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AST Guidelines for Best Practices for Sharps Safety and Use of the Neutral Zone

Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organizations (HDO) reinforce best practices in sharps safety and use of the neutral zone as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the Guidelines is to provide information OR supervisors, risk management, and surgical team members to use in the development and implementation of policies and procedures for sharps safety and use of the neutral zone in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding sharps safety and use of the neutral zone practices according to HDO protocols. Additionally, there are several organizations that establish guidelines, recommendations, and practices that HDOs and surgical personnel must be familiar, and the AST Guidelines are based upon these protocols; they include:

- The Joint Commission (TJC)
- American College of Surgeons (ACS)
- Centers for Disease Control and Prevention (CDC)
- International Sharps Injury Prevention Society (ISIPS)
- Occupational Safety and Health Administration (OSHA)
- Association of periOperative Registered Nurses (AORN)
- National Institute for Occupational Safety and Health (NIOSH)

Rationale

The following Guidelines address sharps safety and use of the neutral zone in the OR. This Guideline provides guidance to ensure the safe handling of sharps in the OR, including implementing *hands free techniques* (HFT) to prevent sharps injuries, and reduce exposure of *bloodborne pathogens* to patients and surgical personnel.

Establishing a safe surgical environment is a challenge because CSTs, surgeons, RNs, and anesthesia personnel work so closely together handling many of the same supplies and surgical instruments in a limited space. Consequently, surgeons and CSTs often sustain sharps injuries in similar ways with the same types of sharps; therefore,

emphasizing the importance of a team approach to safety to reduce the rate of injuries. Surgery personnel are at the highest risk for sustaining a *percutaneous injury* (PI) that exposes them to bloodborne pathogens acquired from a patient and exposes patients to the transmission of diseases from the surgery team.¹⁻³ An estimated 384,000 PIs occur in HDOs per year with 23% of those occurring during surgical procedures and 236,000 (61%) resulting from hollow-bore *needlestick injuries*.⁴⁻⁶ However, it should be mentioned that the estimated 384,000 PIs does not include the unknown number of PIs to *healthcare personnel (HCP)* that work in *nonhospital facilities*, where approximately 60% of HCP are employed.⁶

PIs most often occur after use and before disposal of a sharp device, during use of a sharp device on a patient, and during or after disposal.⁷ The most commonly injured body part is the non-dominant hand.⁸⁻¹² The five sharp devices that are responsible for majority of PIs are in order of frequency: *hollow-bore needles*; disposable syringes; suture needles; winged steel needles; scalpel blades. PIs are classified as *potentially preventable*, such as if a conventional sharps device was used instead of a safety engineered sharp device, and *patient care-related injury*, such as when a patient moves during the insertion or removal of a needle.¹³

It is estimated that patients' blood contacts the skin and/or mucous membranes of OR personnel in as many as 50% of operations with cuts or needlesticks occurring in as many as 15% of surgical procedures.⁴ Surgeons are at the highest risk for injury experiencing up to 59% of the injuries; CSTs in the first scrub role have the second highest frequency of injuries (19%) followed by anesthesiologists and circulating nurses (6% each).^{4,9} Obviously, the risk of sharps injuries increases with longer, invasive procedures with a blood loss of $\geq 100\text{cc}$.^{2,14-17}

The danger of PIs is amplified by the frequency of hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in surgical patients.¹⁸ Sharps injuries are associated primarily with the possible transmission of HBV, HCV, and HIV, but the injuries have been connected to the transmission of more than sixty other pathogens including bacteria, parasites and yeasts.¹⁹⁻³⁷ One study of general surgery patients in an urban academic hospital reported 20 to 38% of all procedures involved exposure to HBV, HCV, and HIV.²⁴

The risk of HBV patient-to-surgical personnel transmission is influenced by the type of hepatitis B antigens and the amount of blood.³⁸ However, since the introduction of the HBV immunization and most HDO's requiring HCP to be immunized, the rate of infections in HCP has significantly declined.^{7, 38-41} In 1983 the reported number of HBV-infected HCP was 10,000 and in 2009 the number had dropped to 100.³⁹ The risk for acquiring HIV depends on two factors: type of exposure and level of blood exposure.⁴²

The exact number of HCP that have occupationally acquired HCV is unknown.^{7,43} There are cases reported of occupational HCV transmission to HCP.⁷ All except two involve PIs with one case of HCV and a second of HCV and HIV transmitted via body fluid splash to the conjunctiva.^{44,45}

The first case of HIV transmission from a patient to a HCW was reported in 1986.⁴⁶ As of December 2001, CDC has received reports of 57 documented cases and 138 possible cases of occupationally acquired HIV infection among HCP in the United States (U.S.) since reporting began in 1985.⁴³ In a retrospective case-control study of HCP with percutaneous exposure to HIV, it was reported that the risk for HIV infection

increases with exposure to larger quantities of blood from the patient as indicated by a device that is visibly contaminated with the patient's blood; procedure that involves placing a needle directly into the patient's artery or vein, or; a deep injury.⁴⁷ Of the 57 documented cases, most involve a PI with a hollow-bore needle that was in a blood vessel.⁷

PIs are just as hazardous for the patient as they are for surgery personnel.^{39, 48-53} A patient is at risk when a surgical team member infected with a bloodborne pathogen experiences a PI and the medical device that caused the PI is not passed off the sterile field and is re-used on the patient, or a surgical team member experiences an unrecognized surgical glove perforation.⁵⁴ 132 cases of HCW-to-patient transmission of HBV, HCV, or HIV have been reported.^{35, 38, 51-53}

Although occupational HBV, HCV and HIV *seroconversion* is infrequent compared to the number of HCP in the U.S., the risks and costs associated with PIs are obviously very serious, including the significant psychological stress the HCW can experience. Direct costs include initial and follow-up treatment, post-exposure prophylaxis or vaccine, are estimated at a range from \$71 to \$5,000 depending on the treatment.^{6, 57, 58} The indirect costs that are difficult to attach a figure include the emotional and psychological cost associated with the fear and anxiety of having experienced a PI and the testing results, and the obligation to share the information with a significant other; lost time from work; loss of a HCW in providing patient care, particularly in these days of shortages of healthcare providers; and the societal economic burden of medical care for a HCW with seroconversion.⁷

The emotional stress of a PI can be severe and have long-lasting effects, often requiring counselling, particularly if the injury involves exposure to HIV.⁶ HBV, HCV, and HIV infections have effects on personal relationships, future employment, and insurance coverage.⁵⁹ However, just as distressing is not knowing the infection status of the source patient and the emotional distress can extend to family members.⁶⁰⁻⁶²

Several organizations, both non-governmental and governmental, have developed guidelines and standards that serve to protect HCP from exposure to bloodborne pathogens by establishing *work practice controls*. The primary document that serves to reduce HCP exposure to HBV, HCV, HIV and *other potentially infectious materials* (OPIM) is the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard CFR 29 1910.1030 issued in 1991. Specifically, the standard requires employers to establish a written exposure control plan to minimize employee exposure, and at a minimum annually review and update the plan to include information on new or revised procedures for reducing exposure; *engineering controls* to isolate or remove bloodborne pathogen hazards from the workplace; requirements for vaccination; requirements for post-exposure treatment; and continuing education of employees.⁶³⁻⁶⁵

OSHA was directed to revise the bloodborne pathogen standard when the Needlestick Safety and Prevention Act was signed into law on November 6, 2000 and became effective on April 18, 2001.^{64, 65} OSHA revised the standard to include modifying the definition of "engineering controls" and added definitions for the terms "*sharps with engineered sharps injury protection*" (SESIP) and *needleless systems*; requires employers to review and implement new technologies when updating their exposure control plan; requires employers to gather input from non-managerial employees who are involved in direct patient care in the identification, evaluation, and selection of safety-engineered

devices as well as their input in the exposure control plan; and requires employers to maintain a *sharps injury* log for the purpose of identifying high risk areas and evaluating sharps devices that could be replaced with a engineered sharps injury protection device.^{64,65} On the heels of federal legislation, 21 states passed their own needle safety legislation that in some instances, have additional provisions.⁶⁶

However, a group of researchers analyzed PI surveillance data from 87 U.S. hospitals gathered from 1993 – 2006, comparing injury rates in surgical and nonsurgical settings before and after the passage of the act. 31,324 sharps injuries were identified and 7,189 were to surgical personnel.⁶⁷ After the legislation was passed, injury rates in nonsurgical settings decreased 31.6%, but increased 6.5% in surgical settings.⁶⁷ 43.4% of the injuries were caused by suture needles; 17% by knife blades; and 12% by hypodermic needles attached to a syringe.⁶⁷ Three-quarters of the injuries occurred during use or passing the sharps devices, and surgeons had the highest rate of injuries. CSTs typically sustained injuries by sharps devices when passing or disassembling devices, or during or after their disposal.⁶⁷ Therefore, despite legislation, standard precautions, and other regulatory requirements, surgical sharps injuries increased while nonsurgical injuries significantly decreased, emphasizing the need for administrative support of a culture of safety, adoption of safer devices, and compliance by surgical personnel.

Two nongovernmental organizations that have published statements and guidelines on sharps safety are ACS and AORN. In October, 2016 the ACS published its *Revised Statement on Sharps Safety* that address work practices, blunt-tip suture needles, use of the neutral zone and SESIP.⁴ AORN first published its *Guideline for Sharps Safety* in 2013, revised in 2014 and has been annually published. The guideline addresses multiple aspects of sharps safety including the evaluation and adoption of SESIP devices; use of blunt suture needles; use of the neutral zone; education and training of employees; and details regarding the written exposure control plan.⁶⁸

The following are two important programs that collect(ed) data on *occupational exposures* to bloodborne pathogens and serve as excellent informational resources: (1) Exposure Prevention Information Network (EPINet®) maintained by the International Healthcare Worker Safety Center at the University of Virginia. It has collected data from 84 hospitals participating on a voluntary basis since 1992 to provide standardized methods for recording and tracking PIs, and blood and body fluid contacts; (2) National Surveillance System for Healthcare Workers (NaSH) established by the Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion from 1995 - 2007. At the height of the program 64 hospitals were participating by 2000. In 2007 NaSH released its report on blood and body fluid exposure data. In the U.S., the most accurate data and estimates on the number of PIs sustained by HCP is arrived at by combining the data from EPINet® and NaSH networks and reports. The following are highlights of the NaSH statistics:

- the total number of blood and body fluid exposure reports for the 12 year period was 30,945,
- PIs accounted for 82% the most commonly reported route of exposure,
- a third (29%) of the reported exposures involved the operating room,
- hypodermic needles and suture needles were involved in the majority of reported PIs,

- the largest percentage (36%) of solid sharps injuries occurred during handling of suture needles,
- 56% of PIs with a hollow-bore needle were considered potentially preventable,
- of the 1,465 HCP that experiences an exposure to an HIV-positive patient, only 63% elected to undergo PEP.¹³

The previous information and statistics point to the importance of sharps safety and prevention of IPs. Using a combination of safety practices including sharps engineered safety devices, *neutral zone*, *blunt needles*, and reducing or eliminating sharps use are the important factors for preventing PIs in the operating room since the use of sharps usually cannot be avoided. The operating room controls that will be addressed in this guideline include:

- use blunt suture needles when feasible,
- using round-tipped scalpel blades when feasible,
- use instruments to load and unload needles and scalpels,
- when appropriate, use electrocautery and lasers for cutting,
- *double gloving* with the use of a glove perforation indicator system,
- use of the neutral zone, hands free technique, and verbal communication when placing sharps in the neutral zone.

Evidence-based Research and Key Terms

The research and review of letters, randomized prospective studies and trials, nonrandomized trials, and articles that analyzed data was conducted through the use of the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of this guideline include: accessory safety device; active safety feature; bloodborne pathogens; blunt needles; double gloving; engineering controls; failure mode analysis; hands free technique; healthcare personnel; hollow-bore needle; needleless systems; needlestick injuries; neutral zone; nonhospital facilities; occupational exposure; other potentially infectious material; passive safety feature; patient care-related injury; percutaneous injury; potentially preventable; root cause analysis; scalpel blade injury; sentinel event; seroconversion; sharps injuries; sharps injury prevention program; sharps with engineered sharps injury protection; surgical glove perforation indicator system; system analysis strategies; work practice controls. Key terms used in the guideline are italicized and included in the glossary.

Guideline I

HDO's must have a written exposure control plan according to OSHA Bloodborne Pathogens Standard CFR 29 1910.1030 requirements that is administered through an injury prevention program. The following requirements are based on the OSHA standard and the CDC publication *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program*. The employer should refer to the OSHA standards and the workbook for additional details.

1. The location of the exposure control plan must be communicated to all employees and easily accessible.⁶³

2. If the exposure control plan includes the terms “sharps with engineered sharps injury protections” and “needleless systems” the mandated definitions for the terms must be used; see glossary for definitions.^{64,65}
3. The exposure control plan must be reviewed and updated annually at the minimum that includes documenting the employer considering and implementing new safety device technologies. When a new task/procedure is added or existing task/procedure is modified, and when a new safety engineered device is adopted for use the exposure control plan must reflect the implementation of these procedures and/or devices.⁶³⁻⁶⁵
 - A. When a new safety engineered device is considered for use the HDO should document the results of the trial period including but not limited to input from the surgical personnel who tested the device, and document the implementation of the device.⁶³
 - 1) Employers are required to ask for input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls, and must document the input in the exposure control plan.⁶³⁻⁶⁵
4. As part of the written exposure control plan, the employer should establish a culture of safety through the administration of a *sharps injury prevention program*. HDOs with a strong safety culture report fewer injuries.^{7,69} Two studies reported correlations between management’s commitment to establishing and supporting a safety culture, and employee compliance with safe work practices and standard precautions leading to a reduction in PIs.⁶⁹⁻⁷¹
 - A. The employer should apply *system analysis strategies* to improve prevention of sharps-related injuries.
 - 1) The employer should identify *sentinel events* and complete a *root cause analysis* to determine the underlying causes of PIs in which the core issue is addressed, and not just the symptoms of the problem.⁷
 - 2) The employer should apply *failure mode analysis* to identify how to prevent PIs from occurring.⁷ The U.S. Department of Veteran Affairs National Center for Patient Safety has detailed information about both root cause and failure mode analysis.
 - 3) The root cause analysis must include a complete list of job classifications that identifies all employees at risk for exposure to bloodborne pathogens.⁶³ The level of risk must be passed on the employee using/wearing no PPE.⁶³

- B. The HDO should complete the following organizational steps when establishing a sharps injury prevention program as outlined in the *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program* (2008).
- 1) Develop organizational capacity that includes establishing a multidisciplinary leadership team that includes representation from senior-level management.
 - 2) Assessing the program operation processes including: culture of safety; procedures for sharps injury reporting; methods for analysis and use of sharps injury data; process for identifying, selecting, and implementing sharps injury prevention devices; programs for the education and training of healthcare personnel sharps injury prevention.
 - 3) Develop a baseline profile of injury risks and how they occur to use for developing an intervention action plan that includes:
 - a) the occupational groups that most frequently sustain sharps injuries,
 - b) the location (e.g. department, work area) where sharps injuries most frequently occur,
 - c) the sharps devices that are most commonly involved in injuries,
 - d) the procedures (e.g., passing sharps to the surgeon) that most commonly contribute to sharps procedures,
 - e) the safety engineered sharps devices that has been implemented,
 - f) the communication tools that have been implemented to promote safe sharps handling techniques,
 - g) policy and procedure for identifying the best locations for sharps containers,
 - h) identifying who is responsible for removing and replacing sharps containers.
 - 4) Measure the economic impact of a sharps injury prevention program and the cost of sharps injury prevention. The *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program* (2008) and U.S. General Accounting Office letter (2000) to Pete Stark formerly of the U.S. House of Representatives, provide details and methods for calculating the costs.

- 5) Decide and prioritize which sharps injuries should be immediately addressed. The priorities should be based on the injuries that pose the greatest risk for bloodborne pathogen transmission, frequency of injury, and specific problem(s) that contribute to a high frequency of injuries.
 - 6) Develop and implement action plans that involve two steps: implementing and measuring interventions to decrease targeted specific types of injuries and measure the improvements that are a result of the action plan.
 - 7) Collection of data to analyze and monitor the overall progress of the injury prevention program, as well as identify areas needing improvement.
5. As part of the written exposure control plan, the HDO should have a written policy and procedure (P&P) that describes how and where HCP should undergo medical evaluation and treatment after exposure to blood or body fluids.⁷

A. The P&P should require HCP to immediately report a PI or other type of exposure such as a splash to mucous membranes.

- 1) Several studies have been completed regarding frequency of sharps injuries not reported by surgeons and surgical residents revealing majority of surgeons do not report needlestick injuries.⁷²⁻⁷⁵ Other surveys of HCP indicate that 50% or more do not report PIs to employee health service.⁷⁶⁻⁸³

A survey of surgical residents at 17 medical centers revealed that 99% had sustained a PI by the final year of residency and 51% were not reported to an employee health service.⁸⁴ Risk factors identified for nonreporting include: embarrassment to report the injury; history of a greater number of injuries associated with decreased likelihood of reporting the injury; PIs involving patients not considered to be at high risk most likely are not reported.⁸⁴ Other studies have reported that surgeons underestimate seroconversion rates with HBV, HCV, and HIV exposures, suggesting that training on the subject during residency might improve rates of reporting PIs.⁸⁵ Lack of time was the primary reason given for not reporting an injury.⁸⁴

The results of a questionnaire to 914 surgeons revealed that 70% never or rarely reported PIs and therefore, rarely participate in post-exposure treatment.⁸⁵

- 2) CSTs must overcome the risk factors listed above and always self-report a personal sharps-sustained injury to employee health service, occupational services or risk management. The CST should take the lead in demonstrating personal and professional ethics towards

self-reporting, no matter the attitudes and outlook of other surgical personnel towards sharps injuries.

- B. The P&P should describe the procedure for immediate provision of medical evaluation and treatment during all work hours, e.g., day, evening and night shifts (see Guideline II for details).
- C. The HDO must maintain a record of sharps injuries that assists in prevention planning and updating the exposure control plan. The incident reports must have sufficient information to determine the causes of the injury: error in design; failure of the device to properly perform; operator error (e.g., failure to use the safety feature), and/or manufacturers' defect.⁷ As of January 1, 2002, HDOs are required to use the OSHA Forms 300 *Log of Work-Related Injuries and Illnesses* and 301 *Injury and Illness Incident Report*. The following is a list of the information that minimally should be collected that also meets OSHA requirements.
 - 1) Identification number should be assigned to the exposure/injury incident/record,
 - a) The records of exposed employees and non-employees (e.g., students, volunteers) must be kept confidential.
 - 2) Date and time of injury,
 - 3) How the injury occurred,
 - 4) Department or work area where the incident occurred,
 - 5) Occupation of the employee,
 - 6) Type of device involved in the incident including if it is a conventional device or one with an engineered sharps injury protection,
 - 7) Brand of the device (OSHA requirement),
 - 8) Procedure for which the device was being used.⁷
- D. If the device is identified as being defective, the lot number, and detailed information about the device and defect are required to be reported to the U.S. Food and Drug (FDA) administration.¹⁴⁴
- E. As part of the written exposure control plan the HDO must have a process for the selection and evaluation of SESIP.^{63, 86} The selection process provides HDOs a systematic method for making an informed decision as to which devices best meet their needs. The key factor is the in-use device evaluation.⁷ Product evaluations are not the same as conducting a clinical trial. Clinical trials are governed by a rigorous, scientific process; whereas, product evaluation involves surgical personnel using the device during a surgical procedure to evaluate its performance informally and formally. The *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program* (2008) provides an eleven-step process for product evaluation as well as the *NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings* (1999); the following is an overview of the process.

- 1) A multidisciplinary product selection and evaluation committee should be formed that includes representatives from all key HDO departments to develop, implement, and evaluate plan to reduce sharps injuries and evaluate devices with safety features: risk management, senior-level administration, central sterile processing, environmental services, materials management, infection control, clinical staff including CSTs, surgeons and RNs. The committee can vary by the type of device being evaluated.⁸⁷
- 2) Priorities should be identified according to device(s) that will have the most effect in decreasing sharps injuries.^{86,87} The highest priorities should be based on how sharps injuries are occurring; patterns of device use in the HDO; the devices most frequently involved in sharps injuries; number of injuries; risk of bloodborne pathogen exposure and transmission; and procedures most often involved in injuries.^{86,87}
- 3) The committee should gather information on the conventional device that is being currently used including effectiveness, and types and frequencies of sharps injuries related to its use.⁷
- 4) The selection criteria for the safety engineered device should be established. Three terms that are important to the criteria are *active* and *passive safety feature*, and *accessory safety device*. Active safety feature requires the user to perform some type of action to activate the safety feature to isolate the sharp after use.^{7,88} A passive safety feature requires no action by the user; however, there are very few devices with passive safety feature on the market.^{7,88} An accessory safety device is an external part of the device that is attached either permanently or temporarily.⁸⁸ One multicenter study conducted in France concluded that passive devices caused less sharps injuries.⁸⁸ However, according to the CDC workbook publication, whether a safety feature is active or passive should not be priority criteria in the selection of a device.
The priority criteria include employee and patient safety, performance of the device, ease and efficiency of use, and user acceptance.^{7, 87}
- 5) The committee should next gather information on the safety device products that are available on the market. Information should be obtained from the manufacturer, research, and feedback from HDOs that are known to already be using the products.

- 6) The committee should request samples of the device to be evaluated from manufacturers/distributors.⁷ If there are multiple devices available on the market that are the same or similar, each manufacturer should be contacted to request samples to evaluate and compare.
 - 7) The committee should identify the HCP who use the device and will be responsible for completing the evaluation. The HCP should already be using the device currently purchased by the HDO. The HCP should be trained in the use of the device(s) that are to be evaluated.
The committee should develop a one-page, easy-to-complete and score product evaluation form for the HCP to use that includes a section for written comments, and the evaluations should be anonymous.^{86, 87} The committee should also establish the time period of the evaluation.
 - 8) At the end of the evaluation period, the committee should tabulate and analyze the results of the evaluations to determine which device to select and implement.^{7,87,89} The final decision should not be solely based on the cost of the product.⁸⁹ Other costs to take into consideration include the cost of educating and training HCP in the use of the device; potential cost savings related to reducing sharps injuries; cost of the conventional device versus the safety engineered device.⁸⁷
 - 9) Once the device has been implemented the committee should monitor its use to determine the device is being correctly used and if HCP need to complete additional training; gather informal feedback on the HCP's experience in using the device; and identify if the device is not safe to use, and is a danger to the HCP and patient.^{7,86}
6. CSTs should cooperate with surgery personnel in eliminating the psychosocial and organizational barriers as well as attitudes to encourage the adoption of a culture of safety, safety-related practices, and standard precautions.
- A. Factors to eliminate include:
 - Perceived poor safety environment and lack of administrative support,
 - Perception that precautions are not needed in some specific situations,
 - Increased job demands by the employer that cause work to be hurried, e.g., OR turnover,^{7,90,91}
 - Perceived conflict of interest between providing quality patient care and protecting oneself from exposure to bloodborne pathogens,

- Risk-taking personality profile – surgery personnel often place patient needs before personal safety. Surgical personnel are less likely to use a safety feature that is perceived to interfere with patient care.⁷
- B. One study that examined compliance with standard precautions among physicians reported a higher level of compliance if the physicians were more knowledgeable about standard precautions and completed training in the precautions; perceived protective measures as being effective; and believed the HDO administration is committed to a culture of safety.⁹²

Guideline II

CSTs must exhibit personal and professional ethics and responsibility in seeking evaluation and if necessary, treatment for a sharps-sustained injury.

1. Reporting an injury initiates the support services the CST will require including counseling, and medical evaluation and treatment.
 - A. The risks of delaying treatment are significant and has consequences related to remaining healthy, future employment, personal relationships and insurance coverage.⁵⁹
 - 1) Reporting the injury allows the CST to seek counseling to assist symptoms of anxiety and stress as well as preventing secondary transmission to patients and in his/her personal life.^{59,61}
 - 2) Reporting initiates medical evaluation, testing, and if needed, medical therapy. Recommendations by the CDC for exposure treatment vary with the type of bloodborne pathogens and patient status.⁹³ Antiretroviral therapy administered within 24 – 36 hours after exposure has been reported to have an 81% reduction in HIV infection.^{47,94} However, the recommendation is that antiretroviral therapy be initiated within 30 minutes after the sharps injury.⁸⁵

CSTs must receive the HBV vaccination. However, if not vaccinated, should complete the immunoglobulin and vaccination regimen. If vaccinated, the CST should have blood drawn for the laboratory to confirm the appropriate level of antibody is present, and be administered immunoglobulin.

There is no PEP available for HCV, but testing for seroconversion over a 12-month period can confirm HCV infection in early stages, and treatment is effective in preventing a chronic infection.^{59, 96}
 - 3) Legislation varies from state-to-state regarding reporting a sharps injury; however, failure to report an occupational exposure could lead to the denial of later claims.⁹⁷

2. The professional ethics of the CST is also related to responsibly contributing to controlling healthcare costs. If the CST does not report a sharps injury that may need treatment and eventually contracts a life-threatening viral infection, the costs of treatment have just escalated to include long-term treatment and continual testing, loss of work, and the healthcare system may have just lost another HCW in these days of worker shortages.^{98,99} The initial post-exposure costs vary and obviously depend on the involved virus; however, estimates are from \$500 to \$3,000 per injury.⁶ But this cost of initial treatment pales in comparison to the cost of long-term treatment. Equally important is if it is confirmed the patient is free from bloodborne pathogens and the CST can discontinue post-exposure treatment that contributes to cost savings.

Guideline III

SESIP devices should meet specific criteria that do not compromise patient care while protecting surgical personnel from injuries.⁸⁷

1. When evaluating SESIP devices the HDO should ensure the safety feature meets all or as many of the following specific criteria to provide protection to the surgical personnel as well as contribute to providing quality patient care. Although each of these characteristics is desirable, some may not be feasible, applicable, or available depending on the situation in which the device is being used. A safety feature that requires activation by the user may be preferred to one that is passive based on the evaluation results of the device. Each device must be evaluated and implemented based on its ability to prevent sharps injuries.¹³
 - A. Cost effective,
 - B. Reliable and automatic,
 - C. Be an integral part of the device,
 - D. Simple and obvious in operation,
 - E. The device is easy to use and practical,¹³
 - F. The safety feature is an integral part of the device,¹³
 - G. Have minimal increase in volume relative to disposal,
 - H. The user can easily tell that the safety feature is activated,
 - I. Ensure the user technique is similar to conventional devices,
 - J. Provide a rigid cover that allows the hands to remain behind the sharp end,
 - K. The safety feature cannot be deactivated and remains protective through disposal,¹³
 - L. Ensure the safety feature is in effect prior to disassembly and remains in effect when disposing,
 - M. Minimizes the risk of infection to patients and should not have additional infection control issues beyond those of a comparable conventional device.⁷
 - N. The device preferably works passively. If user activation is required, the safety feature can be engaged with a single-handed technique and allows the surgical personnel's hands to remain behind the exposed sharp.¹³

Guideline IV

Sterile team members should double glove for all surgical procedures including laparoscopic and robotic procedures in which trocars will be used. Double gloving should involve using a colored inner glove, referred to as a *surgical glove perforation indicator system*, to increase the accuracy of detecting glove perforation.

1. The American College of Surgeons (2016) recommends “the universal adoption of the double glove (or underglove) technique to reduce exposure to body fluids from glove tears and sharps injuries. In certain delicate operations, and in situations where it may compromise the safe conduct of the operation or safety of the patient, the surgeon may decide to forgo this safety measure.”⁴
2. Double gloving significantly reduces the risks of bloodborne pathogen exposure to the patient and sterile team.^{4,8,84,100,101}
 - A. The following data from research studies places the risk for surgical glove (herein referred to as “gloves” or “glove) perforation in perspective to emphasize the importance of double gloving.
 - 1) Glove perforation rates are as high as 61% for thoracic surgeons and 40% for surgical personnel in the first scrub role.¹⁰² Initial intraoperative glove perforation occurs an average of 40 minutes into a procedure and is not detected by the surgeon in up to as many as 83% of cases.¹⁰²⁻¹⁰⁴
 - B. Double gloving reduces the risk of exposure to bloodborne pathogens by as much as 87% when only the outer glove is punctured.¹⁰⁵⁻¹⁰⁷ Punctures of both the outer and inner glove are rare.⁸ If a solid suture needle perforates both gloves, the volume of blood is reduced by as much as 95%, thereby reducing the bloodborne pathogen load in the event a PI occurs.¹⁰⁸
 - 1) An early study concluded that the use of a colored inner glove (herein referred to as a “double gloving system”) provided an accuracy of detecting glove perforations up to 97%.¹⁰¹
 - 2) An open, randomized, prospective study analyzed 885 surgical procedures in which 2,462 gloves were tested. The total perforation rate was 192 out of the 2,462 gloves; the inner glove was punctured in 6 out of 88 times that an outer glove perforation occurred; and intraoperative detection was 28 out of 76 times with single gloving and 77 out of 89 times with a double gloving system.¹⁰⁰ Therefore, the conclusion of the study emphasized the importance of the surgical team to use a double gloving system.¹⁰⁰
 - 3) Two other studies reported double gloving reduces the risk of bloodborne pathogen exposure by a factor of 7 to 8.^{109,110}

- C. Multiple reports suggest that double gloving might protect the patient from exposure of bloodborne pathogens from the sterile surgical team.¹¹¹⁻¹¹⁵
- D. Upon recognition of a perforation, the surgical team member should immediately change the glove. Additionally, the surgical team should consider periodically changing gloves when performing a long surgical procedure. Microperforations can occur in surgical gloves that allow microbes to pass through from the surgical team member to the patient and vice versa.¹¹⁶
- E. Surgical team members particularly surgeons, have resisted double gloving because they report experiencing a decrease in dexterity and tactile sensation. Additionally, in certain types of surgery, such as neurosurgery, surgical team members may avoid double gloving where delicate manipulation of instruments and tissues is necessary.⁴
 - 1) The data from studies is indecisive, reporting both positive and negative outcomes to double gloving. One study of knot-tying ability comparing single- and double-gloved surgeons found no difference.¹¹⁷ A recent study reported that surgeons experienced decreased tactile sensation while a subjective study reported impairment of surgeons' comfort, sensitivity, and dexterity when double-gloved.¹¹⁸ Another clinical study reported that surgeons remove the outer glove before the end of the procedure in approximately 26% of cases.¹¹⁹ Lastly, in one study of members of two professional surgical societies, only 12% of surgeons reported double gloving.^{120,121}

However, surgeons who always or usually double glove reported it takes one to 120 days to fully adjust to double gloving.⁸⁵ Also, surgeons who consistently double glove report decreased tactile sensation less frequently than those who do not double glove.⁸⁵

Guideline V

A neutral zone, also referred to as hands-free technique (HFT), should be utilized during all surgical procedures to prevent two individuals from simultaneously handling a contaminated sharp, including but not limited to scalpel blades, suture needles, hypodermic needles, sharp surgical instruments and wires.

- 1. Utilization of the neutral zone decreases sharps injuries to the sterile surgical team and the possibility of surgical team member to patient transfer of bloodborne pathogens.^{4,10,120,122,123}
 - A. The two most comprehensive studies of the neutral zone confirmed its effectiveness; one study reported when HFT was used approximately 75% or more of the time it was protective by 59% or more in procedures with a blood loss of ≥ 100 ml and the second study confirmed by 35% in all procedures regardless of the amount of blood loss.^{122,124} For

operations with a blood loss of less than 100 ml randomized prospective studies have shown using the neutral zone makes no difference on the number of glove perforations.¹²⁴

- B. The American College of Surgeons' (2016) recommends "the use of HFT as an adjunctive safety measure to reduce sharps injuries during a surgical procedure except in situations where it may compromise the safe conduct of the operation, in which case a partial HFT may be used."⁴
2. Communication between the surgeon and CST is essential towards the safe use of the neutral zone. In large HDOs where surgical team members may not regularly work together, communication is fundamental to the surgeon and CST coordinating their actions that lends a level of improvement to those actions to prevent sharps injuries.
 - A. Before the skin incision is made the surgeon and CST should agree on the location of the neutral zone on the sterile field.¹²⁰
 - 1) There are operations, such as those requiring multiple incisions (e.g., triple arthrodesis of the ankle and obtaining bone from the iliac crest for bone grafting), where the surgeon and CST should openly communicate in determining if the previously agreed upon space for the neutral zone should be moved due to the changing parameters of a surgical procedure.
 - B. There are situations when neutral zone may need to be adjusted.¹²⁵ In this instance, communication is essential; the CST should verbally communicate to the surgeon that a sharp is being passed and upon passing the sharp indicate his/her hand is out of the way/withdrawn. The surgeon should return the sharp to the agreed-upon neutral zone.^{125, 126} Examples of these situations include:
 - surgeon is using a microscope or loupes. Often the OR lights are turned down when a microscope is in use and the work area of the sterile field is smaller, such as during ophthalmic procedures.¹²⁵ The use of a neutral zone that has been adapted to the surgical procedure may reduce the risk of PIs.¹²⁵
 - surgeon cannot reach the neutral zone due to patient positioning,
 - surgeon's discretion when he/she cannot avert his/her eyes from the surgical field to the neutral zone.^{4,126} An example is trauma procedures.
 - 1) If the surgeon does not use the neutral zone, he/she should use forceps to rotate the suture needle 90 degrees toward the box lock of the needle holder before placing the needle holder on the drapes or Mayo stand.^{122,127,128}
 - C. Each time a sharp is placed in the neutral zone the surgeon or CST should indicate this action verbally and completely withdraw his/her hand from the zone until the sharp is retrieved.^{7, 129} The surgeon or CST

should announce the sharp by name when placing it in the neutral zone or indicate in some manner such as “sharp” or “neutral zone”.

- 1) The sharps should be placed in the neutral zone using an emesis basin, instrument mat or magnetic pad.
 - 2) The CST must orient the sharp in a manner so the surgeon may pick it up without needing to reposition and his/her hand is positioned behind the sharp end or point.
 - 3) Only one sharp should occupy the neutral zone at any time.¹³⁰
3. Education and training in the use of the neutral zone is important to its acceptance for preventing sharps injuries. Studies have reported a reluctance on the part of the surgical sterile team in using the neutral zone and questioning its effectiveness.¹²² CSTs should be advocates for sharps safety by completing training in the proper use of the neutral zone and insist on its usage during procedures that involve sharps.
- A. In a multihospital study in which a HFT training video was presented and interactive training was completed by surgical personnel, the use of the neutral zone increased $\geq 75\%$ after the training.
 - 1) The combination of using a video and interactive training is supported by a Cochrane review reporting interactive training results in moderate to large improvements in the practice of HCP, and videos are recognized as an effective training tool for showing HCP how to do something correctly.^{11,17,131}

Guideline VI

When setting-up and managing the sterile back table and Mayo stand, the CST should follow safe sharps management principles to prevent injuries to the surgical team, self, and patient

1. The CST should set-up the sharps in a specific area of the back table and Mayo stand, and maintain that area for sharps throughout the procedure.
 - A. The CST should be vigilant of all the sharps, and properly manage and account for them during the entire procedure until they are disposed or transported to decontamination.
2. The sharps should be pointed away from self and the surgeon when arranged on the back table and Mayo stand, and after use placed in the same position.
3. The CST should use non-penetrating towel clamps to secure the four towels used to square off the incision and any other drapes.

4. The CST should position a sterile sharps container on the back table to form a centralized location for disposable sharps and the surgical team is aware of the location.
 - A. The sterile sharps container should be able to be tightly closed/sealed shut, puncture resistant, leak-proof, and securely hold sharps during the surgical procedure, e.g., magnetic pad, foam pad.
 - 1) The container should not be overfilled by the CST thus preventing being able to be properly closed.
 - B. The surgery department should annually review the type of sterile sharps container that is being used to confirm effectiveness.
 - 1) A review team consisting of CSTs, surgeon, RNs, surgery department administration, materials management, and risk management should be responsible for completing the review.
 - 2) The review should involve gathering comments from surgery personnel who most frequently use the container as well as conduct a formal survey and analyze the results.
 - 3) Samples of other containers should be obtained and compared to the currently used container. The comparison should include real-time use of the containers during procedures to allow the review team to gather comments and agree on the container that is most efficient and safe, including its size to ensure it fits into the non-sterile sharps disposal container at the end of procedures.
5. The CST should use a mechanical safety device to grasp hypodermic needles to load onto or remove from syringes; a needle holder to grasp and load and unload suture needles; and a single-handed blade remover if a safety scalpel is not used. The fingers must never be used for the placement or removal of hypodermic or suture needles, or scalpel blades.^{31, 132}
 - A. When initially loading the suture onto a needle holder, the fingers should not be used to position the suture needle in the needle holder; the CST should use the suture packet for positioning.⁶⁸
 - B. The CST should pass forceps with teeth to the surgeon's non-dominant hand when passing the needle holder; the surgeon should use the forceps or the needle holder to pull the needle through the tissue as well as use the forceps to re-position the needle in the needle holder.
 - 1) An exception is when a surgeon wants to re-use a strand of suture to control bleeding. The CST may need to grasp the needle using needle holders from the sterile suture container, position on the needle holder using forceps with teeth and pass to the surgeon using the neutral zone or pass directly to the surgeon, depending on the urgency of the bleeding.

6. If the procedure necessitates using a hypodermic needle and syringe multiple times on the same patient (e.g., local anesthetic), the needle should be recapped between uses utilizing a one-handed approach or mechanical safety device that enables one-handed recapping.⁷
 - A. The CST should use the “scoop” method by laying the needle cap toward the back of the Mayo stand, slide the needle inside the cap, and leave loose, e.g., not locking or clicking into place.⁶
 - 1) The concept of not recapping needles has been driven by patient care situations that exist outside the OR, e.g., nursing care units and clinics, when a needle is not used more than once. However, in the OR when a syringe with hypodermic needle has the potential for multiple uses on the same patient, leaving the needle uncapped presents a greater threat of possible needlestick, and therefore, is dangerous to leave unprotected on the Mayo stand or back table.
7. The CST should only open and load suture needles onto the needle holder immediately prior to use to avoid open needles on the Mayo stand or back table. However, there are instances when this may not be feasible including:
 - Trauma procedures that require the CST to load suture needles onto needle holders when setting up the Mayo stand and back table to be able to quickly pass to the surgeon. The CST can open suture packets, leaving the needle tips protected within the packet while still loading the needle onto the needle holder.
 - Suture packets that have multiple suture strands each with a single needle or double-armed suture that the CST must open and count during set-up of the Mayo stand and back table.
 - 1) When feasible, the suture needle should be removed from the end of the suture strand prior to the surgeon tying the suture (e.g., CST cuts the needle off or control release suture is used).
8. The CST should avoid manual retraction of tissue which places the fingers and hands at risk when a sharp is being used, when an instrument, such as a retractor, can be used.¹²⁹
9. The CST must be particularly careful when handling burrs, K-wires, Steinmann pins, reamers (femoral), and saw blades. The CST should hand power instruments with the sharp pointing away from him/her and in the locked position to prevent inadvertent activation. When finished using the power instrument, it should be placed onto the Mayo stand or overhead table in a locked position to avoid hand-to-hand transfer.

After placement in the patient, the exposed ends of K-wires and pins should be covered with a sterile plastic sheath.⁵²
10. During endoscopic procedures if a sharp, such as scissors, are too long for the neutral zone, the instrument should be handed to the surgeon handle first with the tip pointing downward.¹²⁹

11. If a CST (herein referred to as “original CST”) is being relieved by another CST (herein referred to as “relief CST”), prior to breaking scrub (removing the sterile gown and gloves), the original CST must complete a count of the instruments, sharps, and sponges with the relief CST that includes verifying the location of the sharps and the area designated as the neutral zone on the sterile field.
12. Prior to placing a surgical wound drain with sharp trocar in the neutral zone for the surgeon, the CST should remove the plastic tip guard with a grasping instrument; the fingers should not be used. After the surgeon pulls the drain trocar through a surgical exit wound and cuts the trocar, he/she should place it in the neutral zone to be retrieved by the CST. The CST should secure it by placement in proper sharps receptacle.
13. When the surgeon has completed the skin closure and the dressing applied, the CST should complete a brief visual inspection of the sterile field for the presence of sharps before the sterile drapes are removed and disposed to ensure no injuries occur to surgical team members or environmental services employees.
14. If a scalpel blade or suture needle falls onto the sterile field, the CST should pick up scalpel blades with forceps or instrument, and suture needles with a needle holder. The same applies to the circulator picking up sharps that have fallen on the floor.
15. Mark Davis, MD (2001) notes the following safety strategy for the prevention of sharps injuries during the surgical procedure that sterile team members should follow: “When sharps are in use on the field, there is rarely a need for excessive speed. The most technically proficient surgeons finish procedures faster than less experienced surgeons not by the use of rapid hand motions, but by avoiding unnecessary and repetitive movements.”¹³⁰

Guideline VII

Surgical personnel should use SESIP during surgical procedures whenever clinically appropriate.⁶³

1. Blunt-tip suture needles should be used for suturing fascia and muscle to reduce suture needle injuries. Sharp-tip suture needles are the leading source of PIs to surgical personnel, causing 51% - 77% of injuries.¹¹ Many sharp-tip suture needle injuries occur when closing the muscle and fascia, often when the fingers are used to manipulate needles and tissue.¹¹
 - A. The ACS recommends “the universal adoption of blunt-tip suture needles for the closure of fascia and muscle in order to reduce needlestick injuries in surgeons and OR personnel.”⁴ The FDA, OSHA and NIOSH strongly encourage HCP to use blunt-tip suture needles as an alternative to sharp-tip suture needles when suturing fascia and muscle to reduce the risk of needlestick injuries.^{133,134} Additionally, OSHA has identified blunt-tip needles as a type of engineering control that reduces PIs.¹³³ Lastly, the U.S. Department of Health and Human Services’ *Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis* (2014) recommends the use of blunt-tip suture needles, when clinically appropriate, to reduce needlestick injuries in HCP.¹³⁵

- B. The results of multiple studies have shown that the use of blunt needles contribute to reducing glove perforations and PIs.
- 1) Published studies show that using blunt-tip suture needles reduces the risk of needlestick injuries by up to 69%.¹³⁶
(Parantainen)
 - 2) Higher than normal PI rates have been reported for gynecologic surgical procedures.¹¹ The CDC conducted a study in three New York City teaching hospitals to evaluate use of blunt-tip suture needles. 87 PIs occurred during 84 of the 1,464 procedures that were observed, and of those PIs there were 61 sharp suture needle injuries, but none with blunt-tipped suture needles.¹³⁷ The study also concluded that blunt-tip suture needles resulted in no clinical adverse effects on patient care.¹³⁷
 - 3) Four prospective randomized trials reported that the use of blunt-tip suture needles significantly reduced and, in some instances eliminated needle injuries to surgical personnel.¹³⁸⁻¹⁴¹ Two case studies reported that blunt-tip suture needles eliminated injuries, and were technically easy to use, producing satisfactory results in colon anastomosis and abdominal wound closure, and hernia repair.^{142,143}
 - 4) A 2007 report suggests that the difference in costs of blunt- versus sharp-tip suture needles is made up for by the economic savings associated with having to treat fewer needlestick injuries.¹⁴⁴
2. Safety engineered scalpels should be used by surgical personnel. Safety scalpels are disposable scalpels with a safety mechanism that is usually a retractable plastic guard sheath that covers the scalpel blade. The safety feature must be activated for each use in order to be effective for reducing sharps injuries.¹⁴⁵ However, it is recommended that the CST be responsible for unsheathing the scalpel blade, place the scalpel in the neutral zone, and when retrieved from the neutral zone after use by the surgeon, reactivate the protective sheath.^{130,146} Surgeons have voiced the issue that it can be difficult and dangerous to try to activate and deactivate the scalpel safety feature when their gloved hands are slippery from blood and body fluids.¹³⁰ Surgeons who are reluctant to use safety scalpels have expressed the following most common reasons: weight and feel is different from non-disposable scalpels; safety device obstructs the view of the surgeon.¹⁴⁶⁻¹⁴⁸
- If a safety scalpel is not used the second recommendation is to use a single-handed blade remover and neutral zone that has been shown to prevent at least as many injuries as safety scalpels.¹⁴⁹⁻¹⁵² A removal device is designed to protect the CST and other members of the sterile team from accidental injury when removing a scalpel blade from a reusable handle.¹⁵³ One study found that using a single-handed blade remover with neutral zone was up to five times safer than a safety scalpel.¹⁵⁰

Scalpel blade injuries can also be prevented by using alternative cutting methods when clinically appropriate such as blunt-tip scissors, blunt electrocautery tips, and lasers.⁸⁰ Two other options include using round-tip scalpel blades and if clinically feasible, performing endoscopic or laser surgery instead of open surgery.^{80,126}

A. The efficacy of safety scalpels has not been studied in-depth as compared to other safety devices and practices.^{151,152,154}

1) The ACS provides the following information regarding SESIPs:

Engineered sharps injury prevention (ESIP) mechanical devices may provide varying degrees of mechanical protection from sharps injuries involving suture needles and scalpel blades. Manufacturers of ESIP devices approved by the U.S. Food and Drug Administration have been permitted to claim prevention of sharps injury as a feature of their use. No study published to date demonstrates the clinical effectiveness of ESIP devices. The design and quality of these devices has been variable and their acceptance among surgeons limited. Nevertheless, these devices may contribute to minimizing sharps injuries in the OR. Therefore, the ACS recommends: The use of ESIP devices as an adjunctive safety measure to reduce sharps injuries during surgery except in situations where it may compromise the safe conduct of the operation or safety of the patient.⁴

2) Two reports site lack of available evidence-based research that provide support for using safety scalpels.^{151,152,154} EPINet® data is unreliable since it doesn't differentiate between injuries caused by non-disposable scalpels versus reusable scalpels.

B. OSHA regulations must be followed if the surgeon opts not to use a safety scalpel.

1) OSHA requires the HDO document an exemption stating that surgeons are not able to use the safety product for patient safety reasons, and the documentation must include specific reasons why the surgeons will not use the safety product.¹⁵⁵

2) The following is stated in an OSHA interpretive letter posted on their web site: "in some surgical procedures, the 'feel' of a device in the hands of the surgeon may be crucial to properly execute a surgical technique. OSHA recognizes there might be unique circumstances where the safety of the patient or the integrity of the procedure might be best served with the use of a device that is not a safety device...In those circumstances it is important that

good work practice controls, such as the prevention of hand-to-hand instrument passing in the operating room be implemented to provide protection to employees who are at risk of getting injured by an unprotected device.”¹⁵⁶

- 3) Another OSHA interpretive letter states that in situations where an employer has proven that the use of a scalpel blade with a reusable scalpel handle is required, the blade removal must be completed by using a single-handed blade remover.¹⁵⁷
- C. The surgery department should have a product evaluation committee that is responsible for evaluating currently used safety scalpel or the adoption of a safety scalpel.
- 1) The committee members should include CSTs, surgeons, RNs, surgery department administration, risk management, infection control, and materials management/purchasing.
 - 2) In order to make a decision if the currently used safety scalpel should be replaced with another model/type of safety scalpel, the committee should solicit feedback from surgical personnel regarding the efficacy of the currently used safety scalpel; gather data on the number of sharps injuries related to the use of the currently used safety scalpel; obtain samples of other types of safety scalpels from manufacturers to compare to the currently used safety scalpels. Additionally, the new safety scalpels should be used in the operating room and feedback obtained from the surgical personnel. The same steps should be taken if adopting the use of a safety scalpel for the first time.
3. Safety engineered needleless system should be used to protect against PIs and bloodborne pathogen exposure.⁶³ In a review of 11 studies, the authors reported the use of surgical assist devices and needleless IV systems significantly reduced glove perforations.¹⁵⁸ Another study conducted at a large Australian university hospital reported a 57% decrease in PIs after introducing the use of retractable syringes and no PIs due to needlesticks when accessing IV lines.¹⁵⁹
- Needleless systems should be used when:
- administering medications,
 - collecting or withdrawing body fluids after the IV is established,
 - performing other procedures that involve needles and the potential exposure to bloodborne pathogens.⁶³

Guideline VIII

When clinically feasible, the use of sharps during surgery should be reduced or eliminated using non-sharp alternatives, or using alternative cutting methods to decrease the risk of intraoperative sharps injuries.¹⁶³

1. Sharpless surgical techniques include the following:
 - Skin incision performed with electrocautery set in the cutting current. Studies comparing midline abdominal wound healing of incisions with electrocautery versus scalpels reported no difference in short- or long-term healing.^{160,161}
 - An alternative to the use of scalpels blades is electrosurgical plasma induced with pulsed radio-frequency energy delivered by a hand piece to incise tissue.¹⁶²
 - Incisions of the deep layers of the skin and other tissue layers can be accomplished with electrocautery.¹⁶³
 - When clinically feasible, specialty staplers (GIA stapler, intraluminal circular stapler, linear cutters) for resection and anastomosis of organs should be used.
 - Skin closure can be accomplished using alternative methods that minimize the exposure to sharp-tip suture needles, including adhesive strips, shielded suturing devices, staples, and skin adhesives.^{50,163-165}
2. Makary et al, demonstrated that sharpless surgery can be accomplished. The results of a one-year study of 358 general surgery procedures reported 25.4% of all the operations were completed without the use of sharps.¹⁶³

Guideline IX

A non-sterile disposable sharps container must be used for the disposal of all sharps to decrease the risk of injury to HCP and patients. Non-sterile disposable sharps containers are an important safety engineering control as part of the sharps injury prevention program.

1. The decision on the type/style of non-sterile disposable sharps container (herein referred to as “container”) to be used should be based on four criteria: functionality, accessibility, visibility, and accommodation.⁸⁶
 - A. OSHA requires containers to be closable, puncture-resistant, leak-proof on all sides and bottom, accessible, ability to be maintained in an upright position, and labeled with the biohazard symbol.⁶³ The container should require nominal training to use, and is easy to assembly and store.¹⁶⁶
 - B. NIOSH recommends the selection should be based upon the following factors:
 - Assessment of size and types of sharps,
 - Assessment of the volume of sharps to be disposed,
 - Assessment of frequency of replacement of containers,
 - Compliance with local, state and Federal regulations,
 - Environmental and disposal laws,
 - Cost considerations,

- Continued evaluation of efficacy of current container in use and new products.⁸⁶
- C. The surgery department should have a product evaluation committee that is responsible for evaluating currently used containers and new container products.¹⁶⁶
- 1) The committee members should include CSTs, surgeons, RNs, surgery department administration, risk management, infection control, and materials management/purchasing.
 - 2) In order to make a decision if the currently used containers should be replaced with another model/type of container, the committee should solicit feedback from surgical personnel regarding the efficacy of the currently used container(s); gather data on the number of sharps injuries related to the use of the currently used container(s); obtain samples of other types of containers from manufacturers to compare to the currently used containers. Additionally, the new containers should be used in the operating room and feedback obtained from the surgical personnel.
2. The opening and size of the container should be large enough to accommodate the intended sharps devices and sterile sharps container.
 - A. The opening should allow for sharps to easily fall into the container unobstructed without catching or snagging, and not have to be forced during insertion.¹⁶⁶
 3. The container should not be overfilled.
 - A. The container be replaced and properly disposed when three-fourths full.¹⁴⁵ The fill status of the container should be easily seen by the surgical team member prior to placing sharps into the container. Sufficient lighting is necessary to determine if any sharp object is protruding from the opening of the container.
 4. The container should be positioned no higher than 56 inches to facilitate the ability of surgical team members to see the opening to dispose sharps.¹⁶⁶ The container should be placed with no obstacles in the way that could force the surgical team member to struggle getting to the container while holding sharps. Examples of inappropriate placement of the container include corners of the OR, back of the OR door, inside OR cabinets, near light switches or environmental controls.¹⁶⁶
 5. Surgical team members must never reach into a container with fingers or instruments. Once disposed, sharps must not be retrieved from the container.⁵
 6. The closure mechanism should be designed to minimize exposure to contents and injury to the hand when sealing shut the container. Once closed, the lid should be resistant to manual re-opening.¹⁶⁶
 7. To establish consistency, it is recommended that an environmental service worker is designated and responsible for replacing full containers in the surgery department.

Guideline X**Reusable sharps should be transported to decontamination in a puncture resistant closed container.**

1. Keeping reusable sharps (e.g., retractors, sharp-tipped scissors, trocars) separate from other instruments will reduce the possibility of sharps accidents.
2. The non-perforating closed container should not be overfilled beyond manufacturer's recommendations.
3. The container should be marked or labeled as containing reusable sharps; recommended wording for the label is "reusable sharps – biohazardous."

Guideline XI**CSTs should complete continuing education and training to remain current in their knowledge of safe sharps practices in the OR.**

1. Surgery department annual employee continuing education and training on bloodborne pathogens and sharps safety is essential to the success of a sharps injury prevention program.^{7,167}
 - A. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and, the learner is actively involved in the learning process.⁷ However, much of the education and training is traditional, and provided for the sole purpose of meeting federal and state regulatory requirements. Therefore, there is a lack of motivation on the part of the learner and in the end, the regulatory requirements may have been met, but learning did not occur.
 - B. It is recommended surgery departments use various methods of education and training to facilitate the learning process of CSTs.
 - 1) If the training is primarily lecture, methods to engage learners include presentation of case studies of exposure and have the audience discuss solutions; audience discussion providing suggestions for improving the sharps injury prevention program; and audience discussing sharp devices currently in use and if they need replacing.
 - 2) Other proven educational methods include interactive training videos and computerized training modules, and teleconferences.
 - 3) The training should include surgical team members practicing using the various types of safety devices to gain experience prior to using during a surgical procedure. The employer should provide the education and training in multiple languages if necessary.⁶³

2. Surgery department is required to keep education and training records for three years that include dates of training; names and job titles of employees that completed the training; synopsis of each training session provided; names, credentials and experience of instructors/trainers.⁶³

Competency Statements

Competency Statements	Measurable Criteria
<ol style="list-style-type: none"> 1. CSTs are knowledgeable of the content of a sharps injury prevention program, and how the policies and procedures are applied in the operating room. 2. CSTs are qualified to practice patient care concepts related to sharps safety including use of the neutral zone, blunt needles, double gloving, and control of sharps at the sterile field. 3. As individuals who are directly involved in the care of surgical patients, CSTs are knowledgeable professionals that can participate in evaluating surgery department policies and procedures for sharps safety, evaluating sharps safety products, and contributing to the efforts of implementing sharps safety protocols. 	<ol style="list-style-type: none"> 1. Educational standards as established by the <i>Core Curriculum for Surgical Technology</i>.⁹⁹ 2. The didactic subject of sharps safety and use of the neutral zone is included in a CAAHEP accredited surgical technology program. 3. Students demonstrate knowledge of sharps safety including use of the neutral zone, blunt needles, double gloving, and control of sharps at the sterile field in the lab/mock OR and during clinical rotation. 4. As practitioner's CST's practice sharps safety techniques including use of the neutral zone, blunt needles, double gloving, and control of sharps at the sterile field during surgical procedures. 5. CSTs complete continuing education to remain current in the knowledge of sharps safety; revisions by the CDC, NIOSH, and OSHA addressing sharps requirements; and surgical department policies and procedures.¹⁶⁷

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Glossary

Accessory safety device: The FDA defines accessory devices as one that is intended to be used with one or more parent/original device that supports, supplements, and/or augments the performance of the parent device.

Active safety feature: Safety feature required to be activated by the user.

Bloodborne pathogens: As defined by OSHA, pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, HBV, HCV and HIV.

Blunt needles: Surgical suture needles that have a slightly rounded end as opposed to sharp-tip suture needles.

Double gloving: Donning two sterile surgical gloves, inner and outer, for additional protection against PIs.

Engineering controls: Defined by OSHA as controls that isolate or remove the bloodborne pathogen hazard from the workplace. The definition was expanded by OSHA in 2001 to specifically state “sharps with engineered sharps injury protections and needleless systems.”^{63, 64}

Failure mode analysis: Identifying the steps to complete a task, and also identifying at which points an error or system breakdown could occur in order to establish prevention measures.⁷

Hands free technique (HFT): See ‘neutral zone’; another term for neutral zone.

Healthcare personnel (HCP): Plural form; all persons whose activities involve contact with blood or body fluids of patients in a healthcare, laboratory, or public setting.¹³

Healthcare worker (HCW): Singular form.

Hollow-bore needle: Needles whose length of the diameter is open (non-solid) including blood-collection needles, hypodermic needles, and IV catheter stylets.

Needlestick injuries: A type of percutaneous injury in which the skin is penetrated by a type of needle, most commonly a hypodermic needle or suture needle that was in contact with blood, tissue, or other body fluid.

Needleless systems: A device that does not use needles for: (A) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (B) the administration of medication or fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to PI from contaminated sharps.⁶⁴

Neutral zone: Designated location on the sterile field for the placement and retrieval of sharps to prevent person-to-person transfer of sharps.

Non-hospital facilities: Includes nursing homes, physician and dental offices, medical and dental laboratories, home health care, outpatient facilities, funeral homes, school clinics, and correctional facility clinics.

Occupational exposure: Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious material that may result from the performance of an employee's duties.

Other potentially infectious material (OPIM): Human body fluids other than blood that includes amniotic fluid, cerebrospinal fluid, pericardial fluid, peritoneal fluid, pleural fluid, saliva, semen, synovial fluid, vaginal secretions, or any body fluid that is visibly contaminated with blood.

Passive safety feature: Safety feature that does not have to be activated by the user.

Percutaneous injury: Penetration of the skin by a sharp object that was in contact with blood, tissue, or other body fluid.¹³

Patient care-related injury: PI that is out of the control of the HCW such as an unanticipated movement by the patient when attempting to insert or remove a needle.

Potentially preventable injury: PI due to the mistake of a HCW including unnecessarily using a sharp device, safety feature of a device is not used or used improperly, sharp was improperly disposed, or conventional sharp device was used when a safety engineered device was available.

Root cause analysis: Root-cause analysis is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance.¹⁶⁸

Scalpel or surgical knife blade injury: Type of sharp injury caused by a scalpel blade. Scalpel blade injuries tend to be more invasive and dangerous due to the sharpness of the single blade exposing the injured surgical team member and patient to an increased risk for acquiring a bloodborne pathogen.

Sentinel event: Defined by The Joint Commission as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness.¹⁶⁸

Seroconversion: Time period during which a specific antibody develops and is detectable in the blood; the change of a serologic test from negative to positive indicates the development of antibodies in response to an infection.

Sharps injury: An incident caused by a needle, scalpel blade, or sharp surgical instrument that penetrates the skin.

Sharps injury prevention program: Administrative program that addresses all aspects of sharps safety and the prevention of PIs.

Sharps with engineered sharps injury protection (SESIP): A non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.⁶⁴

Surgical glove perforation indicator system: Used when double gloving, it involves the members of the sterile team donning colored inner gloves that assist in detecting perforations of the outer gloves.

System analysis strategies: The study of a procedure or task to determine the most efficient method of executing to obtain the desired results.

Work practice controls: Safety procedures that assist in reducing sharps injuries and expose to bloodborne pathogens.

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