Annali di Igiene has been requested to publish a document recently prepared by the Study Group on Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health (GISIO-SItI). The document, *Water safety in healthcare facilities – The Vieste Charter*, has been drawn up by a selected group of researchers and public health workers from Universities, Hospitals and Local Health Authorities from across the country, in collaboration with experts from the Ministry of Health and the National Institute of Health; it has been discussed and improved during the National Convention "Safe Water in Healthcare Facilities" promoted by the Local Health Authority of the Province of Foggia, Apulia, Italy and held in Vieste-Pugnochiuso (hence the definition of *Vieste Charter*) on 27-28 May 2016.

The principles underlying the Charter and its aims are well illustrated in the Foreward, so no further comments are needed.

As for other papers submitted to Annali, the Charter has been reviewed by anonymous referees and approved as such for publication.

The Editor in Chief

Water safety in healthcare facilities. The Vieste Charter

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Abstract

The Study Group on Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health (GISIO-SItI) and the Local Health Authority of Foggia, Apulia, Italy, after the National Convention "Safe water in healthcare facilities" held in Vieste-Pugnochiuso on 27-28 May 2016, present the "Vieste Charter", drawn up in collaboration with experts from the National Institute of Health and the Ministry of Health. This paper considers the risk factors that may affect the water safety in healthcare facilities and reports the current regulatory frameworks governing the management of installations and the quality of the water.

The Authors promote a careful analysis of the risks that characterize the health facilities, for the control of which specific actions are recommended in various areas, including water safety plans; approval of treatments; healthcare facilities responsibility, installation and maintenance of facilities; multidisciplinary approach; education and research; regional and national coordination; communication.

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Foreword

The principles underlying the present document are those of the safeguard of health as a basic right of the individual and the community, as sanctioned by article 32 of the Constitution of the Italian Republic.

The quality of the water in healthcare facilities is acknowledged to be a primary determinant of the health of patients, staff and other users.

Ensuring the safety of the water used in healthcare facilities means preventing and managing multifactorial, dynamic risks; such risks stem, on the one hand, from the structural and functional layout of the plumbing system, and, on the other, from the particular vulnerability of the persons exposed.

The aims of this Charter are:

- to promote a culture of prevention and control of the risks associated with all uses of water in healthcare practice;
- to implement and improve the hygiene management of water in the healthcare setting;
- to reduce healthcare-associated infections.

Preface

For the purposes of this document of intent:

- healthcare facilities include hospitals and residential and outpatient units for treatment and care, hospices, long-term care facilities, medical and dental surgeries, and any public or private structure in which healthcare services are provided;
- the users of healthcare facilities comprise healthcare personnel, administrative staff, persons employed within the facility in any capacity, whether permanently or temporarily, patients and any other persons entering the facility for the purposes

of visiting patients, utilising services, performing administrative operations, carrying out service duties or for any other necessity, for short or long periods.

In healthcare facilities, the water used for drinking, hygiene purposes, the production of hot water for washing and for medical/care purposes, and for the operation of the equipment utilised in the various activities of prevention, diagnosis, therapy and rehabilitation may impact the health of patients, staff and other users of the facility.

In healthcare facilities, the supply of water, from the public water mains or from other sources that are deemed fit, is ensured by the regular provision of the quantity of water required to meet the needs of human consumption.

Responsibility for the quality of the water supplied, in terms of conformity with the requirements set out in Legislative Decree 31/01 and subs. modif., lies:

- with the management of the public network, in the case of facilities connected with the public water mains, but only up the point of delivery of the water; with the management of the facility's internal water system, downstream of this point;
- with the provider¹, as defined under letter c) of article. 2 of Legislative Decree 31/01 and subs. modif.s., in the case of the facilities that are not connected with the public water mains.

Basic considerations

Risks connected with the use of water in healthcare facilities and technologies

- 1) The safety of the water used in healthcare facilities and technologies could be influenced by the complexity of the plumbing systems installed in large buildings; various elements of these systems may give rise to hazardous situations:
- in many cases, the plumbing system of the building constitutes a terminal point of

the water distribution network, thus favouring stagnation of the water in the system and giving rise to risks of microbiological and chemical nature;

- in addition to sanitary water systems, the building may be equipped with networks for the distribution of water and steam for purposes other than human consumption, such as fire-fighting, air-conditioning, supplying heating plants or laundries, irrigation, supplying fountains and producing distilled water or ice; these networks may be fed by the main plumbing system or connected to it;
- the plumbing systems inside the buildings, especially in the past, may not have been specifically designed to reduce risk factors that can jeopardise the safety of the water distributed; for example, there may be inadequately protected cisterns or stretches of piping in which the flow is reduced and the water tends to stagnate;
- the installation, modification and maintenance of plumbing systems are often inadequate, owing to a lack of awareness of the overall scheme of the system and of the functioning and running of the individual plants, which do not always fit into a global management of the system;
- the materials and products used in the plumbing systems in the buildings may give rise to risks, because they are not suitable for contact with the water (e.g. contain lead), because of obsolescence, or as a result of modifications that have taken place over the years;
- the management and maintenance of plumbing systems are handled by different internal and external subjects; thus, the availability of proper maintenance procedures, considering the difficulties of sanitising systems colonised by microorganisms and biofilm, may be thwarted by inadequate communication between managers and operators;
- new building work and/or restructuring may cause malfunctions, in that vibrations

- or significant changes in water pressure in the plumbing system may cause biofilms to detach, thereby releasing micro-organisms into the water; moreover, earth may enter the system during the construction of new stretches of the network.
- 2) In healthcare facilities, safety risks may stem from the characteristics, number and complexity of the plants used to supply water with different quality requirements for dedicated purposes. These include:
- the general distribution of hot and cold water of a quality suitable for human consumption, the preparation of foodstuffs, and personal and environmental hygiene;
- water treatment plants and equipment that utilise various technologies, such as mechanical filtration, membrane separation, the addition of chemical products, and processes of disinfection by means of ultraviolet rays or biocidal products;
- the treatment of water that has particular qualitative requirements and which is distributed to specific environments for dedicated healthcare purposes, in conformity with sectorial technical norms:
- dedicated water supply for use in various technologies and equipment, such as medical devices, diagnostic systems and pharmacological preparations;
- direct therapeutic uses, including delivery tubs, rehabilitation pools, hydromassage baths, hydro-therapy, showers, compresses, irrigations, aerosols;
- sterile water for injectable solutions, dilution media for pharmacological preparations;
 - hemodialysis;
 - ultrapure water for laboratory use.
- 3) Major risk factors are related to the susceptibility and vulnerability of the persons exposed, especially immunocompromised individuals, who are at increased risk of infection or adverse reactions. In this regard, some specific considerations concern the quality standards of water for human consumption, which are designed

to safeguard health, particularly that of vulnerable subjects such as newborns, children and the elderly.

Indeed, the quality standards prescribed (Leg. Decree 31/01 and subs. modif.) may not be able to guarantee the safety of particularly vulnerable populations or individuals.

Specifically:

- Pseudomonas aeruginosa, Staphylococcus aureus and bacteria belonging to the genera Acinetobacter, Enterobacter, Aeromonas and Klebsiella, and non-tubercular mycobacteria and filamentous fungi such as Aspergillus, which may be acquired through the consumption of water, can cause infections in subjects who are severely immunodepressed;
- in patients with burns or severe skin lesions, water can act as a vehicle of infection by contact when it is used to wash medical devices (endoscopes, catheters, etc.), diffused by medical equipment (nebulisers, humidifiers, etc.) or nebulised by showers and taps;
- the presence of opportunistic pathogenic micro-organisms, endotoxins, toxins and chemical contaminants (e.g. aluminium) in water is associated with the risk of infection/ intoxication in patients undergoing dialysis and, more generally, in immunodepressed patients;
- while some groups of enteric viruses (e.g. Rotavirus and Norovirus), which are transmitted via the oro-faecal route, are known to cause healthcare-associated infections (in hospital nurseries, paediatric wards, facilities for the elderly, and in patients hospitalised in bone marrow transplant units), no epidemiological evidence is as yet available to suggest that the water in healthcare facilities is a vehicle for the transmission of these viruses. However, recent assessments by the World Health Organisation (WHO) presented to the European Commission indicate that this risk is underestimated:

- it is known that the colonisation of plumbing or ventilation systems by Legionella can cause legionellosis in hospitals and other healthcare facilities, though this risk is still underestimated. The presence of Legionella is a necessary, albeit not sufficient, condition for the occurrence of cases. Exposure to the risk of contracting the disease takes place through the airways as a result of the inhalation or micro-aspiration of droplets of contaminated water released in aerosol form by showers, air humidifiers and medical devices, including dental equipment.

Tools for risk analysis and prevention

In accordance with current legislation, the safeguard of water utilised in healthcare facilities is based on the standards laid down for drinking water. These are designed to protect human health from potential risks associated with the consumption of water in the domestic setting; they are sometimes integrated by regulations and guidelines concerning the assessment, prevention and management of risk in the healthcare setting.

- Since 2004, within the framework of its Guidelines for Drinking Water Quality², the WHO has set out the criteria of its Water Safety Plan as the most efficacious mean of systematically ensuring the safety of drinking water systems, the quality of the water supplied and the protection of consumers' health. This model, which has been adopted in national guidelines³ and implemented in some regions⁴, pursues the objective of integrated risk assessment and management, in order to protect water supplies at their origin and throughout the distribution network up to the tap. The final objective is to gradually reduce physical, biological and chemical risks for the consumer. When EU Directive 2015/1787 came into force at the national level, risk analysis according to the water safety plans was also introduced at the legislative level,

in order to ensure the quality of water for human consumption.

- The WHO has also drawn up basic indications for risk prevention and the creation of water safety plans regarding the distribution of water in buildings⁵, the installation and maintenance of plumbing systems⁶ in centres for care and treatment⁷ and risk assessment with specific regard to medical and healthcare practices⁸.
- Regulations of an obligatory or voluntary nature concerning various areas of application and implementers have a direct bearing on the quality of water and on safeguarding the health of the users of healthcare facilities. These regulations include:
- with regard to the safety of plumbing and/ or treatment systems and materials in contact with water, Ministerial Decree N° 37/2008°, which mandates the certification of plumbing and sanitary systems; Ministerial Degree N° 174/2004¹¹ regulates the safety of materials in contact with water; and Ministerial Decree N° 25/2012¹¹ disciplines the treatment of water for human consumption;
- CE Reg. 852/2004 on the hygiene of food products, with particular reference to the presence of automatic distributors of drinks, foods¹² and water in dispensers¹³;
- the analysis of risk due to *Legionella*, is dealt with in the guidelines for the prevention and control of legionellosis issued by the Ministry of Health¹⁴.

On the basis of the premises and basic considerations cited above, the following principles and recommendations have been agreed upon:

1. Risk assessment/risk management plans for drinking water systems

Based on the WHO-defined principles of risk assessment and management, and transposed into Italian guidelines, "water safety plans" constitute the most effective means of ensuring the safety of water for human consumption and for supply to

healthcare facilities. Legislation on the supply of water for human consumption should therefore be aligned with these principles and prescribe the obligatory implementation of these plans by water providers and their approval by the central healthcare authority.

2. Safety plans for water in buildings

Application of the principles of risk assessment and management must include the safety of the water used in healthcare facilities for all activities of prevention, diagnosis, therapy and rehabilitation. Plans for "water safety in buildings", as defined by the WHO, must incorporate the norms of good practices contained in international and national standards and guidelines. In this regard, it is necessary to take into account the characteristics of the water entering the building, the types of treatment and distribution of the water. in accordance with the needs of the various sectors of the facility, and the susceptibility and vulnerability of the users.

A safety plan must also establish procedures for dealing with any potential emergency situations and accidents that may impact on the quality of the water and on the health of the users of the facility.

3. Approval of treatments, materials and products in contact with water following third-party certification

With regard to the safety of the materials and products that come into contact with the water in the facility during its distribution or treatment, specific regulations are required. Moreover, existing regulations need to be updated in response to technological advances and progress in the field of certification. The safety of the treatment procedures, materials and products utilised in the production and distribution of water for human consumption should be subject to certification by third parties and approval by the central healthcare authority. This is

a prerequisite to ensuring that the water supplied to the various points of use within the facility meets the necessary qualitative requirements and does not constitute a health risk for users.

4. Responsibilities of healthcare facilities, installers and maintainers of sanitary water systems

In accordance with Ministerial Decree N° . 37/2008, the head of the healthcare facility must ensure that the plumbing system conforms to the requirements and conditions of the law. The work of installation, transformation and extraordinary maintenance of the system is to be carried out by qualified firms that are certified as possessing the specific technical and professional requirements needed; if necessary, specific requirements may be stipulated when the work is commissioned and assigned. As the manager of the plumbing system or of the internal water network, the head of the healthcare facility must implement all necessary measures to ensure the safety and proper functioning of the system over time, through appropriate interventions of control and maintenance, which are to be recorded in a "plumbing system register". Moreover, the system should be designed in such a way as to enable subsequent maintenance work to be carried out easily and sections of the system to be replaced without excessive disruption. In this regard, the management of individual plants within the system should fit into the overall framework of management of the entire system and of the various uses of water inside the facility, as part of a water safety plan for the healthcare facility as a whole.

5. Multidisciplinary interaction between healthcare professionals and technical operators

Within the framework of water safety plans in healthcare facilities, risk analysis requires the multidisciplinary participation and interaction of various subjects: from those involved in designing, managing and maintaining the networks, the individual sanitary plants and treatments, to the various healthcare professionals working in the facility. These latter comprise the entire personnel operating at different levels, including hygienists, clinicians and nursing staff. This multidisciplinary approach is the most effective means of drawing up and optimising strategies for the prevention and management of the risks of water contamination, thereby maximising health protection and optimising the allocation of resources.

In this regard, it is essential that the General Management of the facility, the Medical Director and the Technical Department work closely together to plan all the actions to be undertaken. In particular, all interventions concerning maintenance and the replacement of technological and/or system components should be agreed upon by the various professionals involved. This will enable the performance objectives of the water system to be set in relation to the hygiene criteria and needs of the facility.

6. Training

Specific training oriented towards the multidisciplinary interaction of all the subjects involved is essential to ensuring the safety of water use in healthcare facilities. In this regard, hygienists should play a leading role in implementing models of risk analysis and prevention that integrate the expertise of the various professionals involved. Training is essential in order to ensure that the staff of the facility and all subjects who are in any way involved in the functioning or monitoring of water systems are fully aware of the importance of their own contribution to water safety, and hence to the health of users.

The institutions responsible for education and training – universities, hospital agencies, local health authorities and professional

associations – should promote training initiatives for the technical designers and installers of water systems, healthcare managers, medical and nursing staff and providers of technical services, in order to raise awareness of risk analysis, plant design and management solutions, proper maintenance procedures and adequate risk surveillance. Where necessary, such initiatives should also include the provision of information for high-risk patients, with regard to avoiding the dangers associated with the use of water in healthcare facilities and, subsequently, in their own homes.

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Such activities should be of a multidisciplinary nature. In particular, the culture of hygiene should be consolidated through training programmes for engineers, architects and other operators in the technical sector. Likewise, training initiatives aimed at medical personnel should promote the awareness of technological options capable of solving problems.

7. Technological research and development

The efficacy of measures for the prevention and management of the risks connected with the use of water in healthcare facilities is strictly dependent on advances in scientific knowledge of the emerging risks associated with the treatment and use of water in buildings. In this context, research on risk analysis could also support possible practices for the safe re-use of water in the healthcare setting, which have been promoted at the international and European levels in order to ensure the sustainability of water resources in general.

The knowledge gained by the scientific community in the medical and engineering fields should guide control measures and other interventions envisioned by water safety plans; such measures should include the establishment of parameters, threshold values and other indexes for monitoring the quality of water and plumbing systems, with a view both to risk prevention and to

the optimisation of human and material resources.

8. Hospital Infections Committee

The Hospital Infections Control Committee (HICC) plays a key role in ensuring the safety of the water used in healthcare facilities, both by implementing prompt remedial intervention in the event of ascertained or suspected risk and by optimising the efficacy of preventive intervention on water-distribution systems. The supports Healthcare Management by fostering full interaction with hospital wards in order to improve the early detection of under-diagnosed diseases. In addition, it has to work closely with the technical offices and control laboratories in order to promptly identify any functional anomaly or parameter that may be correlated with the emergence of potential water-related infections.

9. Regional and national coordination

The Ministry of Health's National Centre for the Prevention and Control of Diseases (CCM) recommends the adoption of preventive measures targeting both the general population and vulnerable subjects, as envisioned in its National Prevention Plans, through the introduction of regulatory intervention, common principles and guidelines. To this end, it is important to exploit local and regional experiences that could serve as models for other territorial areas or even guide national preventive interventions in the quest for solutions to healthcare problems that are difficult to solve at the local level. Within the framework of the creation and implementation of plans for the safety of water in healthcare facilities, measures for prevention and control that have already proved efficacious in minimising the risk of water-related infections should be given priority.

10. Communication

The various activities underpinning water safety in the healthcare setting must be integrated into the management of systems aimed at improving the level of satisfaction of those who utilise healthcare facilities for therapeutic or professional reasons. To this end, the management of the facility must pay careful attention to both internal and external communication.

Although internal communication targets subjects within the facility, it is both a complement and a prerequisite to external communication. Every organisation should carefully assess its modes of communication, as it is essential that users be kept informed at all times and, in the event of an emergency, promptly. The information conveyed must be correct and unambiguously expressed. In particular, the technical board responsible for the water safety plan must be immediately updated (at the decisional or informative level, as the case may be) with regard to anything that might constitute a risk for users; this includes any modifications to the internal plumbing system or to production systems, variations in the level of qualification of personnel or in the assignment of responsibilities, and possible complaints about the quality of the water supplied.

External communication influences users' perception of the quality of the service provided and constitutes a permanent channel of feedback that enables user satisfaction to be monitored. External communication must also be integrated into the management's communication network and adequate procedures must be put in place to warn users in the event of accidents involving the water supply.

11. Sustainability of resources and watersaving

At a time when the concept of sustainable development is becoming a priority for the future of our planet, healthcare facilities should adopt policies of environmental, economic and social sustainability. This is in line with the recommendations of the

protocol "Water and health" of the United Nations Economic Commission for Europe (UNECE) and the WHO¹⁵. Within this framework, water consumption should also be taken into account when safety-driven choices are made. Thus, the managers of technical departments must be made aware of the importance of saving water by introducing systems for reducing wastage, monitoring consumption (of drinking water and of energy for the production of hot water) and, where feasible, for the safe re-use of water, notwithstanding the need to implement suitable programmes of controlled water flow in order to reduce or eliminate stagnation, which gives rise to and maintains the formation of biofilm.

Riassunto

La sicurezza delle acque nelle strutture sanitarie – La carta di Vieste

Il Gruppo Italiano Studio Igiene Ospedaliera della SItI e il Dipartimento di Prevenzione ASL FG, a conclusione del Convegno Nazionale "Acque sicure nelle strutture sanitarie" svoltosi a Vieste-Pugnochiuso il 27-28 maggio 2016, in collaborazione con gli esperti dell'Istituto Superiore di Sanità e del Ministero della Salute, hanno presentato la "Carta di Vieste". Tale documento considera i fattori di rischio che possono inficiare la sicurezza d'uso delle acque in ambito sanitario e richiamano gli attuali quadri normativi che regolano la gestione degli impianti e la qualità delle acque.

Gli autori promuovono un'accurata analisi dei rischi che caratterizzano le strutture sanitarie, per il controllo dei quali si raccomandano azioni specifiche in diversi ambiti, tra i quali piani di sicurezza dell'acqua; approvazione dei trattamenti; responsabilità di Struttura sanitaria, installatori e manutentori degli impianti; approcci multidisciplinari; formazione e ricerca; coordinamento regionale e nazionale; comunicazione.

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 Specifically, this means "whoever supplies water to third parties by means of autonomous water conduits or fixed or mobile cisterns".

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