Reporting Regulation (29 CFR Part 1904), established in 1971. Under the original reporting regulation, employers were required to collect and maintain injury and illness data and to have them available for OSHA to examine. It was determined that OSHA needed a separate provision for collection of data by mail. As such, this final rule requires employers, upon request, to report to OSHA their illness and injury data, in addition to the number of workers and the number of days worked in a designated period.

The new rule establishes a procedural mechanism for OSHA to conduct an annual survey of 10 or more employers by mail or other remote transmittal. The specific request may come directly from OSHA or its designee (eg, The National Institute of Occupational Safety and Health). The data will be used for injury and illness surveillance, to evaluate OSHA standards, and to evaluate the effectiveness of enforcement training. In addition, they will be used to direct OSHA's programs for scheduled inspections.

Concerns were expressed throughout the rule-making process that reporting this information was burdensome and duplicative and that the data could be obtained from other sources, such as the workers' compensation files. OSHA argued that this new system would provide more reliable data better suited to OSHA's needs than any available alternative. Considering that OSHA cannot directly visit the over 5 million worksites, this provides information to target their activities, including workplace inspections. OSHA reported that 80,000 workplaces were inspected in 1996.

Employers will have 30 days to submit their data after the request is received. Employers will be notified in an upcoming *Federal Register* notice of the type of information that needs to be collected. Much of the injury and illness information to be reported will be taken from records that employers already are required to create, maintain, and post. The employment figures to be collected are critical to OSHA's ability to evaluate the injury and illness data. This regulation was scheduled to become effective on March 13, 1997.

Occupational health and safety experts have said that this rule will benefit those employers with good health and safety programs.

FROM: Department of Labor, Occupational Safety and Health Administration. Reporting occupational injury and illness data to OSHA. Final Rule. *Federal Register* 62 (28) February 11, 1997:6434-6442.

Safety Devices Prevent Percutaneous Injuries During Phlebotomy

Phlebotomy, one of the most commonly performed medical procedures, has been associated with 13% to 62% of injuries reported to hospital occupational health services and with 20 of 51 documented episodes of occupationally acquired HIV infection in the United States. A collaborative study recently was conducted by the CDC and six university-affiliated hospitals located in Minneapolis, New York City, and San Francisco to evaluate safety devices used for phlebotomy. The assessment was restricted to a comparison of safety devices with conventional devices. Each hospital selected the products to be evaluated (vacuum-tube collection devices or winged steel needles with safety features). Three products were evaluated and included a resheathable winged steel needle (device 1; Safety-Lok, Becton Dickinson, Franklin Lakes, NJ); a blunt vacuum-tube blood-collection needle activated while in the patient's vein (device 2; Puncture-Guard, Bio-Plexus Inc, Tolland, CT), and a vacuum-tube blood collection needle with a hinged recapping sheath (device 3; Venipuncture Needle-Pro, Smith Industries-Concord Portex, Keene, NH). Each product required the healthcare worker to activate the safety feature during or after phlebotomy. During phase I of the study, hospitals used conventional phlebotomy devices and conducted enhanced surveillance for injuries (encourage reporting, newsletters and published notices, inservice training). Underreporting and estimates of number of phlebotomies performed daily was assessed with an anonymous survey. During phase II of the study, investigators replaced conventional devices with safety devices. A second survey was done and also included an assessment of satisfaction with safety devices and any adverse effects in patients.

Overall, respondents acknowledged reporting only 54% of the 564 needlestick injuries that were sustained during the previous year. The findings indicated that, for each of the safety devices evaluated, the number of phlebotomy-related percutaneous injuries was significantly less for the safety devices compared to the conventional devices (both adjusted and unadjusted for underreporting). The percentage reduction in percutaneous injury rate with safety devices was 23% for device 1; 76% for device 2; and 66% for device 3.

The results of this study suggest that safety devices for phlebotomy may be generally acceptable to users. Activation rates of safety features and user acceptability may be influenced by factors such as the perceived risk for occupational infection by the HCW, design of the device, training provided before and after introduction of the device, length of time needed to become adept at using the device, ease of use, necessary changes in technique, and previous experience with a safety device.

FROM: Centers for Disease Control and Prevention. Evaluation of safety devices for preventing percutaneous injuries among health care workers during phlebotomy procedures—Minneapolis-St Paul, New York City, and San Francisco, 1993-1995. *MMWR* 1997;46:21-25.

Blunt Suture Needles Reduce Risk of Percutaneous Injuries

Percutaneous injuries (PIs) have been reported during 1% to 15% of surgical procedures, mostly associated with suturing. Most suturing is done using curved needles, although straight needles are used by some surgeons for suturing skin. Blunt suture needles (curved suture needles that have a relatively blunt tip) may be less likely to cause PIs, because they do not penetrate the skin easily. Based on a few small studies, these blunt suture needles are able to replace conventional curved suture needles for suturing many tissues, although they may require more pressure to penetrate the tissues. During March 1993 to June 1994, the CDC collaborated with three teaching hospitals in New York City to evaluate a blunt suture needle (Ethiguard, Ethicon Inc, Somerville, NJ) in gynecologic surgery. A total of 1,464

gynecologic surgeries procedures were observed. The rates of PIs associated with the use of curved suture needles were 1.9 per 1,000 conventional curved suture needles used (56 PIs among 28,880 conventional curved suture needles used) and 0 per 1,000 blunt suture needles used (0 PIs among 6,139 blunt suture needles used).

During the study, the surgeons retained the option of requesting conventional straight suture needles. In 104 of the procedures, straight suture needles were used in addition to curved needles. The PI rate for straight suture needles was more than seven times the rate associated with conventional curved needles. In 25 (6%) of the 402 procedures during which blunt needles were used, surgeons reported technical difficulties with the blunt needles, including problems with penetrating tissue (18), tearing of tissue (3), needle slippage (3), and bleeding when the needle entered the tissue (1). However, none of these were reported to be clinically important. For procedures performed with and without blunt needles, mean blood loss and mean operative time was similar.

The findings indicated that the use of blunt suture needles significantly reduced PIs, had minimal clinically apparent adverse effects on patient care, and generally was accepted by surgeons in these hospitals. Although some tissues cannot tolerate the increased force required to use a blunt needle, a blunt needle probably could be substituted for a conventional needle in a variety of procedures. In addition, blunt suture needles may be particularly useful in preventing PIs during suturing in a poorly visualized anatomic space.

The authors note that safety devices must be acceptable to the healthcare worker who uses them. Although specific uses and limitations of blunt needles require further delineation, the findings of this study support the use of blunt needles as an effective component of a PI prevention program.

FROM: Centers for Disease Control and Prevention. Evaluation of blunt suture needles in preventing percutaneous injuries among health care workers during gynecologic surgical procedures—New York City, March 1993-June 1994. *MMWR* 1997;46:25-29.

Validation of Cleaning Procedures Used for Medical Devices

Although the principle of cleaning a device prior to sterilization or disinfection is well accepted and has been the subject of many scientific and professional meetings, it has been only in recent years that an attempt has been made to standardize and validate cleaning procedures. Two meetings were held recently where the subject of medical device cleaning was discussed. In November 1996, the Association for the Advancement of Medical Instrumentation (AAMI) and the FDA sponsored a meeting in Los Angeles: "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities." Part of the meeting was devoted to discussing the materials and design features that need to be considered when cleaning devices, testing of actual cleaning procedures, and attempts to standardize the procedures. There were at least 12 oral and several poster presentations on this broad topic. The following were among the points made:

- Medical devices, especially those with lumens, are exposed to blood, body fluids, and excretions, and must be cleaned prior to disinfection or sterilization. Failure to do so can decrease the sterilization or disinfection efficacy.
- There are a variety of automated and manual cleaning procedures for medical devices in general and for specific devices. When these procedures are evaluated, the results, remarkably, show that the level of microorganisms or organic material is reduced consistently by 3.5 to 5 logs.
- There are a number of techniques that can be used to validate cleaning procedures. The techniques described at the meeting included using measured concentrations of bacterial spores in a variety of "soils." Soil is a broad term that describes a mixture of organic and inorganic material meant to simulate a body fluid or excretion and to add a worst-case challenge to disinfection and sterilization procedures. Some examples are rabbit whole blood; mucin; 5% fetal bovine serum plus 300 ppm hard water; serum, dry milk powder, and dye; egg yolk, sheep blood, and hog mucin; peanut butter; butter; flour; lard; egg yolk; milk; India ink; and blood. Standardization problems for some of these are obvious. Most investigators are concentrating on formulations such as 5% fetal bovine serum in 300 ppm hard water. This formulation, as well as similar ones, can be standardized and represent a sufficient and valid challenge.
- Quantitative procedures evaluated for purposes of validation included microbial assays using viable spores, bioluminescence, fluorescence, radioactive isotopes, tests for organic carbon, and tests for proteins. Most of the procedures could be used to validate a specific cleaning procedure.

AAMI held its Sterilization Standards Committee meetings at the end of January 1997 in Arlington, Virginia. One session was devoted to a discussion of a European standard on washer-disinfectors. The chair of the newly formed working group is Dr. Rosemary Simpson from the United Kingdom. The standard would include three broad categories of devices: general instruments, bedpans, endoscopes. The standardization of cleaning procedures and methods to validate them is the primary goal of the working group.

Additional news items in this issue: First Reported Case of Occupationally Acquired HIV From Autopsy, page 243; Two VRE Morphotypes in Six Detroit Hospitals, page 254; Antimicrobial Resistance: Inpatients, Outpatients, and Role of the ICU, page 259; Usefulness of Clinical Predictors for TB Isolation, page 274.