

Technical and regulatory guidelines and developments for the prevention and control of infectious diffusive diseases in hospital

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ABSTRACT

Keywords: Disinfection; Prevention; Pandemic; Devices; Logistics; Regulations

Abbreviations: PPE: Personal Protective Equipment; ISPESL: Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro; ISS: Istituto Superiore di Sanità; ACGIH: American Conference of Governmental Industrial Hygienists; WHO: World Health Organization; ECDC: European Centre for Disease Prevention and Control; ISO: International Organization for Standardization; PEP: Post-Exposure Prophylaxis; PPE: Personal Protective Equipment

Introduction

In order to implement an epidemic-pandemic prevention plan in hospital, several aspects must be considered, including patient management, environmental cleaning and disinfection, bacterial resistance control, surveillance of hospital access, protective measures for healthcare personnel, the use of Personal Protective Equipment and systemic infection surveillance. The implementation of a prevention plan must take into account the logistical conditions of the hospital, its structural and functional characteristics and the prevailing healthcare activities. Normal procedures and protocols take on particular relevance during a pandemic period and need to be reinforced both qualitatively and quantitatively. This article analyses the main and most modern disinfection and prevention techniques applicable to the hospital environment, verifying their regulatory, authorization and multifactorial aspects.

Materials and Methods

Key elements of preventive actions

Here are some key points for the prevention of pandemic events in hospitals:

➤ Patient Management

1. Patients with suspected infection should be identified quickly through pre-triage and referred to dedicated pathways [1].
2. Suspected or confirmed patients should be isolated in single rooms, preferably with a dedicated bathroom and negative pressure [2].
3. Healthcare personnel should use appropriate PPE when caring for infected patients [2].
4. Facilities should provide specific pathways for the labor/delivery management of women with suspected or confirmed

infection [3].

5. Mother and infant should be managed together if the mother is pauci-symptomatic, applying precautions for respiratory illness [3].
6. Patients awaiting diagnosis should be isolated and instructed in the use of a semi-filter mask for them as well [4].

➤ **Environmental Cleaning and Disinfection**

1. Cleaning and disinfection of hospital environments should be carried out regularly, at least twice a day in inpatient areas dedicated to infectious diseases or isolation sections, by trained personnel [5].
2. Rooms must be adequately ventilated prior to cleaning, using natural or mechanical ventilation, possibly with systems/equipment capable of achieving at least 6 effective air changes per hour [5].
3. Surfaces must be cleaned with water and detergent, followed by the application of disinfectants or disinfection with alternative systems of proven effectiveness, as indicated in recent INAIL documents [6].
4. It is preferable to use wet cleaning methods to avoid dust dispersion [6].
5. For the disinfection of surfaces and medical devices, aerosolization can be used, preferably with hydrogen peroxide-based formulations, as indicated in recent INAIL documents
6. Instruments used for cleaning must be dedicated or disposable, and reusable instruments must be disinfected.
7. It is important to control microbial contamination of air and surfaces through environmental monitoring [7].

The main active components reported in the literature in disinfectant formulations for hospital use and their use are as follows: [8]

Chlorine and Derivatives (e.g. Sodium Hypochlorite, Chlorine Dioxide)

- Disinfection of contaminated surfaces, floors and equipment.
- Treatment of water to remove pathogens.
- Disinfection and decontamination of hospital water systems is essential to prevent biological contamination (e.g. Legionella). This requires the use of disinfectants compliant with European technical standards and the installation of advanced filtration systems at terminal outlets or specific nodes of the network, acting as collective protection barriers. In line with the most recent INAIL 2024 safety measures for critical areas, point-of-use water filtration systems with

absolute membrane technology can be implemented at terminal outlets of the hospital water network. These devices act as collective protection barriers, ensuring microbiological safety of water (including against viruses and Legionella) for immunocompromised patients and clinical staff. Independent third-party validation, continuous monitoring and dedicated traceability systems is used to guarantee sustained efficacy and regulatory compliance. These measures, validated by independent third parties, guarantee microbiological safety and traceability of hospital water systems.

- Used in high-risk areas, such as operating theatres.

Alcohol (Ethyl or Isopropyl)

- Rapid disinfection of non-critical medical instruments (e.g. thermometers).
- Cleaning of surfaces in the vicinity of patients.
- Skin preparation prior to injections or surgery.

Hydrogen Peroxide

- Sterilization of complex medical instruments (e.g. endoscopes).
- Disinfection of surfaces, often in sprayed form for hard-to-reach areas.
- Environmentally friendly alternative to other more aggressive disinfectants.

Glutaraldehyde (Active Substance that should not be used in the EU due to its high Exposure Toxicity) and Orthophthaldehyde

- High-level disinfection for heat-sensitive surgical instruments.
- Used in procedures where strict sterility is required.

Quaternary Ammonium Compounds

- Cleaning and disinfection of general surfaces (e.g. beds, furniture).
- Used in non-critical areas such as surgeries or common rooms.

Phenols (Active Substance that should not be used in the EU due to its high Exposure Toxicity) and Derivatives

- Disinfection of floors and non-critical surfaces.
- Used for resistant materials, but less so for sensitive environments.

Peracetic Acid

- Chemical sterilization of medical instruments and sensitive materials (e.g. endoscopes).
- Disinfection of high-risk surfaces.

Iodophores (e.g. Povidone-Iodine)

- Preparation of the patient's skin prior to surgery.
- Treatment of superficial wounds to prevent infection.

Chlorhexidine

- Preoperative skin disinfection.
- Long-term application on catheters and instruments in contact with tissue.

Enzymatic Solutions

- Preliminary cleaning of medical instruments to remove organic residues prior to sterilization.
 - Prevention - protection measures for healthcare workers: [6,9-11]
1. Healthcare workers must be adequately protected with appropriate PPE, including gowns, gloves, filtering half-masks and goggles.
 2. The selection of PPE should be based on the identification of the risk of exposure when carrying out
 3. different activities and the mode of transmission of the pathogen.
 4. It is essential that healthcare personnel are trained on the risks of exposure, prevention and protection measures, and the clinical characteristics of the disease.
 5. Hand disinfection is crucial; it is usually done with alcohol-based solutions/gel for which efficacy can be demonstrated as indicated by the European technical standards
 6. Careful and constant health surveillance should be carried out and when available, the doctor in charge should explain and recommend vaccinations
 7. It is recommended that care activities be grouped to minimize the number of room entries.
- **Infection Surveillance:**
1. It is important to activate a surveillance and reporting system for care-related infections (ICAs).
 2. Monitor pathogen-sentinel germs through periodic reports.
 3. Carry out microbiological monitoring of water, air and surfaces, especially in high-risk areas.
 4. Identify resistant microorganisms in healthcare environments.
- Prevention-protection measures essential for any person present in hospital environments:
1. Healthcare facilities must have protocols in place for disinfection, as indicated in recent INAIL documents [6,9-11],

disinfection and sterilization of environments and materials, as well as for linen and waste management.

2. It is important to define an appropriate staff-to-patient ratio.

➤ The INAIL 2022 technical opinion (Opinion dated November 18, 2021) highlights that, where natural or mechanical ventilation is inadequate and gatherings are unavoidable, risk-assessed spaces should be prioritized for installation of air decontamination units. The systems cited operate with filtration and can process airflow rates between 300 and 1200–1500 m³/h, ensuring controlled reduction of airborne contaminants in confined environments. Selection of units must match room volume and occupancy density to maintain effective air exchange and contaminant removal.

1. Criteria for controlling and limiting visitor access must be established.
2. Procedures for controlling accidents and staff illnesses and vaccination prophylaxis are necessary.
3. It is important to implement prevention-protection measures based on up-to-date bio-risk assessments.
4. Consider the use, when necessary, of equipment for decontamination of airborne pollutants and ultraviolet lamps or 405nm lamps for permanent disinfection in high-risk environments [12-14].
5. Maintaining traceability of disinfection activities.

These points represent an integrated approach to pandemic prevention in the hospital setting, considering both patient management, environmental and personnel protection measures. The above approach we have implemented in our hospital structure, following are the detailed technical characterizations of all health protection measures and their correlations with current Italian and EU legislation

Main Disinfection Methods

Several disinfection procedures are reported in the literature, including both traditional methods and more advanced technologies, with a focus on their effectiveness against pathogens and safety for staff.

Here are the main disinfection procedures:

1. **Manual Surface Disinfection:** This procedure involves the use of manually applied chemical detergents and disinfectants to clean environmental surfaces and medical devices. It is essential that the products used are effective against the biological agents that are the source of infection, as indicated in recent INAIL documents [6,9-11]. Disinfectants must be chosen on the basis of their microbicidal properties and the contact time required. Cleansing is a mandatory step prior to disinfection to remove dirt that may reduce the activity of disinfectants.

2. Disinfection by Aerosol Production: This method is considered optimal for eradicating infections by multi-resistant agents in healthcare. It involves the use of equipment that atomizes disinfectants to homogeneously reach all surfaces, including those that are difficult to reach. The effectiveness of this methodology must be validated by independent third-party laboratories in accordance with European technical standard EN 17272:2020. [6,9-11] It is important to monitor the disinfectant diffusion and air concentration to ensure safety. This procedure is suitable for disinfection of rooms and surfaces of medical devices.

3. Disinfection of Endoscopes: Given the complexity of endoscopes, their reprocessing (decontamination, cleansing and disinfection) requires special attention. Disinfection of endoscopes must be carried out according to technical standard EN 15883-4 [6,9-11]. The equipment used for reprocessing must ensure accurate control of process parameters, data archiving and traceability. In the case of flexible endoscopes used in sterile sites, sterilization through a chemical-physical method in accordance with EN ISO 14937 is required. Recent INAIL 2024 guidelines also underline the importance of integrating advanced reprocessing systems for flexible endoscopes. These systems must not only comply with EN 15883-4 and EN ISO 14937 but should also provide automated control of critical parameters, process traceability, and validated disinfection efficacy against resistant microorganisms. The adoption of innovative reprocessing technologies, as recognized by INAIL, enhances patient safety and reduces infection risks in high-complexity procedures.

4. UV-C Disinfection: UV-C light is known for its germicidal action due to its ability to break the molecular DNA and RNA bonds of microorganisms. UV-C light-based systems are used for the disinfection of rooms and surfaces, but it is essential to define an operating scheme for their efficient and permanent use in order to reduce costs and maximize effectiveness. It is also necessary to ensure that the use of such equipment complies with the provisions of Legislative Decree 81/2008 and in particular with those of Title X and Title IX, considering among other things that the technical-scientific documentation must show that exposure limits are not reached [15].

5. UV-A Disinfection with 405 nm sources [12-14]

Light at 405 nm has significant antimicrobial properties against a wide range of bacterial and fungal pathogens, although its germicidal efficacy is lower than UVC light. This limitation is compensated for by its ease of safe, continuous use, subject to certain precautions, in occupied environments where continuous disinfection is provided. In fact, action times are in the order of hours rather than minutes as with UVC. However, where there are conditions where it is important to keep the level of environmental contamination under control, especially in combination with other systems, their use is promising. In addition, 'near UV' rays have greater penetration power through common transparent media and an important reflection action, which allows them to reach even partially shaded cavities, thus proving

effective even on porous surfaces. This is in contrast to UVC, which is blocked by almost all common transparent media and whose reflection requires special and/or mirror-polished materials. Finally, UV radiation, especially UVC, over time, shows a significant level of deterioration of polymer materials, producing yellowing and obvious surface damage, which appears to be reduced or absent in 'near UV'. Clearly, the considerations regarding the provisions of Legislative Decree 81/2008 expressed above also apply to this optical radiation.

➤ **Disinfection with hydrogen peroxide and silver ion formulation:** Hydrogen peroxide nebulization, often combined with silver ions, is another method used for disinfection. This combination has proven effective against several viruses, including SARS-CoV-2. The certification of the validity of the process depends on the synergy between the nebulizer and the disinfectant [16,17]; efficacy must always be demonstrated as indicated in recent INAIL documents.

➤ **Air treatment:** If it is not possible to isolate infected patients in dedicated areas with negative pressure, air treatment equipment can be used to decontaminate the environment, with filtering systems to reduce the level of contamination. [18,19] The effectiveness of such systems must be ascertained by tests conducted by independent third-party organizations.

➤ **Chemical-thermal disinfection of textiles:** This procedure, described in UNI EN 16616:2015, concerns the treatment of contaminated textiles for disinfection; effectiveness must always be demonstrated as indicated in recent INAIL documents.

It is essential that disinfection procedures are adapted to the context, the type of circulating pathogens and the characteristics of the environments. It is essential that the methodologies for Italian Regulations and in particular for Legislative Decree No 81 of 9 April 2008 are validated by independent third-party bodies and that they comply with European technical regulations.

In this regard, a list of the main European technical standards to follow is highlighted:

- 1. UNI EN 17272:2020:** This standard specifies the requirements and test methods for disinfection of environments by aerosol production. The effectiveness of disinfection by aerosol production, performed by a system consisting of equipment using a disinfectant formulation, must be validated and approved by independent third-party laboratories in accordance with this standard.
- 2. UNI EN 15883-4:** This standard covers equipment for the washing and disinfection of endoscopes. It establishes requirements for the reprocessing of endoscopes, which includes decontamination, cleansing and disinfection, to prevent the transmission of infections. Equipment must comply with this standard and have the relevant technical documentation.

3. **UNI EN ISO 14937:** This standard defines the general requirements for the sterilization of healthcare products and applies in particular to flexible endoscopes used in sterile cavities or sites. The standard specifies requirements for the characterization of a sterilizing agent and for the development, validation and systematic control of a sterilization process for medical devices.
4. **UNI EN 14476:** This standard specifies a quantitative suspension test method for evaluating the virucidal activity of chemical disinfectants in the medical field. It is a key standard for demonstrating the effectiveness of disinfectants against viruses. The standard describes a sequence of tests to be applied. The 2013 version has undergone changes in the demonstration of microbicidal efficacy.
5. **UNI EN 13727:** This standard specifies a test method for evaluating the bactericidal activity of chemical disinfectants in the medical area.
6. **UNI EN 14561:** This standard specifies a test method for the evaluation of the bactericidal activity of chemical disinfectants used for instruments in the medical area.
7. **UNI EN 14348:** This standard specifies a test method for the evaluation of the mycobactericidal activity of chemical disinfectants in the medical area.
8. **UNI EN 13624:** This standard specifies a test method for the evaluation of the fungicidal activity of chemical disinfectants for instruments used in the medical field.
9. **UNI EN 13623:2010:** This standard covers the evaluation of the bactericidal activity of chemical disinfectants against *Legionella* in aqueous systems.
10. **UNI EN 16615:2015:** This standard relates to the evaluation of bactericidal and mildicidal activity on non-porous surfaces with mechanical action using wipes in the medical field.
11. **UNI EN 16616:2015:** This standard specifies a test method for the chemical-thermal disinfection of textiles.
12. **UNI EN 16777:2019:** This standard covers the evaluation of the antiviral activity of chemical disinfectants used in the medical field on non-porous surfaces.
13. **UNI EN 17111:2019:** This standard covers the evaluation of virucidal activity of chemical disinfectants for instruments in the medical field.
14. **UNI EN 17126:2019:** This standard defines test methods for evaluating the sporicidal activity of chemical disinfectants in the medical field.
15. **UNI EN 12353:2013:** This standard specifies methods for the storage of test organisms used to determine the microbicidal activity of disinfectants.
16. **UNI EN 14885:2019:** This standard defines the European standards to which products must conform to support claims of their antimicrobial activity.
17. **UNI EN 1040:2006:** This standard specifies a test method for the evaluation of the basic bactericidal activity of disinfectants.
18. **UNI EN 1275:2006:** This standard specifies a test method for the evaluation of the basic fungicidal or fermentative activity of disinfectants.
19. **UNI EN 1822:2019:** This standard covers high efficiency air filters (EPA, HEPA and ULPA). HEPA H13 filters must have an efficiency > 99.95 per cent.
20. **UNI EN 13098:2019:** This standard concerns the measurement of microorganisms and airborne microbial compounds in work environments.
21. **UNI EN 1500:2013:** This standard describes a test method for assessing the effectiveness of hygienic hand rub products.
22. **UNI EN 12791:2018:** This standard describes a test method for evaluating the effectiveness of surgical hand disinfection products.
23. **UNI EN 1717:2002:** This standard covers protection against drinking water pollution in plumbing systems and general requirements for devices to prevent backflow pollution.

These European technical standards are essential to ensure that disinfection procedures are effective and safe, and their application is required by health and safety legislation and guidelines. Adherence to these standards ensures that the products and equipment used have been tested and validated to recognized standards, thus helping to protect the health of patients and healthcare personnel. For the sake of clarity, please note that the above-mentioned standards are contained in both Italian and international technical documents that provide guidelines and standards for infection prevention and control, occupational safety and disinfection.

Here is a list of the main technical documents:

Italian Documents

- **Legislative Decree 81/2008 as amended:** This is the single text on health and safety at work in Italy. It is important to consider that the aforementioned decree also highlights how accurate health protection can be implemented, even in relation to the types of risks that are important for healthcare activities as biological, chemical and physical risks, including those related to care-related infections (ICA). Titles I, VIII, IX and X of the decree are frequently mentioned, with particular

reference to risk assessment, prevention and protection measures, and the use of personal protective equipment (PPE).

- **ISPESL Guidelines:** The documents refer to the Guidelines of the Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro (ISPESL) concerning the requirements of occupational hygiene in the operating department (December 2009 edition) and the sterilization process as a collective protection measure (June 2010 edition). These guidelines are important for defining safety and hygiene standards in healthcare environments.
- **INAIL documents:** There are several INAIL (National Institute for Insurance against Accidents at Work) documents dealing with issues related to safety and prevention of biological risks, including documents on disinfection of devices and facilities and on safety measures for group 3 agents in healthcare activities.
- **INAIL Document 2020 Safety measures for group 3 agents in healthcare activities:** This document provides specific guidance on the management of biological risk related to group 3 agents.
- **INAIL Document 2022:** Disinfection of the environment and of diverse surfaces as a safety measure in health care and similar facilities.
- **INAIL Document 2024:** Safety measures for infections in critical areas in health care advanced technologies for the continuous use of PPE and disinfection of new design. Within the INAIL 2024 document, special attention is given to water treatment and endoscope reprocessing. In particular, the use of point-of-use water filtration devices in critical areas is recognized as a collective protection measure, while validated endoscope disinfection systems are highlighted as essential for preventing care-related infections. These solutions represent practical applications of advanced technologies for infection prevention and are aligned with the most recent national regulatory requirements.
- **Technical document of the Ministry of Health:** This document provides indications on protective measures for health protection in the transport and extra-hospital management of patients infected or potentially infected by biological agents, in particular those of class IV.
- **ISS COVID-19 reports:** The Istituto Superiore di Sanità (ISS) has published several technical reports on the COVID-19 pandemic. These reports provide guidance on infection prevention and control, disinfection of environments and the use of PPE. The reports include interim recommendations on disinfectants and sanitization of non-sanitary facilities.

- **ISS Report No. 12/2021:** This report provides recommendations on the sanitization of non-healthcare facilities during the COVID-19 emergency, with a focus on environments and surfaces.
- **ISS Report No. 20:** This report focuses on viral contamination of the built environment, the effectiveness of disinfectants and the cleaning of rooms that have housed COVID-19 patients.
- **UNI (Ente Italiano di Normazione):** Several UNI standards are worth mentioning, in particular the ISO 15883 series of standards concerning washing and disinfection equipment, especially UNI EN 15883-4 for the disinfection of endoscopes. Also noteworthy are the UNI EN ISO 14937 standards for the sterilization of sanitary products, UNI EN 1822-1:2019 on air filters, UNI EN 13098:2019 for the measurement of airborne microorganisms and UNI EN 14476 for the evaluation of the virucidal activity of chemical disinfectants.
- **American Conference of Governmental Industrial Hygienists (ACGIH):** The exposure limit values (TLV-TWA and TLV-STEL) established by the ACGIH for free chlorine are mentioned.

International Documents and Regulation of EU

- **World Health Organization (WHO):** The WHO 'Global report on infection prevention and control' is highlighted. This report provides an overview of global infection prevention and control.
- **European Centre for Disease Prevention and Control (ECDC):** An ECDC document on basic skills for infection control practitioners. The ECDC plays a crucial role in providing guidelines and recommendations for the prevention and control of infectious diseases in Europe.
- **European Committee for Standardization (CEN):** Relevant are European technical standards developed by CEN, in particular those of working group TC 216 'Chemical antiseptics and disinfectants'. These standards establish test methods and requirements for chemical disinfectants, such as EN 14476 for virucidal activity and EN 17272:2020 for disinfection of rooms by aerosol production.
- **ISO (International Organization for Standardization):** significant ISO standards, such as ISO 14644/1 for air cleanliness classification, ISO 15714 for UV dose assessment for airborne microorganisms and ISO 16474-3:2013 for light exposure assessment.
- **Directive (EU) 2020/2184:** This directive of the European Parliament and of the Council concerns the quality of water intended for human consumption, including limits for Legionella and Lead.

These technical documents represent the regulatory and scientific reference framework for disinfection procedures and infection prevention practices, both in Italy and internationally. Adherence to these standards is essential to ensure the safety and health of patients and healthcare personnel.

Italian Regulations

Several Italian regulations govern disinfection in healthcare, with the aim of protecting the health of healthcare workers and patients and preventing the spread of infections. Here are the main ones:

- **Legislative Decree No 81 of 9 April 2008** (as amended and supplemented): This decree, known as the Consolidated Occupational Health and Safety Act, is the main reference for the management of biological and chemical risks in work environments, including healthcare environments. In particular, Title X of Legislative Decree 81/2008 concerns protection from risks arising from exposure to biological agents. Articles 223, 224 and 225 of Title IX focus on risk assessment from chemical agents and the safety measures to be taken. Articles 236, 237 and 238 deal with risk assessment from carcinogenic agents. Article 15 indicates the fundamental characteristics for choosing and implementing general protective measures, while Article 18 lists the employer's obligations for the above-mentioned protective measures.
- **Legislative Decree No 502 of 30 December 1992**: This decree, as amended, regulates the reorganization of health matters.
- **Legislative Decree No 219 of 24 April 2006**: This decree concerns the classification of medicinal products.
- **Legislative Decree 46/97 as amended**: This decree regulates medical devices. Disinfectants for invasive medical devices are classified in class IIb.
- **DPR 14 January 1997**: This decree approves the act of address and coordination for the minimum requirements of healthcare facilities.
- **DPR 392/1998**: This decree concerns Medical Surgical Presidia (PMC).
- **Ministerial Decree No 274 of 7 July 1997**: This decree regulates cleaning, disinfection, disinfestation, rodent-control and sanitization activities, establishing the requirements for companies carrying out these activities.
- **Ministry of Health circulars**: Circulars No. 52 of 20/12/1985 and No. 8 of 30/01/1988 provide guidance on combating hospital infections and the need for ICAI surveillance systems.
- **Regulation (EU) 2017/745**: This regulation concerns medical devices.

- **EU Regulation 528/2012**: This regulation concerns biocidal products.
- **EU Regulation (EC) 1907/2006 (REACH)**: This regulation concerns the registration, evaluation, authorization and restriction of chemicals.
- **Regulation (EC) 2008/1272 (CLP)**: This regulation concerns the classification, labelling and packaging of substances and mixtures.
- **Directive 2000/54/EC**: This directive concerns the protection of workers from risks arising from exposure to biological agents.
- **Interministerial Decree 2 May 2020 and 27 December 2021**: These decrees transpose EU directives amending Annex XLVI of Legislative Decree 81/2008, including SARS-CoV-2 in biological risk group 3.
- **Decree of the Ministry of the Environment of 9 December 2020 and 29 January 2021**: These decrees define the minimum environmental criteria (CAM) for the awarding of the service of industrial washing and rental of textiles and mattresses, and for the service of cleaning and sanitation of buildings and environments for civil and sanitary use.
- **Decree of 18 October 2016**: This decree adopts the minimum environmental criteria for the contracting of the sanitization service for healthcare facilities and for the supply of cleaning products.
- **Directive (EU) 2020/2184**: This directive concerns the quality of water intended for human consumption, setting new limits for Legionella and Lead.

These regulations set requirements for disinfectants, medical devices, sanitization and disinfection procedures, bio-risk management and worker protection, highlighting the importance of an integrated and multidisciplinary approach to infection prevention and health protection in healthcare. Furthermore, it is important to consider that the efficacy of disinfectants must be demonstrated through experimental verifications carried out by independent third-party bodies, in accordance with European technical standards in the sector. Healthcare facilities must define documented responsibilities, criteria and resources for the integrated management of environmental risk, operator risk and patient risk, including the prevention and control of care-associated infections (HAI).

The importance of disinfection and sterilization is underlined by several factors:

1. **Prevention of HAIs**: HAIs are infections that occur as a result of exposure to infectious agents in the context of healthcare care procedures. Proper disinfection and sterilization of environments, surfaces, equipment and medical devices reduce the likelihood of such infections.

2. **Reducing the spread of resistant microorganisms:** The use of appropriate disinfection and sterilization methods is crucial to counter the spread of increasingly antibiotic-resistant microorganisms, a growing problem in the healthcare setting.
3. **Protection of vulnerable patients:** Immunocompromised or premature patients are particularly susceptible to infection. Strict disinfection and sterilization practices are essential to protect these patients.
4. **Protection of healthcare workers:** Infections can also affect healthcare workers. Effective disinfection and sterilization help protect staff from the risk of contracting infectious diseases.
5. **Protection through Post-Exposure Protocol:** The Post-Exposure Prophylaxis (PEP) protocol for HIV or other viruses is a preventive measure to reduce the risk of infection in the event of accidental exposure to the virus. [20] This protocol must be performed as a matter of urgency and follow a few key steps:
 - **Immediate Assessment**
 - Wash the affected area with soap and water (for wounds) or rinse thoroughly (for mucous membranes or eyes).
 - **Risk Assessment**
 - Determine the type of exposure (e.g. needle stick, contact with blood or other body fluids).
 - Identify the serological status of the source, if known.
 - **Timely Initiation of PEP**
 - PEP should be initiated within 72 hours of exposure, preferably as soon as possible.
 - Antiretroviral drugs are administered for a period of 28 days.
 - **Medical Monitoring**
 - Serological testing: an initial (baseline) test for HIV, followed by subsequent tests at 6 weeks, 3 months and 6 months.
 - Monitoring for side effects of antiretroviral treatment.
 - **Counselling and Support**
 - Informing the patient/employee about residual risks, the importance of adherence to treatment and preventive measures.

Protection Through Staff Vaccination

For hospital staff in Italy, vaccinations are essential for the prevention and control of infections, both for individual and patient protection. The competent physician has a key role in assessing risk and prescribing the necessary vaccinations.

Vaccinations strongly recommended for healthcare workers include: [21,22]

1. **Hepatitis B (HBV):** This is considered one of the most important vaccinations due to the high risk of infection.
2. **Influenza:** Influenza vaccination is recommended annually, especially for workers working with patients at high risk of complications.
3. **Measles, Mumps, Rubella (MPR):** Two doses of the MPR vaccine are recommended for susceptible workers (who have not had the diseases or are not vaccinated).
4. **Chickenpox:** Also for chickenpox, two doses are recommended for non-immune personnel.
5. **Diphtheria-Tetanus-Pertussis (dtpa):** Vaccination against pertussis is recommended for all healthcare workers, with periodic booster shots.
6. **COVID-19:** Vaccination against COVID-19 is strongly recommended for health and social care workers, with a focus on seasonal recommendations.

In special circumstances, depending on the type of activity or individual health reasons, other vaccinations may also be indicated, including:

1. **Hepatitis A (HAV):** For workers in contact with infected primates, in laboratories with HAV, or solid waste and sewage disposal workers.
2. **Meningococcal (MenC, MCV4, MenB):** Recommended in specific risk situations or for individuals with immune deficiencies.
3. **Pneumococcus:** Recommended for personnel with specific individual risk conditions or comorbidities.
4. **Tuberculosis (BCG):** The only vaccination historically mandatory for healthcare workers, albeit limited to particular cases and with specific screening criteria.

Despite its crucial importance, the implementation and maintenance of disinfection and sterilization practices present several challenges:

1. **Complexity of protocols:** Disinfection and sterilization procedures are complex and require in-depth knowledge of the active ingredients of disinfectants, application methodologies and technical specifications of equipment. European technical standards, such as those developed by CEN, which establish test methods and requirements for disinfectants, must be strictly followed.
2. **Variability of pathogens:** The continuous evolution of pathogenic microorganisms, including multi-resistant ones,

requires constant updating of disinfection and sterilization strategies. The choice of disinfectants must be based on proven efficacy against specific biological agents.

3. **Difficulties in uniform application:** Effective disinfection requires uniform and thorough application of disinfectants, which is often made difficult by uneven or hard-to-reach surfaces. Aerosolization technology can provide a solution to overcome these difficulties, but must be validated according to EN 17272:2020.
4. **Constant monitoring:** Cleaning and disinfection activities must be constantly monitored to verify their effectiveness and make any necessary corrections. This includes microbiological monitoring of environments and traceability of disinfection procedures.
5. **Staff training:** Staff involved in cleaning, disinfection and sterilization must be adequately trained and instructed in correct procedures, the appropriate use of disinfectants and equipment, and the importance of occupational safety.
6. **Costs and resources:** Implementing and maintaining effective disinfection and sterilization practices requires investment in equipment, materials and staff training, as well as efficient process organization. It is important to carefully evaluate the available technologies and products, choosing those that are most cost-effective.
7. **Risk management:** The use of disinfectants and disinfection equipment involves risks of exposure to chemicals and carcinogens. Appropriate safety measures must be taken to protect operators.

Disinfection and sterilization practices are essential for the safety of patients and healthcare workers, but their proper implementation and maintenance requires constant effort, adequate resources and attention to the challenges posed by the continuous evolution of microorganisms and available technologies.

- The challenge of a disinfection activity that can be considered 'permanently effective'
- **Permanently effective disinfection** [18] refers to the adoption of techniques and technologies that aim to maintain an environment permanently free of pathogens, thereby continuously reducing the risk of contamination and infection. This concept goes beyond traditional disinfection practices, which are often periodic or reactive interventions. The objective is to create an environment in which the presence of bacteria, fungi/yeasts, viruses and spores as contaminants is continuously lowered or maintained at the lowest possible levels, a goal that is particularly important in nosocomial facilities and of utmost necessity in critical healthcare areas.

- **Integration of different technologies:** Permanently effective disinfection can be achieved by integrating different technologies and methodologies. For example, combining air filtration, UV-C lamps and the thorough disinfection of surfaces, instruments, devices and equipment by also employing automated disinfection systems by aerosol production to create a continuous barrier of protection against contamination.
- **Monitoring and traceability:** The new disinfection equipment allows activities to be recorded, enabling certification of the process as a whole. Continuous monitoring of disinfection effectiveness is essential to guarantee lasting results.
- **Increasing disinfection logic:** Disinfection of permanent effectiveness should follow a logic that creates environments of increasing disinfection, starting with the air filters, passing through the service and traversing rooms, until arriving at the area that can therefore be considered of permanent effectiveness.

Challenges and Considerations in Implementing Permanently Effective Disinfection

1. **Costs:** The implementation of permanently effective disinfection systems can involve high costs, both for the purchase of the technologies and for their maintenance.
2. **Effectiveness:** The effectiveness of a disinfection system depends on the combination of nebulizer and disinfectant used, and must be certified by independent third-party laboratories.
3. **Risk assessment:** The choice of disinfection technologies and methodologies must be based on a risk assessment specific to each environment.
4. **Staff training:** Staff operating these systems must be trained in the correct use of the technologies and procedures.
5. **Regulatory compliance:** Disinfection activities must comply with current hygiene and safety regulations, such as Legislative Decree 81/2008 and Regulation (EU) 2017/745, as well as the regulations mentioned above.

In summary, permanently effective disinfection [18] requires an integrated approach combining advanced technologies, standardized procedures, and constant monitoring to ensure safe environments protected from contamination. Environmental disinfection programs and air treatment technologies have a significant impact in both healthcare and non-healthcare environments, with the main goal of reducing the presence of pathogens and improving air quality. These interventions are key to preventing infections, protecting public health and creating safer environments.

Impact of Environmental Disinfection programs and Air Treatment Technologies

1. **Reducing the risk of infection:** Environmental sanitization and air treatment help decrease microbial and viral load, reducing the risk of infections, particularly care-related infections (ICAs) in healthcare settings. Disinfectant and aerosol production is an effective methodology for disinfecting surfaces, including those of medical devices and equipment.
2. **Improving air quality:** Air treatment technologies such as filtration systems (HEPA and ULPA) and air purifiers with UV-C lamps or plasma technology can remove or inactivate airborne pathogens, improving indoor environmental quality [23].
3. **Prevention of the spread of pathogens:** Adequate ventilation, together with air filtration, helps to reduce the concentration of microorganisms and viral particles, limiting the spread of infections through the air [24].
4. **Protecting the health of operators and users:** Sanitizing and treating the air is essential to protect both healthcare workers and users from possible infection and contamination. In particular, in healthcare environments, it is essential to constantly monitor the effectiveness of disinfection and sanitization procedures.
5. **Control of epidemic outbreaks:** In the case of epidemic outbreaks, such as those caused by multi-resistant microorganisms (MDR), environmental sanitation programs and air treatment technologies, including the search for sources of infection or reservoirs, become crucial to limit the spread.
6. **Regulatory compliance:** The implementation of these programs and technologies enables compliance with current workplace health and safety regulations, such as Legislative Decree 81/2008 and Regulation (EU) 2017/745.

Challenges in Implementing Disinfection programs and Air and Water Treatment Technologies

1. **Costs:** The installation and maintenance of advanced air treatment technologies, such as HEPA/ULPA filters and aerosol production systems, can be costly.
2. **Complexity:** Managing sanitization and air treatment systems requires qualified personnel and standardized procedures. The choice of the most appropriate disinfection methods and the validation of their effectiveness are complex processes that require experimental verification by independent third-party bodies.
3. **Integration of technologies:** The integration of different disinfection technologies, such as UV-C lamps, air purifiers and hydrogen peroxide nebulizers, requires a strategic

approach to avoid redundancies and maximize effectiveness. It is essential to consider the benefits and limitations of each technology, the time of use and the levels of infectious risk to be managed.

4. **Continuous monitoring:** Sanitization and disinfection activities must be constantly monitored to ensure their effectiveness. Traceability of disinfection processes, especially for aerosol production, and monitoring the concentration of disinfectants in the air are crucial.
5. **Maintenance:** Ventilation systems and air treatment equipment require periodic maintenance to ensure their proper functioning and effectiveness over time.
6. **Staff training:** Staff involved in the sanitization and use of air handling technologies must be adequately trained in the correct procedures and appropriate use of PPE.
7. **Risk assessment:** The choice of disinfection methods must be based on a biological risk assessment specific to each environment and activity, according to the indications of Legislative Decree 81/2008.
8. **Toxicity of disinfectant agents:** Some disinfectant agents, such as chlorine and ozone, can be toxic if used improperly or in high concentrations. It is therefore necessary to carefully assess the risks to the health of operators and users [25].

Use of Ozonized Water Systems: Ozonized water, produced by special generators, is a versatile and sustainable disinfectant solution with many advantages. The generators use electrical discharges or electrolysis to convert tap water into an ozone (O₃) rich solution, a powerful oxidant that expresses a microbicidal action against bacteria, viruses, fungi and spores. For several years in the food industry, ozonated water improves food safety, quality and preservation. It is effective against pathogens such as salmonella and listeria, reduces pesticides, increases shelf life, and can improve organoleptic characteristics. Ozonized water is used to disinfect vegetables and protein raw materials, and to inhibit the growth of fungi and molds. Ozone generators have low energy consumption and operate at low temperatures. Ozonized water does not require rinsing and involves the production of waste water which no longer constitutes a negative environmental impact. The production of ozonized water is environmentally friendly, leaves no chemical residue and decomposes into oxygen. Ozonized water is a viable alternative to chemical disinfectants, improving the safety and sustainability of hygiene practices [26].

Standardization of Procedures: Lack of standardization in sanitization and disinfection procedures can compromise the effectiveness of interventions. It is important to implement protocols based on scientific evidence and current regulations.

In summary, environmental sanitization programs and air treatment technologies are essential to ensure safer and healthier

environments. However, their implementation requires a careful, multi-disciplinary approach, considering cost, complexity, the need for monitoring and staff training, as well as risk assessment and

regulatory compliance. The multimodal approach we have learnt from pandemic events is expressed in the figure below (Figure1).



Figure 1: Healthcare Systems in Action.

The Role of PPE

Personal Protective Equipment (PPE) plays a crucial role in preventing infections in healthcare settings by acting as a protective barrier between healthcare workers and pathogens. The correct use of PPE reduces the risk of infection transmission for both healthcare workers and patients [27].

Role of PPE in infection prevention:

1. **Protective barrier:** PPE prevents direct contact with infectious agents, such as bacteria, viruses, fungi and other

pathogenic microorganisms. These agents may be present in body fluids, respiratory secretions, blood, contaminated surfaces and in the air.

2. **Reducing the risk of transmission:** By using the appropriate PPE, healthcare workers reduce the likelihood of contracting infections and transmitting them to patients or other workers. This is particularly important in the presence of patients with known or suspected infections.
3. **Protection from different transmission routes:** PPE is

designed to protect against different transmission routes, such as droplets (droplets of saliva or respiratory secretions), direct contact with contaminated surfaces or fluids, and aerosols (airborne particles that may contain infectious agents).

4. **Prevention of care-associated infections (HAIs):** The correct use of PPE is essential to prevent HAIs, i.e. infections contracted during healthcare, as appropriate PPE with certification for infectious agents also acts as a barrier for the facility user in case the worker is a healthy carrier of infections. Such infections represent one of the most frequent complications in healthcare.

Evolution of PPE use in the Light of Recent Pandemics

1. **Increased Awareness:** Recent pandemics, particularly COVID-19, have increased awareness of the importance of PPE in preventing infection. There has been an increased emphasis on the correct use and availability of PPE for all healthcare workers.
2. **Strengthening of Guidelines:** Guidelines on PPE use were strengthened and updated, taking into account new scientific knowledge and evidence that emerged during pandemics. The Istituto Superiore di Sanità (ISS), ISPESL and INAIL has published several technical reports with specific guidance on the use of PPE in different care settings.
3. **Priorities in the use of PPE:** In emergency situations, such as during the COVID-19 pandemic, it has been necessary to prioritize the use of PPE, ensuring that healthcare workers at higher occupational risk, particularly those performing procedures that generate aerosols, have priority in the use of devices such as FFP2/3 facial filtering masks and if available is mandatory (see the aforementioned Legislative Decree No 81 of 9 April 2008) the use of certified FFP3 semi-filtering masks for protection from biological agents .-
4. **Use of Certified Semi-Filtering Masks:** Semi-masks classified as Category III PPE pursuant to Legislative Decree 17/2019 (EU Reg 2016/425) with EC/EU Type certification for protection from infectious agents complying with the technical standard EN149:2001+A1:2009 as FFP3 with barrier characteristics for infectious agents as a guarantee of protection of staff and patients. The use of the aforementioned semi-masks that possess the specific protection characteristics for infectious agents constitutes a prevention measure - protection from infectious agents to be implemented on the basis of the risk assessment pursuant to Legislative Decree 81/2008 as amended and indicated in the recent INAIL guidance document "Safety measures for infections in critical areas in healthcare: advanced technologies for the continuous use of dpi and disinfection of new conception" 3 January 2025 [11].

5. **New Devices and Technologies:** The pandemic has stimulated the development of new devices and technologies, such as PPE with modified design for improved adherence to the body, which can reduce the risk of contamination and improve healthcare worker comfort. These include antiseptic uniforms classified as PPE with technologically advanced features: TI ENERGY 100% polyester fabric material with zinc oxide nanoparticles cast into the yarn, optimum water repellency 90% with compliance with European technical standard EN ISO 6530:2005, the devices comply with the essential health and safety requirements as defined in Annex II of the PPE Regulation (EU) 2016/425 and the harmonized standard UNI EN ISO 13688:2013 - with conformity verified by appropriate Notified Body as indicated by the aforementioned EU Regulation, possess optimal antibacterial activity with compliance with the European technical standard EN ISO 20743:2013 and optimal antiviral activity with compliance with the technical standard ISO 18184:2019. These uniforms are reusable devices for 100 washes [11].
6. **Education and Training:** Pandemics have highlighted the need for continuous and specific training for healthcare workers on the correct use of PPE, including dressing and undressing, to avoid contamination.
7. **Increased Attention to the Quality of PPE:** The shortage of PPE during the pandemic led to an increased focus on the quality and certification of devices, with particular reference to compliance with European technical standards.

Future Perspectives

1. **Improved Availability and Accessibility:** It is essential to ensure the availability and accessibility of PPE in every healthcare setting, including in emergency situations, avoiding shortages that may compromise the safety of healthcare workers and patients.
2. **Standardization and Certification:** It will be increasingly important to promote standardization and certification of PPE, ensuring that devices on the market comply with high quality and safety standards, such as CE certification.
3. **Research and Innovation:** Research and innovation in the field of PPE will continue to play a key role in the development of devices that are increasingly effective, comfortable and adapted to the different needs of healthcare workers.
4. **Continuous Training:** Continuous training of healthcare workers on the correct use of PPE will remain an essential element to ensure maximum protection and to adapt to evolving knowledge and technology.
5. **Appropriate use of PPE:** The use of PPE must be based on the risk of exposure, avoiding overuse that can lead to waste and poor adherence to safety protocols.

- 6. Implementation of Surveillance Programs:** It is useful to implement surveillance programs that monitor the effectiveness of PPE use and identify any areas for improvement.

In summary, PPE are indispensable tools for infection prevention in healthcare settings. Recent pandemics have highlighted their importance and led to an evolution in the use, availability and technologies of PPE. In the future, it will be crucial to continue to invest in research, training and standardisation of PPE to ensure maximum protection of healthcare workers and patients.

Discussion

PAN-FLU Plans

The term 'PanFlu' refers to a strategic-operational plan for influenza pandemic preparedness and response. This plan is designed to address a public health emergency caused by a new strain of influenza virus with pandemic potential [28].

Here are some key aspects of PanFlu plans:

- **Objective:** The main objective of a PanFlu plan is to provide a structure and a set of coordinated actions to prevent, prepare for, and respond effectively to an influenza pandemic. This includes surveillance activities, clinical management, risk communication and public health measures.
- **Phases:** A PanFlu plan typically comprises several phases, including:
 - 1. Inter-pandemic phase:** This is the period between pandemics, during which preparedness and capacity building activities for identification, prevention and response take place.
 - 2. Alert phase:** In this phase, the epidemiological situation is monitored and preparedness measures are activated.
 - 3. Pandemic phase:** This is the phase of maximum emergency, characterized by the spread of the virus throughout most of the population. Containment, case management and surveillance measures are implemented.
 - 4. Transition phase:** This is the phase in which there is a transition from the pandemic to the inter-pandemic phase, with a gradual return to normal.
- **Structure and organization:** PanFlu plans clearly define the responsibilities and lines of command of the various actors involved in the pandemic response. This includes regional and national health authorities as well as individual hospitals and health facilities.
- **Activities:** PanFlu plans provide for a range of activities, including:
 - 1. Epidemiological and virological surveillance:** This includes collecting and analyzing data on cases of infection, as well as monitoring circulating influenza viruses.
 - 2. Early case identification:** PanFlu plans include a network of laboratories to rapidly identify influenza virus strains with zoonotic potential, to activate an early warning system.
 - 3. Public health measures:** These include social distancing, hand hygiene, use of masks and other measures to limit virus transmission.
 - 4. Clinical management:** Plans define protocols for patient management, including admissions, drug treatment and respiratory support.
 - 5. Risk communication:** Plans provide for communication activities to inform and involve the population in prevention and control measures.
 - 6. Health system strengthening:** During a pandemic, the human and structural resources of the health system need to be strengthened to cope with the increase in cases. This also includes increasing the number of beds in pneumology and infectious diseases.
- **Update:** PanFlu plans should be regularly updated according to the changing epidemiological situation and scientific advances [28].
- **Regional and national level:** PanFlu plans are defined both at national level, with a national strategic-operational plan, and at regional level, with specific implementation plans. The latter must be in line with national indications, but adapted to the territorial context. A regional plan must be approved by the regional government and must include implementation documents.
- **Network of laboratories:** PanFlu plans provide for the establishment of a network of public laboratories for the early detection of influenza virus strains, including zoonotic ones.
- In particular in the hospital setting for level II Health Emergency Department, the creation of a Level P3 laboratory is suggested [29].
- Biosafety Level P3 (BSL-3) laboratories are designed with very strict technical and construction criteria to guarantee maximum safety for operators and the environment. Here are some key features: [30]

1. Structure and Design

- **Physical barriers:** There are sealed and resistant walls, ceilings and floors to contain pathogens and facilitate cleaning.
- **Controlled access:** Entry via hermetically sealed doors and interlocking systems to ensure that only authorised personnel have access.
- **Negative pressure zones:** The entire laboratory is maintained at a lower pressure than outside to prevent infectious agents from escaping.

2. Ventilation Systems

- **HEPA (High-Efficiency Particulate Air) Filters:** All air exhaust passes through HEPA filters to remove biological contaminants.
- **Air exchange:** The laboratory is equipped with a system that ensures continuous air exchange to reduce the concentration of potentially dangerous aerosols.

3. Operational Safety

- **Biosafety cabinets:** All handling of pathogens takes place in sealed cabinets that protect both personnel and laboratory equipment.

- **Autoclaves and decontamination:** Presence of internal autoclaves to sterilize material before it is removed from the laboratory.
- **Emergency systems:** Sensors to detect leaks or faults, with alarms and automatic containment procedures.
- Operators wear special suits, protective goggles and respirators to protect themselves from possible exposure.
- **DISPATCH network:** For the rapid detection and analysis of useful information to initiate epidemiological investigations, the DISPATCH network was set up, consisting of experts with epidemic intelligence and risk assessment functions [31].

In summary, the PanFlu plan is a key tool to prepare for and respond to an influenza pandemic, defining actions, responsibilities and lines of command, with the aim of protecting public health and minimizing the impact of the health emergency. It is quite clear that at the level of hospital care systems the above-mentioned indications on disinfection, isolation and pathway separation are of fundamental importance in the success of pan-flu plans, which must be understood to extend to all highly airborne infectious diseases. Attached in the table is a summary of the main actions recommended to reduce the area spread of diseases in hospital settings (Table 1).

Table 1: Recommended actions to control the spread of airborne diseases in hospital.

1. Development of infection prevention and control protocols with standard procedures for the management of air-borne diseases with periodic monitoring mechanisms.	Periodic updating of protocols according to emerging pathogen
2. Availability of personal protective equipment (PPE) in sufficient quantity and quality	Periodic quality-quantity control of PPE taking into account expiry and renewal
3. Screening of incoming patients with rapid microbiology methods	Adoption of rapid microbiology techniques for incoming screening of colonised and/or infected patients
4. Availability of isolation areas with clear instructions or signs, appropriate equipment and ventilation	Expansion capacity of the hospital able to change set-up as infected patients enter
5. Availability of negative pressure rooms, adaptation of ventilation facilities	Periodic review of air conditioning systems, where possible implementation of negative pressure rooms
6. Use of transport precautions during medical procedures that generate aerosols.	Management of tracheal intubation, tracheotomy, cardiopulmonary resuscitation, bronchoscopy, autopsy procedures.
7. Availability of precautions at the hospital entrance	Provision of hand washing facilities equipped with water, soap, tissues, hand sanitiser and wastebasket at strategic points in hospital areas
8. Availability of posters and clear information	Hygiene and cleanliness posters with appropriate language and clear illustrations, including information on handwashing, cough management and social distancing
9. Protocols to contain transport needs	Adoption of procedures to treat the patient in isolation
10. Control of water circulating in the hospital	Adoption of the Legionella Plan and periodic microbiological control
11. Actions on staff	Training of hospital staff according to WHO infection prevention and control guidelines Staff vaccination Staff training to identify and screen suspected cases
12. Diversion policies	Implementation of protocols to ensure that beds are spaced at least 1 metre apart, regardless of suspected infectious spreadable disease

13. Area management	Adoption of procedures and protocols validated by the Control Committee for Care Related Infections (ICA) consistent with the main regulatory and bibliographic references for the management of hospital and ambulance surfaces
14. Waste management protocols.	Reinforcement of normal waste collection and disposal procedures
15. Registration of all persons entering risk areas	Adoption of systems to account for people entering infectious risk areas
16. Guidelines for handling dead bodies of patients with communicable diseases	Reinforcement of normal procedures for the reception and handling of corpses in the morgue by disinfection, compartmentalisation and supervision until burial.
17. Hospital Environments	Implement dedicated air decontamination systems in critical areas to reduce airborne infectious agents, and prioritize the installation of high-efficiency water filters at terminal points to minimize exposure risks in the hospital's most sensitive areas.

Conclusion

In conclusion, the prevention of epidemic events and the spread of airborne infectious diseases in hospitals requires a multi-modal approach that integrates cleaning, disinfection, infection control, appropriate - PPE, constant monitoring, rapid microbiology, staff training and contingency planning. It is crucial to implement these measures rigorously and systematically to protect the health of patients and healthcare workers. Recently it should also be noted that for most of the safety measures indicated in this article, a technical approval opinion has been issued concerning the technical-scientific profile and its correlation with current legislation by the Ministry of Health. The ability to use innovative techniques based on validated documentation and legislation allows the circulation of pathogens to be minimised and is a valuable defence argument in the event of medical-legal litigation.

Conflict of Interest Declaration

No conflict of interest to declare. The image reproduced in Figure 1 was obtained with artificial intelligence from Gemini 2.5.

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