

Insulin Self-Administration Instruction: Use of Engineered Sharps Injury Protection Devices to Meet OSHA Regulations

This is an official position statement of the American Association of Diabetes Educators (AADE). AADE is dedicated to advancing the role of the diabetes educator and improving the quality of diabetes education and care.

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Recent federal legislation and regulations will affect the healthcare delivery practices of many diabetes educators who care for or instruct patients with diabetes who require insulin. These regulations apply whether the healthcare employee is in a major medical institution or a private medical office.

This position statement, created through the joint efforts of the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA), will (1) provide background rationale for the evolution of the OSHA bloodborne pathogens standards, (2) delineate the potential impact of these regulations on patient care and education practices, and (3) provide guidance to diabetes care providers and provider institutions to facilitate compliance with the OSHA standards and assure safe and appropriate patient care practices.

BACKGROUND

The Occupational Safety and Health Administration (OSHA) published the Occupational Exposure to Bloodborne Pathogens Standard in 1991 because of the significant health risk associated with exposure to viruses and other microorganisms that cause bloodborne diseases.¹ Of primary concern are the human immunodeficiency virus (HIV) and hepatitis B and C viruses.^{2,3}

In November 2000, the United States Congress passed legislation that directed the Occupational Health and Safety Administration within the Department of Labor to revise the Bloodborne Pathogens Standard. This legislation, known as

the Needlestick Safety and Prevention Act, requires employers to identify and utilize more effective and safer medical devices. This act was published in the Federal Register (January 18, 2001) and became effective April 18, 2001.⁴ States and territories that operate individual OSHA-approved state programs were required to adopt the revisions to the federal bloodborne pathogens standard or adopt a more stringent amendment to their existing standards by October 18, 2001.

The needlestick act applies in all circumstances and workplaces where employees have a reasonable, anticipated risk for exposure to blood and other potentially infectious materials (OPIM), regardless of the number of employees. This act does not impose new requirements for employers to protect employees from sharps injuries; rather it amplifies the requirement to evaluate, select, and implement appropriate engineering controls to minimize risk of employee exposure to blood and OPIM.

The Centers for Disease Control and Prevention (CDC) estimate that healthcare workers suffer between 600 000 and 1 million injuries from conventional needles and sharps annually. At least 1000 healthcare workers are estimated to contract serious infections annually from needlestick and sharps injuries, and the cost of follow-up for a high-risk exposure is almost \$3000 per injury even when no infection occurs.⁵

The original 1991 OSHA standard requires employers to adopt engineering and work practice controls to reduce health worker

exposure to bloodborne pathogens. Many different medical devices have been developed to reduce the risk of needlesticks and other sharps injuries since this OSHA standard was passed. These safer devices incorporate features designed to reduce injury. However, despite these advances in technology since the promulgation of the original Occupational Exposure to Bloodborne Pathogens Standard in 1991, needlesticks and other sharps injuries continue to be of concern due to the frequency of occurrence and the severity of the associated health effects. Thus, Congress passed the Needlestick Safety and Prevention Act of 2000, which clarified employer requirements to use engineering controls and added new requirements.

These new requirements include (1) an annual review of institutional exposure control plans, with incorporation of equipment or technology changes that will further reduce exposure risk, and documentation of employer's ongoing evaluation and selection of appropriate commercially available and effective safety devices; (2) solicitation of input from nonmanagerial employees responsible for direct patient care regarding the identification, evaluation, and selection of effective engineering controls to include safer medical devices; and (3) maintenance of a sharps injury log that includes the type/brand of the device involved, and location and description of the incident. Of note, employers with 10 or fewer employees are exempt from OSHA record-keeping requirements and from maintenance of a sharps injury log.

In addition, the Needlestick Safety and Prevention Act modified the following definitions relating to engineered controls:

- *Sharps with engineered sharps injury protection*—includes nonneedle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury
- *Needleless systems*—includes devices that provide an alternative to needles for various procedures to reduce the risk of injury from contaminated sharps
- *Engineering controls*—includes controls (eg, safer medical devices such as sharps with engineered sharps injury protection) that isolate or remove a bloodborne pathogen hazard from the workplace

IMPACT OF OSHA REGULATIONS ON DIABETES CARE AND EDUCATION PRACTICES

Protection of all healthcare workers from the risk of exposure to bloodborne pathogens is necessary. Concurrently, the impact of these OSHA standards on the health and safety of patients must also be considered.

Initial discussions between diabetes educators and California OSHA representatives, and subsequent discussions with federal OSHA representatives have been instrumental in the clarification of the OSHA standards and critical to understanding the potential impact of these standards on the care and education practices of persons with diabetes.

Use of some currently available insulin syringes with engineered sharps injury protection

(ESIP) may present barriers to effective insulin self-administration training, thereby potentially compromising patient safety. Circumstances such as these must be evaluated and subsequent appropriate devices chosen. This evaluation and selection must be documented in the facility's exposure control plan. The following are some examples in which engineering controls may not be appropriate because they may compromise patient safety:

- Use of a device for training that is different from the device to be used in practice is inconsistent with essential teaching/learning principles and may compromise the success of the training process. This may be especially true for older adults who represent the majority of the diabetes population.
- Patients who have limited learning capabilities or who are experiencing high levels of distraction and/or stress related to the initiation of insulin therapy may experience greater difficulty translating instructions received using a syringe, such as an ESIP syringe, that is different from the syringe that will be used in the home setting.
- Patients with reduced vision often need the assistance of syringe-adapted magnifiers to assure dosage accuracy. These magnifiers are not currently available for insulin syringes with engineered sharps injury protection.
- Patients with limited manual dexterity may experience difficulty maneuvering the engineered sharps injury protection device, thereby potentially increasing risk for the delivery of inaccurate doses of insulin.
- Patients experiencing anxiety related to self-injection often benefit from the use of injection assistance devices.

- These devices are not currently adaptable for use with engineered sharps injury protection insulin syringes.

It should be noted that patients with diabetes are neither required nor expected to use engineered sharps injury protection devices for self-administration of insulin.

RECOMMENDATIONS

The American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA) endorse workplace practices that protect the health and safety of diabetes healthcare workers and persons with diabetes. The following recommendations facilitate healthcare provider compliance with the OSHA standards while addressing the implications of the standards on the process of insulin self-administration education for persons with diabetes:

1. Any injection administered to the patient by the healthcare worker, or for which the healthcare worker provides assistance, will be delivered utilizing engineered sharps injury protection (ESIP) insulin syringes. This applies to any workplace setting, including private medical offices.
2. Individualized patient assessment will guide the licensed healthcare employee's decision regarding use of an ESIP insulin syringe during insulin self-administration instruction. If use of an ESIP device will jeopardize the patient's safety or the success of the insulin self-administration education process, use of an ESIP device is not required for that instance. Guidelines and rationale for use of non-ESIP devices during insulin self-administration education must be documented in the

employer's or healthcare entity's exposure control plan, and devices that become newly available must be evaluated on an annual basis. If a device is not currently available, it may become available at a later date as technology and science advance.

3. The physical environment where insulin self-administration education occurs should allow for reasonable physical distance between the patient and healthcare worker to reduce the incidence of inadvertent needlesticks and the potential for exposure to bloodborne pathogens.

4. A sharps disposal container should be readily available for the disposal of all sharps equipment by the patient immediately after use. The healthcare worker should not transport used syringes and/or sharps.

5. The patient and/or significant other should receive instruction regarding appropriate disposal of all sharps in the home setting.

6. The process of educating patients and/or significant others regarding insulin preparation and self-administration must address individual patient needs without compromising healthcare worker safety. Accuracy in the preparation and delivery of insulin is crucial to minimize the risk of acute symptoms (hypoglycemia and hyperglycemia), maximize the achievement of optimal glucose control, and, ultimately, reduce the risk of long-term complications associated with diabetes.

7. All healthcare entities must have a written exposure control plan, regardless of the number of employees. The plan should include guidelines for

- Specific steps or procedures used in education of the patient/significant other in

insulin self-administration where an employee may have exposure to blood or OPIM.

- Selection and evaluation of sharps safety devices. The employer must solicit input from nonmanagerial healthcare workers responsible for patient care regarding the identification, evaluation, and selection of effective engineering controls, including safer medical devices. Documentation must be provided that includes the devices identified as candidates for use, the method(s) used to evaluate the devices, and justification for the eventual selection. Employers must select devices that will protect healthcare worker safety without compromising patient safety or the medical procedure.
- Documentation of sharps injuries. All employers with 11 or more employees who are required to keep records by current record-keeping standards must maintain a written record of sharps injuries. The written records must insure employee privacy and include the type/brand of the device involved in the injury, and location and description of the incident. The purpose of the sharps injury log is to identify devices that may need to be replaced with safer options.

SUMMARY

Diabetes educators play a vital role in ensuring the safe and effective integration of diabetes treatment strategies into daily life for persons with diabetes. However, efforts to effectively educate and assist patients must be balanced with personal safety. As healthcare workers,

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diabetes educators must be aware of the OSHA standards, understand the implications of these standards on daily care practices, and work in concert with their employer institutions to assure compliance with the OSHA standards while assuring optimal patient care.

EDUCATIONAL RESOURCE MATERIALS

- Further information regarding the OSHA standards can be obtained from the OSHA Web site at <http://www.osha-slc.gov/needlesticks/needlefact.html>.
- Information regarding OSHA's Outreach and Education Effort 2001 can be obtained at <http://www.osha-slc.gov/needlesticks/needlesticks>.
- Additional information regarding safety devices can be obtained from the following Web sites: www.med.virginia.edu/~epinet or www.tdict.org.

DEVELOPMENT OF THIS DOCUMENT

This position statement was developed by a multidisciplinary task force of the American Association of Diabetes Educators. The following members were selected for their expertise, professional discipline, and geographical location to ensure a broad representation of perspectives and practices.

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