

The Appropriate Testing Methods for OR Scrub?

To the Editor:

I have some comments to add to the article "*Serratia marcescens* contamination of antiseptic soap containing triclosan: Implications for nosocomial infections" published in the September 1984 issue.¹

The subject of this article is OR Scrub (Huntington Laboratories, Inc, Huntington, IN). The efficacy of OR Scrub as a surgical scrub and as a health care personnel handwash has been demonstrated by a number of in vivo studies such as the Peterson Glove Juice Test, the Price-Cade Basin Test, the Health Care Personnel Handwash Test, and specific clinical studies in the operating suite. Barry et al used in vitro modified preservative tests.¹

First, "the recent investigation" was conducted in late 1982 and early 1983 and was first reported at the May 1983 APIC poster session.² The authors found that 2 of 23 bottles of OR Scrub in use were contaminated with *Serratia marcescens* at 100 and 600 CFU/ml respectively. They also found "unopened bottles of the same lot were sterile" and "no infections could be attributed to contaminated soap in the ICU." They cite the literature as: "Several reports of intrinsic and extrinsic contamination of commonly used antiseptics and soaps such as chlorhexidine, hexachlorophene, and iodophors have appeared over the past decade." Apparently 2 of 23 bottles of OR Scrub did become contaminated under use conditions. Huntington concluded that OR Scrub needed a more effective preservative system.

In October 1983, Huntington began shipping OR Scrub with an improved preservative system; therefore, any OR Scrub now in use con-

tains the new preservative system and is not the product which is the subject of this article in the September issue.¹

OR Scrub is a surgical scrub and as such is used at full strength; it is not diluted prior to use. In fact, OR Scrub is an oil-water emulsion of antimicrobials, preservatives, surfactants, and emollients; it cannot be diluted with large amounts of water without breaking the emulsion into an oil layer and a water layer. Not only is the concentration of the antimicrobials and preservatives reduced when diluted, but the synergistic interaction of the oil-surfactant-antimicrobial system is destroyed also. In dilution the antimicrobial-preservative system may be in one layer and at least some of the microbial challenge in the other layer. Because of this separation, an accurate assessment of the preservative efficacy of the whole undiluted formulation cannot be extrapolated from tests on dilutions of OR Scrub. The USP Antimicrobial Preservative-Effectiveness Test protocol states "tests and standards apply only to the product in the original unopened container in which it was distributed by the producer."³ The other products, Hibiclens and Wash, reported in the article are not oil-water emulsions and do form homogeneous solutions upon dilution.

The real concern is the ability of OR Scrub as bottled (full strength) to rid itself of an outside contamination while in use. Barry et al reported in the Addendum to this article that their January 1984 work shows that the OR Scrub in use today (with the improved preservative system) surprisingly can be diluted 1:512 and still rid itself of a 15,000,000 organism/ml *Serratia marcescens* challenge within 24 hours; and that OR Scrub diluted 1:4 can rid itself of the same 15,000,000 organism/ml challenge within 1 hour.² Certainly a possible outside contamination challenge of 100 to 600 organisms/ml to

full strength OR Scrub is no longer a concern.

The Barry et al¹ modified preservative tests measure only a product's bactericidal properties; they do not measure a product's bacteriostatic or substantive properties which are very important attributes of a good surgical scrub. In vivo glove juice studies are the accepted protocols for measuring the efficacy of surgical scrubs. Glove juice studies show that OR Scrub is an efficacious surgical scrub.

Huntington is confident that OR Scrub is a good antimicrobial surgical scrub with pleasing cosmetic properties. Many hospitals have used OR Scrub successfully for 12 years.

REFERENCES

1. Barry MA, Craven DE, Goularte TA, et al: *Serratia marcescens* contamination of antiseptic soap containing triclosan. Implications for nosocomial infection. *Infect Control* 1984; 5:427-430.
2. Barry MA, Goularte TA, Lichtenberg D, et al: OR Scrub: Should It Be Used in Operating Rooms and Intensive Care Units. Association for Practitioners in Infection Control, Annual Meeting, Board 52, abstracted. San Diego, CA, May 1-5, 1983.
3. Antimicrobial preservatives-effectiveness. *United States Pharmacopeia* 1980, pp XX, 51, 873-874.

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To the Editor:

We have recently read the article by Barry et al concerning contamination of antiseptic soap containing triclosan. While we appreciate the authors' concern about potential nosocomial infection problems and also the importance of proper handwashing in hospitals, we have some concerns about their study and conclusions.

The subject of "proper handwashing" in health care institutions is one that entails considerable problems and complexities. As the authors point out in their article, handwashing in hospitals is often forgotten or performed inadequately. Also identified

in the article is the problem of bacterial or fungal contamination of handwash products themselves. Again, as they point out, handwashing products such as chlorhexidine, hexachlorophene and iodophors have all been found over the past decade to be contaminated with a variety of bacterial and fungal species. As a result of this study, a triclosan handwash product may be added to the list.

As members of the Indiana University Medical Center Infection Control Committee and one of us the Director of the Department of Hospital Infection Control, we have been concerned for many years about "proper handwashing" in our hospitals. Roughly 12 years ago we began addressing the problem of how to encourage hospital personnel to wash their hands when appropriate. We learned quite early in our efforts that a significant portion of the problem was due to irritation of hands by a variety of handwash products, particularly among nurses who wash their hands frequently as often as 50 or more times a day. We conducted a trial on several of our hospital care units where we had personnel use examples of most of the health care handwash products available. Each product was used for a period of several weeks, and at the end of the trials conclusions were obtained from those who tried the variety of products. OR Scrub was found to be, and has in subsequent similar trials, the one product least irritating to hands of all those tested.

Eager to encourage frequent and appropriate handwashing, we began to use OR Scrub on our Newborn Intensive Care Unit. We were aware, however, of concerns among the Food and Drug Administration about the lack of effectiveness of triclosan with respect to certain gram-negative organisms which might result in selection pressure toward such organisms. As a result, we performed extensive infection surveillance and environmental microbiological surveillance on this particular unit designed to determine whether or not OR Scrub in fact did result in selection pressure toward gram-negative bacterial nosocomial infections and/or gram-negative microbiologic contamination. After approximately one and one-half years of study we concluded

that use of OR Scrub definitely did not result in an increase of either gram-negative nosocomial infections or in gram-negative bacterial contamination of the environment of the hospital unit. At the present time, we have been using OR Scrub on our Newborn Intensive Care Unit for approximately 10 years without an associated gram-negative bacterial infection problem. While this information has not been published, it has satisfied our Infection Control Committee and the Director of our Newborn Intensive Care Unit.

We did, however, publish the results of a study comparing the use of the OR Scrub and a variety of other surgical scrub products in association with one of our orthopedic surgeons who was concerned about optimum infection control in his surgical cases.¹ All of the products tested were done so in actual surgical cases. Among our conclusions was one which indicated that all of the surgical scrub products, including OR Scrub, were effective in reducing the microbial flora on the hands and forearms of the surgical team to an acceptably low level and that choice of a surgical hand scrub product among those tested could be mostly a matter of personal preference. All of the products tested, including OR Scrub, were tested in association with careful surveillance of infections by the surgeon who maintained an incidence of infection of less than 0.5%.

The intent of this letter is to attempt to make infection control practitioners aware of some information that has led us, at least, to make substantially different conclusions concerning the efficacy of OR Scrub. Since the product was sterile when unopened and a very small number of contaminated containers (4) was identified we would strongly encourage a much more extensive investigation of this and other commonly used handwash products before issuing such a serious condemnation. This would be particularly appropriate in view of the fact that the manufacturer improved the product even before this publication. We have found OR Scrub to play a very important role in our efforts to encourage frequent and consistent handwashing and as a result plays an important role in our infection control program.

REFERENCES

1. Eitzen HE, Ritter MA, French MLV, et al: A microbiological in-use comparison of surgical handwashing agents. *J Bone Joint Surg* 1979; 61A:403-406.

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The authors of the article in question offer the following response.

Boyd raises several questions about the in vitro methods used to evaluate his company's product, OR Scrub, a handwashing agent containing 1% triclosan. The purpose of our investigation was to confirm our initial observation that "in-use" OR Scrub appeared to lack activity against *Serratia marcescens*, and to further evaluate the findings of other investigators that triclosan is ineffective against *Pseudomonas aeruginosa*.^{1,2} The in vitro data confirmed our suspicions and to our surprise, indicated that "Wash," a non-antiseptic soap also produced by Huntington Laboratories, had greater activity against *S. marcescens* and *P. aeruginosa* than OR Scrub.

In response to Boyd's concern about the use of dilutional methods for evaluating OR Scrub, we would point out that all ingredients (soap, water, and organisms) were well mixed throughout the experiments, and that OR Scrub is not used on dry hands in the hospital. Furthermore, more recent studies have revealed that direct inoculation of OR Scrub with *S. marcescens* failed to kill the organism. In the absence of specific data, it is difficult for us to comment on the other techniques listed by Boyd.

Apparently Huntington Laboratories was convinced enough by our findings to modify their product. We commend their efforts to improve the product and acknowledged this by adding an addendum to our manuscript after it was accepted for publication. However, the limited activity of the "modified OR Scrub" against *S. marcescens* at one hour, even in the absence of a neutralizer, remains a