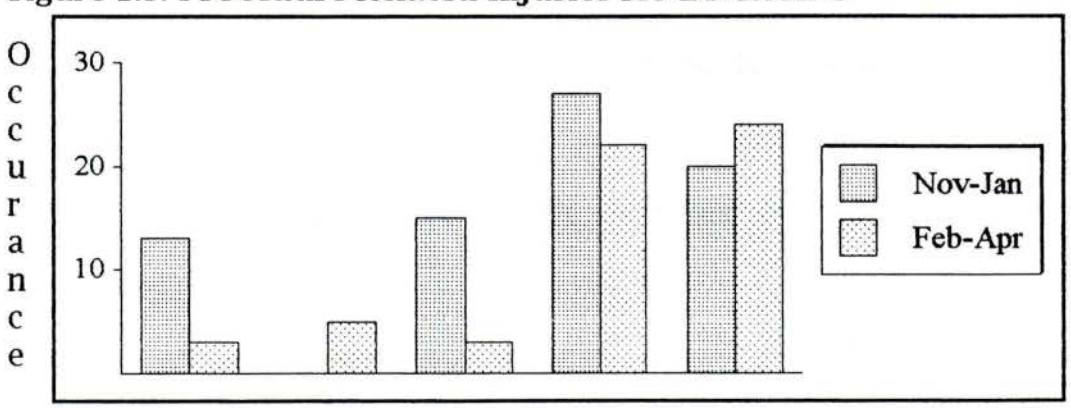
Sharps-related injury trends for Division C differed from the previous two divisions described. In this division, between 1991 and 1993, the number of reported injuries was rising dramatically; 148.5% in 1991 and 70.7% in 1992 (figure 1.1). During 11/93-4/94, the division implemented a safety syringe and recessed needle for IV delivery (piggyback and heparin lock devices) throughout the division as part of the pilot study. Reported sharps-related injuries during this time frame declined 28.6%, and is believed to be directly attributable to the safety intervention.

When six month comparisons were made (figure 1.3), there were declines in three procedure categories; IV delivery, phlebotomy, and injection. Injuries related to IV delivery equipment declined 75% and injection related injuries by 30.4%. When the factors that contributed to injuries in these two categories were examined, it was

determined that nine of sixteen injection-related injuries could have been prevented if the safety device had been used properly (4) or if the devices were truly available (5). Of the two IV related injuries, one was considered non-preventable, the other could have been prevented if the safer IV system had been implemented in all circumstances (this may not always be possible, however).

It is interesting to note that phlebotomy related injuries also declined by a sizable proportion, 80%, in the absence of an apparent intervention. There are a number of possible reasons for this. As speculated before, increased safety awareness because of the study could have influenced how devices were handled and used for withdrawing blood, the safety syringes would have had an impact on phlebotomy injuries as well.

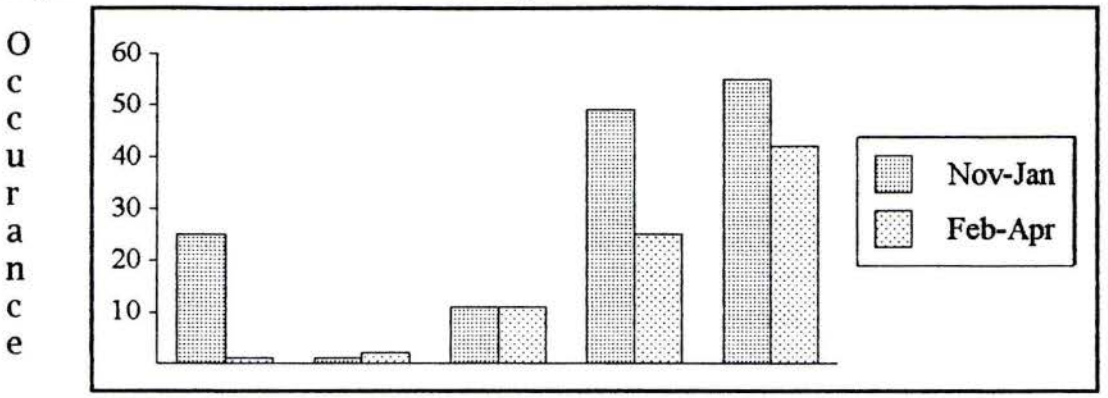
Figure 1.3: **Procedure Related Injuries for Division C**



Effect of the New Technologies on Division D

The injury experience of division D provides an opportunity to observe the benefit of detailed injury data. Between 1991 and 1993, this division experienced yearly declines in sharps-related injuries (APPENDIX C). This was seen most dramatically in 1992, when reported injuries declined 20.4% following an extensive needlestick prevention education campaign. During November, 1993, as part of the pilot study, a needleless system for heparin lock and piggyback sites was introduced division-wide. When sharps related injury data for April, 1994, was compared to the previous year, the decline in injuries was less than dramatic, 2.6%. However, when procedure-specific data for the first and second halves were compared, the impact of the safety intervention became readily apparent; injuries related to IV delivery dropped 93.8% (figure 1.4). (The one IV related injury that did occur was not preventable.) In addition, a 52.7% decline in reported injuries associated with injection equipment also may have been related to the safer IV system since needles (but not syringes) could no longer be used for "flushes" and administration of medication.

Figure 1.4: **Procedure Related Injuries for Division D**



IV Delivery/IV Insertion/Phlebotomy/Injection/Other

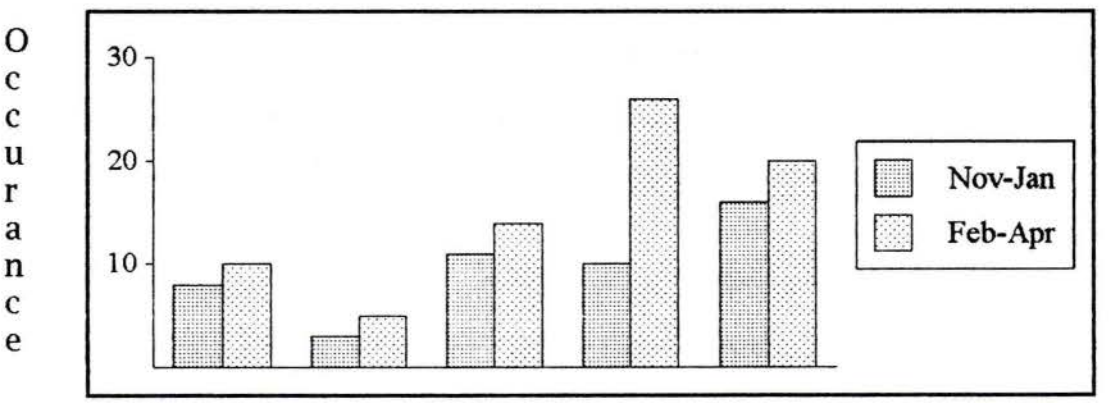
Effects of the New Technologies on Division E

Sharps-related injury trends in division E provide yet another experience that differs from other divisions. The overall pattern between November, 1993 and April, 1994 is one of initial decline (25.3% in December, 1993, a leveling off in January, 1994 by 2.2%, followed by a 30.7% decline in the remaining months of the study) (APPENDIX C) The first impression is that there was an important impact on injuries during the six months of the pilot study. However, when procedure-specific injury data was examined, it became obvious that a reverse trend occurred in the second half of the study (figure 1.5).

No device was implemented division-wide as part of the pilot study; safer phlebotomy devices were evaluated, but only in a limited number of locations. However, the division did implement a needleless IV system division-wide in February, 1994, and had introduced a "safer" phlebotomy holder throughout the division in

January, 1994. During the second half of the pilot, reported procedure related injuries rose in every category. This was most apparent in the area of injection related procedures, where reported injuries more than doubled. This overall trend is believed to be a shift in reporting trends, but it does not account for the 30.7% drop in reported injuries from the previous year. Further investigation is necessary to understand the characteristics of injuries and injury reporting in the division.

Figure 1.5: **Procedure Related Injuries for Division E**



Effects of the New Technologies on Division F

Division F is a large medicine and respiratory unit that reported injury data from two sites, designated as F-a and F-b. As part of the pilot study, a recessed needle for IV piggybacks was evaluated on each nursing unit; widespread implementation was not planned and no appreciable division-wide impact on IV related injuries was anticipated.

At site F-a between November, 1993 and April, 1994, reported sharps-related injuries rose initially by 41.8%. This was followed by small declines of 6.8% and 4.4% the following two months (APPENDIX C). At this site, procedure related injuries fluctuated between the first and second halves of this study. Reported injuries related to phlebotomy and injection, as well as those categorized as "other," rose 47.8%, 73.3%, and 128.6%, respectively (figure 1.6) However, injuries related to IV dropped 90.9%, and those related to IV delivery by 13.9%. There was no explanation for these changes.

At site F-b, a slightly different trend was observed. Data on six months of reported sharps-related injuries was available which reflected a rise of 30.8% in November and December, 1993, followed by a decline of 27.9% in January-April, 1994 (See APPENDIX C). Six month comparisons during the same time frame also showed differences in the epidemiology of needlesticks at the two sites; at this site, declines in injuries associated with injection and "other" types of sharps were observed, while IV and phlebotomy injuries increased (figure 1.7). However, there were only two injuries related to IV catheter insertion reported during the entire study.

The unique difference in these two sites, when compared to the divisions already discussed, is the high proportion of injuries related to IV delivery (25.6% at site F-a, 38.8% at site F-b) in comparison to the proportion of injuries in this category seen in the other

divisions. While the significance of this finding will be discussed later in this section, it is worth noting here that this is the only division of the eight discussed that did not have some type of system division-wide for safer IV delivery.

Figure 1.6: **Procedure Related Injuries for Division Fa**

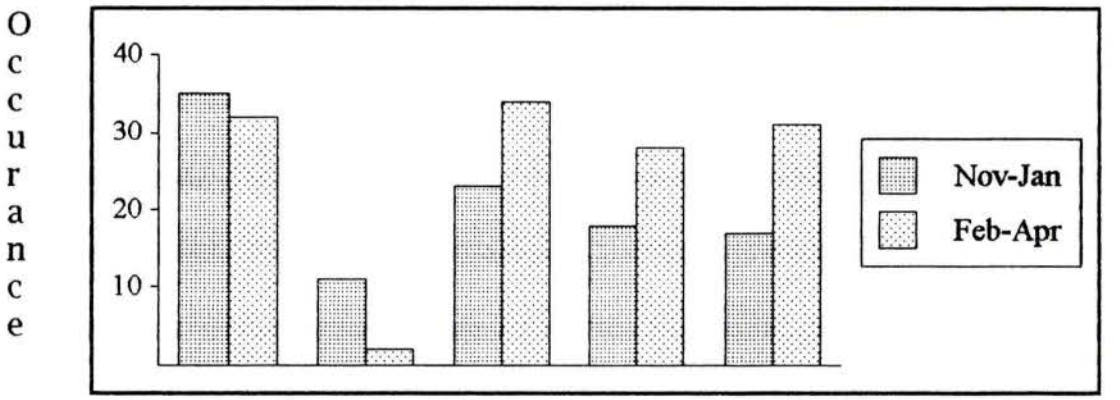
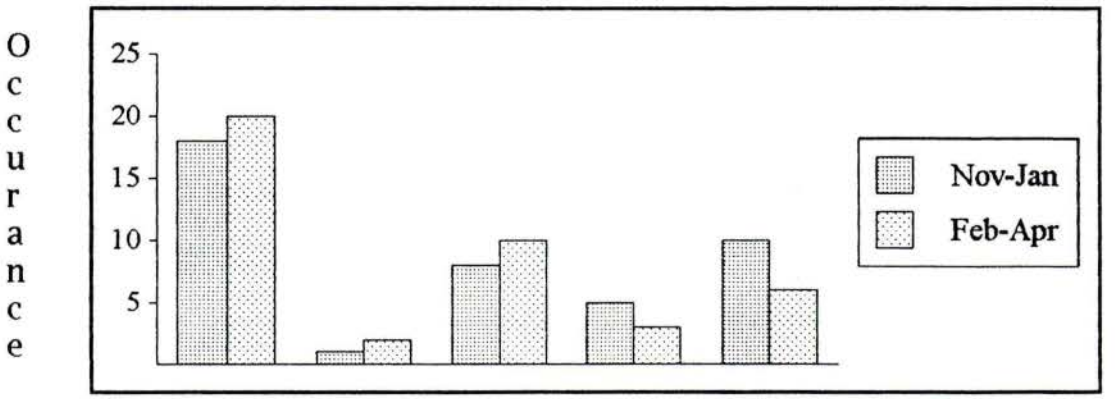


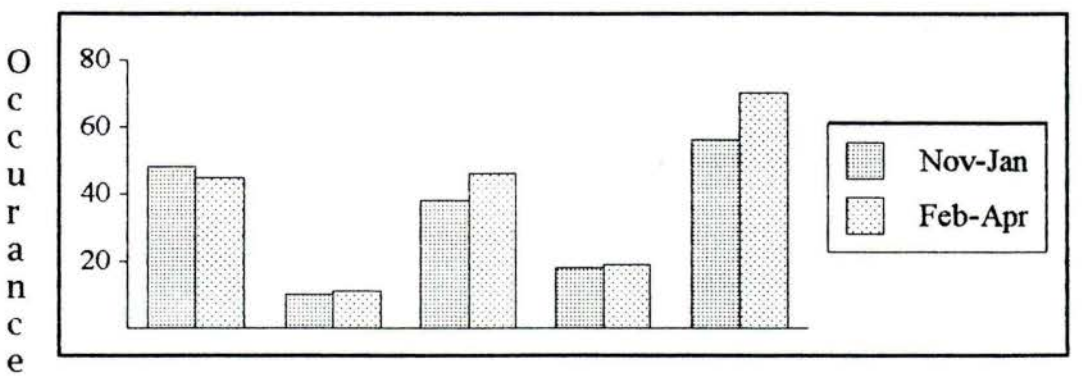
Figure 1.7: **Procedure Related Injuries for Division Fb**



Effects of the New Technology on Division G

Division G also did not implement a safety device division-wide, choosing, rather, to evaluate the safer IV catheter and a recessed needle on four rooms. The volume of reported sharps-related injuries in this division are the highest of any division included in the study. This was particularly true for January-April, 1994 (figure 1.8). The three month comparisons in the institutions reflect the absence of safer devices had division-wide impact (figure 1.8). IV related injuries comprised 26.1% of the reported injuries during January-April, 1994, a proportion, as will be noted, that is considerably higher than in divisions with safer IV systems. Injection-related injuries appear to comprise a smaller proportion of reported incidents. However, in communicating with the division, it was learned that some of the injuries in the "other" category may be related to syringes with needles.

Figure 1.8: **Procedure Related Injuries for Division G**

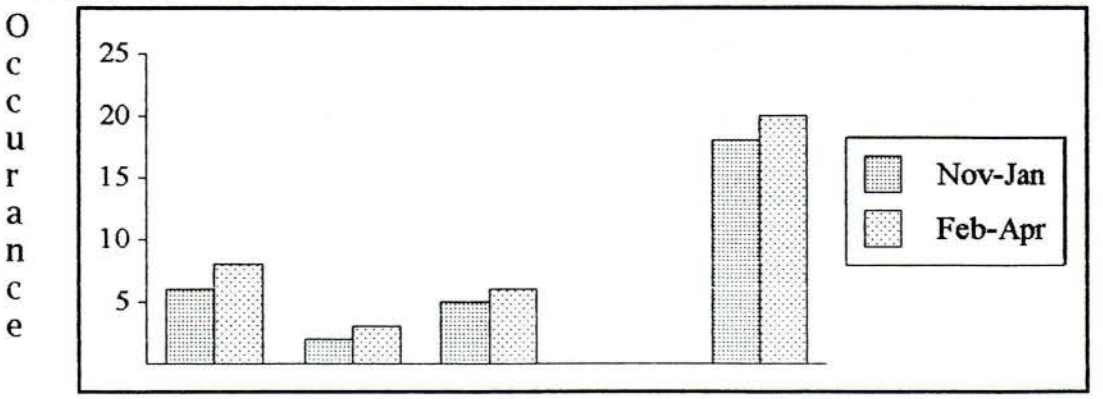


Effect of the New Technology on Hospital H

In some ways, hospital H represents a control for comparison purposes. Through no fault of one division, participation in the pilot study did not lead to widespread implementation of a safer phlebotomy device, as had been anticipated. However, the hospital had implemented a recessed needle for IV piggyback in March, 1994.

Trends in sharps-related injuries between November, 1993 and April, 1994 reflected increases of 7.8% -9.0% followed by a 22% decline in March, 1994 (APPENDIX C). Three month comparisons during the study reflected consistency in the categories of reported procedure-related injuries from the previous three months. Without further detail, one can only speculate as to the contributing factors, including the impact of the recessed needle for IV piggybacks, and increased awareness of needlesticks hazards.

Figure 1.9: **Procedure Related Injuries for Hospital H**



As noted earlier in this study, the effect of new devices by type of device and procedure, including injuries related to safety devices can continue to occur under certain circumstances. The need to use needles for phlebotomy, injection, and IV insertion, for example, presents the opportunity for injuries during procedures, if the needle cannot be continuously protected. In addition, safety devices currently available may not be applicable for all situations, thereby limiting the ability to reach the optimal impact. The question that needs to be answered is whether any of the study devices failed to function as intended and resulted in needlestick injury.

Devices

IV delivery devices. The needleless systems for IV delivery cannot cause needlesticks, and therefore were not directly responsible for any injuries reported in this category. Likewise, recessed needles that were used in the study were not associated with needlesticks. However, exposed needles can be used for accessing IV ports with all but one of the safer IV devices, and in some cases protective devices were not used for both the primary IV port and piggyback or "y" sites. Therefore, the success of the interventions relied on strategies to assure consistency in using the safety devices and assuring the availability of protective devices for all points where exposed needles could be used. In addition, as already noted, the fact

that a device is implemented "division-wide" does not necessarily mean all areas of the hospital have implemented the system. For these reasons, the potential impact of safer devices was not fully realized.

Safety syringes with needle guards. There were 15 injuries related to the safety syringes, eight of which were determined to be associated with preventable factors. These factors included: operator failure to advance the needle guard (1); failure to securely lock the needle guard (3); hand slipping while trying to advance the needle guard (2); approaching the needle guard from above the needle (1); and one instance where a second party was injured because the operator did not know how to activate the safety mechanism. As has been mentioned previously, the need for the user to activate a safety feature is an important variable that is subject to limited control.

Phlebotomy vacuum tube holders. No injuries occurred with the device that permitted ejection of the used needle (E1). With Device E2, which permitted safe recapping of a used needle, there were no injuries related to this device during the study period. However, this device had been in use for almost a year and the impetus for changing to another device included injury reports related to its use. Data were not available to characterize the problems. An important observation was that staff did not consistently utilize the safety

feature, suggesting the issue is more likely user compliance than product failure.

Safety IV catheter, safety needles, and safety winged steel needles. Evaluations of these devices involved too limited numbers of personnel and too short of a time study to adequately assess the potential for injury. However, no needlesticks directly attributed to these devices were reported.. There were reports in the evaluations of the winged steel needle of the needle guard failing to lock, but no injuries occurred as a result. Also, the boot end of the blunted phlebotomy needle failed to retract properly on occasion, causing two blood to skin exposures (these did not pose a significant risk for bloodborne disease transmission) but this was related to a manufacturing defect which is being corrected.

Divisional differences in the proportion of IV-related injuries. The availability of an eight division database containing prospectively collected sharps-related injury data using a common report form provides a useful source for hospital comparison purposes. Data on IV-related injuries for the six month period of November 1993 through April, 1994 was examined to determine whether there was a difference in injuries among divisions with and without safer IV delivery systems, the only intervention that had been introduced division-wide in this pilot study (See Appendix C)

Because rates were not available, it was decided to compare the proportion of IV-related injuries among all sharps injuries in the eight divisions. (The author's data showed that these injuries accounted for 26.7% of all injuries in one division.) It was found that in seven divisions that had safer IV delivery systems in place division-wide, the proportion of IV related injuries ranged from 1.5% to 6.6%, as compared to 20.4% to 27.9% in the three divisions without such systems in place. This pattern also held true for injuries from IV tubing needles. When data on injuries associated with hollow-bore needles was examined, in the seven divisions with safer IV systems, injuries related to needles attached to IV tubing ranged from 0 to 7.8%, as compared to 17.2 to 30.2%. in the other three institutions.

Although the use of proportions as a unit of comparison is a rather imprecise method of analysis, since it will be influenced by changes in other areas, the lack of appreciable influence related to other interventions lead to the belief that it was appropriate for use in the example. Findings from this aspect of the analysis give strength to the conclusion that IV systems are having an important impact on injuries.

Assessment of the impact of implementing a safer technology on hospital costs must consider both the incremental cost of the change in technology and the costs avoided in injury reduction. Because not all devices evaluated through this project were

implemented division-wide, or implemented for a sufficient time period to determine their impact on injury rates, the ability to fully assess cost impact is limited. In addition, because each division's experience with the needlestick injuries is unique, and costs of implementing a different technology will vary, this analysis is provided as a methodological model for conducting impact analysis rather than a definitive comparison of the prevention strategies.

To assist in this analysis, divisions were requested to provide specific costs, volume, and frequency data related to their experience during the project. Included were the costs and frequency of post-exposure follow-up (i.e., patient and employee testing, lost time, use of personnel resources, volume of study devices purchased, and other items of interest). While not all information was received or useful for this purpose, a substantial body of information proved helpful.

Cost Effectiveness Analysis

In this section of the report, some of the results of this project will be analyzed by using the technique known as "cost effectiveness analysis." Cost effectiveness analysis (CEA) is one method from among the family of cost analysis techniques which is useful for determining economic efficiency (Drummond, Stoddart, and Torrance). The method generally involves the determination of a

ratio of incremental costs to changes in outcomes, the latter being a comparable unit of measure among the various interventions under consideration. In the case of the needlestick prevention project, this cost effectiveness ratio was calculated by dividing the increment in certain medical and other costs associated with the usage of the prevention devices by the measured reduction in the number of needlestick exposures:

$$\frac{\text{Incremental costs of Devices}}{\text{\# of injuries without devices minus \# of injuries with devices}}$$

These ratios, expressed in terms of "dollars spent per injury avoided," are generally useful for making comparisons of cost effectiveness.

Data from this study allows performance of some limited, though still significant comparisons of cost effectiveness, not only between different categories of devices tested (injection equipment vs. IV delivery systems) but also between types of devices within these product categories (i.e., needleless IV delivery system vs. recessed needles for IV delivery systems).

It is important to note at the outset that different definitions of "costs" will be encountered throughout. Obviously, costs for the devices are real in terms of dollars and cents. When devices are purchased, a transaction takes place and is reflected in the books of

each division. Similarly, salaries and testing costs of treatment for an injury also can be thought of in financial terms. However, when reference is made to "cost savings" due to the avoidance of needle-stick injuries, more often this relates to the economic concept of "opportunity costs" rather than costs in the financial sense, i.e., when money is spent for one purpose, other alternative purposes are not funded.

Opportunity costs reflect the costs of foregone alternative purpose. For example, if there are ten fewer injuries because of the use of needlestick prevention devices, one can say there have been savings equal to the amount of money it would have cost to treat the injuries of ten workers. However, the effect of this "savings" is more economic than financial, and it is more appropriate to state that these dollars will be used for some purpose which had been previously foregone because of resource constraints.

While there may not be a decrease in actual expenses because of the use of the device (and indeed, it is expected that using these devices will actually increase expenses, as they are typically more costly than what they replace), there is still some savings - even if only in an economic rather than financial sense - accompanying the use of this technology.

Model analysis using data from participant projects

Data provided enabled preliminary analysis for three devices in two of the participating divisions: a syringe with needle guard and two safer IV delivery systems, recessed needles and a needleless reflux valve. For this purpose, these facilities will be referred to as Division X and Division Y. It also should be noted that data collection efforts did not account for injury reduction in activity secondary to the use of the device (e.g., reductions in injuries during IV medication administration by syringe when evaluating safer systems for IV delivery) or in so-called "downstream" injuries, such as housekeeping or transportation personnel.

Syringe with needle guard. By using a syringe with a needle guard, Division X was able to reduce its number of injuries from twenty three during the six month period prior to implementing use of the device to sixteen following implementation, for a decrease of seven injuries, or 30.4%. Projected over a year's time, the number of injuries decreased by fourteen. Using a base cost of an injury of $363, the "savings" amounts to $5, 082 (fourteen injuries times $363 per injury). The annual incremental costs of the device was projected by the facility to be $18,857. From this, however, are deducted the "savings" from not having to treat the fourteen injuries which were prevented by use of this device. Thus, the net incremental cost is $18,857 minus $5,082, or $13,775. The resulting cost

effectiveness ratio for the facility using this type of device is $984 ($13,775/14 injuries prevented). That is, the facility spends about $984 per injury avoided. It is also noteworthy that about 27% of the incremental cost of the devices is offset by the cost savings from the injuries prevented.

Recessed needles. Recessed needles is one subcategory of device used to make IV delivery systems safer. As with the injection equipment above, a similar analysis for these devices can be performed for Division X. Over a six month period, Division X estimated that it would spend $23,240 on the purchase of two types of protected needles, one type for heparin locks, the other for secondary IV sites. Six injuries were prevented during the six month period prior to implementation. Projecting twelve less injuries per year and savings of $4,356 in injury treatment costs, net incremental costs incurred were $18,884. The ratio calculation results show the facility spending $1,574 per injury prevented. Therefore, about 19% of the incremental cost of the devices is offset by the costs saved from injuries prevented.

Needleless reflux valve. Needleless systems are another subcategory of device available for safer IV delivery. Division Y's experience with a needleless reflux valve resulted in a significant decrease in injuries from sixteen during the six month period prior to implementation to only one in the following six months, a decrease of

almost 94%. Division Y estimated it would spend $67,214 per year on these devices. Using a reduction of 30 injuries per year, at a savings of $10,890 (30 injuries times $363 per injury), the net incremental cost is $56,324. Division Y thus spent $1,877 per injury prevented, and the savings from injuries prevented offset about 16% of the incremental costs of this type of safety device.

Cost effectiveness analysis for decision making, including information presented thus far can be used to make initial comparisons about the cost effectiveness of a safer device. This is particularly useful for intra-facility analysis. If a facility has performed the analysis and, assuming there is an established commitment to invest resources in needlestick preventive devices, decide in which device(s) to make its investment.

Within the context of this approach, in the IV delivery device category, recessed needle usage in Division X reduced injuries by 75% at a cost of $1574 per injury prevented; about 19% of the device costs were offset by the cost saved by treatment cost not incurred through improved worker safety. In Division Y, although the use of a needleless reflux valve resulted in a 94% reduction in injury, this was accomplished at a somewhat higher cost than with the recessed needles; also, the reduction in injury treatment cost offsets only about 16% of the cost of the needleless system. Thus, from the data in these two divisions, the recessed needle appears to be slightly

more cost-effective than the needleless IV system (That is, for a given level of cost, using recessed needles will produce greater reductions in needlestick injuries.) Given this information, a facility would need to decide which of the two devices to adopt, the one that is more cost-effective, or the one that is more injury-preventive. Alternatively, the institution may choose to seek ways to improve assurances that the more cost-effective device reaches the injury prevention potential of the more expensive device.

A comparison also can be made between injection equipment and the recessed needles for IV delivery in Division X. Syringes with needle guards reduced injuries by 30% at a cost of $984 per injury prevented: 27% of the device costs were offset by the savings from injury treatments averted. Compared to the recessed needle as it was used in Division X, in this division these syringes prove to be a more cost-effective device. (However, if the number of reported needlesticks used for baseline comparisons shifted, the outcome of the cost effectiveness result may be different). If a facility was temporarily limited in the level of resources it could commit to implementation of prevention technologies, this information may be useful in influencing its decision.

Thus far, this analysis has provided average cost effectiveness ratios - that is, at what costs are benefits (the reduction in injuries) purchased. The comparisons between device types are made here

under the assumption that no strategy is currently in place to prevent a specific type of needlestick injury. Where this assumption cannot be made - for example, if a facility has initiated an intensive education program or some other strategy (i.e., accessory devices for recapping) for which it is incurring certain costs - then the incremental costs and benefits need to be calculated between using these needlestick preventive devices and any other strategy currently in effect (Detsky and Naglie, 147-154; Doubliet, Weinstein, and McNeil, 253-256).

Another perspective for which incremental analysis proves useful is in evaluating each successively more effective device, in terms of the proportion of injuries averted. For example, one should make comparisons among systems, on an incremental cost effectiveness basis, to answer the question "are the additional benefits (i.e., needlesticks averted) worth the additional dollars for the (increasingly) more expensive preventive devices?" More specifically, needleless systems have been shown to reduce injuries by 94%, compared to a 75% reduction with the use of recessed needles, but are more expensive than the recessed needles. From a cost effectiveness perspective, is this gain in effectiveness worth the additional dollars? Assuming data from this present study, it is possible to answer this question from the perspective of Division X - as it might make these comparisons. Using the needleless systems

adopted by Division Y would cost Division X $26,700 (given the device usage reported). There would be an additional three injuries averted which accompanies such use, based on the differences between the 94% and 75% reductions observed with the two systems and using the projected 16 IV-related injuries per year as a base. Therefore, fifteen injuries would be avoided for a "savings" of $5,445, and resulting in net incremental costs of $21,255 ($26,700 -$5,445). The additional net incremental costs between the needleless system and recessed needles is $2,371 ($21,285 - $18,884) and the incremental benefit is three additional injuries avoided ($2,371/3 injuries). This ratio is obviously much lower than the ratio for the recessed needles, thus indicating a more favorable (i.e., cost-effective) strategy. Calculated in another way, we see that dividing the net incremental cost to Division X of using the needleless system ($21,255) by the projected fifteen injuries averted provides a cost effectiveness ratio of $1,417, which is again indicative of a more cost-effective strategy when compared to the ratio of $1,574 for the recessed needle strategy. At a given level of available resources, Division X would then be able to determine whether the additional benefits from implementing needleless devices in place of the recessed needles is worth the additional costs.

It should be noted that there was no attempt to evaluate cost effectiveness of devices using the higher needlestick treatment

costs that were calculated if the number of workers seeking HIV testing and ZDV treatments for exposure to known or suspected HIV positive patients was higher than reported. It was not felt that the available cost and incidence of injury data satisfactorily permits this. It can be said, however, that while the basic findings regarding the cost effectiveness comparisons between the devices would not be altered, higher treatment costs would 1) decrease the dollars spent per injury avoided and 2) result in larger proportions of device cost being offset by the savings realized from the decreased number of injuries treated. These considerations obviously make the use of these devices a more attractive option from a cost effectiveness perspective.

Other cost considerations. It is obvious that several elements need to be considered in determining the estimated cost of needlestick injuries, some of which are easier to obtain than others. How much further investigative time and data analysis is devoted to needlestick injuries, beyond what occurs at the time the health care worker presents himself for treatment? Also not considered are any additional costs involved in the disposal of used preventative devices. Some of these devices are larger in size and weight than those they are replacing, which could translate into increased use of sharps disposal containers and additional disposal costs. There may be some change in the use of these or related supplies - for example,

perhaps, IV tubing needs to be changed more (or less) often with a newer device than with the standard device. Does using the new device, despite its safety features, take more time to use? Are there implications for storage, inventory quantities, training and retraining? Is there an impact of safer devices, or lack thereof, on recruitment and retention of staff? There offer some examples of elements which may or may not have significant impacts on cost analysis. However, limitations of this study did not permit investigation of their implications.

In the future, efforts to assess the impact of safer devices on needlestick injuries should include assurances that device-specific injury rates based on the volume of devices used pre- and post-intervention can be established. Detailed injury data, using a consistent approach for categorizing and distinguishing devices, procedures, and the circumstances of exposures, also should be utilized. Such information enables the recognition of preventable and non-preventable events.

More information also is needed on the impact of devices on patient care, particularly the effect of IV-related equipment. Well designed and controlled studies for sufficient time to adequately assess impact should be established. Devices that have less contact time with the venous system, such as needles for injection, phlebotomy, and IV insertion, are less likely to require this level of scrutiny.

Conclusions

The information provided by participating divisions had significant flaws and speaks to the need for a consistent approach to injury reporting and categorization of such events for comparative purposes. (The review of the literature presented similar problems.) Nevertheless, the available data enabled a level of analysis from which certain conclusions can be drawn.

In seven of the nine divisions analyzed, sharps related injuries declined between 21.4% and 30.7%. Not all of these declines could be attributed to the implementation of a needlestick prevention system. However, six-month comparisons of injuries during this study provided evidence of impact for specific interventions. The body of evidence supports the notion that safer IV delivery equipment can have an important impact on injury prevention. In this analysis, IV-related injuries in three divisions declined between 75% and 93.8% in the six months during implementation of a safer system. Also, the proportion of IV-related injuries in four divisions that had implemented safer IV delivery systems at some point in time, was approximately fivefold lower than in the divisions that did not have such systems in place.

It also appears than injection equipment, if properly utilized, can have an impact as well. Injuries related to needles attached to syringes declined 30.4% in one area that implemented the device

division-wide, but this was countered by an increase of 160% in this injury category in another division that also had implemented this safety approach throughout the division.

There was no opportunity to analyze the impact of devices in the other categories and that is an unfortunate limitation of the project. Further study is necessary to assess the true impact safer equipment can have.

In regard to the cost effectiveness analysis described in this Report, it is offered as one example of a methodology by which facilities can make comparisons between and among needlestick prevention devices. The data used comes from only two hospitals, and may not be representative of other institutions. In fact, as with other aspects of this and other studies, caution must be exercised when extrapolating information for interfaclilty comparisons. In addition, data from cost effectiveness analysis is but one piece of information and must be viewed as a complement to other considerations necessary for effective and informed judgments.

In considering this type of analysis, it is necessary to recognize that it is purely economic and is approached only from an institutional perspective. It would be remiss not to mention the perspectives of other concerned parties, namely third party payors and, most importantly, the health care worker at risk of injury.

Of perhaps greater importance is to consider the use of these devices from the perspective of health care workers at risk of injury. The cost effectiveness analysis described above has no direct applicability to the worker. He or she does not incur any of the direct costs of injury that has been enumerated here - but bears the burden of all of the direct health related consequences. The recent resurgence in injury reporting as well as studies relating to occupational exposures; the issuance by OSHA and other professional associations of guidelines for avoiding or at least reducing the risk of exposure; the interest expressed by Barnes Hospital in conducting this pilot study; and the interest of the participants and other parties in its results - these are just some examples of current activities which have brought to the fore the issues of protecting the health care worker from the unwanted and potentially irreversible effects of occupational exposure through needlestick injury.

Recommendations

Policy Recommendations: The importance of this effort cannot be emphasized enough. With more than 23,000 reported needlestick injuries in Missouri each year, over 2,000 of which are thought to represent exposure to HIV, and thousands more occurring in other sectors of the health care and public service environment, worker

protection must be a public health priority. The hospital being studied and the Advisory Committee have considered the experience of this project in the context of promoting implementation. Based on information accrued through this study, the following recommendations are made for communicating these findings and setting the course for future work in this area.

1. Introduction of a safer technology. Many devices represent first generation technology and need improvement. A general mandate for their use is therefore not justified at this time. However, data has shown the effectiveness of safer IV delivery devices. **This hospital should be encouraged to focus on the evaluation and implementation of safer IV delivery systems as a priority for prevention efforts.** Of all the safety strategies studied, passive systems for IV delivery, either recessed needles or needleless devices, were most effective and acceptable to staff.

2. Ongoing evaluation and dissemination of information. **Through continuing legislation for pilot studies, support the continued evaluation of other safety devices, including those currently being marketed, as well as emerging devices.** Evaluation of current needlestick prevention technology demonstrated that many devices are first generation designs and require modification to achieve desired acceptability. **The**

focus of future efforts should include assessment of injury impact and establishment of design and performance criteria for safety and patient care that are product category specific. Create a task force to establish a mechanism for collection and dissemination of information on the design features, practicality, effectiveness, and cost of needlestick prevention technology to help guide the hospital in deciding from among the many product options. The task force should represent the community of providees affected by these products.

3. Support for implementing safer technology. Cost is an important barrier to implementation of safer technology at this time. **A workgroup should be established to explore issues of cost** and provide the hospital with a set of options for creating fiscal incentives that will influence the cost impact on the hospital and promote market growth of these products.

4. Needlestick Tracking Systems. **Promote the establishment of a consistent approach for the collection and analysis of injury data.** Institutional data on the epidemiology of needlestick injuries is necessary for targeting and prioritizing prevention technology. This Hospital should be given guidance by the Department of Infection Control in the implementation of surveillance programs that will optimize risk analysis.

5. **Consideration should be given to the feasibility of establishing a hospital-wide sharps injury surveillance system.** Considerable knowledge was gained on needlestick epidemiology, and the incidence of HIV and HBV exposures in the eight divisions. It is not known to what extent these results are representative of other divisions. A surveillance system would enable centralized risk analysis and serve as a basis for targeting prevention efforts and measuring the effectiveness of new technologies.

Recommendations for further research:

1. Introduction of a safer technology. Through data accumulated during the evaluation of the safer devices, it has become clear that much of the equipment available is still first generation technology. For many of these devices, the study hospital was a testing ground in clinical use where the strengths and weaknesses were identified. For some of the procedures where needles were used, there is no available technology that has emerged as a safe alternative; continued research and development is needed. It is therefore premature to consider a general mandate for use of a safer technology at this point in time.

However, there are findings from this effort which provide direction for establishing priorities and should be immediately encouraged. In particular, devices for intravenous delivery, either recessed needles or needleless alternatives, were found to work well and to have a positive impact on worker safety. Such devices can virtually eliminate the need to use exposed needles with IV delivery systems; this applies to the IV port as well as connecting ("Y") sites. The use of this safer alternative should be viewed as a priority and strongly encouraged in their health facilities. (The selection of which product to use should, however, be left to the judgment of each facility.)

To determine priorities for the selection, evaluation, and implementation of safer devices for other procedures requiring needles, health care facilities should be encouraged to establish data collection systems which permit them to identify and analyze specific devices associated with sharps-related injuries, including the circumstances and procedures associated with risk, and enable determination of device-specific rates of injury. Such data should be utilized to determine the proportion of preventable injuries and to target and prioritize preventive efforts.

2. Ongoing evaluation and dissemination of information. Perhaps the most important priority at this time is the need for

continued evaluation of the emerging technology and dissemination of information to the health care community concerning the results. There is currently no established mechanism, other than occasional reports in journal articles, by which health facilities can become familiar with the evaluation experience of their peers. Such information can influence manufacturers and alert the study hospital to the issues that may need to be addressed. It can also contribute to a more efficient process for product evaluation and avoid duplication of efforts, and possible adverse outcomes in patient care and worker safety. To accomplish this objective, there is a need for a mechanism to: 1) collect information on safer devices, especially those emerging on the market; 2) comment on their apparent features as safety alternative, and implications for use in patient care; 3) receive comments and/or the results of product evaluation surveys from divisions in the hospital; 4). communicate with manufacturers on their findings; 5) maintain a literature file on device-related studies and synthesize and distill this information for use by the facilities associated with the institution.

This is not a role that should be assumed by the Department of Infection Control. Rather, it should be accomplished in concert with others involved in health care and the protection of workers as part of a planned approach for broadly and collaboratively addressing the issue of needlestick prevention. It is recommended, therefore,

that a task force be convened, similar in composition to the voluntary advisory committee that initially guided the pilot study, to consider the above issues and develop a plan for the collection and dissemination of information.

3. Support for implementing safer devices. As has already been shown, multiple devices cause needlestick injuries and therefore no single device will solve the problem of their prevention. Hospitals will need to consider several safety strategies in order to protect workers, strategies that will be costly and which will be only partially offset by the savings from injury and disease prevention.

Because cost is such a barrier to implementation of the safer technology at the present time, a workgroup should be created to explore the issue of cost as it relates to the purchase of safer devices. The outcome of this group's deliberations should include a report to the hospital detailing a set of options and recommendations for enhancing the ability of health care institutions to implement safer technology, and their practicality and feasibility. Areas to be considered may include enhancements that could be delivered by increased reimbursement through Medicare and Medicaid, decreases in worker's compensation and liability premiums, and other options. In addition, mechanisms to stimulate further research and promote market competition also should be explored.

Without the presence of economic incentives, health facilities will be less able, and therefore less likely, to implement a wide-spread, safer technology on their own. This will result in continued worker injuries and the potential for bloodborne disease transmission.

APPENDIX A: NEEDLESTICK/SHARPS INCIDENT REPORT

File # _____

NEEDLESTICK/SHARP INJURY DEVICE-RELATED INCIDENT REPORT

Instructions: We are concerned and interested in the type of puncture injuries our employees sustain in the course of work. Please take a few minutes to complete this form in order that we may better track the injuries that occur and plan strategies that might reduce the likelihood of such injuries in the future.

1) DATE OF INJURY _____

2) TIME OF INJURY _____

3) AGE _____

4) GENDER: _____Male _____Female

5) OCCUPATION (Check only one):

__ Attending MD (1)	__R/N (6)	__ Clinical Lab Worker (12)
__ Intern/Resident (2)	__ LPN (7)	__ Research Lab Wrkr (13)
__ Physicians Asst (3)	__ Nursing Asst (8)	__Respratry Therpst (14)
__Nurse Practitioner (4)	__ IV Team (9)	__ OR Technician (15)
__ Anesthesiologist (5)	__ Phlebotomist (10)	__ Housekeeper (16)
	__ Pharmacist (11)	__ Maintnance wrkr (17)

Student: (check type)

__ Medical (18) __ Nursing (19) __ Other Student (20)
__ Other (21) _____

6) Clinical Department (if applicable):

__ Nursing (1)	__ Medicine (3)	__ OB/GYN (4)
__ Surgery (2)	__ Pediatrics (5)	
__ Other (6) _____		

7) LENGTH OF TIME YOU HAVE WORKED IN THE ABOVE OCCUPATION:

_____ Years _____ Months (if worked less than 1 year)

8) LOCATION WHERE INJURY TOOK PLACE (check all that apply)

__ Patient Room/ bedside (1)	__ Central Supply (6)	__ Soiled Utility Room (10)
__ Emergency Room (2)	__ Laboratory (7)	__ Morgue/autopsy (11)
__ Operating or Delivery Room (3)	__ Critical Care Unit (8)	__ Laundry Rm (12)
__ Examination Rm (4)	-- Medication Cart or Room (9)	__ Central Trash Area (13)
__ Clinical Out-patient area (5)	__ Other (14) _____	

Indicate below the CATEGORY of device that caused the injury and, within that category, the TYPE of device involved.

9) NEEDLE (HOLLOW BORE) (Check which type)

__ hypodermic attached to disposable syringe (1)

__ unattached hypodermic needle (2)

__ butterfly IV needle (3)

__ IV stylet (4)

__ phlebotomy needle (vacutainer) (5)

__ spinal or epidural needle (6)

__ unidentified needle (7)

__ pre-filled cartridge syringe needle (8)

__ needle attached to IV tubing (9)

10) OTHER NEEDLE TYPE (Describe)

_____

_____

11) SURGICAL INSTRUMENT / OTHER SHARP DEVICE (check which apply)

__ lancet (1)

__ suture needle (2)

__ scalpel blade (3)

__ razor (4)

__ pipette (plastic) (5)

__ Other device (10)

__ scissors (6)

__ bovie electrocautery (7)

__ bone cutter (8)

__ unidentified device (9)

12) GLASS

__ medication ampule (must break open) (1)

__ medication vial (rubber stopper) (2)

__ medication/IN bottle (3)

__ pipette (glass) (4)

__ Other glass item (9) _____

__ vacuum tube (5)

__ test tube (6)

__ capillary tube (7)

__ unidentified glass item (8)

13) OTHER TYPE OF SHARP

14) BRAND NAME OF THE DEVICE

Name: _____ Don't Know _____

INDICATE WHEN AND HOW INJURY OCCURRED (check all that apply)

15) BEFORE PROCEDURE (clean device) _____

16) DURING PROCEDURE

__ Patient moved and jarred device (1)

__ Needle stuck hand holding IV port (2)

__ While withdrawing needle from patient or port (3)

__ While in operative field (4)

__ Passing or transferring instruments (5)

__ Handling devices on sterile field (tray or mayo stand (6)

__ Transferring blood to specimen container (7)

__ Collided with co-worker (8)

__ Other (describe on Page 4 under comments (9)

17 AFTER USE

__ During clean up (1)

__ Recapping (missed or pierced cap) (2)

__ During disassembly (3)

__ Cap fell off after recapping (4)

__ Hit by attached IV line (5)

__ In transit to disposal (6)

__ Collided with co-worker (7)

__ Other (describe on Page 4 under Comments)

18) DURING/AFTER DISPOSAL

__ Item protruding from trash (1)

__ Item protruding from linen (2)

__ Overfilled sharps disposal container (3)

__ Uncontained sharp (i.e., on floor, table, stuck in mattress (4)

__ Other (describe on Page 4 under comments) (5)

IF THE INJURY INVOLVED AN IV-LINE, NEEDLE OR LANCET, COMPLETE THE FOLLOWING PROCEDURE-SPECIFIC INFORMATION AS APPLICABLE.

19) IV LINE RELATED INJURY (check all that apply)

a) type of IV Line

__ continuous (i.e., primary line) (1)

__ intermittent (i.e., heparin lock or well) (2)
__ secondary IV set (i.e., piggyback) (3)

b) Procedure Associated with Injury

__ insertion of IV catheter (4)

__ flushing line (5)

__ blood withdrawal (6)

__ medication administration (7)

__ connecting line (8)

__ disconnecting line (9)

__ Other (10) _____

20) NEEDLE OR LANCET-RELATED INJURY (check only one)

__ IM/SQ/ID injection (1)

__ Phlebotomy (2)

__ Fingerstick/heelstick (3)

__ Other blood collection (i.e., arterial stick for blood gasses) (4)

21 URGENCY OF PROCEDURE

__ routine (planned) (1)

__ emergency situation (2)

__ code situation (3)

COMMENTS:

_____
_____
_____

APPENDIX B: INCREMENTAL COST STUDY

Pilot Study of Needlestick Prevention Devices
Incremental Cost of Study Devices

Note: The following costs reflect individual hospitals' experiences associated with securing devices for the pilot study. Variations in pricing and incremental costs are a result of several factors, i.e., price negotiations, choices from a product line, base cost of existing equipment, etc. These are intended to serve only as examples and may not predict the experience of other institutions.

Needleless IV Systems: Reflux Valve

	Current Device	Study Device	
A	Standard heparin lock: $.29	Reflux valve w/extension set and cover cap*: $1.94	$1.65 (5.7 times)
B	Standard heparin lock: $.29	Reflux valve and cover cap*: $1.27	$.98 (3.4 times)
	Extension set w/hep. lock: $.69	Reflux valve and various extension sets: $2.86 - 3.04	$2.17 to 2.35
	Needle for secondary IV: $.05	Access pin for secondary IV: $.40	(3.1 - 4.4 times)
			$.35 (7 times)

Cover caps @ $.17 each must be changed each time the system is accessed which will increase the cost based on the number of times the system is used.

Needleless IV Systems: Blunted Cannula

	Current Device	Study Device	Increment*
A	"J" loop with heparin lock: $1.38	"J" loop with special injection site: $1.95	$.57 (.4 times)
	Standard hypodermic needle: $.035	"Lever" type access adapter: $.30	$.27 (9 times)
B	Standard heparin lock: $.40	Injection site: $1.15	$2.30 (6 times)
	Standard hypodermic needle: $.05	Extension set: $1.30	
		"Lever" type access adapter: $.30	

* Differences in incremental cost for division B are largely related to addition of an extension set and choice of injection site.

Recessed Needles

	Current Device	Study Device	Increment
A	Standard heparin lock: $.59 Standard hypodermic needle: $.05	Standard heparin lock with extension set*: $1.30 Recessed needle for heparin lock: $.58 (Product C1) Recessed needle for secondary site: $.35 (Product C2)	$.71 (1.2 times) for IV site; $.53 (10 for the hep. lock needle; $.30 (6 tin the secondary needle
B	Standard hypodermic needle: $.0316	Recessed needle for secondary site connection: $.19 (Product C2)	$.16 (5 times)
C	Standard hypodermic needle $.05	Recessed needle for heparin lock: $.93 (Product C3); recessed needle for secondary site connection: $.43 (Product C4)	$.88 (17.6 times) and $.38 (7.6 time

*Extension tubing was necessary to reduce bulk at the IV port and became an incremental cost in divisions not previously using this tubing.

Injection Equipment

	Current Device	Study Device	Increment
A	Standard 3cc syringe: $.06	3cc syringe w/needle guard: $.14 (Product A1)	$.08 (1.3 times)
B	Standard 3cc syringe: $.05 w/0 needle; $.10 w/needle	3cc syringe w/needle guard: $.1350 w/o needle; $.25 w/needle (Product A1)	$.085 (1.7 times) to $.15 (1.5 times)
B	Standard 3cc syringe: $.10 w/needle	3cc syringe w/needle guard: $.18 (product A2)	$.08 (.8 times)
C	Standard 3cc syringe: $.05	3cc syringe w/needle guard: $.17 (Product A2)	$.12 (2.4 times)
B	Injection needle: $.05	Passive safety needle: $.95 Product G1)	$.90 (18 times)

Phlebotomy Devices

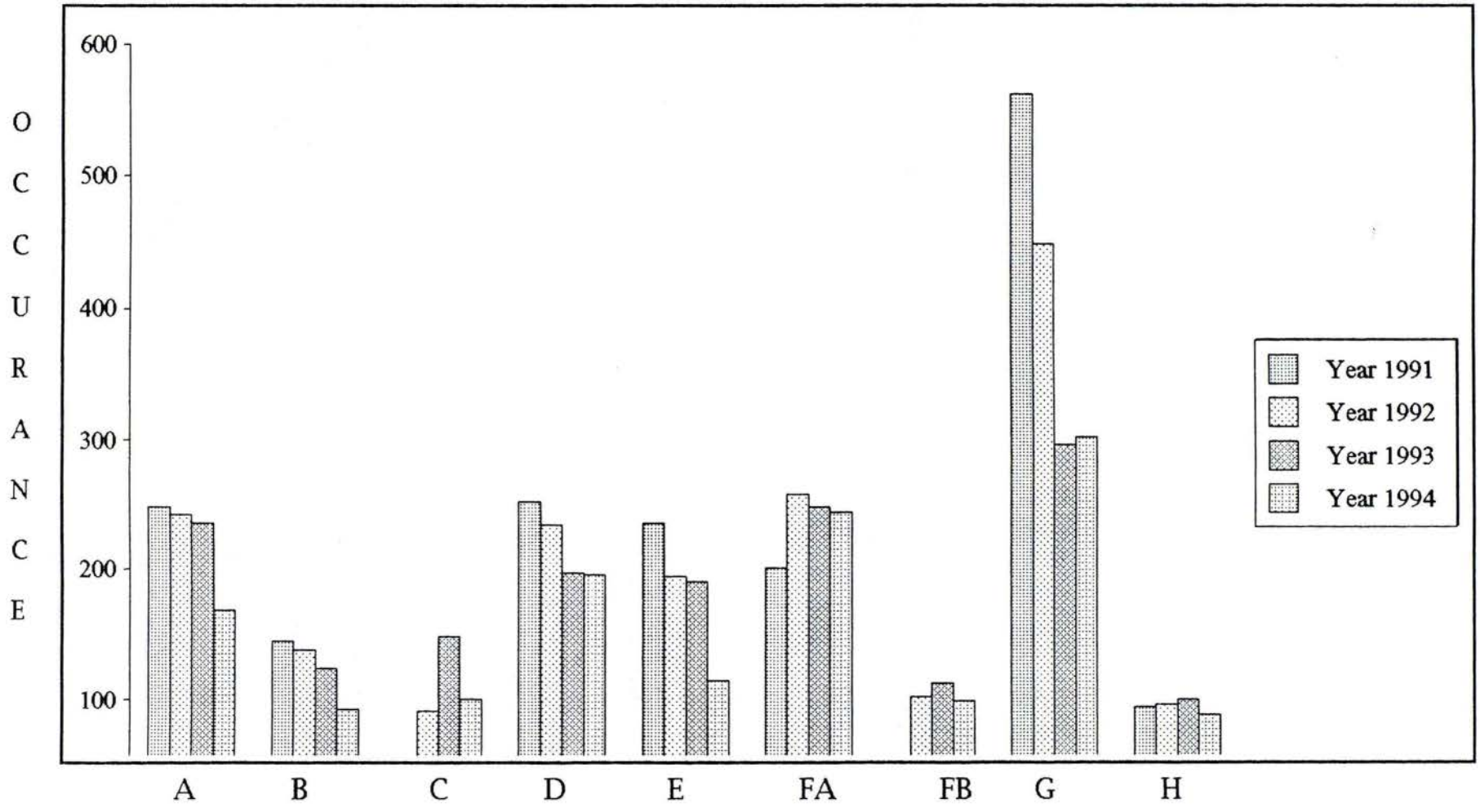
	Current Device	Study Device	Increment
A	Standard vacuum tube holder: $.14	Reusable vacuum tube holder with retractor for safe resheathing: $1.40 (Product E2)	$1.26 (9 times)
A	Standard vacuum tube holder: $.14	Reusable vacuum tube holder with needle ejector $2.56 (Product E1)	$2.42 (17.3 times)
A	Standard winged steel needle: $.56	Winged steel needle with needle protector: $.52 (Product F1)	Savings of $.04
B	Standard winged steel needle: $.26	Winged steel needle with needle protector: $.72 (Product F1)	$.46 (1.8 times)
B	Standard phlebotomy needle: $.12	Safety phlebotomy needle with blunting mechanism: $.72 (Product G2)	$.60 (5 times)

IV Catheters

	Current Device	Study Device	Increment
A	Standard IV catheter: $.75	Safety IV catheter: $1.50 (Product D1)	$.75 (2.0 times)

APPENDIX C: SHARPS RELATED INJURY TRENDS IN EIGHT HOSPITAL DIVISIONS

SHARPS RELATED INJURY TRENDS IN EIGHT HOSPITAL DIVISIONS



APPENDIX E: DEFINITION OF TERMS

CDC: Center for Disease Control — The governmentt agency that sets policy and procedures in the health care field as well as identifies and investigates disease entities.

CHL: Conventional heparin lock — A rubber cap that requires the penetration of a needle to access and infuse into a intravenous line.

HCW: Health Care Worker — Anyone who works in the health care field.

IV Intravenous — Infusion of a substance directly into a vein.

NSI: Needlestick Injury — A cutaneous cut, scratch, or puncture from a needle that has been contaminated with patient's blood, regardless if the wound bled.

HIV: Human Immuno Deficiency Virus — The identifgied cause of Acquired Immuno Deficiency Syndrome (AIDS)

HBV: Hepatitis B Virus — A bloodborne pathogen that effects the liver.

NHL: Needleless heparin lock — A device used to access and infuse into an intravenous line without the penetration of a needle.

NLS Needleless System — Access to peripheral lines without use of needles.

NSI Needlestick Injury — A cutaneous cut, scratch, or puncture from a needle that has been contaminated with patient's blood, regardless if the wound bled.

OSHA: Occupational Safety and Health Administration — A governmental agency whose interest is that of workers and their safety.

SIs: Sharps injuries —Same as Needlestick Injury

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