Editorial

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FDA's new approach – adoption of vaporized hydrogen peroxide for medical equipment's sterilization

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With the advancement in healthcare facilities, much-needed efforts were made to cope with the hazards that healthcare workers face while handling instruments being used everywhere. To deal with such a crisis, many methods were adopted including steam sterilization, flash sterilization, ethylene gas oxide sterilization, low-temperature sterilization technologies, and many more[1]. Out of these techniques, Ethylene Oxide (EO) has been used widely for temperature and moisture-sensitive medical equipment[1]. Now recently on 8 January 2024, FDA (Food and Drug Administration) approved Vaporized Hydrogen Peroxide (VHP) as a method to sterilize medical devices[2].

Distinct procedures, sterilization and disinfection, have differing goals and degrees of effectiveness. The goal of sterilization is to eradicate every type of microbe, including vegetative cells and spores; therefore, the number of colony-forming units must be decreased by $\geq 10^6$. This strict requirement is in line with the FDA's recommendation that medical and surgical products have a minimum Sterility Assurance Level (SAL) of 1×10^{-6} in order to ensure sterility. Disinfection, on the other hand, tries to get rid of microorganisms, excluding their spores, and usually entails a drop of $\geq 10^3$. Sterilization accomplishes a higher degree of microbial eradication, making it indispensable for applications requiring the highest level of cleanliness and safety, even though both disinfection and sterilization are essential for maintaining hygiene and stopping the spread of infections[3]. Both techniques are employed in day-to-day care as many hospitals across the world use surgical instruments daily. Due to the wide usage of invasive procedures, there is a greater risk of transmission of infection from these instruments and thus a risk of introducing a pathogen into patient's body. Additionally, there is also a chance of the spread of infection from patient to patient, from patient to healthcare personnel, and vice versa as well as from environment to patients due to contaminated and improperly sterilized surgical instruments. Contaminated endoscopes that have been used widely are linked to be an important cause of infection in tertiary care settings worldwide[3]. Therefore, it was much required to implement better techniques to sterilize medical equipment before their use can be employed in hospitals. For this purpose, healthcare professionals share the responsibility of controlling the chain of transmission of infection in hospitals. Also, certain guidelines have been given by the authorities to deal with sterilization procedures in tertiary care settings[4]. With its long efficacy and safety, VHP has long been used in indoor as well as outdoor settings and many of the places where its use has been implicated include reusable metal and non-metal devices[4]. The benefit of using VHP is that it does not generate any harmful byproducts. It is compatible with many materials such as polypropylene, brass, and polyethylene and due to its ability to diffuse across spaces that usually have diffusion-restricted spaces such as scissors, its use has been implicated on a broader scale[4].

VHP is a traditionally used technique that includes vaporizing hydrogen peroxide at low temperatures in a vacuum so that effective sanitization can be done[5]. Its sterilization process includes three phases, which are conditioning, sterilant exposure, and post-conditioning and all of them are performed in one compartment[5]. This process is performed under a deep vacuum ranging from 1 to 10 millibar (mbar) (0.03–0.3 inches Hg), and the temperature is set within the range of 28–40°C (82–104°F)[5]. The time to carry out the process usually lasts between more or less 8 h. This time can vary according to the product composition, packaging, temperature, and size of the load used. The concentration of hydrogen peroxide used for bio-decontamination is usually around 30–35% w/w aqueous hydrogen peroxide[6]. The Occupational Safety and Health Administration (OSHA) mandates a permissible exposure limit of 1.0 ppm (1.4 mg/mm^3) for VHP in the workplace to ensure a better working environment around sterilization equipment[7]. Moreover, certain biosensors such as Vaisala H_2O_2 gas detectors are used to measure the concentration of hydrogen peroxide during the decontamination process to maintain optimum conditions for cleaning equipment[8].

VHP is an environmentally friendly sterilization method that has several advantages. Because of its mode of operation, VHP is regarded as a 'Green' sterilization method. During the process, the active hydrogen peroxide vapor used in VHP sterilization disintegrates into innocuous byproducts like oxygen and water

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vapor. VHP sterilization does not carry the same risks as other sterilization techniques like EO processing, which can release harmful emissions as a result of equipment leaks, normal wear and tear, incorrect assembly, etc.[9]. Because it reduces the possibility of hazardous emissions and environmental damage while successfully attaining sterilization, vacuum hydrogen purification is now a safer and more environmentally friendly method of sterilizing medical and surgical equipment[9]. EO, although effective for lumen and tubing, poses a serious health concern as it is a highly flammable gas and requires its use in ATEX (ATmosphères EXplosibles)-classified areas[9]. Materials disinfected with EO require thorough aeration to remove residual EO as it can be dangerous the environment.

Due to its effects, it has been used to decontaminate enclosed spaces, as an airborne disinfectant to prevent the transmission of airborne diseases, as a biocidal agent, and also as a means to disinfect buildings[10]. Its implication has been tested against SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) as it inactivates this virus on N95 respirators, allowing them to be reused[11]. During the pandemic, it became a great source of help as there was a limited supply of medical equipment used to control the hazard of preventing the spread of disease; this was employed so that there is the availability of reusing masks and also prevent the spread of virus. In dental materials, it has been used to attenuate viruses and bacteria that spread by air droplets such as tuberculosis, *Candida auris*, and *Staphylococcus aureus*[12]. This also provided a great opportunity to deal with hospital-acquired infections, and the chances of infection prevention from surgical instruments were minimized with the use of this disinfectant. The primary cause of microbe inactivation is hydrogen peroxide's potent reactivity with vital cellular constituents. DNA, the bacterial cell membrane, and thiol groups found in proteins and enzymes can all react violently with hydrogen peroxide[13]. The microorganisms become inactive as a result of these interactions, which destroy the cellular structure and organelles.

Although its use has been implicated in many places, there are many places where its use is restricted. Since it can be exclusively used for solid objects, liquids, powders, linens, and cellulose material cannot be sterilized with its use. Also, its use is limited to places that have limited diffusion restriction; thus, its use cannot be implicated in endoscopes and bronchoscopes as their diffusion barrier is outside the scope of this technique. Overall, owing to its low cost and newer method, the FDA has given a transforming shift signal to the use of this vaporized technique as it provides insight into a better future of sterilization and patient safety.

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