FDA Task Force on Preventing Complications Associated With the Use of Central Venous Catheters

The Food and Drug Administration (FDA) as well as the Canadian Health Protection Branch (HPB) have become aware of an appreciable increase in the number of complications associated with the use of central venous catheters (CVCs). A multidisciplinary task force consisting of physicians, nurses and manufacturing representatives has concurred that individual healthcare providers, professional medical and nursing associations and healthcare facilities need to address the proper placement procedure, follow-up and care associated with these devices.

SHEA is represented on this task force by Barry Farr, MD, from the University of Virginia. The task force is investigating long-term solutions such as changes in CVC labeling, development of instructional material (including videotapes) and monitoring procedure quality by the Joint Commission on Accreditation of Healthcare Organizations. Some aspects of the CVC complications are well understood, and the task force wishes to publicize this information in an expeditious manner. The FDA has asked each society represented on the task force to publish this news item.

Reports received by the FDA and HPB regarding CVC complications include, but are not limited to: infection; pneumo-/hemo-/hydro-/thorax, vessel and cardiac perforation; cardiac tamponade secondary to pericardial effusion; dysrhythmia; air embolus; and sheared catheters. Many of these complications are related to technique and are associated with substantial mortality.

The current literature indicates that the number of CVC-related problems is estimated conservatively to be as high as 10% of the approximately three million CVCs used annually in the United States. The following recommendations were made by the task force to help reduce or prevent these complications.

- Central venous catheterization should be performed only when the potential benefits appear to outweigh the inherent risks of the procedure.
- Except for pulmonary artery catheters, the catheter tip should not be placed in, or allowed to migrate into, the heart.
- Catheter tip position should be confirmed by x-ray or other imaging modality and be rechecked periodically.
- Central venous catheterization must be performed by trained personnel, well versed in anatomical landmarks, safe technique and potential complications. Users in training must be closely supervised by qualified personnel to assure their technical expertise prior to independent performance of these procedures. Ongoing monitoring of experienced trainees should be undertaken to assure continued competence.
- Those placing CVCs should be familiar with the specific equipment utilized as well as the proper selection of insertion site and catheter type, size and length.
- Those caring for patients with indwelling central venous catheters should be well informed of the appropriate care and associated complications of cvcs.
- Manufacturers should include specific labeling to address the potential complications of CVC use. Therefore, users should read all manufacturers' labels, instructions and warnings, as these contain important and

useful information essential for the safe and effective placement of the catheter.

- Except in emergencies, catheterization should be performed with full aseptic technique to include handwashing, sterile gloves, masks, hats, gowns, drapes and proper use of a suitable skin antiseptic.
- Catheters placed in less than sterile fashion should be replaced as soon as medically feasible.

As the use of central venous catheters has increased in recent years, so has the prevalence of their associated complications. By following these recommendations, the incidence of these complications and resulting sequelae should be substantially reduced. Users and institutions should review and monitor this clinical activity to assure that the process and outcomes are consistent with high quality patient safety standards.

The Name Game With *Pseudomonas*

There appear to be two major changes recently in the life of *Pseudomonas maltophilia*. First, this low pathogenicity "water bug" is becoming a more frequent colonizer (and perhaps pathogen) in many hospitals. Reasons for this increase (such as greater use of new cephalosporins, carbapenem-eating enzymes produced by this species or widely distributed contaminated common sources) are not clear. Second, the genus designation for *P maltophilia* has been changed to *Xanthomanas*.

In our institution we have cultured these strains from tap water and have assumed that occasional breaks in aseptic technique lead to colonization and that use of newer antibiotics selects out *Xanthomonas*. The next Centers for Disease Control (CDC) National Nosocomial Infection Study update should help determine whether or not sporadically reported increases in *Xanthomonas* represent a true national trend.

Quality Connection

We have been impressed by the recent series of articles in *Infection Control and Hospital Epidemiology* edited by Hierholzer and Credé on Quality Assurance. Although many hospital epidemiologists no doubt have hoped that "QA" would go away quietly, it appears that it is here to stay. Moreover, if hospital epidemiology can mate successfully with quality assurance, the offspring hopefully will be greater hospital quality. Decubitus ulcers are a prime example of a problem area where the mating could yield great benefits. If epidemiologic techniques and control measures used successfully over the past four decades in hospital epidemiology can be brought to bear on this problem, perhaps we can prevent the decubiti and learn how to intervene at an earlier step in the development of nosocomial infections.

Brief items of interest for the SHEA Newsletter may be sent to Robert A. Weinstein, MD, Shea Newsletter Editor, Division of Infectious Diseases, Michael Reese Hospital, Lake Shore Drive at 31st St., Chicago, IL 60616. Copy must be typed, double-spaced and may not exceed five pages.