Vesley, but rather only to question their efficacy predicated on a test pack that may not be appropriate for validating the operating efficiency of the sterilizer, let alone the efficacy of a device used in a vitally critical application.

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The authors reply

Dr. Belkin's letter raises an important issue relative to the simulation of in-use conditions in a steam sterilizer using the standard AAMI test pack. However, our purpose was not to validate the performance of the sterilizer, but to evaluate the new rapid readout indicator developed by 3M. Indeed, a denser and larger test pack could result in additional positive indicators at the times we tested, and we would hope that AAMI will continue to seek a standard pack that realistically simulates the actual in-use conditions of these sterilizers. We do not feel qualified to pass judgment on that issue at this time.

Using the currently recommended AAMI test pack, we believe that we have demonstrated conclusively that the new biological indicator (BI) is significantly more sensitive in detecting failures of the sterilizer to maintain the prescribed time and temperature parameters than any other indicator on the market and that it can do so in a much shorter time. It was our observation that the vacuum-assisted sterilizer that we used in our studies rendered all of the tested BIs negative (killed all the spores) in a considerably shorter time than the recommended cycle. Indeed, we had some negative BIs even at zero time. Perhaps this would compensate for the lesser density of the test pack.

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FDA Labeling Requirements for Disinfection of Endoscopes: A Counterpoint

To the Editor:

I would like to offer the following commentary in response to Dr. William Rutala's article, "FDA Label Requirements for Disinfection of Endoscopes: A Counterpoint."[1]

Drs. Rutala and Weber suggest that "The FDA should modify the label of the liquid germicide that requires a 45-minute immersion at 25°C to support a high-level disinfection claim. Their recommendation is for the label to state, "if cleaning is accomplished using a standard cleaning protocol, then a 20-minute immersion at 20°C will be sufficient." Their conclusions are based on the fact that investigators found that cleaning alone reduces the microbial load enough to allow such a reduction in time and temperature. No doubt, when flexible endoscopes are properly cleaned, as would be the case when an investigation or research project is undertaken, the findings would be verified.

But—and it is a big but—under less controlled conditions, such as in a busy hospital or private practice, cleaning is much less adequate. This was demonstrated clearly in an article published in 1992 in the *American Journal of Medicine*.[2] The authors draw very different conclusions from their review of actual processing of endoscopes. Through interviews and observation, they found fundamental errors in the cleaning. They also found that 23.9% of bacterial cultures obtained from the internal channels grew ⩾100,000 colonies after cleaning and disinfection of the scopes. This occurred when personnel knew they were being interviewed and observed; infection control personnel can only guess what happens when no one is checking.

But, even when personnel process these instruments conscientiously and to the best of their ability, they may not achieve the cleanliness they strive for; the structure and materials of the endoscopes hinder efforts for effective cleaning. These conclusions and concerns are voiced in the APIC Guideline for Infection Prevention and Control in Flexible Endoscopy.[3,4]

I oppose having dual label instructions for disinfection, one for instruments that are adequately cleaned and another when adequate cleaning is not achieved. First of all, no one would recognize or want to admit, even to themselves, that they are not adequately doing what they are supposed to be doing. And second, when they see the 20-minute, 20°C instructions, they may read no further.

There is a third reason I oppose such labeling. If the manufacturer feels 45 minutes' immersion at 25°C is necessary, we should not reduce the time. If anything, the time should be increased to allow for errors. And up to now, no one has yet explained to my satisfaction why the 25°C temperature is listed by the manufacturer, and yet 20°C is recommended by Drs. Rutala and Weber. I hope readers will remember, from articles I have published

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previously, that 25°C, or 78°F, is achievable *only* by heating the solution. This can only be accomplished safely in an enclosed machine that cools the liquid before the machine is opened. If the manufacturer recommends 25°C for 45 minutes' immersion, if we use a reduced temperature of 20°C (68°F to 70°F), then should not the immersion time be extended to achieve the same result?

Although I have the utmost admiration and respect for Dr. Rutala, I disagree with his and Dr. Weber's recommendations for dual labeling unless each person who allows the 20-minute immersion at 20°C is 100% certain that the endoscopes in their healthcare facility are impeccably cleaned every time they are used. Even that may not be enough until the structure and materials of these instruments are improved to facilitate and guarantee adequate removal of microorganisms if the instrument is cleaned properly.

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To the Editor:

Rutala and Weber (April 1995 issue) provide a thoroughly researched rationale for their proposal that Cidex (Johnson & Johnson Medical Inc) be considered to produce high-level disinfection of cleaned endoscopes after a 20-minute immersion at 25°C. Do they extend this proposal to all glutaraldehyde preparations achieving a sterilant and tuberculocidal label claim, regardless of the exposure time required to produce 100% *Mycobacterium* tuberculocidal activity? Do they extend this proposal to all other disinfectants with a tuberculocidal and sterilant claim? Would they extend this proposal further to bleach or pasteurization, neither of which are likely to achieve FDA registration?

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The authors reply

In response to Ms. Gurevich's comments, we agree that proper cleaning of endoscopes following each use is a critical and essential step that must precede high-level disinfection and sterilization. All hospitals should adhere rigorously to a standard cleaning protocol.[1] As noted in our paper, high-level disinfection without proper cleaning, even with a 45-minute immersion at 25°C, is not an acceptable practice.[2] We do not believe that having dual label instructions would be confusing, because longer immersion times at a higher temperature would be advised only for the unusual circumstances when cleaning of the endoscope was delayed or performed improperly. Although there is a direct relationship between improved tuberculocidal activity of glutaraldehydes and elevated temperature,[3] excellent tuberculocidal activity has been demonstrated at 20°C temperature (see Table 2 of our paper). Specifically, these studies demonstrated that glutaraldehyde solutions inactivated 4.0 to 6.4 logs of *Mycobacterium tuberculosis* at 20 minutes.

We also believe that longer immersion times at a higher temperature may have several adverse outcomes, including the potential hazard to hospital personnel resulting from higher ambient air levels of glutaraldehyde that may result from use of higher temperature soaks, the increased possibility of chemical colitis in patients due to release of glutaraldehyde from endoscopes subject to more prolonged immersion (ie, prolonged immersion at high temperature may result in absorption of glutaraldehyde by scope material),[4] decreased equipment life expectancy due to moisture damage or corrosion, and increased cost of endoscopic procedures due to increased processing time.

In response to Dr. Rhame's questions regarding the extension of our proposal to other chemical sterilants with a tuberculocidal and sporicidal claim (eg, other 2% glutaraldehydes, 6% hydrogen peroxide), we offer the following comments. Chemical sterilants, prior to having their tuberculocidal label claim cleared by the Food and Drug Administration, should be shown to inactivate reliably at least 5.0 logs of *M tuberculosis* (and other microorganisms, with the exception of bacterial endospores) within 20 minutes at 20°C. Based on current data, all 2% glutaraldehyde preparations should possess similar tuberculocidal activity.[5,6] However, because of the risk of approving an ineffective agent, the tuberculocidal claim for each agent should be independently verified. Any agent or process that is demonstrated scientifically to achieve the above tuberculocidal activity (ie, >5-log reduction) following proper cleaning, is safe for use on endoscopes and other semicritical medical devices, and does not represent an occupational hazard could be an acceptable alternative to glutaraldehyde.

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