

such a procedure, but as long as the safety is not proven and the manufacturers of such disposable items place warnings on the packaging of such items against their re-use, it would appear to be prudent to obtain appropriate legal consultation before embarking on a policy of recommending such procedures.

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Today, the majority of insulin-dependent diabetics use the disposable plastic syringes that are intended for one-time use only. In this era of cost containment however, some diabetics have been using the disposable syringe for multiple injections. Your question regarding the safety of this procedure focused on two published articles that examined this issue.

Work done prior to these studies resulted in varying conclusions. Tuazon et al¹ stated that there may be a greater carrier rate for *Staphylococcus aureus* among diabetic patients. Yet, Elek² indicated that a minimum of 7.5×10^6 staphylococcal organisms had to be injected intradermally for the occurrence of pus formation, while Koivisto and Felig³ failed to note such high bacterial skin counts during their investigation. The latter study even showed that routine skin swabbing may not be necessary at all.

Recent studies undertaken to determine the risk of infection with this procedure showed promising results. Greenough et al⁴ initiated a study of 30 patients, all of whom reused the same syringe for up to two months. After each injection the needle was capped, placed in the original container and stored in the refrigerator. Throughout the study there was no soreness, redness, or infection at the site of injection. Some patients only changed needles every three to four days. Syringes sent for culture grew no organisms, except for one which

yielded *Staphylococcus aureus*.

In another study, Hodge et al⁵ investigated 14 diabetic patients and the effects of re-using the same syringe three times in succession. Each patient participated in a one-month control period prior to the study. After an average duration of 20 weeks, no patient showed signs of infection at the injection site, and all the syringes cultured sterile. During the study the needles were wiped with alcohol, capped, and stored in the refrigerator after use. There was a less than 0.25% risk of infection estimated from this procedure. Also, to test for possible reservoirs of growth, six vials of insulin were injected with *Staphylococcus aureus*. No bacterial growth was found after 48 hours.

The most recent study was undertaken in the developing country of Nigeria, where, according to the authors, some rural diabetics do not have refrigerators for storing syringes and insulin. Oli et al^{6,7} investigated the repeated use of an insulin syringe in 21 diabetics. After use, the needle was recapped and stored with the insulin in a dry, clean container covered with a lid. The average duration of use for a syringe and needle was 26 days and five days respectively. Only one patient complained of soreness at the injection site. Cultures of each patient's insulin also yielded no organisms.

Judging from these initial studies, multiple use of a disposable insulin syringe appears to be relatively safe and cost effective. However, in evaluating these studies, it would be imprudent to correlate their results with your situation. The articles discussed above have drawn positive conclusions based on their own individual situation and predefined criteria. Using the studies as a guide, each separate environment can test and judge new ideas accordingly.

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Chemical Versus Physical Cleansing

To the Editor:

The May-June issue of *Infection Control* (3:240-244, 1982) contained an article by Townsend et al entitled, "An Efficacy Evaluation of a Synergized Glutaraldehyde-Phenolate Solution in Disinfecting Respiratory Therapy Equipment During Patient Use." The content, and especially the title, is a good example of equipment-disinfection articles in which there is too much emphasis on the contribution of the chemical and not enough on physical cleansing.

In-use tests are definitely the best way to evaluate equipment-disinfection procedures; this one used ventilator tubes. The study reflects a good deal of careful work particularly in the identification of survivors, a step too often neglected. However, I find the report misleading because the authors attribute to the chemical solution a greater role in decontamination than their results demonstrate.

This is not at all unusual. It has been my observation over the years that a majority of such reports tend to emphasize the chemical component and minimize or ignore the large proportion of contaminating microorganisms and organic soil removed by mechanical cleansing (*physical disinfection*). This is an unfortunate situation because it gives non-experts the wrong impression. Indeed, pre-cleansing, rinses, etc., are the basic and often major part of satisfactory procedures for decontaminating reusable equipment. How much the subsequent chemical exposure contributes to the overall result depends upon the potency of the chemical (whether it is a low-level disinfectant, a high-level disinfectant or a sterilant) and upon

the contact time.

It is important that practitioners of hospital disinfection have this perspective when assessing reports such as that by Townsend et al. For example, their procedure consisted first of bottle-brush cleansing with detergent solution, followed by four water rinses and some air-drying. Their figures show that this physical disinfection step reduced the number of contaminated tubes from 92% to 72% and the mean survivor count by more than 99%. Yet, the article's title puts great emphasis on the chemical component even indicating its composition. Although the authors did mention the "detergent wash" in the text, they also said, "... our study design did not permit us to determine if the cleansing procedure was necessary..." The implication is clear that the chemical might have done as much without pre-cleansing. The writer from long experience with tests of this nature can attest that that is most unlikely.

Another reason for questioning the emphasis on chemical action is that the data fail to provide the information needed for the chemical efficacy evaluation that is part of the title. To be able to do this there should have been a control in which water was substituted for disinfectant. Consequently the role of the chemical component has to be surmised from other results. Following contact with chemical (followed by three rinses and air-drying) there were significant reductions in the number of contaminated tubes, but the proportionate reduction in the mean count was of the same order as that following the detergent-wash alone. And among the 30 different types of survivors were some that are generally quite susceptible to disinfectants (Neisseria, for example). This finding leads one to suspect that the level of chemical action may not have been high.

There is a great need for in-use studies on equipment disinfection that provide a balanced assessment of the whole decontamination procedure and compare two or more procedures one of which is in common use. The purpose of this communication is to encourage such studies.

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Dr. Timothy R. Townsend, who authored the article in question, was invited to respond.

Dr. Spaulding is correct in that to evaluate the specific contribution to the disinfection process of either the pre-cleansing procedure or the disinfectant itself, a different study design would be needed. It was not our intent to imply that pre-cleansing was not necessary. Our intent was quite the opposite, to caution the reader that our study design was such that the importance of pre-cleansing could not be properly evaluated.

I agree with Dr. Spaulding that there is a great need for more in-use studies that provide a balanced assessment of the entire decontamination procedure. Our hope was that our study might stimulate more and better studies. With Dr. Spaulding's permission, I would like to extend his plea for more studies to include controlled studies that directly compare different disinfectants available to hospitals. In this regard, it was very unfortunate that funding was withdrawn in 1981 for the Centers for Disease Control sponsored study (Microbiologic Evaluation of Chemicals and Methods Used for High-Level Disinfection of In-Use, Naturally Contaminated Respiratory Therapy Breathing Circuits, RFP No. 200-81-0628) which would have evaluated both manual and machine processing of ventilator tubing as well as many different types of disinfectants. Such a study would have been invaluable not only in providing practical in-use data to hospitals, allowing them to choose the best disinfectant for the job, but in furthering our understanding of which components of the disinfection process are most efficacious.

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Length of Sterility in Self Sealing Wrap

To the Editor:

Regarding the article in *Infection Control*, Vol. 2, No. 2, page 143, we use "Ameri-Wrap Self Sealing Wrap" of American Hospital Supply Corporation for gas and heat sterilization.

Have you done studies on length of sterility in this type of a wrap? At this time we allow six months sterility in a closed cabinet for the wrap.

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The preceding letter was referred to George F. Mallison, MPH, PE, for a reply.

I have seen no articles in medical or scientific literature on studies of the safe length of sterility using this particular product. However, the wrapper appears to be essentially the same as a number of other wrappers — it consists of transparent plastic (probably polypropylene or PVC) on one side bonded on the other to white kraft paper. Sold as a pouch, it has a press-on seal (that appears quite effective) on one end and easy-to-open tabs on the other end.

Studies on the safe storage times of pouch-type wrappers were reported by Dineen (*AORN Journal* 13:63-64, 1971). His work indicated that sterile storage for more than one year was possible.* Nonetheless it seems entirely inappropriate to me to keep in storage any sterile-wrapped item more than a few weeks; long-term storage represents an expensive, unused inventory. I recommend a considerably shorter time for safe use, to reduce both inventories as well as the chance of excessive handling of pouches causing cuts or tears in packaging. Three months would seem to be reasonable.

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*The 1981 CDC Guidelines for Hospital Environmental Control recommended that such types of wrappers (if heat sealed and, as indicated above, the press-on seal appears effective) should provide sterility for at least one year (*Infect Control* 1981; 2:143.).