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THE IMPLEMENTATION OF A NEEDLELESS IV SYSTEM AND ITS IMPACT IN NEEDLESTICK INJURIES

Renée Gadilhe Childers

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THE IMPLEMENTATION OF A NEEDLELESS IV SYSTEM AND ITS IMPACT ON NEEDLESTICK INJURIES

by

Renée Gadilhe Childers

A Thesis Submitted to the Faculty

of the College of Graduate Studies

At Georgia Southern University

in Affiliation with Armstrong State College

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Master of Health Science

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1995

THE IMPLEMENTATION OF A NEEDLELESS IV SYSTEM AND ITS IMPACT ON NEEDLESTICK INJURIES

by

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INTRODUCTION

Needlestick injuries are the most pressing occupational hazard facing the health care worker today. Six million health care employees use six billion needles annually, and all are at risk of being stuck with contaminated needles (Larkin, Toska, Hudson, & Eybands, 1993). It is estimated that over one million accidental needlesticks are incurred annually by health care workers (Jagger, 1992). The Centers for Disease Control (CDC, 1989) contend that approximately 12,000 health care workers acquire the Hepatitis B virus annually in the workplace, and of those infected, 200-300 die each year. The risk of seroconverting from HIV negative to HIV positive as a result of an injury by needlestick contaminated by the virus is about one in 200 (CDC, 1989). Based on these conservative estimates, it is expected that between 50 and 80 health care workers will become infected annually due to occupational needlestick exposure to HIV.

The annual incidence of sharps injuries increased more than threefold in the years from 1930 to 1990, despite prevention efforts (McCormick, Mersch, Ircink, & Maki, 1991). This is due in part to improved reporting by health care workers, institutions, and federal agencies. In recognition of these alarming

statistics, and in response to growing concern from the health care community, legislation has been enacted to develop strategies and equipment to address the problem of needlestick injuries.

Needleless intravenous systems were introduced as a method to decrease the potential for needlestick injuries, and health care facilities nationwide are evaluating the effectiveness of these safety systems.

Purpose

To advance the development of safer medical products, it is necessary to conduct studies that measure the effectiveness of the products in the clinical arena. Information obtained from such studies can be communicated to manufacturers of medical equipment to improve the products they provide.

In 1992, Southeast Georgia Regional Medical Center (SGRMC) in Brunswick, Georgia, exchanged their traditional intravenous equipment for one of the needleless systems. This study was undertaken to establish the effect of that implementation on the number of reported needlesticks in this 340-bed healthcare facility.

Hypotheses

The introduction of products designed to reduce needle injuries was anticipated to decrease the number of needlestick injuries.

The research questions for this study are:

- What effect did the IV needleless system have on the overall rate of needlestick injuries?

- Which department (s) or area(s) was most impacted by the new system?
- Which occupation(s) had the greatest change in number of injuries?

Definition of Terms

For the purpose of this study, a needlestick is defined as a cutaneous cut, scratch, or puncture from a needle contaminated with a patient's blood or body fluid.

Limitations

The most significant limitation of this study deals with the issue of underreporting of needlestick injuries. Janine Jagger, PhD, MPH, is the director of the Health Care Worker Safety Project at the University of Virginia Medical Center, and is considered the expert in the field of needlestick injuries. She spoke at the 5th National Forum of AIDS, Hepatitis, and other Blood-borne Pathogens, and said that two out of every three needlestick injuries are never reported (Doan-Johnson, 1992). Other research indicates that 40-60% of HIV needlesticks are not reported (Bohoney, 1993). In a U.S. Air Force Base Hospital survey (Subcommittee Staff Memo, 1992), one-third of 334 needlesticks studied were not reported.

Ippolito's study (1994) also recognized the potential bias from factors that influence health care workers to report or ignore their accidental injuries. Italian laws favor more thorough reporting than other countries, according to the

authors, thereby facilitating the reporting process. But since underreporting and reporting bias are so important in studies based on self-reported injuries, the authors advise that the results may represent underestimates of actual injury rates.

Another limitation of this study is that during the implementation of the IV system, other worker safety projects were in progress. Extensive hospital-wide education concerning the safe handling of contaminated waste was being conducted, the use of safety syringes for injections was begun, and sharps containers for needle disposal were placed at the point of use.

So, the results of this study may be influenced not only by the IV needleless system, but by the combination of new, safer equipment, and by an educational component. Wolfrum's study (1994), recognized the opportunity to reinforce safety issues to employees during hospital-wide inservice of the IV system, so that education was not a limitation in that study, but an instrument leading to the success of the change.

REVIEW OF LITERATURE

The literature review was conducted by searching the topics "needlestick injury", "occupational hazards", seroconversion", "safety equipment and products", and " HIV exposure" on the InfoTrac® Health Reference Center™ database. Indexes in medical periodicals at SGRMC were scanned for pertinent articles, and the Infection Control and Employee Health departments submitted literature that they had accumulated during the past few years.

Since needlestick injuries have only recently become such an important issue, the literature search covered the years 1992-1994, although earlier articles and studies were used for background information.

Legislation

Safer medical devices became a landmark issue with the advent of the concept of Universal Precautions in 1984. These guidelines recommended that needles not be bent, broken, or recapped by hand, and that they be discarded promptly in puncture-resistant disposal containers near the point of use (Gray, 1992). In December of 1991, OSHA issued the final rule for bloodborne pathogens, emphasizing that engineering controls are the preferred method for reducing needlesticks (Mazer, 1992). Hospitals are required to evaluate and

adopt engineering controls and safe work practices as the primary means of eliminating or minimizing employee exposure to potentially infectious materials. OSHA also requires an evaluation of exposure incidents, including needlestick injuries.

In spite of the widespread acceptance and adherence to universal precautions nationwide, some researchers, including Dr. Jagger (1993), say that in the six years following their implementation, the overall rate of needlestick injuries was not affected.

The first patent ever issued for a safe needlestick device was to a San Francisco nurse in 1977, who invented a retractable needle and syringe device (Jagger, 1994). Since that time over 400 patents have been issued to inventors of safe medical devices by the U. S. Patent Office. The FDA has approved an increasing amount of needlestick safety devices. A total of 110 devices have been approved; these include re-cappers, safety syringes, needle guards, and needleless IV systems. This continuing trend indicates that the business community and the engineering community have strongly responded to the need for these devices.

According to Dr. Jagger, safer needleless systems and needle alternatives are currently available that could eliminate 50% of needlestick injuries if hospitals "were adequately informed and motivated" (Jagger, 1994). She recommends elimination of all unnecessary exposed needles, among them are those on IV lines, or syringes used to access IV ports or injection sites.

Exposed needles are only necessary for procedures that involve penetrating the skin. Included here are intravenous catheters, blood-drawing devices and syringes used for intramuscular or subcutaneous injections.

The Occupational Safety and Health Administration (OSHA) mandated new guidelines to protect health care workers, and began issuing citations to health care employers in 1990 (Bohoney, 1993).

In April of 1992, the FDA issued a safety alert specifically warning health care practitioners against the practice of using needles to access IV administration sets (Appendix A). The alert stated that needles should be used only in situations where there is a need to penetrate the skin, and strongly urged the use of needleless systems to replace standard hypodermic needles for accessing IV lines. The FDA, though not endorsing specific products, also outlined the devise characteristics that have the potential to reduce the risk of needlestick injuries.

Members of Congress have also become involved in the issue of sharps injuries. In 1992, a US House of Representatives subcommittee held a hearing to gather information on needlestick injuries and to assess institutional adoption of safer medical devices. Congressman Pete Stark (D-CA) introduced legislation that would impose an excise tax on sales of syringes and IV systems that did not meet specific needlestick prevention standards developed by the FDA (Bohoney, 1993).

Two California hospitals were cited by CalOSHA for failing to evaluate and adopt safer needle devices (Hospital Employee Health, 1994). In both incidents, the hospitals said that they had evaluated systems, but had not implemented the use of the safer devices. CalOSHA felt that they were "dragging their feet", and were jeopardizing health care workers' safety. The citations also warned the healthcare facilities against the practice of instituting the needleless systems in so-called high risk areas, and not hospital-wide.

The American Hospital Association (AHA) testified before various executive branch agencies that these governmental groups could ease health facilities' adoption of new devices by supporting legitimate evaluations of safety devices (Pugliese & Kroc, 1993).

EPINet

Vital to the goal of achieving a safer healthcare workplace are good information systems that describe exposures, provide reliable documentation of the impact of prevention measures, and allow an efficient means to disseminate new findings to those who can put them into practice (Jagger, 1994). The Exposure Prevention Information Network (EPINet™) was developed at the University of Virginia in 1991 by Dr. Janine Jagger, to help in meeting these information goals, and to give hospitals an opportunity to advance the progress in prevention by sharing and exchanging data with many institutions. The EPINet system consists of standard incident report forms to be completed by each health care worker reporting an exposure incident, and includes

preprogrammed software for data entry and automatic report printing. One important feature of EPINet is the classification of devices causing percutaneous injuries, which is essential for device-specific risk assessments and for conduction product evaluations and clinical trials of devices designed to prevent needlesticks or other sharp object injuries.

EPINet became widely available in September 1992; since then, an estimated 1,000 hospitals in the United States have obtained EPINet. Currently, 58 hospitals in diverse locations across the U. S. provide data directly to the International Health Care Worker Safety Research and Resource Center at the University of Virginia for use as a surveillance and research database. For the first time, differences in incidence rates and exposure mechanisms among hospitals can be compared.

Overview of Needlestick Injuries

Needlestick injuries are caused by various devices during many different procedures. According to the Association for Practitioners in Infection Control, Inc. (APIC, 1992), devices most frequently linked with occupational injuries include:

- Disposable needled syringes used for injection
- Prefilled cartridges
- IV catheters
- Butterfly or winged catheters

- Vacuum-tube phlebotomy assemblies
- IV connectors or piggybacks

The most frequently cited causes of documented needlestick injuries are:

- Recapping incidents
- Assembling or accessing intravenous tubing devices
- Disposing of contaminated sharps
- Hypodermic needles protruding from overfilled needle disposal containers
- Using alternate methods to cover used needles on IV needle assemblies such as introducing them into drip chambers, IV ports, or IV bags
- Intentionally or inadvertently detaching IV lines

Over half of all needlestick injuries are caused by unnecessary needles (Doan-Johnson, 1992). These needles are used to pierce the IV equipment, not the patient's skin. Such makeshift equipment puts patients and caregivers at risk. Not only might the nurse be stuck with the needle and possibly exposed to blood-borne pathogens, but patients' IV therapy could be interrupted if the needle is disconnected from the port. The needle also could wobble and break in the port, migrating to the patient's vein. The Food and Drug Administration's (FDA) Device Experience Network has received at least 24 reports describing hypodermic needles that have broken off inside IV administration set ports (FDA, 1992).

A study conducted at the University of Virginia Hospital in Charlottesville showed that needles used to pierce IV tubing accounted for 36.7% of all

needlestick injuries, while disposable needles accounted for only 6.9% (Curry, 1993).

According to the Centers for Disease Control and Prevention (CDC, 1994), nurses and clinical laboratory workers ranked first among the documented or possible cases of occupationally acquired HIV in the United States through December 1993, with each of the two accounting for 24% of the 123 reported cases.

A fourteen-year study at the University of Wisconsin Hospital and Clinics (McCormick, et al, 1991), showed that environmental workers reported the highest number of sharps injuries (305.8 per 1000 employees), followed by nurses at 196.5 per thousand. The injuries occurred during disposal of waste, linens, or procedure trays; surgery; administration of parenteral injections or IV therapy; blood drawing; and needle recapping.

In a 33-month study of sharps injuries in a Charlottlesville Hospital (Juillet, 1992), 152 injuries were reported: 72% from nursing personnel, 11% from phlebotomy staff, 9% from environmental staff, 4% from OR aides or technicians. No physicians reported injuries during this period. This study grouped sharps injuries by device into three categories: hollow-bore needles, surgical instruments and other sharp devices, and glass. Hollow bore needles caused 104 of the 152 injuries, and were the focus of this study. Most of the hollow bore injuries were caused by prefilled syringes (24), piggyback needles (23), and disposable syringes (22). The most valuable outcome of this study

was the realization that many of the injuries associated with IV applications could have been prevented by using needleless systems.

In a recent large study (Ippolito, 1994), the distribution of needlestick injuries according to healthcare worker category showed that nurses accounted for 69.8% of injuries, housekeeping 13%, and physicians 10%.

Causes

Although needlesticks have often been attributed to carelessness by health care workers, research by Dr. Janine Jagger and her colleagues (1988), challenges this view, stating that the bigger culprit in causing injury is poor equipment design. Dennis Maki, M. D. (McCormick, 1991), concurs:

> "As have others, we have come to the conclusion that the greatest impact in reducing sharps injuries in healthcare workers might be achieved by innovative technology-based approaches to prevention that implicitly reduce the risk of injury, despite carelessness or apathy on the part of a healthcare worker... analogous to mandating airbags in cars."

If poor design is the problem, then, according to Stringer (1993), an ergonomic approach to occupational health offers a common sense solution. Ergonomics focuses on achieving a safe workplace by fitting the environment to the worker rather than the other way around. If a tool is associated with injury, it means changing the design of the tool rather than attempting to change the behavior of the worker.

Many education advocates view worker injuries as practice-related problems. This assumption suggests that needlestick injuries can be avoided if workers are aware of the dangers and exercise caution when using a needle device. However, several studies (Kransinski, et al, 1987; Gray, 1992; Weatherly, Young, Andresky, and Peterson, 1993), indicate that education programs often have no appreciable impact on reported injury occurrence. Jagger (1987) states that many current methods of controlling needlestick injuries are too simplistic to be effective in the complex healthcare environment.

Weatherly, Young, Leech, Andresky, and Peterson (1993), suggest that strategies to reduce injury must control multiple variables concurrently. For example, strategies must address bedside and downstream injuries, disposal and activity-related injuries, and device and practice related injuries concurrently. This multifactorial approach was implemented over a period of 18 months in a 160-bed tertiary care pediatric hospital, and included five elements: A needleless IV access system, a shielded syringe system, a sharps disposal system, a blood borne pathogen risk education system, and an injury prevention compliance system. Needlestick injury occurrence decreased 77% following full program application, and injuries among non-nurse workers were eliminated.

Related Studies

In Pittsburgh, at Montefiore University Hospital, a needleless IV system was initiated due to a safety committee's finding that IV piggyback needles were found "loose" more frequently by environmental services employees than any

other sharp. This 400-bed community hospital implemented a needleless system that uses a blunt plastic cannula and a pre-pierced injection port. A 51% reduction in the needlestick injury rate was reported in the first six months following implementation of the new system. The hospital attributed widespread education prior to implementation an important factor in their success (Gartner, 1992).

A study at 392-bed Columbia Hospital in Milwaukee following an IV needleless system implementation demonstrated similar results. This hospital began their project by initiating intensive educational efforts prior to the actual implementation of the needleless system. They recognized a 20% reduction in needlestick injuries as a result, but IV needles continued to be a problem. With the advent of the needleless system, the total IV needlesticks dropped from 17 to zero in six months; a trend which continued for the next six months. A 60% reduction in total needlesticks was realized (Rutowski, 1993).

A follow-up of the Columbia study was conducted by Wolfrum in 1994, and analyzed the four-year effectiveness of the Columbia Hospital's program. Although there continued to be needlestick injuries, some as a result of carelessness, others at times of high stress, the total number of injuries decreased by 39% over the four-year time period.

A longitudinal study conducted in Italy (Ippolito, DeCarli, Puro, Petrosillo, Arici, Bettuci, Bianciardi, Bonazzi, Cestrone, Daglio, Desperate, Francesconi, Migliori, Monti, Peitroban, and Jagger, 1994), was designed to identify the types

of devices causing needlestick injuries, to document the injury rates and time trends for different needles, and to compare injury rates from these devices with those reported in the United States. This large study involved thirty-three hospitals who reported a total of 2524 injuries from hollow-bore needles.

IV catheter stylets had the greatest overall injury rate of any device (15.7 / 100,000 during a 2-year period). The distribution of types of devices causing injury in this study were similar to those reported in the United States. One problem associated with this study, and identified by the authors, was that the U. S. data was collected before full implementation of universal precautions. The Italian study was conducted after universal precautions were implemented.

A very noticeable pattern of needle use between Italy and the U. S. was also noted. The use of hypodermic needles for piggyback connections and intermittent IV therapy is not practiced in Italy. Needleless access to IV lines with the use of stopcocks and Luer locks has been standard practice in Italy and most developed countries, with the exception of the U. S. and English-speaking Canada.

Only one study revealed in the literature search did not show a decrease in needlestick injuries after the implementation of an IV needleless system. At Emory University, a study was conducted by Berry (1992) to measure the effectiveness of an IV needleless system among the anesthesia personnel.

Prior to implementation, the contents of needle disposal containers in the pre-operative holding area and five operating rooms were categorized by

needle type. Three weeks following implementation of the needleless system, the count was repeated. Considering the number of surgical cases performed during each time period, there was no difference in the total number of needles collected after the introduction of the needleless administration system. The author suggested that the practice of anesthesia is associated with a specific pattern of needle usage, and that strategies for reducing needlestick injuries in anesthesia personnel should be directed toward finding alternatives to small-bore hollow needles and IV catheter stylet needles.

Some hospitals, during their needleless system changeover, have evaluated not only the effectiveness of the system in terms of decreased injury, but also the failure and infection rates for the devices.

At Spartenburg Regional Medical Center a one-month study of a needleless system was conducted on a medical/ surgical unit and an oncology unit, both of which had consistently large volumes of intravenous catheters and medications (Beason, Bourguignon, Fowler, and Gardner, 1992). The following research objectives were identified:

- To assess the prevention or reduction of needlestick risks and injuries
- To identify associated reductions in expenditures
- To implement product and ease of use
- To assess nursing satisfaction levels

Forty nurses evaluated the system, and after 3500 intravenous procedures, zero needlesticks were reported, the leakage rate was less than 0.1%, and the infection rate showed no increase.

One element of this study that is common to many of the studies cited is the post-implementation evaluation process. Surveys, questionnaires, and roundtable discussions were some of the methods used to evaluate the needleless products for ease of use, reliability, and durability.

Staff Involvement

Infection control practitioners realize the importance of staff members "buying in" to the new products during the implementation process. Simkins (1994) recommends that the workers who will be using the safety devices first should evaluate them. Although ICPs may have the theoretical knowledge and the information about national data and trends, the direct-care staff are more familiar with day-to-day applications.

The development of a multidisciplinary task force is a basic component of a successful new product implementation process (Skolnick, LaRocca, Barba, and Paicius, 1993). Representatives from nursing, infection control, employee health, housekeeping, materials management, and administration are among those employees to be included on such a task force.

Costs

In today's health care market, the discussion of any new technology must include the issue of cost. The IV needleless systems can increase the cost of IV

administration from two to twenty times the cost of the products they replace (Bohoney, 1993; Pugliese, 1993). The cost of implementing safer devices should, however, be compared to the cost savings that occur as a result of decreased needlestick injuries.

Needlestick injuries can cost health care facilities from three hundred to one thousand dollars per needlestick (Dugger, 1992). These costs reflect immunoglobulin, titers for HBV and HIV, tetanus vaccination, and the possible use of AZT. Lost time from work, counselling, and follow-up are difficult to put a price tag on. It is also difficult to measure, in financial terms, the anguish the employee and his family are subjected to during this time.

One way to offset the increased cost of the new IV systems is to examine the usage of the components. Olive View Medical Center in California was challenged to institute a needleless IV system and remain within budgetary limitations (Skolnick, et al, 1993). After evaluating the procedure being used to administer IV medications, the staff realized that a few changes could help reduce the cost of the new system. The former practice was to use a primary IV tubing for each piggyback medication. A typical patient might have had three or more IVPB medications, each delivered through a separate primary IV tube. The revised procedure uses only one secondary IV tubing for all IVPB medications. The secondary IV tubing is flushed after each use, eliminating the use of multiple tubes. Revision of this procedure resulted in an overall cost saving of $1.85 per patient.

Product Evaluation

The following recommendations for product evaluation were provided by Owens-Schwab & Fraser (1993).

- Establish an effective task force. This should be a multidisciplinary team representing purchasing, infection control, administration, pharmacy, employee health, respiratory therapy, medical staff, and nursing.
- The task force should evaluate needlestick injury data, and analyze areas of high risk and high frequency.
- Evaluate documentation and guidelines regarding needleless and needle protection devices.
- Review clinical studies or abstracts on the different products available.
- Before evaluating the product, ask the seller or distributor for a copy of their letter of equivaling from the FDA. All medical devices must meet these basic requirements.
- Allow adequate time to assemble information and evaluate risk data.
- Establish trial areas with controls.
- Evaluate the device for the exact type of needlestick injury the device was supposed to prevent.
- Have health care workers evaluate the product.
- Determine if needlestick injuries are due to device failure or failure of the device to be used correctly.

METHODOLOGY

Southeast Georgia Regional Medical Center is a 340-bed acute care facility in Brunswick, Georgia. There are approximately 1350 employees, of which 650 are nursing personnel (registered nurses, licensed practical nurses, nursing assistants and technicians). All permanent staff members were included in this study; contract personnel and physicians were not.

According to policy, any employee sustaining a needlestick or puncture injury is to seek first aid, and report to the Employee Health Department, or to the Emergency Department when the Employee Health office is not open. An Employee Accident report is filled out, giving information about the device and circumstances of the injury (Appendix B). The Employee Health Department reviews each injury report, following up on each case as appropriate. Monthly reports of injuries are filed and submitted to SGRMC's Safety Committee.

The needlestick injury reports for the years 1991-1994 were obtained through the hospital's Information Development Team (IDT), and reviewed for the following information: the department or area of the hospital where the injury occurred, the occupation of the person involved, and the device causing the injury.

Areas of SGRMC included were the Emergency Department (ED), the Maternity Center (MC), all nursing units, the operating room (OR), environmental services, the laboratory, radiology, and respiratory therapy. Categories of departments were grouped according to similar functions. The intensive care units were combined, as were the medical and surgical nursing units. The ED, MC, and OR were tabulated separately due to their unique functions.

The occupations of workers were identified as nurses (RNs and LPNs), nursing aides/ assistants/ techs, laboratory workers, radiology or respiratory technicians, environmental attendants, operating room technicians, and students. Registered nurses and licensed practical nurses were combined into one group for analysis of needlestick data. Both are responsible for starting IV's, administering intravenous medications, and are trained, inserviced, and tested for competency on an equal basis. Also, the mix of RN's and LPN's varies from year-to-year in this health facility. Many of the nursing units are "upgrading" their LPN positions to RN positions to accommodate the increased number of professionals available, so there are fewer LPN's throughout the hospital.

Devices and circumstances causing the reported injuries were grouped into the following categories: IV-related needles (heparin trap, IVPB), lancets, non-safety syringes, safety syringes, IV stylets, trash, sharps boxes, procedure trays, suture needles, vacutainers, and arterial blood gas needles.

Non-safety syringes are traditional hypodermic syringe and needle units used to administer intramuscular and subcutaneous medications. Safety

syringes additionally have a rigid plastic sheath that locks in place over the needle following injection of medication.

The "trash" category defines the injuries that occurred as a result of improperly discarded needles, of any type. Sharps box injuries include those that occurred as a result of overfilling or mishandling the containers for contaminated needles.

In this study, only needlestick injuries involving contaminated needles were included: scalpel, glass, and clean needle injuries were excluded. Clean needlesticks were defined as needles that had not been injected into a patient or patient's device, such as IV lines, urinary catheter, or heparin lock.

Implementation of Needleless System

In February of 1992, the Infection Control Coordinator reported to the Safety Committee the provisions of OSHA's bloodborne pathogen standard. The evaluation of several engineering controls, including IV needleless systems, had begun by that time. Educational events concerning body substance isolation (BSI) and infectious waste were also discussed.

The evaluation of IV needleless systems was initiated in two of the critical care units, the cardiac care unit (CCU), and the medical intensive care unit (MICU). Baxter's InterLink™ system was the safety system under investigation.

The IV needleless system in this study consisted of several parts. The major change from the traditional system is the use of pre-pierced compressed rubber that replaced the old latex injection cap. These ports previously were

punctured by a needle to inject medications. The x-cut, which is not visible, allows a rigid cannula to penetrate the cap, and then reseal. This 15-gauge cannula replaces metal needles used for drawing up medication from a vial, for administering intravenous medications through infusion tubing, or IV catheters.

Costs of needlestick injuries were identified and reported to the purchasing manager at SGRMC during the evaluation process (Appendix C), and the average cost of $583 per needlestick was established.

By June the two units evaluating the IV systems had completed their preliminary reports to the Product Review Committee, recommending the use of the InterLink™ system. The Safety Committee also urged the immediate purchase and hospital-wide implementation of the safety system.

Now a problem was identified that might have been anticipated. The manufacturers of the needleless equipment could not keep up with the demand for it's safety products. Obviously many health care facilities were responding to OSHA's requests, and were converting to safer IV devices.

The components of the needleless system were finally stocked by mid-August, and unit-to-unit, around-the-clock inservice education was in progress. The joint effort by the Baxter representative and SGRMC's Education and Research Department included posters with the IV components pictured, step-by-step instructions and demonstrations, and return demonstration by nursing staff.

Another issue surfaced in October, when several needlesticks were investigated. Evidently some of the "old" IV equipment was still being stocked, and a few areas of the hospital had continued to use them. Also, some nurses were using needles to access vials and ports on the needleless systems, stating that the appropriate devices were not available. The old system components were removed from all nursing units and the central supply, and the Baxter representative returned to re-educate. This time, the education was extended to include the medical staff, some of whom had shown resistance to using the new needleless system.

Analysis of Data

The Statistica™ software program was used to analyze the compiled data on needlestick injuries. Frequency distributions and chi-square analysis were performed on the variables: year, occupation, department, and device. Statistical significance was established at $p < .05$.

The 242 reported injuries in the four-year period occurred as follows: 73 in 1991, 64 in 1992, 51 in 1993, and 54 in 1994. Since 1992 was a transition year for the implementation of the needleless system, that year's data was not included in the analysis. The 1991 and 1993 data were compared, and demonstrated a 30% decrease in overall injuries.

Of the total injuries, 72, or 30% were IV-related. Other devices responsible for injury were: sharps boxes, 14%, lancets, 12%, non-safety syringes, 10%, trash, 8%, vacutainers, 7%, IV stylets, 6%, suture, 5%, and

procedure trays, 5% (Table 1). Prior to the needleless system's implementation, the number of IV related injuries was 27, or 38% of all injuries. Following implementation they accounted for 10, or 20% of reported needle injuries, a decrease of 47% in IV related injuries.

The combined intensive care units were responsible for 53 of the total 242 needle injuries. Before the safety system was in effect, 25 of the 73 reported injuries took place in these units; after one year they accounted for only 8 of the 51 needlesticks, a 36% decrease. The medical/ surgical nursing units had 18 of the 73 pre-implementation needlesticks (25%), and 19 of the 51 post-implementation needlesticks (35%). The environmental services department accounted for 11 (15%) of 1991 injuries and 3 (6%) of the 1993 injuries (Table 2).

Nursing personnel reported 72% of all needlestick injuries for the 4-year period. Environmental services attendants reported 9.5%, laboratory personnel 7%, respiratory and radiology technicians 6%, OR techs 4%. For the pre-implementation year, 51 (70%) of the injuries were reported by nurses, and 37 (73%) were reported post-implementation (Table 3).

Table 1

Needlestick Injuries

By Device

	Y1991	Y1992	Y1993	Y1994
IV	27	22	10	13
Lancet	6	11	6	5
NSafety	8	7	6	4
Safety	0	0	0	3
Trash	7	4	2	6
IV stylet	2	3	4	5
Shrpbox	15	7	7	5
Tray	0	3	5	3
Vacut	6	5	3	3
Suture	2	1	5	4
ABG	0	1	3	3
Total	73	64	51	54

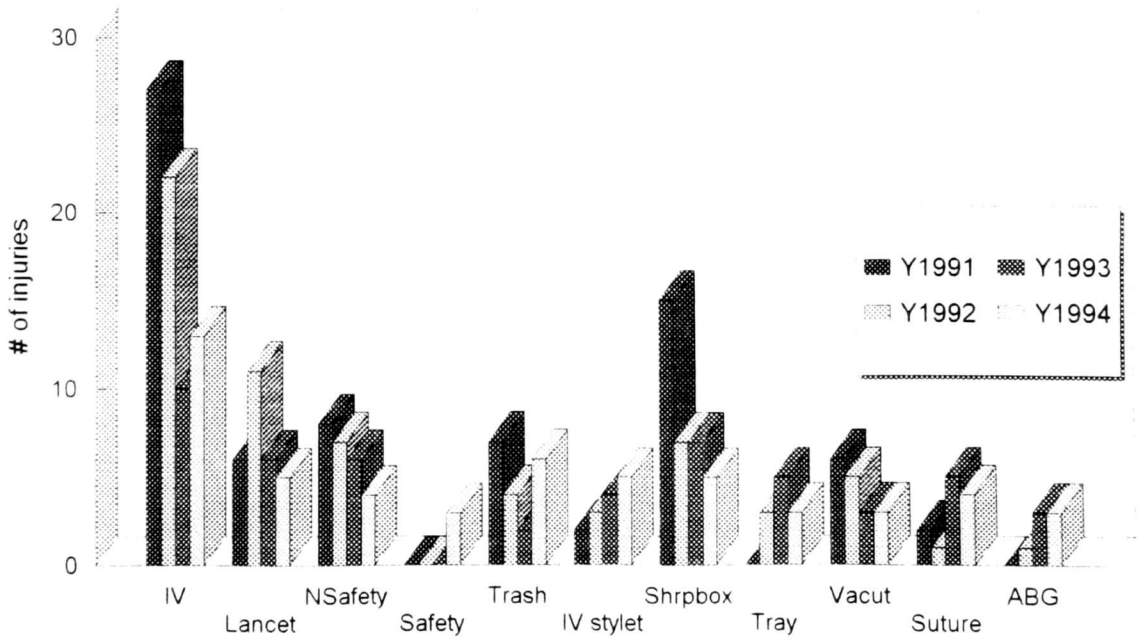
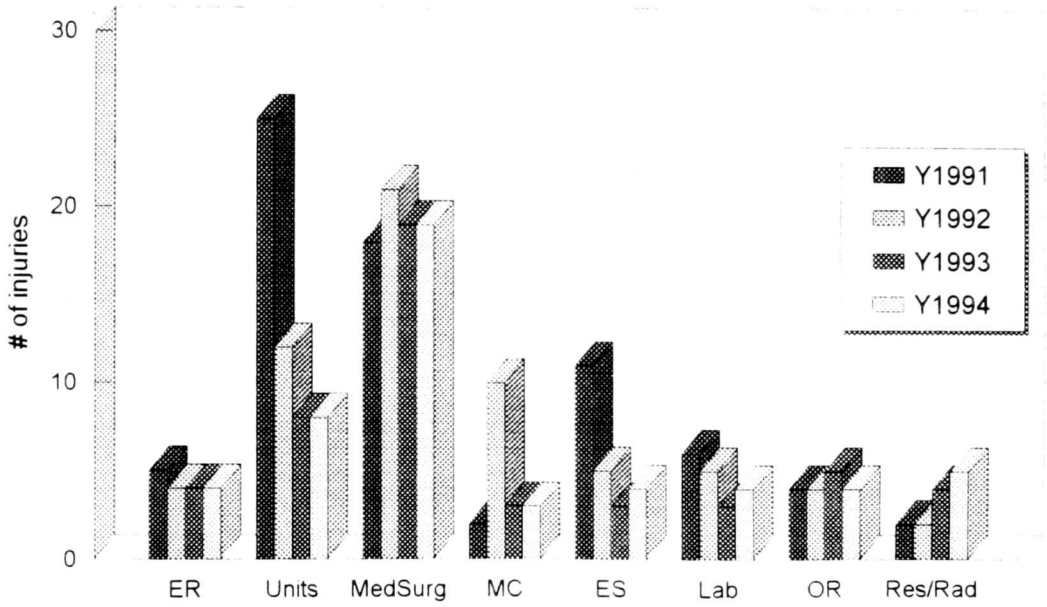


Table 2

Needlestick Injuries

By Department

	Y1991	Y1992	Y1993	Y1994
ER	5	4	4	4
Units	25	12	8	8
MedSurg	18	21	19	19
MC	2	10	3	3
ES	11	5	3	4
Lab	6	5	3	4
OR	4	4	5	4
Res/Rad	2	2	4	5



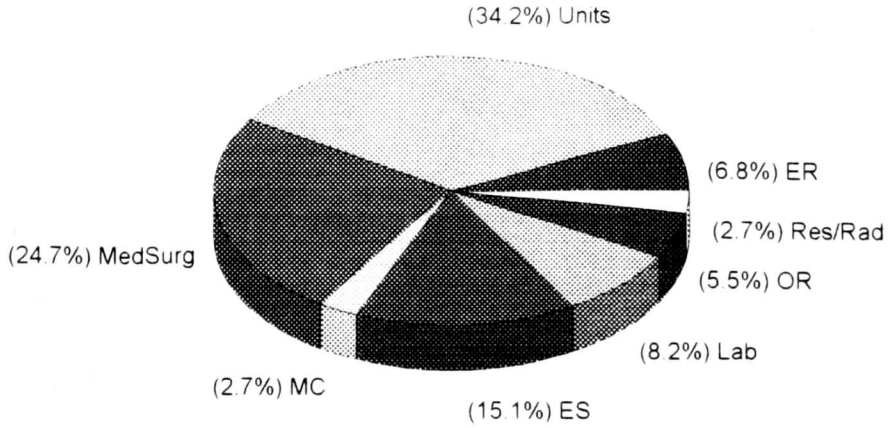
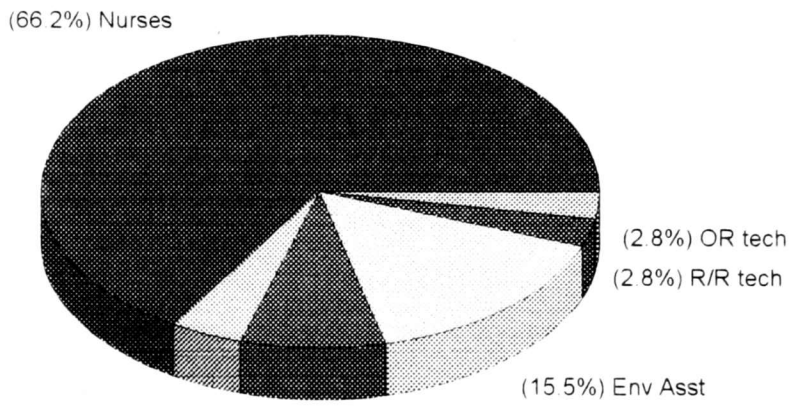


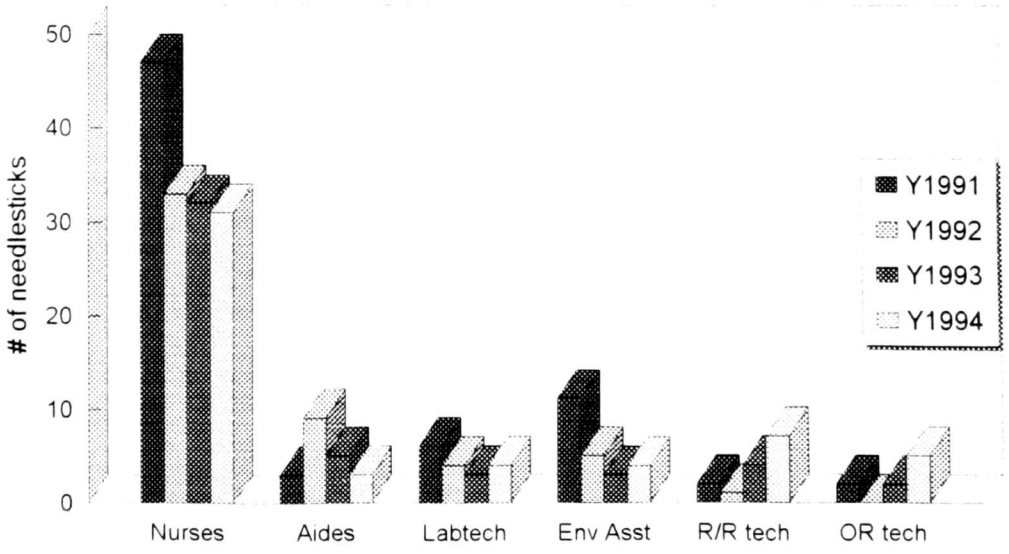
Table 3

Needlestick Injuries

By Occupation

	Y1991	Y1992	Y1993	Y1994
Nurses	47	33	32	31
Aides	3	9	5	3
Labtech	6	4	3	4
Env Asst	11	5	3	4
R/R tech	2	1	4	7
OR tech	2	0	2	5





RESULTS / DISCUSSION

In the year following the implementation of the IV needleless system, the overall number of needlesticks at SGRMC decreased by 30%. This was not a dramatic decrease when compared to some of the studies conducted in similar health care facilities, but was significant. Gartner (1992) reported a 51% reduction in overall injuries following a change-over to a needleless system. A 60% reduction in total needlesticks after six months was documented at the 390-bed Columbia Hospital by Rutowski (1993), although over a four year period that decrease was only 39%. One study (Weatherly, Young, Andresky, and Peterson, 1993) stated a 77% decrease in total needlesticks, but this implementation included the introduction of a shielded safety syringe as well as an IV needleless system.

The multifactorial approach by Weatherly, Young, Leech, Andresky, and Peterson (1993) noted a 77 % decrease following full program implementation, which included not only an IV system and a shielded syringe system, but a revised sharps disposal system and a risk and prevention education program.

Isolating the change in IV related injuries yielded more promising results. The 60% decrease in these needlestick injuries demonstrated that the IV system

did reduce the number of injuries occurring as a result of unnecessary needles. This number compares to the national average of 50% reported by Jagger (1994) for hospitals that institute IV needleless systems.

Impact on Departments

The intensive care units demonstrated the greatest decrease in number of injuries, overall and IV-related. The number of needlesticks occurring in the combined CCU, MICU, and SICU, were 25 in 1991, and accounted for 35% of the total injuries that year. There are some explanations for this. The patients treated in these areas require multiple IV lines and IV medications, and the seriousness of their illnesses and injuries requires quick action. Procedures are sometimes performed at the bedside, increasing the possible exposure to contaminated needles. Payton's study (1993) also noted a disproportionately large percentage (43%) of nurses and housekeepers had been stuck by needles in critical care areas. Due to the large number of IV administrations in these areas, it is not surprising that they realized the greatest change (68%). Another factor in the success of these areas could be that, as part of the evaluation process, they were more comfortable with the new equipment.

Of particular interest was the comparison of the needlestick rates before and after implementation in the medical and surgical units. The 18 needlestick injuries reported in 1991 increased to 19 in the years 1993 and 1994. None of the studies reviewed noted this discrepancy. Although the med/surg division employs more nursing staff than the combined intensive care units, the ratio had

not changed in the years studied. There are, however, some possible reasons for the lack of measurable impact on these nursing units.

At SGRMC, new nurses are usually assigned duty on the general units for the first year of their practice. The reason for this is that the skills they have been taught during their time in nursing school can be further developed by the hands-on experience in general care areas. Intensive care nurses are required to have one year of general experience prior to being assigned to these specialty areas. The inexperience of new nurses could affect their use and handling of needles. The study by Weatherly, Young, Andresky, and Peterson (1993), indicated that nurses with less than two years of experience were twice as likely to suffer needlestick injuries than more experienced nurses.

Another opportunity for research exists when examining the med/surg units. Between 1991 and 1994, the acuity of the patient population in these areas has greatly increased. Patients who are sicker require more extensive treatment: blood transfusions, hydration, antibiotics. With more IV therapy encountered on the general nursing units, the potential for greater number of needlesticks exists. A study comparing the number of devices used to the number of needlesticks might reveal a possible explanation for the lack of change in injuries. This could possibly be achieved by calculating the umber of needles used by these units and compare needlesticks to number of devices. This was done in Ippolito's study (1994), in which needlesticks were calculated per 100,000 devices used.

Another possible explanation for the great difference between the ICU and med/surg post-implementation rates might be that the evaluation for the safety devices took place in the ICU's, and the med/surg personnel had no part of the process. As Simkins (1994) notes, the involvement of all types of staff who use the devices contributes to the overall success of safety equipment implementation programs.

The environmental services department also had a significant decrease ($p < .05$) in injuries following the introduction of the needleless system (73%). Since most of these injuries occurred when ES personnel were emptying trash or cleaning floors, the fewer needles used by the nursing staff should lead to fewer needles being disposed of improperly. The educational effort to increase compliance of proper needle disposal may also have been a factor in this decrease.

The emergency department, maternity center, laboratory, operating room, respiratory department, and radiology department demonstrated no significant change in number of reported needlestick injuries before and after the IV safety system was implemented. Since these departments are exposed to the IV system less than the other nursing units, these results were not unexpected.

Nursing staff were responsible for 65% of all needlestick injuries using the traditional needled system, and 63% of the injuries documented following the needleless implementation. These figures compare to the national data that has been collected on the EpiNet™system, which indicates that 70% of needlestick

injuries are reported by nurses. The number of injuries suffered by the nursing staff did decrease however, from 48 in 1991, to 32 in 1993.

Environmental services employees reported 70% fewer injuries following the IV safety implementation, impacting their injury rate greater than any of the other occupations.

CONCLUSION

The importance of health care facilities providing a safe work environment for its employees cannot be underestimated. Regulating agencies in this state, to this point, have only made recommendations to hospitals about providing engineering controls to increase worker safety. There is pressure being exerted on these agencies to mandate that health care organizations implement the available safety devices, including intravenous needleless systems.

A safe work place can also increase a facilities retention and recruitment. Participants of one research study (Wolfrom, 1994), indicated that they felt the IV system was a positive factor for retention and recruitment, and that they felt safer in their jobs since the needleless systems were instituted. Staff morale can also improve, knowing that the administration of the facility recognizes the importance of a safe work environment.

The responsibility of the health care community is to provide appropriate evaluation of newer and safer technology, and to reduce the hazards that health care workers must face. The collaborative and communicative efforts of health care workers, administrators, manufacturers of health care equipment, and regulatory agencies are vital in achieving a safer work place.

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Appendix A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administra
Rockville MD 20857

FDA SAFETY ALERT:

Needlestick and Other Risks from Hypodermic Needles on Secondary I.V. Administration Sets - Piggyback and Intermittent I.V.

April 16, 1992

To Hospital Administrators, Directors of Nursing, Risk Managers, and Infection Control Directors:

This is to alert you to the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (I.V.) equipment.[1, 2, 3] The use of exposed hypodermic needles on I.V. administration sets or the use of syringes to access I.V. administration set ports or injection sites are unnecessary and should be avoided. Hypodermic needles should only be used in situations where there is a need to penetrate the skin.

The terms "piggyback" or "intermittent I.V." are commonly associated with this equipment configuration. In these procedures, a hypodermic needle is inserted either into a connecting "Y" site on a primary I.V. line ("piggybacking"), or directly into the I.V. access port ("intermittent I.V.").

Research shows that I.V. tubing-needle assemblies have a higher risk of needlestick injury than any other needle devices; needlestick rates more than six times as high as those from disposable syringes have been documented.[2] Although the risk is low, such needlestick injuries have the potential for transmitting bloodborne pathogens such as HIV, hepatitis B virus, and hepatitis C virus. Additionally, health care workers (HCWs) sustain needlesticks from exposed needles dangling from unintentionally disconnected secondary medication sets and from needles which protrude from disposal containers. FDA's Device Experience Network has received at least 24 reports describing hypodermic needles which have broken off inside I.V. administration set ports. Injuries to patients may be incurred if these needles travel directly into the patient's bloodstream.

Although FDA can not recommend use of specific products, we strongly urge that needleless systems or recessed needle systems replace hypodermic needles for accessing I.V. lines. There is no evidence that patient bloodstream infection rates have increased with the implementation of needleless systems which have been cleared for marketing. Patient infection rates, however, should be monitored to ensure appropriate use of these products, as well as minimize risks to patients.

For recessed needle systems, we agree with researchers who have stated that devices with the following characteristics have the potential to reduce the risk of needlestick injuries:

- A fixed safety feature to provide a barrier between the hands and the needle after use; the safety feature should allow or require the worker's hands to remain behind the needle at all times.
- The safety feature as an integral part of the device, and not an accessory.
- The safety feature in effect before disassembly and remaining in effect after disposal, to protect users and trash handlers, and for environmental safety.
- The safety feature as simple as possible, and requiring little or no training to use effectively.

Products with these characteristics are currently available on the market. During 1991, some of these products were evaluated as part of a pilot study by the State of New York. Preliminary analysis of these data from hospitals which used a safer technology for I.V. delivery (i.e., recessed needle or needleless systems), alone or in combination with other safety devices, showed a dramatic decline in sharps-related injuries and reductions of up to 93 percent in I.V.-related injuries.[4]

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) promulgated a final rule which is intended to minimize or eliminate the occupational exposure to bloodborne pathogens. In promulgating the standard, which became effective on March 6, 1992, OSHA concluded that exposures can be minimized or eliminated using provisions which include engineering controls (e.g., use of self-sheathing needles), work practices (e.g., universal precautions), and personal protective clothing and equipment.

FDA is interested in information concerning the role of medical devices in the transmission of bloodborne pathogens, including HIV. We encourage you to report potential hazards for patients and/or health care professionals to the Product Problem Reporting Program at 1-800-638-6725.

I would appreciate your sharing this Safety Alert with those on your staff who might find it useful, including I.V. teams, nurses, ward supervisors, employee health programs, and product evaluation committees.

If you have questions, please contact: Thomas Arrowsmith-Lowe, DDS, MPH, Deputy Director, Office of Health Affairs, Center for Devices and Radiological Health, FDA at 301-427-1060.

Sincerely yours,

James S. Benson

James S. Benson
Director
Center for Devices and
Radiological Health

1. Jagger J. Testimony on preventable needlesticks, preventable HIV infections, preventable deaths among health care workers. Presented before U.S. Congress Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy. Washington, D.C., February 7, 1992.

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3. Jagger J. [Letter to James S. Benson, Director, Center for Devices and Radiological Health, Food and Drug Administration]. February 14, 1992.

4. Chiarello L. Testimony on needlestick prevention technology. Presented before U.S. Congress Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy. Washington, D.C., February 7, 1992.

Appendix B

SOUTHEAST GEORGIA REGIONAL MEDICAL CENTER

Employee Accident Investigation Report

1 — TO BE COMPLETED BY EMPLOYEE

NAME AGE TIME OF ACCIDENT DATE OF ACCIDENT

SOCIAL SECURITY NUMBER JOB-TITLE/DEPT. HOW LONG ON THIS JOB?

DEPARTMENT-SHIFT (LOCATION OF ACCIDENT)

What happened? Describe what took place

Nature and extent of injury?

Employee Signature

2 — TO BE COMPLETED BY SUPERVISOR

Why did it happen? What was the cause?

Get all the facts by studying the job and situation involved. Answer the questions:

What? Where? When?
Who? How? Why?

What action should be taken and by whom to prevent recurrence?

Determine which of the 12 items below require additional attention.

EQUIPMENT	MATERIAL	PEOPLE
Select	Select	Select
Arrange	Place	Place
Use	Handle	Train
Maintain	Process	Lead

What have you, as a supervisor, done to eliminate the cause of the accident?

Take or recommend action depending on your authority.

Disposition: Referred to ED _____ First Aid _____ Referred to Physician _____
No Treatment _____ Returned to Work _____ Excused from work due to accident _____

FOLLOW-UP

Supervisor's Signature: Date:

Reviewed by:

Department Manager: Date: Safety Committee: Date:

Service Director: Date: Employee Health: Date:

Employer's First Report of Injury Filed? Yes _____ No _____ Date _____

DISTRIBUTION: — Risk Manager/Safety Committee: Service Director: Employee Health Nurse: Jones, Hill & Mercer Claims: Supervisors

Appendix C

MEMORANDUM

DATE: April 13, 1992

TO: Brenda Quinn, Purchasing Manager

FROM: Shelby Childers RN, Employee Health Nurse

SUBJECT: Costs of Needlesticks $58,361

Hard Costs:	ER visit	31.39
	ER MD	60.50
	Vaccine Dose	95.60
	H-BIG	335.80
	tetanus	104.20
	HIV x 4	140.48
	SPAB	35.00
	TOTAL	$802.97

Not every employee has this many hardcosts. $267.37 is a minimum. The employee who incurred above $802.97 would also recieve a minimum 2 more vaccine doses for a total $994.17 not to mention the cost of 9 letters they would receive from me as part of the federally mandated followup. Depending on the employee and the source patient their is also counselling in reference to 1) How needlestick occurred and how to avoid same mistake again. 2) Relative risk to self and sex partners. 3) Stress related to the unknown. Very seldom do I not have several hours devoted to each needlestick over the 9 months of followup. I will place an arbitrary value of $75.00 for my time and a value of $3.00 on each letter for $102.00 of additional costs.

Recent studies have shown that 60% of our employees who suffer exposures are HBV immune and 40% are non-immune. We have approximately 100 needlesticks per year. TYhe relative costs are listed below.

904.97	369.37	We have a potential cost of $58,361
x 40	x 60	which at $583 each is well within
$36,198.80	$22,162.20	nationally published estimates.

SOUTHEAST GEORGIA REGIONAL
MEDICAL CENTER
3100 Kemble Avenue • Brunswick, GA 31520