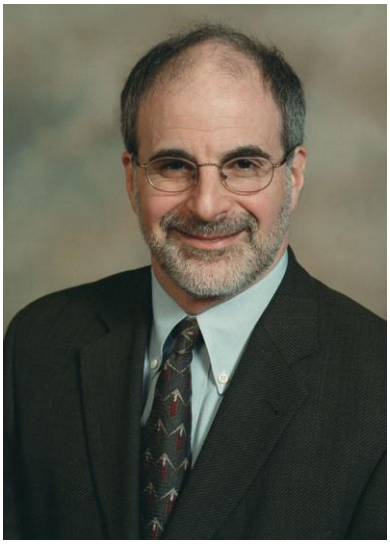

Robert Wise, M.D., Vice President of the Division of Standards and Survey Methods at The Joint Commission

Robert Wise, M.D., is the vice president of the division of standards and survey methods at The Joint Commission. In this position, he is responsible for the development of all standards and survey methods for current and new accreditation programs. Additionally, in response to emerging critical issues in health care quality and safety, Dr. Wise conducts research to assess the value of creating or modifying accreditation standards. He earned his medical degree from the University of Maryland School of Medicine and holds board certification from the American Board of Psychiatry and Neurology.

In an interview with the Academy, Dr. Wise explained the genesis of the Joint Commission's updated statement on steam sterilization, its significance to ophthalmologists and proper technique to ensure compliance. The full statement from the Joint Commission can be found here. http://www.jointcommission.org/Library/WhatsNew/steam_sterilization.htm.

Interview with Dr. Wise about the Joint Commission's Updated Statement on Steam Sterilization

Q: A good place to start is to acknowledge that there has been concern and confusion about the interpretation of standards and survey process regarding sterilization in ophthalmic facilities. How did the Commission come to look into this problem?

Robert Wise: A little over a year ago, an accreditation survey of several ambulatory eye clinics found that steam sterilization was the only method of sterilization being used for surgical instruments. Following discussions with the organizations, we talked with the CDC about this practice, which appeared to be outside of compliance with the current disinfection and sterilization guidelines.

Q: So it sounds as if this problem was particularly an issue for ophthalmologists as opposed to other physicians.

RW: They were just the tip of the iceberg. We began our own research to understand if this practice involved a small number of surgical centers or if it was widespread. We found the use of steam sterilization as the predominant and sometimes the sole source

of sterilization was not uncommon. There also appeared to be some other clinical areas such as oral surgery that at times used a similar practice. We then understood it was a common practice in the country, and so we decided to do more research into the issue.

Q: How did the Joint Commission come to its latest position on steam sterilization?

RW: We had a number of discussions with clinicians and scientists interested in the issue. We engaged a number of experts at both the CDC and FDA to understand the rationale for the existing guidelines and how they relate to the use of steam sterilization throughout the country. As we began to better understand the issue, it was apparent that an *effective process* was *dependent on* more than just the method of sterilization. We realized that we needed to broaden our view to include the entire process of disinfection and sterilization, starting with dirty instruments leaving the OR, how they are disinfected and sterilized and finally the process of their return to the OR.

The recently released Joint Commission position on steam sterilization includes all of these aspects. There are three processes that surveyors will now be reviewing: the cleaning and decontamination of instruments, the process of sterilization of those instruments, and the storage of the instruments and return of the instruments to the sterile field.

Q: Why is it important not to use the term flash sterilization?

RW: When you read our new position, you'll note it is called the Joint Commission position statement on steam sterilization. Over the last several decades the term "flash sterilization" has come to describe lots of different processes. Its specificity has been lost. There is another term being used, "rapid cycle sterilization." We also do not use that term because it too is not particularly descriptive and we believe it also will cause confusion.

As we began to talk with the different participants, we understood that the term flash sterilization has a very specific technical definition. It describes sterilizing unwrapped instruments at 270 degrees at three minutes at a pressure of 28 pounds. It became clear that there are many different processes in use in the field and all of them were being called flash sterilization. Few of them met the original flash sterilization criteria as described in the CDC guidelines.

The technique of flash sterilization is still a useful one. It's common that in the middle of a surgical procedure a unique instrument will fall on ground and need to be flashed.

That is a legitimate way to use flash sterilization as it is described in the CDC guidelines.

Q: What are some examples of protecting instruments from recontamination during the transport to the sterile field?

RW: The instrument can be wrapped or placed in a hard container or covering. There are a number of these devices available, depending on whether you intend to use the instruments immediately or store them for some period of time. All of these methods allow instruments to be safely transported from the sterilizer to the sterile field. An unwrapped instrument moved from the sterilizer to the surgical field can present an infection-control problem, especially if you have to transport it a long distance or through a potentially contaminated area. When unwrapped instruments need to be processed, it is common to keep the distance between the sterilizer and the OR short and only pass through reasonably clean areas.

Q: Can you describe in detail what Joint Commission surveyors will be looking for as they evaluate the sterilization process for ophthalmic instruments?

RW: We are now in the middle of taking a look at these three steps to create a standardized process that will be integrated into the survey process.

Q: What happens if the facility does not meet the criteria? What opportunities do they have to make amends?

RW: Improper sterilization of surgical instruments can be a serious issue. An organization that does not sterilize instruments properly is potentially directly harming patients. Depending on how serious the breach is, the organization could be expected to immediately fix the problem. For a not-so-serious breach, there would be 30 days to make changes to the process.

Q: Why is it so important to follow the manufacturer’s recommendations for cleaning instruments and using the sterilizer?

RW: Let’s focus on the sterilizer for a moment, because these devices will become one of the focuses of the survey process. We’re realizing that often the documentation for the use of the machine has been lost or for some reason is no longer available. Not having ready access to the specifications of the sterilizer can produce a number of significant issues. Say the organization has been using a sterilizer for three or four years and over that time multiple people have been assigned the task of operating the

sterilizer. Often the new operator is trained by the current operator. If no document exists, how does anyone know if the new operator is being trained properly, or even if the current operator is appropriately using the machine? How would a question be answered if someone asked about how to handle a novel situation? Clearly it is important that the organization knows the specs of their machines and trains operators accordingly. The machine is effective only if you follow the specs.

Q: What are the key take-aways for ophthalmologists?

RW: Steam sterilization is a broader issue than ophthalmology, but obviously very relevant to those surgeons. The process of disinfection and sterilization really is an integrated process, and all the steps, starting with the instruments leaving the OR to returning to the OR, need to be thought through and standardized. Anyone involved in that process needs to be properly trained. Sterilization is such a critical part of a sound infection control and prevention program that some kind of oversight by the organization should be ongoing, not for the Joint Commission, but for the health and safety of patients.

Q: Is there anything in the statement that will surprise doctors and make them step back?

RW: Anybody who has been part of infection control and prevention will not be surprised at any of these steps. The only area that we believe may require some effort by organizations is making sure that the documentation for their sterilizers is readily available and routinely used in training. Organizations need to be able to demonstrate that they are operating within the specs and are training operators within the specs. We believe the process described in our recently released document is quite reasonable and follows basic infection control prevention practices.

Q: Anything you'd like to add?

RW: I do want to give a plug for ophthalmologists. The clinicians with whom I spent the most time discussing this issue of steam sterilization were the ophthalmologists. I have found the group to be very forthcoming and easy to work with. They were patient and supportive as the Joint Commission did the necessary research. Working with this group of surgeons was not only a pleasure but also highly informative.

Approvals

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