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Evaluation of Needlestick Prevention Devices

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Abstract

Needlestick injury, the cause of 80% to 90% of the occupational transmissions of disease, is the most critical occupational hazard facing the health care worker today. Six million workers use 6 billion needles annually, and all are at risk of being stuck with contaminated needles. The health care workers who use or are around hollow needles, and therefore incur needlestick injuries, are nurses, laboratory technicians, and housekeeping personnel. Nurses, mainly those working in emergency rooms, operating rooms, intensive care units, on intravenous teams, and in dialysis units, account for almost 80% of those infected occupationally.

Though general agreement exists regarding safer needle devices, needlestick prevention devices are the best long-term answer to preventing needlesticks. A more cautious approach to reducing the number of needlestick injuries is advised by some researchers, epidemiologists, and occupational health experts. They note that the devices currently on the market are largely "first generation" designs that will undergo continued refinement and require assessment in carefully designed clinical trials. Although the Occupational Safety and Health Administration's final ruling on occupational exposure to bloodborne pathogens may not directly address the issue of needlestick prevention devices, hospitals should be prepared to justify their practices and selection of equipment. Consequently, this paper examines the factors to be considered in the evaluation of needlestick prevention devices prior to purchasing and introducing them into hospital programs: device efficacy, device costs, and staff issues.

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Chapter 1

Introduction

Needlestick injury, the cause of 80% to 90% of the occupational transmissions of disease, is the most critical occupational hazard facing the health care worker today (Kelen, 1990). Six million workers use 6 billion needles annually (Larkin, Toska, Hudson, & Eybands, 1990), and all are at risk of being stuck with contaminated needles. The health care workers who use or are around hollow needles, and therefore incur needlestick injuries, are nurses, laboratory technicians, and housekeeping personnel. Nurses, mainly those working in emergency rooms, operating rooms, intensive care units, on intravenous (IV) teams, and in dialysis units, account for almost 80% of those infected occupationally. This figure includes all such cases, worldwide, reported since 1981 (Gerberding, 1990).

Needlestick injuries have been shown to be one of the more efficient modes of transmitting the hepatitis B virus (HBV) and the human immunodeficiency virus (HIV). The most commonly documented, occupationally acquired, infectious disease in health care workers, HBV, has an estimated annual incidence of 12,000 cases. It is often assumed that HBV is not a deadly disease, and certainly, compared to acquired immunodeficiency syndrome (AIDS), its mortality rate is low. However, when HBV is present in the blood of an infected person, it is present at an extremely high level. A health care worker stuck by a needle with HBV-infected blood has a 10% to 35% chance of acquiring infection (Gerberding, 1990). Of these 12,000 individuals who acquire HBV, 500 to 600

will require hospitalization, 700 to 1,200 will become chronic carriers of HBV, and 250 will die (Centers for Disease Control [CDC], 1989).

Little concern was given to the frequency of needlestick injuries in the workplace prior to the AIDS epidemic, despite the risk of acquiring more than 20 different infectious diseases from blood- or body fluid-contaminated needlestick injuries (Friedland & Brown, 1992). The risk of HIV transmission, however, is estimated by most sources to less than 1%. Data were collected over time in three major studies, including one from the CDC, one from the National Institutes of Health (NIH), and one at San Francisco General, where 25% of all medical patients have AIDS or AIDS-related complex (ARC). A summary of these data indicates that there is a 1-in-250 chance that a needlestick injury will result in seroconversion. Furthermore, the needlestick injuries responsible for transmission of HIV are generally not superficial injuries but incidents of unintentional injection of blood or deep intramuscular sticks (Gerberding, 1990). Although the number of health care workers who have contracted HIV or HBV is considered small, the risk of fatal or serious injury from such an accident is real.

The number of needlestick injuries among health care workers may exceed 800,000 per year (CDC, 1983), but the true scope of the risks and consequences of needlestick injuries remains undefined. The Occupational Safety and Health Administration (OSHA) requires hospitals to document needlesticks, but the statistics are not reported routinely to any state or federal agency. In addition,

health care workers often fail to report needlestick injuries (Hamory, 1983; McGeer, Simor, & Low, 1990).

Over the past decade, various approaches have been attempted to prevent the transmission of pathogens via needlestick injury. The introduction of an effective vaccine for the prevention of HBV infection in 1982 was a promising step. Unfortunately, the vaccine has had only a 30% to 40% acceptance rate among health care workers in high-risk settings. The introduction of the concept of universal precautions by the CDC, with the use of appropriate barrier precautions, has failed to prevent the primary route of occupational HBV and HIV transmission--needlesticks. Another approach used has been greater distribution of needle disposal systems; the goal being greater accessibility at the point of use. While each of these has had some impact on the transmission of infectious pathogens to health care workers, the incidence of occupationally acquired infection has remained unacceptably high (CDC, 1989). Needlesticks remain potentially the single most preventable hazard in the health care workplace, although the approaches aimed at reduction of this occupational hazard are disappointing.

A change in health care workers' perspective is necessary in order to focus on the correctable causes of the problem. In reality, needlestick injuries are not incurred by recapping, improper needle disposal, or carelessness. They are caused by hazardous devices that health care workers are required to handle under difficult circumstances. The replacement of hazardous devices with safer ones has more potential for reducing

needlestick injuries than any other approach (Jagger & Pearson, 1991). For this reason, improved design of needle devices has been cited as a major factor in efforts to reduce the risk of needlestick injuries (Ribner & Ribner, 1990). Jagger and Pearson (1991) found that 90% of needlesticks could be prevented if needles were designed differently.

The University of Virginia Hospitals conducted a 10-month, descriptive study, involving employee-reported, hollow-bore, needlestick injuries. The devices involved in the 326 injuries reported were disposable syringes, IV tubing and needle assemblies, prefilled cartridge syringes, winged steel needles, IV sets, phlebotomy needles, and IV catheter stylets. Once the number of injuries per device was tabulated, the data were adjusted for the needlestick rates of each device per 100,000 purchased. It was found that those items which required disassembly prior to disposal had the higher needlestick rates. These items included IV tubing with hypodermic needles attached (36.7 needlesticks per 100,000), vacuum tube phlebotomy assemblies (25.4 needlesticks per 100,000), IV catheter stylets (18.4 needlesticks per 100,000), winged steel needle IV sets (18.2 needlesticks per 100,000), and prefilled cartridge injection syringes(8.3 needlesticks per 100,000). Disposable syringes, which do not require disassembly, had the lowest rates (6.9 needlesticks per 100,000). In this study, 70% of the needlestick injuries occurred when the device was being prepared for disposal and 13% during or after disposal. The investigators concluded that new designs with a safety feature for covering contaminated

needles needed to be developed. Recommendations were for the new design to incorporate a safety feature that was an integral part of the device, kept the health care workers' hands behind the needle as it was covered, was in place before disassembly, and would remain in place during and after disposal (Jagger, Hunt, Brand-Elnaggar, & Pearson, 1988).

The OSHA issued the final bloodborne pathogen standard on December 6, 1991, after careful review of comments from 3,000 interested parties and testimony from more than 400 participants in public hearings. One of the standard's requirements deserves special attention. It states that engineering controls shall be used to eliminate or minimize exposure. Although the standard does not provide specific guidance regarding when specific devices would be required to replace standard needle systems, the compliance assistance guide explains that it is the employer's responsibility to evaluate existing needle devices and review the feasibility of implementing more advanced engineering controls (Pugliese, 1992).

Though general agreement exists regarding safer needle devices, needlestick prevention devices are the best long-term answer to preventing needlesticks. A more cautious approach to reducing the number of needlestick injuries is advised by some researchers, epidemiologists, and occupational health experts. They note that the devices currently on the market are largely "first generation" designs that will undergo continued refinement and require assessment in carefully designed clinical trials (American Health Consultants, 1992d). Although OSHA's final

ruling on occupational exposure to bloodborne pathogens may not directly address the issue of needlestick prevention devices, hospitals should be prepared to justify their practices and selection of equipment. Consequently, the purpose of this paper is to examine the factors to be considered in the evaluation of needlestick prevention devices prior to purchasing and introducing them into hospital programs: device efficacy, device costs, and staff issues.

Chapter 2

Device Efficacy

Device efficacy is the first factor to be considered in the evaluation of needlestick prevention devices. Many manufacturers market devices that claim to reduce the risk of needlestick injuries, and the number of different devices available is rapidly increasing. In the technology of hazard abatement, four types of controls are advocated in their order of decreasing efficacy: substitution, engineering controls, administrative controls, and personal protective equipment. In May 1991, the Emergency Care Research Institute (ECRI), an independent, nonprofit agency devoted to the evaluation of health care equipment, technology, and facilities, published a unique and comprehensive review of 26 products from 22 manufacturers that currently market needlestick prevention devices. It reviewed devices that address the first two categories: substitution and engineering controls (ECRI, 1991).

The devices can be grouped into eight categories by application: needleless medication/vaccine injectors, prefilled medication systems, IV starters with catheters, IV medication connectors, blood collection systems, disposable syringes, needle guards, and needle-recapping devices. The ECRI assessed devices by their ease of use and effectiveness in preventing needlesticks in various applications. Caution should be used when evaluating devices because some are marketed as risk-reducing products when they actually offer no protection from needlesticks. This chapter focuses on the general description and effectiveness of each

device group, and when applicable, hospital studies, many using the brand names of needlestick prevention devices, also are included.

Needleless Medication/Vaccine Injectors

Needleless medication/vaccine injectors are an example of hazard abatement by substitution. In this group, the medication or vaccine is delivered intramuscularly or subcutaneously by a pressurized system using carbon dioxide cartridges, thus eliminating needle use. Although most often employed to administer vaccines, it can also administer medications such as narcotics, analgesics, anticoagulants, vitamins, antibiotics, and hormones, but only in a fixed unit dose (0.5 ml). The one medication/vaccine injector examined by ECRI is effective in preventing needlesticks, but it has limited applications. It has been used primarily in clinics administering large numbers of immunizations because of its efficiency, therefore, eliminating time needed to use multiple disposable syringes (ECRI, 1991). The limited applicability should not deter hospitals from investigating its use in preventing needlesticks with standard methods of delivery. This writer is unaware of any other evaluations of this device.

Prefilled Medication Systems

These systems, which are marketed as preventive devices by the manufacturers, were designed as convenient methods for administering medications and minimizing errors by supplying premeasured unit doses. Current products consist of a reusable cartridge holder and prefilled medication cartridge with a needle

and are intended to be dropped into a nearby needle disposal container after use (ECRI, 1991). The prefilled cartridge syringe differs from the disposable syringe in that, after use, the contaminated cartridge and needle unit must be disengaged from the reusable holder for disposal.

Jagger, Hunt, Brand-Elnaggar, and Pearson (1988) in their study at the University of Virginia Hospitals found that most injuries with this device were directly or indirectly related to disassembly. In all, 82% of the needlesticks from these devices occurred during recapping in preparation for disassembly or during disassembly. Prefilled cartridges were used most frequently for performing heparin flushes after the IV administration of medication, a procedure that produces at least three contaminated needles. It was standard practice to dispose of all contaminated items after completing the procedure. Because of the apparent risks of transporting several contaminated items to the needle disposal container, the incentive to recap the needles was reinforced.

None of the systems examined by ECRI (1991) prevent the type of needlestick that has the potential of transmitting disease. They do eliminate the need for using needles to withdraw medications from a vial or ampule, but after the dose is given, the user is at similar risk of injury until properly disposing of the needle. Because of the risks of transporting the exposed needle and cartridge, this especially affects those health care workers that do not have a needle disposal container nearby.

The remaining six groups attempt to provide safer working conditions by unique engineering design. This is achieved mainly by placing a barrier between the sharp end of the device and the user. Depending on the design, ease of use, and other factors, some of these devices provide a safer alternative to standard needles.

IV Starters with Catheters

In the study by Jagger and colleagues (1988), 8 of the 326 reported needlesticks involving conventional IV catheters resulted from difficulties in disposing of the catheter stylet. It was common practice to place the stylet in a container positioned within arm's reach of the worker. Access to the container must be immediate so that the worker can minimize the leakage of blood from the catheter that occurs after the stylet is withdrawn. Two injuries occurred when stylets pierced or fell out of makeshift containers. In three cases, stylets were placed on beds or bedside tables because no container was immediately nearby, and workers were later injured when they attempted to pick up the exposed stylets for disposal. Two injuries were sustained during emergency procedures when workers encountered difficulties in finding a safe place to dispose of the stylets.

Four IV starters with catheters were on the market at the time of the ECRI review. In these devices, stylets are either enclosed upon removal from the catheter by a guard inherent in the device design, or they are so pliable that the risk of needlestick appears to be minimized. In the latter case, concern has been raised about the difficulty of proper disposal, either by being

forgotten in the sheets or improperly disposed of in the disposal container. Another concern revolves around the possibility of splash upon removal from the catheter. One product applicable for intermediate- to long-term use (10 days to several weeks) must be placed under sterile conditions. All require some degree of education which must be taken into account at the time of purchase. Furthermore, haphazard use may negate the potential benefit and create a greater risk (ECRI, 1991).

IV Medication Connectors

Conventional IV tubing-needle assemblies are standard hypodermic needles on IV tubing. Of all the groups, Jagger and colleagues (1988) found that these had the highest rate of injury. Because IV lines remain in use for long periods, needle caps were often not available when IV lines were changed. Needlesticks occurred when alternative methods were used to cover used needles on IV needle assemblies such as sticking them into drip chambers, IV ports, or IV bags. Both intentional and inadvertent detachment of IV lines resulted in needlestick injuries when the needles became lost in sheets or bedside trash or dangled freely from IV poles. Finally, the difficulty of disposing of a needle attached to a length of IV tubing was demonstrated by injuries that occurred when health care workers fumbled with the items on the way to the trash container or were injured by IV tubing and needle assemblies protruding from the openings of trash containers.

Although the United States Food and Drug Administration (FDA) does not have the authority to force health care institutions to follow the recommendation, it issued an alert on April 16, 1992

warning health care providers of the risks associated with hypodermic needles used to connect IV equipment. The alert states that the use of syringes to access IV 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 (American Health Consultants, 1992a). The implicated equipment configurations include using a hypodermic needle in connecting a "Y" site on a primary IV line (piggybacking) or using a needle directly in the IV access port (intermittent) (American Health Consultants, 1992b; Yassi & McGill, 1991). The safety alert advises health care institutions to use a needleless device or a recessed needle to connect IV equipment (American Health Consultants, 1992a).

The recommendation mostly occurred as a consequence of research conducted by Jagger, an associate professor of neurosurgery at the University of Virginia in Charlottesville. She wrote a letter to the FDA requesting them to issue the medical alert following a congressional hearing on health care worker safety. At the hearing, Jagger reported the finding of a study done at the University of Virginia which ascertained that 50% of needlesticks were caused by unnecessary needles, primarily those used to connect IV lines or access IV sites. However, the argument has been made that those needles, not having penetrated the skin, are less likely to be contaminated with patient blood and therefore pose a low risk for transmitting infections. However, Jagger reported the cases of at least three workers injured by those types of needles who have become infected with

HIV. In each of those cases, the needles were connected into a heparin lock (American Health Consultants, 1992a). In addition, the FDA's Device Experience Network has received at least 24 reports describing hypodermic needles that have broken off inside IV administration set ports, creating the possibility of injury to patients if the needles travel directly into the patients' bloodstream (American Health Consultants, 1992b).

In July 1992, Jagger estimated that between 15% and 20% of hospitals had already replaced their old IV devices with needlestick preventions devices. The FDA alert appears to provide more impetus to hospitals to purchase safety designs that eliminate or minimize the use of needles with IV equipment. The action of the federal agency has placed an emphasis on product substitution and engineering controls that will ultimately result in a new standard of care (American Health Consultants, 1992b).

Intravenous medication connectors comprise the largest group of devices reviewed by ECRI (1991). The intention behind the design is to eliminate the exposed needle before and after medication administration through an already existing IV line or catheter. They may also be used to collect blood via a syringe or a blood collection tube adapter. Many of the devices consist of a needle recessed in a plastic covering while others substitute the needle with a plastic cannula that can pierce a unique diaphragm multiple times.

All of the IV medication connectors reduce the risk of needlesticks when a standard needle would otherwise be used to give intermittent IV or piggyback medications. Because a needle

is used only for withdrawing medication from a vial and not for injecting the patient, there is little risk of infection. However, users may be tempted to use this needle for injection. Potential buyers must realize that some devices can only be used with specific adapters which will be additional costs. Other devices will adapt to a variety of systems that the hospital may already use (ECRI, 1991).

A concern with these devices revolves around the frequency they need to be replaced to maintain asepsis. Depending on the packaging of the device and its design, it may need to be replaced either every time a medication is given or possibly not until the IV set is changed. As devices are connected and disconnected, some concern also may exist about the degree of asepsis protection. For example, Luer connectors cannot be effectively wiped with alcohol, a common procedure with septum interfaces, but placing a cap over exposed Luer ports may help maintain an aseptic interface (ECRI, 1991).

Most of these products have not had sufficient clinical trials to determine whether they pose any increased risk for patient infection. Therefore, infection control committees and users should review the use of these devices before implementing, as well as, monitoring sepsis frequency. The most effective way of using these devices should be determined and monitored to assure proper usage.

At the University of Massachusetts Medical Center in Worcester, replacing standard IV tubing-needle assemblies with the Baxter Interlink IV Access System resulted in an initial 45%

decrease in IV-related needlesticks among patient care staff and housekeepers in a 6-month trial. An 80% reduction is expected after the system becomes fully implemented in conjunction with an aggressive education program to improve compliance. The system consists of several different connector devices that are chosen depending on the application, and in some cases, the preference of the user. The essential components are a blunt plastic cannula that replaces the usual steel needle and an injection cap that is specially designed to be pierced by the plastic cannula (American Health Consultants, 1992b).

Two other studies found in the literature examined the Interlink System. Implementation of the system at the Montefiore University Hospital, part of the University of Pittsburgh Medical Center, also resulted in a significant reduction in IV-related needlesticks. A 5-year review of reported IV-related needlesticks revealed that an average of 17 injuries occurred every 6 months at the hospital. After a 2-month transition period that included education and phasing in the IV equipment, IV-related needlesticks decreased to two in the following 6-month assessment period. Further investigation revealed that one of the needlesticks occurred with the conventional needle-connecting system, and the other occurred in the emergency department when a needle was used to connect the system rather than the plastic cannula. Though the latter needlestick showed that the system can be circumvented, a system adaptable to needles was intentionally selected in case an emergency warranted using whatever equipment was available (Gartner, 1992).

The final study which examined the use of the Interlink System was conducted at the Spartanburg Regional Medical Center in South Carolina by Beason, Bourguignon, Fowler, and Gardner (1992). The study took place on a medical-surgical unit and an oncology unit which reported consistently large volumes of both central and peripheral catheters, administration of IV medications, and handling of blood components. Throughout the investigation of the system, in which more than 3500 IV procedures occurred, zero needlesticks were reported. In fact, the incidence of medication, IV fluid, and blood leakage was less than 0.1%. Nurses using the system indicated no difficulties in learning to use it and noted that it proved highly durable during a variety of procedures. A weakness of this study is the short evaluation period of 1 month.

In Atlanta, at the Crawford Long Hospital, use of the Burron Safsite system to connect IV tubing with intravascular devices resulted in a corresponding decline in needlestick injuries. The system uses a two-way valve to eliminate needles with IV line connections and manipulations such as administration of medication and phlebotomy. In 1990, prior to the introduction of the new system, 45 needlesticks were directly related to IV line manipulations at the hospital. The following year after the implementation of the system, the number of IV-related sticks fell to eight, all of which were related to failure to use the new equipment. The use of the system lowered overall needlestick injuries at the hospital approximately 25% (American Health Consultants, 1992b).

Blood Collection Systems

In Jagger, Hunt, Brand-Elnaggar, and Pearson's study (1988) examining rates of needlestick injury caused by various devices, vacuum tube phlebotomy assemblies accounted for only 5% of needlestick injuries, but the rate per 100,000 items purchased was almost four times as high as for disposable syringes. Injuries most often occurred during recapping. Because the contaminated needle must be unscrewed from a reusable holder, it was common practice either to recap it before disassembly or to secure the needle with clamps during disassembly.

According to ECRI (1991), blood collection systems, which use vacuum/color-coded collection tubes, consist of disposable and reusable adapters. Only the disposable type completely eliminates user contact with needles. The reusable type exposes the user to the inner collection needle during disposal and, therefore, fails to eliminate the risk of injury from a potentially infectious source. A disadvantage of the disposable system relates to the sheer bulk. An adapter is used once and then discarded, making it inconvenient for phlebotomists to transport on their trays. In addition, large needle disposal containers are needed to get rid of the adapter and needle. Although these problems are not insurmountable, they need to be taken into consideration prior to deciding which system would be most beneficial.

Disposable Syringes

Jagger, Hunt, Brand-Elnaggar, and Pearson (1988) found that recapping was the most common mechanism of injury from disposable syringes. Recapping incidents occurred in three ways. First, the

worker missed the cap, and the needle stuck the opposing hand. Second, the needle pierced the cap during recapping. Third, the cap fell off a recapped needle. This suggests that a hazard remains after a cap is replaced because of variability in the friction fit securing the cap to the needle hub. Except for recapping incidents, needlesticks from syringes usually occurred after medical procedures with several steps. Workers attempted to dispose of accumulated trash in a single trip to the trash container to avoid interrupting the procedure. Injuries occurred when workers were picking up the trash or fumbling with it in transit to the disposal container.

The devices in this group have a syringe and needle with a plastic sheath that locks over the needle after use. They are easy to use and offer excellent protection against needlesticks after the protective sheath is locked into position. The sheath must be locked when over the needle, or the potential for injury remains. The disadvantages include limited sizes (5 cc being the largest), additional disposal bulk, and higher cost (ECRI, 1991).

In a study by Younger, Hunt, Robinson, and McLemore (1992), health care workers at three medical centers in the United States participated in a three-phase evaluation of the Monoject Safety Syringe, a single-use, 3 cc shielded syringe. During the baseline phase lasting 60 days, the three centers recorded 134 needlestick injuries. The total number of injuries rose to 140 during the study phase of 60 days, but the overall rate of needlesticks involving 3 cc syringes declined significantly from the baseline. In the baseline phase of the study, 3 cc syringes were involved in

27 needlestick injuries, resulting in an overall injury rate of 14 per 100,000 items purchased. That compared with three needlesticks and an injury rate of 2 per 100,000 for the study phase. One of the three needlesticks in the study phase involved a nonshielded 3 cc syringe. In this study, use of a shielded safety syringe significantly reduced the occurrence of needlestick injuries involving 3 cc syringes.

Needle Guards

Jagger, Hunt, Brand-Elnaggar, and Pearson (1988) found that unattached hypodermic needles accounted for 6% of needlestick injuries. The needles were encountered by nurses, housekeeping staff, and technicians, on floors, hidden in bedside trash, in wads of gauze or paper towels, at the bottom of supply trays, or protruding from plastic trash bags. In every case but one, workers were handling trash or were stuck by a needle protruding from an overfilled container. Despite safety guidelines, needles continued to be disposed of in inappropriate trash containers while posing a constant risk to housekeeping staff.

Needle guards provide one of the most adaptable designs for hospitalwide use by providing needles with sheaths that can be secured after use to prevent sticks. They can be purchased separately or with syringes. One manufacturer supplies needle guards only, and these can be used with already existing supplies. The major limitations of this group are the size selection and the possible awkwardness in using the device. The distance between the user's hand and the patient's vein is significantly greater

because of the length of the needle guard and may make it difficult to control the needle during insertion (ECRI, 1991).

As part of a New York state pilot study of needlestick prevention devices, Mount Sinai Medical Center tested the SteriMatic Safety Needle. The medical center made the automatic resheathable needle available in the outpatient phlebotomy unit and the hemodialysis unit. Phlebotomists were given the option of using the SteriMatic, a standard 21-gauge Vacutainer needle, or a Butterfly (winged steel needle). For first attempts at vein access, phlebotomists used the SteriMatic 198 times in 18 days, 60% of the possible attempts. Of the 198 SteriMatics used, only 4.5% required a second attempt at vein access, suggesting that the device was successful 95% of the time. The device primarily was used when veins were visible or palpable. When veins were neither visible nor palpable, phlebotomists felt more comfortable using a Butterfly. In the hemodialysis unit, only 1.5% of the 966 SteriMatics used required second attempts to access arterial and venous ports (American Health Consultants, 1992c).

In the above study, no needlestick injuries were reported with the SteriMatic Safety Needle. Workers reported that the device increased worker safety, required minimal training, and the safety sheath locked 100% of the time. However, second tries at vein access in the phlebotomy unit were sometimes needed because workers had difficulty locating veins. Slow flow of blood occurred after drawing one or two vacuum collection tubes, and it was difficult to manipulate the device due to the long barrel. In the hemodialysis unit, workers sometimes had difficulty obtaining

a specimen unless the device was in the center of the port. Due partly to the results of the Mount Sinai study, the SteriMatic has been modified by the manufacturer. The size has been reduced, the needle has a wider bore to allow adequate blood flow using the Vacutainer, a wider selection of gauges is available, and techniques were developed to allow safe sheath manipulation (American Health Consultants, 1992c)

Needle-Recapping Devices

According to ECRI (1991), needle-recapping devices that are currently available provide some system where the user can recap the needle with either one hand (separate stand to hold the recapping device) or two hands with some type of guard for the hand containing the cap. There are two disadvantages with this type of device. First, it is not intimately associated with the needle and therefore would require the health care worker to remember to carry a separate device whenever a needle must be capped. Users are likely to forget this in emergency situations. Second, these devices enable users to continue a high-risk practice, making it more difficult to abandon old habits and as a result, perpetuating conventional hazardous technology. Hospitals should be cautioned about inadvertently supporting such practices given that the final OSHA standard states that contaminated needles should not be recapped or removed unless the employer can demonstrate that no alternative is feasible (OSHA, 1991). Perhaps the only justification for use would be for specific controlled situations where one-handed technique is performed such as in critical care units and dental clinics where medications are

administered serially from a single syringe and must be recapped to maintain sterility.

Two Australian studies have investigated the impact of a recapping device, Needleguard, manufactured by Biosafe Products of New Zealand. Needleguard is an extruded plastic shield-shaped device with a central hole designed to retain a needle cap placed within it. Goldwater, Law, Nixon, Officer, and Cleland (1989) found that the Needleguard was effective in certain circumstances, but their study was conducted in an outpatient laboratory involving a relatively stable group of phlebotomists whose very occupation makes them particularly aware of the dangers of needlestick injuries. In addition, vacuum tube collectors, in which recapping is less likely, were used to collect blood in their study. This scenario differs markedly with that of a large general hospital where staff turnover is much greater and capped hypodermic needles are in common use. In another study, Whitby, Stead, and Najman (1991) were unable to detect any significant reduction in the rate of needlestick injuries among hospital staff using the Needleguard though there was more accurate reporting of needlestick injuries. Despite this finding, these researchers maintain that recapping using the device rather than not recapping remains a justified approach to the needlestick problem.

McCormick and Maki (1981) were the first researchers to make an explicit recommendation not to recap used needles. In this study and in others that followed, an association was noted between recapping needles and the incidence of needlesticks (Jackson, Dechairo, & Gardner, 1986; Jagger, Hunt, Brand-Elnaggar,

& Pearson, 1988; Neuberger, Harris, Kudin, Bichone, & Chin, 1984). The CDC adopted the conclusions of these studies when formulating Universal Precautions guidelines. The recommendation was based on the assumption that because recapping accounts for a large proportion of needlestick injuries, the avoidance of recapping should result in a proportionate decrease in needlestick rates. According to Jagger and Pearson (1991), this assumption is neither logical nor correct (Jagger & Pearson, 1991).

First, it must be recognized that most recapping attempts do not result in needlesticks. Furthermore, studies have consistently found that the majority of needlesticks occur while handling or coming in contact with exposed needles and not during the act of recapping (Jagger, Hunt, Brand-Elnaggar, & Pearson, 1988; Marcus & CDC Cooperative Needlestick Surveillance Group, 1988; McCormick & Maki, 1981; Neuberger, Harris, Kudin, Bichone, & Chin, 1984). There is a risk of injury during recapping, but there is also a risk while handling exposed needles. Therefore, the consequence of eliminating recapping is a tradeoff in which the risk of recapping is replaced by the risk of handling exposed needles (Jagger, Hunt, & Pearson, 1990b).

Health care workers give several reasons for recapping despite Universal Precautions guidelines against it: (a) to protect themselves during disassembly of a device with an exposed contaminated needle, (b) to protect themselves from exposed needles when several items have to be carried to a disposal container in a single trip, (c) to store a syringe safely between uses if its contents are to be administered in two or more doses

at different times, and (d) to protect others whom the worker has to pass at close quarters on the way to the disposal container. Rather than disregarding safety guidelines, many workers are perceiving two competing hazards, of recapping and of not recapping the needle, and attempt to choose the lesser. Until the incentive for recapping needles is reduced, it is likely that health care workers will continue this hazardous practice (Jagger, Hunt, Brand-Elnaggar, & Pearson, 1988).

Although there is a lack of evidence to support its effectiveness, the recommendation against recapping has become entrenched as a chief defense against needlesticks. Studies have found that recapping continues despite the increasing intensity of safety messages directed toward health care workers (Becker, Janz, Band, Bartley, Snyder, & Gaynes, 1990; Edmond, Khakoo, McTaggart, & Solomon, 1988). Response to persistent recapping occurs too frequently to promote further measures to correct the noncompliant behavior rather than to question the effectiveness of the policy (Becker et al., 1990; Krasinski, LaCouture, & Holzman, 1987; Jackson, Dechairo, & Gardner, 1986).

Chapter 3

Device Costs

Beyond the obvious ethical and medical motivations to prevent needlesticks, there is the very real issue of cost in the current health care economic climate. Thus, the next factor to be considered in the evaluation of needlestick prevention devices is device costs. Needlestick prevention devices usually cost more than comparable standard devices currently being used in most hospitals. This price increase, however, may be offset by savings that result from a decreased number of needlesticks.

The expense that an occupational needlestick injury incurs depends on the needlestick follow-up procedures taken; the procedures necessary vary depending on the likelihood of infection. When the source of the needle is known and HIV or HBV contamination is unlikely, prophylactic treatment usually is limited to testing the patient (source) for HIV and HBV, testing the worker receiving the needlestick for adequate HBV and possibly HIV antibodies, and administering gamma globulin. When the source is unknown or likely to have been HIV or HBV infected, additional measures may be appropriate (ECRI, 1991). Zidovudine (AZT) may be offered to those health care workers who are exposed to HIV and desire prophylactic therapy despite the inadequacy of studies that establish efficacy or safety (Armstrong, 1991).

In examining the costs of needlestick injuries, most studies include the costs of employee health personnel, laboratory tests, hepatitis B immune globulin, and the hepatitis vaccine. The expense per needlestick was found to be from $110 to $350 (Edmond,

Khakoo, McTaggert, & Solomon, 1988; Krasinski, LaCouture, & Holzman, 1987; Ribner, Landry, Gholson, & Linden, 1987). Jagger, Hunt, and Pearson (1990a) analyzed the price of needlesticks according to the type of medical device and found it to total $405 per injury. Of the costs, 60% were attributed to HBV screens, 23% to HIV screens, and 9% to employee health personnel time. However, none of these studies considered the cost of AZT prophylaxis. Two studies have examined the cost of AZT prophylaxis and found the cost for the medication, evaluation, and follow-up ranged from $900 to $2,000 (Sacks & Rose, 1990; Sowa & Miller, 1989). These figures do not include the indirect costs of morbidity due to AZT side effects.

In addition to the cost to hospitals for needlestick injuries, the expenses relayed to those health care workers who contract HBV and HIV must be considered. The hospital and society bear the costs of these occupational transmissions. Several researchers have examined the direct and indirect cost of AIDS. Scitovsky and Rice (1987) estimated the direct cost for personal medical care to be $32,000 and the indirect cost of morbidity and mortality to total $13,000 and $210,000 respectively. The indirect costs include the lost earnings to the patient and the productive losses to society due to sickness and premature death. Therefore, the total cost for each AIDS patient was $255,000. Other researchers estimate the cost of AIDS to be significantly higher. The direct cost of seroconversion and HIV infection for medical care has been found to total $44,000 to $77,000 and the

indirect costs to equal $500,000 to $620,000 (Sacks & Rose, 1990; Stock, Gafni, & Bloch, 1990).

The studies discussed thus far do not consider the numerous intangible monetary consequences of needlestick injuries. The costs of psychological disruption, negative impact on recruitment of health care workers, medical discrimination, loss of insurance, and possible loss of housing are not included due to measurement difficulties (Drummond & Davies, 1988; Gerberding, 1988). In addition, the estimated costs for needlestick evaluation excludes, in most studies, the expense of counseling health care workers.

Another potential cost to hospitals could be litigation. Hospital employees who contract an infection as the result of a needlestick are entitled to Workers' Compensation benefits. Because Workers' Compensation is a no-fault system, benefits are available regardless of whether the employee followed safety rules and preventive practices. Although Workers' Compensation is generally an exclusive remedy, an employee might however be able, in some jurisdictions, to sue the hospital in tort on the theory that it intentionally created a hazardous work environment by disregarding proper safety precautions. Physicians and other nonsalaried employees are not bound by Workers' Compensation and could bring a tort suit against the hospital. For example, in a highly publicized lawsuit, Veronica Prego, MD, contended that she acquired AIDS from an accidental needlestick at a New York city hospital where she had been an unpaid extern. The hospital settled the case for $1.3 million. The potential for hospital liability likely is to increase with safer product availability,

especially if the hospital fails to provide such devices (ECRI, 1991).

Regardless of the expense of needlestick follow-up, hospitals are obligated to provide adequate preventive measures for their workers. Industry and government standards are likely to reinforce this obligation. For example, OSHA may impose fines up to $70,000, for repeated violations, on hospitals that fail to take measures to protect workers. If hospital policies are at variance with CDC recommendations, documented and defensible reasons should be provided for the hospital's policies (ECRI, 1991). The high costs of needlestick injuries means that successful prevention has the potential for considerable cost savings. The financial benefit of needlestick prevention will depend on the cost of the new method of prevention and the proportion of needlesticks it prevents.

In order to make the most cost-effective selection, the hospital must know its experience with needlesticks. Because different jobs and departments perform varying procedures, location and job class of the injured worker must be examined. Post injury analysis can be as simple as a one-page, multiple choice questionnaire given at the time of the reported exposure. Such a survey could be anonymous and should include the job classification of the worker, the type/size of the needle involved, and the location of the incident. Further elucidating factors include the time of the exposure, access to disposal containers, shift worked, and any other element believed to be important by the worker. For hospitals that have not already been

performing such surveys, one could be devised with input from relevant committee members. A 6 to 12-month retrospective survey could serve as an interim measure to assess immediate needs. These data could be used to determine the most problematic areas and provide a rank-ordered list by priority. During times of limited resources, administrators would welcome such information (Wugofski, 1992).

Jagger has developed such a form for institutions to use to evaluate needlestick injuries and the devices causing those injuries. The form is designed to be completed by workers when they report injuries. In addition to the form, Jagger and her colleagues have developed a software program to help hospitals enter information collected on the form into their computer system and perform device evaluations. The software program is entitled EPINet, Exposure Prevention Information Network, and is available through Becton Dickinson and Company in Franklin Lakes, New Jersey, and the American Hospital Association in Chicago. The EPINet system also has established a network of at least 10 institutions that merges data on baseline needlestick rates and enables Jagger and her colleagues to track device-specific needlesticks and identify effective risk-reducing devices as quickly as possible. By linking needlestick injury surveillance data from diverse hospitals, Jagger is able to do the following: (a) compare the effects of different prevention methods on needlestick rates in different settings, (b) merge surveillance from participating institutions as a first step in creating a national baseline of needlestick rates against which any

institution can compare its own experience, (c) permit faster product evaluations of needlestick prevention devices by merging data from EPINet institutions testing the same devices, and (d) establish a centralized point for communicating successful exposure-reducing strategies for institutions and product performance concerns to device manufacturers (American Health Consultants, 1992c).

A few hospitals may wish to circumvent this issue by reviewing published literature regarding types of needles involved in needlesticks. In fact, some manufacturers use this information to market their products. While this appears to be a valid alternative, available information could prove limiting given the increasing trend towards specialization of community and university hospitals. As each hospital develops its own unique specialty, the nature of injuries will be predicated on the type of work performed. The efficacy of a needlestick prevention device in one hospital may not translate to efficacy in another. Therefore, hospitals are urged to carefully evaluate their needlestick injuries and target resources accordingly in purchasing the new designs (Wugofski, 1992).

Jagger, Hunt, and Pearson (1990a) compared the costs of needlesticks to the costs of six devices and found that hospitals could break even if safer devices prevented 100% of needlesticks and cost on average only 36% more. The study only examined the price of needlesticks, not the expense of nosocomial disease, prophylactic therapy, or potential litigation. Needleless IV connectors were found to be very economical due to their

effectiveness. The number of needlestick injuries prevented by this device merited paying 457% above the current device prices. Needlesticks due to IV stylets, however, occurred more often during use, and since injuries were not as likely to be reduced by safer designs, only a 10% increase in price would be budget neutral when purchasing this device (Jagger, Hunt, Brand-Elnaggar, & Pearson, 1988).

It has been noted that manufacturers confront barriers in the introduction of needlestick prevention devices. Most of the manufacturers of these devices are not anxious to introduce products that compete with their own successful markets (Armstrong, 1991). Some designs are inherently difficult to manufacture in quantity and require expensive retooling which is reflected in the price of the devices. A wide market would give industry incentive to retool, possibly causing the price per unit to drop , but meanwhile, the costs remain dauntingly high. Furthermore, with over 100 needlestick prevention devices from which to choose, manufacturers appear to be waiting for feedback from hospitals before making commitments to specific models (White, 1990).

Because most hospitals are concerned with the impact of needlestick prevention devices on their budget, it is helpful to compare the expense of using each new alternative to the expense of using current conventional devices, then use this difference for comparing alternative preventive products. This method will show how each new alternative under consideration compares with current costs and also will help organize institutional thinking

in considering all the changes that will be required in converting from the current system to an alternative system.

Three major guidelines should be used in this cost assessment. First, calculate prices on an annual basis using cost per se. Using cost per patient or other similar comparisons can be misleading. Because the market-place is likely to change rapidly, estimates should be made for no more than a 1-year period. Prices used should be those negotiated with the supplier; list prices can be misleading. Second, in performing a comparison, include all relevant expenses in the analysis of each alternative. Do not include expenses that are common to both alternatives. Third, the analysis should take into account all clinical applications. Because of the overlap between applications and device types, the analysis should encompass all anticipated changes. An overall assessment allows alternatives to be compared and price differences to be kept in perspective. Cost analysis following these principles will provide a useful guide in estimating the cost of preventive devices, compared both with current devices and with other similar devices.

Chapter 4

Staff Issues

The last factor to be considered in the evaluation of needlestick prevention devices prior to purchasing and introducing them into hospital programs regards issues with the staff. One of these issues is assessing the extent of staff education required for a device. Effective education must involve all potential users, including part-time workers, rotating house staff, and all shift workers (Wugofski, 1992). Generally, using a device with a well-designed, convenient, integral, protective mechanism will be more effective than relying heavily on education. Ideally, the device should require no user action. Otherwise, the action should be minimal and convenient (ECRI, 1991).

Users may be tempted to ignore or bypass any protective mechanism that is inconvenient or requires extra steps as was discovered in one hospital that found approximately 50% of the protective collars on safety syringes were not pushed forward over the needle prior to disposal. As a result, the weight of the collar on the barrel of the syringe tended to tilt the bare needle upward in the needle disposal containers, creating the potential to stick the hands of workers disposing of needles. There were actually injuries on these units because that safety feature was not being implemented correctly (American Health Consultants, 1992d).

The other issue, staff acceptance, is critical but seldom receives enough attention. A method to determine this includes performing clinical trials with the device. Though informal, the

design of such trials must be consistent and involve representatives of all classifications of health care workers affected (Wugofski, 1992). Their input is often overlooked even though they are the day-to-day users of the devices and are likely to make valuable contributions to the selection process, both in reviewing demonstration devices and during final decision making. Users who believe that a product is forced on them without their input are certain to find faults with the final selection and may fail to use it correctly (ECRI, 1991).

Because a single device will not meet all of a hospital's needs, staff should carefully assess available devices and attempt to select the minimum number of devices necessary. Using multiple devices increases the amount of education needed and the associated risk of confusion and misuse (ECRI, 1991). Devices that require a great degree of user education or that can be easily misused may not be a wise investment. The best needlestick prevention device is the one health care workers will use most often.

Chapter 5

Nursing Implications

Occupational injury by needles is a risk for health care workers mainly because of the possibility of contracting serious infectious diseases such as AIDS and hepatitis B. Those caring for emergency patients may be at particularly high risk, given the increasing prevalence of unsuspected HIV infection in the population and the propensity of such patients to seek care in emergency departments (Kelen, 1990). Innovative, technology-based approaches to prevention that implicitly reduce the risk of injury have the greatest impact in reducing needlestick injuries in health care workers.

The emergency clinical nurse specialist (CNS) is uniquely prepared to make a significant contribution to the process of evaluating needlestick prevention devices. The Emergency Nurses Association (ENA) delineates the emergency CNS as "a registered nurse who, through advanced study of scientific knowledge and supervised advanced practice at the masters or doctoral level, has become an expert in emergency nursing" (ENA, 1991, p. 13). The emergency CNS exemplifies professional nursing practice through the role functions of both direct and indirect patient care. These role functions include the following: expert clinical practitioner, educator, consultant, researcher, and administrator/leader. This chapter focuses on these five roles and their application to the evaluation of needlestick prevention devices.

Expert Clinical Practitioner

In this role, the emergency CNS functions as a facilitator and innovator for state-of-the-art nursing care with direct involvement in implementing and evaluating new products marketed to prevent or decrease needlestick injuries (ENA, 1991). One derives expert authority from knowledge and expertise, both of which increase and are advertised during the evaluation of a device. Because many other health care workers are involved in device evaluation, the emergency CNS demonstrates both role and expertise to many who do not observe one's function in direct patient care. The CNS's clinical knowledge of emergency nursing is crucial to making the best choices for available resources.

Argument for changing from standard needle devices to needlestick prevention devices is most successful if results from clinical trials and cost analysis data is presented in defense of the change. According to Harrison (1989), a clinical trial involves the use of a specific number of donated or purchased sample items in a clinical setting followed by an evaluation summary. Cost analysis data compare the price, quality, standardization potential, and other related factors of the device to that currently used in the hospital. A sound knowledge of the clinical setting and the scientific rationale for the requested needlestick prevention devices provides an articulate and businesslike presentation and reinforces the CNS's advanced level of practice.

Screening devices prior to clinical trial should be based on specific criteria. The most beneficial criteria include cost,

quality, safety, standardization, and simplicity. When possible, the emergency department and inpatient units should collaborate on device criteria while acknowledging instances where differences are firmly based on divergent practice. Combining the orders to the same brand when possible lowers prices for all involved.

The device evaluation process involves the selection of devices to evaluate in the clinical setting, length of time or total number of devices to evaluate, education of staff, coordination of the trial, and comparison of the data. Frequent checks with staff during education sessions and data collection are important to ensure that the device is being used properly, problems are quickly identified and corrected, and the trial is terminated promptly. The emergency CNS reviews the collected and collated data with the involved staff to elicit any further information not gathered by the instrument before preparation of the final report.

Once the data are combined with cost analysis data, the emergency CNS formulates a recommendation and prepares a final report. If the recommendations are accepted, plans for implementation include necessary revisions to current emergency department policies and procedures. Staff education arrangements include all affected clinical areas and the support staff involved in usage of the product. Once the device is in use, careful follow-up for several months by the emergency CNS is essential to ensure a smooth transition.

A larger scope of device evaluation is involved when the emergency CNS serves as a member of a product evaluation committee

for the nursing department. Active participation in these evaluations leads to a better understanding of cost and value. Combining the expertise of advanced practice in the systematic review and evaluation of needlestick prevention devices builds a stronger base for collaboration in other areas.

Educator

As an educator, the emergency CNS serves as a resource to emergency department staff, nursing students, and other health care personnel in the acquisition of knowledge and skills related to emergency nursing practice (ENA, 1991). The CNS is responsible for assessing educational needs on the departmental level, planning and implementing educational programs to meet these identified needs, and evaluating program effectiveness. Education involving needlestick prevention devices occurs through the use of formal and informal teaching methods, such as inservices, orientation and preceptoring of new staff members, and bedside teaching of new techniques.

The departmental-based task force provides an opportunity for the emergency CNS to educate staff. When staff nurses express interest in a needlestick prevention device they have seen in a journal or at a convention, the CNS encourages their interest and directs them in a systematic and scientific process of evaluation. The anticipated benefits from the new devices and a feeling of involvement in shaping the delivery of care are effective motivators for learning. Making pertinent literature available for discussion results in an informal research seminar and stimulates evaluation and utilization of research. Stimulating

interest may lead to a device-specific publishable research project in the department. The emergency CNS contributes to professional nursing literature by publishing scholarly works (ENA, 1991). By sharing as well as delegating tasks, the CNS participates in education of self as well as others. This departmental-based device evaluation assists in cost containment and leads to changes in practice because of increased awareness.

Consultant

Through the role of consultant, the emergency nurse functions as a clinical expert in emergency nursing by providing consultation, education, and information to health care providers and organizations (ENA, 1991). Participation in a departmental, multidisciplinary task force is an option for the CNS. This type of internal consultation improves communication among disciplines and encourages collaborative planning. The CNS has an excellent opportunity to raise ongoing issues involving device usage. This is also an excellent forum for sharing recent research findings. Input from purchasing, material management, and infection control exposes both physicians and nurses to aspects of device selection. Increased collaboration and communication in the selection and use of needlestick prevention devices offer promise for better quality patient care in the future.

For emergency CNSs broadening their perspectives beyond the institution, participation in multihospital groups offers an avenue for device evaluation. With mergers, joint ventures, and larger networks forming to combine purchasing volume to realize economies of scale, new demands exist for clinical expertise to

identify device improvements, set generic standards, educate manufacturers and vendors, and design and implement large scale device evaluations. Larger networks allow the CNS to establish contact with colleagues in many different areas where device availability and practice may vary. Comparing clinical observations and validating perceptions stimulates hypothesis formation and enables collaborative studies.

Researcher

The emergency CNS expands the scientific base of emergency nursing practice by conducting and facilitating nursing research (ENA. 1991). As expertise in device evaluation increases, the CNS has an opportunity to function in this role. Small, carefully designed studies strengthen the CNS's scientific knowledge base and when combined with other studies, improve the overall level of health care worker safety. Dissemination of research findings through presentations and publications enable larger numbers of health care workers to benefit from the CNS's efforts as well as increase the scope of expert authority.

Because these devices are designed to prevent needlesticks, fairly infrequent events, especially when tracked on a device-specific basis, it is difficult for one department or institution to show a significant decrease in exposures associated with a safety device during a time-limited evaluation period. The emergency CNS analyzes the number of needlestick injuries on a consistent basis. The number, category of personnel, location, etiology, and device are important details to obtain. In analysis reports, the CNS includes data from previous years in order to

illustrate trends. Communication of the results of analysis to appropriate personnel on a continuous basis allows one to elicit feedback on strategies to improve needlestick prevention devices.

Administrator/Leader

According to the ENA (1991), the emergency CNS provides clinical leadership in the formulation, review, and revision of emergency nursing policy and procedures. The policy and procedures should reflect the current standard of care in regard to needlestick prevention device usage. In addition, designing and implementing quality improvement systems to evaluate patient care and patient outcomes are responsibilities of the emergency CNS functioning in the role of administrator (ENA, 1991). Most of these devices have not had sufficient clinical trials to determine whether they pose any increased risk for patient infection. Therefore, monitoring the use of the devices and patient infection rates is paramount.

Finally, the emergency CNS collaborates with others involved in the development, implementation, and evaluation of a fiscally responsible budget to assure the delivery of quality emergency care (ENA, 1991). This leads to an important component of this role--cost containment. The CNS evaluates devices marketed at prevention of needlestick injuries in health care workers. Careful evaluation of these devices may save money for the hospital. Furthermore, educating, mentoring, and empowering staff increases job satisfaction and retention thus decreasing staff turnover. This translates into further savings.

The CNS is a catalyst for change. Protective devices that replace standard systems are by nature different and therefore invoke the resistant behavior associated with change. Using well developed leadership skills, the CNS increases staff nurse receptiveness to new technology such as needlestick prevention devices. Involving staff nurses from the inception of change facilitates a smoother transition.

Summary

The emergency CNS role is a multifaceted, dynamic role that encompasses a wide variety of functions. Opportunities exist for expert clinical practitioners to provide consultation to the institution, educate self and staff, participate in research, and develop in the administrative role through active participation in device evaluation. Potential benefits to the CNS from investing time in product evaluation are numerous. Perhaps the most important benefit is the opportunity to function in all the CNS roles and maintain high visibility within an institution while demonstrating concrete cost effectiveness. Through active participation in the process of device evaluation, the emergency CNS assists in the ultimate goal of prevention of needlestick injuries in a high-risk work population.

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