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From Regulatory to Technical High-Level Disinfection of Surfaces: A Risk Approach

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Abstract

Cleaning, disinfection and High-level disinfection are essential steps that must be carried out under international parameters. These guidelines should be considered when talking about institutions providing health care, because having elements that have direct (instrumental) or indirect (surface) contact with the patient puts their safety and health at risk. Research has shown that 55% of the surfaces inside the health centers still be with the presence of microorganisms that can cause disease, the most common nosocomial infections within health centers are related to potential reservoirs, where opportunistic pathogens have the necessary conditions to grow and proliferate (organic matter), which is why, to avoid transmission of these pathogens, the chain must be interrupted. It has been proved that the cleaning must be carried out with enzymatic powder formulations, since these are more stable than their liquid counterparts, in the same way; it has been proved that disinfectants that have better microbicide action are those based on aldehydes and peroxygenated compounds.

Keywords: Cleaning; Indirect contact; Infections; Opportunistic micro-organisms; Patient care

Introduction

Joseph Lister in the late nineteenth century made one of the most important contributions to the prevention of infections, which at that time accounted for up to 50% of deaths after surgery (hospital gangrene, pyemia, erysipelas), which thanks to the phenic acid techniques employed by Joseph Lister decreased by up to 15%, setting a precedent for health care providers, since the relevance of disinfection processes of instruments and environments in patient health was demonstrated [1].

In 2008, the Pan American Health Organization (PAHO) regional office of the World Health Organization (WHO) in conjunction with the United States Agency for International Development (USAID) developed the latest Manual of Good Practice on Sterilization, with the aim of unifying scientifically proven methods, to have techniques that can ensure the patient's health [2].

Prior to 2004, Colombia did not have a regulation of cleaning, disinfection and high-level disinfection processes that would audit practices. Thanks to the consideration of Ministry of Social Protection, in 2004 Resolution 02183 "Manual of Good Sterilization Practices" was approved, applicable to all health care providers. This was due to the considerable risks posed by nosocomial infections for both patients and the personnel who aid them and it was therefore necessary to set up procedures and activities in the sterilization plants, which could ensure that the elements and supplies needed to meet the needs of the patients.

To meet these needs, the Ministry of Protection decided:

1. Set up the Manual of Good Sterilization Practices for Health Service Providers, which is contained in the technical document that is an integral part of this resolution, as a fundamental tool of the Compulsory Health Care Quality Assurance System, within the framework of the provisions of Decree 2309 of 2002 and Resolution 1439 of 2002 and other regulations that change, add or replace them, which may be voluntarily adopted by the Ministry of Health.

2. If the intention is to set up another Manual of Good Sterilization Practices, it can only be set up if the manual to be adopted has scientific evidence to prove its effectiveness, to guarantee the control and quality of the elements and inputs that are given to the sterilization process.

This Manual has become more relevant because of studies and publications that have been carried out on the emergence of 12 families of multi-resistant bacteria classified according to priority **(Table 1)** [3,4].

We conducted a 6 year retrospective cohort study of 140 patients with *K. pneumoniae* bacteremia from January 2010 to December 2016 in a 3000 bed tertiary care university teaching hospital, Qilu Hospital, in China. The need to select suitable disinfectants for disinfection processes in biomedical equipment and the hospital environment has been highlighted for several decades in multiple scientific articles [5-9]. Dozens of notes and research studies have also been published documenting infections in patients, after inadequate disinfection procedures have been applied to the elements used for their care and treatment [10]. Considering that a growing number of disinfectant formulations are available on the market and that

different techniques of use have proliferated, it is concluded that each institution should apply a clear policy of reprocessing biomedical elements and cleaning surfaces [11-13].

Similarly, the role of surfaces in the transmission of infections has been reconsidered as one of the most important reservoirs of potentially pathogenic microorganisms [14]. The Center for Disease Control in Atlanta, USA (CDC) states that direct contact transmission from surfaces or substances in the body, and indirect, from inanimate objects, is one of the main pathways of transmission of microorganisms [15]. In this sense Carling et al. [16], have carried out research on the evaluation of the techniques used, through different processes of routine cleaning and disinfection, documenting that only between 45% and 56% of the important spaces, related to the environment, still been free of microorganisms, concluding that the cleaning processes should be evaluated to control their compliance.

Table 1 Classification by level of criticality of bacterial species which, according to the WHO, is a danger to human health.

Levels	Species	Resistance
Critical	*Acinetobacter baumannii*	Carbapenems
	Pseudomonas aeruginosa	Carbapenems
	Enterobacteriaceae	Carbapenems
High	*Enterococcus faecium*	Vancomycin
	Staphylococcus aureus	Methicillin and Vancomycin
	Helicobacter pylori	Clarithromycin
	Campylobacter spp.	Fluoroquinolones
	Salmonellae	Fluoroquinolones
	Neisseria gonorrhoeae	Cephalosporin and
Median	*Streptococcus pneumonia*	Fluoroquinolones
		Penicillin sensitivity
	Haemophilus influenzae	Ampicillin
	Shigella spp.	Fluoroquinolones

Surfaces should therefore be considered as one of the most important potential reservoirs that harbor opportunistic pathogens in form, air and water [17]. Because of technological advances and medical treatments, the risk of susceptibility in patients is increased, facing the risk of getting opportunistic infections in health institutions [18].

The Institute of Hygiene and Public Health at the University of Boon, Germany, has reported that considering new evidence of pathogen persistence and transfer to environmental surfaces and patients, the transmission chain should be interrupted with disinfectants that have proven their effectiveness by reviewing surface cleaning and disinfection guidelines [19]. Problems according to different authors are multifactorial, emphasizing materials (e.g. mops, cloths or rags) used for cleaning and disinfectants, it is reported that aldehyde-based disinfectants and peroxygenated compounds are useful for removing organisms from the environment, where quaternary ammoniums, surfactants, glycol derivatives and alkylamines did not show effectiveness [20].

As described above, this document is intended for the purposes of this document:

- Obtain the opinion and criteria of national and international experts, referring to the detersive and disinfectant ability of enzymatic products in powder form, both mono and multienzymatic, demystifying the action by their physical conditions of presentation (solid).
- Get the concept of experts; related to high-level disinfection (DAN) applied to surfaces.
- Give guidelines to the intra-hospital infection committees of Health Service Provider Institutions.

All the above, to raise awareness of the procedures for cleaning and disinfecting equipment, surfaces and their follow-up process, because many disinfectants are used alone or in combinations in health facilities, including alcohols, chlorine and chlorinated compounds, formaldehyde, phenolic and quaternary ammonium compounds [21]. Therefore, users should be clear about the needs they required to meet, emphasizing that the choice of disinfectant should be careful to ensure that the right product has been selected for the intended use and application efficiently [22-25].

Incorrect concentrations and inappropriate disinfectants may result in excessive costs, registered disinfectants should be chosen and used according to the manufacturer's instructions (technical file), showing conditions of use and potential hazards (e.g. respiratory tract diseases) because of sensitivity to exposure to any airborne chemicals, including germicides [22,24,25].

Cleaning agents include various categories such as broad-spectrum disinfectants, disinfectant detergents and sanitizers

[26]. The choice of each one depends on the surface to be cleaned, the level of contamination and the patient population [14]. Cleaning products should be selected according to intended use, safety, cost, efficacy, water compatibility and staff acceptance, as well as to remove dirt without residue [12]. Different cleaning agents are available and each one has different properties that should be considered to find their effectiveness.

Following the above, Cortés et al. [12] and Cortés & Galvis [13] have carried out applied research aimed at finding answers to errors in the composition, formulation or presentation of products used conventionally for cleaning and disinfection, with the aim of finding the enzymatic viability (presence and activity) of various products marketed nationally (Colombia) and internationally, demystifying the effects of mono and multi-enzymatic products.

In those researches, was evidenced that the powder formulation allows to obtain more effective actions than the products in liquid presentations, these results were validated by luminometry of ATP (Luminometer Hygiena System Sure Plus) and spectrophotometry UV-Vis, concluding that, in solid state, presents greater stability with respect to light, temperature and pressure, as well as the variable pH and presence of mineral salts, without affecting the process of cleaning a surface or the life. Liquid detergent does not allow: 1) Delete mineral salts and 2) Not having an efficient germicidal action, because the enzyme contacts with a disinfectant agent, for a long time, denatured them. All the information is supported by theoretical references, from different areas such as chemistry, biology and biochemistry [27-29].

In addition, it is important to bear in mind that, when adding a germicidal agent to the formula in liquid state, a very bad cleaning capacity is generated (main function of a detergent), due to the fact that every substance in liquid state has the possibility of being photosensitive and thermolabile [30], which impacts in the catalytic activity of the different enzymes present in the products, and in turn, in the function for which they were used.

The aims of this document are ensuring that the highest national and international benchmarks, their concepts and opinions, around the following questions:

- What criteria should be considered for the choice of a certain product for cleaning and disinfecting surfaces, medical devices and biomedical equipment?
- Do you think it is advisable to use high-level disinfection protocols on surfaces with products composed of alcohols, chlorine and/or chlorinated compounds, formaldehyde, phenolic and/or quaternary ammonium compounds?
- Does the formulation of enzymatic detergents, which have multiple protein composition, seem useful and relevant?

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