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INFECTION CONTROL

LETTERS TO THE EDITOR

To the Editor:

One of the recommendations in the new CDC Guidelines on Infection Control appears to create a problem for my hospital and, I suspect, for many others. The Guidelines for Hospital Environmental Control include a section entitled "Cleaning, Disinfection, and Sterilization of Hospital Equipment." Recommendation 7B in this section states that every steam sterilizer load should be monitored with a spore test if it contains implantable objects. Moreover, these objects should not be used until the spore test is determined to be negative at 48 hours. "Flash" sterilization is specifically cited as inadequate. Although the recommendation has received Category I status, there are no adequate scientific studies to document validity of this recommendation. Thus, a majority of the CDC panel members who developed this recommendation must have viewed it as useful and practical to implement in a majority of hospitals. While the recommendation may represent an ideal, I contend that it is impractical for our hospital and the great majority of other institutions which operate on tight budgets.

All would agree, I think, that spore tests are not infallible. Indeed, the introductory paragraphs in this section of the Guidelines emphasize this fact. The recommendation as written appears to require individual wrapping of every screw, pin, nail and other items, in addition to such larger implantables as total joint prostheses and silicone implants. It is probable that many institutions will have to employ additional personnel to process this increased workload. Each item processed will have a limited shelf life and, if not used within an appropriate time period will have to be unwrapped, rewrapped, and resterilized. Certain implantable items (e.g. vascular grafts) are limited by the number of times they can be subjected to sterilization, and may, on occasion, have to be discarded without ever having been used. Additional costs to institutions will include the substantially larger inventory that will be required, the increased costs of the spore tests themselves, and the increased amount of space which will be required to hold each individually wrapped item.

It seems to me that the cost of this single recommendation will be impossible to bear in many institutions. Indeed, an informal survey of ten hospitals in this state indicated that none presently comply with the recommendation, nor could they comply for the reasons I have stated. It is my understanding that some members of the working group on the Guidelines for Hospital Environmental Control argued strongly against this particular recommendation, but were outvoted by the majority of the members on the committee. I was even more dismayed by the lead article in the June issue of *Hospital Infection Control,* which quoted malpractice attorneys as stating that new guidelines will be considered the national standard of care and that institutions which fail to comply will be held liable.

I am concerned that those who developed this recommendation did not adequately consider the practical implications for most hospitals. I would be interested in the thoughts of other readers and hope that a representative of the CDC panel might be asked to respond to my concerns in this forum.

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This letter was referred to Dr. Layman and to the Centers for Disease Control, for the following replies:

Dr. Weinstein's letter was referred to me, presumably more for my comment as a pragmatic surgeon than as a consultant in infection control. Dr. Weinstein's points are difficult for me to comprehend, because they make short shrift of the realities of the hazards of infection in implant surgery.

If implanted prostheses never or rarely became infected, there would be no need for all sorts of special precautions currently being taken by orthopedic surgeons—let alone spore testing of the prostheses. But, alas, infections do occur, some catastrophic. The vectors of many infections defy detection. But that does not stop us from taking aseptic precautions, some ad-

mittedly in the overkill range. Among the techniques suggested through the years by orthopedic surgeons in their efforts to control the bacterial seeding or contamination of surgical wounds in implant surgery are: no-touch technique, multiple surgical trays, laminar airflow, impermeable gowns, vacuumized apparel and helmets, no visitors in the operating rooms, and a variety of special surgical techniques. The extra cost of these techniques has been acknowledged by those who introduced them, but their cost-benefit ratios are staunchly defended in favor of the benefits.

In view of this background, it is indeed surprising to find that Dr. Weinstein finds that it would be too costly to ensure that an implant prosthesis was free of anaerobes before implanting it.

Although it is true that it may take special packaging techniques, such as individual packets and transparent sealed envelopes, and additional inventories of prosthetic devices to make sure that the sterility of the implant device is assured, the cost of such requirements is no more excessive—and in some cases less excessive—than some of the other measures mentioned. It is not true, however, that safe practices require the hiring of unaffordable additional personnel or require unreasonable changes in functional systems or management of a surgical suite.

Regardless of whether the CDC recommendations for implantable devices are adopted as the standard to be followed in medicolegal proceedings, I would think that it would be desireable for a patient's record to contain documentation on the procedure of sterilizing an implanted prosthesis and the results of efficacy tests. Without such documentation, the surgeon and the hospital could conceivably expose themselves for litigation in the event of catastrophic infection, on the grounds that they did not insist upon stringent sterility processes. Moreover, if the surgeon or a hospital goes on record opposing stringent sterility processes as being impracticable because of cost of extra instrumentation or packaging, both the surgeon and the hospital will weaken their images as responsible health-care providers. Most important, the patient is the one who suffers the morbidity and the financial burden of infection. If, in the light of these considerations, Dr. Weinstein would like to persist in his refusal to have the sterility of his implant prostheses tested, I would think he would be willing to sign a statement in the patient's chart taking responsibility for his stand.

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Spore testing has been recommended as a method of assessing the adequacy of a sterilization cycle. However, a positive spore test (spores not killed) cannot be equated with sterilization failure because there may be other causes of positive tests.[1] Because spore test results may be difficult to interpret, and because of the relative safety of full-cycle steam sterilization, CDC's panel decided not to recommend that most items be withheld from use pending spore test results, nor recalled for a single positive test.

However, CDC's panel does recommend that implantable devices be withheld from use until spore tests have been shown to be negative (48 hours). This recommendation has been made because CDC and our working group on sterilization guidelines felt that, because of the severity of infections that are associated with such devices, the "margin of safety" associated with sterilization should be as wide as possible. If a spore test is positive (which can mean that a sterilization failure has occurred), implantable devices that are withheld can be sterilized again to be certain that there is no risk to patients.

Dr. Weinstein's letter was shared with panel members; the issues were reexamined, and the results of these deliberations appear below. It is true that following the CDC recommendation mentioned by Dr. Weinstein may result in increased costs for some hospitals; the amount depends on present practices and the volume of implantable devices sterilized. Personnel time accounts for most of the costs of sterilization. Since implantable devices normally constitute an extremely small portion of all items sterilized (estimated at <1%), the total increase in personnel time and costs for sterilization should be small. Most increases in cost should result from the need to maintain a larger inventory of implantable devices because of the 48-hour holding period after sterilization. But after an initial buildup of inventory, little additional costs should result.

Although implantable devices need not be individually wrapped, this practice has some advantages with large or expensive devices. Since surgeons working with implantable devices frequently must choose between several sizes to find the one that best fits the patient, many devices of various sizes may be packed and sterilized together. But if this is done, once a pack is opened, all devices that are not used must be sterilized again even if not touched. However, if these devices are individually wrapped in heat-sealed, transparent, paper-plastic pouches, they can first be visually examined and then opened as needed for fitting in the operating room; those not opened can be used again or stored for up to one year without resterilization. In other words, individual wrapping of large or expensive devices should not increase the need for sterilization and wrapping and may actually reduce it, except when surgeons must open many packs to find the proper size. In addition, some companies that make implantable devices also make inexpensive sizing devices which can be sterilized and used to find the proper size without opening the packages containing implantable devices.

Smaller devices, such as screws, pins, and some nails, can be sterilized in sets because costs of maintaining a slightly larger inventory for these devices should be quite low. Storage space for sterilized implantable devices may need to be increased slightly, but it should still be small in comparison with the space required for other sterilized items. The additional costs of spore testing for implantable devices should also be small, since the tests are easy to perform, inexpensive, and many devices can be sterilized and tested together.

Our recommendation not to use flash sterilization for implantable devices is the result of reports of more failures using this method than with conventional sterilization. Laboratory

studies done at CDC showed that, with flash sterilization, the "margin of safety" may be relatively small. In point of fact, a recent outbreak of meningitis on a neurosurgical service was traced to inadequate flash sterilization of central-nervous-system tubing.[2]

Although following the CDC recommendation mentioned by Dr. Weinstein may result in increased costs for some hospitals, we believe that the costs are reasonably small and acceptable for most hospitals, considering the potentially enormous costs of an undetected sterilization failure involving an implanted device. However, CDC and its working group realize that: **1)** *the proper period of time to withhold implantables from use pending spore test results is not known, although it is probably at least 24 hours;* **2)** *even with the best planning, not all implantable devices necessary for an operation will have been sterilized 48 hours in advance; and* **3)** *strict compliance with the recommendation as written may be very expensive and impractical for a few hospitals with a large volume of implant surgery and limited storage space. Thus, the recommendation in the Environmental Control Guidelines has now been changed, with the agreement of panel members, to the following:*

1. Every load (sterilized) should be monitored with a spore test if it contains implantable objects. These objects should not be used until the spore test is found to be negative (at 48 hours). Category II
2. Implantable objects should not be sterilized by "flash" steam sterilization. Category I

We will soon incorporate this change into our next revision of the Guidelines and bring this change to the attention of hospital personnel. We appreciate the comments and criticism presented by Dr. Weinstein; such comments give us the opportunity to improve our guidelines. As we said in our preface to these guidelines, we welcome all comments, suggestions, and criticisms.

REFERENCES

1. Centers for Disease Control. False-positive results of spore tests in ethylene oxide sterilizers—Wisconsin. MMWR 1981; 30: 238-40.
2. Ho JL, et al. Common-source *Pseudomonas aeruginosa* infection in neurosurgery. In: Proceedings of the Annual Meeting of the American Society of Microbiology, 1981. Dallas, Texas. Paper L10, page 80. Abstract.

To the Editor:

Medical research continues evolving into an increasingly sophisticated, technologically intensive endeavor. It is not uncommon now to have multimillion dollar grants awarded to teams of researchers employing myriads of postdoctoral fellows and technicians, just to study the molecular structure of slightly aberrant polypeptides. Admittedly this is an overstatement, but it does highlight the fact that health care practitioners in many smaller institutions are finding it increasingly difficult to conduct original research. However, there is still at least one fruitful area of study available to practitioners of infection control: nosocomial infections caused by nonfermentative gram-negative bacilli—NFB.

NFB are a diverse group of bacteria that have two common features. They are unable to grow in the absence of available oxygen and cannot generate energy fermentatively. Additionally, they have simple nutritional requirements, resist most antimicrobial agents, and are ubiquitous in nature.

Although hundreds of NFB species have been described, less than 40 species are routinely encountered in clinical microbiology laboratories. The most common of these species, *Pseudomonas aeruginosa,* is already an old friend (or enemy) of infection control personnel. It is a significant pathogen with fairly straightforward modes of transmission within hospitals.

What about all of the other NFB isolates? For example, are CDC Va-1 or CDC IIk-2 potential pathogens? What about the pathogenicity of *Alcaligenes faecalis* or *P. acidovorans*? How are NFB other than *P. aeruginosa* transmitted within the hospital? Can hospital water systems be reservoirs for pathogenic NFB? Infection control programs can provide answers to these questions through three relatively simple steps.

1) Insist that your microbiology laboratory identify all NFB isolates to the species level. Laboratory reports that list "*Pseudomonas* species" should be considered unacceptable. Do three isolates of "*Pseudomonas* species" from one ward equal an outbreak? Probably not if, in reality, one is actually *P. maltophilia,* one is *Acinetobacter lwoffi,* and the third is *P. acidovorans.* The problem is, you just won't know until you get accurate information. If your laboratory has limited resources, you should encourage them to use reference laboratories, such as those supported by states and counties. Most of these laboratories do not charge for reference services.

2) Review patient charts for evidence of significant infections caused by correctly identified NFB. Pay particular attention to pure culture isolates, recovered more than once from body sites with documented evidence of infection.

3) Publish your findings. Infection control practitioners are in a unique position to correlate and disseminate this type of information. In this way, you might be responsible for discovering one of the "new" nosocomial pathogens of the 1980s.

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To the Editor:

Following publication of "Guidelines for Prevention of Catheter-Associated Urinary Tract Infections" in *INFECTION CONTROL*'s March/April issue, the Centers for Disease Control received a letter pointing out a problem with the recommendation that concerns bladder irrigation. That recommendation, Number 6a, has now been changed. The recommendation as originally written implied that continuous irrigation of the bladder to prevent anticipated obstruction was inadvisable. This implication was not intended. With the agreement of the Guideline working group, the recommendation has now been changed and combined with recommendation 6e, so that it reads as follows:

> Irrigation should be avoided unless obstruction is anticipated (e.g., as might occur with bleeding after prostatic or bladder surgery); closed continuous irrigation may be used