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INFECTION CONTROL

LETTERS TO THE EDITOR

Germicidal Capability of Glutaraldehyde-Phenate Disinfectant

To the Editor:

The recent report by Townsend et al[1] is a welcome addition to the literature on hospital disinfectants since indeed there has been a paucity of clinical studies of such products. For well over a year we have been using the same glutaraldehyde-phenate disinfectant they evaluated and would like to offer the following comments:

The data in Table 1 are somewhat confusing in view of the statement that "of those few tubes from which organisms were recovered, the number of organisms was small." An *average* of 182 ± 356 organisms from 22 tubes soaked in five-day-old or less glutaraldehyde does not seem to be a particularly small number, especially if our interpretation of Figure 1 is correct in that only three of the 22 tubes involved supported growth of organisms. While Fisher's exact test suggests that no significant differences existed between the *proportion* of contaminated tubes, the *degree* of contamination in the tubes failing the disinfectant might also be relevant. In the absence of the rough data, one might even reach the rather implausible conclusion from Table 1 that the disinfectant became more effective with time since the only perfect results were obtained with the 26 to 30-day-old disinfectant.

Detergent wash alone appeared to reduce the number of organisms by 100 fold in contaminated tubing, and a further treatment in the disinfectant resulted in a second 100 to 10,000 fold decrease in average number of organisms found. Since the treatment with a disinfectant also involved a second immersion in a liquid and three additional rinses one wonders what effect this physical treatment alone might have had on the results. Apparently this aspect was not controlled.

We performed our own AOAC use-dilution tests on samples of the glutaraldehyde-phenate as it was being used over a 30-day period. The test organism was *Pseudomonas aeruginosa,* and all tests were conducted according to AOAC protocol in which killing in 59 of 60 replicate tubes is required for a 95% confidence level.[2] In these tests freshly prepared disinfectant produced killing in all 60 tubes. The killing proportion dropped to 54/60 and 36/60 after three and four weeks use respectively. Even though routine sterility monitoring of cleaned, re-usable respiratory therapy equipment during that period gave satisfactory results for up to 30 days use-life, we have decided to change the solution after 14 days as an added precaution.

Thus, although our cultures of cleaned and dried equipment is consistent with the conclusions of Townsend et al that this glutaraldehyde-phenate can be used for up to 30 days, we doubt that the results reflect the true germicidal capability of the disinfectant. Since Rutala[3] also found that on-site AOAC use-dilution tests of disinfectants did not support manufacturers' laboratory test results, we believe it may be important for each institution to make an assessment of the efficacy and use-life of such products in their own clinical setting. This may be especially pertinent to dilutable disinfectants where the load volume and water quality may differ radically from one geographic area to another. This is not a new idea since it was suggested by Litsky and Litsky[4] almost 15 years ago, but perhaps it bears re-stating.

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Dr. Timothy R. Townsend, author of the article in question, was invited to respond.

I appreciate the thoughtful comments from Pfaffenroth and co-workers. They raise an issue that we debated during preparation of the manuscript and their letter provides an opportunity to present some of the pertinent raw data and explain in

some detail what could not be explained, due to scientific publication conventions, in our paper.

The numbers of microorganisms recovered from the 22 ventilator tubes treated with disinfectant that had been used 5 or fewer days were as follows: 19 had zero, 1 had 2, 1 had 6, and 1 had 4,000 organisms. In the Materials and Methods section we indicated that the numbers of microorganisms recovered from ventilator tubing would be expressed as means (averages) with 95% confidence intervals. We chose this method expressing the data for several reasons. First, confidence intervals take into account both population variability and sample size in expressing "confidence" in the population sample estimate ($\bar{X}$). Second, our other option for presenting the data was to use median values and show ranges. Although a perfectly legitimate method for describing the central tendency of data, I am not sure the readers would have appreciated having numbers of organisms recovered from untreated and washed tubes expressed in means ± 95% confidence intervals and those from disinfected tubes expressed in medians and ranges. Similarly, the use of medians and ranges throughout would have been awkward in tabular form and unless careful notation of the range (0 to 4000 in the ≤ 5 day group) was taken the median values for all 6 (≤ 5 days through 26 to 30 days, Table 1) groups would have been zero. Such data presentation would have made it appear to the more casual reader that if this disinfectant were used for 30 days, *zero* organisms would be expected. Certainly, the data do not support that. Finally, means and 95% confidence intervals are useful in easily comparing populations. Since the confidence intervals of all groups (see above) included zero the reader can easily conclude that no difference was apparent between groups and if repeated samples were taken the probability of a zero result was high.

I am not surprised by the AOAC test results reported in Pfaffenroth and coworkers' letter. After use, most disinfectants become diluted because wet equipment is immersed in the solution. The Environmental Protection Agency which must approve manufacturers' claims does not take this "real world" variable into account in their testing procedure (for further EPA disinfectant problems see Gröschel's editorial, *Infection Control,* May/June 1983). We emphasized in our paper by way of a special note (p. 243) that routine microbiological monitoring of liquid chemical disinfected respiratory therapy equipment was recommended by the Centers for Disease Control. I am a little disturbed by Pfaffenroth and co-workers' finding that routine monitoring showed efficacy at 30 days but AOAC tests showed only 36/60. Such data should be submitted for publication; if for no other reason than to stress the far from perfect methods we have available to evaluate disinfectants.

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Use of Multidose Vials

To the Editor:

We have received conflicting information regarding the use of multidose vials and have been unable to obtain authoritative sources of information. The question is how long can the contents be considered safe for injection once the diaphragm of the vial has been punctured? Some sources state 30 days from the first puncture and others state until the expiration date for the contents of the vial.

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The preceding letter was referred to Mark Eggleston, PharmD, and John P. Burke, MD, for their replies.

Presently, there are conflicting results reported in the literature. Multiple dose vials (MDVs) for parenteral use are potentially a source of nosocomial infections. Similar parenteral products (improperly used IV catheters, contaminated single use IV fluids) have been implicated in sporadic as well as epidemic cases of bacteremia.[1]

Actual clinical infections resulting from contaminated MDVs have not been reported frequently in the medical literature. However, Olsen et al[2] documented eight cases of Flavobacterium meningosepticum bacteremia caused by extrinsic contamination of MDVs by poor aseptic technique.

There are several studies and reports that address the possibility of contamination of MDVs during use and the ability of organisms to survive in a variety of medications packaged in MDVs.[3-7] Most have discovered a low rate of contamination. Highsmith, Allen and Greenhood[8] showed that the risk of significant microbial contamination for some types of medication appears low. They noted, however, that several organisms survived or grew in a MDV containing lidocaine. The lidocaine solution also contained endotoxin after contamination with *Pseudomonas cepacia,* as did insulin contaminated with enterococcus. Borghaus et al[9] reported that if an MDV is contaminated with a particular agent that is resistant to the bacteriostatic agent present, it very quickly may become a potential source of infection to patients. These researchers found that bacteria recovered from unopened vials of the anesthetic fentanyl could be grown in the drug alone and in the preservative, parahydroxybenzoic acid. The generation time was less than four hours.

In contrast, a study conducted at the National Naval Medical Center examined 1,223 samples from 864 vials which had been in use from 1 to 402 days. They could find no contamination in any MDV, and concluded that MDVs may safely be used until empty or until the manufacturer's expiration date, whichever occurs first.[10]

Bawden et al[11] examined MDVs after collection from hospital nursing units and after deliberate contamination. Bacteria were isolated from deliberately contaminated MDVs when inoculated with 1 to 100 colony forming units/ml or greater when the sample was tested within one hour after contamination. Only one vial was positive at 16 hours and none were positive beyond that time. No bacterial contamination was found in the MDVs collected from the nursing stations. The researchers concluded

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