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A Planning Guide to the Implementation of Safety Engineered Medical Sharps



A Planning Guide to the Implementation of Safety Engineered Medical Sharps

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PSHSA: Planning Guide to the Implementation of Safety---Engineered Medical Sharps

PREFACE

The Public Services Health & Safety Association (PSHSA) is a non---profit organization designated as the Safe Workplace Association for the healthcare, education and municipal sectors under the Workplace Safety and Insurance Act, 1997.

What are safety---engineered medical sharps?

Safety-engineered medical sharps, or SEMS, are sharp medical devices or instruments designed to include safety features to help protect workers from injuries. Many other terms have also been used to describe SEMS, including Safety---Engineered Devices (SEDs), Safe Medical Devices (SMDs) and Safety---Engineered Medical Devices (SEMDs). In Ontario, “hollow---bore needles” must be safety---engineered as outline in the Needle Safety Regulation (474/07). As a Safety Association, we recognize that many other sharp devices used in healthcare practice can and should be “safety---engineered,” whether that be for ergonomics, for exposure prevention or for general worker safety. For this reason we have chosen to refer to these devices as Safety---Engineered Medical Sharps in order to be specific about devices that are medical sharps or, in some cases, devices that replace medical sharps.

The Public Services Health & Safety Association (PSHSA) recognizes that there are many excellent resources available for organizations to use in the planning and implementation of a sharps injury prevention program. Many of these documents have been referred to in the completion of this tool and are listed in the reference section at the end of this planning guide. Readers may wish to refer to these documents for more background information. The abundance of information related to sharps injury prevention is rather daunting. We have attempted in this planning guide to summarize in a step---by---step fashion the key issues that need to be addressed as an organization moves forward to implement and use safer sharps.

This planning guide may also help healthcare organizations in addressing the legislated requirements under Ontario’s Occupational Health and Safety Act, Needle Safety Regulation and Healthcare and Residential Facilities Regulation, and establishing best practices in occupational health and safety.



The needle safety regulation was introduced in 2007 and expanded in 2009 and 2010. The regulation applies to all work environments where workers use hollow-bore needles on persons for therapeutic, preventive, palliative, diagnostic or cosmetic purposes.

The regulation requires that all hollow-bore needles must be safety-engineered. Three general exceptions will be allowed based on if:

- A safety-engineered version cannot be commercially found
- The worker has reasonable grounds to believe there will be risk of harm
- There is an emergency or crisis, the supply of safety-engineered needles have been exhausted, and waiting for new supplies would present a risk of harm to person or public interest

Employers should refer to the regulation for details regarding requirements and exceptions.

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This second edition now includes reference to the Ontario Needle Safety Regulation, 474/07. The Public Services Health & Safety Association greatly appreciates the time and expertise of the following individuals who provided their time and expertise in the development of the first edition of this manual. Their participation does not imply an endorsement by these individuals or their respective organizations, unions, associations etc.

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This resource is dedicated to the healthcare professionals who strive to make their workplaces and communities safer and healthier places in which to work.



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INTRODUCTION TO THE PLANNING GUIDE

This resource is intended to guide organizations in their program implementation of safety engineered medical sharps. It provides information to assist in the development of an action plan and implementation strategy. Appendix A provides a summary table of all key elements. By completing this table as you move through the document, you will develop an action plan.

A participative approach in all stages of program planning and implementation is recommended.

Management and staff of relevant services and the joint health and safety committee (JHSC) or Health and Safety Representative (HSR) should be involved. This guide follows five steps in the implementation process. It is recommended that other resources be reviewed during the implementation. A list of other resources appears in the references section at the end of this guide.

Each section is subdivided into key elements and includes:

- Element Statement (*italics and numbered, e.g., 1.1*)
- Suggestions for Implementation
- Standards or Rationale (provided following each major section).

Case Reports

With any sharps related injury, or blood and body fluid exposure, there is a risk of blood borne pathogen transmission. While some exposures have resulted in tragic outcomes most do not. They can however have a significant impact on the life of those involved.

Throughout this document we have included case reports based on health care worker sharps injuries.

We hope these serve to highlight some of the incidents that occur all too often.

As you read these reports imagine the discomfort and uncertainty that these workers faced as a result of their sharps related injuries. Although the workers in our stories were not found to have acquired an infection from their injuries, consider the upset and stress through the follow-up period while waiting to learn the final outcome of the injury.

And it's not just the worker; the fear and anxiety also impacts their family and intimate partners. These relationships share the worry until the injury's final outcome is known. The emotional toll on the injured worker, their family and loved ones, cannot be measured in monetary costs.



This guide can be used by any organization that uses medical sharps. Some organizations may have to modify some elements of this guide depending on size and the number of medical sharps in use. Where that is the case, it is the ideas expressed in each step or element that are important, not the specifics of the text itself.

This document cites current Ontario statutes and regulations at the time of publication. We recommend that the user obtain a copy of the Ontario Occupational Health and Safety Act (OHS), the Health Care and Residential Facilities Regulation (HCRFR) and Needle Safety Regulation (Appendix B).

BACKGROUND INFORMATION

Prevention of Blood and Body Fluid Exposure—Safety Engineered Medical Sharps

Blood and body fluids may carry infectious disease agents such as the HIV, hepatitis B virus and hepatitis C virus, and are a hazard for healthcare employees. Exposure may come from a splash or spray onto open skin surfaces and mucous membranes, as well as from cuts and punctures (percutaneous injuries) from sharp objects contaminated with blood and body fluids.

Review of Available Statistics

Data regarding blood and body fluid (BBF) exposures are available from a number of sources such as formal surveillance systems and research studies. However, the total number of workers exposed to blood and body fluids is unknown.

*The Centers for Disease Control (CDC) in the United States has estimated that as many as 384,000 percutaneous injuries occur annually in hospitals, with most of these resulting from hollow---bore needles (US GAO, 2000). This estimate is based only on data collected from the hospital sector and does not reflect workplaces such as long---term care and retirement homes, clinics or community care. In Canada, the **Alliance for Sharps Safety and Needlestick Prevention**, a coalition of manufacturers and worker groups, estimates approximately 21,264 injuries annually. Again, this is an underestimation based primarily on data from the hospital sector.*

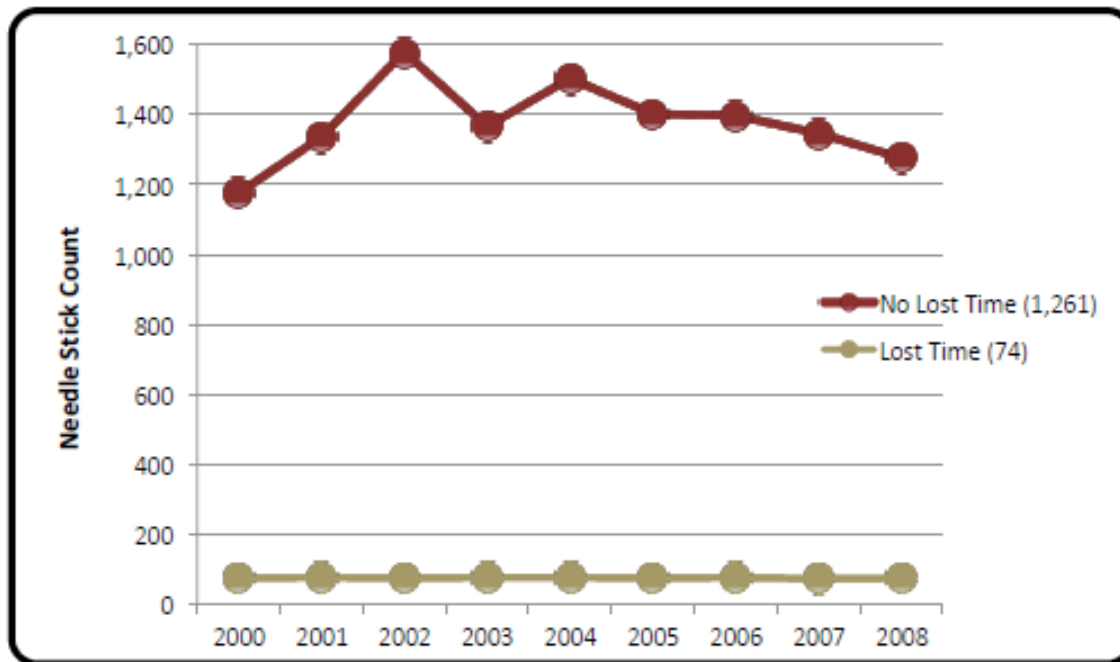
In Ontario, the Workplace Safety and Insurance Board (WSIB) collects data related to workplace injury and illness claims. Figure 1 shows the WSIB data for claims related to needlestick injuries.

The graph in Figure 1 is beginning to show a trend toward a decrease in the number of reported WSIB claims.



One of the principal sources of information about rates of BBF exposures and percutaneous injuries is from a data collection system known as EPINet™. The EPINet™ data is drawn from healthcare facilities in the US using the EPINet™ software. EPINet™ data suggests that the number of percutaneous injuries among staff may be as high as 26 per 100 occupied beds annually in teaching hospitals, and 18 per 100 occupied beds annually in non-teaching healthcare facilities (Perry, Parker and Jagger, 2005)

Figure 1—Needlestick Claims, 2000 to 2008



Between April 2000 and March 2002 (24 months), the Canadian Needle Stick Surveillance Network (CNSSN) gathered data from 12 hospitals or health authorities that voluntarily reported information. This data identified that the number of reported exposures from blood and body fluid was approximately 15.3 per 100 beds each year. In cases specifically related to percutaneous injuries, the estimate was 12.9 per 100 beds each year. Other data further reports approximately 3.2 injuries per 100 full-time equivalent (FTE) staff (Nguyen, Paton and Koch, 2003) and research conducted in Montreal hospitals estimates as many 12 injuries per FTE each year (Robillard and Roy, 1995).

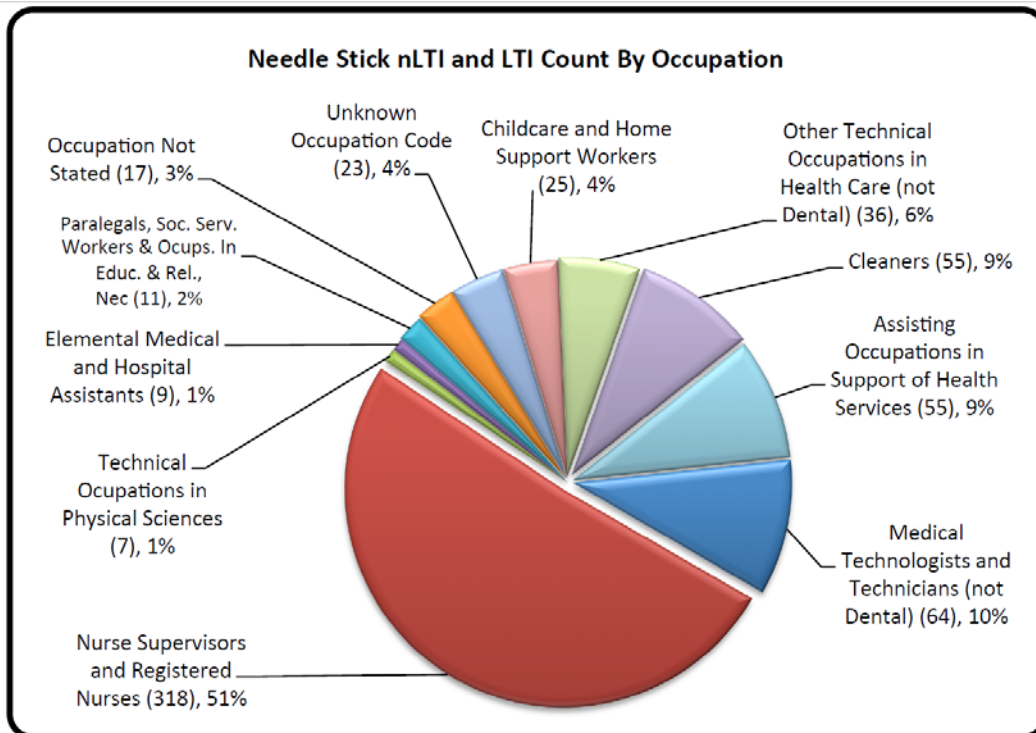


Within the overall exposure data, some job-specific exposure rates appear to be significantly higher. Data from a variety of blood and body fluid exposure sources indicate that the following job categories are among the most exposed (CNSSN; Perry, Parker and Jagger, 2005; Laramie and Davis, 2004):

- Nursing occupations
- Medical doctors, residents and students
- Phlebotomists/clinical lab technologists
- Sterilization and surgical attendants

Ontario WSIB data, in Figure 2, identifies similar results with nursing occupations having the greatest number of reported exposures. Physician-related exposures are not represented in WSIB data as, for the most part, they are not covered by the WSIB. Their exposure data is often captured in data collection systems or through study surveys.

Figure 2—Occupations Experiencing Punctures from Needle Sticks in the healthcare Sector, 2000 to 2008





As a group, physicians, including specialists and surgeons, have an alarming risk of sharps-related injuries and are reported by many sources to have among the highest rates of injury (CNSSN; Perry, Parker and Jagger, 2005; Laramie and Davis, 2004).

Researchers in Montreal noted that physicians and surgeons were poor performers regarding sharps safety, prompting the researchers to remark that “education to physicians is needed” (Robillard and Roy, 1995).

As mentioned at the outset, one of the greatest problems with analysis of blood and body fluid exposures and sharps injuries is the general lack of good reporting. While it is clear from the WSIB data presented in Figure 1 that the reporting of injuries is on the rise, one can still expect that under-reporting remains a problem. Studies suggest anywhere from 30% to 90% of incidents go unreported. In their research in Montreal, Robillard and Roy (1995) found that as many as half of the exposures went unreported through official channels.

A study at a medical centre in California (Radecki, Abbott and Eloi, 2000) found that, among respondents of a confidential survey, 71% had an exposure but only 9% reported the incident. The top three reasons cited for not reporting were:

- Reporting would not change outcome
- There was not enough time
- Occupational health services were too far away

In efforts to encourage better reporting of sharps incidents, it is obvious that educating people about the need to report all incidents is very important. It should be noted that researchers have found that sites where reporting was highest occurred within organizations that provided the best service to exposed workers (Robillard and Roy, 1995).

Risk of Exposure

The risk of acquiring blood-borne disease is related to three factors:

- The circumstances of the injury
- The infectious status of the of the source patient or source blood
- The susceptibility of the healthcare worker



The “circumstances” of an injury include the type of device, the degree of the blood contact, and the blood load or volume. Based on studies to examine injuries, the risk of transmission of diseases is greatest with those devices that contain larger volumes of blood such as larger-gauge and hollow-bore needles (NIOSH, 1999).

Information from the CNSSN indicated that, when source patients could be identified following an occupational exposure to blood and body fluid, test results showed the following infection rates among those patients:

- Hepatitis C—7.6%
- Hepatitis B—2.6%
- HIV—1.8%

Of all of the blood tested from source patients, 17% had co-infection with two or more of the blood-borne viruses tested for. Previous data from the Centers for Diseases Control has shown that HIV infections among healthcare workers were most prevalent among nurses, followed by healthcare aides and technicians (CDC, 1999).

A research study conducted at one health centre in California estimated that there would be one occupationally acquired HIV seroconversion every 2 to 3 years among the 1,100 late-year medical students and residents at the centre (Radecki, Abbott and Eloi, 2000).

The devices responsible for sharps injuries have been well documented by a number of sources. Based on data from EPINet™, as well as from a number of other sources, the following appear to be common causes of sharps-related injuries:

- Syringes/hypodermic needles
- Needles used for blood collection
- Suture needles
- IV catheter stylets
- Scalpel blades

Injection needles represent a significant number of injuries and, as a device, they also represent a significant number of sharps present in a healthcare setting. However, when calculated by number of devices used (e.g., rate of injury per 100,000 devices), other devices



may in fact pose a greater risk. Research conducted in Montreal found that needles associated with vacuum blood collection tubes, butterfly needles and IV catheter stylets posed a significantly higher risk, based on rate, than hypodermic needles (Robillard and Roy, 1995).

Data has also been collected on the type of work activity staff was engaged in when a sharp-related injury occurred. A national surveillance of healthcare workers in the US indicated that approximately 38% of injuries occur during use of a device, and 42% after use (NIOSH, 1999). Canadian data collected as part of the CNSSN between 2000 and 2002 show similar results.

According to the National Institute for Occupational Safety and Health, risk of injury appears to be higher with:

- Devices that require handling after use, such as disassembly or needle disposal from attached flexible rubber tubing
- Recapping of needles
- Transferring blood and body fluids between devices
- Failure to dispose of sharp objects immediately and properly (NIOSH, 1999)

Risk Control Measures

A long standing practice for controlling hazards in occupational health has been to employ the “occupational hygiene” model, which describes control measures for any hazard as being directed either at the source of the hazard, along the path to the workers, or at the workers themselves. The model holds that the most effective strategy to control any hazard is at the source of the hazard itself, or where that is not possible as close as possible to the source of the hazard. Where a control at the source or along the path between the hazard and the worker is not possible, controlling a hazard at the worker themselves may be the only alternative.

In essence, the model is a hierarchy of controls and is known as the “occupational hygiene hierarchy” of controls. Use of the hierarchy of controls for any hazard is considered a best practice. The hierarchy of controls can be described as risk control measures in descending order of effectiveness.



These risk control measures would include such measures as; (1) elimination of a hazard; (2) engineering controls; (3) administrative controls; (4) work practices, and; (5) personal protective equipment.

With respect to medical sharps and sharps injuries, the hierarchy of controls may be described in the following manner in terms of most effective to least effective:

1. Elimination

Removing the source of potential exposure by eliminating the sharp device altogether is the most effective risk control measure. Examples include the use of needleless IV systems and replacing wound suturing with adhesives.

2. Engineering Controls

Where a sharp cannot be eliminated it may be controlled using engineering and safety engineered features. This would be considered a less effective solution as it allows the hazard (the sharp object) to exist, but applies controls at the sharp object itself. There is extensive data on the efficacy of safety engineered medical sharps. In Ontario, engineering controls must be implemented for all hollow-bore needles as outlined in the Needle Safety Regulation.

3. Administrative Controls

Administrative controls are the next most effective risk control measure. They include an effective occupational health program with clearly defined objectives, adequate staffing, relevant policies and procedures, including those to ensure adequate surveillance and analysis of injuries and potential exposure to infection and infection control measures, including vaccination of healthcare workers.

4. Work Practices

Safe work practices includes such things as a strict adherence to prohibitions on the re-capping of needles, requiring that sharps are disposed of using an appropriate sharps disposal container, ensuring that sharps containers are not overfilled and that they are handled and disposed of properly. Safe work practices will also extend to issues such as requiring that personal protective equipment is removed before leaving the work area, and that there is appropriate interactive training of all staff who are at risk from blood and body fluid exposures.

5. Personal Protective Equipment



Personal protective equipment is not very effective against the prevention of a sharps related injury. Gloves, as an example, provide very little defense against puncture from a sharp object. Personal protective equipment such as gloves, masks, gowns and facial shields which are used to provide a barrier against exposure to blood borne pathogens through splash and spray do provide some protection to workers and are a necessary part of routine infection control practices. However, it should be understood that although appropriate personal protective equipment lowers the risk of exposure, it is still considered to be a less desirable control than other measures as an overall control strategy. The Public Health Agency of Canada refers to this in its' guideline *Prevention and Control of Occupational Infections*, where it states that "...engineering controls decrease or eliminate the hazard, whereas the use of personal protective equipment only provides a barrier between the healthcare worker and the hazard." (PHAC, 2002).

Use of Safety Engineered Medical Sharps

Research has shown that the use of safety engineered medical sharps can reduce the incidents of sharps-related injury within a healthcare setting. CDC reported studies have shown a reduction of up to 76% of reported injuries in some cases where phlebotomists have used SEMS (CDC, 1997). NIOSH has also reported on studies that have identified injury reductions of 62% to 88% (NIOSH, 1999). Furthermore, analysis of EPINet™ data collected in the US shows a clear decline in the number of sharps injuries after implementation and use of SEMS (Perry, Parker and Jagger, 2003).

Studies have demonstrated general acceptance of safety features. Factors that will influence staff use of SEMS include such things as:

- Perceived risk of infection
- Design of the device
- Training in the use of the device
- Length of time to become adept
- Ease of use
- Required changes in technique
- Previous experience with safety devices



Rejection of new devices is associated with a lack of training or support for change in the clinical environment (OSHA, 1997).

The use of SEMS on their own is not sufficient. A comprehensive approach to BBF exposure prevention is required, with safety devices being part of the program. Without appropriate support and education, SEMS may not be used, or may be used incorrectly. One CDC (2004) study found that 61% of the injuries with sharps that had a safety feature occurred prior to activation of the safety feature. This finding underscores both the need for consistent education and support for the devices and, where possible, the use of devices that are “passive”—that is, they do not require any additional action by the user.

When implementing a sharp injury prevention program, NIOSH offers the following advice to employers:

- Analyze sharps injuries and identify hazards and trends
- Set priorities and strategies for prevention by examining local and broader risk factors
- Ensure proper training
- Modify work practices that pose a needlestick hazard
- Promote safety awareness
- Establish procedures and encourage reporting of all injuries and incidents
- Evaluate the effectiveness of all prevention activities

The variety of SEMS available on the market is extensive, and new models and features are being introduced all the time. It is important for any organization making the transition to safer products to thoroughly investigate and conduct trials of new devices within the context of a comprehensive program. Applying the occupational hygiene model to the use of sharps provides a good foundation. In the model, the best way to protect staff is to eliminate the “sharp” object altogether. This approach is possible and has been achieved in many hospitals with the use of needleless IV access systems.

Where a sharp cannot be eliminated, an engineered solution would be the next most desirable course of action. Sharps with engineered safety features are classed either as passive or active devices.



- **Passive:** the safety feature of the device is engaged automatically or without any additional action required on the part of the care provider
- **Active:** the safety feature requires an additional action on the part of the care provider

From a safety perspective, a passive device is more desirable. Where engineered solutions are not possible, work practice controls are the next line of defense, followed by personal protective equipment (PPE).

The desirable features of a safety engineered medical sharp have been described by the National Institute for Occupational Safety and Health (NIOSH, 1999) (see Appendix C).

Costs

The WSIB average cost for no-lost-time claims related to needlesticks is approximately \$91. The average cost for lost-time claims is approximately \$2,357. The total claim count of needlestick injuries, excluding all other sharps injuries and blood and body fluid exposures in the healthcare sector was \$132,000 in 2004. Claim counts are rising fast, from 700 in 1999 to almost 1,400 in 2003. These figures do not include all of the claims made in other sectors, including those healthcare settings that are part of the WSIB Schedule 2 workplaces (employers that self-insure). Within this context, costs will go up. Moreover, the potential costs to any specific organization are significant. For example, one WSIB claim related to a case of hepatitis B seroconversion exceeded \$300,000.

Given the habitual under-reporting and the increased awareness of the issue among healthcare staff, employers can expect costs to escalate.

The claim costs, of course, do not take into account the other associated organizational costs related to staff replacement, training new staff, investigations, lab costs, the psychosocial impact on a family or partner of the injured staff and incident related follow-up. These indirect costs are estimated to be five to seven times the direct costs of injuries. The net result for Ontario healthcare is that needlestick and other sharps-related injuries could potentially cost millions of dollars.

In a 1998 cost analysis, the California Department of Occupational Safety and Health estimated that each needlestick injury costs between \$2,234 and \$3,832 (US). It calculated the median increase of cost for safer devices at 24 cents, which it estimated would cost the health system an additional \$104 million (US) per year, plus an additional



\$81 million (US) per year in costs associated with implementing a program. The cost of treating injuries from sharps was estimated at \$291 million (US) per year. Even with the additional costs of a SEMS program, an estimated savings of \$106 million (US) per year could be realized (California DOHS, 1998).

A report prepared by the Ontario Hospital Association estimated that the conversion to safer sharps could cost approximately \$7.5 million each year in Ontario, but could eliminate between \$10 million and \$27 million in costs to the hospital sector (OHA, 2003).

Perhaps one of the most quoted cost estimates related to sharps injury prevention and the benefits of SEMS comes from the General Accounting Office (GAO) of the US government. Prior to introduction of legislation in the States, the GAO researched sharps safety and costs associated with sharps injuries and safety engineered sharps. It estimated that 69,000 needlesticks could be prevented each year in the US with the use of needles with safety features, and that 109,000 injuries could be prevented just by eliminating use of needles in IV lines. The GAO also concluded that, while costs of safety engineered devices exceed the cost of conventional devices, savings will be realized overall when the costs of sharps-related injuries are factored in (US GAO, 2000).

Conclusion—A time to move forward

The literature related to sharps injuries is abundant. There is clear evidence of the causes of sharps injuries, the type of devices involved and the improper work practices that result in sharps injuries. The technology available today in the form of safety engineered medical sharps is accessible and affordable. Furthermore, estimates currently available indicate that the implementation of SEMS could result in net savings to the healthcare system. In short, there are no longer any compelling reasons why every healthcare facility should not be moving toward wide-scale implementation of safety engineered medical sharps.

IMPLEMENTING A SHARPS INJURY PREVENTION PROGRAM

A program for the prevention of exposure to blood-borne pathogens will include a multi-faceted approach. This guide for implementing safety engineered medical sharps is an important component of an overall blood-borne pathogen exposure prevention program. The implementation process has five steps, as follows:

- Securing management commitment, support and leadership
- Assessing the program needs
- Developing the program components and selecting SEMS
- Implementing the program
- Evaluating the program and planning for further activities

These steps are in many respects cyclical in nature. Some will need to be visited more than once. For example, gaining management commitment, Step 1, is critical to the undertaking of any project, yet assessing the program and making a business case, Step 2, may be required before getting the full commitment of management. Likewise, following an evaluation of the program, Step 5, it may be necessary to revisit Steps 3 or 4 in order to make changes that are based on the evaluation.

Case Report #1

It's not just the point of care staff who are at risk. A non--care provider received a needlestick injury while carrying out his normal duties. Despite a thorough search, the "source" of the contaminated needle could not be found. This meant the injured worker had to endure a long, stressful series of blood tests to ensure that he had been infected.

While the worker did not lose time from work, he did require counseling. And in order to protect his partner, he was advised to use condoms until the test results indicated he was infection free.

1.0 SECURING SENIOR MANAGEMENT COMMITMENT, SUPPORT AND LEADERSHIP

Gaining the support of the organization's leadership for implementing safer sharps is critical. There are many compelling reasons for the use of safer sharps which have been discussed in the background information supporting this resource.

Gaining the support of senior management may require the use of statistical data and information related to the costs of implementing safer sharps as well as the potential benefits from the use of safer sharps. Tools for summarizing data are located in the appendices to this resource to help organizations compile information. Tools to help organizations build a

business case by examining the costs associated with sharps injuries are also included (see Appendices D and E).

1.1 MANAGEMENT COMMITMENT TO THE PROGRAM

There is senior leadership, commitment and support for the program.

Suggestions for Implementation

- Senior management identifies and communicates that the implementation and use of SEMS is an organizational priority and corporate goal. This commitment is reflected by the:
 - Appointment of a program leader to assume overall program responsibility
 - Formation of a multidisciplinary committee to assist and guide the implementation
 - Allocation of adequate human and financial resources to support program planning, development and implementation

1.2 APPOINTMENT OF A PROGRAM LEADER

A program leader has been designated to lead the program.

Suggestions for Implementation

- A program leader must be appointed to assume overall responsibility for program coordination and implementation.

1.3 MULTIDISCIPLINARY COMMITTEE

A multidisciplinary committee has been formed to assist with the planning and implementation of the SEMS program.

Suggestions for Implementation

Establish a multidisciplinary committee, coordinated by the program leader. The committee should consist of key stakeholders who provide input into the development of the program. Recognizing that in smaller organizations one individual may have responsibility for multiple services, we suggest that the committee could include representatives from the following areas of expertise:

- Senior management



- Program leader for the sharps injury prevention program
- Occupational health and safety department
- Nurse Manager
- Front-line caregiver
- JHSC/HSR
- Infection control
- Staff educators
- Clinician/physician
- Union representation
- Purchasing department
- Product evaluation committee

Case Report #2

A health care worker in a long term care home received a needlestick injury while administering a treatment to a resident. Based on the circumstances of the injury it was determined that a high risk of disease transmission was present. The worker was required to take a difficult and uncomfortable course of post exposure medications, as well as undergo blood testing.

The result—the medication’s side effects caused the worker to lose four weeks of work. But that wasn’t the end of it! To ensure that the worker had not become infected, periodic blood tests were required during the full year following the injury.

- The roles and responsibilities of the multidisciplinary committee should include:
 - Developing terms of reference, including defined authority and accountability (see sample terms of reference in Appendix F)
 - Identifying goals and objectives
 - Establishing timelines and deliverables
 - Developing a communications plan
 - Developing an evaluation plan

Standard or Rationale

- Research indicates the necessity of senior management commitment to achieve program excellence in health and safety (Stewart, 1999). Best-practice guidelines related to implementation of sharps injury prevention programs identify



management commitment as a key. Organizations that have successfully implemented SEMS have reported the necessity of senior management commitment.

- OHSA, sec. 25(2) (j) (Duties of the Employer) requires an employer to develop a health and safety policy and to implement and maintain a health and safety program to support the policy. Since blood and body fluid exposure is recognized as a significant risk, this issue should be considered as part of the health and safety program.
- The needle safety regulation requires a safety---engineered device where a worker is to do work requiring the use of a hollow---bore needle on a person for a therapeutic, preventative, palliative, diagnostic or cosmetic purpose, in any workplace.
- A multidisciplinary committee solidifies program support, contributes to program compliance, capitalizes on a broad base of skills and expertise, and provides additional human resources in developing and implementing the program. A multidisciplinary committee engages a broad base of skills to ensure consideration of best practice outcomes.

2.0 ASSESSING PROGRAM NEEDS

An assessment of the organizational factors that relate to sharps injuries should be undertaken when developing a new program or when strengthening an existing one.

A comprehensive assessment will identify the existing and potential risks with respect to issues related to handling medical sharps within the organization. Based on the outcome of these assessments, you can prioritize, plan and develop aspects of your existing situation to put together a comprehensive SEMS program. The program steering committee should identify who would be appropriate to complete the assessment.

Consider these categories in the assessment:



- Incident analysis
- Equipment use
- Organizational culture

At this time, it may also be advantageous to consider a review of the current status of some other key issues that will be a necessary part of the overall program. These assessments may help an organization in understanding future needs. Additional program assessment items include:

- Current data collection systems
- Current staff reporting system
- Current training and education provided to staff regarding BBF exposures and sharps injuries

An extensive summary of survey methods and tools that can be used to assess sharps safety activities is available in the CDC's Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program (CDC, 2004). This workbook can be accessed on the Internet at <http://www.cdc.gov/sharpssafety/index.html>. A review of the CDC workbook is encouraged as part of the process in planning for the implementation of a sharps safety program.

2.1 INCIDENT ANALYSIS

An analysis of injuries and incidents related to blood and body fluid exposures and sharps injuries has been conducted.

Suggestions for Implementation

- Conduct an analysis of all injuries associated with sharp medical devices, using computer-based or paper-based data collection tools.
- Summarize incident data (see Appendix G and Appendix H). The summary will be helpful in setting future priority action. The data will be most useful if it is organized to describe:
 - Total number of sharps injuries and blood and body fluid exposures
 - Number of sharps near misses, injuries and exposures by location or service area of the incidents



- Type of equipment involved in the incident
- The task or activity that was being performed when the incident occurred
- Occupation of the affected worker

In many situations the data available regarding sharps injuries within an organization will not be very comprehensive. This may occur for various reasons, including for instance:

- A relatively small number of devices are used by the organization
- There is under reporting of injuries
- Baseline data on sharps injuries has not been integrated or amalgamated properly following consolidation or restructuring of a number of organizations and workplaces
- Poor data collection processes exist within the organization

Data on sharps related injuries is available from external data sources such as The EPINet™ database at the University of Virginia, the data compiled by Health Canada through the Canadian Needle Stick Surveillance Network, and through various other research and third party data sources.

Where sharps injuries are not well characterized by the organization's own data, an assessment of injuries should also be based on the information that can be learned from external data with respect to devices most often implicated in injuries, occupations that are most often exposed and circumstances that are involved in sharps related injuries.

Standard or Rationale

- Risk Assessment: OHSA, sec. 25(2)(h) (general duty to take reasonable precautions for protection of workers)
- Analysis of the location and nature of previous incidents is critical to determine the service areas, occupations or devices with the greatest need for attention.
- The risk assessment should initially rely on risk profile of sharps injuries established by robust external data rather than waiting for a complete data set produced by new in-house data collection.

2.2 ASSESSMENT OF DEVICES USED

The organization has completed an assessment of medical sharps and other equipment.

Suggestions for Implementation

Complete an inventory of all sharp medical devices by department/service and record the findings on the Departmental Medical Sharps Inventory Tool (Appendix I).

Standard or Rationale

Analysis of sharp medical equipment will identify the type, number, location and status of existing equipment.

- Information gained from an inventory assessment will help with the planning and implementation of new SEMS products and procedures particularly for hollow-bore needles as the needle safety regulation requires the use of a safety-engineered device when a worker is to do work requiring the use of a hollow-bore needle, The employer must provide a safety-engineered device unless they are unable, despite making efforts that are reasonable in the circumstances, to obtain a safety-engineered needle that is appropriate for the work.

2.3 ASSESSMENT OF ORGANIZATIONAL CULTURE

The organization has conducted an assessment of how sharps injury prevention strategies are valued in the organization and what systems are in place to maintain a safe working environment.

Suggestions for Implementation

- Survey the management and staff of each department/service area to identify issues related to work organization and their perception of, attitude toward and experience with safety-engineered medical sharps (Appendix J Part 1). This assessment is especially important where a previous program has been unsuccessful.
- Some of the key points of interest regarding the culture of the organization:
 - There is a blame-free environment for reporting sharps injuries and injury hazards
 - Employees know that management will discuss problems in an open and blame-free fashion
 - The organization encourages staff to report near misses and observed hazards in their workplace



- There are effective communication methods that provide information and feedback on the effectiveness of the sharps injury prevention program in the organization
- Findings from hazard investigations, unresolved problems with sharps injuries, and prevention improvements are captured in articles in the organization's newsletter, staff memos or electronic communications tools
- There are brochures and posters that enhance sharp safety awareness, reinforcing prevention messages and highlighting management's commitment to the program
- The organization promotes personal accountability for safety performance at all levels
- A sample *Assessment of Safety Culture Tool* and employee survey can be found in Appendix J Part 2, and much more comprehensive tools are available from the CDC workbook.

Standard or Rationale

- Identifying problems, barriers and successes within workplace culture will help with the development of appropriate program components.
- Identifying previous and potential issues involving work organization or staff perceptions will allow appropriate remedial and educational solutions to be developed.
- In order to do meaningful sharps injury prevention planning or make adjustments to the current program, all relevant data on sharps incidents and injuries need to be analyzed and properly interpreted.

2.4 ASSESSMENT OF SHARPS INJURY REPORTING

Sharps injury reporting procedures are adequate to collect essential data for meaningful analysis.

Suggestions for Implementation

- The procedures encourage prompt reporting from all workplace parties.
- Records are maintained as per the organization's policies for workplace incidents.



- Confidentiality of medical and health records is maintained.
- At a minimum, the following data should be captured on the report form:
 - Descriptive information to help monitor sharp injury causation and the effectiveness of interventions and control measures
 - Information to guide medical exposure management
 - Specific regulatory requirements such as design flaw, manufacturing defect, device failure, operator error, etc.
- Sample sharp injury report forms can be found in Appendix K & Appendix L.

2.5 ASSESS BLOOD AND BODY FLUIDS EXPOSURES AND SHARPS INJURY DATA

The organization should assess how data is collected and whether it is utilized to its full potential.

Suggestions for Implementation

- Data from the report forms is properly collected with an appropriate system. Computerized systems make improved data management possible, especially for larger organizations.
- Appropriate back-up measures exist.
- System access control ensures confidentiality.
- Data are categorized, at a minimum, by:
 - Occupation
 - Location
 - Types of devices
 - Types of procedures or activity at time of incident
 - Time
 - Other
- Data categories are summarized to provide a clearer picture of how, when, where and to whom incidents occur.
- Incident rates are being calculated in an appropriate fashion, using correct numerators and denominators (e.g., hours worked, number of employees, number of employees exposed). Rates of incidents might be reported as injuries per:
 - Occupation

- Device
- Procedure

Examples of Calculations of Rates

Summarizing data about sharps injuries and blood and body fluid exposures using rates is helpful. A rate involves performing a calculation using a numerator (top number) divided by a denominator (bottom number) and multiplying the result by a multiplier (usually 100). A time factor is also required so data used in the calculation is related to a specific period of time, such as “per year”.

Examples:

- 1) An organization may want to determine the overall exposure rate for all workers. The numerator would be the combined total of all sharps injuries plus all other BBF exposures for a given period of time (e.g., a year). The denominator would be the total number of workers in the workplace, usually expressed as the “full-time equivalents” or FTE:

$$\frac{\text{Total of all exposures (injuries and exposures)}}{\text{\# of FTE workers}} \times 100 = \text{exposures per 100 workers (per year)}$$

- 2) The organization may want to describe only the sharps injuries by department:

$$\frac{\text{Total of sharps injuries in the department}}{\text{\# of FTE workers in the department}} \times 100 = \text{sharps injuries per 100 workers in the department (per year)}$$

- 3) The organization might also want to report on the rate of injuries related to a specific type of device each year:



$$\frac{\text{Total \# of injuries per year from that device}}{\text{\# of that device used per year}} \times 100$$

- 4) Because a large hospital might use thousands of a specific device, it might be easier to use 10,000 as the final multiplier and report the result as “injuries per 10,000 of the device used”:

$$\frac{50 \text{ injuries related to butterfly needle}}{20,000 \text{ butterfly needles used per year}} \times 10,000 = 25 \text{ injuries per 10,000 butterfly needles (per year)}$$

Calculations of device-specific rates are especially useful as they can provide a comparator for injury rates using safety-engineered alternatives to the device in question. Other rates (e.g., rate per bed, rate per procedure conducted, etc.) can also be used depending on how one chooses to describe injury and exposure data. Incident rates are used as one technique to measure improvement. Appropriate adjustments should be made for under-reporting.

2.6 ASSESSING THE EDUCATION PROGRAM

The current education program related to blood and body fluid exposure prevention is reviewed.

Suggestions for Implementation

- The organization should assess its current blood-borne pathogen prevention program with specific reference to the use of SEMS.
- Content of the program should include:
 - Practical skill-development exercises
 - Facility-specific statistics on incidents
 - Typical occupations, procedures and devices involved
 - Most frequent cause of sharps injuries and BBF exposures
 - The “hierarchy of control” concept (at the source, along the path, at the worker) with practical examples
 - The role and function of the SEMS implementation team
 - Reporting procedures and relevant changes



- Other safety culture initiatives

Standard or Rationale

- Analysis of the location and nature of previous sharp-related incidents is critical to determine the service areas with the greatest need and the type of SEMS required.
- Trend analysis might show specific shortfalls such as non-compliance with reporting protocol, fear of reprisal or lack of appreciation of the importance of the effort.
- In order to do meaningful sharp injury prevention planning or adjustments to the current program, all relevant data on sharps injuries need to be analyzed.
- Appropriate knowledge of blood-borne pathogen prevention principles needs to be applied to ensure the success of the SEMS program.
- There is a required skill and knowledge level regarding the specific SEMS being used, to ensure the success of the SEMS program.
- The worker may use a hollow-bore needle that is not a safety-engineered needle if he or she believes on reasonable grounds that, in the particular circumstances, the use of a safety-engineered needle would pose a greater risk of harm than the use of the hollow-bore needle. The employer shall develop, establish and provide training for workers to assist them in applying the exemption to use a safety-engineered device related to determining risk of harm.

...“risk of harm” refers to any or all of the following risks:

- A risk of harm to the worker or to another worker
- If the work involves the use of a needle on a person, a risk of harm to him or her
- An immediate or potential risk to the public or to the public interest

3.0 DEVELOPING THE PROGRAM COMPONENTS AND SELECTING SEMS

The use of safety-engineered medical sharps must be considered part of an overall program aimed at preventing and reducing exposures to blood-borne pathogens.

This section describes basic elements to include in a program aimed at the implementation of SEMS. They are:



- Policies and procedures
- Protocols for trials
- Purchasing products
- Reporting incidents and injuries
- Responding to exposures (sharps and mucosal)
- Management of waste
- Safe work practices
- Needle Safety Regulation

Case Report # 3

A health care worker in a hospital incurred a needlestick injury while removing a needle from a patient.

The health care worker was taken to their emergency department where blood testing began. The worker started taking post exposure medications but fortunately, in this case, investigations of the source patient indicated that continued treatment was not required.

Even this fairly commonplace needlestick injury had the potential to become something far more serious. The amount of time, resources and anxiety associated with needlestick injuries can be significant for both affected workers and their employers.

3.1 POLICIES AND PROCEDURES

Administrative controls including policies and procedures to protect workers from exposure to blood and body fluids are documented and reviewed annually.

Suggestions for Implementation



Develop a policy that clearly indicates the organization's commitment to worker health and safety. The policy should contain the following elements:

- Commitment statement
- Goals
- Objectives
- Definitions
- Roles and responsibilities of all workplace parties
- Evaluation

A sample policy can be found in Appendix M.

Program procedures developed to support the policy should address at least the following:

- An exposure control plan that covers such issues as:
 - Safe work practices
 - Safe work conditions
 - Use of SEMS for all hollow-bore needles and for other sharps when such alternatives are available
 - Reporting hazards/incidents where workers are exposed to blood and body fluids (mucosal) or sharps injuries
 - Training of workers regarding prevention of exposure to blood and body fluid and the use of safe engineered medical sharps
 - Policies and procedures to obtain consent for all testing, including tests for HBV, HCV and HIV
- Reporting requirements for unsafe or defective devices or equipment
- Purchasing of equipment that is properly designed and constructed
- Staff education
- Equipment-specific procedures
- Proper disposal of sharps

In accordance with the Health Care and Residential Facilities Regulation under the OHSA, review the "measures and procedures" in consultation with the JHSC/HSR annually, and more often if required.

Standard or Rationale



- Policies and procedures development and review: HCRFR, sec. 8 and 9
- Education/training: OHSA, sec. 25, 26, 27; HCRFR, sec. 9(4)
- Reporting of occupational injuries/illness: WSIA, Reg. 1101 (first aid); OHSA, sec. 51 and 52; HCRFR sec. 5(5)
- Regulation 474/07—Needle Safety Regulation
- The policy communicates senior management’s commitment and provides general program expectations and directions to guide performance requirements.
- Written procedures ensure that the program operation is defined and consistently applied by management and that compliance requirements are communicated to staff.
- Guidance for post-exposure policy and procedures is available in the most current OHA/ OMA document *Blood-Borne Diseases Surveillance Protocol for Ontario Hospitals*.

3.2 PURCHASING

To support the successful implementation of the SEMS program, the organization should develop a process to plan for the selection and purchase of equipment.

Suggestions for Implementation

The organization should identify and obtain samples of licensed products available in each category of device, including:

- Syringes and injection equipment
- IV equipment
- Blood collection/phlebotomy equipment
- Suture equipment
- Lancets
- Operating room equipment

Standard or Rationale



- The purchasing department should identify suppliers and obtain product samples.
- The requirement of the employer to provide a safety-engineered medical device does not apply if the employer is unable, despite making efforts that are reasonable in the circumstances, to obtain a safety-engineered needle that is appropriate for the work. The employer must be prepared to demonstrate “reasonable effort” to secure a safety-engineered device. Refer to Appendix N, *Information Tracking Form—Sharps not converted to SEMS*.
- Products must have a current Health Canada license as a medical device. Current licenses can be verified at <http://www.mdall.ca/>.

3.3 PROTOCOLS FOR TRIALS

Protocols have been established for the selection and trial of safety-engineered medical sharps.

Suggestions for Implementation

The selection and trial of SEMS is an important part of the implementation process. The trial of a new device may occur in specific departments or service areas but the protocols for each pilot project or trial should be established by the SEMS implementation committee in advance.

In planning the launch of the trial in the selected unit/department, ensure that:

- All stakeholders have received appropriate communication
- Staff understand policies/procedures
- Identified needs and barriers have been addressed
- Appropriate equipment is in place
- Environmental issues have been addressed
- Training has been scheduled
- Staff preceptors have been chosen (if applicable)
- An education/training evaluation tool has been developed



Evaluate the trial of devices and enhance the program based on the findings of the evaluation.

Selecting and trial testing SEMS involves three distinct steps (American Nurses Association, 2002):

Step 1: Initial screening of the devices based on safety feature criteria

- Develop evaluation criteria
- Rank the selection criteria
- Rate each device utilizing the criteria
- Test a select number of devices to ensure the safety feature works and track occurrences when the safety device failed to activate
- Select devices from each category for the next step

Step 2: Intermediate selection based on comparison of product features

- Select a site/department to test the products for a predetermined period, e.g., two weeks
- Evaluate the device using a checklist (see Appendix C for sample)
- Device-specific evaluation checklists have also been posted on the Internet as part of the Training for Development of Innovative Control Technologies Project in the US:
<http://www.tdict.org/criteria.html>
- Involve workers in the work location
- Examine autoclaved contents of sharps containers periodically to determine if the safety features and products have been used
- Evaluate the impact on patient care and safety

Step 3: Trial use of the device

- Make the final selection of products that will be used
- Train front-line workers in the use of the equipment prior to implementation
- Solicit feedback from users to determine if more training is needed
- Monitor the use of products

The SEMS implementation committee should lead the processes for the selection, evaluation and implementation of SEMS.

Set priorities

The SEMS team should determine which device types to consider. A summary tool to assist in setting priorities can be found in Appendix H.



Considering only one or a few device types at a time will help reduce confusion and enhance the focus on the product being evaluated.

Gather information—conventional device

- Relevant information about the conventional device being replaced is gathered to ensure that the proposed SEMS will be able to fulfill all the clinical or other relevant requirements associated with the device. An inventory list of devices was discussed as part of the initial program assessment (Appendix I) in Section 2 of this guide.
- Device information surveys of applicable departments might be used to identify any additional issues. Information required includes:
 - Frequency of use and purchase volume
 - Most-used sizes
 - Specific uses
 - Compatibility with other devices and processes
 - Unique clinical needs
 - Clinical expectations

Determine selection criteria

- **The SEMS team should determine the criteria for selection.**
 - The selection criteria being used are based on both the design specifications and the performance characteristics required
 - Other aspects to be considered include waste volume and packaging

There are numerous features to look for when selecting SEMS (NIOSH,1999) (see Appendix O):

- The device is needleless
- If not needleless, there are built-in safety features
- The device is passive
- If active, it is easily activated with a single hand while the user's hand remains behind the exposed sharp
- The user can tell if the safety feature has been activated, e.g., from an audible click
- The safety feature can't be deactivated through disposal
- The device is easy to use and practical



- The device comes in a variety of sizes/gauges
- The device is safe and effective for patients

Gather information—available products

The following resources should be considered when gathering information about a proposed SEMS:

- Vendors' research material and product trials
- Materials management department
- Other similar facilities that had implemented the proposed SEMS
- Peer review articles
- Internet search. Many sites show the type and variety of safety-engineered medical devices. Links to some can be found in the SEMS section of the PSHSA website at www.pshsa.ca

Gather samples of devices

- Invite manufacturers/vendors to present their SEMS to the team
- Evaluate SEMS based on the design and performance criteria and other relevant issues

The team should also verify that the manufacturers/vendors:

- Can supply sufficient quantities and sizes
- Will supply technical support and training
- Will provide free products for trial evaluation

A product evaluation form should be used (see sample Appendix C). The team should ensure that:

- The form clearly identifies who is using the new SEMS
- The form captures all relevant information required to make an informed decision on selecting a newly proposed SEMS
- Standardized forms are being used to ensure proper comparisons
- There is space for comments on the form

SEMS trial evaluation plan



- An appropriate area has been selected for the evaluation process
- The trial period has been decided on
- Employee training has been considered (employees must know how and have the necessary skills to properly use the new SEMS)
- Operational logistics has been considered (distribution, removal, etc.)
- Information feedback mechanisms are established

Analysis of results

- Data from the trial is collected and tabulated to make analysis possible
- Response rates by occupation and clinical function are considered to establish a better understanding of the appropriateness of the proposed SEMS
- These factors should be kept in mind when the data is analyzed:
 - Internal politics
 - Employee preference for conventional devices
 - Attitude
 - Opinions of leaders/unions
 - Perceived need for new device
 - Patient concerns

Selection of new product

- The SEMS team makes the selection, based on the evaluation feedback and appropriate data analysis
- Training is coordinated with device implementation
- Phasing-in over several weeks is considered
- There is a back-up plan in place in case of unforeseen issues

Monitoring



- Continued satisfaction with the new SEMS is monitored
- Post-implementation compliance with use of the safety feature is monitored

Standard or Rationale

- The evaluation and selection process will vary with each organization. The pilot areas selected should involve staff interested in participating. Typically, staff are more receptive to using new products when they have received adequate training, when they are involved in the process and when new products are gradually introduced.
- It may be more effective and manageable to select a particular unit to pilot use of the devices. More than one unit may be selected for a product trial. Also, consider conducting trials of one product at a time. The length of the trial may have to be extended, so it is important to be flexible.
- Ontario Needle Safety Regulation requires safety-engineered devices for all hollow-bore needles

3.4 SELECTION OF PRIORITIES FOR CHANGE

An area, department or device has been selected as a priority for replacing conventional sharps with SEMS.

Suggestions for Implementation

- Conduct a risk assessment and summarize key information to determine where program implementation will begin and to identify and address any potential implementation barriers.
- Activities in a risk assessment include:
 - Summarize injury demographics and determine the area with the highest frequency and severity for incidents related to sharp medical devices.
 - Determine which sharp medical devices are considered to be of highest risk for blood-borne pathogen. For instance, hollow needles vs. solid needles,



large-bore hollow needles vs. smaller-bore needles. Some service areas may be considered higher risk due to the type of patient or clientele.

- Valid third-party data indicate that implementation of SEMS should be done in the following order, which corresponds to the risk associated with various device categories:
 - IV catheters;
 - blood collection sets;
 - multi-sample blood collection needles;
 - hypodermic needles;
 - surgical scalpels;
 - suture needles.

See Section 2 of this document for details about data collection for assessment. Appendix H contains a *Summary of Sharps Injury Data* tool to assist with the setting of priorities.

Select the priority area or device based on the findings. This will be the unit/department with the highest frequency/severity for injuries or the department with injuries related to the highest-risk devices. In smaller facilities, a safer sharps program may be introduced facility-wide rather than in small stages.

In the selected unit/department, conduct an assessment of the following:

- Procedures requiring medical sharps
- Listing of all medical sharps currently used in the area (use Appendix F)
- Placement of proper disposal containers close to point of use
- Environmental concerns or barriers (e.g., lack of work space, crowding, fast-paced environment)
- Work organization concerns and barriers

Standard or Rationale

- An organization-wide program can be introduced all at once or in phases. For large organizations, it is recommended that one or two areas be selected for pilot implementation.



- Implementation of the program should be initiated in departments/services where there may be highest risk. Highest-risk devices or procedures may be identified by the frequency of injury in the area or by the nature of the device or procedure.
- All identified needs should be summarized and an action plan developed so that management can assess and address all needs prior to the pilot implementation. This is critical to the success of the program. For example, sharps containers with openings too small for easy disposal of sharps connected to rubber tubing should be replaced with more appropriate containers.
- Careful planning with the department/unit supervisor/manager will ensure that the pilot implementation runs smoothly.

3.5 REPORTING OF SHARPS INJURIES AND BLOOD AND BODY FLUID EXPOSURES

Policies and procedures have been developed for the reporting, management and follow-up of exposure to blood and body fluids or near misses.

Suggestions for Implementation

- Reports of all BBF exposures include the date, time and location of the incident, the worker's task at the time of exposure, any equipment or device involved in the exposure, first aid and advice given to the worker, post-exposure prophylaxis if required, and follow-up actions. Sample forms for recording exposures and injuries can be found in Appendix K and Appendix L.
- All exposures are reported immediately. Assessment of exposed staff should occur as soon as possible, preferably within two hours of exposure, to determine if prophylaxis and surveillance are required.
- All needlestick and sharps injuries and near misses are investigated to determine appropriate follow-up measures.
- An employee incident report form and a WSIB Report on Needle-stick Injury or Body Fluid Splash are completed. Information about WSIB reporting obligations and report forms can be found on the WSIB website at <http://www.WSIB.on.ca>
- BBF exposures are reported to the Workplace Safety and Insurance Board in accordance to Board policy and are shared with the JHSC/HSR, as provided by the OHS.A.



Standard or Rationale

- Guidance for post-exposure policy and procedures is available in the OHA/OMA document Blood-Borne Diseases Surveillance Protocol for Ontario Hospitals.
- Also refer to Public Health Agency of Canada's Prevention and Control of Occupational Infections in Health Care, 2002.
- Reporting obligations to the Workplace Safety and Insurance Board (WSIB) must be in accordance to the Workplace Safety and Insurance Act and the WSIB policies as described in the Operational Policy Manual available from the WSIB at: <http://www.wsib.on.ca/wsib/wopm.nsf/home/opmhome>
- Reporting obligations under the OHS, Section 51 and 52.

3.6 RESPONDING TO EXPOSURES (SHARPS AND MUCOSAL EXPOSURES)

Written procedures for the management of exposed workers follow current standards.

Suggestions for Implementation

- Reporting procedures and incident report forms must be available and easily accessible for injuries that occur after hours as well as during regular working hours.
- Reporting procedures are in place for contract and student workers.
- Post exposure follow-up procedures are well known by all staff and particularly by staff designated to assess and initiate treatment.
- Guidance on post-exposure follow-up and response has been developed (see checklist for response procedures, Appendix P).
- Post-exposure prophylaxis (PEP) starter kits (see explanation below *) are available on-site or arrangements have been made for rapid access to PEP.
- First-aid treatment and post-exposure counseling are available for all injured workers.
- Procedures are in place both for circumstances in which the source of blood is known and when it is not known.
- Consent forms for testing the patient source and the exposed healthcare worker are available.



- There are documented procedures for exposure to Hepatitis B, Hepatitis C and HIV.

* Post Exposure Prophylaxis (PEP) starter kits refers to a short-term supply of anti-viral drugs that are taken to limit or minimize the replication of blood-borne viruses such as HIV. It is important that antiviral drugs be taken as soon as possible after an exposure where there is potential transmission of a blood-borne virus. A PEP starter kit provides a limited supply of drugs until a full regimen of the appropriate drugs can be prescribed. Details about appropriate antiviral treatments are beyond the scope of this resource, but are readily accessible to medical professionals who can assist with the establishment of appropriate PEP starter kits.

Standard or Rationale

- Guidance for post-exposure policy and procedures is available in the OHA/OMA document *Blood-Borne Diseases Surveillance Protocol for Ontario Hospitals, 2004* (and as amended)
- Also refer to Public Health Agency of Canada's Prevention and Control of Occupational Infections in Health Care, 2002

3.7 SHARPS INJURIES AND BLOOD AND BODY FLUID EXPOSURES DATA COLLECTION

Data about sharps injuries and BBF exposures are tracked and compiled in such a way that retrieval and meaningful analysis are possible.

Suggestions for Implementation

- A data collection system for documentation and tabulating all sharps injuries and exposures is required. Options for a system include:
 - A manually compiled log of injuries and exposures, compiled at the workplace using data collection forms for summarizing inquires and incidents
 - Computerized systems using standard software programs adapted to on-site data collection needs
 - Computerized systems specifically designed for collection of data and information related to sharps, injuries and exposures. The EPINet™ system



developed at the University of Virginia is well known, widely used and works with Microsoft Access® software. The program can be obtained at no cost by contacting the developers at:
http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm

Standard or Rationale

An appropriate data collection system must be implemented so that accurate analysis of blood and body fluid exposures can be made. Future priorities for change as well as evaluation of the program will be facilitated with a good data collection system.

3.8 MANAGEMENT OF WASTE

Waste disposal policies, procedures and systems have been implemented.

Suggestions for Implementation

All sharps, including SEMS, must be discarded in sharps containers in accordance with current CSA standards.

Containers must:

- Be sturdy enough to resist punctures
- Be clearly identified as sharps containers
- Have lids capable of being tightly closed
- Have a biohazard symbol (and also a cytotoxic hazard symbol displayed when applicable)
- Have a fill line
- Have features to prevent withdrawal of the contents
- Have handles or other carrying devices
- Where feasible, have a mounting bracket and lock in public-access areas
- Be appropriate to the type of waste for which they are to be used, for instance larger containers in high-volume areas, or larger openings to accommodate disposal of larger devices



All used sharps, including SEMS, should be disposed of at the point of use by the person who used the device. A review of current sharps disposal must be made to ensure that current systems can accommodate new SEMS.

Some SEMS will require larger container openings to accommodate the shape or size of the device. Filled sharps containers should be picked up for disposal or treatment by a licensed waste management contractor.

Standard or Rationale

- All sharps, including SEMS, must be disposed of in puncture-proof sharps containers—HCRFR, sec. 114
- Safe work practices—HCRFR, sec. 8 and 9
- CSA Z316.6-07—Evaluation of Single-Use and Reusable Medical Sharps Containers for Biohazardous and Cytotoxic Waste
- *Guideline C4—Management of Biomedical Waste in Ontario* (Ministry of Environment), available for download at www.ene.gov.on.ca

3.9 SAFE WORK PRACTICES

Safe work practices for the protection of workers from sharps injuries and blood and body fluid exposures have been prepared.

Suggestions for Implementation

In addition to the use of SEMS, safe work practices should address the use of other medical sharps and routine practices including the handling of blood and body fluids. Safe Work Practices may include but are not limited to:

- No bending, re-capping or removing needles
- Routine practices including handwashing and the use of appropriate PPE—gloves, gowns, procedure masks or face shields to protect from splashes or sprays of blood/body fluids



- Cleaning procedures for surfaces contaminated with blood and body fluid spills in accordance with current guidelines
- Immunization of healthcare workers at risk of exposure to blood-borne diseases
- Procedures for blood collection at bedsides or at designated stations

Standard or Rationale

- The document *Prevention and Control of Occupational Infections in Health Care* (Public Health Agency of Canada, 2002) will provide guidance in the development of safe work practices
- Safe work practices, HCRFR (O.Reg. 67/93) secs. 8 and 9
- Requirement to use safety-engineered needles for all hollow-bore needles—Ontario Regulation 474/07—Needle Safety

3.10 TRAINING PROGRAM

A training plan has been developed for educating workers about the use of the new devices as well as other program components.

Suggestions for Implementation

- Prepare for the training of the caregivers in consultation with the JHSC/HSR in accordance with sec. 9(4) of the Health Care and Residential Facilities Regulations and section 4 of the Needle Safety Regulation. A comprehensive staff education program should include:
 - Legislation
 - Goals/objectives of the program
 - Overview of injury demographics/statistics
 - Research/evidence for SEMS
 - Policy regarding medical sharps and associated procedures
 - Device-specific training
 - Reporting procedures



- When not to use a SEMS due to risk of harm to self or others
- Plan for launching the program in a selected unit/department. Ensure that:
 - All stakeholders will receive appropriate communication
 - Staff will be educated about policies/procedures
 - Identified needs and barriers will be addressed
 - Appropriate equipment will be in place
 - Environmental issues will have been addressed
 - Training is scheduled
 - Staff preceptors are chosen (if applicable)
 - An education/training evaluation tool has been developed

Case Report # 4

Starting a new job can be stressful, and your first position after graduation is even more challenging. Imagine getting a needlestick injury in your first week of work. Now imagine if the patient was a self-identified former intravenous drug user, who also had hepatitis.

A young health care worker found herself in this scary position. Blood testing was immediately started on both the worker and the source patient (with consent).

The results indicated that the patient was positive for both Hepatitis B (HBsAg) and Hepatitis C (anti-HBc) but not HIV. Fortunately the worker was found to have sufficient immunity to Hepatitis B that she wouldn't become infected. However ongoing blood testing was required to monitor for Hepatitis C infection.

To help her through the trauma, counseling was required and condoms were needed to protect her partner.



4.0 IMPLEMENTING THE PROGRAM

After the organization has completed assessments, conducted product trials, selected the specific devices to be used and prepared the written program components to support the program, the new SEMS must be introduced and the program implemented.

4.1 INTRODUCING SELECTED PRODUCTS

After the completion of the product trial and development of written policies and procedures, new SEMS should be formally introduced to workers.

Suggestions for Implementation

- Ensure that specific instructions for the use of the new devices have been prepared.
- Train workers in how to use the new devices. Workers should be able to demonstrate their familiarity with the products.
- Train workers on when they might not use a safety-engineered needle if there is a “risk of harm”
- Ask the supplier to provide product training to all identified staff on all shifts.
- Appoint staff preceptors or mentors, ensuring that they are trained and comfortable with the devices.
- Make sure sufficient quantities of the product are available from the supplier.
- Remove supplies of conventional devices being replaced (exceptions can be made with approval of the implementation team).
- Obtain feedback on use of the new devices.
- Develop a process for notifying supervisors regarding needles that are not safety-engineered.
- Monitor and assess the need for additional training.
- Monitor the impact on patient care.
- Develop an action plan to address needs and/or barriers as they are identified.

Standard and Rationale

Appropriate device-specific training is critical to the success of the program. Once implemented, only safety-engineered devices should be permitted. Exceptions should be



made only with the approval of the implementation committee. The needle safety regulation requires training for employees regarding exceptions for using a safety-engineered device for hollow-bore needles.

4.2 REPLACEMENT OF OLD DEVICES

Instructions for purchasing new devices and replacing the old devices are provided.

Suggestions for Implementation

- Ensure that specific instructions for ordering new supplies are made available to the department and to the purchasing department/agent.
- Monitor the use of new devices for misuse, problems or concerns.
- Old devices are to be removed from wards, nursing stations and other storage locations such as cabinets, carts and supply cupboards.

Standard and Rationale

- There should be a clear process for ordering and distribution so that the replacement devices will be the ones approved by the implementation committee.

4.3 SHARPS DISPOSAL

All sharps, including SEMS, are disposed of in appropriate containers.

Suggestions for Implementation

- All sharps, including SEMS, must be discarded in sharps containers in accordance with current standards.
- Ensure that procedures are followed.
- Used SEMS should be disposed of at the point of use by the person who used the device.
- Filled sharps containers should be picked up for disposal or treatment by a licensed waste management contractor.
- Procedures for transporting sharps containers from client homes or other remote locations should be established.



Standard or Rationale

- All sharps, including SEMS, must be disposed of in puncture-proof sharps containers—HCRFR, sec. 114
- Safe work practices—HCRFR, sec. 8 and 9
- CSA Z316.6-07—Evaluation of Single-Use and Reusable Medical Sharps Containers for Biohazardous and Cytotoxic Waste
- *Guideline C4—Management of Biomedical Waste in Ontario* (Ministry of Environment), available for download at www.ene.gov.on.ca

4.4 WORKER TRAINING

Staff have received training in program components and identification of “risk of harm” when using safety-engineered needles.

Suggestions for Implementation

- Ensure that training is completed when new devices are introduced and on an ongoing basis as the need arises.
- The training of workers should be assessed to verify knowledge transfer such as with quizzes or by having workers demonstrate their skills to a trainer or supervisor.

5.0 EVALUATING THE PROGRAM

5.1 COMPONENTS OF THE PROGRAM ARE EVALUATED

Program indicators are monitored.

Suggestions for Implementation

Identify indicators to be measured during and following implementation of the sharps injury prevention program. They may include:

- Number of staff training sessions provided and attendance at same
- Audit of worker adherence to policies and procedures
- Visual inspection of used sharps in sharps containers to estimate number of safety devices activated (Note: Emptying sharps containers to count the number of safety features activated has been reported as a means of monitoring use of SEMS.



However, as this can be very risky, it is strongly advised that the container and contents be autoclaved first.)

- Reports of sharp devices found in downstream locations such as in waste containers or laundry

5.2 PROGRAM OUTCOMES ARE EVALUATED

The overall outcomes of the program are monitored.

Suggestions for Implementation

- Program outcomes are monitored in order to allow the organization to plan for future activities and to measure successes or opportunities for improvement.
- Two key outcomes to be monitored are:
 - Injury and exposure statistics, which can be summarized in many ways, largely based on the method of data collection used
 - Costs of injuries
 - Number of sharps currently in use that are not safety-engineered

Standard or Rationale

- OHSA, sec. 25, 26, 27 (Duties of the Employer and Supervisor)
- An organization cannot evaluate program effectiveness if there are no measurable indicators. Measuring and evaluating your program are vital to identifying and guiding program quality improvement opportunities.
- Overall performance of the program must be measured in order for planning and enhancements to be made.
- Under the needle safety regulation, the employer must provide a safety-engineered medical device unless unable, despite making efforts that are reasonable in the circumstances, to obtain a safety-engineered needle that is appropriate for the work.



GLOSSARY OF TERMS

BBF	Blood and body fluid
CDC	Centers for Disease Control
CNSSN	Canadian Needle Stick Surveillance Network
CSA	Canadian Standards Association
FTE	Full Time Equivalent
GAO	General Accounting Office
HCRFR	Health Care and Residential Facilities Regulation
HSR	Health and Safety Representative
JHSC	Joint Health and Safety Committee
OHA	Ontario Hospital Association
OHSA	Occupational Health and Safety Act
OMA	Ontario Medical Association
NIOSH	National Institute for Occupational Health and Safety
PEP	Post-exposure prophylaxis
PPE	Personal protective equipment
PSHSA	Public Services Health and Safety Association
SEMS	Safety-engineered Medical Sharps
WSIA	Workplace Safety and Insurance Act
WSIB	Workplace Safety and Insurance Board



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International Sharps Injury Prevention Society: Sharps Safety Products by Category

http://www.isips.org/safety_products.html

International Health Care Workers Safety Center, University of Virginia:

<http://www.healthsystem.virginia.edu/internet/epinet/>

National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI),

<http://www.nappsi.org/>

OHA/OMA, Communicable Disease Protocols:

<http://www.oha.com/SERVICES/HEALTHSAFETY/Pages/CommunicableDiseasesSurveillanceProtocols.aspx>

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APPENDIX A: SAFETY-ENGINEERED MEDICAL SHARPS KEY ELEMENT CHECKLIST

	Yes	N/A
1.0 Securing management commitment, support and leadership		
1.1 There is management commitment to the program		
1.2 A leader has been designated to the program		
1.3 A multidisciplinary committee has been formed to assist with the planning and implementation of the SEMS program		
2.0 Assessing program needs		
2.1 An analysis of injuries and incidents related to blood and body fluid exposures and sharps injuries has been conducted		
2.2 An assessment of medical sharps and other equipment has been completed		
2.3 An assessment of how sharps injury prevention strategies are valued in the organization and what systems are in place to maintain a safe working environment is complete		
2.4 An assessment of current staff reporting of sharps injuries and blood and body fluid exposures has been conducted using survey tools		
2.5 An assessment of how data is collected and whether it is utilized to its full potential is complete		
2.6 A review of the current education program related to blood and body fluid exposure prevention has been completed		



	Yes	N/A
3.0 Developing the program components and selecting SEMS		
3.1 Administrative controls including policies and procedures to protect workers from exposure to blood and body fluids are written and reviewed annually		
3.2 To support the successful implementation of the SEMS program, the organization has developed a process to plan for the selection and purchase of equipment		
3.3 Protocols have been established for the selection and trial of SEMS		
3.4 An area, department or device has been selected as a priority for replacing conventional sharps with SEMS		
3.5 Policies and procedures for the reporting, management and follow-up of exposure to blood and body fluids have been developed		
3.6 Written procedures for the management of exposed workers follow current standards		
3.7 Data about sharps injuries and blood and body fluid exposures are tracked and compiled in such a way that retrieval and meaningful analysis are possible		
3.8 Waste disposal policies, procedures and systems have been implemented		
3.9 Safe work practices for the protection of workers from sharps injuries and blood and body fluid exposures have been prepared		
3.10 A training plan has been developed for educating workers about the use of the new devices as well as other program component		



	Yes	N/A
4.0 Implementing the Program		
4.1 After completion of the trial and development of policies and procedures, new SEMS have been formally introduced		
4.2 Instructions for purchasing and replacing the new device are provided		
4.3 All sharps including SEMS are disposed of in appropriate sharps containers		
4.4 All staff have received training on program components		
5.0 Evaluating the Program		
5.1 Program indicators are monitored		
5.2 The overall outcomes of the program are monitored		

APPENDIX B—NEEDLE SAFETY REGULATION

Occupational Health and Safety Act ONTARIO REGULATION

474/07 NEEDLE SAFETY

Consolidation Period: From July 1, 2010 to the e-Laws currency date.

Last amendment: O. Reg. 439/09.

This is the English version of a bilingual regulation.

Definition

- In this Regulation, “safety-engineered needle” means,
 - a hollow-bore needle that,
 - is designed to eliminate or minimize the risk of a skin puncture injury to the worker, and



- is licensed as a medical device by Health Canada, or
- (b) a needleless device that,
 - ⌋ replaces a hollow-bore needle, and
 - ⌋ is licensed as a medical device by Health Canada. O. Reg. 474/07, s. 1.

Application

2. (1) This Regulation applies in each of the following circumstances:
- 1 A worker is to do work requiring the use of a hollow-bore needle on a person for a therapeutic, preventative, palliative, diagnostic or cosmetic purpose, in any workplace.
 - 2 A worker is to do any work requiring the use of a hollow-bore needle, in a workplace listed in subsection (2). O. Reg. 439/09, s. 1 (1).
- (2) The workplaces mentioned in paragraph 2 of subsection (1) are the following:
1. Every hospital as defined in the Public Hospitals Act.
 2. Every private hospital as defined in the Private Hospitals Act.
 3. Homewood Health Centre Inc.
 4. Every laboratory or specimen collection centre as defined in the Laboratory and Specimen Collection Centre Licensing Act.
 5. Every psychiatric facility as defined in the Mental Health Act.
 6. Every long-term care home as defined in the Long-Term Care Homes Act, 2007.

7., 8. REVOKED: O. Reg. 439/09, s. 1 (2).

Provision of safety-engineered needles

O. Reg. 439/09, s. 1.

3. (1) When a worker is to do work requiring the use of a hollow-bore needle, the employer shall provide the worker with a safety-engineered needle that is appropriate for the work. O. Reg. 474/07, s. 3 (1).
- (2) Subsection (1) does not apply if the employer is unable, despite making efforts that are reasonable in the circumstances, to obtain a safety-engineered needle that is appropriate for the work. O. Reg. 474/07, s. 3 (2).



Use of safety-engineered needle

4. (1) A worker who has been provided with a safety-engineered needle for work described in subsection 3 (1) shall use the safety-engineered needle for the work. O. Reg. 474/07, s. 4 (1).
- (2) Despite subsection (1), the worker may use a hollow-bore needle that is not a safety-engineered needle if he or she believes on reasonable grounds that, in the particular circumstances, the use of a safety-engineered needle would pose a greater risk of harm than the use of the hollow-bore needle. O. Reg. 474/07, s. 4 (2).
- (3) In subsection (2), “risk of harm” refers to either or both of the following risks:
 - i. A risk of harm to the worker or to another worker.
 - ii. If the work involves the use of a needle on a person, a risk of harm to him or her. O. Reg. 474/07, s. 4 (3).
- (4) The employer shall develop, establish and provide training for workers to assist them in applying subsection (2). O. Reg. 474/07, s. 4 (4).

Exceptions, emergencies and risks to health

5. (1) Subsection 3 (1) does not apply if all of the following conditions are satisfied:
 - 1 The workplace is located in a part of Ontario in which,
 - a declaration of emergency made under the Emergency Management and Civil Protection Act is in effect, or
 - a situation exists that constitutes or may constitute a serious risk to public health.
 - 2 The employer’s supplies of safety-engineered needles appropriate for the work have been exhausted.
 - 3 The risk of harm from postponing the work until a safety-engineered needle appropriate for the work becomes available is greater than the risk of harm from using a hollow-bore needle that is not a safety-engineered needle. O. Reg. 474/07, s. 5 (1); O. Reg. 317/08, s. 3; O. Reg. 439/09, s. 2.



(2) In paragraph 3 of subsection (1), “risk of harm” refers to any or all of the following risks:

1. A risk of harm to the worker or to another worker.
2. If the work involves the use of a needle on a person, a risk of harm to him or her.
3. An immediate or potential risk to the public or to the public interest. O.Reg. 474/07, s. 5 (2).



APPENDIX C: SEMS PRODUCT EVALUATION FORM—DEVICES WITH NEEDLES

Name of Person Completing Form: _____ Date _____

Department: _____

Name of Product: _____ Number of Times Used: _____

	Strongly Disagree	Disagree	Neutral	Agree Strongly	Agree
Impact on Patient Care					
1. Needle penetration is comparable to standard needles					
2. Patients do not report more pain or discomfort than with the standard product					
3. Use of SEMS does not increase the number of needle penetrations required to complete the procedure					
4. No change in procedure is required					
5. The SEMS is compatible with other equipment					
6. Additional comments, observations related to patient care:					



	Strongly Disagree	Disagree	Neutral	Agree Strongly	Agree
The Safety Feature					
1. The safety feature is easy to activate					
2. The safety feature activates at the right time					
3. Once activated, the SEMS can't be reused					
4. I did not experience a needlestick injury or near miss while using the SEMS					
5. Additional comments, observations related to the safety feature:					
Training					
I received training on the use of this product				<input type="checkbox"/> Yes	<input type="checkbox"/> No
I require more training on the use of this product				<input type="checkbox"/> Yes	<input type="checkbox"/> No

(Adapted from Sharps Injury Prevention Workbook, CDC: Sample Device Evaluation Form)



APPENDIX D: FINANCIAL COST WORKSHEET FOR INCIDENTS RELATED TO BBF EXPOSURES

COSTING A SHARPS INJURY OR BLOOD AND BODY FLUID EXPOSURE	Total costs
Initial Visit Costs	
Reporting/Treatment:	
Exposed employee time (time x wage)	
Employee health nurse (time x wage)	
Other first aid/treatment provider (e.g., emergency department, WSIB cost for ER visit if employee health nurse not available)	
Claims manager (time x wages)	
Post-exposure Prophylaxis:	
Tetanus toxoid	
Hepatitis B vaccine (3 doses)	
Hepatitis B immune globulin (2 doses)	
Zidovudine prophylaxis protocol (28 days)	
3TC prophylaxis protocol (28 days)	
Indinavir prophylaxis protocol (28 days)	
Baseline laboratory tests, employee:	
HIV antibody (ELISA)	
Hepatitis B surface antibody	
Hepatitis C antibody	
Toxicity screen (CBC renal/liver function tests)	
Other (e.g., Western blot)	



COSTING A SHARPS INJURY OR BLOOD AND BODY FLUID EXPOSURE	Total costs
Laboratory tests, source (if known)	
HIV antibody (rapid)	
Hepatitis B surface antigen	
Hepatitis C antibody (plus confirmatory RIBA if positive)	
Other (e.g., Repeat ELISA, Western blot)	
Employee Counselling:	
Employee time (time x wage)	
Occupational health nurse time (time x wage)	
Other (e.g., infectious diseases consultation, family/peer counselling)	
Line A—SUBTOTAL: (INITIAL COSTS)	
Follow-up Costs	
Laboratory tests, employee:	
HIV antibody (ELISA) (at 6 weeks, 3 and 6 months)	
Hepatitis B surface antigen + surface and core antibodies (1 at 6 months)	
Hepatitis C antibody (1 at 6 months)	
Toxicity screen (at 2 and 4 weeks)	
Initial Treatment Costs (if required)	



COSTING A SHARPS INJURY OR BLOOD AND BODY FLUID EXPOSURE	Total costs
Evaluation & Counselling:	
Employee time (time x wage)	
Occupational health nurse time (time x wage)	
Other (e.g., infectious diseases consultation, family/peer counselling)	
Administrative (if HIV/HBV/HCV positive):	
Claims manager time (time x wage)	
External reporting	
Other costs not defined	
Line B—SUBTOTAL (FOLLOW-UP COSTS):	
Line C—TOTAL (INITIAL & FOLLOW-UP COSTS): (Line A + Line B)	
Further Financial Impact of Injury	
Amount of increased WSIB premium costs (avg. per year)	
WSIB surcharges (if applicable)	
Average replacement cost of injured worker	
Costs related to OH&S Act prosecutions, contraventions, penalties	
Legal fees	
Line D—Total other costs:	
Line E—Total of all costs: (Line C + Line D)	
Total Costs	

(Adapted from *Sharps Injury Prevention Program*, American Hospital Association, 1999)



APPENDIX E: INFORMATION RELATED TO A BUSINESS CASE AND CALCULATION OF RATES RELEVANT TO SHARPS INJURIES

Building the Business Case

While some of this appendix focuses on the economic costs associated with injury and injury prevention, organizations must not lose sight of some of the other “human” costs and benefits with the use of safer devices. It is important for employers to understand that they have a legal obligation to take every reasonable precaution to protect the safety of their workers. An injury with the potential to cause a life-threatening illness such as HIV/AIDS can provoke fear, concern and disruption to normal family and work life. As sharps injuries can be demoralizing, an employer implementing safer devices may see benefits such as improved morale and fewer disruptions at work.

Research has shown that the use of SEMS is cost-justified (California DOHS, 1998, US GAO, 2000, OHA, 2003). Much of the research in this regard comes from the United States, however estimates have been made in Ontario and elsewhere in Canada regarding the amount of money that can be saved in our healthcare system with the use of SEMS. Costs related to the use of SEMS for any specific organization will vary. Some organizations have very few sharps injuries. For them, the costs of safety-engineered alternatives may not seem justified. However costs must be examined in light of costs to our healthcare system as a whole and, for individual facilities, the potential costs should an injury occur.

Calculations of the costs of implementing SEMS in a workplace must not be based entirely on the replacement costs of safer devices, but also on a complete analysis of all direct and indirect costs involved.

Cost factors to consider in implementing SEMS:

- As costs of a safety-engineered alternative to a conventional sharp vary depending on the device itself and on the manufacturer, a range can be expected.
- Estimates ranging from 1.5 to three times the cost of conventional sharps have been used.
- The use of SEMS will also require expenditures related to training staff in the use of the new device.
- Depending on the device in question, costs of disposal may either decrease or increase—this will depend on whether the safety-engineered device tends to “fill”



sharps containers faster due to increase in the volume of material, or not as fast, as might be the case with retractable devices. The cost of waste disposal may be a null issue if there is no increase or decrease.

- The type of sharps containers required for a comprehensive program may also change. As an example, larger containers may be required for disposal of sharps connected to rubber tubing.

Potential savings from the use of SEMS have generally been seen to exceed the costs of implementing the program. Some of the savings include:

- Costs of staff time in the investigation and follow-up from an injury
- Costs related to post-exposure prophylaxis related to a blood-borne pathogen (estimated in excess of \$1,000 in the case of HIV)
- Costs related to ongoing surveillance—blood testing and staff time
- Costs related to WSIB expenditures (lost time, healthcare, loss of earnings)
- Costs related to ongoing medications should a worker seroconvert

See Appendix G for a worksheet that can be used to tabulate the financial costs related to a sharps injury. Data from this worksheet can be used in the final cost-benefit analysis.

Costs and potential costs of sharps injuries

The proposal for a SEMS program might be supported with clearly identified potential opportunities for cost savings. Such information will assist in projecting the monetary benefit of funding and supporting the initiative.

The costs of sharps injuries, including the potential costs should an injury be one of “high risk,” must be determined. They represent the potential for cost savings.

Using tools such as the financial cost tool appended to this resource (Appendix G), an organization can tabulate the estimated costs of sharps injuries.

Costs of implementing the program

The costs of implementing a program should be tabulated.

Costs associated with a safer sharps program will include the cost of the devices as well as the staff and administrative time required for preparation, planning and training.



Other costs may also be identified.

The Business Case

A business case for the SEMS program should include a cost/benefit analysis of the program. The analysis should identify and compare all direct and indirect costs and associated program benefits that are attributed to the development and implementation of the program.

- Calculating the Benefit Portion of the Equation

The benefit of a program represents the money that can potentially be saved as a result of implementation of the program. The benefits of a prevention program are largely composed of the “costs” of sharps injuries as identified above

- Calculating the Cost Portion of the Equation

Costs are all expenditures attributed to planning, establishing and maintaining a successful program. The costs portion of the equation (discussed above) will include:

- One-time capital and other associated equipment costs, including program development and education costs
- Annual ongoing costs
- Ongoing educational and orientation costs
- Calculation of Cost-Benefit Analysis
- There are two components in the cost---benefit analysis:
- B represents the benefits of the program
- C represents the costs of establishing and maintaining the program

Once the sums of all benefits and costs are calculated, a ratio is obtained by dividing the sum of the benefits by the sum of the costs: $(B_1 + B_2 + \dots + B_n) / (C_1 + C_2 + \dots + C_n)$.

If the result is 1 or greater, then the decision is economically sound. The benefit portion of the calculation should outweigh the cost portion over time.

Device-specific Costs

Another method of analyzing cost effectiveness of a specific product is to consider the amount of money spent for each injury avoided. The following formula has been proposed (AHA, 1999):

$$\frac{\text{Incremental cost of devices}}{\text{Injuries without safety features minus injuries with safety features}}$$

Consider the following example: A 300-bed hospital uses 17,000 butterfly needles each year. At present, there are 15 sharps injuries related to butterfly needles each year. It is estimated (based on research) that the number will be reduced by up to 80% (12), to a total of three, with the use of the safety version of the device.

Butterfly needles—cost 31 cents x number used annually = \$5,270

Safety butterfly—cost 72 cents x number used annually = \$12, 240

The incremental cost of the new devices would be \$6,970

\$ 6,970 (incremental cost) / 12 (injuries avoided) = \$580.00 cost per injury avoided

This equipment cost per injury avoided must be compared now to the total costs related to an injury. The costs related to an injury from a butterfly needle will vary depending on the assessed risk of the exposure. For a high-risk exposure involving potential transmission of HIV, the costs of the post-exposure alone quickly show the benefit of safer devices.

Calculation of Rates Relevant to Sharps Injury Prevention (From section 2.5 of the Guide)

Examples of Calculations of Rates

Summarizing data about sharps injuries and blood and body fluid exposures using rates is helpful. A rate involves performing a calculation using a numerator (top number) divided by a denominator (bottom number) and multiplying the result by a multiplier (usually 100). A time factor is also required so data used in the calculation is related to a specific period of time, such as “per year”.

Examples:



- 1) An organization may want to determine the overall exposure rate for all workers. The numerator would be the combined total of all sharps injuries plus all other BBF exposures for a given period of time (e.g., a year). The denominator would be the total number of workers in the workplace, usually expressed as the “full---time equivalents” or FTE:

$$\frac{\text{Total of all exposures (injuries and exposures)}}{\text{\# of FTE workers} \times 100} = \text{exposures per 100 workers (per year)}$$

- 2) The organization may want to describe only sharps injuries by department

$$\frac{\text{Total \# of sharps injuries in the department}}{\text{\# of FTE workers in the department} \times 100} = \text{sharps injuries per 100 workers in the department(per year)}$$

- 3) The organization might also want to report on the rate of injuries related to a specific type of device each year.

$$\frac{\text{Total \# of injuries per year from that device}}{\text{\# of that device used per year} \times 100} = \text{number of injuries per 100 (device used)}$$

- 4) Because a large hospital might use thousands of a specific device, it might be easier to use 10,000 as the final multiplier and report the result as “injuries per 10,000 of the device used”:

$$\frac{50 \text{ injuries related to butterfly needle}}{20,000 \text{ butterfly needles used per year} \times 10000} = 25 \text{ injuries per 10,000 butterfly needles per 100 (per year)}$$

Calculations of device-specific rates are especially useful as they can provide a comparator for injury rates using safety-engineered alternatives to the device in question. Other rates (e.g., rate per bed, rate per procedure conducted, etc.) can also be used depending on how one chooses to describe injury and exposure data. Incident rates are used as one technique to measure improvement. Appropriate adjustments should be made for under-reporting.



APPENDIX F: SAMPLE TERMS OF REFERENCE: SEMS IMPLEMENTATION COMMITTEE

Goals of the Multidisciplinary Committee:

- 1) To support the organization's goal of increased staff safety
- 2) To reduce the number and severity of staff sharps injuries and blood and body fluid exposures

Purposes of the Committee:

- To develop policies and procedures related to sharps safety
- To identify desired outcomes based on policies, procedures and best practice
- To participate in the selection of safety-engineered medical sharps
- To assess learning needs of clinical staff
- To develop a training program for clinical staff based on the learning-needs assessment and desired outcomes
- To coordinate the implementation of the training program for clinical staff
- To conduct an evaluation of the training program based on the desired outcomes
- To develop an ongoing training program for staff education annually

Accountability:

The Committee is accountable to the senior team through the SEMS Team Leader. The Committee provides timely progress reports to the senior team, the joint health and safety committee and other committees deemed appropriate by the organization (e.g., quality practice committee).

Membership:

- Senior management
- Sharps Safety Program Leader



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- Nurse Manager
- JHSC representative/HSR Purchasing/financial support
- Staff educator
- Clinician (maybe department specific) Front-line caregiver
- Physician (if necessary or available)
- Infection control practitioner

Quorum: A majority of members

Meetings: Monthly and as required, at the call of the Chair

Agenda and Minutes:

- 1) An agenda will be circulated prior to each meeting of the Committee
- 2) Minutes of the meetings will be distributed to members following each meeting
- 3) Minutes will be copied to appropriate senior team members and other clinical or services leaders as designated by the organization



APPENDIX G: SHARPS INJURIES AND BLOOD AND BODY FLUID EXPOSURES SUMMARY

Year:													
Dept. or Unit	Occupation	Exposure		Equipment		Incident Type				Totals			
		Sharps	Blood or body fluid	Device	Was it a SEMS?		Near Miss	First Aid Injury	Medical Aid Injury	Lost-time Injury	Total Incidents	Total Days Lost	Total Claim Costs
					Y	N							
Organization TOTAL													



APPENDIX H—SUMMARY OF SHARPS INJURIES DATA

The goal of this worksheet is to organize sharps injury data for the purpose of identifying immediate priorities for intervention.

Reported injuries in past the three year		
Year	# Injuries	
What are the three most common occupational groups that have reported injuries in the past year? (Option: report for last 3 years if appropriate)		
Occupational Group	# Injuries	Occupational Injury rate (# of injuries /number of FTE X 100)
1.		
2.		
3.		
What are the five most common work locations where injuries occurred in the past year? (Option: report for last 3 years if appropriate)		
Location	# or % of injuries	
1.		
2.		
3.		
4.		
5.		



<p>What are the five most common devices that contributed to injuries in the past year? (Option: report for last 3 years if appropriate)</p>	
Device	# or % of injuries
1.	
2.	
3.	
4.	
5.	
<p>In the past year, what proportion of injuries occurred due to the following circumstances? (Option: report for last 3 years if appropriate)</p>	
Circumstances	# or % of injuries
Recapping	
Discarding into sharps container	
Improper disposal	
During clean up	
Manipulating needle in patient/client	
Manipulating needle in IV line	
Suturing	
Other	



In the past year, what proportion of injuries occurred during the following procedures?	
Procedure	# or % of injuries
Insertion of a catheter	
Phlebotomy	
Arterial blood puncture	
Giving an injection	
Other:	
Based on the assessment, what are top five priorities to be addressed:	
Priorities	Rationale (why are they considered a priority)
1.	
2.	
3.	
4.	
5.	

(Based on Sample Baseline Institutional Injury Profile Worksheet, CDC Sharps Injury Prevention Workbook)



APPENDIX I—DEPARTMENTAL MEDICAL SHARPS INVENTORY TOOL

Unit/department:					
Date:					
Assessment completed by:					
Device			Number of pieces used each day	Estimated cost per unit	Estimate of annual number used (pieces per day X 365)
Device Type	Manufacturer	SEMS (indicate if yes)			
Survey questions			Yes	No	Comment
Are sharps containers present?					
Are sharps containers located appropriately close to point of use?					
Comments:					



APPENDIX J PART 1: ORGANIZATIONAL SAFETY CULTURE ASSESSMENT TOOL

Unit/department:			
Date:			
Assessment completed by:			
Issue	Yes	No	Explanation
Are there documented policies and procedures regarding the use of medical sharps?			
Do staff comply with procedures for use of SEMS?			
Does management audit use of SEMS?			
Is there a positive attitude toward use of SEMS?			
Do workers and managers accept responsibility for worker safety by following safe techniques?			
Are safe procedures followed consistently by all staff? (e.g., no recapping, engaging safety devices on SEMS?)			
Does staff have sufficient time to use SEMS?			
Are casual or agency staff knowledgeable in using SEMS?			



APPENDIX J PART 2: ORGANIZATIONAL SAFETY CULTURE ASSESSMENT/EMPLOYEE SURVEY TOOL

The following survey will give staff an opportunity to provide information to the employer that will assist in identifying strengths or weaknesses in the sharps injury prevention programs.

Policies and Procedures	
Is there a written sharps injury prevention policy for your workplace?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, have you ever seen a copy of the policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are there written procedures for handling sharps that deal with your work area?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, are they easy to understand and follow?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you ever seen a copy of the procedures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Incident Reporting	
Is there a system for reporting sharps injuries and blood and body fluid exposures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, is it easy to understand and follow?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are you required to report all sharps injuries and blood and body fluid exposures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, can you do so without fear of reprisal?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the supervisor or manager investigate incidents without undue delay?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the supervisor or manager take suitable corrective action without undue delay?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is occupational health called immediately when an incident occurs?	<input type="checkbox"/> Yes <input type="checkbox"/> No



Are co-workers briefed about information learned from incidents?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is there a program to provide support for workers who require ongoing treatments related to a sharps injury or blood and body fluid exposure?	<input type="checkbox"/> Yes <input type="checkbox"/> No
When an incident occurs which has resulted in you seeking medical attention or losing time from work, does the employer reported the incident to WSIB?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Education and Training	
Have you received training related to the use, and disposal of sharps?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, do you feel that training was adequate?	<input type="checkbox"/> Yes <input type="checkbox"/> No
When new sharps are introduced to your workplace, do you receive training on the device?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is your training tailored to the particular job that you do?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Incidents and Injuries at Work	
Have you ever had a sharps related injury (or of blood and body fluid to non- intact skin or mucous membranes)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please answer these questions:	
Type of incident(s) (describe)	



Were you injured? (If yes, describe injuries)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you receive first aid or medical treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, describe:	
Did you lose time from work?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you report the incident to the employer? If you received medical attention or lost time, was the event reported to WSIB?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Were you offered any health counseling following the incident?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, was it done?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you require any post exposure treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you ever had a sharps injury that you did not report?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please provide comments related to why you did not report the injury:	
Have you ever had a blood or body fluid exposure that you did not report?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please provide comments related to why you did not report the exposure:	

Thank you for completing this survey!



APPENDIX K—SAMPLE OF EXPOSURE REPORT FORM (SIMPLIFIED VERSION)

Name of Employee:			
Date of Incident:			
Department:			
Employment status of exposed healthcare worker:			
<input type="checkbox"/> Temp	<input type="checkbox"/> Agency Employee	<input type="checkbox"/> Pool Nurse	
<input type="checkbox"/> Contractor	<input type="checkbox"/> Employee	<input type="checkbox"/> Other	
Type of incident (cut, puncture, exposure, etc.):			
Outcome:			
<input type="checkbox"/> Near Miss	<input type="checkbox"/> First aid	<input type="checkbox"/> Healthcare	<input type="checkbox"/> Lost time
Follow-up required?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Time of Incident:			
Occupation:			
Department or work area where exposure incident occurred:			
Device or item involved in the injury:			
Brand/model of device:			
Was the device a safety device?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Purpose or procedure for which the sharp was intended or used:			
How the incident occurred:			
Recommendations to prevent similar injuries:			



APPENDIX L—SAMPLE OF EXPOSURE REPORT FORM

Bloodborne Pathogen Exposure Incident Recording Form			
EMPLOYER:		UNIQUE EXPOSURE #:	
EXPOSED WORKER'S NAME (or ID number):		WSIB Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No	
STATUS of EXPOSED WORKER: <input type="checkbox"/> Employee <input type="checkbox"/> Volunteer <input type="checkbox"/> Other <input type="checkbox"/> Non Employee Practitioner <input type="checkbox"/> Temp / Contract <input type="checkbox"/> Student			TIME WORK SHIFT BEGAN: <input type="checkbox"/> am <input type="checkbox"/> pm
DATE OF INCIDENT / /	TIME of INCIDENT: : am/pm	DATE REPORTED: / /	TIME REPORTED: : am/ pm
TYPE OF EXPOSURE: <input type="checkbox"/> Percutaneous <input type="checkbox"/> Mucous membrane <input type="checkbox"/> Skin Was skin intact?: <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN <input type="checkbox"/> Bite	TYPE OF FLUID: <input type="checkbox"/> Blood / blood products <input type="checkbox"/> Visibly bloody body fluid <input type="checkbox"/> Non-visibly bloody body fluid <input type="checkbox"/> Visibly bloody solution (iv fluid, etc.) <input type="checkbox"/> Non-visibly bloody solution <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown	FOR PERCUTANEOUS DEPTH OF INJURY: <input type="checkbox"/> Superficial <input type="checkbox"/> Moderate <input type="checkbox"/> Deep <input type="checkbox"/> Unknown	INJURIES: BLOOD VISIBLE ON DEVICE BEFORE EXPOSURE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
BODY PART INJURED: <input type="checkbox"/> Arm <input type="checkbox"/> Mouth /nose <input type="checkbox"/> Hand <input type="checkbox"/> Leg <input type="checkbox"/> Finger <input type="checkbox"/> Other (specify)		PERSONAL PROTECTIVE EQUIPMENT WORN BY WORKER AT TIME OF EXPOSURE: <input type="checkbox"/> Gloves (single pair) <input type="checkbox"/> Eye protection <input type="checkbox"/> Other <input type="checkbox"/> Gloves (double pair) <input type="checkbox"/> Face shield (specify) <input type="checkbox"/> Gloves (triple pair) <input type="checkbox"/> Gown/Garment <input type="checkbox"/> None of the above <input type="checkbox"/> Mask	
OCCUPATION:			
<input type="checkbox"/> Attendant / orderly <input type="checkbox"/> Attending physician <input type="checkbox"/> Central supply <input type="checkbox"/> Clerical / administrative <input type="checkbox"/> Clinical lab technician <input type="checkbox"/> Counselor / social worker <input type="checkbox"/> Dentist <input type="checkbox"/> Dental assistant / tech <input type="checkbox"/> Dental hygienist <input type="checkbox"/> Dental student <input type="checkbox"/> Dietician <input type="checkbox"/> EMT / paramedic	<input type="checkbox"/> Fellow <input type="checkbox"/> Fireperson / First responder <input type="checkbox"/> Food service <input type="checkbox"/> Hemodialysis technician <input type="checkbox"/> Housekeeper <input type="checkbox"/> Intern / resident <input type="checkbox"/> Laundry staff <input type="checkbox"/> Law enforcement officer <input type="checkbox"/> Licensed Practical Nurse <input type="checkbox"/> Maintenance <input type="checkbox"/> Morgue technician	<input type="checkbox"/> Medical student <input type="checkbox"/> Nurse Anesthetist <input type="checkbox"/> Nursing Assistant <input type="checkbox"/> Nurse Midwife <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Nursing student <input type="checkbox"/> OR / surgical technician <input type="checkbox"/> Patient care technician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Phlebotomist <input type="checkbox"/> Physician assistant	<input type="checkbox"/> Physical therapist <input type="checkbox"/> Public health worker <input type="checkbox"/> Psychiatric technician <input type="checkbox"/> Radiologic technician <input type="checkbox"/> Registered Nurse <input type="checkbox"/> Researcher <input type="checkbox"/> Respiratory Therapist / tech



			<input type="checkbox"/> Safety / security <input type="checkbox"/> Transport / messenger <input type="checkbox"/> Volunteer <input type="checkbox"/> Other (specify)
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DEPARTMENT OR WORK AREA WHERE EXPOSURE INCIDENT OCCURRED: Select all that apply—Identify specific location (room number, floor etc.):

<input type="checkbox"/> Ambulance <input type="checkbox"/> Blood bank <input type="checkbox"/> Central sterile supply <input type="checkbox"/> Central trash area <input type="checkbox"/> Clinical chemistry <input type="checkbox"/> Dialysis <input type="checkbox"/> Dental Clinic <input type="checkbox"/> Emergency Department	<input type="checkbox"/> Endoscopy/bronchoscopy/ cytoscopy <input type="checkbox"/> Exam room <input type="checkbox"/> Hematology <input type="checkbox"/> Histology / pathology <input type="checkbox"/> Home health visit (home) <input type="checkbox"/> Hospital grounds	<input type="checkbox"/> Intensive care unit <input type="checkbox"/> Jail unit <input type="checkbox"/> Labor and delivery <input type="checkbox"/> Laundry room <input type="checkbox"/> Medical / surgical ward <input type="checkbox"/> Microbiology <input type="checkbox"/> Morgue / autopsy room <input type="checkbox"/> Nursery	<input type="checkbox"/> Obstetrics / gynecology ward <input type="checkbox"/> Operating room <input type="checkbox"/> Pediatrics <input type="checkbox"/> Procedure room <input type="checkbox"/> Psychiatry ward <input type="checkbox"/> Radiology department <input type="checkbox"/> room <input type="checkbox"/> Other location _____(specify)
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IS THIS THE DEPARTMENT TO WHICH THE WORKER IS REGULARLY ASSIGNED?

Yes No N/A

IF NO, TO WHICH DEPARTMENT IS THE WORKER REGULARLY ASSIGNED?

What device or item was involved in the injury?

Hollow-bore needle	Other sharp object	Suture needle
<input type="checkbox"/> Biopsy needle <input type="checkbox"/> IV stylet <input type="checkbox"/> Hollow-bore needle, type unknown <input type="checkbox"/> Huber needle	<input type="checkbox"/> Bone chip / chipped tooth <input type="checkbox"/> Bone cutter <input type="checkbox"/> Bovie electrocutary device <input type="checkbox"/> Bur <input type="checkbox"/> Explorer	<input type="checkbox"/> Curved suture needle <input type="checkbox"/> Straight suture needle
		Glass



<input type="checkbox"/> Hypodermic needle attached to a Disposable syringe <input type="checkbox"/> Hypodermic needle Attached to IV tubing <input type="checkbox"/> Prefilled cartridge syringe <input type="checkbox"/> Spinal or epidural needle <input type="checkbox"/> Unattached hypodermic needle <input type="checkbox"/> Winged steel needle <input type="checkbox"/> Winged steel needle attached To a vacuum tube collection holder <input type="checkbox"/> Winged steel needle Attached to IV tubing <input type="checkbox"/> Vacuum tube Collection holder / needle <input type="checkbox"/> Other type Of hollow---bore needle	<input type="checkbox"/> Histology cutting blade <input type="checkbox"/> Lancet <input type="checkbox"/> Laser <input type="checkbox"/> Pin <input type="checkbox"/> Razor <input type="checkbox"/> Retractor <input type="checkbox"/> Scaler / curette <input type="checkbox"/> Scalpel blade <input type="checkbox"/> Scissors <input type="checkbox"/> Sharp object, type unknown <input type="checkbox"/> Tenaculum <input type="checkbox"/> Trocar <input type="checkbox"/> Wire <input type="checkbox"/> Other type of sharp object _____ (specify)	<input type="checkbox"/> Capillary tube <input type="checkbox"/> Medication ampule / vial / IV bottle <input type="checkbox"/> Pipette <input type="checkbox"/> Slide <input type="checkbox"/> Specimen / test / vacuum tube <input type="checkbox"/> Other glass item (specify)
BRAND / MODEL OF DEVICE:		
WAS IT A SAFETY DEVICE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
IF YES, WHEN DID THE INJURY OCCUR?		
<input type="checkbox"/> Before activation of safety feature <input type="checkbox"/> During activation of safety feature <input type="checkbox"/> Safety feature improperly activated	<input type="checkbox"/> Safety feature failed; after activation <input type="checkbox"/> Safety feature not activated <input type="checkbox"/> Passive safety feature, activation not required	<input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown
IF YES, WAS THE WORKER TRAINED IN THE PROPER USE OF THIS SAFETY DEVICE? <input type="checkbox"/> Yes <input type="checkbox"/> No	Describe training:	
PURPOSE OR PROCEDURE FOR WHICH SHARP WAS USED OR INTENDED:		



<p>Line procedures:</p> <ul style="list-style-type: none"> <input type="checkbox"/> To insert a peripheral IV line or set up a heparin lock <input type="checkbox"/> To insert a central IV line <input type="checkbox"/> To insert an arterial line <input type="checkbox"/> To connect IV line (intermittent IV / piggy back / IV infusion / other IV line connection) <input type="checkbox"/> To flush heparin / saline <input type="checkbox"/> Other injection into IV injection site or IV port (specify) <input type="checkbox"/> Other line procedure _____ (specify) <p>Blood procedures:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Percutaneous venous puncture (e.g. phlebotomy) <input type="checkbox"/> Percutaneous arterial puncture <input type="checkbox"/> Central or peripheral IV line or port <input type="checkbox"/> Arterial line <input type="checkbox"/> Dialysis / AV fistula site <input type="checkbox"/> Umbilical vessel <input type="checkbox"/> Fingerstick / heel stick <input type="checkbox"/> Other blood sampling _____ (specify) 	<p>Other procedures:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cutting (e.g. surgery / autopsy) <input type="checkbox"/> During disposal <input type="checkbox"/> Epidural / spinal anesthesia <input type="checkbox"/> Intramuscular (IM) injection <input type="checkbox"/> Subcutaneous / intradermal injection / skin test placement <input type="checkbox"/> Suturing <input type="checkbox"/> Transferring blood / body fluid to another container <input type="checkbox"/> To obtain a body fluid or tissue sample (CFS / amniotic / biopsy) <input type="checkbox"/> To obtain laboratory specimens <input type="checkbox"/> Other procedure (not a line procedure or blood sampling procedure)(specify) <input type="checkbox"/> Unknown 	<p>Dental procedure:</p> <ul style="list-style-type: none"> <input type="checkbox"/> During disposal <input type="checkbox"/> Hygiene (prophy, root plane, curettage) <input type="checkbox"/> Oral surgery <ul style="list-style-type: none"> • Simple Extraction • Surgical Extraction • Fracture Reduction • Other (specify) • Unknown <input type="checkbox"/> Orthodontic procedure <input type="checkbox"/> Periodontal surgery <input type="checkbox"/> Restorative (amalgam, composite, crown) <input type="checkbox"/> Root canal <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown <p>Where did the injury occur?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inside the patient's mouth <input type="checkbox"/> Outside the patient's mouth <input type="checkbox"/> Unknown
<p>HOW DID THE INJURY OCCUR? Choose up to two</p>		



<ul style="list-style-type: none"> <input type="checkbox"/> Before use of the item <input type="checkbox"/> During use of the item <input type="checkbox"/> Collided with co-worker or other person <input type="checkbox"/> Collided with sharp <input type="checkbox"/> Incising <input type="checkbox"/> Manipulating suture needle in holder <input type="checkbox"/> Palpating / Exploring <input type="checkbox"/> Passing or receiving equipment <input type="checkbox"/> Passing or transferring equipment Patient moved and jarred device <input type="checkbox"/> Sharp object dropped <input type="checkbox"/> Suturing <input type="checkbox"/> Tying sutures <input type="checkbox"/> While inserting needle in line <input type="checkbox"/> While inserting needle in patient <input type="checkbox"/> While manipulating needle in line <input type="checkbox"/> While manipulating needle in patient <input type="checkbox"/> While withdrawing needle from line <input type="checkbox"/> While withdrawing needle from patient <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown 	<ul style="list-style-type: none"> <input type="checkbox"/> After use, before disposal <input type="checkbox"/> Activating safety device <input type="checkbox"/> Cap fell off after recapping <input type="checkbox"/> Collided with co-worker or other person <input type="checkbox"/> Collided with sharp after procedure <input type="checkbox"/> Disassembling device or equipment <input type="checkbox"/> Decontamination / processing of used equipment <input type="checkbox"/> During clean-up <input type="checkbox"/> Handling equipment on a tray or stand <input type="checkbox"/> In transit to disposal <input type="checkbox"/> Opening / breaking glass containers <input type="checkbox"/> Processing specimens <input type="checkbox"/> Passing or transferring equipment <input type="checkbox"/> Recapping (missed or pierced cap) <input type="checkbox"/> Sharp object dropped after procedure <input type="checkbox"/> Struck by detached I.V. line needle <input type="checkbox"/> Transferring blood / bodily fluids into specimen container <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown 	<ul style="list-style-type: none"> <input type="checkbox"/> During or after disposal of item <input type="checkbox"/> Collided with co-worker or other person <input type="checkbox"/> Collided with sharp during / after disposal <input type="checkbox"/> In trash <input type="checkbox"/> In linen / laundry <input type="checkbox"/> In pocket / clothing <input type="checkbox"/> Left on table / tray <input type="checkbox"/> Left in bed / mattress <input type="checkbox"/> On floor <input type="checkbox"/> Over-filled sharps container <input type="checkbox"/> Punctured sharps container <input type="checkbox"/> Protruding from opened container <input type="checkbox"/> Sharp object dropped during / after disposal <input type="checkbox"/> Struck by detached I.V. line needle during / after disposal <input type="checkbox"/> While manipulating container <input type="checkbox"/> While placing sharp in container, injured by sharp being disposed <input type="checkbox"/> While placing sharp in container,
--	--	--



		injured by sharp already in container <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unknown
Narrative description of the incident:		
What suggestions does the worker have for preventing similar injuries in the future?		
Prepared by:	Date:	
Title:		

APPENDIX M—SAMPLE OF SHARPS SAFETY PROGRAM POLICY

Organization Name

Subject: Sharps Safety Program Commitment Statement

Organization name is committed to providing a safe and healthy working environment for all staff and clients. Our organization will demonstrate its commitment by providing financial, physical and human resources to reduce the risks of injury from sharp medical devices and exposure to blood and body fluid. To this end, the organization will implement the use of safety-engineered medical sharps and other safe work practices aimed at reducing the risks of injury from sharp objects wherever possible.

Goals

- To decrease the risk of transmission of blood-borne pathogens through injuries from sharp medical devices
- To promote and support the health and safety of all employees through a comprehensive program of safety-engineered medical sharps
- To provide equipment, resources and effective training
- To achieve compliance with relevant legislation including The Occupational Health and Safety Act, The Health Care and Residential Facilities Regulations (O. Reg. 67/93) and the Needle Safety Regulation (O. Reg. 474/07).

Definitions

Sharp: Any sharp object used during the care, treatment or diagnosis of patients that could cause an injury to a worker or other person.

Safety-engineered medical sharps (SEMS): are sharp medical devices or instruments designed to include safety features to help protect workers from injuries.

“safety-engineered needle” means:

- 1) a hollow-bore needle that,
 - a) is designed to eliminate or minimize the risk of a skin puncture injury to the worker, and
 - b) is licensed as a medical device by Health Canada, or
- 2) a needleless device that,
 - replaces a hollow-bore needle, and



- is licensed as a medical device by Health Canada.

Roles and Responsibilities of Workplace Parties

Employer

- Enforce the policy, procedures and program
- Provide equipment, necessary resources and initial and ongoing staff training
- Maintain the sharps safety program through continuous quality improvement
- With respect to hollow-bore needles, provide in the workplace only safety-engineered needles when suitable needles are commercially available.
- Ensure that all staff use safety-engineered medical sharps when such devices are available and provided
- Appoint a “program leader” whose role will be to take a lead role in the planning, coordination and implementation of the sharps safety program
- Ensure that an appropriate training program on sharps safety, including the use of safety-engineered medical sharps, is developed in consultation with the joint health and safety committee and implemented in the workplace.
- Evaluate and update the program annually

Managers/Supervisors

- Enforce program through regular monitoring strategies
- Conduct incident investigations
- Submit a monthly summary report of all findings of investigations to senior management
- Ensure all staff are trained in the use of safety-engineered medical sharps (SEMS) and in safe work practices required to reduce the risk of exposure to blood and body fluids
- Maintain training records for a three-year period
- Ensure all new staff receive general and site-specific orientation to the policy and program
- Include the auditing of worker practice in the planned inspections and report on findings to senior management
- Take every reasonable precaution for the protection of the worker



Workers

- Comply with policy and procedures at all times
- Participate in regular training as established by the organization
- Report any unsafe acts, hazards, equipment problems or any other untoward issue immediately to the supervisor or delegate
- Report any incidents and near misses to the supervisor immediately and co-operate in the investigation as required by management
- Report any use of non-safety-engineered medical sharps which have not been previously approved for use in the workplace.

Joint Health and Safety Committee

- Review quarterly incident data related to sharps injuries or exposures to blood and body fluids
- Review policy and program annually
- Participate, through consultation, in the development of a SEMS program
- Participate, through consultation, in the development of an education and training program that supports the sharps safety program
- Make recommendations in writing to management
- Exchange relevant information with other committees (such as the Infection Prevention and Control committee) through sharing of minutes and cross appointment of membership

Program Leader

- Will be a leader in the planning and coordination of the sharps safety program
- Will facilitate the implementation of the program
- Function as the chair person for the sharps safety committee
- Act as an in-house consultant with respect to sharps safety issues



Evaluation

The sharps safety program will be evaluated annually, as per HCRFR, sec. 9(2). The following indicators will be collected in a timely manner by (the designated authority) and forwarded to the program leader, who will collate, analyze and summarize the data and make recommendations for program enhancements to senior management:

- Employee incidents
- Incident investigations
- Near misses/hazards
- Planned monthly inspections—auditing of worker practice

Any changes to the program will be documented and communicated immediately to all affected staff and management. The designated authorities will implement any changes within their area and will keep the program leader informed.

General Provisions

Each department where medical sharps are used or are otherwise present shall develop specific procedures outlining the use and disposal of the product as appropriate and in keeping with the following general provisions:

- All needles and sharps shall be handled and disposed of in a manner that will not endanger the health or safety of the user or others.
- It is the responsibility of the user to ensure appropriate handling and safe disposal of needles and medical sharps.
- Needleless products and products with inherent safety features shall be used when such alternatives are available.
- Needles will not be recapped, bent or removed.
- Uncapped needles, scalpels or other medical sharps must not be left unattended or covered with a towel/drape.
- All needles and medical sharps shall be disposed of properly in appropriate sharps containers by the person who used the device.
- All sharps injuries must be reported immediately to a supervisor and occupational health nurse. A risk assessment shall be performed and appropriate follow-up measures taken as per policies and procedures related to blood and body fluid exposures.



Failure to comply with provisions of this policy or department-specific procedures developed in support of this policy may result in disciplinary action being taken as outlined in the organization's progressive discipline policy.

Procedures

The workplace should have (or develop) specific procedures to support this policy and program, which may include:

- The reporting of blood borne pathogen (BBP) exposures and sharps injuries.
- The process for follow-up of BBP exposures and sharps injuries.
- The purchasing of safety-engineered medical sharps (refer to HCRF reg section 9(1) paragraph 11). (E.g. product evaluation committee; Sharps Safety committee)
- The process for reporting on the use of non-safety-engineered needles
- The documentation of investigation related to devices that can not be converted to SEMS.
- The content and delivery of staff training related to SEMS and the Needle Safety Regulations



APPENDIX N: INFORMATION TRACKING FORM—SHARPS NOT CONVERTED TO SEMS

Section A: Background	
Date Investigation Completed:	
Name of medical sharp:	
Purpose/Use of medical sharp:	
<input type="checkbox"/>	A safety-engineered version was not found to be commercially available
Go to Section B	
<input type="checkbox"/>	A safety-engineered version was found to be available but was determined to be unsuitable at this time
Go to Section C	
Section B: Commercial Availability	
The following sources of information were reviewed or investigated, but a safety-engineered version of the device was not identified:	
<input type="checkbox"/>	Internet
<input type="checkbox"/>	Peers
<input type="checkbox"/>	Product/supplier brochure
<input type="checkbox"/>	Literature search
The following suppliers were contacted:	
	Date:
	Date:
	Date:
	Date:



Section C: Suitability of SEMS	
A safety-engineered version was identified but was considered unsuitable at this time due to the reasons that were identified during investigation:	
<input type="checkbox"/>	The device is not yet licensed by Health Canada as a Medical Device in Canada
Impact on Patient Care	
<input type="checkbox"/>	needle penetration not comparable (unfavorable) to conventional device
<input type="checkbox"/>	requires increased number of needle penetrations during use
<input type="checkbox"/>	patients report a higher degree of pain or discomfort
<input type="checkbox"/>	device is not compatible with other equipment currently used
<input type="checkbox"/>	an infection control concern has been documented
Technique	
<input type="checkbox"/>	requires change in technique that has yet to be adopted
Safety Features	
<input type="checkbox"/>	activates prematurely during difficult procedures
<input type="checkbox"/>	causes pain or discomfort to staff using the device
Other concerns raised and considered valid:	
Section D: Follow-up	
Action Items for follow-up:	
Bring forward date for re-evaluation:	
Approved by committee:	



APPENDIX O—SEMS KEY FEATURES CHECKLIST

	YES	NO
The device is needleless or sharp-free		
If the sharp cannot be eliminated, there are built-in safety features		
The safety features are passive		
If active, the safety feature is easily activated with a single hand while the user’s hand remains behind the exposed sharp		
The user can tell if the safety feature has been activated, e.g., from an audible click		
The safety feature cannot be deactivated through disposal		
The device is easy to use and practical		
It comes in a variety of sizes/gauges		
It is safe and effective for patients		



APPENDIX P: CHECKLIST—INITIAL ASSESSMENT & TREATMENT FOLLOWING A SHARP INJURY

Name:			
Department:			
Time of Injury:			
	YES	NO	COMMENTS
Injured Employee			
1. Received first aid			
2. Reported incident to supervisor			
3. Completed Exposure Report form			
4. Reported to designated treatment centre			
5. Received counseling for risk factors			
6. Signed consent form for blood work			
7. Signed consent form for treatment			<i>if applicable</i>
8. Received a follow-up appointment			
Manager/Supervisor			
1. Completed a source-patient risk assessment and provided information to attending physician			
2. Assisted the injured employee to complete the Exposure Report form			
3. Arranged for injured worker to be assessed and treated ASAP (notification, transportation if required)			
4. Sent completed documentation to designates			



	YES	NO	COMMENTS
Attending Physician			
1. Assessed hepatitis B immunization status and hepatitis B titre			
2. Assessed TD status			
3. Conducted HIV PEP assessment according to protocol			
4. Reviewed source patient exposure info			
5. Provided education regarding hepatitis B, hepatitis C and HIV			
6. Ordered blood work			
7. Prescribed medication, discussed side effects			<i>if applicable</i>
6. Arranged for initial doses of medication			<i>if applicable</i>
8. Arranged for follow-up, referred if necessary			
9. Completed documentation of assessment and treatment			



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