

American Nurses Association's

Needlestick Prevention Guide



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Introduction

Every year, hundreds of thousands of health care workers are exposed to deadly diseases like HIV and hepatitis C through needlestick and sharps injuries. With today's technology, nurses no longer need to face such high risks. The American Nurses Association (ANA) is dedicated to working with nurses across the country to significantly reduce needlestick and sharps injuries. Nurses should not have to risk their lives every time they use a needle or sharps device.

ANA, as part of its ongoing Safe Needles Save Lives campaign, has created this guide to help educate you and your colleagues about the risks of needlestick injuries and how to prevent them—particularly through the evaluation, selection, and implementation of safe needle and sharps devices. Chapter One details the exposure risks from injuries—especially from HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV)—and how these injuries can be prevented. It also outlines what steps you should take after an injury and your legal rights and protections—especially under the federal 2000 Needlestick Safety and Prevention Act. Chapters Two and Three

Nurses should not have to risk their lives every time they use a needle or sharps device.

focus on how you and your colleagues can take specific steps toward needlestick prevention in your health care institution. These steps include creating a needlestick prevention committee, identifying and documenting injuries, evaluating, selecting, and implementing safe devices, filing a complaint with the Occupational Safety and Health Administration (OSHA), and using contract language.

In 1999, ANA and the Training for the Development of Innovative Control Technologies Project (TDICT) partnered to develop training based on the TDICT process for the evaluation, selection, and implementation of safe devices. Chapter Three outlines that process, developed from dozens of workshops held across the country and from material created during 10 years of research by TDICT, using the expertise of frontline health care workers, especially nurses.

This book is dedicated to the hundreds of health care workers across the country who have fought for needlestick prevention—especially to those nurses who themselves have been infected with serious diseases from needlestick and sharps injuries and to those who died from those diseases. ANA also owes a special thanks to Lynda Arnold, who started the inspirational, pioneering National Campaign for Health Care Worker Safety after she became infected with HIV from a needlestick injury. Together, we will continue the battle to protect health care workers, so that nurses can take care of patients without risking their own lives.

Chapter One: The Information You Need

ONE NURSE'S STORY

The Unthinkable Happens

In 1997, Lisa Black, a 26-year-old nurse and single mom with two young daughters, was excited about her career. She had always wanted to be a nurse. One night, she was caring for a patient in the terminal stages of AIDS. She noticed that his intravenous (IV) tube was backed up with blood and the line was occluded. To quickly irrigate the line, she filled a syringe with saline and inserted the pre-attached needle into a rubber port on the patient's IV line. While Black was attempting to aspirate the coagulating blood and then flush the IV line, the patient became startled and jerked, causing the needle to dislodge from the rubber port of the IV line. The needle punctured the palm of her left hand. She was terrified.

Black followed protocol and immediately scrubbed the wound, reported her injury, and went to the emergency department. She was started on a regimen of antiretroviral medications and a protease inhibitor. She put up with the difficult side effects,

If her hospital had exclusively used needleless IV systems, she never would have been injured and would not be taking over 20 pills a day to fight her diseases.

thinking that if she just could get through the side effects and stay on the post-exposure prophylaxis (PEP) protocol, she would not acquire HIV. Eight months later, she began to feel ill, and nine months and nine days after her injury, she was diagnosed with HIV. Several months later, she learned she also was infected with hepatitis C.

Today, she is an active member of her state nurses association. She has devoted herself to educating others and fighting for occupational health and safety protections, so that other health care workers will not have to suffer her pain.

A Tragedy That Should Never Have Happened

Lisa's injury was 100% preventable. If her hospital had exclusively used needleless IV systems, she never would have been injured and would not be taking over 20 pills a day to fight her diseases. Lisa's story is just one of thousands. Today, thanks to the efforts of ANA, state nurses associations and other concerned health care workers, there is a federal law that mandates that health care facilities exclusively use safe needle devices.

The Needlestick Safety and Prevention Act was signed into law in November 2000 and became effective in April 2001. While it is too late for Lisa to be protected by this law, it is not too late for you. By working with your colleagues, your state nurses association, and the ANA, you have the power to bring dramatic change to your health care facility. You have the power to make sure that what happened to Lisa never happens to you or any of your colleagues.

WORK-RELATED BLOODBORNE PATHOGEN EXPOSURE: THE RISKS FOR HEALTH CARE WORKERS

Every day, health care workers are exposed to dangerous and deadly bloodborne pathogens through contaminated needlesticks, sharps, or splash exposures. It is one of the greatest risks faced by the frontline health care worker. Every percutaneous needlestick and sharps injury carries a risk of infection from bloodborne pathogens. Yet, these exposures often have been considered “part of the job.” Health care workers primarily are exposed to these pathogens via contaminated needlestick and sharps injuries. You probably know at least one colleague who has sustained an injury, or perhaps you have been stuck yourself. It is important that you and your colleagues fully understand these risks.

The Facts About Occupational Infection:

Every year, health care workers experience between 600,000 and 800,000 exposures to blood (United States Department of Labor-Occupational Safety and Health Administration [USDOL-OSHA], 2001). Registered nurses working at the bedside sustain an overwhelming majority of these injuries (Perry, Parker, & Jagger, 2003). These exposures carry the risk of infection with Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV), the virus that causes AIDS. Each of these viruses poses a different risk if a health care worker is exposed. More than 20 other infections can be transmitted through needlesticks, including syphilis, malaria, and herpes (Centers for Disease Control and Prevention [CDC], 1998a). At least 1,000 health care workers are estimated to contract serious infections annually from needlestick and sharps injuries (International Health Care Worker Safety Center, 1999). According to the National Institute of Occupational Safety and Health (NIOSH), the design of the device can increase the risk of injury. Specific features make certain devices more dangerous. These include: (National Institute for Occupational Safety and Health [NIOSH], 1999).

¹ OSHA Compliance Directive, *CPL2-2.69 -- Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*. Office of Health Compliance Assistance. U.S. Department of Labor. Occupational Safety and Health Administration. Washington, D.C. November 27, 2001.

² See EPINet data at www.med.virginia.edu/epinet

³ Centers for Disease Control and Prevention (1998a), “Guidelines for Infection Control in Health Care Personnel,” *Infection Control and Hospital Epidemiology* 19, 6 (1998): 445.

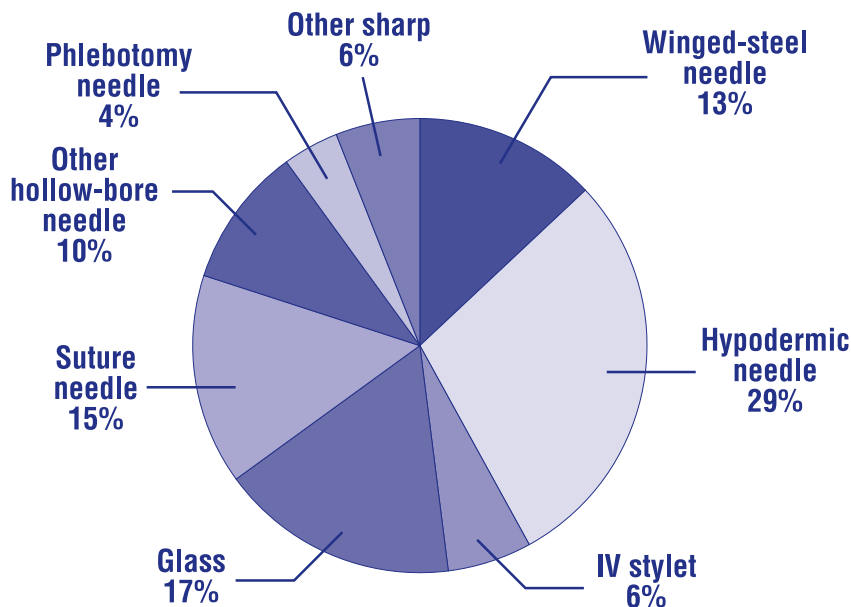
⁴ International Health Care Worker Safety Center, “Estimated Annual Number of U.S. Occupational Percutaneous Injuries and Mucocutaneous Exposures to Blood or Potentially At-Risk Biological Substances,” *Advances in Exposure Prevention* 4, 1 (1998):3.

- Devices with hollow bore needles.
- Needle devices that need to be taken apart or manipulated by the health care worker like blood drawing devices that need to be detached after use.
- Syringes that retain an exposed needle after use.
- Needles that are attached to tubing like butterflies that can be difficult to place in sharps disposal containers.

The highest risk of injury is from blood filled hollow bore needles. They accounted for 63% of the needlestick injuries from June 1995 July 1999 (NIOSH, 1999). Ninety percent of the Centers for Disease Control and Prevention (CDC) documented cases of health care workers who contracted HIV from needlestick injuries involved injuries with hollow bore, blood filled needles (CDC, 1998a).

These data may appear to be “old”, dating back five or six years. It continues to have relevance when discussing the 2000 Needlestick Safety and Prevention Act since it was the science available at the time the law was debated, and ultimately, passed. These data proved to be very persuasive, and helped make the case for the law. Current data suggest that improvements in the design and distribution of equipment are making a positive impact on the incidence of needlesticks. Many references are provided that will direct the reader to data that is continuously updated and reflects current science. Some of the websites cited are continuously monitoring the epidemiology of these injuries and should be used in current discussions of the subject.

Figure 1. Hollow-bore needles and other devices associated with percutaneous injuries in CDC surveillance hospitals, by % total percutaneous injuries (n=4,951), June 1995—July 1999.⁸



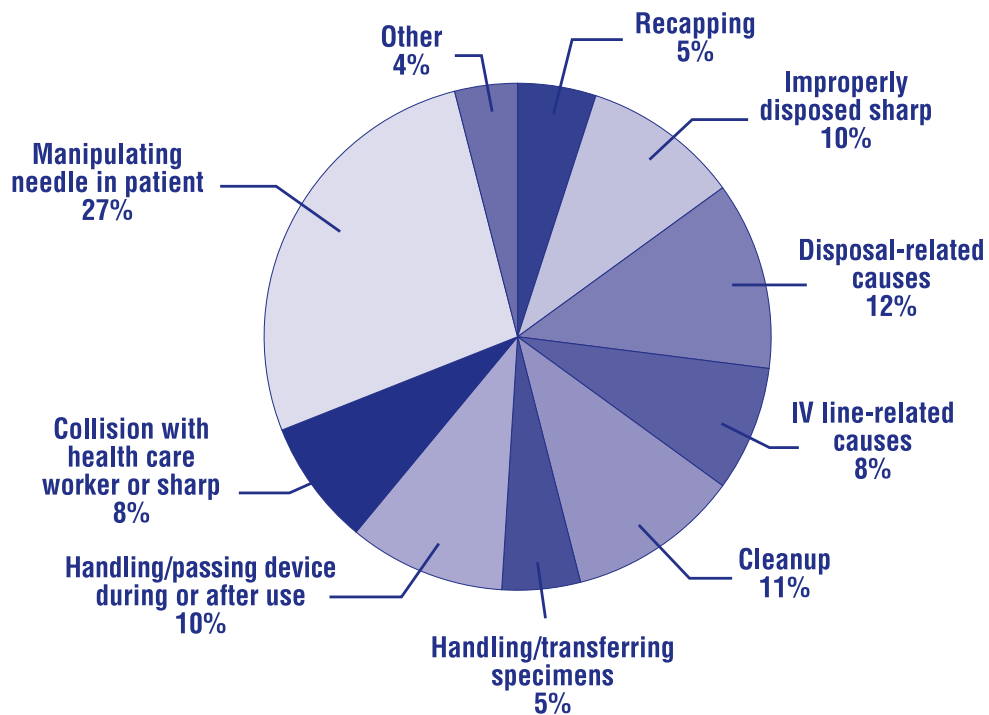
⁵ NIOSH Alert: *Preventing Needlestick Injuries in Health Care Settings* Publication No. 2000-108 (1999). www.cdc.gov/niosh/2000-108.html

⁶ *Ibid.*

⁷ CDC (1998b), “U.S. HIV and AIDS Cases Reported Through December 1998,” *HIV/AIDS Surveillance Report* 10, 2 (1998): 26.

⁸ NIOSH Alert.

Figure 2. Causes of percutaneous injuries with hollow-bore needles in CDC surveillance hospitals, by % total percutaneous injuries (n=3,057), June 1995—July 1999.⁹



HIV/AIDS¹⁰

HIV Transmission From Infected Patients to Health Care Workers

While the transmission rate of occupationally acquired HIV remains very low (.3%),¹¹ AIDS is a debilitating and ultimately fatal disease. Many nurses throughout the world are living with occupationally acquired AIDS, and many have died from it. Concerns about HIV-contaminated blood led to the 1991 OSHA Bloodborne Pathogens Standard and CDC's Universal Precautions¹² (Post-exposure prophylaxis (PEP) is essential to reduce the risk of transmission and should be started within two hours of exposure—see page 10).¹³

- The transmission rate of occupationally acquired HIV after an exposure is 0.3% (1 in 300). In other words, if a health care worker is stuck by a needle or cut by a sharp that is contaminated with the blood of an HIV patient, there is a 1 in 300 chance that she or he will be infected with HIV.

⁹ *Ibid.*

¹⁰ All data and information come from the CDC Web site on HIV, www.cdc.gov/hiv/dhap.htm, unless otherwise indicated.

¹¹ CDC (1998b).

¹² www.osha.gov/OshStd_data/1910_1030.html

¹³ CDC (2001), *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis* (June 29, 2001) www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm

- The risk of transmission can increase up to 5% (a 1 in 20 chance) if the needle or sharp is contaminated by an HIV-infected patient with a high viral load (usually either with a new infection or during the terminal stages of the disease), the health care worker sustains a deep cut with lots of blood, and the procedure involved accessing the patient's vein or artery.¹⁴
- As of June 2001, there were at least 57 CDC-documented cases of health care workers with occupationally acquired HIV and at least 137 cases of possible transmissions.¹⁵
- Based on the prevalence of HIV, 35 new cases of occupationally acquired HIV are estimated to occur annually.¹⁶
- Health care workers primarily have been infected with HIV after needlestick and sharps injuries or, rarely, after infected blood gets into a worker's open cut or a mucous membrane (for example, the eyes or inside the nose).
- The majority of infections have resulted from injuries from hollow-bore, blood-filled devices. Less frequently, workers have been infected via solid sharps (like suture needles or scalpels) and splash exposures.¹⁷
- The body fluids of most concern for HIV transmission are: blood, semen, vaginal fluid, breast milk, and other body fluids containing blood.
- Other body fluids that may transmit the virus include: cerebrospinal fluid surrounding the brain and the spinal cord, synovial fluid surrounding bone joints, and amniotic fluid surrounding a fetus.

The Risk of Transmission of HIV From Infected Health Care Workers to Patients:

- There has been only one instance of patients being infected by a health care worker in the United States. Investigations have been completed involving more than 22,000 patients of 63 HIV-infected physicians, surgeons, and dentists, and no other cases of transmission have been identified in this country.
- There are no data to indicate that infected workers who do not perform invasive procedures pose a risk to patients. Thus, infected health care workers should modify their participation in invasive, exposure prone procedures, except in extreme emergency situations.¹⁸
- Infected workers should seek counsel from an expert panel to review and modify their practice based on the best available scientific information.

The Disease:

- The CDC estimates that at the end of 1998, approximately 800,000-900,000 people were living with HIV and AIDS in the United States.

¹⁴ Cardo, D., et al., "A Case-Control Study of HIV Seroconversion in Health Care Workers After Percutaneous Exposure," *New England Journal of Medicine* 337, 21 (1997): 1485-1490.

¹⁵ www.cdc.gov/hiv/pub/facts/hcwprev.htm

¹⁶ International Health Care Worker Safety Center, "Estimated Annual Number of U.S. Occupational Percutaneous Injuries and Mucocutaneous Exposures to Blood or Potentially At-Risk Biological Substances," *Advances in Exposure Prevention* 4, 1 (1998): 3.

¹⁷ NIOSH Alert.

¹⁸ CDC (1998a).

- There have been 448,060 **reported** deaths caused by AIDS.
- HIV destroys CD4+ T cells, which are crucial to the normal function of the human immune system. Loss of CD4+ T cells in people with HIV is also a predictor of the development of AIDS.
- Most people infected with HIV carry the virus for years before enough damage is done to the immune system for AIDS to develop. However, recently developed sensitive tests have shown a strong connection between the amount of HIV in the blood and the decline in CD4+ T cell numbers and the development of AIDS. Reducing the amount of virus in the body with anti-HIV drugs can slow this immune system destruction.
- In addition to occupational exposure, HIV is spread by sexual contact with an infected person, by sharing needles and/or syringes (primarily for drug injection) with someone who is infected, or, less commonly (and now very rarely in countries where blood is screened for HIV antibodies), through transfusions of infected blood or blood clotting factors.
- Babies born to HIV-infected women may become infected before or during birth or through breast-feeding after birth.

Treatment:

- There is no HIV vaccine. While aggressive vaccine research continues, it is still years and probably decades away.
- New medications, including antiretrovirals, can slow the development of HIV/AIDS. For the latest information on drug guidelines, contact the HIV/AIDS Treatment Information Service (ATIS) at www.hivatis.org.
- PEP can greatly reduce the risk of transmission and should be started within 2 hours of exposure.¹⁹ See page 10 for more PEP information.

Hepatitis C²⁰

Lately, hepatitis C, caused by HCV, has become a great concern for nurses. Hepatitis C is a serious disease of the liver and can be fatal. HCV was not identified until 1989; before that it was referred to as non-A, non-B virus. The method to test for hepatitis C in blood products was not developed until 1992, meaning that people who received blood products before 1992 might have been exposed to HCV. Testing for hepatitis C after needlestick injuries was not recommended by the CDC until 1998.²¹ However, even after that, many health care workers were unaware of the need to be tested for hepatitis C. There could be thousands and thousands of nurses with occupationally acquired hepatitis C who simply do not know it. It is a silent epidemic.

¹⁹ CDC (2001).

²⁰ All data and information can be found on the CDC hepatitis C Web site: <http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm>

²¹ CDC (1998c), "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease," *Morbidity and Mortality Weekly Report* 47 (1998): 21.

The Disease:

- Hepatitis C can lead to liver failure and liver cancer. It is the leading cause for liver transplants in the U.S. A liver transplant costs hundreds of thousands of dollars.
- Hepatitis C is the most common chronic bloodborne infection. The CDC estimates that almost four million Americans are infected with HCV, whereas less than one million are infected with HIV.
- Eighty percent of people infected with HCV are asymptomatic, but symptoms can include jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea.
- Seventy percent of chronically infected persons develop chronic liver disease.

Transmission:

- HCV is primarily spread by exposure to infected blood, primarily via IV drug use, occupational exposure like needlestick and sharps injuries, or having received a blood product prior to 1992. Transmission can also occur from an infected mother to her baby during birth.
- HCV also can be sexually transmitted, but this is rare.
- Hepatitis C is the most frequent infection resulting from needlestick and sharps injuries with a transmission rate of 2.7%-10%.²²

Treatment:

- There is no vaccine for hepatitis C.
- There is currently no approved PEP for HCV.
- Interferon monotherapy or combination therapy with ribavirin are the current treatments.
- Combination therapy is currently the preferred treatment and has been shown to be effective in 40% of infected persons.
- These drugs can cost thousands of dollars per month.
- Alcohol use can make the disease worse.

Hepatitis B²³

Hepatitis B, caused by HBV is now preventable due to the vaccine that must be offered to all health care workers and is given to children at birth. After the 1991 Bloodborne Pathogens Standard required that the vaccine be offered, cases of hepatitis B in health care workers dropped from 17,000 annually to 400 annually—and continue to drop.²⁴ **ANA strongly recommends that all health care workers be vaccinated since it is the best means of prevention.**

²² *Ibid.*

²³ All data and information in this section can be found on the CDC hepatitis B page:

<http://www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm>

²⁴ Mahoney, F., et al., "Progress Toward Elimination of Hepatitis B Virus Transmission Among Health Care Workers in the United States," *Archives of Internal Medicine* 157 (1997): 2601-2603.

The Disease:

- About 30% of infected people demonstrate no symptoms. Symptoms can include jaundice, fatigue, abdominal pain, loss of appetite, nausea, vomiting, and joint pain.
- Death from liver disease can occur in 15-25% of chronically infected people.
- Transmission occurs via blood and body fluids and is spread via unprotected sex with an infected partner, IV drug use, and mother-child transmission.
- There are approximately 1.25 million chronically infected people in the U.S., 20-30% of whom acquired their infection during childhood.
- The highest rate of disease occurs among 20-49-year-olds.

Who is at risk?

- Health care and public safety workers
- People with multiple sex partners
- Men who have sex with men
- IV drug users
- Infants born to infected mothers
- Hemodialysis patients

Treatment:

- Alpha interferon and lamivudine are used to treat chronic hepatitis B. They are effective in up to 40% of patients.
- These drugs should not be used in pregnant women.
- Alcohol use can make liver disease worse.

PROCEDURE TO FOLLOW AFTER A NEEDLESTICK OR SHARPS INJURY

Now that you know the risk of infection from needlestick and sharps injuries, what should you do if you sustain an injury? Under the OSHA Bloodborne Pathogens Standard, employers must evaluate and treat health care workers in accordance with the latest post-exposure assessment, prophylaxis, and treatment guidelines published by the CDC. These guidelines and documents are available on the CDC's web site: <http://www.cdc.gov/ncidod/hip/guide/phs pep.htm>.²⁵

Before an exposure occurs, make sure your employer is able to provide:

- Immediate evaluation and risk assessment of needlestick injuries—e.g., a hospital hotline.
- Confidential testing for HIV, hepatitis B, and hepatitis C.

²⁵ CDC (2001).

- Access to post-exposure treatment and prophylactic medications within two hours of exposure.
- Counseling, education, and follow-up testing for up to one year after exposure.

If you sustain a needlestick injury, take the following actions immediately:

- Wash the wound with soap and water.
- Alert your supervisor and initiate the injury reporting system used in your workplace.
- Identify the source patient, who should be tested for HIV, hepatitis B, and hepatitis C infections. Your workplace will begin the process to test the patient by seeking consent.
- Report to employee health services, the emergency department, or other designated treatment facility.
- Get tested immediately and confidentially for HIV, hepatitis B, and hepatitis C infections.
- Get PEP in accordance with CDC guidelines when the source patient is unknown or tests positive for:
 - HIV: Start prophylaxis within **two hours** of exposure. HIV PEP should include a four-week regimen of two drugs (zidovudine [ZDV] and lamivudine [3TC]; 3TC and stavudine [d4T]; or didanosine [ddI] and d4T) for most exposures and an expanded regimen that includes a third drug for HIV exposures that pose an increased risk for transmission. When the source patient's virus is known or suspected to be resistant to one or more of the PEP drugs, the selection of drugs to which the source patient's virus is unlikely to be resistant is recommended.
 - Hepatitis B: If vaccinated no treatment, but if unvaccinated get HBIG and initiate HB vaccine series.
 - Hepatitis C: No treatment is currently recommended, but you may want to consult a specialist about experimental PEP.
- Document the exposure in detail, for your own records as well as for the employer and for workers' compensation. Under the new needlestick law, employers must maintain a confidential sharps injury log that contains, at a minimum, the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred.

Follow-Up:

- Get confidential follow-up, post-exposure testing at six weeks, three months, and six months, and depending on the risk, at one year.
- Receive monitoring and follow-up of PEP.
- Take precautions (especially by practicing safe sex) to prevent exposing others until follow-up testing is complete.

- Don't be afraid to seek additional information or a referral to an infectious disease specialist if you have any questions. Also, consider counseling—a needlestick injury can be traumatic, regardless of the outcome.

For more information, call the National Clinicians PEP Hotline at 1(888) 448-4911.

PREVENTION

While exposure to bloodborne pathogens is one of the most deadly hazards that nurses face on a daily basis, it is also one of the most preventable. Over 80% of needlestick injuries can be prevented with the use of safe needle devices,²⁶ which, in conjunction with worker education and work practice controls, can reduce injuries by over 90%.²⁷

The first safe needle designs were patented in the 1970s. In 1992, the FDA issued an alert to all health care facilities to use needleless IV systems wherever possible.²⁶ That alert was merely a recommendation, and it took another eight years for it to be required by law. Despite FDA approval of hundreds of safe devices, less than 15% of

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U.S. hospitals used safe needle devices and systems prior to the implementation of state and federal laws.²⁹

With the rapid development of technology and engineering controls, prevention is becoming easier and easier. By using safe devices, your institution will not only protect workers, but also save

money. Safe needle devices can cost from cents to dollars more than standard devices, but prices continue to decrease with increased market competition and technology.

Prevention is cost-effective. The cost of follow-up for a high-risk exposure is almost \$3,000 per needlestick injury, even when no infection occurs.³⁰ According to the American Hospital Association, one case of serious infection by bloodborne pathogens can soon add up to \$1 million or more in expenditures for testing, follow-up, lost time, and disability payments.³¹ A liver transplant due to hepatitis C costs hundreds of thousands of dollars. Other costs from needlestick and sharps injury include workers'

²⁶ CDC, "Evaluation of Safety Devices for Preventing Percutaneous Injuries Among Healthcare Workers During Phlebotomy Procedures--Minneapolis-St. Paul, New York City, and San Francisco," *Morbidity and Mortality Weekly Report* 46 (1997): 21-23.

²⁷ Jagger J., "Reducing Occupational Exposure to Bloodborne Pathogens: Where do We Stand a Decade Later?" *Infection Control Hospital Epidemiology* 17, 9 (1996):573-575.

²⁸ Food and Drug Administration, *FDA Safety Alert: Needlestick and Other Risks From Hypodermic Needles on Secondary I.V.* (Rockville, MD: Food and Drug Administration, 1992).

²⁹ McCormick, R., "Selecting Safety Products for Evaluation," in Pugliese, G., and Salahuddin, M., *Sharps Injury Prevention Program: A Step-By-Step Guide* (Chicago: American Hospital Association, 1999).

³⁰ Jagger, J., et al., "Direct Costs of Follow-up for Percutaneous and Mucocutaneous Exposure to Body Fluids: Data from Two Hospitals," *Advances in Exposure Prevention* 3 (1998): 25-35.

³¹ Pugliese, G., and Salahuddin, M., *Sharps Injury Prevention Program: A Step-By-Step Guide* (Chicago: American Hospital Association, 1999).

compensation, overtime, and expenses related to recruitment and training of staff to replace a worker who becomes ill.


There is solid evidence that devices with safety features significantly reduce needlestick injuries:³²

- Needleless or protected-needle IV systems decreased needlestick injuries related to IV connectors by 62% to 88%.
- Phlebotomy injuries were reduced by 76% with a self-blunting needle, 66% with a hinged needle shield, and 23% with a sliding-shield, winged-steel (butterfly-type) needle.
- Phlebotomy injuries were reduced by 82% with a needle shield, but a recapping device had minimal impact.
- Safer IV catheters that encase the needle after use reduced needlestick injuries related to IV insertion by 83% in three hospitals.

You can work with your health care facility to reduce preventable exposures by identifying the highest risk procedures and devices and implementing the most effective control measures. Methods to control hazards are usually discussed in terms of the hierarchy of controls.³³ The box below demonstrates how to apply the hierarchy of controls framework to bloodborne pathogen hazards. In addition to eliminating sharps, using safe needle devices is one of the best ways to prevent injuries. Chapter Three explains how you can work with your facility to evaluate, select, and implement safe devices.

Hierarchy of Controls

Most Effective

- 
- **Elimination of hazard**—remove sharps and needles and eliminate all unnecessary injections. Jet injectors may substitute for syringes and needles. Other examples include the elimination of unnecessary sharps like towel clips, and using needleless IV systems.
 - **Engineering controls**—examples include needles that retract, sheathe or blunt immediately after use.
 - **Administrative controls**—policies aimed to limit exposure to the hazard. Examples include allocation of resources demonstrating a commitment to health care worker safety, a needlestick prevention committee, an exposure control plan, removing all unsafe devices, and consistent training on the use of safe devices.
 - **Work practice controls**—examples include no re-capping, placing sharps containers at eye-level and at arms reach, emptying sharps containers before they're full, and establishing the means for safe handling and disposing of sharps devices before beginning a procedure.
 - **Personal Protective Equipment (PPE)**—barriers and filters between the worker and the hazard. Examples include eye goggles, gloves, masks, and gowns.

Least Effective

³² NIOSH Alert.

³³ For more information see Gochnour, M., et al., *ANA Workplace Health and Safety Guide for Nurses: OSHA and NIOSH Resources* (Washington, D.C.: American Nurses Association, 2001).

RIGHTS AND PROTECTIONS: OSHA BLOODBORNE PATHOGENS STANDARD³⁴

After years of lobbying efforts by ANA and others, there are significant laws and regulations that provide nurses with rights and protections. In addition to the Occupational Safety and Health (OSH) Act, you are protected by OSHA's 1991 Bloodborne Pathogens (BBP) Standard. Despite this standard, needlestick injuries continued to occur at frightening levels. Thus, ANA launched a campaign for federal legislation to provide more protection. ANA's Safe Needles Save Lives campaign ultimately secured passage of the 2000 Needlestick Safety and Prevention Act. **This federal law amended the 1991 BBP Standard to provide stronger protections including additions to the exposure control plan, detailed recording of needlestick injuries, involvement of frontline health care workers in the selection of safety devices, and more details and instruction on engineering controls and safer devices that must be used to prevent exposure.** The OSH Act covers all employees working in the private sector (for-profit and not-for-profit institutions) and in states with OSHA-approved occupational health and safety plans. The law applies to state, county and municipal workers. Federal employees receive the same protections under a separate law. As the law amends the BBP Standard, workers who are not covered by OSHA remain unprotected. However, ANA is vigorously lobbying for additional legislation to protect all public workers, including those in states without OSHA-approved occupational health and safety plans.

The OSHA BBP Standard, including the amendments from the federal Needlestick Safety and Prevention Act, requires health care facilities to do the following in these five areas:

Engineering Controls

- ❑ Use “safer medical devices, such as sharps with engineered sharps injury protections and needleless systems,” and other engineering controls. These devices have built-in safety features that reduce the risk of injury and can include syringes with a sliding sheath, needles that retract into the syringe after use, shielded or retracting catheters, and IV systems that use a catheter port with a needle housed in protective covering. Needleless systems include IVs that administer medication and fluids through a catheter port using non-needle connections and jet-injection systems that deliver liquid medication beneath the skin or through a muscle.
- ❑ Make safer needles and other sharps with integrated safety features available in syringes, blood collection devices, IV access products, lancets, and blunt suture needles.
- ❑ Use puncture-proof containers to dispose of sharps and needles. Containers must be closed, puncture resistant, leak proof, color coded, and emptied routinely to prevent overfilling.

³⁴ These protections are based on the 2000 Needlestick Safety and Prevention Act which amended the Bloodborne Pathogens Standard. For more information on rights and protections, visit OSHA's Web site: <http://www.osha.gov/SLTC/needlestick/index.html>

Frontline Health Care Worker Involvement and Training Requirements

- Include the involvement of frontline health care workers (non-managerial employees responsible for direct patient care) in device evaluation and selection, with evidence of this participation documented in the exposure control plan.
- Provide frontline health care workers with interactive training on the use of safer devices, work practices, and PPE from a knowledgeable person. Workers must receive training when hired and at least once a year. Training must be provided during working hours and at no cost to employees. Training records must be maintained for three years.

Exposure Control Plan

- Have a written exposure control plan (ECP) and make a hard copy of the ECP available to employees or their representatives within 15 working days of a request. (See Appendix B for OSHA's model ECP.)
- Review and update the ECP annually or more frequently whenever new or modified procedures are adopted or whenever employee positions are revised in such a way that creates new potential exposures. This review must include an examination of the most recent technological advances.
- Inform workers of the location of the ECP and the procedures to follow if an exposure occurs.

Other Control Measures: Administrative, Work Practice, and Personal Protective Equipment

- Provide access, within two hours, to post-exposure follow-up that conforms to CDC guidelines for testing and prophylaxis.
- Make the hepatitis B vaccine available at no cost to employees.
- Make purchasing decisions based on the proven safety and efficacy of the product.
- Prohibit work practices of bending, re-capping, or removing needles unless required by a specific medical or dental procedure.
- Clean and decontaminate all work surfaces after contact with blood and other infectious body fluids following CDC guidelines.³⁵
- Provide PPE including gloves, gowns, goggles, masks or face shields. These devices must be in sizes that fit all workers, of good quality and readily available. Non-latex alternatives must be provided.

Recordkeeping

- Maintain a sharps injury log updated regularly with the details of all needle-stick injuries, including date, place, situation, and device brand and type.

³⁵ CDC (1998a).

Chapter Two: Taking Action

NEEDLESTICK PREVENTION COMMITTEE

Key Players in Committee Formation

Chapter One provided you with the facts about needlestick and sharps injuries, the risks, and your rights to protection. Now that you have the information, you can take action to make sure your workplace is safe. The strategies outlined in this guide can be used by nurses, in all settings and in all roles, to advocate for themselves and their colleagues. Nurses represented by a union can use their contract for additional protections.

The first step toward a comprehensive exposure control program is the creation of a needlestick prevention committee. After gaining support and commitment to prevention from top level administrators, establish a multidisciplinary needlestick and

With frontline staff nurses involved, the most appropriate devices are more likely to be selected, and staff are more likely to accept and use the new devices and practices.

sharps injury prevention committee, required in some states, to bring together various departments, such as nursing, purchasing, housekeeping, infection control, employee health, risk management, and employee education and training. For the committee to be effective it must have power—the decision-makers in your institution should be represented. In some cases, it might be easier to work with an existing health and safety

committee or infection control committee that already has the decision-making authority in this arena. It is essential to be aware of the roles and levels of authority of all the related committees. If you face resistance in initiating safe devices, you may need to seek assistance from some of these committees.

Whether you're working with an existing committee or forming a separate needlestick prevention committee, make sure frontline health care workers—those most at risk for injury and with the most experience using needles and sharps—are equally represented on that committee. Some states require that 50% of the committee be comprised of frontline health care workers.³⁶ With frontline staff nurses involved, the most appropriate devices are more likely to be selected, and staff are more likely to accept and use the new devices and practices. When committee meetings occur during patient care shifts (they should occur in the workplace during work hours), adequate nursing staff for patient care must be ensured for the frontline staff's full attention to the committee. The expertise of employees cannot be provided without pay or offered at the expense of patients.

³⁶ Perry, J., "Needle Safety Laws Now on Books in Fourteen States," *Advances in Exposure Prevention* 5,2 (2000): 17.

The committee will need access to data—in a way that protects confidentiality—regarding the specific devices involved and the conditions in which each injury took place. And it’s equally important that the committee has final say on device selection to maintain its power.

Role of the Committee

The needlestick prevention committee should seek training on the principles of the industrial hygiene hierarchy of controls, product design features, and applying criteria for device evaluation to ensure a consistent knowledge level among device evaluators and for an effective selection process. The training should not be conducted by or in the presence of product representatives. Once a device is selected, the manufacturer can provide useful in-service education on the use of that device prior to implementation.

This committee’s primary goals are to prevent needlestick and sharps injuries and to ensure that the hospital is adhering to state and federal standards. The committee should have clearly defined authority and not just serve in an advisory role. The committee’s responsibilities should include:³⁷

- Defining bloodborne pathogen exposure problems.
- Developing strategies for improved needlestick injury reporting procedures.
- Overseeing the exposure control plan as mandated by OSHA, including post-exposure follow-up.
- Monitoring the post-exposure treatment program.
- Developing surveillance systems to monitor needlestick injuries.
- Reviewing the sharps injury log.
- Reviewing the OSHA 300 Log, which tracks all occupational injuries and illnesses.
- Obtaining and disseminating information about new devices as they develop.
- Evaluating, selecting, and implementing safe devices.
- Ensuring health care workers’ input into product selection.
- Training on new safety devices.
- Documenting the committee’s work in meeting minutes.
- Informing and assisting those responsible for preparing for Joint Commission on Accreditation of Healthcare Organizations (JCAHO) inspections to be prepared to demonstrate compliance with the Needlestick Safety and Prevention Act. JCAHO requires hospitals to comply with applicable local, state, and federal regulations including OSHA standards.³⁸

³⁷ Fisher, J., “Strategies for Integrating Health Care Workers into the Process of Design, Selection and Use of Control Technology,” in Charney, W. and Schirmer, Eds., *Essentials of Modern Hospital Safety, Volume 3* (Boca Raton: Lewis Publishers, 1994).

³⁸ Wilburn, S., and Worthington, K., “JCAHO Becomes a Force in Needlestick Prevention” *American Journal of Nursing* 102,1 (2001): 104.

IDENTIFY AND DOCUMENT NEEDLESTICK AND SHARPS HAZARDS

The first step for the needlestick committee is to identify and document where and why needlestick and sharps injuries are occurring. There are various tools you can use to assist you in this task including: the needlestick and sharps injury log, the OSHA 300 Log, a survey, and a workplace walk-through.

Document! Document! Document!

All nurses have a responsibility to document. Documentation is always the first step, and it is essential that you and your colleagues report and document every needlestick and sharps injury to:

- Ensure timely post-exposure follow-up, including testing and treatment.
- Ensure workers' compensation payment and that all health expenses are charged to workers' compensation and not to the individual's health insurance.
- Collect data to evaluate the health and safety of your workplace.
- Collect data that can be used by the ANA and state nurses associations to lobby state and federal agencies for additional protections.
- Forward the data to OSHA for inclusion in the Bureau of Labor Statistics, which drives national policies.

The importance of documenting cannot be overstated. Help your colleagues understand that documenting will improve their own health and safety. Promptly reporting a needlestick and starting PEP can protect you in the future. It is in your best interest—no matter how busy you are—to document illnesses and injuries. While each health care facility must now keep a sharps injury log, they also must maintain the OSHA 300 Log, which tracks all occupational injuries—like back injuries—and illnesses—like latex allergy. So document all injuries and illnesses, not just sharps injuries.

Sharps Injury Log

The newly revised Bloodborne Pathogens Standard requires employers to “maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps.”³⁹ The log must contain, at a minimum, the following information:

- Date of the injury
- Type and brand of the device involved
- Department or work area where the incident occurred
- Explanation of how the incident occurred

³⁹ 2000 Needlestick Prevention and Safety Act.

You can use the data contained in the log to:

- Analyze injury frequencies by specific attributes like work units, devices, and procedures.
- Identify high-risk devices and procedures.
- Identify injuries that could be prevented.
- Evaluate the efficacy of newly implemented safe devices.
- Share and compare information and successes with other institutions.

Your needlestick committee should regularly review the sharps injury log. You will find crucial information there. By learning which types of devices are involved in injuries, you will be able to determine which devices are not safe and must be replaced. While reviewing the log, you also might notice that certain departments or units seem to have a high number of injuries. Armed with that information, you can work with that unit to determine why they are sustaining so many injuries. Did nurses on that unit receive training on the use of safe devices? Is there a lack of safe devices available on that unit? Recognize that short staffing and other work organization issues might contribute to needlestick injuries. Adequate staffing might help prevent needlestick injuries.⁴⁰ The information contained in the log will help you develop the answers to prevent more injuries. You will know if you need to increase training, stock more safe devices, and/or increase staffing.

As you analyze the log data, the committee should identify high priorities for action, especially to eliminate the highest risk devices and prevent the highest risk and most frequently occurring injuries. However remember, according to federal law, the goal of the committee is to prevent **all** types of exposures and minimize all risks.

A sample reporting form for a sharps injury log is provided in Appendix C. The International Health Care Worker Safety Center at the University of Virginia produced this form. They created EPINet, a surveillance system that gives health care facilities a standardized system to track exposures and injuries. Your facility can use EPINet for free and adapt it to fit any specific needs.

OSHA 300 Log⁴¹

While your facility must record all information on the sharps injury log, they also still must record these injuries on the OSHA 300 Log. You should review the OSHA 300 Log and compare it with the information in the sharps log and make sure both are accurate. Ask the following questions as you review the OSHA 300 Log:

- Are there needlestick and sharps injuries? Columns F
- When and where do they occur? Columns D and E
- Were employees on restricted duty due to the injury or illness? Column L
- Did employees take leave due to the injury or illness? Column K
- Have these injuries led to infection, e.g., HIV or Hepatitis C? Column M-6

⁴⁰ Aiken, L., et al., "Hospital Nurses Occupational Exposure to Blood: Prospective, Retrospective, and Institutional Reports," *American Journal of Public Health* 87,1 (1997): 103-107.

⁴¹ For more information on how nurses can use the OSHA 300 Log, see Gochnour, M., et al.

Survey

While every needlestick and sharps injury should be documented, many people do not report them. In addition, many health care workers simply are unaware of the laws that protect them or the policies already in place at their health care facility. When your needlestick prevention committee begins its work, you will need to assess the situation in your workplace. In addition to the logs, a survey can help determine whether needlestick injuries are being reported, whether staff are using safe devices, and whether they are aware of the laws and policies in place. Often, increased attention to needlestick injury prevention will result in an increase in the number of reported injuries. If used for an initial assessment and follow-up annually, this survey will help the needlestick prevention committee determine whether a change in the number of needlestick injuries recorded is, for example, really an increase in the number of injuries occurring or an improvement in the reporting of existing injuries.

Sample Assessment Survey

Name (optional) _____

Telephone (optional) Work _____ Home _____

Job title _____

Unit _____

In the past year, did you sustain a needlestick or sharps injury? _____

Did you report the incident? _____

If not, why not? _____

Did you receive medical attention for your injury within 2 hours? _____

If not, why not? _____

Are you aware of the new federal law that requires the use of safe devices (except for public facilities, although these may be covered by state laws and regulations)? _____

Have you received training on the use of safe devices in the last year? _____

Are you aware of this facility's exposure control plan? _____

Are you aware of the procedure to follow if you sustain an injury? _____

Are safe devices provided to you for each procedure requiring a sharp? _____

Are safe devices exclusively provided or are they provided alongside unsafe traditional devices? _____

Do you use the safe devices when provided? _____

If not, why not? _____

Are there devices or procedures used on your unit that have a high risk of causing needlestick or sharps injuries? _____

If so, what are they? _____

What suggestions do you have for preventing needlestick or sharps injuries on your unit? _____

Workplace Walk-Through

A walk-through, which is a workplace inspection, is a crucial way to identify workplace hazards. Walk-throughs should be regularly planned and conducted by the needlestick prevention committee. They should be conducted during work hours and during different shifts. Walk through all units and speak with supervisors and front-line health care workers. You can use the following checklist to help you gather information.

Checklist:

- What kinds of sharps are available on the unit?
- What procedures require needles and sharps?
- What type of patients are involved in these procedures?
- Where is the procedure done?
- Who does the procedure?
- Are there alternative methods to perform the procedure that can eliminate the sharp? For example: oral versus injectable administration of medication or needleless IV connectors.
- Are safe devices for all categories of sharps available on the unit?
- Are they used? Why or why not?
- Are there legitimate uses of conventional devices, and are there procedures that cannot use safe devices?
- Are unsafe devices still on the unit?
- If so, why and how can use and access to these devices be monitored and controlled?
- What equipment is available in the supply closets?
- Are the sharps boxes available within arm's reach, in sight and routinely replaced when full?
- What other conditions, such as short staffing, exist that may contribute to the risk of needlestick and sharps injuries?

USING CONTRACT LANGUAGE

Another step you can take is to negotiate strong contract language through your union. You can work with your state nurses association to negotiate contract language specific to needlestick prevention. If you work in a public facility in a state without an OSHA-approved health and safety program, and therefore are not covered by OSHA regulations, you should negotiate contract language incorporating OSHA's BBP Standard. Contract language goals should include:

- Establishing a joint labor-management needlestick prevention committee with equal representation that has the authority and responsibility discussed at the beginning of this chapter (see page 16).

- Presumptive compensability, which means that if a nurse is infected with HIV, hepatitis B, hepatitis C, or other infectious diseases, it shall be presumed to be work-related for the purposes of workers' compensation. In other words, if you become infected, you will not have to prove that you became infected at work.
- Financial compensation for workers infected with a deadly virus like HIV.
- Paid administrative leave during the administrative waiting period for state workers' compensation.
- Accommodation for injury/illness, e.g., if you are ill while taking PEP medications after an exposure to HIV.
- Return-to-work guidelines and modified work assignments.

Your contract is a powerful tool that can be used to ensure worker safety. Even if you do not have specific language regarding needlesticks, almost all contracts have some general health and safety language. While your collective bargaining unit works toward negotiating the language goals above, make sure you administer your current contract. For example, if management is not sufficiently addressing needlestick prevention or not involving union representatives in this process, consider filing a grievance through your union.

FILING AN OSHA COMPLAINT ⁴²

Many employers are still learning about the federal Needlestick Safety and Prevention Act. Documenting the specifics of the amended Bloodborne Pathogens Standard (See Rights and Protections) and offering solutions can convince management to correct the hazard. Hopefully, you will either be able to establish a needlestick prevention committee or work with an already established committee to prevent injuries. Work with your facility's health and safety committee, labor-management committee or whichever committee has the authority on this issue to make your employer aware of state and federal laws. Make it clear that employees are concerned enough to contact OSHA for an inspection if no action is taken.

If management refuses to correct the problem and is violating the Bloodborne Pathogens Standard, you should file a complaint.

If management refuses to correct the problem and is violating the OSHA Bloodborne Pathogens Standard, you should file a complaint. A complaint is a notice of an alleged uncontrolled occupational hazard or a violation of the OSH Act or specific OSHA Standard, like the BBP, given by a past or present employee or an employee representative—such as a union. Complaints can be filed anonymously.

⁴² For more information, complaint forms, and instructions, see OSHA's Web site at www.osha.gov/as/opa/worker/complain.html

It's your responsibility to report the hazard to a supervisor. While you are not required to discuss concerns with your employer before filing a complaint, when possible you and your employer should work together to resolve the problem. If you are unionized, work with the union to file the complaint.

To file a complaint, fill out OSHA's official complaint form, including if possible, the specific violation of either the OSH Act or the BBP Standard. OSHA recommends including the following information:

- The number of employees who work at the site and how many are at risk for exposure to the hazard.
- Details regarding the status of compliance, such as types of sharps used in all areas of the employment setting and whether safe devices are in place for all procedures requiring sharps.
- The units on which the use of safety devices has NOT been implemented.
- The number of needlestick injuries recorded in available needlestick logs.
- Whether or not frontline staff nurses and other health care workers were involved in the evaluation and selection of the safety devices.
- Data documenting the trials of safety devices and evidence regarding the decision to use the particular product.
- Examples of near-misses (e.g., sharps left in a bed).

It's against the law for an employer to discriminate against an employee for filing an OSHA complaint. Consult your local OSHA office or your state nurses association for assistance.

Chapter Three: Device Evaluation, Selection, and Implementation

Evaluating, selecting, and implementing safe devices are among the most important tasks for the needlestick prevention committee. OSHA requires that institutions review their exposure control plan annually and evaluate the effectiveness of the control measures, including safe needle devices. New devices are entering the market at a rapid pace and even an annual evaluation could miss opportunities for innovations that might reduce injuries. Not all devices are alike or equally effective. Just because the manufacturer claims that a device is a safety device does not mean that it is safe.

Desirable Characteristics of Safety Devices

- The device is needleless.
- The safety feature is built into the device.
- The device works passively (i.e., requires no activation by the user). If user activation is necessary, the safety feature can be engaged with a single-handed technique, allowing workers' hands to remain behind the exposed sharp.
- The user can easily tell whether the safety feature has been activated. Some safety features have a sound, such as a click, indicating that the feature has been activated. Others change color when the feature is engaged.
- The safety feature cannot be deactivated and remains protective through disposal.
- If the device uses needles, it performs reliably with all needle sizes.
- The device is easy to use and practical.
- The device is safe and effective in patient care. (Does the use of the safety device impact the number of tries necessary to give the injection or start the IV? What is the impact on patient discomfort or bruising at the site?)

Health care facilities purchase equipment and supplies in a variety of ways, and the needlestick prevention committee needs to work within that system. It is important to learn the process for approval and purchasing of new devices in your workplace, particularly in the case of large health networks and group purchasing organizations (GPOs), which might have complex purchasing systems. The needlestick prevention committee should work closely with the purchasing department to ensure that safe devices are purchased. Find out who is responsible for new product purchases in your facility and schedule a meeting between the needlestick prevention committee



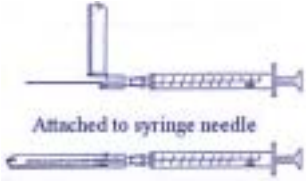
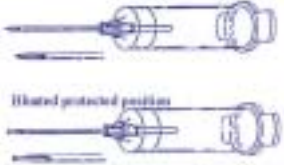
and the identified contact persons. Share the changes in the OSHA regulation with them and ask what steps are necessary for bringing a new product into the facility. Ideally, someone from purchasing will be a member of the needlestick prevention committee. The purchasing department can provide a list of devices that already are included in your institution's formulary and can contact manufacturers to request samples of products for screening. Be aware of "narrowed down" selection procedures. Some facilities only offer products that have been pre-approved by purchasing or management personnel. These often are based on recommendations or limitations by GPOs. These "narrowed down" device choices often are only based on price and neglect the safety features. This is especially true in facilities that are owned and operated by nationwide corporations. OSHA requires the use of safe and effective devices. If a safe and effective device is not available from the GPO, an exception to the purchasing contract will be necessary.

The Training for the Development of Innovative Control Technologies (TDICT) Project developed the following four-step, user-based systems approach for the evaluation, selection, and implementation of safe medical devices. It is comprehensive in scope, geared to developing and maintaining an ongoing program, and is predicated on the involvement of those who use the devices: frontline health care workers.


STEP ONE: BROAD IDENTIFICATION OF ALL MARKET-AVAILABLE DEVICES

The needlestick prevention committee should identify, obtain samples, and screen all products available on the market in each category of device. The box on the next page provides examples of the types of safe devices available. The California Occupational Health Branch (www.ohb.org/sharps.htm) and the University of Virginia International Health Care Worker Safety Center (www.med.virginia.edu/epinet/safetydevice.html) maintain updated lists of safety devices on the market along with the contact information for the manufacturer or distributor. Nursing convention exhibits also are good sources for product information and samples. Obtain samples in all sizes of syringes and needles to be screened because the safety feature might not be effective for all sizes.

EXAMPLES OF SAFETY DEVICES

<i>Type of Device</i>	<i>Safety Features</i>
Syringes and Injection Equipment	<p>Needleless or jet injection – the medication/immunization is injected under the skin without a needle, using the force of the liquid under pressure to pierce the skin.</p> <p>Retractable needle – the needle (usually fused to the syringe) is spring-loaded and retracts into the barrel of the syringe when the plunger is completely depressed after the injection is given.</p>  <p>Protective sheath – after giving an injection, the worker slides a plastic barrel over the needle and locks it in place.</p>  <p>Hinged re-cap – after the injection, the worker, using the index finger, flips a hinged protective cap over the needle, which locks into place. This safety feature may be fused to the syringe or come separate and detachable from the syringe.</p> 
IV Access – Insertion Equipment	<p>Retractable – the spring-loaded needle retracts into the needle holder upon pressing a button after use or the needle withdraws into the holder when withdrawn from the patient’s arm.</p> <p>Passive – a metal safety clip unfolds over the needle as it is withdrawn.</p> <p>Shielded IV catheters (midline and peripheral) – a protective shield slides over the exposed needle.</p> <p>Hemodialysis safety fistula sets (butterfly) – a protective shield slides over the needle as it is withdrawn.</p>
Blood-Collection and Phlebotomy	<p>Retractable needle – the spring-loaded needle is pulled into the vacuum tube holder after use.</p> <p>Shielded butterfly needle – a protective shield slides over the needle after use.</p> <p>Self-blunting needle – after use, the needle is blunted while still in the patient.</p>  <p>Plastic blood collection tubes — used to replace glass tubes.</p>

EXAMPLES OF SAFETY DEVICES *(continued)*

<i>Type of Device</i>	<i>Safety Features</i>
Suture Needles	Blunt suture needles — used for sewing internal fascia.
Lancets	Retracting lancet – following skin puncture, the sharp automatically retracts back into the device. 
Surgical Scalpels	Retracting scalpel – after use, the blade is withdrawn back into the body of the scalpel. Quick-release scalpel blade handles – a lever is activated that allows for a “touchless” attachment of the blade to the handle and releases it after use.

STEP TWO: THREE-STEP SELECTION PROCESS

The selection process involves a three-stage process—initial screening of devices, clinical simulation and intermediate selection, and clinical pilot testing—for evaluation and selection of safe devices and recognizes that a good plan must reflect each institution’s specific needs.

Initial Screening of Devices

Using the TDICT safety feature evaluation forms provided in Appendix D, the needlestick prevention committee should try each product in all sizes. The committee should consider involving additional workers as device evaluators, especially if the committee doesn’t include representatives from every clinical area. Initial screening involves the following steps:

1. Try the product **before** reading the accompanying manufacturer’s instructions to see how intuitive the device is to figure out and use.
2. Review the evaluation criteria and brainstorm additional criteria that might be important for your institution, the particular procedure, or clinical specialty.
3. Rank the priority selection criteria for your use.
4. Rate each device utilizing the criteria.
5. Perform a failure analysis exercise with the acceptable devices by taking 100 of the devices out of the package and activating the safety feature. Record the number of devices with the safety feature adequately engaged. Some devices have demonstrated a 7-17% failure rate right out of the package.
6. Select up to four devices in each category for the next evaluation step, clinical simulations. If all devices function equivalently during the screening process, you may choose to evaluate them all in a clinical simulation.

Clinical Simulation and Intermediate Selection

Clinical simulation and scenarios are methods of “test driving” the device and assessing its application in a particular clinical situation without threatening the health and safety of either patients or health care workers. TDICT developed simulation variables (see Appendix E) to assist in approximating the clinical situation.

In a small group of five to six members of the needlestick prevention committee, identify a common clinical situation and procedure requiring the use of a sharp. Next, choose variables in each category from the TDICT list.

Each person in the group will choose a role to play in the simulation. One member of the simulation team will assume the role of the patient and one will act as the nurse giving the injection, starting the IV or attempting another procedure using a sharp with a safety feature. Other simulation team members may act as additional hospital staff, family members, or other roles defined in the simulation. One of the participants should act as the observer/reporter.

While in your small group, role-play the same clinical simulation three or four times in succession using a different safety device each time. Following each clinical simulation, rate the device with the TDICT safety feature evaluation forms. Repeat the exercise rotating the roles among the group. Compare the evaluation ratings, and select the device(s) for clinical pilot testing.

Repeat the failure analysis exercises conducted during the screening process. Push the device to failure. Can you disengage the safety feature by dropping it on the floor, hitting the device on a bedrail, or other common practices that may occur clinically during use of the device? Will the safety feature disengage if the patient moves suddenly?

At the end of the clinical simulation exercises, determine which products warrant clinical pilot testing for the next step. The needlestick prevention committee will need to work closely with the purchasing department to develop criteria based on the screening exercise for bid specification for vendors.

Clinical Pilot Testing

It is important to test devices in “real use” situations before buying the device in large quantities and implementing the device throughout the health care facility. The purpose of pilot testing is to gain clinical information to assist in making the final selection decision. Pilot testing can identify potential problems prior to institution-wide implementation, identify training needs, and determine procedure changes that might be needed.

The needlestick prevention committee should select a site where the device will be used frequently and where the workers are enthusiastic about trying new products and critical of their application. It is important to involve the frontline health care workers on that unit in the design of the trial.

The pilot testing protocol should be clearly defined to include:

- Selecting a site that would use the device frequently enough to adequately evaluate the product during the time of the trial.
- The length of the trial – at least two weeks.
- A written evaluation tool based on the priority criteria identified during the screening process and incorporating the needs of the specific clinical unit. The tool should have an easy recording format.
- Involvement of the health care workers on the unit in the design of the trial and the product evaluation criteria appropriate for the specific clinical area.
- The minimum number of devices to be tested.
- Evaluating and recording the result for each device at time of use.
- Collecting and evaluating reports.
- Examining contents of sterilized sharps boxes on a regular basis to determine whether the safety devices are being used and if the safety features have been engaged prior to disposal.
- Evaluating the impact on the safety and quality of patient care (redness, pain, infection at site of IV insertion, etc.).

STEP THREE: INSTITUTIONALIZING SELECTED DEVICES

As the pilot testing is completed, the needlestick prevention committee should work closely with purchasing to ensure that the product chosen is available in the required quantities. In addition to providing a written guarantee of product availability, the product manufacturer often will provide training for health care workers onsite during all shifts to assist with implementation and ensure that products are used according to manufacturer specifications.

Successful implementation of devices requires training frontline health care workers on the use of the new devices **prior** to implementation. Providing safe devices that no one knows how to use defeats the purpose of selecting the devices. A well-trained staff will become as comfortable using new devices as they were using old devices.

Successful implementation of devices requires training frontline health care workers on the use of the new devices prior to implementation.

Ideally, the training should use “champions” from the needlestick prevention committee and other workers who have suffered needlestick injuries and are enthusiastic about prevention. The training should acknowledge that some devices might require more practice than others. Once the devices are institutionalized, solicit informal feed-

back and monitor the use of these new devices to determine the need for additional training and identify possible adverse effects of the devices on patient care.

STEP FOUR: ONGOING SURVEILLANCE FOR EFFICACY AND FOR BETTER DEVICES

The law requires that employers annually review the efficacy of their exposure control plan and review the market for new and better products. By evaluating the exposure control plan, the needlestick prevention committee can ensure ongoing surveillance to help measure the success of the action taken to prevent needlestick and sharps injuries. The committee should develop a mechanism for review of device performance including near-misses—such as when a contaminated needle is found outside of a sharps container, the safety feature does not engage reliably, or the sharps container is overfull. Discuss specific device problems with the manufacturer and with the purchasing department. The committee should also make sure that frontline health care workers are involved in the evaluation, selection, and implementation of devices and that they are receiving adequate and sufficient training on the use of new devices.

Conclusion

ANA has written this guide to help nurses across the country become key players in preventing exposure to deadly bloodborne pathogens from needlestick and sharps injuries. With the new federal and state laws and new technology, the time is right to make widespread changes in health care, so that needlestick and sharps injuries will no longer be considered “part of the job.” Now that you have the information you need and know the steps to take action, you and your colleagues have a crucial role to play in preventing nurses from facing the daily possibility of contracting HIV, hepatitis C, and other deadly diseases. You are not alone. ANA is training hundreds of nurses across the country to become involved in needlestick prevention. ANA and your state nurses association are valuable resources and want to work with you as we continue the Safe Needles Save Lives campaign.

With the new federal and state laws and new technology, the time is right to make widespread changes in health care, so that needlestick and sharps injuries will no longer be considered “part of the job.”

Appendix A: Resources

Occupational Safety and Health Administration (OSHA) Sources:

OSHA needlestick prevention Web site includes information on the Needlestick Safety and Prevention Act, the Bloodborne Pathogens Standard, and OSHA Compliance Directives: www.osha.gov/SLTC/needlestick/index.html

OSHA Needlestick Fact Sheet: www.osha.gov/needlesticks/needlefact.html

OSHA FAQs: www.osha.gov/needlesticks/needlefaq.html

OSHA Bloodborne Fact Sheets: www.oshaslc.gov/OshDoc/data_BloodborneFacts/:

- Reporting Exposure Incidents
- Protect Yourself When Handling Sharps
- Hepatitis B Vaccination—Protection For You
- Personal Protective Equipment Cuts Risk
- Holding the Line on Contamination

National Institute of Occupational Safety and Health (NIOSH) Sources:

NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings. Publication No. 2000-108: www.cdc.gov/niosh/2000-108.html

NIOSH Guidelines for Selecting, Evaluating and Using Sharps Disposal Containers. Publication No. 97-111: www.cdc.gov/niosh/sharps1.html

Centers for Disease Control and Prevention (CDC) Sources:

CDC needlestick prevention Web site: www.cdc.gov/health/needlesticks.htm

CDC HIV/AIDS Web site: www.cdc.gov/hiv/dhap.htm

CDC hepatitis C Web site: www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm

CDC hepatitis B Web site: www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm

CDC prophylaxis information: www.cdc.gov/ncidod/hip/guide/phssep.htm

CDC guidelines for infection control in health care personnel:
www.cdc.gov/ncidod/hip/GUIDE/infectcont98.htm

Other Web Sites:

ANA's needlestick prevention Web site: www.needlestick.org

California OSHA Sharps Injury Control Program: www.sharpslist.org

Training for the Development of Innovative Control Technology (TDICT) Project:
www.tdict.org

ECRI evaluation of needlestick devices: www.ecri.org

International Health Care Worker Safety Center and EPINet:
www.med.virginia.edu/epinet

Additional Sources:

ECRI Sharps Safety and Needlestick Prevention: An ECRI Resource for Evaluating and Selecting Protective Devices (Plymouth Meeting, PA: ECRI, 2001).

Gochmour, M., et al., *ANA Workplace Health and Safety Guide for Nurses: OSHA and NIOSH Resources* (Washington, DC: American Nurses Association, 2001).

Pugliese, G., and Salahuddin, M., *Sharps Injury Prevention Program: A Step-By-Step Guide* (Chicago: American Hospital Association, 1999).

Royal College of Nursing, *Be Sharp - Be Safe: Avoiding the Risks of Sharps Injury* (London: Royal College of Nursing, 2001).

Appendix B: OSHA Model Exposure Control Plan

The Model Exposure Control Plan is intended to serve employers as an example exposure control plan which is required by the Bloodborne Pathogens Standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing a written exposure control plan. Each employer will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the OSH Act or any provisions of OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

POLICY

The (Facility Name) is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- * Determination of employee exposure
- * Implementation of various methods of exposure control, including:
 - Universal precautions
 - Engineering and work practice controls
 - Personal protective equipment
 - Housekeeping
- * Hepatitis B vaccination
- * Post-exposure evaluation and follow-up
- * Communication of hazards to employees and training
- * Recordkeeping
- * Procedures for evaluating circumstances surrounding an exposure incident

The following is a list of job classifications in which some employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

<u>JOB TITLE</u>	<u>DEPARTMENT/LOCATION</u>	<u>TASK/PROCEDURE</u>
<u>(Example: Housekeeper</u>	<u>Environmental Services</u>	<u>Handling Regulated Waste)</u>
_____	_____	_____

Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the ECP.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting (Name of responsible person or department). If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

(Name of responsible person or department) is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

- * (For example: non-glass capillary tubes, SESIPs, needleless systems)
- * _____
- * _____

Sharps disposal containers are inspected and maintained or replaced by ___ (Name of responsible person or department) every ___ (list frequency) or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through (Examples: Review of OSHA records, employee interviews, committee activities, etc.)

We evaluate new procedures or new products regularly by (Describe the process, literature reviewed, supplier info, products considered)

Both front line workers and management officials are involved in this process: (Describe how employees will be involved)

(Name of responsible person or department) will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by ___ (Name of responsible person or department) in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows:

(Ex., gloves, eye protection, etc.)

PPE is located (List location) and may be obtained through (Name of responsible person or department) (Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)

All employees using PPE must observe the following precautions:

- * Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- * Remove PPE after it becomes contaminated, and before leaving the work area.
- * Used PPE may be disposed of in (List appropriate containers for storage, laundering, decontamination, or disposal.)
- * Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated

items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.

- * Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- * Never wash or decontaminate disposable gloves for reuse.
- * Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- * Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: (may refer to specific agency procedure by title or number and last date of review)

(For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling sharps disposal containers is: (may refer to specific agency procedure by title or number and last date of review)

The procedure for handling other regulated waste is: (may refer to specific agency procedure by title or number and last date of review)

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____ (must be easily accessible and as close as feasible to the immediate area where sharps are used).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.

Laundry

The following contaminated articles will be laundered by this company:

Laundering will be performed by (Name of responsible person or department)
_____ at (time and/or location).

The following laundering requirements must be met:

- * handle contaminated laundry as little as possible, with minimal agitation
- * place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use (red bags or bags marked with biohazard symbol) _____ for this purpose.
- * wear the following PPE when handling and/or sorting contaminated laundry:
(List appropriate PPE) _____

Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED _____ LABEL TYPE (size, color, etc.)
(e.g., specimens, contaminated laundry, etc.) (red bag, biohazard label, etc.)

(Name of responsible person or department) _____ will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

HEPATITIS B VACCINATION

(Name of responsible person or department) _____ will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at _____ (List location or person responsible for this recordkeeping).

Vaccination will be provided by _____ (List Health care Professional who is responsible for this part of the plan) at _____ (location).

Following the medical evaluation, a copy of the health care professional's Written Opinion will be obtained and provided to the employee. It will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact _____ (Name of responsible person) at the following number: _____.

An immediately available confidential medical evaluation and follow-up will be conducted by _____ (Licensed health care professional). Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- * Document the routes of exposure and how the exposure occurred.
- * Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- * Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- * If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- * Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- * After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
- * If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90

days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(Name of responsible person or department) _____ ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

(Name of responsible person or department) _____ ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- * a description of the employee's job duties relevant to the exposure incident
- * route(s) of exposure
- * circumstances of exposure
- * if possible, results of the source individual's blood test
- * relevant employee medical records, including vaccination status

(Name of responsible person or department) _____ provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

(Name of responsible person or department) _____ will review the circumstances of all exposure incidents to determine:

- * engineering controls in use at the time
- * work practices followed
- * a description of the device being used (including type and brand)
- * protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)
- * location of the incident (O.R., E.R., patient room, etc.)
- * procedure being performed when the incident occurred
- * employee's training

(Name of Responsible Person) _____ will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.

If it is determined that revisions need to be made, (Responsible person or department) _____ will ensure that appropriate changes are made to this ECP. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by _____ (Name of responsible person or department) _____. (Attach a brief description of their qualifications.)

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- * a copy and explanation of the standard
- * an explanation of our ECP and how to obtain a copy
- * an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- * an explanation of the use and limitations of engineering controls, work practices, and PPE
- * an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- * an explanation of the basis for PPE selection
- * information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
- * information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- * an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- * information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- * an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- * an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least three years at _____ (Name of responsible person or location of records) _____.

The training records include:

- * the dates of the training sessions
- * the contents or a summary of the training sessions
- * the names and qualifications of persons conducting the training
- * the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to _____ (Name of Responsible person or department)

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

_____ (Name of Responsible person or department) is responsible for maintenance of the required medical records. These confidential records are kept at _____ (List location) for at least the duration of employment plus 30 years.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to _____ (Name of responsible person or department and address)

OSHA Recordkeeping

An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by _____ (Name of responsible person or department)

Sharps Injury Log

In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. All incidences must include at least:

- the date of the injury
- the type and brand of the device involved
- the department or work area where the incident occurred
- an explanation of how the incident occurred.

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If

a copy is requested by anyone, it must have any personal identifiers removed from the report.

Appendix C: EPINet Sharps Reporting Form

Needlestick & Sharp Object Injury Report

Last Name: _____ First Name: _____

Injury ID: *(for office use only)* S _____ Facility ID: *(for office use only)* _____ Completed By: _____

1) Date of Injury: 2) Time of Injury:

3) Department where Incident Occurred: _____

4) Home Department: _____

5) What is the Job Category of the Injured Worker: (check one box only)

- | | |
|----------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| <input type="checkbox"/> 1 Doctor (<i>attending/staff</i>), specify specialty _____ | <input type="checkbox"/> 10 Clinical Laboratory Worker |
| <input type="checkbox"/> 2 Doctor (<i>intern/resident/fellow</i>), specify specialty _____ | <input type="checkbox"/> 11 Technologist (<i>non-lab</i>) |
| <input type="checkbox"/> 3 Medical Student | <input type="checkbox"/> 12 Dentist |
| <input type="checkbox"/> 4 Nurse: specify <input type="checkbox"/> 1 RN | <input type="checkbox"/> 13 Dental Hygienist |
| <input type="checkbox"/> 5 Nursing Student <input type="checkbox"/> 2 LPN | <input type="checkbox"/> 14 Housekeeper |
| <input type="checkbox"/> 18 CNA/HHA <input type="checkbox"/> 3 NP | <input type="checkbox"/> 19 Laundry Worker |
| <input type="checkbox"/> 6 Respiratory Therapist <input type="checkbox"/> 4 CRNA | <input type="checkbox"/> 20 Security |
| <input type="checkbox"/> 7 Surgery Attendant <input type="checkbox"/> 5 Midwife | <input type="checkbox"/> 16 Paramedic |
| <input type="checkbox"/> 8 Other Attendant | <input type="checkbox"/> 17 Other Student |
| <input type="checkbox"/> 9 Phlebotomist/Venipuncture/IV Team | <input type="checkbox"/> 15 Other, describe: _____ |

6) Where Did the Injury Occur? (check one box only)

- | | |
|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 1 Patient Room | <input type="checkbox"/> 9 Dialysis Facility (<i>hemodialysis and peritoneal dialysis</i>) |
| <input type="checkbox"/> 2 Outside Patient Room (<i>hallway, nurses station, etc.</i>) | <input type="checkbox"/> 10 Procedure Room (<i>x-ray, EKG, etc.</i>) |
| <input type="checkbox"/> 3 Emergency Department | <input type="checkbox"/> 11 Clinical Laboratories |
| <input type="checkbox"/> 4 Intensive/Critical Care unit: specify type: _____ | <input type="checkbox"/> 12 Autopsy/Pathology |
| <input type="checkbox"/> 5 Operating Room/Recovery | <input type="checkbox"/> 13 Service/Utility (<i>laundry, central supply, loading dock, etc.</i>) |
| <input type="checkbox"/> 6 Outpatient Clinic/Office | <input type="checkbox"/> 16 Labor and Delivery Room |
| <input type="checkbox"/> 7 Blood Bank | <input type="checkbox"/> 17 Home-care |
| <input type="checkbox"/> 8 Venipuncture Center | <input type="checkbox"/> 14 Other, describe: _____ |

7) Was the Source Patient Identifiable? (check one box only)

- 1 Yes 2 No 3 Unknown 4 Not Applicable

8) Was the Injured Worker the Original User of the Sharp Item? (check one box only)

- 1 Yes 2 No 3 Unknown 4 Not Applicable

9) The Sharp Item was: (check one box only)

- 1 Contaminated (known exposure to patient or contaminated equipment) was there blood on the device? 1 Yes
- 2 Uncontaminated (no known exposure to patient or contaminated equipment) 2 No
- 3 Unknown

10) For What Purpose was the Sharp Item Originally Used? (check one box only)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 1 Unknown/Not Applicable | <input type="checkbox"/> 16 To Place an Arterial /Central Line |
| <input type="checkbox"/> 2 Injection, Intra-muscular/Subcutaneous, or Other Injection through the Skin (<i>syringe</i>) | <input type="checkbox"/> 9 To Obtain a Body Fluid or Tissue Sample (<i>urine/CSF/amniotic fluid/other fluid, biopsy</i>) |
| <input type="checkbox"/> 3 Heparin or Saline Flush (<i>syringe</i>) | <input type="checkbox"/> 10 Finger stick/Heel Stick |
| <input type="checkbox"/> 4 Other Injection into (<i>or aspiration from</i>) IV injection site or IV Port (<i>syringe</i>) | <input type="checkbox"/> 11 Suturing |
| <input type="checkbox"/> 5 To Connect IV line (<i>intermittent IV/piggyback/IV infusion/other IV line connection</i>) | <input type="checkbox"/> 12 Cutting |
| <input type="checkbox"/> 6 To Start IV or Set up Heparin Lock (<i>IV catheter or winged set-type needle</i>) | <input type="checkbox"/> 17 Drilling |
| <input type="checkbox"/> 7 To Draw Venous Blood Sample <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 13 Electrocautery |
| <input type="checkbox"/> 8 To Draw Arterial Blood Sample <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> if used to draw blood was it? <input type="checkbox"/> Direct stick? <input type="checkbox"/> Draw from a Line? | <input type="checkbox"/> 14 To Contain a Specimen or Pharmaceutical (<i>glass item</i>) |
| | <input type="checkbox"/> 15 Other, Describe: _____ |

11) Did the Injury Occur? (check one box only)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 1 Before Use of Item (<i>item broke/slipped, assembling device, etc.</i>) | <input type="checkbox"/> 16 Device Left on Floor, Table, Bed or Other Inappropriate Place |
| <input type="checkbox"/> 2 During Use of Item (<i>item slipped, patient jarred item, etc.</i>) | <input type="checkbox"/> 8 Other After Use-Before Disposal (<i>in transit to trash, cleaning, sorting, etc.</i>) |
| <input type="checkbox"/> 15 Restraining patient | <input type="checkbox"/> 9 From Item Left On or Near Disposal Container |
| <input type="checkbox"/> 3 Between Steps of a Multi-step Procedure (<i>between incremental injections, passing instruments, etc.</i>) | <input type="checkbox"/> 10 While putting item into Disposal Container |
| <input type="checkbox"/> 4 Disassembling Device or Equipment | <input type="checkbox"/> 11 After Disposal, Stuck by Item Protruding from Opening of Disposal Container |
| <input type="checkbox"/> 5 In Preparation for Reuse of Reusable Instrument (<i>sorting, disinfecting, sterilizing, etc.</i>) | <input type="checkbox"/> 12 Item Pierced Side of Disposal Container |
| <input type="checkbox"/> 6 While Recapping Used Needle | <input type="checkbox"/> 13 After Disposal, Item Protruded from Trash Bag or Inappropriate Waste Container |
| <input type="checkbox"/> 7 Withdrawing a Needle from Rubber or Other Resistant Material (<i>rubber stopper, IV port, etc.</i>) | <input type="checkbox"/> 14 Other, Describe: _____ |

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EXPOSURE PREVENTION
INFORMATION NETWORK

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12) What Type of Device Caused the Injury? (check one box only)

- Needle-Hollow Bore
- Surgical
- Glass

Which Device Caused the Injury? (check one box from one of the three sections only)

Needles (for suture needles see "surgical instruments")

- 1 Disposable Syringe
 - a Insulin
 - b Tuberculin
 - c 24/25-gauge needle
 - d 23-gauge needle
 - e 22-gauge needle
 - f 21-gauge needle
 - g 20-gauge needle
 - h "Other"
- 2 Pre-filled cartridge syringe (includes Tubex™, Carpuject™ - type syringes)
- 3 Blood gas syringe (ABG)
- 4 Syringe, other type
- 5 Needle on IV line (includes piggybacks & IV line connectors)
- 6 Winged steel needle (includes winged-set type devices)
- 7 IV catheter stylet
- 8 Vacuum tube blood collection holder/needle (includes Vacutainer™ -type device)
- 9 Spinal or Epidural Needle
- 10 Unattached hypodermic needle
- 11 Arterial catheter introducer needle
- 12 Central line catheter needle (cardiac, etc.)
- 13 Drum catheter needle
- 14 Other vascular catheter needle (cardiac, etc.)
- 15 Other non-vascular catheter needle (ophthalmology, etc.)
- 28 Needle, not sure what kind
- 29 Other needle, please describe: _____

Surgical Instrument or Other Sharp Items (for glass items see "glass")

- 30 Lancet (finger or heel sticks)
- 31 Suture needle
- 32 Scalpel, reusable (scalpel, disposable code is 45)
- 33 Razor
- 34 Pipette (plastic)
- 35 Scissors
- 36 Electro-cautery device
- 37 Bone cutter
- 38 Bone chip
- 39 Towel clip
- 40 Microtome blade
- 41 Trocar
- 42 Vacuum tube (plastic)
- 43 Specimen/Test tube (plastic)
- 44 Fingernails/Teeth
- 45 Scalpel, disposable
- 46 Retractors, skin/bone hooks
- 47 Staples/Steel sutures
- 48 Wire (suture/trauma/guide wire)
- 49 Pin (fixation, guide pin)
- 50 Drill bit/bur
- 51 Pickups/Forceps/Hemostats/Clamps
- 58 Sharp item, not sure what kind
- 59 Other sharp item. Describe: _____

Glass

- 60 Medication ampule
- 61 Medication vial (small volume with rubber stopper)
- 62 Medication/IV bottle (large volume)
- 63 Pipette (glass)
- 64 Vacuum tube (glass)
- 65 Specimen/Test tube (glass)
- 66 Capillary tube
- 67 Glass slide
- 78 Glass item, not sure what kind
- 79 Other glass item. Describe: _____

12a) Brand/Manufacturer of Product: (e.g. ABC Medical Company) _____

12b) Model: _____

- 98 Please Specify: _____
- 99 Unknown

13) If the Item Causing the Injury was a Needle or Sharp Medical Device, Was it a "Safety Design" with a Shielded, Recessed, Retractable, or Blunted Needle or Blade?

- 1 Yes
- 2 No
- 3 Unknown

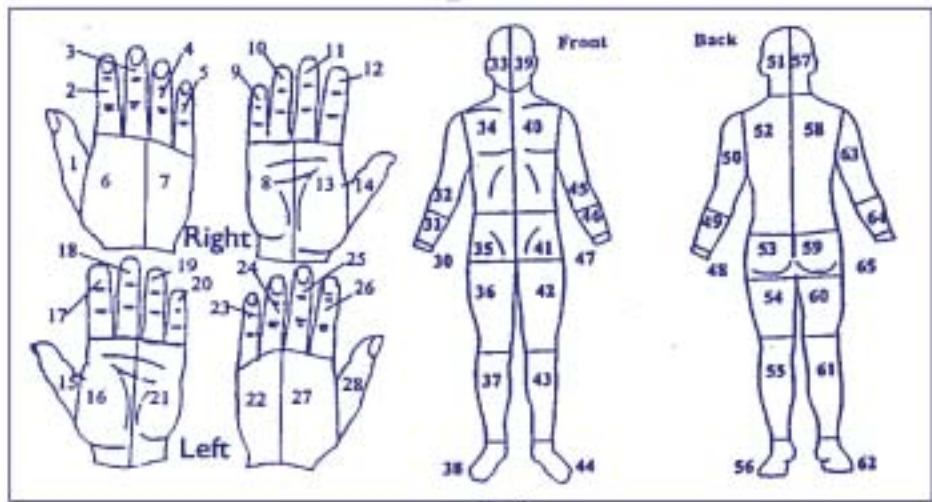
13a) Was the Protective Mechanism Activated?

- 1 Yes, fully
- 2 Yes, partially
- 3 No
- 4 Unknown

13b) Did Exposure Incident Happen?

- 1 Before activation
- 2 During activation
- 3 After activation
- 4 Unknown

14) Mark the Location of the Injury:



15) Was the Injury?

- 1 Superficial (little or no bleeding)
- 2 Moderate (skin punctured, some bleeding)
- 3 Severe (deep stick/cut, or profuse bleeding)

16) If injury was to the hand, did the Sharp Item Penetrate?

- 1 Single pair of gloves
- 2 Double pair of gloves
- 3 No gloves

17) Dominant Hand of the Injured Worker:

- 1 Right-handed
- 2 Left-handed

18) Describe the Circumstances Leading to this Injury (please note if a device malfunction was involved):

19) For Injured Healthcare Worker: If the Sharp had no Integral Safety Feature, Do you have an Opinion that such a Feature could have prevented the injury? 1 Yes 2 No 3 Unknown

Describe: _____

20) For Injured Healthcare Worker: Do you have an Opinion that any other Engineering Control, Administrative or Work Practice could have prevented the injury? 1 Yes 2 No 3 Unknown

Describe: _____

Cost:

_____	Lab charges (Hb, HCV, HIV, other)
_____	Healthcare Worker
_____	Source
_____	Treatment Prophylaxis (HBIG, Hb vaccine, tetanus, other)
_____	Healthcare Worker
_____	Source
_____	Service Charges (Emergency Dept, Employee Health, other)
_____	Other Costs (Worker's Comp, surgery, other)
_____	TOTAL (round to nearest dollar)

Is this Incident OSHA reportable? 1 Yes 2 No 3 Unknown

If Yes, Days Away from Work? _____
 Days of Restricted Work Activity? _____

Does this incident meet the FDA medical device reporting criteria? (Yes if a device defect caused serious injury necessitating medical or surgical intervention, or death occurred within 10 works days of incident.)

- 1 Yes (If Yes, follow FDA reporting protocol.)
- 2 No

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Appendix D: TDICT Safety Feature Evaluation Forms

SAFETY FEATURE EVALUATION FORM I.V. ACCESS DEVICES



Date: _____ Department: _____ Occupation: _____
 Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree.....disagree
1. The safety feature can be activated using a one-handed technique.....	1 2 3 4 5 N/A
2. The safety feature does not interfere with normal use of this product.....	1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature.....	1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device.....	1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes.....	1 2 3 4 5 N/A
6. The device allows for rapid visualization of flashback in the catheter or chamber...	1 2 3 4 5 N/A
7. Use of this product does not increase the number of sticks to the patient.....	1 2 3 4 5 N/A
8. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping.....	1 2 3 4 5 N/A
9. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.....	1 2 3 4 5 N/A
10. The safety feature operates reliably.....	1 2 3 4 5 N/A
11. The exposed sharp is blunted or covered after use and prior to disposal.....	1 2 3 4 5 N/A
12. The product does not need extensive training to be operated correctly.....	1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

SAFETY FEATURE EVALUATION FORM

I.V. CONNECTORS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree.....disagree
1. Use of this connector eliminates the need for exposed needles in connections.....	1 2 3 4 5 N/A
2. The safety feature does not interfere with normal use of this product.....	1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature.....	1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device.....	1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes.....	1 2 3 4 5 N/A
6. The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles.....	1 2 3 4 5 N/A
7. The connector can be secured (locked) to Y-sites, hep-locks, and central lines.....	1 2 3 4 5 N/A
8. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.....	1 2 3 4 5 N/A
9. The safety feature operates reliably.....	1 2 3 4 5 N/A
10. The exposed sharp is blunted or covered after use and prior to disposal.....	1 2 3 4 5 N/A
11. The product does not need extensive training to be operated correctly.....	1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

- DURING USE:** agree.....disagree
1. The safety feature can be activated using a one-handed technique..... 1 2 3 4 5 N/A
 2. The safety feature does not obstruct vision of the tip of the sharp..... 1 2 3 4 5 N/A
 3. Use of this product requires you to use the safety feature..... 1 2 3 4 5 N/A
 4. This product does not require more time to use than a non-safety device..... 1 2 3 4 5 N/A
 5. The safety feature works well with a wide variety of hand sizes..... 1 2 3 4 5 N/A
 6. The device is easy to handle while wearing gloves..... 1 2 3 4 5 N/A
 7. This device does not interfere with uses that do not require a needle..... 1 2 3 4 5 N/A
 8. This device offers a good view of any aspirated fluid..... 1 2 3 4 5 N/A
 9. This device will work with all required syringe and needle sizes..... 1 2 3 4 5 N/A
 10. This device provides a better alternative to traditional recapping..... 1 2 3 4 5 N/A

- AFTER USE:**
11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated..... 1 2 3 4 5 N/A
 12. The safety feature operates reliably..... 1 2 3 4 5 N/A
 13. The exposed sharp is permanently blunted or covered after use and prior to disposal..... 1 2 3 4 5 N/A
 14. This device is no more difficult to process after use than non-safety devices..... 1 2 3 4 5 N/A

- TRAINING:**
15. The user does not need extensive training for correct operation..... 1 2 3 4 5 N/A
 16. The design of the device suggests proper use..... 1 2 3 4 5 N/A
 17. It is not easy to skip a crucial step in proper use of the device..... 1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

SAFETY FEATURE EVALUATION FORM

VACUUM TUBE BLOOD COLLECTION SYSTEMS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree.....disagree
1. The safety feature can be activated using a one-handed technique.....	1 2 3 4 5 N/A
2. The safety feature does not interfere with normal use of this product.....	1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature.....	1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device.....	1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes.....	1 2 3 4 5 N/A
6. The safety feature works with a butterfly.....	1 2 3 4 5 N/A
7. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated.....	1 2 3 4 5 N/A
8. The safety feature operates reliably.....	1 2 3 4 5 N/A
9. The exposed sharp is blunted or covered after use and prior to disposal.....	1 2 3 4 5 N/A
10. The inner vacuum tube needle (rubber sleeved needle) does not present a danger of exposure.....	1 2 3 4 5 N/A
11. The product does not need extensive training to be operated correctly.....	1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

Appendix E: TDICT Scenarios and Simulation Variables



What is a scenario?

A scenario is a product testing method in which the actual circumstances of use are simulated as closely as possible. Factors such as lighting, noise, crowding, slipperiness of the hands, etc. are assigned values. These variables are depicted on a series of overlays that can be used in conjunction with an approximate drawing of the room in which the simulation is being enacted. Several drawings of typical room layouts are included with the packet of materials. The variables are then stacked on top of the room layout drawings to give a visual reminder of the simulation conditions.

Who are scenarios intended for?

These scenarios were designed to be useful to Product Evaluation or Product Selection Committees at healthcare institutions, healthcare workers, healthcare worker labor unions, medical product manufacturers, as well as designers and inventors.

Why use a scenario?

Scenarios enable individuals to create the circumstances in which a medical product will be used without threatening the health and safety of either patients or healthcare workers. Because many medical products invade the body of the patient, or are actually implanted in the patient, certain procedures are quite difficult to replicate in a manner which closely approximates "real life". Having made that concession, a great amount of information can be gleaned from a mock-up, or trial run, of a procedure involving the use of a new or improved medical product. As a metaphor for this process of evaluation, it may be useful to imagine test-driving a car before purchase. Almost no one would consider buying a car without actually getting behind the wheel and driving it out on the open road; however, this is exactly what happens with medical products. Many times, the individual responsible for making the choice between competing products has no experience with the actual performance of the product nor do they attempt to test the product in a manner consistent with its intended usage. Instead of test-driving the car, decisions are being made on the show-room floor based on factors that can be readily assimilated through simple observation. Qualities such as cost, color, feel, inventiveness, and familiarity affect decisions at this level of evaluation. Using the show-room metaphor, one might be attracted to the newest sports car because of its elegant appearance or the more conservative car that reminds the buyer of the car being traded in might also be chosen. The fundamental flaw with this level of evaluation is that the user's feet may not even reach the pedals, or, as a more subtle example, the car may be hard to get out of third gear making city driving an onerous task. Though the example may seem to over exaggerate the truth about medical product evaluation, our experience leads us to believe that a number of decisions are made while looking at the glossy brochures.

How are scenarios enacted?

Typically, the evaluating group will choose the site of use and the procedure which will be performed using the medical product in question. Both the medical product under scrutiny and the existing product which the new one may replace will be run through the simulation. A group of individuals will be assembled to conduct the evaluation. This group will consist of one or more healthcare workers who routinely perform the procedure as part of their job. These people are the PLAYERS. In addition, there will be an individual responsible for observing the process and recording comments and situations that arise during the evaluation session. This person is called the RECORDER. There also needs to be an individual responsible for directing the session. The actual tasks undertaken by this person will be varied in complexity, depending on the intricacies of the situation being simulated. This last person is titled the FACILITATOR.

HOW TO SIMULATE VARIABLES

1. Patient State

Helpful	Still	Uncooperative	Thrashing
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One member of the simulation team will lie in the bed and act the part of the patient. Any invasive procedure should be done on a fake arm that the "patient" is holding.

2. Lighting

Dark	Dim	Normal	Bright	Surgical Bright
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Adjust the lights and/or shades in the room to get the desired light level.

3. Noise

Very Loud	Noisy Bursts	Conversation	Sleep	Silence
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- "Very Loud" - all alarms sounding, people talking, and the "patient" making some noise
- "Noisy Bursts" - people talking, alarms turn on and off, patient groans intermittently
- "Conversation" - people talking
- "Sleep" - quiet conversation
- "Silence" - no talking, only machine operating noise (not alarms)

If you need to simulate the noise of equipment use a radio/ tape recorder.

4. Number of people at the bedside

8	5	3	1
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Do not count the "patient" as one of these people. These will be the people who will perform the procedure you select.

5. Condition of hands

Slippery	Wet	Wet inside	Dry	Double Gloved
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- "Slippery" - put oil (vegetable, k-y jelly, etc.) on gloves
- "Wet" - run gloved hands under the tap for 5-10 seconds
- "Wet inside" - run hands under tap and then put gloves on
- "Dry" and "Double Gloved" - put one or two pairs of clean gloves on dry hands

6. Visibility

Poor	Fair	Good
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This should simulate blood/ body fluids making it hard to see through safety glasses/safety shields. Spray paint the glasses/shields lightly/heavily before the simulation. Allow time to dry.

7. Floor Conditions

Slick & Debris	Slick	Debris	Clean
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- "Slick" - make small puddles of water on the floor
- "Debris" - put crumpled paper on the floor

8. Room Temperature

Cold ($\leq 60^\circ$)	Comfortable (about 70°)	Hot ($\geq 80^\circ$)
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Adjust the thermostat in the room accordingly if you have access to it.

9. Sharps boxes

0	1	2	3
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Make sure that the indicated number of sharps boxes are in the room.

10. Room

Trauma	ICU	2 bed patient room
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American Nurses Association's

Needlestick Prevention Guide



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SNL2004

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