NHS England

HM Assistant Coroner, Keith Morton KC
Area of Cambridgeshire and Peterborough
Lawrence Court
Princess Street
Huntington
PE29 3PA

National Medical Director
NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

06 February 2023

Dear Mr Morton,

RE: Inquests into the deaths of Karen Lesley Starling and Anne Edith Martinez: Report to Prevent Future Deaths (PFD)

I am writing on behalf of NHS England in response to the PFD sent to the Secretary of State for Health and Social Care dated 14th November 2022. Health Technical Memorandum 04-01, Safe Water in Healthcare Premises (HTM 04-10), the subject of the PFD, was published by the Department of Health and Social Care (DHSC) in 2016, but responsibility for this guidance transferred from the DHSC to NHS England in 2017.

My colleagues in NHS England's National Estates Team and regional East of England Team have contributed to this response to assist in outlining the wider support that has been provided to the Royal Papworth Hospital NHS Foundation Trust (the Trust).

NHS England was not involved in these inquests, but we would like to extend our condolences to Ms Starling and Ms Martinez's families for their losses.
NHS England is grateful to HM Coroner for identifying your concerns in respect to Health Technical Memorandum 04-01, Safe Water in Healthcare Premises (HTM 04-01). I have endeavoured to respond to your concerns below, which I understand from the PFD are as follows:

1. *It is recognised that M abscessus poses a risk of death to those who are immunosuppressed. That will be so for many patients at specialist hospitals such as Royal Papworth and more generally for hospital patients. To date, 34 patients at Royal Papworth have contracted M abscessus from the hospital's water. Cases continue to be reported, albeit at a declining rate;*
2. *There is an incomplete understanding of how M abscessus may enter and/or colonise a hospital water system;*
3. *Health Technical Memorandum 04-01 Safe Water in Healthcare Premises was published by the Department of Health in 2016. It is concerned with the design, installation, commissioning and operation of hospital water systems. This*

guidance requires urgent review and amendment, whether by way of an Addendum or otherwise because:

a. *It is a key document for hospital estate managers and Water Safety Groups;*
b. *It purports to provide comprehensive guidance on waterborne bacteria;*
c. *However, it provides no relevant guidance in relation to mycobacteria and none in relation to M abscessus. It provides no guidance on the identification and control of M abscessus. It does not require routine testing for mycobacteria, including M abscessus or provide guidance on acceptable levels (if any). Compliance with the guidance does not identify or guard against the risk from M abscessus;*
d. *It provides no guidance on any additional measures that may be required in respect of "augmented care" patients, including those who are immunosuppressed;*
e. *It is not in any event consistent with British Standard BS 8580-2:2022 on Water Safety.*

4. *There is evidence that the risk from M abscessus is especially acute for new hospitals. Consideration needs to be given to whether special or additional measures are required in respect of the design, installation, commissioning and operation of hospital water system in new hospitals.*

Support provided to the Trust

Oversight and governance

Following notification by the Trust regarding the initial patients' testing positive for **Mycobacteroides** abscessus (M. abscessus), from 25th November 2020 incident management meetings were established between the Trust and NHS England with representation from Infection, Prevention and Control, Leadership and Quality and Commissioners. The purpose of these meetings was to:

- Understand the incident and the effect on patients;
- Be assured of the actions being undertaken by the Trust to mitigate risk to patients;
- Be assured of the communication and duty of candour actions regarding current and future events and informed patient and carer decisions;
- Be assured that all necessary expert input had been sought and actions implemented, and
- Offer support and advice.

In addition to the above meetings, NHS England's Leadership and Quality Team hold quarterly Clinical Quality Review Group (CQRG) meetings. This meeting is chaired by the Director of Nursing, Leadership & Quality for NHS England (East of England), and includes senior members from the Trust and NHS England, along with representatives from Cambridge & Peterborough Integrated Care Board.

For the initial period of the M. abscessus incident the CQRG meeting paid particular attention to M. abscessus. Assurance regarding patient communication and Duty of

Candour was a significant component of the assurance required at the CQRG meetings by NHS England.

Assurance on patient experience

NHS England reviewed that the Trust's website has clear explanations about the M. abscessus incident on its website and the risk of M. abscessus is routinely discussed as part of the pre-operation / consent process and decision making. NHS England has been informed that, as of 22 November 2022, no patients have opted not to continue with surgery.
Assurance was also required and given from the Trust regarding the mitigation and on-going surveillance that was implemented to protect vulnerable patients and to support them in the pre-operative decision making that was required by the patient. NHS England has been given assurance that risk assessments are undertaken for all patients on admission. Patients who are immunocompromised or at a higher risk are provided with bottled water and additional Infection Prevention measures are implemented. All patient rooms are single rooms with ensuite facilities, and all taps and showers are fitted with additional filters which are changed regularly and in between patients.

Stakeholder Collaboration

In addition to the quarterly CQRG meetings, a specific monthly meeting was established between NHS England's Leadership and Quality Team, chaired by the Director of Nursing, Leadership & Quality for NHS England (East of England), and colleagues from the United Kingdom Health Security Authority (UKHSA). The purpose of these meetings was for UKHSA to provide assurance to NHS England of the governance, the progress and completion of agreed actions from the incident management meetings, and to ensure that optimum support and collaboration was provided to the Trust in the management of the incident.

Meeting frequency reduced from July 2022 once support and collaboration were evident, but the frequency will be increased if there are any concerns, which are regularly monitored. Actions following the meeting are outlined below. Increased support for the Trust from UKHSA colleagues at UKHSA's Porton Down site has been confirmed with offers to:

- Develop a sampling rationale/strategy and take samples from water sources and outlets in Royal Papworth Hospital;
- UKHSA now attends the operational meetings internally at the Trust;
- Carry out air sampling using active and passive air sampling;
- Using nontuberculous mycobacteria (NTM) isolates recovered from the hospital environment to assess efficacy of disinfectants and compare their susceptibility to isolates from elsewhere. The purpose of this is to ascertain if there is evidence to suggest that Royal Papworth Hospital isolates have increased tolerance; and
- Assess the impact of water chemistry, to establish if there is evidence to suggest that the incoming water may facilitate persistence.

NHS England's East of England Infection Prevention and Control lead has been supporting and facilitating the collaborative working between the Trust and UKHSA. This led to further specialist input from UKHSA National mycobacterium reference lab, field services, and the environmental microbiologist at the Porton Down laboratory, to support the Trust with water and environmental sampling.

The Trust's Estates Team are actively engaged with NHS England's Estates Team and several visits from the regional team have taken place, including conversations regarding the pipe work and recommendations for enhanced cleaning. These actions are included and monitored through a Trust Executive Oversight Committee which was established in July 2022, of which NHS England and UKHSA are core members. This Committee meets quarterly and is chaired by the Director of Nursing at the Trust. NHS England attendance at this meeting continues (with attendance from the Director of Nursing, Leadership & Quality, Head of Nursing and Medical Director for NHS England (East of England)), and the M. abscessus incident remains a standing agenda item as it does at the CQRG meetings.

It is noted that as part of the collaborative working with external stakeholders, the Trust reviewed its internal governance structure which led to a new M. abscessus governance structure. This allowed for NHS England and UKHSA to be part of the discussions via the Trust's Executive Oversight Committee which directly feeds into the Trust's Quality and Risk Committee and in turn the Trust's Board of Directors.

The Trust's Executive Oversight Committee is multi professional and multi organisational and provides a system of oversight of the recommendations and action plans associated with the M. abscessus incident. It brings together the updates and actions from the groups within the Trust's M. abscessus governance structure and provides oversight and assurance of the actions and their progress whilst offering a forum for discussion and clarification.

Principal Engineer site visit

NHS England's National Principal Engineer undertook a site visit of Royal Papworth Hospital on 23rd February 2022 in conjunction with the Trust's Director of Estates and Facilities, to look at the physical environment and the water system.
A large, complex water system has been installed at the hospital which has required 40 flushing valves to subsequently be installed. It was understood that a number of different disinfectants had been tried on the system and was having a deleterious effect on the pipework and fittings with valves only two years old being changed due to degradation.

At the site visit the design intent, configuration, operation, material/product suitability and control strategy for the pre-heat of make-up water system were discussed with the Trust, with a view to the Trust reviewing these aspects of the water system.
It was also fed back to the Trust at this site visit that the larger press-fit fittings that had been used on the system needed further investigation. This was due to the potential for the fittings to retain a quantity of stagnant water that would be against a

polymeric seal which could prove an ideal habitat for bacterial growth and would be virtually impossible in normal use to clean/sanitise. In turn this may lead to a harbour area where NTM's could grow and be pushed into the flow stream in the pipe and detach and contaminate the system. These fittings are approved under the Water Regulations Approval Scheme, but this does not mean that there is any evidence of their suitability for healthcare applications.
Ongoing work to support required changes continues. A follow-up site visit is in the process of being arranged with the Trust.

Background to HTM 04-01

HTM 04-01 was published by the Department of Health and Social Care (DHSC) in 2016, but responsibility for this guidance transferred from the DHSC to NHS England in 2017.

HTM 04-01 provides guidance on the legal requirements, design applications, maintenance and operations of hot and cold-water supply storage and distribution systems in all types of healthcare premises. It also provides advice and guidance on the control and management of the risk posed by water borne pathogens within a healthcare setting such as Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Mycobacteria as well as Legionella.

The guidance on the control of waterborne pathogens is divided dependent upon the route of administration of the infection. For instance, with Legionella there is no evidence of patient-to-patient or patient-to-outlet transfer, whereas Pseudomonas aeruginosa and Mycobacteria may be transferred to and from outlets and the water from both patients and staff.

Part C of HTM 04-01 focuses on additional measures that should be taken to control and minimise the risk of Pseudomonas aeruginosa. Whilst the main focus of Part C is on the control of Pseudomonas aeruginosa, given this is the most common pathogen, the document explicitly states that it may also have relevance to other waterborne pathogens such as atypical Mycobacteria. There are many different species of Pseudomonas and Mycobacteria. M abscessus, the subject of the PFD, is a species of Mycobacteria and is also referred to as a NTM.

Commissioned review

NHS England is committed to improving patient safety and has therefore taken your concerns extremely seriously. As a result, we have commissioned Dr Susanne Surman-Lee to undertake the following work:

1. To carry out a review of HTM 04-01 specifically in relation to immunosuppressed patients and NTM, to determine if HTM 04-01 contains suitable advice regarding testing, and to ensure any additional required measures are identified;

2. The above review is to include identification of any specific measures required for new hospital premises; and

3. To carry out a gap analysis between British Standard BS 8580-2:2022 on Water Safety and HTM 04-01 with respect to safe water in healthcare premises.

[redacted] is a leading expert in the detection, survival and control of pathogenic microorganisms, especially the prevention of infections from opportunistic waterborne pathogens, with unique experience in dealing with healthcare building water systems.

Any suggested amendments to HTM 04-01 which derive from this review will be carefully considered, and appropriate amendments will be written into a technical bulletin, which in turn will be published to ensure HTM 04-01 is accurate and up to date. The aim is to publish the technical bulletin by the Spring.

I hope this is of assistance, and please let me know if there is anything else NHS England can assist you with in this matter.

Yours sincerely

National Medical Director
NHS England

Cc. [redacted], Director of Estates and Head of Profession at NHS England