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Learning Objectives

1. Define disinfection and its levels
2. Explain the science behind thermal disinfection
3. Describe the different types of chemical disinfectants used in healthcare practice

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A primer on disinfection

by Dr. Gerald McDonnell

Disinfection: defined

Disinfection may be defined as a reduction in the number of viable microorganisms on a surface to a level previously specified as appropriate for its intended handling or use. It can be achieved by a variety of physical and chemical processes or products such as:

- Moist heat disinfection of surgical instruments, after cleaning, to render them safe for handling and packaging for sterilization.
- Chemical disinfection of flexible endoscopes between patient uses.
- Use of chemical disinfectants for routinely wiping down various environmental surfaces.

There are various levels of disinfection, defined by their ability to kill certain types of microorganisms. Figure 1 provides a summary of the most common types of microorganisms, listed from those that are considered very sensitive to disinfection (enveloped viruses such as HIV and Hepatitis B) to those that are more resistant (bacteria known as *Mycobacterium*

and in particular bacterial spores). While sterilization is a process that should render a surface or device free from microorganisms and inactivate all types of microbes, disinfection may only be expected to reduce the levels of microorganisms and inactivate certain types. There are three traditional and widely used levels of disinfection (HICPAC, 2008):

- Low level disinfection: Reduces the number of many types of bacteria, some fungi and some viruses. Is not expected to inactivate other more resistant forms of viruses (non-enveloped), bacteria (specifically mycobacteria) or bacterial/fungal spores. Low level disinfectants are often considered appropriate for environmental surfaces and some reusable devices. Examples may include stethoscopes and blood pressure cuffs.
- Intermediate level disinfection: Also reduces the number of bacteria, fungi and viruses including mycobacteria and most non-enveloped viruses, but not necessarily bacterial spores. Intermediate level disinfectants are widely used for environmental surfaces and also some reusable devices.

- High level disinfection: Should be expected to inactivate most forms of microbial life, including mycobacteria and some bacterial spores (although this may require extended time). High level disinfectants are most often used for reusable medical devices such as semi-critical flexible endoscopes (see below).

Be aware that this definition serves only as a general guide; each disinfectant product or process can vary in its antimicrobial effects. In addition, the intended level of disinfection can only be achieved when the product or process is used in accordance with the manufacturer's labeled claims. The antimicrobial claims are based on a series of standardized test methods that are conducted with the disinfectant and then registered with a governmental agency, such as the United States Food and Drug Administration (FDA) or Environmental Protection Agency (EPA). The test methods and registration requirements can vary internationally, and at the time of writing they have not been globally harmonized.

	Microorganism Types	Antimicrobial Process			
		Sterilization	Disinfection		
			High-Level	Intermediate-Level	Low-Level
More Difficult ↑	Bacterial Spores	↑	↑	↑	↑
	Mycobacteria				
	Non-enveloped viruses				
	Fungi				
	Gram Negative Bacteria				
	Gram Positive Bacteria				
Less Difficult ↓	Enveloped Viruses				

Figure 1. The levels of disinfection

Two methods; numerous options

There are two basic types of disinfection methods: *physical* and *chemical*. Physical methods include heat (example: heat pasteurization, a process that uses heat or hot water generally between 149°F/65°C and 203°F/95°C) and different types of radiation methods (example: the use of UV light for water treatment or room disinfection).

Chemical disinfection can be performed with a variety of antimicrobial chemicals (often called 'biocides') for the same purpose, with common examples including hydrogen peroxide, peracetic acid, glutaraldehyde, orthophthalaldehyde (OPA), alcohols, iodine, chlorine and quaternary ammonium compounds ("QUATS"). In most cases these

chemicals are not used alone but are ingredients in formulated products (mixtures with other chemicals). Disinfectant formulations can sound similar but vary significantly in antimicrobial activity, surface compatibility and safety aspects. The antimicrobial effects of thermal and chemical methods are often combined to enhance their effects.

With the wide variety of disinfection products and processes that are available, it can be difficult to decide what should or should not be used for a facility's specific disinfection needs. There are at least three factors that should be considered:

1. What the various governmental and professional guidelines suggest or require
2. What the product/process labels (or registrations) claim they can do
3. How the product should be used to be effective and safe

What the guidelines and standards recommend

The most widely used guidelines and standards recommend using the Spaulding Classification to decide what disinfection process is appropriate (e.g., HICPAC, 2008; AAMI, 2010; AORN, 2012). This classification system is based on the risk to a patient or staff member

from a contaminated surface. It identifies three different levels: *non-critical*, *semi-critical* and *critical*. A minimum level of disinfection (or sterilization) is recommended for each level to safely reduce contamination risks.

Non-critical surfaces only contact intact skin and are considered to have the lowest risk to staff/patients. The skin is an excellent barrier to many types of pathogenic (disease-causing) microorganisms. It is important to note that 'non-critical' does not mean that these surfaces are not a risk, as this can depend on the clinical situation. Low or intermediate-level disinfection is recommended, but in some cases cleaning alone can even be sufficient. Appropriate disinfectants can include alcohols, QUATS, phenolics and chlorine. In other cases, more effective disinfectants may be required by the infection prevention team (for example, in the case of contamination with spore-forming bacteria like *Clostridium difficile* in a patient ward).

Semi-critical surfaces are a greater risk as they may also contact mucous membranes or non-intact skin. Sterilization is preferred, but if this is not practical then high level disinfection is considered acceptable. The most common use of high level disinfection is for the reprocessing of flexible endoscopes such as colonoscopes. In the U.S., many high

level disinfectants are also labeled as sterilants due to their activity against bacterial spores over time (spores are difficult to inactivate). Examples of high level disinfectants include glutaraldehyde, OPA, hydrogen peroxide, and peracetic acid-based products.

Critical devices present the highest risk as they enter a normally 'sterile' area of the body, such as the bloodstream. Sterilization of these devices is recommended, defined as a process used to render a surface or product free from viable microorganisms, including bacterial spores. Sterilization is distinct from, but includes, disinfection. Typical sterilization processes use steam, ethylene oxide, liquid peracetic acid chemical sterilization and hydrogen peroxide gas.

It is also important to remember that cleaning is typically required before disinfection/sterilization. Pre-cleaning is particularly important when reprocessing devices, but may or may not be required when using disinfectants for environmental surfaces (depending on each product's instructions for use).

In general, each facility should have an infection prevention policy that describes the practical application of the Spaulding Classification System. The policy should

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include when and how various disinfection and sterilization processes are used. It is important that this policy not only addresses the reduction of microbial risks, but also considers any safety risks that may occur during the use of disinfectants. For example, glutaraldehyde and OPA have been particularly highlighted in recent years for risks related to staff exposure during disinfection, and patient exposure due to insufficient rinsing after disinfection. Some disinfectants, particularly aldehydes, are recommended to be used under controlled ventilation conditions and can often require many water rinses post-disinfection to ensure their safe use.

In addition, guidelines recommend establishing designated areas for cleaning, disinfecting and rinsing; along with a uni-directional workflow from dirty to clean areas. Infection prevention staff may also define the appropriate method for performing environmental disinfection (in particular in patient rooms or high risk areas of a facility). Staff should also be educated and trained, and should be able to demonstrate their competency in the safe and effective use of all relevant disinfectants.

Labels and instructions for use

It is important to read and understand the labeling provided by the manufacturer with each disinfectant or disinfection process. "Labeling" can include what is actually written on a disinfectant product and other written materials provided by the manufacturer, such as safety data sheets. These products often require registration for use in different countries. In the U.S., chemical products used for environmental surfaces should be registered by EPA and those for device reprocessing are required to be registered with FDA (similar but often distinct registration requirements are required in other countries and/or regions).

In general, disinfection should be performed according to manufacturer's instructions, which should include directions for proper storage, preparation (e.g., activation, dilution, checking concentration using a chemical indicator or solution test strips), temperature, re-use (or not) of the disinfectant, and disposal. If a disinfectant is not labeled for a particular use, such as for medical devices, there are important reasons why it should not be used for that purpose (the use of environmental disinfectants on reusable devices can lead to device damage and/or to toxicity problems, for example).

The manufacturer will also define the necessary exposure time for disinfection; shorter times are unacceptable and longer exposure times should be avoided. Chemical disinfection is designed to inactivate microorganisms

but these products can also be considered toxic. The use of the disinfectant may require specific handling, using personal protective equipment (PPE) and in some cases dedicated ventilation during use and/or storage to prevent exposure risks for staff.

Residual chemicals are a particular concern during device reprocessing. Devices must be rinsed after use, with close attention to the method and number of rinses defined by the manufacturer. The purity of the water used for rinsing or thermal disinfection is also important (AAMI TIR34, 2007).

Effective and safe use of disinfectants

Staff should understand how to use disinfectants to assure effective disinfection, but should also be able to use them safely. Meeting effectiveness goals will require close attention to product labels and instructions for use; particularly to proper preparation and exposure time for disinfection. Routine equipment maintenance and practice auditing are also essential to maintaining an effective process.

As for the safety aspects, staff should focus on at least four safety targets: the staff, the patients, the environment, and the surfaces being disinfected. Staff should read and understand risks, including reviewing chemical safety data sheets and learning the correct handling of devices/loads after thermal disinfection to prevent burns. Management also needs to ensure that the correct facilities and environmental conditions are made available to ensure the safe use of disinfectants (e.g., adequate ventilation in compliance to guidelines).

Assuring patient safety requires that surfaces are correctly disinfected and, especially during device reprocessing, that no toxic chemicals are carried over to the patient. Disinfectants should be selected carefully so as not to damage instrument, equipment or room surfaces when used as directed. Finally, care should be taken to ensure careful and responsible disposal of all disinfectants after use (for example, aldehyde-based disinfectants may require specific disposal requirements).

Thermal disinfection

Moist heat (heated water) has been widely used as a disinfection method. This is also referred to as pasteurization. Moist heat disinfection is most often conducted in washer-disinfectors, disinfectors or pasteurizers.

Thermal disinfection, similar to steam sterilization, requires a time-temperature relationship. Above a certain temperature (typically 149-158°F/65-70°C), as the temperature increases the antimicrobial effect

also increases; therefore as the temperature increases the exposure time needed for disinfection decreases. One way to define this relationship is the A_0 method, as described in the international standards for washer-disinfectors (the ISO 15883 series). The ISO 15883 series of standards describes the design, performance and testing of washer-disinfectors, including disinfection requirements. Part 1 describes the requirements for all washer-disinfectors, and subsequent parts of the standards provide more details on specific types of machines (e.g., for surgical instruments).

Mathematically speaking, the term A_0 is defined as the equivalent time in seconds at 176°F/80°C to produce a given disinfection effect (when the z value, a measure of thermal resistance, is 50°F/10°C).

It is each manufacturer's responsibility to ensure this time-temperature alignment in the equipment design. To illustrate, when an A_0 of 600 is recommended (as specified in ISO 15883-2 for the disinfection of surgical instrumentation), the following time-temperature conditions would be examples of a system's disinfection cycles:

- 80°C/176°F x 10 minutes
- 90°C/194°F x 1 minute
- 100°C/212°F x 6 seconds

Different A_0 values are specified in the various parts of ISO 15883 depending on the type of washer-disinfector (e.g., for surgical instruments or bedpans and carts). The ISO standard requires the temperature distribution to be verified in a washer-disinfector to ensure that loads are exposed to the minimum temperature-time conditions during defined cycles.

In addition, FDA guidance for washer-disinfectors specifies that disinfection should be verified by biological challenges. These are performed with different challenge organisms. Examples include:

- Low level disinfection: demonstrated activity against bacteria such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella* and *Enterobacter*
- Intermediate level disinfection: bacteria listed above and a *Mycobacterium* species. Most thermal washer-disinfectors for reprocessing surgical devices prior to packaging and terminal sterilization provide low or intermediate-level disinfection
- High level disinfection: a defined level of activity (typically a 6-log reduction) with a wider range of microorganisms including *Mycobacterium*. The level of microbicidal activity is based upon further guidance

These requirements are also included in the AAMI/ANSI version of the ISO standard.

The temperature and contact time should be verified during clinical use of the washer-disinfector, in addition to recommended equipment maintenance (e.g., routine servicing).

Chemical disinfection

A variety of antimicrobial chemicals can be used in disinfectant products, commonly provided as disinfectant product formulations.

These combinations of ingredients are specifically developed to optimize the product's disinfection activity, stability, device or surface protection, soil or water quality tolerance, rinsibility, and/or other beneficial characteristics. Therefore, each disinfectant product has unique benefits and requirements relating to its safe and effective use.

Remember there are two types of chemical disinfectants: *environmental and device disinfectants*. These are designed for different applications and have defined requirements to ensure their safe and effective use. They should not be used interchangeably. Be careful to review the disinfectant label (and other written material from the manufacturer) to confirm the intended use.

Environmental disinfectants are designed for use on general surfaces (usually 'hard' and non-porous, such as walls, floors, countertops and sinks). They are labeled and registered with this in mind; for example, in the U.S. these products and their associated claims are registered by the EPA in accordance with their requirements (EPA, 2012). They are designed to reduce the levels of microorganisms on these surfaces, to prevent cross-transmission. They are widely used in healthcare facilities in combination with hand hygiene products (soaps, antimicrobial soaps and alcohol-based handrubs) and other infection prevention products/practices. (Note that antimicrobial soaps or rubs, known as 'antiseptics,' are designed for use on the hands/skin. They are only specified for this purpose, are not designed for environmental (or device) disinfection, and are regulated differently (in the U.S., by the FDA)). These environmental disinfection products can be widely used in a facility, including in reprocessing areas. The impact of correct environmental disinfection has been the subject of recent discussion in infection prevention circles; in particular, the correct use of disinfectants to reduce staff and patient risks (Donskey, 2012).

For *environmental disinfection*, available technologies include:

- Liquid disinfectants: these include disinfectant concentrates (diluted in water for use), ready-to-use products (require no preparation) and disinfectant-impregnated wipes. These disinfectants are directly applied to surfaces by staff using a variety of methods such as mopping, soaking, wiping,

etc. They are typically labeled as low or intermediate-level disinfectants. They may also be labeled using terms such as 'germicide,' 'sanitizer,' 'bactericidal,' 'sterilant,' and others. Label claims for these products should be carefully reviewed. For example, the term 'germicide' is the ability to kill certain types of bacteria (*Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*) using a defined test under certain conditions. The term '-static,' as in bacteriostatic, refers to the ability to inhibit growth, but not necessarily to kill. Other examples of similar claims will include fungicidal (kills certain types of fungi in a defined test), virucidal (where the specific viruses tested are listed and may not include all types) and sporistatic (inhibits the growth of spores). It is also important to note the recommended contact times with these disinfectants to ensure their optimal use. Examples of liquid disinfectants include:

- Chlorine or chlorine-releasing agents (the most common example is 'bleach'): bleach solutions are widely used for environmental disinfection but often lead to surface damage over time or from repeated use
- Iodine or iodine-releasing agents: less widely used than chlorine, but good antimicrobial activity. Note: some products are surgical scrubs (antiseptics) and are not designed for environmental or device applications
- QUATS: widely used for combined cleaning-disinfection environmental applications. These can vary widely in antimicrobial claims depending on the formulation
- Phenolics: also range in activity claims depending on their formulation and labeling, from low to high level disinfection.
- Hydrogen peroxide: these formulations offer the benefit of low to no odor, and vary in antimicrobial activity claims.
- 'Non-touch' disinfectants: these types of disinfection technologies do not require direct application to surfaces by staff. Various technologies have become available to hospitals in recent years. These include:
 - Hydrogen peroxide-based processes. These utilize equipment for dispersal of hydrogen peroxide into an area for disinfection ('fumigation'). Examples include the use of mobile or fixed equipment for room disinfection. Care should be taken to understand the control, effectiveness and safety capabilities of such systems, since they can vary significantly.
 - Ultraviolet (UV) light. Controlled light sources provide a given dose of UV light to an area for disinfection. These systems also vary in activity, claims, safety, and room size capabilities.

Device disinfectants, in particular high level disinfectants, are separately labeled and have different requirements. They are required to pass a series of tests to ensure high level disinfection, but also must meet safety requirements (device compatibility and toxicity risks). They are different from liquid chemical or gaseous low temperature sterilization processes. These include:

- *Aldehydes*, such as glutaraldehyde and OPA containing disinfectants: glutaraldehyde products (containing 1-4% antimicrobial agent) can vary considerably, requiring contact times ranging from 5 to 90 minutes, temperatures from 68-77°F/20-25°C (with higher temperatures defined for exposure in automated machines), and reuse time from 14 to 28 days. OPA is an alternative aldehyde used for high level disinfection. It can be effective against many types of microorganisms, but has slow activity against bacterial spores. Claims will also vary depending on the manufacturer.
- *Oxidizing agents*, in particular peracetic acid (PAA) and/or hydrogen peroxide containing disinfectants: hydrogen peroxide disinfectants can vary in activity and compatibility. They are ready to use, reusable, and range from 2-7% hydrogen peroxide in formulation with other ingredients. Peracetic acid disinfectants also vary in activity, compatibility and instructions for use. They are provided as single or two-component chemistries, for single or multiple use applications and with typically in the 0.1-0.4% PAA range in formulation. In addition to disinfectants, there is one PAA-based process that is used for liquid chemical sterile processing.

Informed selection yields benefits

Disinfection is a complex and important process in every healthcare facility, involving responsibility for both medical devices and environmental surfaces. As we have learned, it can be achieved using a variety of physical and chemical methods. These options vary significantly as to how they are used, how effective and productive they are, and whether they meet a department's patient, staff, and material safety objectives. Care should be taken to read and understand all written claims and instructions provided with each product/technology, since each disinfection option can potentially have an impact on many aspects of a department's infection control activities. **HPN**

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Dr. Gerald McDonnell is vice president of clinical and scientific affairs for STERIS Corporation. He has more than 18 years of experience in the

infection prevention and contamination control arenas, and has worked in the US and Europe. He has over 150 publications and patents, including a book published in 2012 entitled 'A Practical Guide to Decontamination.' McDonnell holds a BSc in Medical Laboratory Sciences and a PhD in Microbial Genetics. He is actively involved in the development of national and international standards and guidelines.

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A primer on disinfection

Circle the one correct answer:

- _____ is defined as the reduction of the number of viable microorganisms on a surface previously specified as appropriate for its intended handling or use.
 - Sterilization
 - Disinfection
 - Steam Cleaning
 - Moist Heat
- There is only one level of disinfection used in today's healthcare facilities.
 - True
 - False
- What are the traditional and widely used levels of disinfection?
 - Intermediate level disinfection
 - High level disinfection
 - Sterilization
 - Low level disinfection
 - B,C,D
 - A,B,D
- In the United States, antimicrobial claims are based on a series of standardized methods conducted with the disinfectant and registered with what government agencies?
 - OSHA
 - EPA
 - FDA
 - APIC
 - B and C
 - All the above
- What are the basic methods of disinfection?
 - Chemical
 - Physical
 - A and B
 - None of the above
- Which are examples of antimicrobial chemicals, commonly known as biocides, used in today's healthcare environment?
 - Peracetic acid, alcohol
 - Hydrogen peroxide, glutaraldehyde
 - All the above
 - None of the above
- The _____ Classification can be used to determine the most appropriate disinfection process for reprocessing.
 - Pasteur
 - CDC
 - Spaulding
 - AAMI
- When reprocessing medical devices, cleaning is typically required before the disinfection and sterilization process; however, this may or may not be the case when using disinfectants on environmental surfaces.
 - True
 - False
- When performing chemical disinfection of medical devices, which of the following statements are accurate?
 - The designated areas for cleaning, disinfection and rinsing should be from dirty to clean in a uni-directional flow
 - Cleaning can be avoided if the device looks clean
 - The label claims should be followed when using chemical disinfectants
 - A and C
 - Use an EPA-registered chemical disinfectant
- High level disinfection should inactivate:
 - Most vegetative bacteria and most types of viruses
 - Mycobacteria
 - Bacterial and fungal spores (over time)
 - A and D
 - All the above

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