## Editorial

# Strategies for Disinfection and Sterilization of Endoscopes: The Gap Between Basic Principles and Actual Practice

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In this issue of *Infection Control and Hospital Epidemiology,* Drs. William Rutala and Geoffrey Gorse and their co-workers report results of their surveys in North Carolina and the United States, respectively, on methods used to clean and disinfect or sterilize flexible fiberoptic endoscopes and other medical devices.[1,2] Both surveys showed a wide variety of practices and procedures for reprocessing medical instruments that require, at the very least, high-level disinfection. Under ideal circumstances, some of the medical devices discussed (e.g., "critical" instruments such as laparoscopes, arthroscopes, and biopsy forceps) should be sterilized between uses. A substantial proportion of these practices, however, even when high-level disinfection is the chosen method of reprocessing, is not consistent with current recommendations of the infection control community. This editorial comments on some of the implications of these two surveys regarding the potential for infection transmission in hospital settings.

In the United States, disinfection and sterilization procedures for medical devices are influenced by a number of organizations. The Environmental Protection Agency (EPA) regulates chemical germicides formulated as disinfectants or sterilants and approves claims made on the labels of these products. The Food and Drug Administration (FDA) regulates medical devices and approves the label claims regarding the use, safety, and efficacy of the devices; the FDA also approves sterilants or disinfectants recommended by the manufacturer for use in the operation or reprocessing of the devices. The Centers for Disease Control (CDC) publishes guidelines on strategies for disinfection and sterilization of medical devices, and professional organizations, such as the Association for Practitioners in Infection Control, recommend similar strategies and procedures.

Almost 30 years ago, Dr. Earl Spaulding proposed that medical devices could be grouped according to risk of infection during their use. He also recommended generic categories of chemical germicides based on germicidal potency that should be used on the different categories of medical devices. Briefly, devices that penetrate skin during use (e.g., surgical instruments) should be sterilized between uses; devices that touch mucous membranes during use (e.g., flexible endoscopes and anesthesia breathing circuits) should either be sterilized or, at a minimum, receive high-level disinfection; and devices that only touch intact skin (e.g., blood pressure cuffs and stethoscopes) should be disinfected with intermediate or low-level germicides or simply cleaned with soap and water, depending on the device and the degree of contamination.

In the context of these categorizations, Spaulding not only defined the terms "sterilization" and "high-level disinfection," but also characterized attributes of the "sterilants" and "high-level disinfectants." These concepts have been accepted widely by the infection control community and have been incorporated into the guidelines of CDC as well as many medical specialty organizations. Sterilization is defined as a

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***Favero MS. Strategies& disinfection and sterilization of endoscopes: the gap between basic principles and actual practice.*** Infect Control Hosp Epidemiol. *1991;12:279-281.*

procedure that inactivates all microorganisms, including high numbers of resistant bacterial spores, resulting in a device that is free of living microorganisms.

Drs. Rutala and Gorse and co-workers report that very few institutions sterilized either flexible fiberop tic gastrointestinal endoscopes that come into contact with patients' mucous membranes or rigid endoscopes that penetrate to sterile areas of the body. The minimal procedure recommended for reprocessing all types of endoscopes is high-level disinfection, which Spaulding defines as a procedure that inactivates all fungi, viruses, and vegetative microorganisms, but not necessarily all bacterial spores.

The specific attributes of chemical germicides that should be used to accomplish high-level disinfection are very clear. Specifically, the germicide should be very powerful and approved by EPA as a sterilant/disinfectant. In other words, healthcare workers should choose from among chemical disinfectants that the EPA has approved for sterilization when the contact time is relatively long (i.e., six hours to ten hours), and for disinfection (by the Spaulding definition, "high-level" disinfection) when the contact time is much less (i.e., ten to 30 minutes).

As clear as these recommendations and definitions are, and as long as they have been accepted in the infection control community, there appears to be an abundance of confusion about them, and this is especially true with practices for reprocessing endoscopes. These two reports highlight numerous practices that have become institutionalized over the years but are not supported by any scientific rationale or endorsed by the infection control community. Clearly, medical devices designed to penetrate skin or contact normally sterile areas of the body should receive a sterilization process. The vast majority of rigid endoscopes and flexible endoscope biopsy forceps are not being sterilized between uses. Rather, they are being subjected to a much less rigid procedure of high-level disinfection. Even here, seemingly adequate protocols labeled as being high-level disinfection may fall far short of that goal which, as mentioned before, is the absence of fungi, viruses, and vegetative microorganisms. For example, endoscopes can be cleaned and exposed for an adequate period of time to a high level disinfectant, but then rinsed with tap water, thereby contaminating the device again with a variety of waterborne microorganisms. This practice alone was reported by 48% to 54% of institutions in these two studies.[1,2]

Although the concentration and contact time of the chemical disinfectant are important, advertising claims by a number of manufacturers of disinfectants for medical devices carry an almost subliminal recommendation to use the chemical germicide in a low concentration and for the shortest possible contact time. Presumably shorter contact times and less potent germicides are perceived as eliminating the risk of residual toxic chemical exposure to the patient, the healthcare worker, and even the environment. This rationale can be a problem because endoscopes in general and flexible fiberoptic devices in particular, are not optimally designed for adequate cleaning before the disinfection step, which necessitates the use of a germicide having high potency.

Additionally, the consistent efficacy of these procedures is in question. My colleague, Walter W. Bond, in a presentation before the American Society for Microbiology's International Symposium on Chemical Germicides in July 1990, stated that virtually all flexible fiberoptic endoscopes sold in the United States are so designed that the users cannot be assured that these instruments have been adequately cleaned prior to disinfection. To illustrate his point, he showed several photographs taken with a small rigid endoscope of the inside of flexible gastrointestinal endoscopes after they had been cleaned and disinfected according to the endoscope manufacturer's recommendations. Even after meticulous cleaning and disinfection, the channels of these endoscopes still contained body substances (e.g., feces and blood) from a patient or patients on whom the device had been used.

He further pointed out that the manufacturers of these devices, in spite of the fact that FDA regulations so state, do not provide users with precise, data-based information on cleaning methods, or on the types of germicides and accessory devices to use when reprocessing devices. As indicated by 58% of the respondents in the survey by Rutala et al,[1] another common practice not supported by scientific rationale is sterilizing rather than disinfecting a device after it has been used on a patient infected with hepatitis B virus or human immunodeticiency virus. I do not know how to interpret this type of practice except that the practitioner must believe the usual reprocessing procedures are not adequate, and that when there is a "known" potential for infection transmission, the device should be sterilized. If that were true, then these devices should be sterilized at all times; there are a number of infection control practitioners and microbiologists who, at the various seminars and meetings of professional societies, have expressed this view.

In the face of all these considerations, it is evident that the medical specialty and infection control communities do not really know the exact risks or the current extent of infection transmission by these devices. I agree with the conclusions in these two papers and concur that the time for surveys and anecdotal observations is over. If the extent to which

patients are at risk from these procedures is to be adequately defined, well-designed prospective studies involving sensitive and targeted infection surveillance of patients must be conducted.

These studies must take into account the fact that most endoscopic procedures are done on an outpatient basis. Furthermore, there is a clear need on behalf of the infection control community to educate healthcare professionals responsible for performing disinfection and sterilization procedures. The FDA needs to direct, under its existing authority, the manufacturers of these devices to provide clear, data-based instructions for reprocessing. Specifically, these instructions should include effective and implementable methods for cleaning, disinfecting, and sterilizing. They should direct germicide manufacturers to provide specific directions on using germicides marketed for use on specific medical devices.

In summary, a huge gap exists between what is generally recommended for reprocessing endosopes and other medical devices and what is practiced. If this were an area of science complicated by high technology, perhaps I could understand the extent of this gap. The recommended practices, however, are all rather basic, and as Dr. Rutala and co-workers point out in their report,' Spaulding's classification scheme is so logical that it has been used for many years in disinfectant guidelines; it is a very simple and consistent approach to instrument sterilization or disinfection. It is the responsibility of the infection control community to educate its constituency and influence government agencies to respond to this problem by exerting their regulatory authority.

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https://doi.org/10.1086/646339 Published online by Cambridge University Press