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Protective System from Medical Needle-sticks. Part I: Background and System Development

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Abstract: Previous research on healthcare workers' protection has concentrated on liquid barrier protection by providing impermeable personal articles such as latex gloves. This property is of high importance but since most blood-borne pathogen transmissions in the healthcare industry are caused by needle-stick injuries, protection from sharp invasive instruments should also be of high concern. And since latex and alike provide no protection against needle-stick injuries, new protective systems need to be developed and evaluated. This part of the study provides a review regarding the current practice of protection and the serious problems that arise from needle-stick injuries. Additionally, the development of new protective system is described. In part II of the study, evaluation of the new system will be provided.

Keywords: Medical needle-stick injuries, Bifid medical needle, Bloodborne pathogen infection, Needle force, Medical protective system

Introduction

Healthcare workers such as nurses, phlebotomists, doctors, maintenance personnel and emergency medical technicians are in fear while on the job. If they should be stuck accidentally, this tool (needle) that they use every day, several times a day, can bring on the devastating and ravaging symptoms of AIDS[1]. Statistics from the Centers for Disease Control show that the number of medical employees who have contracted AIDS through occupational exposure is low. Many healthcare workers have been confirmed to have been infected with the AIDS-virus through work related accidents and 22 % of them have developed full-blown AIDS. The Centers for Disease Control has acknowledged that the actual number of infected persons may be much higher because workers are either unaware of the exposure or reluctant to disclose it for fear of losing their jobs. There are nearly one million needle-sticks reported annually and again many cases go unreported[1].

Critical Issues Involving Personal Protective Equipment in the Medical Industry

Although the medical industry has the highest risk of bloodborne pathogen exposure, there are numerous other occupations (Table 1) that directly involve contact with bodily fluids also. Although AIDS is the most widely known and spread epidemic today, this disease is only part of the needle-stick problem. Other common and rare diseases that may develop from needle-stick injuries are listed in Table 2.

Despite training by OSHA's (Occupational Safety and Health Act) guidelines and educational programs that emphasize the low risk of HIV transmission to healthcare workers, healthcare personnel feel they are at high to moderate risk for contracting AIDS. Even though the actual risk is low, most workers indicate that they would not take a position that involved taking care of AIDS patients. Most AIDS

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Table 1. Population at risk of bloodborne pathogen infections

Type of facility or service	Work force at risk to HIV	Work force at risk to HBV
Hospitals	2,386,165	1,163,655
Dental Offices	316,237	97,066
Physician's Offices	640,681	313,206
Medical and Dental Labs	62,854	33,703
Nursing Homes	485,303	367,944
Residential Care Facilities	49,102	29,461
Home Health Care	212,246	141,703
Hospice Care	10,856	7,142
Hemodialysis	12,688	3,977
Drug Treatment	6,722	3,110
Public Clinics	56,345	27,533
Blood Banks; Plasma Centers	18,788	9,841
Industrial Facilities	178,732	123,987
Correctional Facilities	120,224	98,366
Personnel Services	163,477	132,945
Funeral Homes	57,013	32,903
Research Labs	89,151	42,583
Linen Services	50,000	42,500
Medical Equipment Repair	6,185	4,843
Law Enforcement	341,546	241,402
Fire and Rescue Units	252,048	89,586
Life-Saving	5,000	3,230
Schools	41,362	35,158
Waste Removal	13,300	11,305
Totals	5,576,026	3,057,145

Source: OSHA Bloodborne Pathogens Exposure Control Plan (1992).

Table 2. Diseases transmissible by blood and body fluids

Hepatitis B, C, D	Malaria
Cytomegalovirus infection	Babesiosis
Syphillis	Brusellosis
Relapsing fever	Cruetzfeldt-Jakob disease
Viral hemorrhagic fever	Colorado tick fever

Source: Becton-Dickinson and Company Pamphlet (1993).

related programs focus on OSHA requirements for protection and on the psychological problems of the AIDS patient. But the needs and attitudes of healthcare providers must be addressed. Negative attitudes and concerns result in personal and administrative problems, such as illness, requests for transfer, upward and lateral progression away from bedside care and career changes. Less definitive, but taxing behavior is also observed: tension irritability, lack of productivity, and loss of commitment to staff goals[2]. With all the negative statistics, healthcare employee pessimism, and defenseless providers, one can see why there is great concern surrounding personal protective equipment.

OSHA Regulations

To address the hazards associated with occupational exposures to disease-causing agents, OSHA issued a final rule that covers all employees who may be exposed to bloodborne pathogens through work-related contact with blood or other bodily fluids. OSHA has concluded that health risks involving exposure to blood and bodily fluids can be minimized or eliminated through compliance with the Bloodborne Pathogen Standard, Title 29, Code of Federal Regulation 1910.1030. This rule was designed to protect over 5.6 million healthcare workers and is predicted to prevent over 200 deaths and 9200 bloodborne infections annually by:

1. Vaccination against HBV
2. Care in the disposal of needles without recapping and sharp instruments (including a recommendation to dispose of used needles into puncture resistant disposal containers)
3. Wearing gloves and personal protective equipment such as masks, gowns, and protective eyewear in situations where health workers may be in contact with blood and bodily fluids and
4. Changing gloves between patients and washing hands when gloves are changed[3-6].

This rule took effect March 6, 1992 and hospital and other such facilities had to be in full compliance with the rule by July 6, 1992. The rule mandates engineering controls, work practice controls, personal protective equipment and employee training for any and all employees who may be exposed to blood and other potentially infectious materials[4-8].

Hepatitis B virus (HBV) has long been recognized as a pathogen capable of causing serious illness and death. Because the virus is transmitted through blood and certain bodily fluids, persons who come in contact with blood and other potentially infectious materials while on their jobs have been at increased risk of contracting HBV. This virus that causes AIDS, HIV, has only been recognized for about two decades. Because HIV transmission is considered less efficient than HBV, the risk of HIV infection to employees who must handle hazardous fluids or materials is less than for HBV infection. The consequences of HIV infection are grave, however, because the virus causes the fatal disease AIDS. A few inefficient and incomplete regulations have led to the 1992 Bloodborne Pathogens Act. In 1983, OSHA issued a set of voluntary guidelines designed to reduce the risk of occupational exposure to hepatitis B virus. The voluntary guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices, and recommendations for use of immune globulins and the hepatitis B vaccine[6].

On September 19, 1986, the American Federation of State, County, and Municipal Employees (AFSCME) petitioned OSHA to take action to reduce the risk to employees from exposure to certain infectious agents. They requested that OSHA issue a rule requiring employers to provide the HBV vaccine at no cost to employees at risk for HBV infection and would require employers to follow work practice guidelines such as those issued by the Centers for Disease Control. The AFSCME organization also requested OSHA issue a standard to require a training program for employees exposed to infectious diseases, require counseling for pregnant employees about diseases that have reproductive effects, and mandate posting of isolation precautions in patient areas and in contaminated areas[6].

On September 22, 1986, the Service Employees International Union, the National Union of Hospital and Healthcare Union petitioned the Agency to promulgate a standard to protect healthcare employees from the hazard posed by occupational exposure to HBV. They requested that, as a minimum, the standard should contain all the provisions in OSHA's 1983 guidelines with special emphasis on making workers aware of the benefits of vaccination. In addition, the organizations asked OSHA to immediately issue a directive stating that employers must provide the HBV vaccine free of charge to all high-risk healthcare workers[6].

On November 27, 1987, OSHA published in the Federal Register and Advanced Notice of Proposed Rulemaking (ANPR) announcing the initiation of the rulemaking process. The Agency requested relevant information to reducing HBV and HIV occupational exposure. The public was asked to comment on the scope, the modes of controlling exposure, personal protective equipment, vaccination programs, management of exposure incidents, medical surveillance, training and education, generic standards, advances in hazard control, effectiveness of alternative approaches and the environmental effects. OSHA received an overwhelming response to the ANPR in the 60-day period from interested parties including

Table 3. Mechanism of injury[5]

Task being performed	% of injuries
Recapping needle/lancet	24 %
Removing needle from intravenous tubing/ implanted port	22 %
Disposal related (between removal from client or intravenous device and needle box	20 %
Removing needle/syringe from client	7 %
Unseen needle when manipulating equipment/lines	7 %
Removing lancet from blood drawing device	3 %
Needle box related	3 %
Other	14 %

employers, unions, health professionals, trade representatives, professional associations, and government agencies. The comments were analyzed and summarized to produce the Notice of Proposed Rulemaking (NPRM) and on May 30, 1989, the NPRM was published in the Federal Register. The final rule of the Bloodborne Pathogens Act takes into consideration all of the previous regulations, comments, and exhibits received[6,9].

Causes of Needle-stick Injuries

Recapping is the most common mechanism of needle-stick injury. Every year, this route injures 9.3 % to 23 % of hospital nurses. Recapping injuries occur in three ways. First, the worker misses the cap and the needle sticks the opposing hand. Second, the needle pierces the cap during recapping, the user attempts to recap a long needle with a short cap. Third, the cap falls off a recapped needle. Intravenous tubing-needle assemblies are standard hypodermic needles on intravenous tubing. Shown in Table 3 this type of assembly is the second highest cause of needle-stick injuries. Included in these units besides intravenous tubing are prefilled cartridge injection syringes, winged steel-needle intravenous sets, intravenous catheter stylets, and vacuum-tube phlebotomy assemblies. Recapping is an old practice method still taught in nursing schools today[5,10].

When interviews were held with a number of healthcare workers they offered four common reasons for recapping:

1. To protect themselves during disassembly of a device with an exposed contaminated needle
2. To protect themselves from exposed needles when several items had to be carried to a disposal box in a single trip
3. To store a syringe safely between uses if its contents were to be administered in two or more doses at different times and
4. To protect others whom the worker had to pass at close quarters on the way to the disposal box[11].

This old method of recapping is done so unconsciously now that the habit will be hard to break[4,6,12]. A needle-stick injury not resulting in disease transmission may incur follow-up costs of $200-$1000. This range excludes the resulting anguish, lost time and administrative costs associated. The global costs of such injuries should be enough to spur hospitals [industries] toward the pursuit of safer needles and methods.

Medical Protective Systems

The use of gloves in the operating room dates back to the nineteenth century when they were introduced as a mean of protecting the hands of operating nurses. Soon thereafter, surgeons began wearing gloves routinely to prevent passage of microorganisms from their hands to patients and vice versa. Today, the use of gloves has become the norm, and latex is the material of choice for surgical gloves because it is impermeable, flexible, and inexpensive[13]. Increased strength, increased puncture resistance and better fit are other advantages latex has over vinyl or butyl[14]. Latex is an excellent barrier against bloodborne pathogens, but this material alone or double layered provides little to no protection against needle-stick injuries.

Cut-resistant gloves from Spectra1000® fibers are used as liners between two rubber latex gloves, over latex gloves or under latex gloves to protect physicians and staff members from cuts and slashes incurred during use of sharp instruments[15,16]. No material alone provides protection against needle-stick injuries, not even Spectra® fabrics, which are used in the manufacturing of bulletproof vests[17].

While gloves have been improved and manipulated, needle systems have also changed. A self-sheathing IV catheter intended to prevent injuries was tried at a San Francisco hospital. Interestingly, the device led to more injuries when first brought into the hospital. The problems were attributed to the catheter's unusual insertion technique.

While several organizations and industries have scurried around searching and inventing safer needles or safer gloves since the final ruling, one inventor has designed a system, which involves both the glove and the needle. Gordon, III has developed a new needle termed as bifid (Figure 1), which involves an apparatus and method for protecting users of invasive instruments from inadvertent skin puncture, by

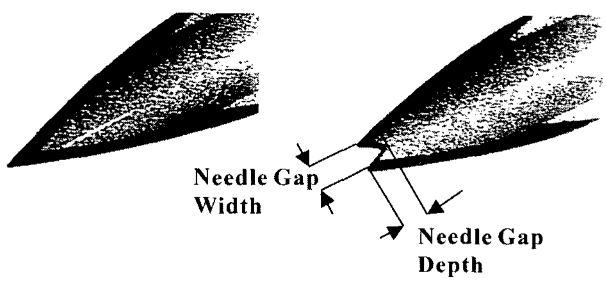

Figure 1. Standard (left) and the newly developed bifid needle (right)[18].

providing the user with an article of protective clothing and an invasive instrument[18]. Both the clothing and the instrument should be designed so that the instrument will become entangled with the clothing during contact, thereby preventing penetration of the skin. In prior discussions of this area of protection, most focused on the protection of the hands and arms with reinforced gloves and gauntlets, which are impervious to the specific instrument used, for example protective butchers' knives or cleavers. In addition, the prior art emphasized protection only through the covering of the skin with an impervious covering (such as latex or vinyl), not through a method wherein the skin covering is specifically associated with a modified instrument as to prevent skin puncture. Preferably, the glove will comprise a woven or knitted material. The optimum construction of the glove and its fiber matrix will be determined by a number of factors and measures. The composition, tensile strength, number of layers of the fiber composition, along with the number and configuration of the serrations in the invasive instrument are all important parameters which will have to be considered.

Major problems arising from needle-stick injuries and the invention of the bifid needle have inspired our team to conduct research to provide healthcare workers with a protective system. In order to achieve such a goal, it is essential to study the mechanism of medical bifid needle penetration through woven fabrics and understand the influence of medical needle parameters (needle gap depth and width; defined in Figure 1) and the woven fabric parameters (cover factor, number of layers, fabric orientation with respect to needle orientation, etc.) on the resistance of the fabric to needle penetration. An additional objective is to develop a technique or testing method to evaluate or characterize such resistance. In this part of the study, the description of a device to measure dynamic forces experienced by medical needles as a result of penetration through a protective textile structure is given.

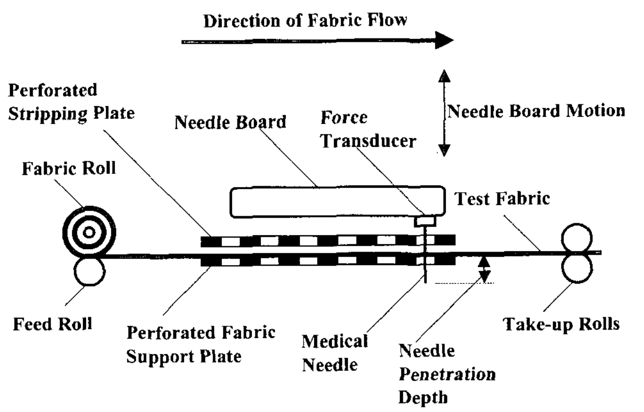

Figure 2. Basic arrangement of the needle force measurement system.

Developemnt of Needle Force Mesurement System

As mentioned above needle-stick injuries occur in dynamic mode. To simulate such situations, a 30-cm wide James Hunter laboratory scale needlepunching loom available in the manufacturing facilities of the NC State University College of Textiles, with maximum speed of 600 strokes/min, was modified and converted to a needle force measurement system (Figure 2). The system consists of needle board, stripping and fabric support plates, and fabric feed and take-up rolls. The needle board was modified to accommodate an assembly of medical needle and force transducer. Details of the assembly are provided elsewhere[19]. The test fabric is moved in the machine direction while the needle board is reciprocating vertically so that the needle penetrates the fabric during the needle board downward motion. Thus the fabric receives punches from the needle at different locations. It should be mentioned here that the needlepunching loom is of index type. In an index type needle loom the fabric feed is not continuous but the fabric is advanced certain distance per stroke. The fabric is stationary for a certain portion of the needling cycle. This portion takes place while the needle is engaged with the fabric.

For the detection of forces, a quartz load washer (piezo-electric force transducer) or foil-based transducer can be mounted and interfaced with a standard acquisition system combined with data analysis software (Figure 3). The system is designed to online acquire data points at high rate. During needle penetration through the test fabric, the needle experiences compression forces. The transducer generates an output electrical signal (in Volt) that is proportional to the force. The amplifier magnifies the signal and sends the signal to the analog to digital converter (A/D converter), which in turn sends the signal to the data acquisition hardware.

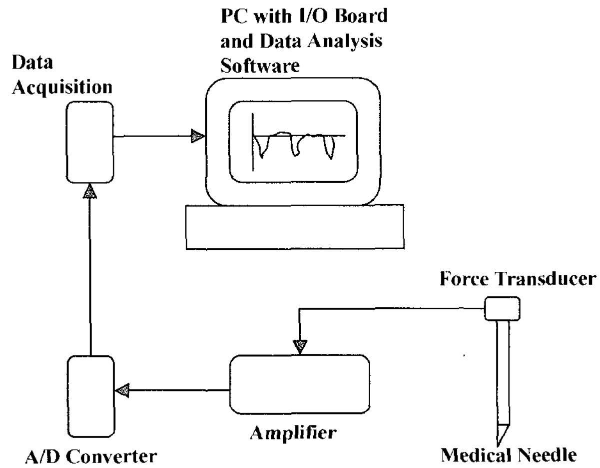

Figure 3. Schematic of the on-line needle force signal capturing and data analysis system.

Conclusion

Literature review disclosed that needle-stick injuries are causing serious health problems that require the attention of healthcare and textile researchers. While the bifid needle is an excellent invention in this vein, development of suitable personal protective textile articles is a must since it is the combination of the needle and the articles that provide the protection. Basic research is required to understand how the bifid needle parameters and the textile fabric variables interact when needle penetrates through the fabric. A suitable force measurement system to evaluate the protective system is described in this paper. Our next publication will deal with studies to evaluate the bifid needle and protective fabrics using the force measurement system.

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