Re : NICHOLAS HUGH WINTERTON DECEASED

REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Public Health England** **2. National Institute for Cardiovascular Outcomes Research** **3. Society for Cardiothoracic Surgery** **4. College of Clinical Perfusion Scientists**
1	**CORONER** I am Alison Hewitt, HM Senior Coroner for the City of London.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7 of Schedule 5 to the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** I commenced an investigation into the death of Nicholas Hugh Winterton. The investigation concluded at the end of the inquest on the 17th December 2020. The conclusion of the inquest was that the medical cause of death was - Ia Chronic Systemic Sepsis and Multi-organ Failure Ib Mycobacterium Chimaera Endocarditis Acquired During Cardiac Bypass Surgery Ic Aortic Valve Disease (Operated in May 2016) II Cerebral Infarction and my conclusion as to the death was that the Deceased – Died as a result of infection from equipment used in necessary surgical treatment.
4	**CIRCUMSTANCES OF THE DEATH**

	Nicholas Winterton suffered severe aortic regurgitation and on the 20th May 2016 at St. Bartholomew's Hospital, London, he underwent elective aortic valve replacement surgery, for which purpose he was placed on cardiopulmonary bypass. The surgery was uneventful and the Deceased made a good post-operative recovery. In May 2018, however, he became unwell with symptoms of infection; whilst still under investigation for those symptoms, on the 31st May 2018 he suffered a stroke and was admitted to hospital, and subsequently, on the 29th June 2018, he was transferred to the National Hospital for Neurology and Neurosurgery, London. By mid-July 2018 blood cultures had established that the Deceased's infection was from mycobacterium chimaera and he was suffering infective endocarditis. Surgical intervention was judged not to be feasible; he was treated with an appropriate anti-biotic regime but it proved ineffective and he developed systemic inflammatory response syndrome, sepsis, and multi-organ failure, from which he died on the 29th September 2018. The mycobacterium chimaera infection had been acquired from the heater-cooler unit which was used as an essential part of the cardiopulmonary bypass equipment for his cardiac surgery in May 2016. The heightened risk of this infection from this device, which stemmed principally from its design, had been identified prior to the surgery, including through guidance for minimising the risk issued in October 2015 by Public Health England. St. Bartholomew's Hospital's systems were largely in compliance with that guidance, although their regular decontamination of their heater-cooler units was performed on about a monthly basis, rather than two-weekly as recommended by the manufacturer. The evidence did not reveal which unit was used for the Deceased's surgery, as this was not recorded as required, and it was not possible to establish what, if any, effect the hospital's cleaning regime had on the risk of infection from the operation.
5	**CORONER'S CONCERNS** In the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could 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. It is apparent that it is important that the nationally recognised level of the risk of developing Mycobacterium Chimaera from exposure to a heater cooler unit is accurate, in that it accurately reflects the most current statistical data, and is based on the best gathering of statistical data as to the true incidence of such infection as can practicably be achieved. This is because the nationally recognised level of risk is the proper basis upon which –

   (i) The informed consent of a patient for a relevant surgery is obtained, and

   (ii) Post-operatively, the patient and the clinician(s) caring for him (including his General Practitioner) will base their "threshold for suspicion" for Mycobacterium Chimaera if the patient develops an infection which cannot quickly be identified and treated.

2. Public Health England, together with the National Institute for Cardiovascular Outcomes Research, the Society for Cardiothoracic Surgery, and the College of Clinical Perfusion Scientists, are the national bodies which are able to co-ordinate collation of relevant statistical evidence and then formulate and disseminate accurate information about the level of risk. It is inappropriate for individual hospitals, cardiac centres, or Trusts to formulate risk level on the basis of their own data as this would result, nationally, in the dissemination of inconsistent information.

3. Public Health England's "Clinical guidance for secondary care" and "Information for general practice" are based on January 2017 data. Further, on its website, under the heading "Who could be at risk of Mycobacterium chimaera infection", Public Health England currently states,

   "People most at risk are those who've had heart valve surgery since January 2013. About 1 person in every 5,000 who has this type of surgery will develop the infection."

	This assessment is also based on data collated to January 2017. 4. The evidence at the inquest showed that the figure of "1 person in every 5,000" is inaccurate, in that : (i) It is based on data from 2017 and not updated data, and (ii) It is based on data which reflects only those patients who are reported to Public Health England as having died of Mycobacterium Chimaera infection, whereas the true incidence of the infection is very likely to be higher; the likelihood is that there is a potentially significant number of deaths from undiagnosed Mycobacterium Chimaera, given the patient cohort's usual level of co-morbidities and clinicians' low threshold of suspicion for this infection. 5. A more accurate assessment of the risk, and more accurate guidance, would therefore result from – (i) An immediate review by Public Health England of all data held to date with a re-calculation of the incidence of Mycobacterium Chimaera infection and consequential risk being reflected in updated guidance and web-site information, and (ii) Consideration being given by all the bodies to whom this Report is sent of whether there is a better investigative basis which could be used for obtaining relevant data and statistics as to the true incidence of Mycobacterium Chimaera infection, whether by means of a research study or otherwise.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths by addressing the concerns set out above and I believe your organisation 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 the 27th May 2021**. I, as 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, to the following Interested Persons and to the other organisations listed below which may find it useful or of interest : [redacted] [redacted] Barts Health NHS Trust I am also under a duty to send the Chief Coroner a copy of your response. I may also send a copy of your response to any other person who I believe may find it useful or of interest. 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	**31st March 2021** **Alison Hewitt**