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.