M. E. Voisin
His Majesty's Senior Coroner
Area of Avon

29 June 2023 [redacted]

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **UK Health Security Agency**
1	**CORONER** I am Dr Simon Fox KC, Assistant Coroner for Area of Avon
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 26th July 2022 an investigation into the death of Mr. Clinton Peter Fear was commenced. The investigation concluded at the end of the inquest 29th June 2023. The conclusion of the inquest was - **Mr Fear died from a Mycobacterium Chimaera infection acquired from a Liva Nova heater cooler unit during open heart surgery.** The cause of death was – 1a) Hospital acquired pneumonia; b) Disseminated Mycobacterium Chimaera infection following a composite aortic root replacement (November 2012).
4	**CIRCUMSTANCES OF THE DEATH** Mr Fear underwent cardiac valve replacement surgery in November 2012 and during surgery he contracted Mycobacterium Chimaera infection from a Liva Nova heater cooler unit (part of the heart bypass machine). He developed symptoms of Mycobacterium Chimaera in the form of night sweats in 2017/2018, was diagnosed and started on treatment in October 2019, suffered a protracted disabling illness for 3 years and died from the infection in July 2022.

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	He was not notified of the risk of Mycobacterium Chimaera infection from the operation when this risk became known in 2015 because his operation was before January 2013 – the date from which patients were then considered to be at risk and adopted in guidance from Public Health England. Mr Fear contracted his Mycobacterium Chimaera infection at surgery before January 2013 and other cases have been reported from surgery dating back to at least 2008.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – 1. There is an inconsistency between – Previous Public Health England and current NHS guidance only to notify patients undergoing surgery from January 2013 of the risk of Mycobacterium Chimaera infection And Evidence of patients contracting Mycobacterium Chimaera infection from surgery substantially earlier than January 2013 (at least as far back as 2008); 2. There appears to be no current basis for maintaining a start date of surgery in January 2013 for patient risk notification when there is evidence of infection substantially earlier than this date; 3. Patients who have contracted Mycobacterium Chimaera infection from surgery before January 2013 may be suffering a delay in diagnosis and consequent harm as a result of a lack of notification due to the existing guidelines.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 31st August 2023. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the chief coroner and to the following interested persons - Deceased's family; - University Hospital Bristol and Weston NHS Trust. I have also sent it to North Bristol NHS Trust who may find it useful or of interest. I am also under a duty to send the chief coroner a copy of your response. The chief coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the chief coroner.
9	29/06/2023  Dr. S. Fox KC H. M. Assistant Coroner

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