NHS England

NHS Estates Technical Bulletin (NETB) No.2024/3

Designing safe spaces for patients at high risk of infection from nontuberculous mycobacteria and other waterborne pathogens

Date of issue: 27 August 2024

Applicability

This NETB applies to all healthcare settings.

Objective

The objective of this NETB is to:

1. To enhance existing guidance set out in HTM 04-01 safe water in Healthcare premises, to address risks from nontuberculous mycobacteria (NTM) and other waterborne pathogens; and
2. To identify specific measures required for new hospital premises and major refurbishments for those patients at greatest risk of healthcare-associated infections.

Status

The information contained within this bulletin is a supplement to the current HTM. It should be read in conjunction with HTM 04-01 safe water in Healthcare premises, and its contents should be implemented in the same way.

Content

This technical bulletin identifies which patient groups are high risk and provides recommendations on how to adopt a precautionary approach to protect them. It outlines who should be involved in the design, construction and delivery of the project, the skills

and competence needed and how to ensure that all potential hazards and risks have been considered.

NHS Estates Technical Bulletin (NETB)

With responsibility for producing Standards and Guidance for the NHS Estate, we are responsible for ensuring that the information and guidance they contain remains up-to-date and relevant for users. This can involve revising and updating the documents themselves, but this is not the optimum approach in all cases and therefore an alternative approach is needed where such full revision is not appropriate. Where appropriate, NHS Estates Technical Bulletins (NETB) will be issued instead.

NETB need to be considered by all applicable organisations, as noted above, and implemented as required. Boards are responsible for its assessment and application to their organisations.

Background

In November 2022 a coroner published a prevention of future deaths report. The report highlighted his concerns around the risk that *M. abscessus* and its colonisation in healthcare water systems may have on patients who require augmented care, especially those who are immunosuppressed.

He recommended a review of the current guidance, and for consideration to be given to additional measures which may be required in relation to the design, installation, commissioning and operation of hospital water systems in new hospitals.

Monitoring of Implementation

The implementation of this NETB will be monitored in line with overall compliance to the HTMs and HBNs through the NHS Premises Assurance Model.

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Contents

Executive summary

This technical bulletin has been developed to enhance the current (2016) HTM 04-01 following a recent outbreak of *M. abscessus* (*Mab*), a nontuberculous mycobacterium (NTM), associated with a newly constructed lung transplant unit. This bulletin aims to ensure that the design, construction and operation of new specialised wards/units, or major refurbishments of existing clinical spaces intended for patients at high risk of healthcare-associated infections (HCAI), do not cause harm from exposure to water, sprays or aerosols derived from water, wastewater systems and associated equipment.

Drinking water, even when complying with all regulatory standards, contains a range of microorganisms, including opportunistic waterborne pathogens such as *Legionella, Pseudomonas aeruginosa* and NTM. These rarely cause harm to the general population but can cause serious illness and sometimes death for patients at increased risk of HCAIs

because of their compromised immune status, underlying chronic conditions or breaches in skin integrity.

Outbreaks and pseudo-outbreaks of waterborne infections, including those caused by NTM, have been associated with water in distribution systems, wastewater systems and associated equipment. Patients at increased risk of NTM infections (see at-risk patient groups) need spaces which are designed, managed and operated to prevent exposure as much as possible, taking into account all possible modes of transmission including ingestion, inhalation, aspiration and contact (both direct and indirect).

Patients at risk of infection from NTM are also at risk from other opportunistic waterborne pathogens. Following the guidance in this technical bulletin, combined with good infection prevention and control practices, will minimise the risk of exposure to all potential sources of waterborne infections as far as is practicably possible.

Aims

This technical bulletin aims to enhance the current HTM 04-01 (2016) to ensure new projects for the development or refurbishment of spaces intended for patients at increased risk of all waterborne infections are designed, constructed and commissioned so that they minimise the risk of harm from exposure to water, sprays or aerosols derived from water, wastewater systems and associated equipment as far as possible.

It focuses on ensuring healthcare buildings are safe for the at-risk patient group rather than simply giving guidance on how to comply with the prescriptive requirements of standards and guidance (see Hackitt, 2018).

Owing to the gaps in the knowledge around NTM infections (see section on "Gaps in current knowledge" below) and because patients who are at increased risk of NTM are also at risk from other opportunistic pathogens associated with exposure to water, this guidance adopts a precautionary approach. This technical bulletin advocates early action to protect against reasonably foreseeable threats of harm, even if full scientific certainty about the risk is lacking.

To achieve this, a Project-specific Water Safety Group (PWSG) (see paragraphs 2.24–2.33) with the required skills and competencies should develop and implement a Project Water Safety Plan (PWSP) that addresses the infection risks of NTM and other opportunistic pathogens. The PWSP should be developed in conjunction with current HTMs and HBNs and relevant British Standards such as BS 8680, BS 8580-1 and BS 8580-2, which provide additional information for the development of water safety plans, the appointment of water safety groups and the factors to consider in risk assessments for NTM and other waterborne pathogens.

At-risk patient groups

Patient groups designated at high risk include:

1. lung transplant patients
2. cystic fibrosis (CF) patients

3. haematology/oncology patients undergoing chemotherapy where neutropenia is expected

4. solid organ transplantation after intensive treatment

5. allogenic stem cell transplantation

6. any patient with a long line (e.g. central venous catheter) in situ.

Patients in groups 1 and 2 are at high risk of pulmonary disease. Disease in the other patient groups is infrequently manifested as pulmonary disease. Bloodstream infections are commonly related to the presence of in-dwelling venous catheters. Skin and lymphatic infections may also occur. A precautionary approach is necessary to protect these patients.

Gaps in current knowledge

There are several gaps in current knowledge with respect to:

1. the pathways and risk factors leading to infection from NTM

2. the dose and length of exposure needed to cause infection by all potential infectious NTM

3. all the potential routes of transmission for each pathogenic NTM

4. the time between exposure and infection

5. the safe target level for each of the potentially pathogenic NTM species in water systems and associated equipment to which patients may be exposed, to ensure no harm to highly susceptible patients

6. the long-term effective control methods for preventing NTM colonisation and growth in water systems.

The above may differ depending on the NTM species.

There is a large gap in the ability of laboratories to detect all NTM in samples from healthcare water systems. The current methods for the sampling and detection of NTM from water and the associated environment are not currently standardised (see Chapter 8). This means that the sensitivity and specificity of detection methods varies between laboratories and so sampling results from different laboratories are not comparable. As a result, it is difficult to interpret test results in the context of determining the risk to patients.

Summary of main recommendations

The key to bringing about effective change is to ensure that all potential hazards and risks to high-risk patient groups which could cause harm are identified and assessed at the concept stage of a hospital development or upgrade project, before the design brief has even been developed. Potential hazards and risks which could have an adverse impact on the project may be identified by referencing the existing risk register maintained by the healthcare organisation and/or Water Safety Group (WSG). This allows for implementing appropriate

mitigations from the earliest point in the project. These should then be reviewed and amended as necessary throughout each stage of the project to ensure all water, wastewater systems and associated equipment are delivered so that they will cause no harm to at-risk patients.

A soft landings approach (as outlined in BS 8680) should be adopted. The benefits of this approach include ensuring clarity on the requirements to keep at-risk patients safe. The soft landings team should champion these requirements on behalf of the healthcare organisation throughout the project. They should establish clear communication channels to ensure the design goals and system performance targets are met, enabling a smoother transition and continued support after handover. See the UK BIM Framework Government Soft Landings on applying BS 8536.

Fundamental and simple actions to ensure safe water systems and patient safety include:

Improved governance

a) **Boards**: the Board of each healthcare organisation is responsible for ensuring effective governance is in place to deliver a building that is safe for its intended population. For each project, there should be a clear and identifiable project duty holder with the required competence to take responsibility for the safety of the whole building (see the Hackitt report 2018). This can be achieved, for example, by the Board appointing an Executive Director/Senior Responsible Owner (SRO) for the project with support from the healthcare organisation's Authorising Engineer (Water)/specialist adviser/subject matter expert.

b) There should be appropriate governance, accountability, policies, assurance and oversight at Board level by those with the required skills and experience from the inception onwards throughout the whole project.

c) **Duty holders**: the project duty holder should ensure there are clear targets for expected outcomes which are set out at the start of a new build or major refurbishment project, i.e. that the building poses no risk of harm to patients from waterborne hazards, and this target remains the primary focus throughout all stages of the project.

d) **Project Water Safety Group (PWSG)**: a PWSG should be formally appointed and led by the project duty holder (Executive Director/SRO). It should include appropriate client representatives, architects, the Authorising Engineer (Water)/specialist adviser/subject matter expert, design teams, and those involved in procurement, construction, commissioning, ongoing operation and maintenance. Additionally, it should include infection prevention and control teams with appropriate experience in identifying and managing infection risks caused by the built environment. The PWSG should regularly report to, and brief, the healthcare organisation's WSG. This PWSG should be empowered and given the time and resources to ensure the project delivers a safe building for the intended at-risk patient group. The Trust board has the ultimate responsibility for the safe delivery of patient care.

Note:

Part A in HTM 04-01 identifies that the healthcare organisation's water safety group (WSG) (see HTM 04-01 Part B) is pivotal in ensuring that decisions affecting the safety

and integrity of the water systems and associated equipment do not go ahead without being agreed by them (this includes consultations relating to decisions on the procurement, design, installation and commissioning of water services, equipment and associated treatment processes).

For new build projects in healthcare premises, the appointment of a multidisciplinary PWSG with the experience, skills and competency required to review and approve the design brief and make any recommendations necessary from the start of the project should include the involvement of existing WSGs responsible for the water safety in the existing estate (BS 8680).

Risks

e) The needs of each project should be clearly defined and take account of all identifiable risks and experience gained from previous projects at the local, national, and international levels.

f) The PWSG, with input from all relevant stakeholders, should develop a project-specific water safety plan (PWSP) in accordance with BS 8680 and based on risk assessments carried out in accordance with BS 8580 parts 1 and 2. The PWSP should identify all potential sources of exposure to water and wastewater and all potential hazards and hazardous events which could pose a risk to patients, staff or visitors.

g) Each stage of the process, from concept to handover and beyond, should be risk-assessed by taking account of the susceptibility of this patient group. The hazard analysis and critical control point (HACCP) principles of risk assessment (as used in the food industry) should be used, and effective barriers put in place to prevent harm (see paragraph 2.17).

h) As the project progresses, the PWSG should review the project stage risk assessments following the processes and documented procedures within the PWSP in order to validate and monitor the effectiveness of the performance of control measures. Where necessary, the PWSP should be updated to ensure the barriers and controls remain effective to prevent harm before progression to the next stage (see BSRIA Guide BG54). This will ensure the focus remains on patient safety as the primary aim throughout the project, thereby avoiding expensive downstream costs and patient harm.

i) System designs must be completed on a rationale that minimises the risk of microbial contamination. The PWSG should ensure that no materials, components or fittings of the water system infrastructure should be procured and/or installed that presents a risk of microbial contamination of water systems or associated equipment components, i.e. components, fittings or any equipment to be used during installation and commissioning should not have previously been used and/or wet tested. For these high-risk patients, each item should be individually packaged and be accompanied by a manufacturer's certificate which states that the fittings will have no adverse effect on water safety and that they have been tested by a validated process.

Note:

- Wet-testing introduces the risk of water and/or damp areas remaining in water systems, components, fittings or equipment, which can support the colonisation of NTM and other waterborne pathogens. It is important that transport and storage conditions ensure that system materials and components, including where systems are constructed off-site, are protected from ingress of water, nutrients and contamination. Poor management, before and during installation, can lead to systemic colonisation which can remain a risk for the life cycle of the system and have the potential to cause serious infections in high-risk patients.
- Augmented care units require the highest standards of water safety. Wet-tested components and fittings may not meet these stringent requirements; supplying non-wet-tested components and fittings aligns with these evolving standards and protects patients from harm.
- Alternative quality assurance testing methods should be explored that do not introduce water into components and fittings.
- Certification should be sought by and provided to procurement teams on behalf of the PWSG, stating that components and fittings have been tested by a validated process that does not compromise water safety for high-risk patients.

Skills and competence

j) Appropriate training should be provided for all involved throughout the project so they understand the factors which can lead to harm from water, wastewater systems and associated equipment and how to prevent them. This includes all those involved from the inception and design stage of the project, through preparation of the design brief, tender specification, procurement, construction, installation, filling, commissioning, handover to normal operation and maintenance.

k) Ensuring there is relevant experience and competence, rather than relying solely on job titles, is the key to delivering success. It is essential that the Executive Director/SRO ensures the PWSG includes individuals with the necessary range of experience, competence and skills required to deliver a building which will do no harm to the at-risk patient group.

l) The periphery of the water system (comprising the interface between the point of use and the wastewater system, as well as thermostatic mixing valves (TMVs), U-bends and the area within the 2 m splash zones) requires specific training and competence. Most occurrences of infection transmission relate to this area and the associated clinical practices. Detailed consideration and expertise are needed to ensure all system hazards and associated risks have been identified and mitigated in the design, construction, installation and operation of the water system.

m) Installation works associated with water systems should only be carried out by those who have been specifically trained to work on healthcare water systems and following processes approved by the PWSG. This is to ensure that all individuals understand the risks to patient safety from their actions.

Procurement and contract management

n) Procurement practices must take account of the need to ensure that water safety is a critical element of the new build process and does not introduce risks to patient safety throughout the lifecycle of the building. This includes premarket engagement with manufacturers and suppliers to improve the supply chain's understanding of product risks and how to reduce or mitigate these.

o) The water and wastewater safety criteria and documentation for the building's handover and acceptance, in the form of a commissioning plan should be agreed at the design brief stage and included in the PWSP.

p) Site welfare facilities must be provided for all contractors on site so that all water and wastewater system fittings and components, such as drains, water outlets and toilets, cannot be used and remain sealed until the system is filled and managed by the commissioning team as described within the PWSP (see "System commissioning" section below). This is to avoid water, wastewater systems and associated equipment becoming contaminated by contractors before handover.

q) The water system acceptance criteria should be clearly defined within the tender specification and agreed by the PWSG. The tender specification should include the sampling and monitoring plans and the data required to determine all systems are safe for the at-risk patient group over the time specified before acceptance for handover as agreed by the PWSG.

System commissioning

r) The filling of water systems, pressure testing and commissioning are high-risk processes in the life of a water system, which continue to be a major source of system colonisation. Hence, they should not be regarded as an additional process. The filling and commissioning plan must follow the PWSP and reflect that all systems should only be filled and operated with disinfected water through the point of entry filtration system (see Chapter 6). Commissioning should occur at the latest possible time before handover, after all other building elements have been commissioned. This plan needs a high level of focus and effort to prevent contamination of the water and wastewater systems as set out at project inception and agreed upon by the PWSG.

s) For acceptance at handover, all commissioning records, temperatures (hot and cold water), hot water hydraulic balancing, flushing regimens, flow and throughput parameters, assurance of free flow in wastewater systems with no pooling in fittings or on shower floors (for example, commissioning and validation of any secondary biocide and water quality results should be available in electronic format prior to handover and signed off by the PWSG prior to acceptance). The records should form part of the BIM as-fitted model handed to the operations team.

Previous guidance

The current HTM 04-01 (Parts A-C) (2016) gives guidance on the design and operational management of water systems in healthcare premises with specific focus on how to minimise the risks from waterborne microbial pathogens commonly found in water systems such as *Legionella* species and *Pseudomonas aeruginosa*. While the 2016 guidance took account of the then-recent international outbreak of *M. chimaera* associated with heater-cooler units primarily used in cardiac surgery, it did not address the risk from other NTM

species that pose a high risk to patients who are immunocompromised and/or have underlying conditions which make them more susceptible to infection.

Scope

Patients at risk from NTM are also at risk from all other opportunistic waterborne pathogens, not just NTM. This technical bulletin, therefore, is also applicable to preventing infections from other infectious waterborne hazards.

It incorporates best practice from BS 8680 for the development of water safety plans specific for each project (PWSP) by a healthcare organisation-appointed project WSG (PWSG).

Since the current HTM 04-01 (2016) was published, evidence of the contribution of wastewater systems to HCAIs and the acquisition of antimicrobial resistance has increased. This technical bulletin also incorporates guidance to minimise the risks from the design and construction of wastewater systems.

Application of this guidance will ensure improved management of all microbial hazards, associated hazardous events and risks by putting patient safety first in the design of any new build or major refurbishment project which involves water, wastewater systems and associated equipment intended for patients at high risk of waterborne infections including those caused by NTM.

This technical bulletin is applicable throughout all stages of capital and major refurbishment projects from inception to handover, normal operation and planned and reactive maintenance.

Waterborne infections are not just transmitted directly to patients from outlets in their rooms (such as taps, showers and drains) but also, for example, from non-patient-facing staff-only areas, kitchens, pharmacy production areas, cleaning equipment and cleaning fluids and areas with water-containing equipment such as heater-coolers. This guidance is therefore applicable to these areas also.

Whilst this technical bulletin is focused on new build and major refurbishment projects, the information provided will be helpful for use in existing buildings where the infrastructure allows, to protect patients at high risk of water and wastewater infections, following risk assessment by those with the competencies, skills and experience to carry out such an assessment and agreed by the WSG. Guidance on safe ventilation for these areas also needs to be considered (see HTM 03-01). Further guidance for existing premises in use by patients at risk of NTM infections will be provided in the update of HTM 04-01 2016.

Note:

This technical bulletin acknowledges the critical importance of competency, skills, knowledge, experience and training for key personnel involved in water safety management in healthcare settings. Comprehensive guidance will be provided on these topics in the forthcoming revision of the parent HTM 04-01. This revision is currently in development and will address:

- detailed competency frameworks for key groups and roles in healthcare water safety

- qualifications, certifications and experience criteria for individuals deemed appropriately qualified in healthcare water safety
- recommended training requirements for key personnel involved in healthcare water safety.

These areas are under active review and development.

Acknowledgements

Susanne Surman-Lee, Technical author, Independent Consultant Clinical Scientist (public health microbiology), Leegionella Ltd

George McCracken, Responsible Person – Water, Belfast Health & Social Care Trust

Ginny Moore, UK Health Security Agency (UKHSA)

Jimmy Walker, Water microbiology consultant, Walker on Water

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1 Introduction

Note on terminology

For the purposes of clarity and consistency throughout this document, the term "NTM and other waterborne pathogens" is used as a representative term for all opportunistic waterborne pathogens associated with exposure to water and sprays and aerosols derived from water.

It should be understood that wherever "NTM and other waterborne pathogens" appears in the text, it refers broadly to the full spectrum of waterborne pathogens relevant to water safety concerns, not exclusively to nontuberculous mycobacteria.

This terminological consolidation aims to enhance readability and maintain consistency without compromising the comprehensive nature of the guidance provided.

Readers should interpret "NTM and other waterborne pathogens" in this expanded context throughout the document unless otherwise specified.

Nontuberculous mycobacteria (NTM)

1.1 Nontuberculous mycobacteria (NTM), sometimes called environmental mycobacteria or nontuberculous *Mycobacteroides*, are commonly found in the environment, in soil and water, as well as within constructed water systems and associated equipment such as those installed within healthcare premises.

1.2 NTM are not contaminants but part of the natural background microbial population entering the incoming supply and can colonise and grow within biofilms attached to water system infrastructures where conditions allow.

1.3 NTM like other opportunistic waterborne pathogens, including *Legionella* and *Pseudomonas aeruginosa,* when present in the supply entering the premises, typically cause no harm to the general population. However, if allowed to colonise water and wastewater systems and equipment that are poorly designed and managed, they can rapidly grow to levels which can cause harm to those who are more susceptible to infection than the general population, such as those who are severely immunocompromised as a result of their illness or treatment and those with underlying conditions which make them more susceptible to infection.

1.4 NTM are categorised as emerging human pathogens of concern as the number of cases is increasing worldwide, especially in developed countries with declining incident rates of *Mycobacterium tuberculosis* infection.

1.5 NTM are acid-fast, Gram-positive, non-motile, non-spore-forming bacteria with characteristic lipid-rich cell walls which help to protect them from adverse environmental factors, including the common control measures such as heat and biocides as used to control *Legionella* and *P. aeruginosa* growth in water systems.

1.6 NTM can survive at relatively high temperatures; however, their heat tolerance is dependent on the species. Research has identified that when water heaters in homes of patients were set at ≤50°C, they yielded NTM, but when temperatures were set at

≥55°C, NTM were rarely recovered. NTM can grow also in low nutrient and low oxygen conditions and multiply within both protozoa and biofilms. They are also able to survive in water dosed with biocide at levels above those used for shock treatment during the commissioning of new systems and/or associated equipment.

1.7 More than 200 species of NTM have been identified to date. Of these, approximately 50% are associated with causing infections in humans, from self-limiting cutaneous infections to life-threatening widespread disseminated disease in lung transplant patients.

1.8 They have been isolated in potable water, taps and showers, and have been associated with causing infections through colonised medical equipment, including heater-cooler units used in surgical procedures, dialysis machines, bronchoscopes, ice-machines and contaminated surgical solutions. In addition, NTM have been linked with causing pseudo-outbreaks in colonised healthcare water systems and equipment such as ice machines.

1.9 BS 8580-2 includes information to assist with the identification NTM and other waterborne pathogens. It also includes useful information on sources, transmission pathways, references, factors to consider during the risk assessment process, and developing a scheme of control.

Slow-growing and rapid-growing NTM

1.10 NTM can be categorised as either rapid-growing (visible in up to seven days to appear on culture media in the laboratory) or slow-growing (which can take several weeks). Both types can pose a risk of life-threatening HCAIs in high-risk patient groups, especially those who are immunocompromised and more susceptible to infection as a result of illness or treatment.

Slow-growing NTM

1.11 Slow-growing NTM include *M. chimaera*, which was responsible for the international outbreak associated with heater-cooler units (see HTM 04-01 Part B).

1.12 In addition to *M. chimaera,* the major slow-growing NTM of concern include the *Mycobacterium avium* complex (MAC), which currently comprises nine species: *M. avium, M. intracellulare, M. chimaera, M. colombiense, M. marseillense, M. timonense, M. boucherdurhonense, M. vulneris, M. arosiense,* and a small number of unclassified "MAC others".

1.13 MAC is associated with causing chronic pulmonary and disseminated disease as well as lymphadenitis. In the USA, MAC organisms, including *M. intracellulare*, are reported to be responsible for ~80% of NTM lung disease cases characterised by bronchiectasis, nodules and cavities. There is some evidence that rheumatoid arthritis patients are also at increased risk. HCAIs in susceptible patients (for example, CF patients) have also been associated with *M. intracellulare* subspecies *chimaera*.

Rapid-growing NTM (RGM)

1.14 RGM include the *M. abscessus* complex (which consists of three distinct subspecies: *M. a. abscessus, M. a. massiliense* and *M. a. bolletii*), *M. abscessus (Mab)*, *M. chelonae* and *M. fortuitum* (BS 8580-2). They are associated with rapid biofilm formation within water systems, increasing their resistance to biocides, relatively high temperatures and acidic environments.

1.15 The increasing prevalence of *Mab* worldwide, especially in countries where *M. tuberculous* infections are declining, is of increasing concern for several reasons:

a. It is one of the most commonly identified NTM species responsible for severe respiratory, skin mucosal and systemic infections in humans, and is of particular concern when present in areas where there are patients at high risk of infection.

b. Infections caused by rapid-growing *Mab* are considered one of the most antibiotic-resistant of all mycobacterial infections that are very difficult to treat. Infections caused by *Mab* can require long periods of complex antimicrobial therapy, which some patients are unable to tolerate.

c. The inherent antibiotic resistance of NTM also poses an increased risk of the transfer of multiple antibiotic-resistant genes, which is not just of concern locally as the increase in multiple antibiotic-resistant bacteria is also of global public health significance.

Infections caused by NTM

1.16 NTM can colonise in the gastro-respiratory tract and are responsible for a broad spectrum of infections ranging from hypersensitivity pneumonitis and mild infections of the skin to life-threatening disseminated infections i.e. those in which a localised infection spreads from one area of the body to others.

1.17 Patients at high risk of waterborne infections caused by NTM are those who are severely immunocompromised or have underlying conditions or breaches in the skin integrity, which cause them to be more susceptible to infection (see at-risk patient groups).

1.18 NTM can cause infections in lungs, sinuses, lymph nodes, joints and the central nervous system. People with weakened immune systems or certain pre-existing medical conditions are at an elevated risk of developing NTM infections. These infections can result in high rates of illness and death among these high-risk patient populations.

Challenges in managing the risk of NTM infections

1.19 “Hazards” is the term used for the agents which cause harm. These can be of a chemical, biological, physical or radiological nature (see BS 8680). The ingress of microbial hazards and/or nutrients which support their growth can lead to colonisation and growth of NTM in water systems, components, fittings and associated equipment.

1.20 It is well-documented that the presence of NTM in pipework, on fittings such as showerheads and in tap outlets and aerators has been associated with these bacteria causing HCAIs. Studies on the growth of NTM within biofilms shows trends similar to those leading to the colonisation and growth of *Legionella* species. Specifically, organic materials such as plastics and natural materials, which are often used in shower hoses, tend to increase the risk of colonisation compared with inorganic substances such as copper and glass. Like *Legionella* species, NTM have been shown to be able to grow within protozoa, increasing their ability to survive and grow in adverse conditions including aggressive water treatment regimes.

1.21 Large, reticulated water systems in healthcare premises pose a risk of HCAIs, especially to those at increased risk of infection, largely because of poor design and intermittent use, which means that neither temperature nor biocide dosing regimens

can be consistently achieved. Because of the inherent resistance of NTM to water treatment, extreme care must be given to the prevention of ingress of microorganisms into any system, component or associated equipment. The use of biocides alone in complex systems therefore is highly unlikely to achieve long-term control and poses the risk for selectively increasing the potential for more resistant microbial colonisers such as NTM to survive and grow.

1.22 To minimise the risk of waterborne infection for patients at high risk of NTM infections, particularly lung transplant and CF patients, additional measures are therefore required when planning and constructing specialised units for these patients. These measures are over and above those generally applied to the design and operation of healthcare premises as described in the current HTM 04-01 Parts A and B

1.23 This can only be achieved if all those involved in the project – from its inception through all stages, including developing the business case, design brief, engineering design, tender specification, procurement, construction, installation, managing and monitoring systems during filling, commissioning, and fit-out, to handover, full occupation and operation – are fully aware of the implications of their role in keeping patients safe.

1.24 Ensuring patient safety for those at high risk of waterborne infection depends on eliminating the potential for exposure to non-sterile water or ice. Where water is deemed safe in their recovery pathway, the PWSG should ensure there are appropriate clinical risk assessments to ensure safe and effective design, construction and commissioning processes, and safe operation of all engineered water systems, equipment and associated drainage.

Potential sources of infection

1.25 NTM infections have been associated with a range of sources and NTM species (see Table 1).

1.26 All those involved should understand and follow the processes in the PWSP to ensure that the design, specification, procurement, installation and commissioning phases minimise the risk of NTM infections. Examples of sources include:

a. distribution system outlets such as showers, taps and associated drainage

b. water and ice used for drinking, food preparation and post-surgical wound management

c. water used in patient diagnosis and treatment including water used for cleaning and decontamination of instrumentation

d. water used for personal hygiene

e. water used for environmental cleaning

f. toilet flushing

g. fittings, components and equipment which has been wet tested at manufacture (for example, heater-cooler units with *M. chimaera*).

1.27 All those involved in preparing the design brief, tender specification and procurement should have undergone awareness training (see paragraphs 2.34-2.39) so that they understand the factors that have led to HCAIs as a result of exposure to unsafe water and wastewater systems.

1.28 An example of the potential harm that can occur when designers, manufacturers, suppliers and procurement teams fail to understand the risks from pre-wetted systems and equipment is demonstrated by an international outbreak of *M. chimaera* infections that occurred in 2012. This outbreak resulted from contaminated heater-cooler units (HCUs) used during heart and lung transplant surgeries; the contamination occurred at the manufacturing site, where the water in the HCUs became infected with *M. chimaera*.

Possible routes of transmission of NTM in healthcare premises

1.29 The importance of the various transmission routes varies between organism and source. For example, patients with legionnaires' disease are not considered a source of infection for other patients whereas those patients with NTM infections can be, and thus require isolation. *M. abscessus* and *M. avium* transmission may occur between CF patients. However, according to Lipworth et al. (2021), the risk of acquisition of *Mab* in healthcare settings is low. A holistic approach is therefore needed when designing areas for these patients to minimise the risks of transmission from all potential sources.

1.30 The quality of water that is safe for these patients (see WHO's (2022) 'Guidelines for drinking-water quality') depends on their level of susceptibility (determined by their immune status) and all potential routes of access of infectious hazards (for example, through open wounds, in-dwelling catheters and central lines). All potential sources of transmission should be considered in the design risk assessment including areas where patients at high risk of waterborne infections may be exposed, including those which may be outside the designated unit such as areas used for diagnosis and treatment where these high-risk patients may be exposed to water such as where pharmacy preparation and sterile ice are produced, interventional radiology, etc.

1.31 The main routes of transmission are primarily inhalation of aerosolised water from showers or tap outlets, or aspiration of contaminated fluids including drinking water, leading to colonisation and/or infection of the gastro-respiratory tract. Skin and soft tissue infections can also occur via contact with contaminated surfaces, dust, air or water (see Table 1).

1.32 Direct or indirect contact with splashes from sinks and wastewater systems, can also cause waterborne infections. Therefore, when designing spaces for these patients, designers need to be aware that water splashes from outlets can travel up to 2 m.

1.33 Specific risk assessments need to detail how the patient will be protected from splash and aerosol contamination from equipment, outlets and drains and the additional measures to be taken (for example, avoiding exposure to water, only using sterile water or installing effective splash screens).

(i) Table 1 Examples of sources of NTM applicable to healthcare premises (not exhaustive)

Sources indicated within peer-reviewed literature	NTM associated with these sources
Drinking/tap water, including taps and showers, drinking water dispensers, water coolers and electronic outlets	*M. abscessus, M. avium, M. chelonae, M. fortuitum, M. genavense, M. mucogenicum, M. neoaurum, M. phocaicum, M. porcinum, M. simiae*

Peritoneal dialysis	*M. abscessus, M. fortuitum, M. neonarum, M. chelonae, M. smegmatis, M. goodii*
Ice-machines	*M. chelonae, M. porcinum*
Heater-coolers	*M. chimaera*
Bathing/hot tubs	*M. mucogenicum*
See also Kaula et al (2022)	

2 Governance and management of water safety during construction of high-risk patient care areas

Introduction

2.1 For patients at high risk of waterborne infection (for example, those patients in augmented care), all potential sources where patients could be exposed to water, wastewater systems and associated equipment could pose a high risk of increased morbidity and mortality.

2.2 To mitigate these waterborne infection risks, healthcare organisations should have comprehensive governance policies and practices in place, with clear responsibilities at the executive and board levels. They should be able to demonstrate that they have taken all reasonable measures to ensure their primary focus of any project involving water is the safety of their patients and others who may be exposed to any potential sources of waterborne infections in the existing and future healthcare estate.

2.3 Healthcare organisations should ensure there are policies in place which define the ownership of all new build and major refurbishment projects and there is effective governance, management, organisational arrangements and supporting programmes as well as access for oversight and independent audit and assurance on behalf of the healthcare organisation throughout all stages of the project.

Project governance

2.4 Each healthcare organisation, led by its CEO and supported by its board of directors, is ultimately responsible for ensuring there is effective governance in place for all new build and major refurbishment projects and there is ongoing oversight at Board level of projects involving water systems to which patients may be exposed. Key roles, deliverables and responsibilities should be clearly defined and assigned with demonstrable lines of accountability and communication for the project between the duty holder and the project team.

2.5 As recommended in the Hackitt report (2018), for each project there should be a clear and identifiable duty holder. For the purpose of this document, a project duty holder should be an Executive Director/Senior Responsible Owner (SRO) with Board level responsibility for the safety of new build or major refurbishment projects.

2.6 The Executive Director/SRO should be able to provide documented and demonstrable assurance throughout each stage of the project (for example, using tools such as the project risk register, the project health and safety plan and the project training needs analysis) that the healthcare organisation has taken all the steps necessary, as far as is reasonably practicable, to ensure that any new build or major refurbishment is safe for the at-risk patient group. This can be achieved by ensuring there are multiple barriers in place to prevent exposure and transmission of NTM and other waterborne pathogens.

2.7 Those managing each stage of these projects, either on-site or off-site, should be trained and competent and provide assurance to the Board at each stage of the project that the water systems are safe. BS 8680 gives guidance on how this can be achieved with:

- the development and implementation of PWSPs and
- appointment of a project-specific multidisciplinary WSG (PWSG) with the range of skills, competencies and resources to ensure the strategic direction of the project remains first and foremost to deliver safe premises. The PWSG should regularly report to, and brief, the healthcare organisation's WSG.

2.8 A gap analysis of the skills and competencies needed to ensure a safe project is delivered should be carried out by the appointed Executive Director/SRO. Where the necessary skills are not available in-house, appropriate external subject matter experts should be appointed as needed.

2.9 The involvement of these key professionals who are empowered and given the necessary resources to develop and implement a PWSP will ensure there is multidisciplinary input into identifying and designing-out all potential hazards, hazardous events and risks from the concept stage. This will ensure there is effective risk mitigation for the lifecycle of the building, encourage innovation and create a sharing and supported learning environment to deliver successful outcomes.

Multidisciplinary risk assessment

2.10 Each step in a capital or major refurbishment should be reviewed and risk-assessed by a competent multidisciplinary team, which includes the end-users and those who will be required to operate and maintain the systems. This group should have the skills and experience to identify all potential waterborne hazards, hazardous events and risks to patient safety which could occur during the project and throughout its lifecycle.

2.11 This assessment should then be reviewed at each gateway stage taking into account all potential sources where exposure and transmission of opportunistic pathogens could occur. Multiple barriers should then be put in place to control any identified risks.

2.12 Ongoing assurance and revision where necessary to ensure barriers remain effective throughout the project will ensure water, wastewater systems and associated equipment are designed and constructed to be safe for the at-risk patient group at handover and throughout the lifecycle of the buildings (see BSRIA Guide BG54/2018).

Project water safety plan

2.13 The development and implementation of WSPs for water systems in buildings as advocated by WHO (2007, 2011) has been incorporated into guidance from the Health and Safety Executive (HSE) since 2014 and the Department of Health since 2016.

2.14 Healthcare organisation WSPs should incorporate processes supported by documented procedures to ensure that all patients, staff and visitors are protected from all harm arising from the healthcare estate. The WSP should include the processes to be followed to ensure the development and implementation of a PWSP is put in place from the inception stage of a new build or refurbishment project in order to ensure patient safety is the primary aim and focus of the project.

Developing the project water safety plan

2.15 The main focus of a PWSP is to ensure all water, wastewater systems and associated equipment are designed and operated to prevent transmission of NTM and other waterborne pathogens in all areas intended for use by patients susceptible to NTM infections as well as staff and visitors. All potential sources of exposure should be identified, and effective barriers put in place to prevent transmission of infectious hazards.

2.16 For each project, a PWSP (which follows BS 8680) should be developed at the earliest stage and before the design brief is developed. An effective PWSP will ensure there are processes in place, supported by documented procedures to be followed throughout the project, to prevent the ingress of opportunistic pathogens for every stage of the project, from its inception and spanning the development of the business case and design brief, all the way through to normal operation and beyond. These processes should take into account the absolute requirement to minimise the risks of microbial hazards entering and growing within water and wastewater systems, associated equipment fittings and components to which patients, staff and visitors may be exposed throughout all stages of the project.

2.17 Risk assessments should be carried out at each stage of the project using the hazard analysis of critical control points (HACCP) approach (as used widely in the food industry and recommended by WHO for building water systems (WHO, 2007). This approach should be used to identify each point from the supply onwards through each system and item of equipment which is filled or uses water, where hazards (biological, chemical, physical (as well as radiological, where indicated) could ingress or increase to levels which could cause harm and, therefore, where a control measure is needed (this is a critical control point (CCP)). These assessments should be reviewed by the PWSG at each stage in the project to ensure all sources of exposure to water or sprays and aerosols derived from water are identified.

Note:

Control measures are activities or processes applied to a system to prevent hazards from occurring. These measures are implemented at identified control points. Control points are steps where effective barriers can be applied to prevent or eliminate a water safety hazard or reduce it to an acceptable level. Some plans contain key control points, which are critical locations where control is essential to prevent or eliminate a hazard (WHO, 2007).

2.18 It is essential that the project plan identifies and eliminates (or where this is not possible, minimises) the risk from all potential hazards and hazardous events at each CCP. All relevant hazards and hazardous events should be identified before the design brief is developed by the multidisciplinary PWSG, with input from clinical teams and, where applicable, specialist service providers and subject matter experts.

2.19 Where a potential risk is identified, using a precautionary approach, the design should incorporate multiple barriers so that if one control measure fails there is a backup.

2.20 Because of the complexity of protecting these patients, multidisciplinary input into the design and management of spaces used by high-risk patients is especially important when risk-assessing project and commissioning plans. This includes input from infection, prevention, and control (IPC) teams with experience of managing infection risks from the built environment as well as microbiologists, clinical teams and commissioning specialists to enable and support infection prevention and control in the new project spaces.

2.21 For high-risk patients, any exposure to non-sterile water may pose too high a risk of life-threatening infection. This multidisciplinary approach is therefore necessary to ensure the design takes account of all hazards and risks to these patients and prevents the potential for cross-contamination between areas and patients as far as possible.

2.22 Those carrying out risk assessments need to be competent and familiar with the building's water and wastewater systems and any relevant equipment to be installed as well as the applicable hazards, hazardous events and the HACCP principles of risk assessment. For each CCP, the design and commissioning plans should include how the controls will be validated and managed once installed, as well as the ongoing monitoring plan through commissioning and onwards to normal operation (see Chapter 6). The plans should include the acceptable levels for each target (for example, temperature, biocide levels, pH, microbiological and chemical parameters).

Note:

Where a private water supply is used by the healthcare organisation, a risk assessment to ensure the supply meets the Private Water Supply Regulations 2016 must be carried out by the local authority.

2.23 For patients at high risk of infections from NTM, the PWSP must take account of their susceptibility to infection and all potential sources of exposure and modes of transmission throughout all stages of the project and include processes supported by documented policies and procedures that:

a. define the governance required including the lines of accountability, responsibility and communication for water safety throughout all stages of new build or refurbishment projects

b. define the processes in place at the earliest possible stage in the project and throughout the project to ensure all potential sources of exposure are identified and that they do not pose a risk of NTM infection throughout the project and at handover and throughout the lifecycle of the water systems and equipment

c. include the criteria for the appointment of PWSG members who have sufficient training and the range of skills and competencies needed to ensure the project is managed to ensure a safe building is delivered

d. define the criteria for project design approval, agreement and implementation of design amendments, commissioning plans and sign-off at handover. This should include the documentation and data required to verify the building is safe for these patients before occupation and beyond and all control measures have been appropriately validated with appropriate on-site verification of performance

e. ensure there is time built in for project gateway stage reviews by the PWSG and implementation of any review recommendations

f. ensure the PWSG is empowered to ensure their recommendations are taken into account and members have the time and resources to develop and review the project design plans, ensure the project plans take account of all aspects of the PWSP and they are supported by a competent Executive Director/SRO with direct lines of communication to the Board

g. ensure there is sufficient awareness training and consultation with all relevant stakeholders as necessary throughout the project from its inception so that they can make informed decisions on what is required to keep the at-risk patient group safe from waterborne hazards

h. ensure that the water quality targets for the design, build, installation, commissioning of water systems, equipment and above-ground drainage are defined for each use so that water delivered at each point of exposure is safe for each at-risk user group. These include, but are not limited to, water used for personal hygiene, food and pharmacy production, drinking water, the flushing of toilets, wastewater drainage provision, the disposal of fluids, decontamination, laundry and water used in diagnosis and treatment

i. define the water quality criteria acceptable at handover and the processes in place to monitor control measures to ensure they are effective and compliant with the design criteria and relevant legislation and standards

j. ensure there is a risk-based approach used when applying best practice guidance (see Appendix 2). However, compliance is not to be the primary aim (Hackitt, 2018). It is important that all parties involved understand that buildings that are compliant are not necessarily safe, especially for this patient group. When derogations are needed, i.e. where existing standards, guidance, etc. will not deliver safe systems for the at-risk patient group, these should be risk-assessed, documented and agreed by the PWSG, and ratified by the Board

k. ensure there is a culture of openness and no blame so that when things go wrong or there are near misses, there is learning to ensure mistakes are not repeated. In these situations, learning from such events should be documented and widely disseminated both internally within project teams to include all stakeholders, contractors, user groups, etc. and wider within the NHS

l. ensure the design and the selection of components and fittings used within water systems, drainage and equipment (including the installation of components and equipment used for delivery of water) do not have any adverse effects on the microbiological or chemical quality of water, either in the short or long term

m. define how site access and security which supports project supervision, monitoring and review will be achieved ensuring:

    i. when and how the systems are to be filled and commissioned and observed as agreed by the PWSG

    ii. there is adequate supervision of commissioning teams during filling and commissioning

    iii. there are PWSG-approved risk assessment method statements (RAMS) and monitoring and sampling plans for use during filling and commissioning

n. evaluate decisions that have an impact on water safety (for example, the checks in place for purchasing of major plant and equipment as specified in the design)

o. ensure water safety throughout the lifecycle of water and drainage systems with a Board-approved process for assessment of cost against quality and long-term effectiveness

p. ensure that, once the design and commissioning plans have been approved by the PWSG and at SRO/Board level, there are no further changes unless reviewed and signed off again by the PWSG and SRO/Board

q. ensure ongoing verification of control measures to ensure they remain effective

r. ensure all relevant documentation, including risk assessments, risk assessment reviews and RAMS, are kept up-to-date and available to all who need access to them

s. ensure there are processes to ensure safe storage for all components, fittings and equipment on site as well as for safe installation and commissioning

t. ensure the design ensures ease of access for maintenance and security of all water system components and equipment

u. ensure no component, fitting, tool or equipment used for installing, commissioning, repairing or maintaining water systems and associated equipment poses a risk from cross-contamination (for example, items that have been pressure tested, leak-tested or wetted with water or used on other systems) (see also paragraph 4.16)

v. there are PWSG-approved processes, training, supervision and assurance to ensure the use of separate tools, equipment and PPE between clean and dirty systems and effective personal hygiene of those removing and/or installing fittings and components of water systems and associated equipment to eliminate the risk of cross-contamination.

Note:

The processes for preparation of the tender specification should be included within the PWSP (Tender specification).

Project-specific water safety group

2.24 For new build hospitals intended for patients at risk from waterborne infections, it is essential that persons with the required skills, competencies and expertise are identified and formally appointed to the project water safety group (PWSG) to ensure the project delivers a building which is safe for these patients at handover and onwards throughout the lifecycle of the building.

2.25 The PWSG should be formally appointed and led by the Executive Director/SRO and include appropriate client representatives including the healthcare organisation's operational WSG (see HTM 04-01 part B), architects, design teams and those involved in procurement, construction and commissioning.

2.26 The PWSG should have direct access to the Executive Director/SRO responsible for the project through to completion.

2.27 To ensure water safety is the prime consideration throughout the project, the PWSG should also include contractors, engineers, finance teams, clinical team end-users, microbiologists, those who will be responsible for normal operation and maintenance, an independent professional adviser/Authorising Engineer (Water)/Subject Matter Expert, specialist service providers (for example, where water is to be used in patient diagnosis and treatment), those providing decontamination services, patient support services (food preparation, cleaning, laundry, etc.), and infection prevention and control professionals with appropriate experience in identifying and managing infection risks caused by the built environment.

2.28 The PWSG should ensure there is a competent evaluation of all plans, specifications and risk assessments to ensure there are effective barriers in place to prevent ingress of NTM and other waterborne pathogens through all stages of the development of water, associated equipment and drainage systems in order to ensure that the safety of the intended patients will not be compromised when the building is completed and occupied.

2.29 To ensure that the project delivers safe water, wastewater systems and associated equipment for these patients, the PWSG should include an appointed on-site person (clerk of works) to monitor compliance with the PWSP, the competence of those working on site and the quality of workmanship.

2.30 The PWSG should review the design drawings and the construction project plan to ensure that the system and its components and fittings do not pose a risk to the safety of patients, visitors and staff. This entails evaluating factors such as the incoming water quality, hot and cold-water distribution systems, hot water storage, components, fittings and any associated equipment. It also involves assessing the potential for splash contamination, including systems and equipment used in diagnosis and treatment of these patients (see Chapter 3).

2.31 The PWSG should also review the commissioning plan and the future maintenance regime to ensure the lifecycle of the system has been considered.

2.32 The PWSG should challenge all elements within the process to ensure patient safety remains a primary focus of the project.

2.33 There should be regular assurance reports to the Board and the Trust's WSG concerning the project's ability to deliver safe spaces for susceptible patients. These reports should be at intervals prescribed by the PWSG including the on-site healthcare organisation's representative (for example, clerk of works). The reports should include performance criteria, progress against the agreed water system design and project plan, stage risk assessment review reports and any changes required to ensure the project's aims will be achieved and any matters of concern raised will be addressed in a timely way to ensure patient safety.

Note:

Whilst Part A in HTM 04-01 identifies that the healthcare organisation's WSG (see HTM 04-01 Part B) is pivotal in ensuring that decisions affecting the safety and integrity of the water systems and associated equipment do not go ahead without being agreed by them (and that includes consultations relating to decisions on the procurement, design, installation and commissioning of water services, equipment and associated treatment processes), they do not usually have the necessary time, skills and competencies to ensure all aspects of the design and specification of a new build will deliver a safe project. A dedicated PWSG should

include representation from the healthcare organisation's WSG, where applicable. All personnel should be given the time and resources to ensure the project delivers a safe building for the at-risk patient group.

Training

2.34 Risks from waterborne infections in very susceptible patients are increased where there is a lack of knowledge about the hazards, hazardous events and risks associated with poor design, engineering, specification, procurement, filling and commissioning of the water system infrastructure. Training is needed for those who are responsible for the governance and oversight of the project as well as all relevant stakeholders (see paragraph 2.35) including those responsible for preparing the project brief, business case and through each subsequent stage (see the RIBA-plan-of-work 2020).

Relevant stakeholders

2.35 In addition to those who are members of the PWSG, relevant stakeholders include:

a. the appointed project duty holder (Executive Director/SRO)

b. the CEO, the Board, executive and non-executive directors (also councils of governors in NHS Foundation Trusts)

c. the appointed duty holder and all those designated as accountable and responsible for managing water safety (see HTM 00) throughout the projects

d. those responsible for the business case, design brief, tender specification, design, procurement, engineering, installation, filling and commissioning, monitoring and acceptance at handover

e. those responsible for the ongoing operation, cleaning and maintenance of the water system components, fittings and associated equipment as well as the drainage infrastructure

f. those responsible for risk assessment and their review during all design and development stages to handover and normal operation and maintenance

g. representatives from clinical teams and those responsible for the safety of water used in diagnosing, treating and protecting these patients from infection

h. IPC team members with expertise in the built environment

i. WSG members and Authorising Engineers (Water)/specialist advisers/subject matter experts

j. estates and facilities management teams

k. risk management teams

l. procurement teams

m. clerk of works

n. contractors and subcontractors

o. manufacturers and suppliers

p. patient support services

q. those providing specialist uses of water for diagnosis and treatment associated with the intended patient groups

r. organisations responsible for clinical accreditation of units intended for high-risk patients

s. soft landings teams (see BS 8680 and BSRIA Guide BG54/2018).

2.36 The Executive Director/SRO responsible for the project should ensure all those involved in all stages of new build or major refurbishment projects receive training appropriate to their role. As a minimum, by attending sessions/workshops to provide adequate awareness of water hygiene, ensuring that everyone understands how to eliminate or, if not possible, minimise the risks from water exposure as far as practically possible to ensure there is an understanding of all risks associated with water systems and associated drainage as well as from equipment, materials, fittings, components, proximity of outlets to patients, and the consequences of insufficient space and other preventative measures and how these can be designed-out and/or minimised to prevent transmission from splashing and aerosols, backflow and blockages.

2.37 In addition, relevant training updates are essential for continuous professional development. This will equip all to make informed decisions to safeguard the at-risk patient group from potential hazards stemming from poor water system design, choice of components and fittings, poor installation, filling, commissioning and operational risks inherent in the built environment, especially considering the susceptibility to infection of these at-risk patients.

2.38 Water hygiene awareness is also required for those involved in the diagnosis and treatment of susceptible patients using systems and or equipment that involve exposure to water. They should understand how to keep patients safe from NTM infections and have received training before using such equipment. Specialist system and equipment users should be consulted to ensure the design delivers safe water for each type of use.

2.39 Training should cover:

a. the factors which increase the risk of harm from water, sprays, aerosols and wastewater to susceptible patients in newly built or refurbished healthcare premises

b. the importance of good project governance, communication and oversight

c. the importance of ensuring all those involved before the tender specification stage understand the need that the specification and procurement of materials, components and fittings does not increase the risk of NTM ingress, colonisation and growth both in the short and long term. This includes understanding the adverse effects on water safety as a result of incompatible materials, including the potential for galvanic corrosion, the leaching of nutrients from plastic products, the incorrect use of jointing compounds and the effects of water treatment chemicals resulting in corrosion of metals and deterioration of plastics used for pipework and components

d. the ecology of the relevant pathogens and the factors resulting which lead to colonisation and growth of microorganisms

e. the healthcare organisation’s design and acceptance criteria for water systems

f. the relevant legislation, guidance and British Standards and the requirements of the water undertakers (see HTM 04-01 Part A paragraphs 2.7 to 2.10 where appropriate). BS 8680 and BS 8580-2 provide guidance on conducting gap analyses of existing water safety plans and risk assessments for NTM and other waterborne pathogens (*Legionella* is covered in BS 8580-1)

g. the hazardous events which increase the risk of opportunistic pathogen ingress and their continued presence in water systems and associated components, fittings and equipment

h. the potential sources of exposure and the pathways by which NTM and other waterborne pathogens can be transmitted to patients and the consequences of exposure to these patients

i. the importance of preventing ingress and colonisation by the multiple-barrier WSP approach throughout the lifecycle of the building

j. the importance of a competent and experienced multidisciplinary team working to ensure the project delivers safe water systems for patients susceptible to NTM infections.

3 Designing for patient safety

Prevention of transmission from water, wastewater systems and associated equipment

3.1 All proposed water and associated wastewater systems as well as equipment which uses, stores or is cleaned by water to which patients may be exposed should be risk-assessed for their suitability for use by patients at increased risk of waterborne infections. This should take account of all potential modes of transmission including their ability to produce sprays and aerosols during normal use, during maintenance and when being emptied and cleaned.

Note:

Even relatively small volumes of water can produce infectious aerosols (for example, when reservoirs from equipment such as floor cleaners are emptied into a sink, sluice or drain).

3.2 Providing patients who are at highest risk of infection due to their immune status with sterile water for drinking and personal hygiene instead of tap-water has been a consistent message for more than 20 years (Bartram et al., 2003).

Note:

Guidance has been updated in this document to incorporate insights from peer-reviewed publications into microbial hazards and risk factors and experience since the publication of Bartram et al. (2003).

3.3 Risks from all potential opportunistic waterborne pathogens can be achieved by designing-out all potential sources of exposure to water, sprays and aerosols derived from water. In critical care areas, Hopman et al. (2017) have shown the beneficial effects from removing tap water resulting in an overall reduction in the incidence of Gram-negative infections. Design risk assessments should be carried out by the multidisciplinary PWSG with input from clinical and IPC teams to consider the appropriateness of installing (or not installing) water outlets in high-risk patient care areas.

3.4 Depending on the intended uses and susceptibility of the users, a clinical risk assessment may indicate the need to protect patients at high risk of NTM infection by eliminating the potential for exposure to water and associated drainage. For example, the risk assessment should determine the appropriate location of wash-hand basins for patients and staff. Where risk assessment allows, these basins should be situated outside the patient area (such as in a lobby or en-suite) rather than within the patient's bedroom. This placement helps avoid exposure to sprays and aerosols from the outlet and associated drainage. Hand-gel dispensers should be provided inside the room for convenient access.

3.5 The use of filtered water using a sterilising-grade point-of-use filter has been shown to reduce the incidence of NTM infections. Where outlets are considered to be safe for these patients (for example, when progressing through their recovery pathway), these outlets should be removable for effective disinfection and be fitted with sterilising-grade point-of-use filters (see POU filters).

3.6 Raising awareness of NTM-associated risks is crucial for reducing infection transmission. Education should be provided to all patients, relatives, staff, visitors, and estates operational and maintenance personnel. This education should aim to ensure they understand:

- how to avoid introducing nutrients that support microbial growth into water systems via wash-hand basins and the drainage system
- the potential consequences for patients if this guidance is not followed (for example, the risks associated with disposing of liquids in wash-hand basins).

3.7 As the patient progress down the recovery pathway and as their risk to infections decreases, there needs to be an informed clinical decision for how and when water can be safely introduced.

3.8 Where exposure to water is considered safe based on clinical risk assessment for these high-risk patients:

- all outlets should be capable of fitting sterilising-grade point-of-use filters
- patients' personal items, those used for personal hygiene, treatment and diagnosis, furniture (including beds) should be located at least 2 m away from sinks, wash-hand basins and showers to minimise the risk of splash contamination reaching those surfaces (see also paragraph 3.79). A screen to prevent splashing should also be considered. In en-suite facilities, there should be no space on the basin for storage of personal items, and protected cupboard space should be provided to minimise the risk of personal items being contaminated
- all drains should be fast-draining, without any pooling in the basin, sink or shower drain, to avoid contamination backflowing from the drain on to touch surfaces
- vacuum toilets and remote flushing (see paragraphs 3.99–3.100) should be considered to avoid infection risks from aerosols released during flushing.

Note:
Pathogens may survive for long periods of time (hours) in aerosols with a negative falling velocity depending on temperature and humidity. Preventing aerosol release is therefore an important prevention strategy.

Issues to consider when preparing the design brief

3.9 All potential sources of water and all possible modes of transmission should be considered by the design team and multiple barriers included in the design to minimise risks from exposure from water, sprays and aerosols when preparing the design brief.

3.10 Healthcare organisations should ensure there is good communication between IPC and clinical teams and the PWSG at the inception stage of any such project to inform the design brief of all the requirements needed to keep these patients safe.

3.11 The PWSG should ensure the PWSP includes robust processes to ensure that all the specific water delivery, associated equipment and drainage requirements are sufficiently detailed to address and mitigate all identified risks to patient safety. This

should ensure that all spaces associated with their care are safe and adopt the soft landings approach. This will facilitate an inception-to-disposal approach to the delivery of safe buildings (see BS 8680).

3.12 The design brief should be reviewed and challenged by those competent to do so – with input from clinical teams, those involved in the day-to-day operation and management of the spaces, and subject matter experts (where required) – to ensure the design will deliver safe water and spaces for the care of the at-risk patient group. Following review and risk assessment, designs should be amended as necessary and be formally agreed by:

- the PWSG
- all relevant stakeholders including patient representatives and
- the Board.

Risk factors to consider

3.13 Factors that could affect the safety of patients who are susceptible to NTM as well as staff and visitors who need to be considered and assessed by the PWSG when preparing the design brief (see also BS 8580-2) include the following:

a. All those having input into the design brief should be trained so that they understand the risks to their patients from water, wastewater systems and associated equipment and how these risks can be prevented.

b. The PWSG with input from relevant clinical teams should define the water quality criteria (see WHO's (2022) 'Guidelines for drinking-water quality') that are safe for the intended patients throughout their treatment and recovery pathway (see Appendix 3).

c. The design and specification of all water and wastewater systems, materials, fittings and components and any equipment to be connected into the systems should be identified and risk-assessed for their potential to cause harm to these high-risk patients before inclusion in the design brief. The clinical teams and specialist service providers where relevant should be involved in this process.

d. Water outlet provision in patient rooms should be agreed by the PWSG with input from relevant clinical teams. There is good evidence that limiting exposure to water from wash-hand basins in patient spaces decreases the risk of infection in high-risk patients.

e. Patient wash-hand basins should be designed so that the outlet is not directly over the drain and splashing is minimised; designs should incorporate demountable spouts for outlet decontamination and refitting without compromising splash minimisation.

f. All potential sources of water, sprays or aerosols to which patients may be exposed should be identified and effective barriers put in place to prevent exposure to unsafe water.

i. Where the use of sterile water or ice is indicated (for example, bathing, teeth cleaning, cooling and comfort), adequate provision should be made for storage in a clean room area. The area should be designed as a drug preparation space with sufficient clean cold storage and freezer space. To

prevent cross-contamination, there should be no wash-hand basin in this space.

Note:

Ice-making machines should not be present in augmented care areas. Instead, sterile ice can be prepared using the following process:

a. Use sterile water in food-grade ice bags.
b. Prepare the ice in a designated drug preparation area.
c. Freeze and store the prepared ice in a dedicated freezer until required.

g. It should be established how the water used for patient hygiene or treatment purposes will be disposed of safely outside the patient room after use. Suitable provision for the disposal of greywater used for patient hygiene should be made outside, but close to, patient areas to avoid:

   i. waste disposal via the sinks and wash-hand basins and thereby providing nutrients within the drains for microbial growth

   ii. clinical teams spending unnecessary time away from high-risk patients and

   iii. the risks of slips and falls from spilt water.

h. The design (for example, pipework sizing and fall) of wastewater systems should ensure the risk of blockages (for example, through hair loss following chemotherapy treatment) is minimised and there is adequate flow and backflow protection so that wastewater does not contaminate sinks and floors spaces in showers that patients will be direct in contact with.

Sustainability and water/wastewater safety

3.14 There are potential conflicts which need to be taken into account when designing for this high-risk patient group. Using smaller units and reducing the number of outlets offer benefits that contribute to net-zero goals: they decrease water consumption and lower energy requirements. The PWSP should ensure there are processes for risk assessment of all measures intended for meeting green/net zero carbon/BREEAM goals to ensure there is no conflict between meeting sustainability targets and maintaining patient safety.

3.15 Measures to reduce energy consumption may have unintended consequences with regard to the safety of patients from waterborne infections. A multidisciplinary team with the skills and competencies should carry out informed risk assessments.

3.16 Any derogation from current guidance and standards to enhance patient safety relating to water system design should be accompanied by a documented risk assessment for approval by the PWSG. For example, low temperature hot water systems increase the risk of NTM colonisation; samples from hot water temperatures below 55°C have been shown to support the presence of viable NTM. In wastewater systems, reduced water flow increases the risk of blockages and backflow. This can potentially lead to cross-contamination of the clean water system and pose risks to patients. Contamination can occur both directly and indirectly (for example, through splashes and aerosols from sinks, basins and showers).

3.17 Patient safety must always remain the prime target for any new build or major refurbishment project.

Design based on patient safety

Advantages of small modular units with independent water and wastewater systems

3.18 Large, complex, reticulated water systems (i.e. piped water and wastewater networks) cannot be safely controlled throughout the whole system at all times. Large distribution systems in healthcare premises have been responsible for severe illness and death of susceptible patients from a wide range of waterborne pathogens. Extended pipe runs leading to intermittently used outlets increase the potential for stagnation, heat loss or gain and ineffective disinfection residuals throughout the whole system.

3.19 Stagnant or low water flow leads to colonisation and growth by NTM and other waterborne pathogens in biofilms. Once formed, they cannot be effectively removed. Over time, and especially in warm water areas with low flow, sections of biofilms will slough off and be carried around system, colonising other areas.

3.20 NTM are particularly difficult to control as they are inherently highly resistant to control methods such as heat and biocides and once present in a large complex system cannot be eliminated. The aim has to be to identify the points (CCPs) where ingress could occur by developing a multiple barrier approach to preventing ingress at every stage.

3.21 Current guidance in HTM 04 01 which is referenced in the HSE's HSG 274 part 2 advises "that it may be preferable to provide separate small systems, with independent supply and local heating sources for patients in augmented care units with patients susceptible to invasive disease from environmental and opportunistic pathogens". Smaller systems have many advantages of being much easier to control. They can also have sufficient flow to achieve hot- and cold-water target temperatures in seconds. It is simpler to engineer and balance an independent system to optimise flow and minimise the potential for stagnation than it is for large reticulated systems.

3.22 Risks can be significantly reduced by designing an independent ward-specific system. These systems should include the following key elements:

- point-of-entry filtration that prevents microbial ingress into the module from the mains supply
- cooling mechanisms for incoming water, where necessary, depending on the incoming water temperatures
- smaller above-ground drainage systems designed to minimise the risk of blockages and backflow by air gaps
- sufficient space in voids avoiding right-angled bends and appropriate sizing of wastewater pipework to take account of the requirements of attached equipment (for example, bedpan macerators)
- shorter pipework runs helping to maintain target temperatures and flow rates to minimise the risk of colonisation.

3.23 Based on risk assessment by the PWSG with input from the clinical teams, designs should take account of the fact that exposure to any non-sterile water or wastewater is not safe for the highest risk patients. Hand-washing facilities should therefore not be located in patients' rooms.

3.24 Soap dispensers, hand cream, gel dispensers and towel holders where provided should be placed so that they do not allow nutrients to drip onto outlets, sink surfaces and drains (see BS 8580-2).

3.25 Where risk assessment allows, installation of vacuum wastewater and toilet systems with external flushing activation may reduce the risk from aerosols from toilets and drains.

Note:

Vacuum drainage systems have been installed in some NHS healthcare premises to reduce the risk of aerosolisation from drains and toilet flushing. PWSGs should ensure that there is adequate validation data to demonstrate these are safe for use by these high-risk patients.

3.26 Where en-suite bathrooms are provided based on clinical risk assessment (this may include a shower depending on the risk assessment), all access for maintenance, replacement or calibration of water system components should be accessed from outside the patient rooms to minimise the risk of cross-contamination.

3.27 Correctly fitted sterilising-grade POU filtration will provide an additional barrier for both wash-hand basins and showers where the multidisciplinary risk assessment identifies a need (see also paragraph 3.74 on POU filters). However, risk assessments still need to evaluate the risk of infection from the drains both during patient use and flushing.

Point of entry filtration (POEF)

3.28 Because of the inherent resistance to disinfection and heat treatment, once water systems are colonised with NTM and other waterborne pathogens, they are not safe. Prevention of ingress through POEF for these patients is therefore essential. This includes the filling of water systems and equipment.

3.29 The specification should ensure that POEF equipment is supplied contamination-free with validation data to verify that the pore size is suitable for retaining NTM and other waterborne pathogens (i.e. 0.2-micron sterilising-grade filtration as per ASTM F838-20) and that it can be installed, filled, commissioned and operated safely without the risk of cross-contamination.

3.30 The specification should take account of the initial cost of the plant as well as the ongoing cost of maintenance over its complete lifecycle. POEF systems that require replacement of filters should be avoided as there is a risk of introducing contamination during filter replacement.

3.31 POEF should be back-washable and be capable of achieving sterilising-grade performance (typically 0.2-micron, absolute filtration). All filter materials should comply with the Water Supply (Water Fittings) Regulations.

Independent hot- and cold-water systems

3.32 Those designing hot and cold-water systems should meet the design criteria as defined in the specification with input from clinical teams. This should be agreed by the PWSG.

Defined water quality criteria must be met for each at-risk group depending on the type of use and the susceptibility of the patients potentially exposed.

3.33 Independent ward-specific water systems and unit-specific water systems for both new builds and major refurbishments should be designed and constructed using processes to prevent the ingress of microorganisms as well as nutrients that could support the colonisation and growth of NTM and other waterborne pathogens. This can be achieved by utilising a cold-water supply obtained through a back-washable POEF system. This filtered water should also be used for hot water provision via a plate heat exchanger unique to the area in question. All those involved in the installation should be trained in aseptic technique to avoid the potential of introducing contamination. The details of any aspect of design and all risk assessment method statements for the installation process should be agreed with the PWSG.

3.34 All outlets, fittings components and any associated equipment attached to water systems should carry certification to confirm they will not have any adverse effect on water hygiene or safety.

3.35 A trained and competent clerk of works should ensure that all precautions specified to minimise the risk of microbial contamination of these units are followed during the construction and installation processes.

3.36 The manufacturer's processes to avoid contamination should form part of the PWSP.

3.37 All basins, toilets and drains should be sealed to prevent use until the unit is in place, connected to the on-site supply and commissioned.

3.38 Storage and transport conditions should prevent the ingress of water, as damp conditions can lead to microbial colonisation of the construction materials, including pathogenic fungi.

3.39 All systems and any connected equipment should be filled with potable disinfected water through sterilising-grade POE filters and should take place at the latest opportunity at a time and date agreed by the PWSG to reduce the risk of ingress of microorganisms and nutrients.

3.40 If the system is constructed off-site, the client's PWSG clerk of works should be given unrestricted access to the construction site. This allows them to validate that the processes in place will not put the at-risk patient group at risk of infection throughout the construction, on-site installation and commissioning processes, including during transport and storage.

Hot and cold water systems

3.41 All hot- and cold-water systems should be designed to keep cold water at a temperature below 20°C and hot water distributed so that it reaches the outlets at 55°C within seconds (typically well within 15 seconds). The minimum temperature as it returns to the hot water generating plant should be not less than 55°C to prevent growth of NTM, and should be maintained at all times. For localised hot water provision, a local plantroom with a plate heat exchanger(s) will ensure target hot water temperatures for health premises as described in HTM 04-01 and HSG 274 part 2.

3.42 In areas where it can be predicted there will be intermittent use (for example, patient en-suites, where risk assessment allows their installation), automated flushing devices can be set to flush all outlets at time intervals agreed by the PWSG. Microbial profiling and remote temperature monitoring may be needed to establish flushing frequencies.

3.43 Installing continuous remote monitoring sensor devices will alert when temperatures, flow and pressures fall below set targets.

3.44 All pipework should be hard plumbed except where there is a need for flexible hoses to facilitate movement. Where these are required, the material should minimise the risk of microbial growth as far as possible. Ethylene propylene diene monomer (EPDM) lined hoses are not considered suitable for use in healthcare premises because of their propensity to support complex biofilms. Cross-linked polyethylene (PEX) is considered a safer alternative. PEX flexible pipework must be compliant with the Water Supply (Water Fittings) Regulations 1999 as well as the outlet arrangement (for example, shower handset).

3.45 There should be no 90-degree bends in water or wastewater pipework as these increase the risk of blockages, corrosion and scaling which adversely affect the system flow and temperature controls.

3.46 All valves where the risk assessment indicates they are necessary, including isolation valves and those used for temperature and pressure regulating (for example, thermostatic mixing valves), should be easily accessible for maintenance from outside the patient spaces (see paragraph 3.26).

Cold water supplies

3.47 For cold water supplies, historical evidence should be sought to determine the highest incoming supply water temperatures (usually towards the end of summer although higher than average spring temperatures may result in increases over 20°C occurring earlier). Where temperature data suggests incoming temperatures are likely to rise above 18°C (to allow for a maximum of not more than 2°C above that measured at the incoming water supply at the property boundary and the effects of climate change (BS 8680)), design risk assessments should consider the cooling of the incoming supply water (HSG 274 part 2).

Drinking water

3.48 Drinking water for patients at high risk of infection should either be sterile or obtained through an absolute sterilising-grade (0.2 µm) point-of-use filter.

3.49 When filling a receptacle such as a water jug or a basin used for patient hygiene, even when filled through the filter, contamination from drain microorganisms can be transmitted to patients if the receptable makes contact with the drain or is splashed by being in close proximity to the drain. Therefore, careful consideration in the design is required for collection points (i.e. from taps, outlets, etc.) that provide drinking water and water for hygiene in order to prevent contamination from contact or splashing from the drain.

Case study 1 – the image above shows a sterilising-grade point-of-use filter installed in a ward kitchen to provide drinking water for high-risk patients. Such a location introduces a number of risks. Besides the outlet with the filter is a high-pressure spray outlet which may either introduce splashing on top of the filter or create droplets which splashback from the sink to the base of the point of use filter and into the jug used to provide drinking water. Contamination post filter poses significant risk. Additionally, the placement of a water jug in the sink whilst filling is high risk for acquisition and transmission of wastewater organisms from the drain. Designers should ensure that there is safe provision of drinking water without the risk of contamination from drains and splashing which could result in direct contamination of the water itself and of introducing drain associated opportunistic pathogens into the patient care environment.

Hot water systems

3.50 Systems should be designed to deliver hot water with no risks to patient safety, i.e. no potential for stagnation or delivery of water below 55°C at the outlet.

3.51 Hot water delivery requirements to protect patients from NTM infections are more stringent than those specified in HTM 04-01 and HSG 274 part 2 for healthcare premises. For example both HTM 04-01 and HSG 274 state that hot and cold water systems should be maintained to keep cold water, where possible, at a temperature below 20°C and distributed so that it reaches the outlets at 55°C. However, in the smaller systems described as suitable for these at-risk patients, the temperature of water delivered at the outlet or entry into a thermostatic mixing valve (TMV) (where the risk assessment states they are required) should be reached and maintained within seconds of turning on the tap.

3.52 To protect against NTM growth, the flow from the hot water generating plant must be ≥60°C and a minimum return of 55°C.

3.53 An integral plantroom should be located within the module with a hot water generating plant to provide local supplies of safe hot water with circulating target hot water

temperatures at 60°C to ensure satisfactory maintenance of hot water temperatures throughout the module and facilitate 55°C at each outlet.

3.54 Expansion vessels contain bladders that pose risks due to microbial growth. Stagnation and heat gain within the bladder can occur with no facility to drain and flush it. Therefore, flow-through type expansion vessels should be used instead of bladder-type vessels and fitted vertically. Flow-through vessels are designed to allow continuous water flow, minimising the risk of stagnation and microbial growth, making them a safer choice for high-risk patient areas.

3.55 The installed hot water capacity should be sized for current needs and should not be designed with built-in capacity for future extensions.

3.56 The risk of scalding is an NHS “never event” and is of particular concern where there are vulnerable patients (young children and older people, disabled people and those with neuropathy). Therefore, thermostatic mixing devices may be needed for hot water outlets such as clinical and patients’ wash-hand basins depending on the scald risk assessment. However, it is recognised that TMVs increase the risk of colonisation. For these patients, it is essential that there is a scalding risk versus infection risk assessment carried out by a multi-disciplinary team. For outlets intended for use where there is the intention of whole-body immersion, TMVs should be fitted which comply with HTM 04-01: Supplement – 'Performance specification D 08: thermostatic mixing valves (healthcare premises)'. These should be accessible for calibration servicing and maintenance from outside the patient spaces.

3.57 Where risk assessment allows, water from wash-hand basins should be blended at the outlet with a simple mixing device and a physical stop to prevent scalding rather than using TMVs (see HTM 04-01 Part A for further guidance on manual taps with a physical stop).

Provision of showers, wash-hand basins and clinical sinks

3.58 Wash-hand basins and clinical sinks should not be fitted in high-risk patient rooms where the risk assessment indicates there is too high a risk of infection from outlets and associated drainage. The number, location and specification for showers, basins, sinks, sluices, etc. and specialist equipment should be agreed by the PWSG. Where the clinical risk assessment determines wash-hand basins and/or sinks are appropriate in the patient spaces, they should be designed so that:

- water distribution systems are designed to ensure good and balanced flow to all outlets and to achieve target hot and cold temperatures with no potential for stagnation
- there is appropriate provision and positioning of sinks, clinical wash-hand basins and drinking water sources whilst minimising the risk of waterborne infection from outlets and drains as well as spray and splash contamination to patients and within the patient care spaces
- wastewater drainage systems are designed so there is no potential for standing water or backflow onto shower trays/floors and basins and sinks
- all outlets and sanitary fittings are designed and fitted to minimise the risk, as far as possible, from splashing whilst maintaining sufficient flow for effective hand-washing and showering (for example, using safe distance (>2m) splash screens)
- there is no space within the splash zone for storage of personal or clinical items; sloping the back of the sink will prevent storage by patients

- there are sufficient storage areas within patient bathrooms, dirty utilities, kitchens, clean utilities to avoid cross-contamination from splashing
- there is sufficient storage to enable the safe set-down of contaminated articles (for example, bedpans), and separation of dirty equipment (such as wheelchairs, commodes, drip stands, etc.) before cleaning and for storage of clean equipment in separate areas
- there is effective ventilation (see HTM 03-01 – 'Specialised ventilation for healthcare premises')
- there is good flow at all times
- they drain freely so that there is no backflow from the drain to contaminate the basin
- fittings designed to minimise splashing are robust and not subject to misalignment
- outlets, sinks and wastewater drains should be designed to minimise the risk of colonisation and transmission of NTM and other waterborne pathogens and should not have inserts which increase the risk of biofilm formation
- sanitary fittings are of a suitable size and depth to facilitate adequate activity space without the need to touch the outlets and drain when washing hands. They should be designed and fitted so that they comply with the Water Supply (Water Fittings) Regulations, including when fitted with a POU filter.

3.59 All outlets should be suitable for fitting with a POU filter with no leakage around the fitting.

3.60 Sanitary fittings should be designed and manufactured using materials that are easy to clean and compatible with high-dose exposure of common biocides.

3.61 Tap and shower fittings should be demountable for disinfection (for example, by autoclaving or reprocessing in a washer-disinfector) following a documented and validated method approved by the PWSG.

3.62 All valves where the risk assessment indicates they are necessary, including isolation valves and those used for temperature and pressure regulating (for example, thermostatic mixing valves), should be easily accessible for maintenance from outside the patient spaces (see paragraph 3.26).

3.63 Soap, gel and towel dispensers should be located away from being directly over sinks and outlets to minimise the risk of nutrients supporting microbial colonisation and growth falling onto taps and sanitary fittings.

Remote monitoring

3.64 Remote monitoring should be designed into the system to continuously verify that outlets are being used, target temperatures and flow rates are being achieved and systems remain safe with appropriate remote alarm systems and procedures when targets for temperature and flow are not as specified and agreed by the PWSG.

3.65 For these specialist units, each outlet should be remotely monitored to ensure there is no stagnation in the pipework leading up to and including the outlet itself. The PWSP should include processes to ensure there is a design risk assessment for the installation of automatic flushing outlets through POU filtration where it is anticipated there may be little use from outlets so that they can be programmed to flush where there has been no flow for a defined period of time.

3.66 The requirements for maintenance, without the need to access patient spaces, should be included within the design of the water system infrastructure and identified in maintenance schedules at the design stage. Care should be taken to ensure that automatic flushing is programmed to take place during normal waking hours to reduce the risk of disturbing patients.

Design of dirty utilities

3.67 To protect these patients from NTM and other waterborne pathogens, dirty utilities should have a dirty-to-clean workflow that clearly demarcates clean and dirty areas with separate access for collecting clean items. There should be sufficient space in the dirty area for setting down contaminated articles. Waste disposal areas should be on the dirty side with sufficient space to prevent blocking access to

- set-down surfaces for contaminated articles and
- hand-washing facilities.

3.68 There should be a separate area for storage of clean items so there is no potential for cross-contamination. Clinical hand-washing facilities should be provided between the clean and dirty areas.

3.69 See Figure 1 for examples of poor design showing the consequences of insufficient space in dirty utilities.

Figure 1a Dirty utility above left: with no set-down space by the macerator and insufficient space for waste disposal.

Figure 1b Dirty utility above right: no space designed-in for cleaned and disinfected equipment to be stored once decontaminated so cross-contamination from splashing is likely.

3.70 Designs should be such that there is no storage of clean consumables and equipment in the dirty set-down area. Dirty utilities should also have sufficient space for storage and cleaning and disinfection of equipment such as wheelchairs, commodes and drip stands. Once decontaminated, there should be space for the storage of these on the clean side to prevent recontamination.

3.71 Sufficient void space should be incorporated into the design to accommodate swept bends for wastewater pipework. These bends should adhere to the manufacturer's requirements in order to reduce blockage risks, especially from macerators. There should be no right-angled bends and appropriate backflow protection.

Design of clean utilities

3.72 Areas used for preparing sterile fluids for infusion, including total parenteral nutrition (TPN), thickened drinks for patients with swallowing difficulties, and sterile water for

patient consumption, hygiene, etc. should not contain hand-washing facilities. Hand-washing stations pose a risk of cross-contamination from drains and splashing. There should be a sink immediately prior to the entrance and hand gel provision within the area.

POU filters

3.73 The use of POU filtration has been shown to be successful at significantly reducing the numbers of NTM from outlets (Norton, Williams, Falkinham, & Honda, 2020) in existing premises. Factors that PWSGs need to risk-assess and consider when specifying POU filters and include within the PWSP to ensure their ongoing safety include:

- verification that the filter retains NTM and other waterborne pathogens (0.2 µm absolute sterilising-grade filtration) over the claimed installation life of the product under operational conditions commonly found within healthcare water systems (i.e. intermittent on/off use, water pressures of between 0.5 and 5 bar, water temperatures of between 10°C and 70°C, realistic daily volume throughput) and compliance with EU food contact legislation
- proven robustness of the component manufacture (i.e. an air-pressure test to assure no leaks as part of the manufacturing quality release criteria)
- proven robustness of the casing (i.e. confirmation of proportional destructive burst-testing as part of the manufacturing quality release criteria)
- outlet designs are suitable for attaching a POU filter/connector adaptor without leakage around the fitting whilst maintaining sufficient activity space for the intended use of the basin and without splashing from the drain to contaminate the filter outlet
- there are processes within the PWSP for comparisons of on-filter performance which take into account water quality effects: adverse impacts on water flow and therefore lifecycle where there is a risk of scale and particulates
- compatibility with water treatment regimens (i.e. all materials in the water flow pathway should be compatible with relevant biocides at both continuous and shock dosage levels and for the duration of installation filter life)
- the PWSP should specify that POU filters should not be refitted once removed to prevent cross-contamination
- cleaning protocols should be agreed before fitting and should specify who is responsible for regular cleaning and how to clean the outlet to prevent contamination
- the PWSP should have processes in place to ensure compliance with the Water Supply Water Fittings Regulations 1999, and training should be provided to those specifying, installing, changing and using the products
- filter changes, filter identification and any failures should be documented (for example, leakage around the filter connection, blockages, unscheduled removal by staff and/or patients, visible contamination, cracks in housings)
- the PWSP should include the criteria for when POU filters should be installed and the criteria for their retention and safe removal. These should be agreed in advance and prior to initial installation
- there should be an understanding of the investigation pathway if POU filters show reduced flow or blockage during their claimed installation life (i.e. support from the manufacturer(s) to investigate parameters on-site which could lead to blockages).

Risks from wastewater systems

3.74 Obtaining water from outlets poses a risk of transmitting opportunistic pathogens through spray and splash contamination or backflow from drains on to surfaces of basins, sinks, shower trays as well as any trolleys, equipment or personal effects left within the splash zone. Whilst the risk of splashing is reduced by offset drains, it is not eliminated entirely. This is especially true when inappropriate disposal of nutrient-containing fluids and objects into the waste outlet results in backflow.

3.75 Opportunistic pathogens exhibit multiple resistance to antibiotics from the wastewater systems not just within healthcare facility wards/units but also downstream and out into the community. In effect, wastewater systems provide a superhighway for transmission of multi-drug-resistant strains which is seen as a global threat to the continued availability of effective antibiotics (WHO reference).

3.76 Although a wide range of microorganisms may be transmitted from wastewater systems, most outbreaks are related to infections due to multi-drug-resistant organisms which surveillance systems are more likely to identify. It is likely that infections caused by sensitive strains remain under the radar.

3.77 Multi-drug-resistant strains are of particular concern for these patients even though the sensitive organisms may be just as invasive. NTM are inherently resistant to a range of antibiotics, and the complex and lengthy treatment regimens are often not tolerated by patients.

Protecting high-risk patients from exposure to water and wastewater

3.78 In recent years, there has been growing recognition of the high risk of waterborne infections stemming not only from water distribution systems but also from wastewater systems and associated equipment. These risks cannot be mitigated by standard IPC measures alone. Studies have shown (see Hopman et al., 2017) that eliminating sources of exposure to non-sterile water not only reduces overall infections caused by Gram-negative bacteria but also decreases antibiotic use.

3.79 Baker et al. (2021) have shown that the implementation of a “water-free protocol” which involved four study units resulted in an overall decrease in pulmonary NTM acquisition by 76%. The PWSG, with input from clinical teams, should carry out a risk assessment to determine if the provision of water and associated wastewater is safe for patients at high risk of waterborne infections at each stage of their recovery pathway before and including discharge. Water-free care eliminates all possible exposure and transmission of NTM and other waterborne pathogens and also results in a reduced need for antibiotics and shorter patient stays.

Note:

A recent German study (Fucini et al., 2023) on clinical wash-hand stations in critical care single rooms has also shown the risk of infection is increased when they are in proximity of patients and carry a significantly higher risk of HCAIs including *P. aeruginosa* compared with placement outside of the room.

3.80 Ensuring the safety of these patients has to be the main focus of any design. The project duty holder should ensure that there are personnel represented on the PWSG with an understanding and expertise of the types of hazards, hazardous events and risks to patients associated with the periphery of the water system and associated

drainage and the potential for transmission of NTM and other waterborne pathogens from contact with, and splashing from, the drain.

3.81 Clinical wash-hand stations and outlets for patient use should only be installed in high-risk patient spaces following a risk assessment of their potential to cause infection.

3.82 As mentioned in paragraph 1.31, splashing from sink and drain outlets has been shown to travel up to 2 m. A 2 m zone around outlets should therefore be kept clear to avoid the risk of transmission of NTM and other waterborne pathogens by splashing originating either from water or wastewater. To clearly demarcate this splash zone, it is recommended that contrasting colours on the walls and floors extending 2 m from the outlets should be used. This visual cue will help to ensure that trolleys, patient beds, equipment and other items are not parked or placed within the splash zone, even temporarily. If a 2 m zone is not possible, the use of splash screens should be considered.

3.83 As a general consideration, anything which interferes with effective and fast drainage is likely to incur a risk of transmission of wastewater organisms to patients.

Wastewater installation factors

3.84 Training should be provided to installation teams to ensure that they understand the risks of harm to patients from poor installation practices. Manufacturers' installation instructions should be reviewed for their appropriateness for use in these high-risk settings. If needed, the instructions should be modified to prioritise patient safety and then be approved by the PWSG. Audits should be carried out to ensure installers are adequately trained and the amended method statements are being followed.

3.85 Designs should ensure the camber of wastewater pipework provides a sufficient fall to maintain a self-cleansing velocity, there is easy access for rodding and there is sufficient space provided for waste bins to avoid unwanted items being flushed. The use of vacuum-assisted waste disposal with integral macerators should be considered.

3.86 When connecting any device to the wastewater system, the route taken to the soil drain is the shortest, with the minimum number of bends. Enough room must be designed to ensure the voids facilitate the use of swept bends, which reduce the potential for blockage. Ninety-degree bends significantly increase the risk of blockages and should not be used.

3.87 Installers should make sure that:

a. there are no obstructions to reduce flow by ensuring there are no burrs or reducing shoulders

b. (where plastic pipework is used in the wastewater system) there is no reduction in the bore size, including where jointing compounds are used, and that there is adequate support for horizontal runs to prevent sagging which can encourage pooling and blockages, taking account of the temperature in the ceiling voids which can get very warm

c. drain lines are not near, or run across, hot water pipes

d. anti-siphon precautions are in line with general practice.

Clinical wash-hand stations and wash-hand basins for use by patients

3.88 A rear drain is preferred in all fittings used for hand-washing (clinical teams and patients) as this reduces the risk of dispersal of wastewater organisms, provided installation and use ensures there is no impairment of flow.

3.89 To prevent introducing avoidable risks to patients, installers should be trained and competent to ensure:

- all jointing compounds/sealants are approved by the PWSG and comply with the Water Supply (Water Fittings) Regulations
- excessive sealant is not used, as it can occlude pipework and components
- there are no gaps between the basin/sink's rear drain and the external rear pipe that could produce a trough, which can cause retained drainage and biofilm formation.

3.90 Wash-hand basins should be of a design that prevents objects being deposited in the basin/sink drain. Such objects can cause blockages, reduce water flow and increase the risk of backflow of drain contents into the basin/sink. This puts patients at risk of infection from both direct contact and splashes from the sink surface and/retained water.

3.91 Sieves currently used in the drains of some basins should not be used as they encourage biofilm development and increase the risk of transmission to patients.

3.92 Outlets should not be fitted with the drain located at the bottom of the basin/sink as this will present an extremely high risk for dispersal of wastewater organisms and significantly increase the risk of infection from cross-contamination.

3.93 Drains located at the base of the sink/basin, but offset so that water emanating from the outlet does not directly hit the drain, still pose a risk of cross-contamination. Therefore they should not be used in these patient spaces.

Showers

3.94 Outbreaks of waterborne infection have been linked to shower drainage systems. Where it is deemed (following clinical risk assessment) that these are safe for the at-risk patient group, the specification should ensure there is no potential for breaching the Water Supply (Water Fittings) Regulations. Multidisciplinary risk assessments should be carried out, which take account of the needs of patients and the risks associated with showers with flexible hoses. Shower hoses pose an increased risk of colonisation and growth compared with fixed overhead showerheads.

3.95 All showers should be fitted with sterilising-grade POU filters (0.2 µm). Showers with hoses should be effectively tethered so they cannot reach the floor, toilets, etc. Drains should be offset so that water from the showerhead does not directly hit the drain, causing the splashing of drain contents.

3.96 Drainage outlets in the floor should be located such that the patient does not make direct contact with the drain by standing over it.

3.97 The camber of the floor, diameter of the drain and camber of the wastewater pipes should ensure sufficient drainage to prevent build-up of water on the shower floor. The pipe should be adequately sized in diameter to account for gradual radius reduction over time from soap scum deposits, hair build-up and other accumulations.

Minimising the risks of transmission from toilets

3.98 The design risk assessment, with input from the relevant clinical teams, should consider whether bathrooms with toilets should be provided for high-risk patients. Where toilets are fitted, the risk from infectious aerosols should be reduced as far as possible.

3.99 For some patients, vacuum toilets may provide a safer option as the vacuum draws air into the toilet when flushed, minimising the risk of aerosol transmission. Care needs to be taken to ensure that the water pressure for refilling the toilet does not produce aerosols. To further minimise the risk, a remote flushing mechanism (i.e. flushing when the patient is not in the bathroom) located outside the bathroom should be provided. This will create an additional barrier against aerosol transmission, provided the bathroom door is shut first and there is sufficient extract ventilation.

3.100 Vacuum toilets are already in use in many countries and in some UK healthcare facilities. The vacuum can be used to remove wastewater as well as the surrounding air and toilet contents and so potentially remove the risk from aerosols. Healthcare facilities using these systems have reported predominantly positive experiences, with minimal incidence of blockages observed. These systems demonstrate considerable advantages compared to current wastewater systems and have shown that they could substantially reduce risks of aerosol transmission to these patients. Robust performance data is at present limited so healthcare organisations should carry out due diligence and assess the validation of their effectiveness to eliminate aerosols when flushed and ensure the fittings and systems are robust, easily maintained and cleaned for use in healthcare environments.

3.101 When assessing the risk from traditional toilets for these patients, the assessment should consider that waterborne pathogens can remain viable in aerosols for long periods of time. *Legionella* species, for example, can survive and remain viable for hours in aerosols. Survival is influenced by temperature, humidity and virulence, with 90% of the strain most associated with outbreaks remaining viable after two hours. Provision of remote flushing therefore cannot be guaranteed to provide sufficient protection.

3.102 The design of all toilets should facilitate ease of cleaning and minimise aerosols as far as possible by providing rimless toilets with well-fitting lids. Well-fitting lids reduce but do not eliminate aerosol release.

Maintenance

3.103 Designs should take into account that the risk of drain blockage is increased in high-risk areas, especially where, for example, patients are undergoing chemotherapy and incur hair loss. Access for regular preventative maintenance without entering patient spaces to avoid cross-contamination should be provided wherever possible.

3.104 RAMS for each task approved by the WSG should be prepared for those carrying out installation, remedial work, upgrades and maintenance. These should be documented, controlled and approved by the PWSG.

3.105 The PWSP should include processes to ensure that all those who install wastewater systems, as well as those who provide maintenance and carry out remedial actions, receive training. This training should address:

- potential risks to patients from any impaired drainage or smells from impaired drainage to ensure these are reported at the earliest opportunity

- RAMS prepared for carrying out installation maintenance and remedial work on both the water and wastewater systems and any associated equipment; they should demonstrate understanding of these protocols and their correct implementation
- the risks of contaminating clinical areas when installing or working on water and wastewater systems, especially for these high-risk patient areas
- the concept of separate teams working on the clean and dirty (waste) systems to prevent inadvertent cross-contamination from hands, tools, workwear and PPE
- the need for good personal hygiene and aseptic techniques, and avoiding practices which could lead to cross-contamination of these areas. Regular update training should be delivered and audits carried out to ensure compliance
- the protocol for recording these including what was the underlying predisposing factor and the PWSG-approved remedial actions immediately taken as required.

4 Tender specification

4.2 The preparation of the tender is a key stage in ensuring that the project delivers its aim to keep these high-risk patients safe. While the steps below may seem onerous, getting it right at this stage is the most important step in ensuring patient safety.

4.3 Healthcare organisations should ensure there is sufficient governance and support for the PWSG to ensure contractors and design and procurement teams follow the PWSP. This is to ensure all involved receive sufficient resources including time, instruction, information and training. These resources should allow them to specify and procure materials, fittings, components and equipment that eliminate or at least minimise as far possible the risk of ingress of nutrients and harmful hazards into the systems when installed, commissioned and managed to normal occupation (including during transport and storage).

4.4 Project duty holders should ensure there are learning exercises from previous projects and there is provision for water hygiene workshops for PWSG members and all invited to tender, to support and inform them of the relevant hazards and hazardous events leading to the development of healthcare facilities that are unsafe for the at-risk patient group.

4.5 The PWSP should include processes to assess the contractor's plans to deliver a building that poses no risk of harm to this high-risk patient group, including assurances at each stage of the project, as part of accepting their tender. These plans should be formally assessed by the PWSG and taken into account when assessing tenders before awarding contracts.

4.6 Those responsible for specification and procurement should ensure the specification ensures that all pipework, fittings, components and any equipment that will be temporarily (for example, during commissioning) or permanently attached to water systems are free from contamination from manufacture to the point of installation.

4.7 To prevent the ingress of humidity, insects, rodents, etc., installation contractors should ensure that pipework and fittings:

- are capped at both ends by the manufacturer
- are dry with fittings being individually wrapped, and
- are always stored securely off the ground in clean, dry conditions.

4.8 BS 8680 states that the specification should require that all pipework, fittings, components and equipment attached to water systems carry certification to confirm they will not have any adverse effect on water hygiene or safety.

4.9 To ensure the design reflects the water safety needs of the patients and avoids the introduction of water safety risks, the processes within the PWSP for preparing the tender specification before being offered require:

- time for review
- risk assessment
- remedial actions
- communication at each stage and agreement with all stakeholders.

4.10 In addition, if any changes are made to the design or specification during the preparation of the design brief and tender, there should be time allocated for review,

risk assessment and update of the proposed changes. The PWSG should document, address and agree any risk assessment findings. No changes should be allowed to any part of the design and specification without documented assessment and approval by the PWSG.

4.11 The specification should ensure that a filling and commissioning plan, as-fitted drawings and system-specific documentation are made available for both commissioning of water and wastewater systems and handover. The commissioning plan should make it clear that commissioning should be carried out as close to handover as possible and only when all fitting-out, decorating, etc. has been completed. However, if using modern methods of construction (MMC), any risk assessment related to the water system and subsequent mitigation actions may need to be incorporated into the design for manufacturing and assembly (DFMA) process. This is to prevent the misuse of water fittings and drainage by contractors on site leading to nutrient ingress supporting microbial growth once the system and any attached equipment has been filled.

4.12 Each system should be designed to include all the features required to ensure ongoing water hygiene as defined by the PWSP for these patients is maintained. This includes the subsequent commissioning, operation, maintenance, monitoring and sampling stages.

4.13 At handover, the water delivered at each outlet and the associated equipment must meet all the specified target parameters as defined both within the Water Supply (Water Quality) Regulations 2016, the agreed specification and the PWSP. *Legionella*, *P. aeruginosa* and NTM should not be detected pre- and post-flush as the incoming supply has been filtered and disinfected.

4.14 The design brief and tender specification should be risk-assessed by the multidisciplinary PWSG. This should include input from subject matter experts with the required skills to (1) critically review design drawings and specifications and (2) advise on whether the designed and engineered water, drainage and ventilation systems will provide a safe environment for these high-risk patients or whether improvements in the design are necessary to improve patient safety. Any amendments should be risk assessed, agreed and documented by the PWSG and the project duty holder.

4.15 As part of the tender process, the tender specification stage should require that bidders detail and document how they will manage the project on site to ensure that all water and drainage systems are delivered as safe for the intended patients at the point of handover, during normal operation and throughout the design lifecycle (this also apples to ventilation, fire safety, electrical safety, etc).

4.16 The PWSP should include processes for those drafting the tender specification to ensure:

- the contractor’s compliance with a recognised quality management system such as ISO 9001
- the contractor can provide proof that their employees have received training on water quality and water hygiene in line with the healthcare organisation's WSP, belong to the Energy and Utility Skills Register (EUSR) (Blue Card) scheme and hold an up-to-date WaterSafe or similar recognised qualification
- those tendering understand the primary goal to deliver a building which will do no harm, taking account of the susceptibility of its at-risk patient group to infection

- the design, construction, installation, commissioning and handover processes have sufficient detail to ensure that patients will not be exposed to potentially infectious water, wastewater systems and associated equipment; this includes the infrastructure such as stagnant or standing water, sprays and aerosols from fittings, components and equipment
- all pipework and components are chosen to achieve the design flowrates up to the point of use, with no areas which encourage low flows, stagnation or poor drainage including fittings or attached equipment
- there is engagement with preferred contractors and suppliers as part of the process to ensure they understand the primary goals of the project and how they can help to protect these susceptible patients from infection throughout all stages of the project
- risk assessments of all fittings, components, materials, etc. are carried out in consultation with manufacturers, suppliers, building operators, maintenance teams, users and IPC teams; this is to ensure no materials, components, fittings or equipment will be installed that could cause harm from waterborne infections (for example, water used for leak-testing and/or testing of the water system and associated fittings, components and associated equipment has been responsible for introducing waterborne pathogens including *P. aeruginosa* and *Legionella* into water systems within healthcare systems. The specification should therefore state that no component, fitting (including TMVs, outlets, etc.) or associated equipment (or component used within equipment) should be installed or connected that has been wetted, leak- or pressure-tested by the manufacturer, or has been used previously in other systems during the installation or commissioning process)
- all components, pipework, fittings and equipment will be sealed, transported and stored to prevent contamination during delivery, storage on-site and installation
- there is sufficient space in voids to avoid blockage such as the use of 90-degree bends in water supply and drainage
- water drains completely without pooling in any areas, with sufficient brackets/clips for pipework to prevent sagging where wastewater can collect
- the safety, quality, ongoing lifecycle cost, ease and accessibility for maintenance, and availability of parts and components are taken into account when specifying system components, materials, fittings and any associated equipment, and not just the initial capital cost
- rather than defaulting to identical replacements, the lifecycle replacement strategy aims to adopt products, materials and designs that have demonstrated improvements in hygiene performance and the inhibition of microbiological growth
- all pipework, pumps, storage tanks, valves, fittings and components and associated equipment are designed to be safely accessible for inspection and maintenance from outside the patient rooms, with a risk assessment and appropriate scheme of control developed at the design stage and signed off by the PWSG
- there is a formal process for review and approval by the PWSG and Board before the specification goes out to tender.

4.17 Once the specification and design has been approved and agreed by the PWSG, there should be no alterations, including value engineering, unless risk assessment by

competent assessors verifies there will be no adverse impact on patient safety. Any changes should be approved and signed off by the PWSG.

4.18 The commissioning plan should also state that system filling should only be carried out at a time and date agreed by the PWSG to facilitate supervision and witnessing to ensure systems are only filled with disinfected potable water through the POE filtration system.

4.19 The water system acceptance criteria should be clearly defined within the tender specification and agreed by the PWSG. This should include sampling and monitoring data that demonstrates the system is safe for the at-risk patient group over the time specified and agreed by the PWSG.

4.20 For acceptance at handover, the specification should state all temperatures, biocide levels (if used), flow parameters and water quality targets should be as defined within the tender specification as agreed by the PWSG.

4.21 Tender specifications should not include a list of all guidance from various organisations that should be adhered to without first having subject matter experts. This is necessary to verify that the guidance is up-to-date, relevant, does not conflict with other guidance, will not cause harm to the intended patient groups, and reflects lessons learned from previous projects, taking into account any recent policy updates. This could be achieved by the subject matter expert undertaking a targeted literature review. Where derogations are determined to be necessary for reasons of protecting these susceptible patients, they should be risk-assessed and agreed by the PWSG before the specification goes out to tender.

5 Installation

5.1 Before any installation work, the water risk assessment should be reviewed and updated, and the control scheme implemented following the processes agreed within the PWSP to ensure water safety is not compromised. This should be agreed by the PWSG before installation work commences.

5.2 Poor installation practices can lead to risks to patient safety by:

a. introducing nutrients by inappropriate use of unapproved materials including adhesives, jointing compounds (for example)

b. causing corrosion from incompatible materials

c. allowing backflow from inadvertent cross-connections

d. compromising wastewater systems, for example:

i. occlusion of pipework from overuse of jointing compounds

ii. blockages and backflow to sinks, basins, shower trays, toilets, etc. caused by debris and rubble introduced during the construction process

e. allowing cross-contamination from hands, tools, equipment, clothing, shoes, etc. where installers work on both clean and dirty water systems.

5.3 The PWSP should include robust processes on site to ensure the safe storage of fittings and components to maintain water hygiene throughout the installation to ensure:

a. the installation and maintenance of new systems, fittings, components and associated equipment is only carried out by those trained and competent, with the appropriate qualifications and competence, and have their training and competency verified as being up to date and relevant for the items to be installed

b. installers have an up-to-date knowledge of manufacturers' instructions, relevant regulations, guidance and appropriate standards

c. all personnel involved in the installation of water systems and equipment are trained in aseptic techniques: installers should belong to the Energy and Utility Skills Register (EUSR) (Blue Card) and hold a WaterSafe, or equivalent, qualification

d. there is a culture of supported learning with a lead plumber/installer to support and supervise installation teams

e. separate teams, equipment/tools and clothing are used for those installing clean water systems and associated fittings, components and equipment and those installing above-ground drainage systems

f. larger items of plant that require offloading from delivery vehicles before delivery to their final location are appropriately covered and protected from damage and ingress of contamination

g. all components and subassemblies are inspected before installation to ensure the packaging is intact and that they are dry, clean and free of defects

h. regular checks are carried out during installation by an appropriately trained and competent clerk of works to ensure that:

    i. all components are as specified and comply with the Water Supply (Water Fittings) Regulations, and the work is being carried out according to the design specification

    ii. all pipework, valve ends, cylinder connections, etc. are sealed to prevent the ingress of dust/debris

    iii. joints or welds in the pipework are approved for use in drinking water systems and do not restrict water flow in either the water distribution or wastewater systems (excess use of jointing compounds and 90-degree elbows avoided) and that the design of the joints minimises the use of synthetic flexible seals, irregularities and crevices where biofilm may develop.

5.4 Where specialist skills are needed (for example, external water services for below-ground pipework, catering equipment and point-of-use (chilled water) equipment, etc.), competent installers should have evidence of appropriate training and belong to the appropriate professional standards schemes (for example, APLUS, Watermark or WIAPS).

6 Filling and commissioning water systems

6.1 The filling and commissioning of water systems is one of the highest risk stages of any new build or major refurbishment project. This technical bulletin aims to ensure that there are multiple barriers in place to prevent ingress of hazards throughout each stage of the project. All systems and equipment should be filled with disinfected water through the POE filtration system at the outset and then flushed through the whole system.

6.2 The PWSP should include processes to ensure pre-commissioning checks and the filling and commissioning plan is agreed by the PWSG during the design stage. It is essential that all involved in the practical aspects of filling and commissioning:

- have received training in aseptic techniques i.e. belong to the Energy and Utility Skills Register (EUSR) (Blue Card) scheme and hold an up-to-date WaterSafe or similar recognised qualification
- are aware of the absolute requirement to avoid ingress of contamination to prevent patient harm.

6.3 The PWSP should include processes to ensure all steps in the commissioning process do not result in harm to patients. These steps include:

- initial pressure-testing with inert gas or air
- filling the system with disinfected potable water through the POE filtration system
- pressure-testing with water and
- any engineering interventions.

6.4 Each step should be overseen by at least one suitably trained and competent representative of the PWSG to ensure compliance with the agreed processes and procedures in the PWSP.

6.5 The commissioning plan should:

a. document all details for individual systems and items of equipment, to be commissioned or used in the commissioning process as well as detailed commissioning processes and identification of the personnel involved

b. ensure and document that all those involved have the skills and understanding needed to carry out the commissioning stage without introducing hazards and risks to the system or patient safety

c. ensure that the systems and associated equipment are filled at the latest possible time at a time and date agreed by the PWSG and after all other aspects of building commissioning have been completed

d. detail that all water added to the system should be disinfected and through a POE filtration system. In no circumstances should any other water source be added to any part of the system or associated equipment

e. detail that the PWSG-agreed biocide (after conducting a risk assessment that considers its impact on the selection and tolerance of microorganisms, corrosion effects, potential health impacts of by-products and appropriate microbiological monitoring) is used to fill systems and equipment and at the specified level to ensure the system/s are appropriately disinfected and flushed before being returned to operational levels. Before handover, systems should run at normal operational levels for at least eight weeks to verify they are safe for occupation. This process involves flushing through one volume of water per day, seven days per week, at every outlet and plumbed-in equipment. During this period, the results of post-commissioning biological checks can be reviewed by the PWSG

f. detail that no temporary equipment is connected to the system that has been previously exposed to water from a different source including water used in pressure- or leak-testing by manufacturers

g. detail that, where possible, the installed system pumps should be used for pressure testing

h. detail that all valves are fully opened; no isolating valves should be used to balance systems as part of the commissioning process

i. incorporate the sampling plan agreed by the PWSG for all relevant microbial hazards including *Legionella*, *P. aeruginosa* and NTM, and ensure it is sufficient to provide the necessary assurance that no patients will come to harm from any outlet as a result of system design, installation, commissioning or construction processes

j. ensure that the wastewater system is freely flowing and there is no debris/rubble in the system or backflow resulting in contamination of sinks, basins, shower floors and shower trays.

6.6 All outlets within the system should be incorporated in the commissioning sampling plan to determine the health of each outlet connected into the system.

6.7 The PWSP should specify the criteria for acceptance and handover of the project and the actions to be taken in the event of positive sample results being identified (see Chapter 2). It is essential that any positive results are investigated to determine the scale and extent of any contamination. Each instance should be robustly examined and remediated as agreed by the PWSG and specified within the PWSP. Any systemic colonisation must mean system rejection.

6.8 Once filled, the contractor should ensure that the system is operated and used as if the building was fully operational. Regular audits should be carried out and reviewed at regular intervals by the PWSG representative to verify flushing and system management are consistently in place and to ensure barriers and controls are effective as specified within the PWSP.

6.9 The commissioning plan should be reviewed by the PWSG before pre-commissioning checks are performed and the system filled.

7 Handover

7.1 BS 8680:2020 includes useful information to ensure a safe handover process. The processes required to ensure safe handover and completion should be clearly stated within the PWSP with agreed timescales for snagging and occupation. This is to ensure that:

- all aspects of water system design meet the design intent
- all water meets the targets defined within the specification and
- all water, wastewater systems and associated equipment are safe for the at-risk patient group before admission of patients.

7.2 The PWSG should receive documented assurance from the contractors and healthcare organisation's representative (clerk of works) that the tender specifications and PWSP processes have been followed throughout all stages of the project and that all components, fittings and equipment installed do not, as far as possible, result in the ingress of microbial hazards into water systems.

7.3 The contractors should verify that the water systems have been constructed and installed so that they meet the design and water-quality-standard targets for each system and associated equipment as agreed within the design project plan.

7.4 All processes for monitoring and control of water systems should have been validated, with systems for ongoing verification in place (such as remote monitoring and BMS). These should demonstrate that all systems have been running for the time specified in the PWSP as if fully occupied.

7.5 All processes for filling, commissioning, monitoring and sampling should be carried out as specified within the PWSP. Before handover, all monitoring and sampling-related records, documentation and data should verify that all systems and associated equipment:

- comply with legislation and the PWSP targets and
- will not pose a risk of infection.

7.6 Biocide dosing as agreed by the PWSG should be maintained at all times to achieve the agreed target levels. For example, when using chlorine dioxide, normal operational levels should be sustained between 0.2 and 0.3 ppm at the outlet, per the multiple-barrier approach to keeping water safe.

7.7 Elevated levels of biocide should not be necessary as all water entering the system must have been through the specified POE filtration system and disinfected on filling. All outlets should be flushed daily until full occupation to mimic normal operation to ensure the temperatures and biocides levels are maintained at each outlet at all times.

7.8 All wastewater drain systems should be designed and maintained to ensure:

- free-flowing drainage
- no 90-degree bends

- absence of debris, rubble or other obstructions
- adequate backflow protection.

7.9 All documentation should be available pre-handover. The building should not be accepted by the PWSG until all necessary documentation is available. This will include but should not limited to:

a. records for filling and commissioning of systems and equipment
b. validation certificates
c. monitoring and microbiological sampling data
d. as-fitted and up-to-date drawings and schematics
e. updated risk assessments
f. instruction and maintenance manuals
g. pre-handover operation records and documentation including those for validating systems and equipment to show they meet the design and specification targets
h. verification data that all legislative and design water-quality targets have been met
i. calibration certificates of equipment used
j. a copy of the requested and approved derogations relating to the water systems
k. documented assurance that the wastewater system is free-flowing and that there is no risk of backflow to sinks, basins, shower floors or associated equipment.

7.10 Records of any remedial actions following commissioning checks and sampling should be reviewed and approved by the PWSG before formal handover.

8 Microbiological examination of water

Project assurance sampling following commissioning

8.1 Pre-flush samples should be taken from each outlet to verify that the system has not been contaminated and that water quality meets current legislative standards and project specification parameters.

8.2 Samples should be taken from all outlets for total viable counts (TVC), *E. coli*, coliforms, *Legionella* species, *P. aeruginosa* and NTM.

8.3 Temperatures and biocide levels should be taken by those trained and competent to do so at the same time as water samples and at the same location as indicated by the PWSG-approved water sampling plan.

8.4 Microbiological sampling should follow the method statements as agreed by the PWSG to assist in the interpretation of results.

8.5 To be considered safe at handover, TVC should be <10 cfu/ml, and the other target organisms should be absent. Any positive TVC or *P. aeruginosa* samples should be followed up with pre- and post-flush samples to determine if the positives are systemic or from local outlet contamination.

8.6 If positive sample results are then found in pre- and post-flush samples, further investigation, remediation and verification will be necessary, potentially delaying occupancy or building opening.

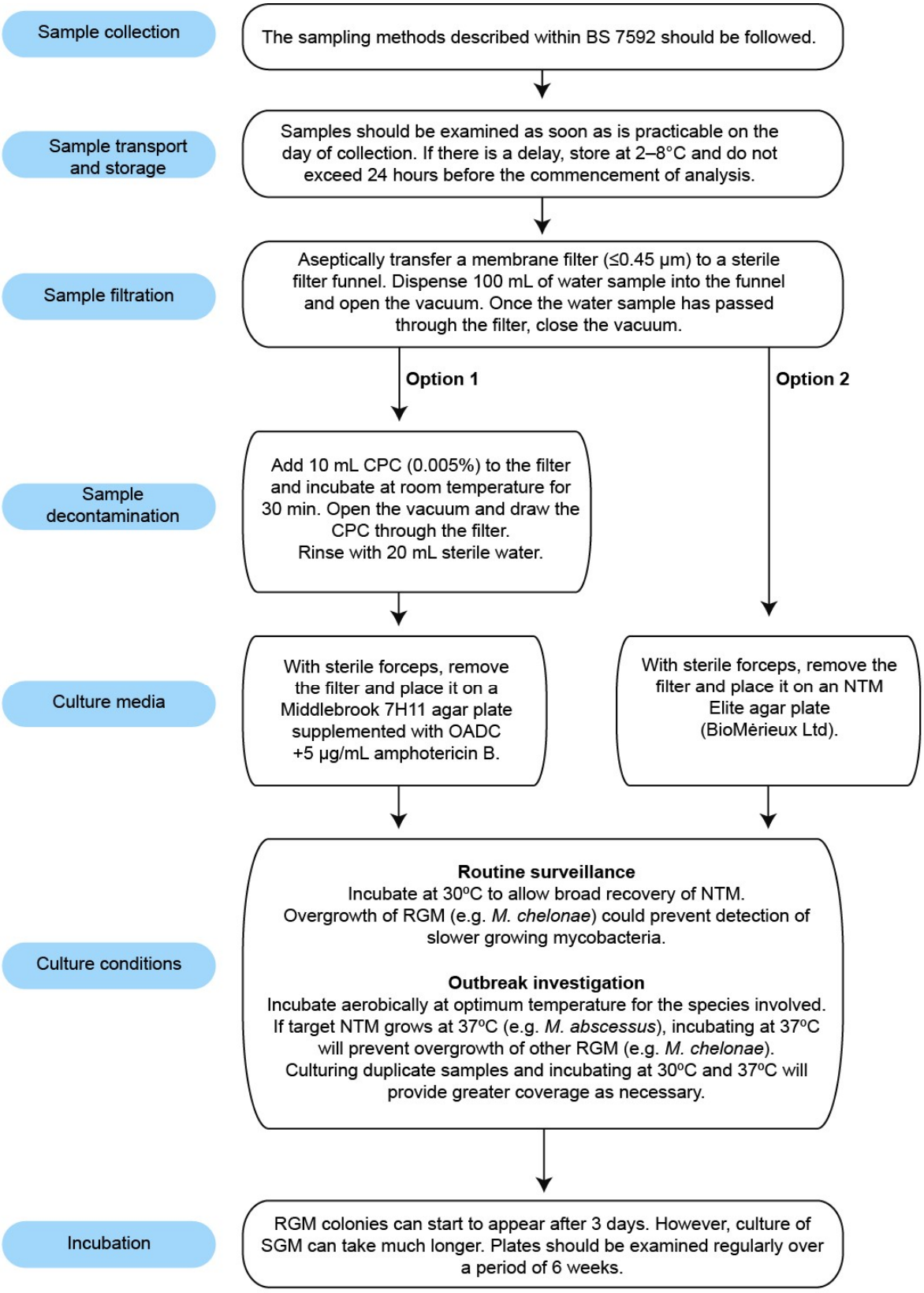
Nontuberculous mycobacteria

8.7 Currently there is no standardised method available which is aimed at detection of both slow-growing and rapid-growing forms of NTM by culture or molecular methods.

8.8 The method shown in Figure 2 has been provided by the UK Health Security Agency as an interim while a standard method is developed. Those commissioning testing should ensure the laboratory is UKAS-accredited to ISO 17025.

8.9 For these high-risk patients, there should be no NTM detected. However, because of the lack of availability of a standard method at present with associated sensitivity and specificity data, a negative laboratory result could still mean that NTM are present. The reason is that the testing method might have failed to detect a small number of NTM that were in a VBNC state.

8.10 Any positive results mean that alternative strategies to deliver safe water must be put in place before admission of patients. The PWSG together with subject matter experts when required should make the decision as to the appropriate action to take to ensure patients remain safe on admission.



CPC = Cetylpyridinium chloride; NTM = Nontuberculous mycobacteria; OADC = Oleic acid-albumin-dextrose-catalase; RGM = Rapid growing mycobacteria; SGM = Slow growing mycobacteria

Figure 2 Interim detection method for nontuberculous mycobacteria

Appendix 1 Glossary and abbreviations

Augmented care: there is no fixed definition of “augmented care”; individual providers may wish to designate a particular service as one where water quality must be of a higher microbiological standard than that provided by the supplier. The water quality required will be dependent on both the type of patient and its intended use. Most care that is designated as augmented will be that where medical/nursing procedures render the patients susceptible to invasive disease from NTM and other opportunistic pathogens. For this document, this means:

a. lung transplant patients

b. cystic fibrosis (CF) patients

c. haematology/oncology patients undergoing chemotherapy where neutropenia is expected

d. solid organ transplantation after intensive treatment

e. allogenic stem cell transplantation

f. any patient with a long line (e.g. central venous catheter) in situ.

Competent/Competence: the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely. Other factors, such as attitude and physical ability, can also affect someone's competence.

Competent person: a person with the skills, knowledge, experience and training required to carry out their tasks effectively and are aware of all applicable legislation, guidance, codes of practice and standards, as well as intended uses of water, routes of exposure, susceptibility of those likely to be exposed, consequences of poor design, the relevant hazards and hazardous events and how inherent risks can be minimised by good design and appropriate uses of materials and fittings (see Table 1 BS 8680).

Disinfection: this means the addition of an oxidising biocide as agreed by the PWSG. Note: The effectiveness of a disinfectant depends on the type of disinfectant, the concentration and the contact time. Even at 50 ppm of sodium hypochlorite, which is commonly used for shock dosing, not all opportunistic waterborne pathogens, such as those in biofilms and or within protozoan cysts, will be killed.

Duty Holder: as recommended in the Hackitt report (2018), for each building there should be a clear and identifiable "duty holder". For the purposes of this document a duty holder with responsibility to ensure the safety of new build or major refurbishment projects should be appointed at Board level i.e. an Executive Director/Senior Responsible Owner (SRO).

Hazard is a biological, chemical or physical agent in water, or a condition of water, with the potential to cause an adverse health effect (WHO 2007)

Hazardous analysis The process of collecting and evaluating information on hazards and conditions leading to their presence, for the purpose of deciding which are significant for water safety and therefore should be addressed in a water safety plan (WHO 2007).

Hazardous events a hazardous event is an incident or situation that can lead to the presence of a hazard (what can happen and how);(WHO 2011)

Hazard Analysis and Critical Control Point (HACCP) was initially developed to provide assurance that food and water provisions to be sent into space on manned space missions was safe and then widely adopted by the food industry as a food production safety management system. It is a systematic preventive approach for the identification and management of hazards and hazardous events in water systems and the effectiveness of barriers in place to protect water quality against physical, chemical and biological risks.

Highly immunocompromised: for the purposes of this document; those patients suffering from underlying health conditions that increase their susceptibility to waterborne infections, including following transplantation (especially lung transplants), haematology/oncology patients, cystic fibrosis and those with indwelling venous catheters (for example, in critical care areas)

Note: Clinical surveillance and/or risk assessment may indicate this definition may be applied to other patient groups.

Major refurbishment: construction that results in the fundamental remodelling or adaptation of existing elements of the building envelope and structure, and the renewal of key building services. And where, on completion of the work, such remodelling/renewal will materially impact on the performance of the building.

Nontuberculous mycobacteria: mycobacterial species other than *M. leprae* and the *Mycobacterium tuberculosis* complex (based on the British Thoracic Society guidelines for the management of non-tuberculous mycobacterial pulmonary disease (see Haworth et al., 2017)).

Opportunistic waterborne pathogens in the context of this document these are defined as: microorganisms that are normal inhabitants of the natural aquatic environment, constructed water, wastewater systems and associated equipment that can cause infections when able to access tissues and organs not normally accessible to them (for example, patients who are immunocompromised as a result of illness or treatment and those with breaches in the skin's integrity).

Point of use (POU filtration): for high-risk patients, 0.2 µm sterilising-grade POU filters complying with regulation (EC) No 1935/2004 and the Water Supply (Water Fittings) Regulations should be specified.

Project-specific water safety group (PWSG): a multidisciplinary group with the necessary expertise, skills and competence to ensure the safety of the patient is put first and foremost

throughout all stages of new build and major refurbishment projects and are responsible for overseeing the development and implementation of the project water safety plan (PWSP).

Pseudo-outbreak is an increase in the incidence of identified organisms but without evidence of infection. They may be associated with contaminated decontamination equipment, for example bronchoscope or endoscope washers.

Project water safety plan (PWSP): a water safety plan developed specifically for each new build or major refurbishment project which defines and documents the arrangements through all stages of a new build or major refurbishment project to ensure the project delivers safe water systems and associated equipment as well as above ground wastewater systems, to prevent harm to patients, staff and members of the public. The PWSP must take into account the susceptibility those who may be exposed to water or aerosols derived from water, wastewater systems and associated equipment as well as all potential sources and all potential modes of transmission for each type of water use.

Soft landings approach is based on BSRIA Guide BG54/2018 and included in BS 8680:2020 with the aim to deliver a safe building for the intended patient groups by setting the success criteria at the start of the project and then maintaining the primary focus on patient safety throughout the project from the concept to completion and beyond. It includes taking account of lessons learned from other projects locally and nationally.

Note: for the purposes of this guidance success criteria means that the project delivers a building which is safe for the intended patients at handover and beyond.

Water safety group (WSG): as defined within BS 8680:2020, is a multidisciplinary group of people formed to undertake the commissioning, development and ongoing implementation and management of the water safety plan (WSP) with the skills and responsibility for ensuring that the water is safe at the point of use for all uses and all users of water within buildings. The composition of the WSG and the complexity of its role varies depending on the design, size and complexity of the systems and attached devices and risk assessments based on the types of hazards, the potential for hazardous events, and routes of exposure and transmission for all intended uses and users of the system or device. It also advises on the remedial actions required when water systems or outlets are found to be contaminated, and the risk to susceptible persons is increased. The PWSG are also responsible for reviewing risk assessments at each gateway between project phases and to provide assurance to the WSG and Board there are appropriate barriers in place throughout the project to prevent harm to patients.

Water safety plan: is a strategic plan which defines and documents the arrangements that are required for the safe use and management of all water systems together with all associated systems and equipment within each building or estate to prevent harm arising from all forms of exposure (Institution), 2020)

Waterborne infections are infections caused by water, sprays and aerosols derived from water, wastewater systems and associated equipment to which patients may be exposed via direct and indirect contact, inhalation or aspiration.

Waterborne pathogens are the causative agents (usually living organisms) for waterborne infections.

Abbreviations

CF: Cystic fibrosis

GNB: Gram-negative bacteria

HCAI: Healthcare-associated infection

IPC: Infection prevention and control

Mab: *Mycobacterium abscessus*

MAC: *Mycobacterium avium* complex

NHSE National Health Service England

NTM: Nontuberculous mycobacteria

POU: Point-of-use (filter)

POUF: Point of use filter

PWSG: Project-water safety group

PWSP: Project- water safety plan

RAMS: Risk assessment method statement

RGM: Rapid-growing mycobacteria

SGM slow growing mycobacteria

TMV: Thermostatic mixing valve

WHO: World Health Organization

WSG: Water safety group

Appendix 2 Applicable legislation, standards and guidance

1. BS 8680:2020 Water quality. Water safety plans. Code of practice BS 8680:2020

2. Bs 8580-1: 2019 Water quality. - Risk assessments for *Legionella* control. Code of practice BS 8580-1:2019

3. BS 8580-2:2022 Water quality. Risk assessments for *Pseudomonas aeruginosa* and other waterborne pathogens. Code of practice BS 8580-2:2022

4. BS 8536:2022 Design, manufacture and construction for operability. Code of practice BS 8536:2022

5. Health and Safety Executive, Legionnaires' disease, The control of legionella bacteria in water systems, Approved Code of Practice and Guidance, L8

6. Health and Safety Executive, Legionnaires' disease Part 2: The control of legionella bacteria in hot and cold water systems, HSG 274-2

7. The Water Supply (Water Fittings) Regulations 1999 https://www.legislation.gov.uk

8. Health Technical Memorandum 04-01 (A-C) : Safe water in healthcare premises HTM 04-01,

9. HBN 00-09 – 'Infection control in the built environment

Note: A risk assessment by PWSG must be carried out to ensure the application of these guidance documents will not adversely affect patient safety. It is expected that there will be derogations from the current guidance. Any derogation, however, should state why the derogation is needed and that applying the derogation will improve patient safety in both the short and long term.

10. The Construction (Design and Management) Regulations 2015 (as amended) https://www.legislation.gov.uk/uksi/2015/51/contents/made

11. Soft landings framework 2018 : six phases for better buildings, M. Agha-Hossein, Building Services Research and Information Association. Series: BSRIA Guide ; B54/2018.

12. BS EN 806-4:2010 Specifications for installations inside buildings conveying water for human consumption. Installation;

13. BS EN 806-2 Section 11 gives guidance on the design and installation of water meters,

14. BS 8558:2011, Guide to the design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages. Complementary guidance to BS EN 806;

15. BS EN 1717:2000; Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow;
Note: This is under review and due for republication, this copy 2000 actually conflicts in the category of water and is corrected with a UK specific amendment.

16. BS8536:2022 Design, manufacture and construction for operability. Code of practice

17. ISO 19650

18. BIM Framework Government Soft Landings Revised guidance for the public sector

19. Hackitt Final Report Building a Safer Future 2018

20. ISO9001: 2015 Quality Management Systems

Appendix 3 Stages of immunosuppression and appropriate protection measures

Based on tables within Bartram et al., 2003, and referenced in WHO (2022).

These definitions below are not exclusive and to be used as a guide for WSGs, PWSGs and clinical teams to assess their patient susceptibilities and adjust as ended

Proposed definitions of protection levels for immunocompromised patients

Protection level I: Mild immunosuppression

- Acute or chronic leukaemia, malignant lymphoma, childhood histiocystosis X under maintenance therapy without neutropenia
- Solid tumours (within six months of chemotherapy)
- Long-term corticosteroid therapy with <20 mg/day prednisone or equivalent
- Autologous stem cell transplantation (within six months of discharge)

Protection level II: Moderate immunosuppression

- Acute or chronic leukaemia, malignant lymphoma, childhood histiocystosis X, solid tumours under intensive treatment (expected duration of neutropenia <500/µl for ≤10 days)
- Long-term corticosteroid therapy with ≥20 mg/day prednisone or equivalent
- Solid organ transplantation after intensive treatment phase
- AIDS with a count of CD4+ cells less than 200/µl

Protection level III: Severe immunosuppression

- Acute or chronic leukaemia, malignant lymphoma, childhood histiocystosis X, solid tumours under intensive treatment (expected duration of neutropenia <500/µl for >10 days)
- Solid organ transplantation under intensive treatment phase (induction or rejection therapy)
- Allogeneic stem cell transplantation (first 6–12 months after engraftment)
- AIDS with a count of CD4+ cells less than 200/µl and an additional factor of
- immunosuppression (e.g., neutropenia, corticosteroids)

Protection level IV: Extreme immunosuppression

- Allogeneic stem cell transplantation (until engraftment)

Proposed protection measures to prevent drinking-water-borne infections in immunocompromised patients

These measures are aimed not only at HPC bacteria but also at other potentially more pathogenic microorganisms, such as fungi, Legionellae, Cryptosporidiae and *M. avium* complex.

Protection level I: Mild immunosuppression

Avoid any circumstances with elevated infection risks (like drinking water from uncontrolled sources)

Protection level II: Moderate immunosuppression

- Drinking-water should have an additional antimicrobial barrier to tap water
- Bathroom installations should be controlled for bacterial reservoirs

Protection level III: Severe immunosuppression

- Any water for human use should have a very low bacterial count (use water filters/controlled carbonated water)
- Strict control of bath installation and water for showering (showering to be avoided if no control possible)

Protection level IV: Extreme immunosuppression

Only sterile fluids for drinking, mouth care and washing allowed

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