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**Learning Objectives**

1. Discuss the various classes of chemicals available for disinfection and sterilization
2. Explain the benefits and variations among formulated chemistries
3. Describe the latest oxidizing chemistries and processes and their advantages for disinfection and sterilization
4. Discuss the importance of labeling and instructions for use

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# Oxidative chemistries for disinfection and sterilization

by Gerald McDonnell, BS, PhD

**D**isinfection and sterilization practices help ensure that surfaces and materials are safe for human use (McDonnell & Sheard, 2012). In healthcare environments these practices are applied for uses such as disinfection of the hands or skin (often referred to as antisepsis), disinfection of various environmental surfaces (e.g., bedside tables, bed rails and other patient contact surfaces), treatment of water or other fluids, and for sterilization of surgical/invasive devices. They all focus on removing or inactivating microorganisms; particularly those pathogens that can cause harm to patients or staff. A number of methods can be used, and they are usually classified as being physical (e.g., the use of heat or radiation) or chemical (Block, 2000; McDonnell, 2007; HICPAC, 2008).

There are several types of chemicals that can be used to inactivate microorganisms. These include alcohols, aldehydes, phenolics, quaternary ammonium compounds, halogens (e.g., chlorine and iodine) and oxidative chemistries. Many traditional types of chemical-based disinfectants and sterilants such as glutaraldehyde, orthophthalaldehyde (OPA), formaldehyde and ethylene oxide (ETO, EO) are being used less in modern facilities due to practical, safety and, in some cases, efficacy concerns such as:

- Long cycle times (sometimes up to 18 hours) and stricter staff safety guidelines for the use of ETO sterilizers (OSHA Regulation 29 CFR 1910.1047)
- Patient toxicity reports of residual levels of glutaraldehyde and OPA on reusable devices (Farina et al, 1999; Anderson et al, 2010)
- Risks of biofilm development and promotion in devices disinfected with aldehyde-based chemicals (Alfa & Howie, 2009)
- The development of bacterial resistance to aldehydes such as glutaraldehyde and OPA (Duarte et al, 2009; Fisher et al, 2012).

These issues have led to new types of disinfectants and sterilization processes that help reduce safety risks and provide

efficient processes that better meet the needs of healthcare facilities. This lesson discusses the basic types and uses of oxidative chemistries, which are being widely applied for these purposes.

**Chemicals used for disinfection/sterilization**

Disinfection has been defined as having three levels: low, intermediate and high-level disinfection (HICPAC, 2008). Other terms that are used to describe disinfection processes are antisepsis, sanitization, fumigation and sterilization. Sterilization is a different term, referring to the elimination of all microorganisms (with 'sterile' meaning 'free from living microorganisms').

There are many chemicals that can be used to kill microorganisms on surfaces, but typically only a few are widely used (Block, 2000). There are several reasons; some have limited efficacy against certain types of harder microorganisms, and some have safety issues, for the patient, devices, staff (using the chemicals) and/or the environment. As an example, a chemical at high concentrations can be very effective against many types of microorganisms, but if it significantly damages devices it has little practical use. Another example, glutaraldehyde, has been widely used due to its antimicrobial efficacy and compatibility with device materials, but it also can be difficult to remove from device surfaces (sometimes requiring up to 5 fresh water rinses), and has been highlighted as a patient safety (toxicity) concern.

**Formulation and process**

Furthermore, the antimicrobial chemical itself is not the only safety or efficacy factor. Other factors, such as a product's complete chemical formulation and how it is used in a disinfection or sterilization process, may also have an effect.

A chemistry formulation includes the combination and amounts of ingredients, including antimicrobials and other content, that go into a product for its intended use. It

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is rare to see an antimicrobial chemical used alone; it is more likely to be formulated with a variety of other ingredients that can assist with optimizing chemical activity, minimizing surface damage, ensuring an adequate shelf life, and improving effectiveness in varying water qualities. What this also means is that different disinfectant products will have variations in antimicrobial effectiveness, surface compatibility, activity in the presence of water, and safety profiles, among other things. For this reason, it is important to review each product's labeling and other data, rather than depending solely on the presence of a certain concentration of the antimicrobial chemistry.

In addition to formulations, process factors including temperature, exposure time and the method of exposure will impact the activity and compatibility of a disinfectant on a surface. Although these variables can often be automatically controlled by reprocessing machines such as washer-disinfectors, the machine itself needs to be used and maintained properly to assure reliable control for every cycle.

The key to understanding these factors is to read and understand the labeling and literature provided with each disinfectant or process. Because of all the factors that can impact disinfection, it is wise to use a registered product for this purpose. In the United States, chemical products used for environmental surfaces should be registered by the US Environmental Protection Agency (EPA) and those for the reprocessing of medical devices are required to be registered with the US Food and Drug Administration (FDA). Similar, but often distinct, registration requirements are required in other countries and/or regions.

## What are oxidizing chemistries?

Oxidizing agents are a class of chemicals that have the ability to remove oxygen from a molecule (in a process called 'oxidation'). Many molecules play an important role in the structure and function of life, including microorganisms, and the removal of oxygen can lead to the loss of structure and function of the various components that make up life (such as proteins, lipids and nucleic acids; McDonnell, 2007). Examples of oxidizing agents include the halogens, such as *chlorine* (the major antimicrobial in bleach solutions) and *iodine* (e.g., used in iodophor-based products such as antimicrobial surgical skin preparations). Chlorine is one of the most widely used disinfectants for general environmental surfaces, while iodine is also used for this purpose and on the skin. Neither is routinely used as a disinfectant or sterilant

of medical devices, although chlorine is the important disinfectant in 'activated-water' systems (where an electric current is added to water to create active chlorine) for high-level disinfection of some devices (Sampson & Muir, 2002). The most widely used disinfectants for such applications use other oxidizing agents such as *hydrogen peroxide* and *peracetic acid*. They are also referred to as 'peroxygens.'

Hydrogen peroxide is one of the more common oxidative liquids used for cleaning and disinfection applications (Block, 2000). It is practically odorless and colorless. Typical concentrations range from 1 to 6% in water (e.g., 6% peroxide, 94% water). Although these solutions can inactivate many microorganisms, they have limited activity against some bacteria (e.g., mycobacteria), viruses and bacterial spores. High concentrations of hydrogen peroxide can be more effective, but they pose other safety risks and are more aggressive on surfaces, which limits their use. The effectiveness of low concentrations can be dramatically improved by careful formulation. In the last 20 years hydrogen peroxide gas has been used as an alternative because it is more effective at low concentrations and less aggressive on surfaces (depending on how it is used). Peroxide gas (also applied as a vapor) can be used for disinfection and sterilization purposes. It has been shown to be effective against a wide range of microorganisms such as bacteria, viruses, bacterial spores and fungi. There are also reports documenting its effects against prions (Fichet et al, 2007). Another benefit of hydrogen peroxide is that it readily breaks down into water vapor and oxygen, two beneficial by-products found in the natural environment.

Liquid peracetic acid is also used for disinfection and sterilization (Block, 2000). It is a very effective antimicrobial agent at low concentrations (e.g., 0.1%), even against bacterial spores. It is also colorless in solution and has a pungent vinegar-like odor. As the concentration increases it can have a stronger odor and be more aggressive on surfaces. For these reasons, formulation and process control are very important to ensure its optimum use. Peracetic acid has also been used in gas form, but rarely, because of surface compatibility and safety concerns. Liquid or gaseous peracetic acid readily breaks down to water and a low concentration of acetic acid (vinegar).

Other oxidative examples include *chlorine dioxide* (not to be confused with the chlorine discussed above) and *ozone*. Both can be very effective antimicrobials in liquid or gas

form, and are widely used for water disinfection applications. Ozone gas is a very effective antimicrobial at low concentrations, and is used for air disinfection. At higher, controlled concentrations it is also used for sterilizing devices. However, ozone is considered very reactive on surfaces, so device surfaces must be evaluated for compatibility with the process.

## Disinfection advances

New types of disinfectants and disinfection processes based on oxidizing agents have been developed in recent years. Hydrogen peroxide formulations have been developed for general area disinfection and for high-level disinfection of reusable devices (such as flexible endoscopes). For environmental surfaces, products use relatively low levels of peroxide, and some are formulated with other ingredients for optimal effectiveness. They are available in a variety of forms, including concentrates, impregnated wipes and ready-to-use solutions.

For device disinfection, there are formulations ranging in peroxide concentrations from 2 to 8 percent on the market today. These formulations are usually designed for multiple disinfection cycles, and are used in combination with chemical indicators/test strips to ensure they are at the correct concentration for each use. Recent advances in oxidative technology have allowed the development of formulations for rapid high-level disinfection at low concentrations (e.g., 8 minutes using 2% 'accelerated' hydrogen peroxide), which are safe for use even with very sensitive devices, such as flexible endoscopes.



**Figure 1:** Examples of hydrogen peroxide-based liquid disinfectants, including environmental surface disinfectants (left), and reusable liquid disinfectants.

In addition to advances in hydrogen peroxide chemistries, a number of peracetic acid-based high level disinfectants have been developed recently as reprocessing alternatives. These vary in formulation, concentrations, antimicrobial claims and compatibility statements. Material compatibility in particular will differ from product to product, so manufacturer's recommen-

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dations and instructions for use should be read in detail.

An overall advantage of oxidative chemistries can be their ability to remove residual levels of soil, due to some intrinsic cleaning activity. Cleaning is always required before disinfection or sterilization (regardless of the process and chemistry used), but low levels of patient residual (e.g., proteins) can often still be found due to inadequate cleaning and the use of chemicals such as aldehydes (glutaraldehyde or OPA) that can fix such materials onto surfaces when they contact them. These materials can build up over time and can also lead to the development of biofilms. Biofilms are communities of microorganisms that grow on surfaces and can protect themselves from disinfectants (McDonnell, 1997; AMMI ST58, 2010). Close attention to cleaning and the use of oxidative chemistries for disinfection can reduce the risk of biofilm development on reusable devices.

## Importance of “labeling”

It is important to note that all current USFDA and EPA registered disinfectants and sterilants are required to have detailed instructions for use and labeling stating their recommended applications. Care should be taken to read and understand all claims and instructions for use, to ensure the most correct, safe and effective application of each product. For example, some products will only be labeled (and registered) for use on environmental surfaces, while others are specifically designed for use with medical devices.

## Sterilization advances

Some traditional low-temperature sterilization methods, such as those based on humidified ethylene oxide, are being used less today, due to safety concerns and the fact that these processes have a long cycle time that slows down the turnaround of reusable devices. Oxidative processes are proving to be safer and more efficient for sterilization.

Sterilization is not just the ability to be able to inactivate all types of microorganisms, including the more resistant forms such as bacterial spores; it is a defined and controlled process. The requirements for sterilization processes are stated in standards such as AAMI ISO 14937 and guidelines such as those in FDA 2000. All new liquid or

gas-based chemical sterilization processes, such as those shown in Figure 1, should be compliant with these requirements.

The most widely used liquid chemical sterilization process uses formulated peracetic acid under controlled temperature conditions. Devices processed in this system are chemically sterilized using the peracetic acid liquid chemical sterilant, and then rinsed with extensively treated potable water.

A wider range of gas-based processes have become available, using hydrogen peroxide or ozone. An ozone sterilization process is conducted under vacuum (low pressure) and consists of three phases: conditioning, sterilization and ventilation. Sterilization is achieved at ~35°C (95°F) in the presence of humidified ozone (high humidity is essential for the sterilization process). The ozone is oxygen-generated and breaks back down to oxygen. However, the overall process can be long (cycle times of up to six hours) and it is incompatible with certain types of device component materials.

Hydrogen peroxide gas systems employ two types of processes to achieve sterilization; gas alone or gas with plasma. They all proceed through three basic phases: conditioning, sterilization and aeration. Although these two types of processes seem similar, the sterilization systems have distinct differences and can also vary in safety, efficacy and material compatibility (McDonnell, 2007). In all cases, cleaned, dried and packaged devices are placed into a chamber for sterilization. The sterilization process consists of repeated exposure to hydrogen peroxide gas (that can vary in temperature, saturation and concentration) under vacuum (or low pressure); this ensures the removal of air and contact of the chemical process to device surfaces. The number and length of gas exposures, and the process temperatures can vary. Today, typical cycle times range from 30-60 minutes (depending on the sterilizer design and load), which is a significant improvement over traditional ethylene oxide sterilizers.

Plasma is used in some of these systems as part of the sterilization process, but not

necessarily for any significant antimicrobial benefit. For example, during a typical hydrogen peroxide gas plasma process, the peroxide gas is used to sterilize the load but the gas is then removed from the chamber and then plasma is excited

by applying energy. This “excited gas” breaks down and removes any peroxide residuals that remain. The device compatibility and claims associated with these sterilizers can vary significantly. Care should be taken to understand manufacturer’s claims and instructions for reprocessing (including device preparation, types of device materials, compatible and registered packaging materials, and lumen lengths/diameters). Particular attention should be given to any lumened devices, as these can be particularly challenging for any sterilization process (including steam, ethylene oxide and alternative low temperature processes).

## Make an educated choice and use with care

Traditional low temperature disinfection (e.g., liquid glutaraldehyde or OPA formulations) and sterilization (e.g., humidified ethylene oxide) processes are becoming less acceptable for clinical use due to safety and efficacy concerns and time constraints. In the search for alternatives, oxidizing chemistries have been shown to have many advantages for such applications, including broad spectrum antimicrobial activity, device materials compatibility, ease of preparation and use, environmental benefits and reasonable costs. A range of alternative disinfection and sterilization products and processes have been developed based on these advantages. It is important to understand these methods based on their individual label claims and registrations, since they can vary in safety, efficacy and use application (such as process or exposure times, installation requirements, preparation requirements and restrictions).

A few words of caution are also needed. Despite the many advantages of oxidative chemistries, disinfection and sterilization of reusable devices can only be assured after completing a thorough cleaning process. In addition, these oxidative chemical processes are designed to inactivate microorganisms and should be handled with respect and care. Although they can be considered ‘safer’ than traditional chemicals, they should not be considered completely harmless since they have the potential to cause harm under certain circumstances. However, with careful use, oxidative formulations and processes can provide many advantages to staff and patients as alternatives for disinfection and sterilization in clinical practice. **HPN**

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**Figure 2:** Examples of hydrogen peroxide vapor (left) and liquid peracetic acid (right) oxidative chemical sterilization processes.

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# Oxidative chemistries for disinfection and sterilization

Circle the one correct answer:

- Which of the following is true about disinfection and sterilization practices?**

  - A. They help ensure that surfaces and materials are safe for human use.
  - B. They are performed to disinfect the hands or skin, remove microorganisms from various environmental surfaces, treat water or other fluids, and to reprocess surgical/invasive devices.
  - C. They all focus on removing or inactivating pathogens that can cause harm to patients or staff.
  - D. All of the above
  - E. A and C
- Glutaraldehyde, orthophthalaldehyde (OPA), formaldehyde and ethylene oxide (ETO, EO) are being used less in modern facilities due to:**

  - A. Safety and toxicity concerns
  - B. Risk of biofilm development and promotion in devices disinfected with aldehyde-based chemicals
  - C. Being older chemistries
  - D. The development of resistance to glutaraldehyde and OPA
  - E. A, B and D
  - F. All of the above
- An antimicrobial chemical is more likely to be formulated with a variety of other ingredients that can help optimize chemical activity, minimize surface damage, ensure an adequate shelf life, and improve effectiveness in varying water qualities.**

  - A. True
  - B. False
- Oxidizing agents:**

  - A. Have the ability to remove oxygen from a molecule by oxidation
  - B. Are all peroxygens
  - C. Can cause the loss of structure and function of proteins, lipids and nucleic acids
  - D. Include hydrogen peroxide, peracetic acid, chlorine dioxide and ozone
  - E. A, C and D
  - F. B, C and D
- The formulation of a liquid disinfectant and process factors such as temperature, exposure time and the method of exposure will impact the antimicrobial activity and compatibility of a disinfectant on a surface.**

  - A. True
  - B. False
- Which of the following are false?**

  - A. Oxidative chemistries can remove residual levels of soil.
  - B. Low levels of patient residual proteins can remain on devices because of inadequate cleaning and/or the use of aldehydes that can fix residues onto surfaces.
  - C. Close attention to cleaning and the use of oxidative chemistries for disinfection can reduce the risk of biofilm development on reusable devices.
  - D. A and C
  - E. None of the above
- Which are true about disinfectant and sterilant labeling in the United States?**

  - A. All current USFDA and EPA registered disinfectants and sterilants are required to have detailed instructions for use and labeling stating their recommended applications.
  - B. To ensure the most correct, safe and effective application of each product, users must understand all claims and instructions for use.
  - C. Product claims are not considered to be part of a product's labeling.
  - D. Some products will be registered and labeled for use on environmental surfaces; others are labeled for use with medical devices.
  - E. All of the above
  - F. A, B and D
- Sterilization is:**

  - A. A process that is outlined in standards such as AAMI ISO 14937 and FDA 2000.
  - B. The ability to inactivate all types of microorganisms, including bacterial spores.
  - C. A defined and controlled process
  - D. All of the above
  - E. B and C
- Ozone sterilization:**

  - A. Consists of three phases: conditioning, exposure and aeration
  - B. Is achieved at ~35°C (95°F) in the presence of a dry ozone vapor
  - C. Can take up to six hours and is incompatible with certain types of device component materials
  - D. All of the above
  - E. None of the above
- Hydrogen peroxide gas systems, with and without plasma, are essentially the same process in terms of safety, material compatibility and efficacy.**

  - A. True
  - B. False

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