



8 June 2021

Regulation 28 report dated 31 March 2021 to prevent future deaths pursuant to Her Majesty's Coroner inquest into the death of Nicholas Winterton

Patient's Name: Nicholas Hugh Winterton

Date of death: 29.09.2018

Response from:

Public Health England ("**PHE**");

National Institute for Cardiovascular Outcomes Research;

Society for Cardiothoracic Surgery ("**SCTS**"); and

College of Clinical Perfusion Scientists

- 1) The Coroner has asked for actions to be taken, without which in her opinion, there is a risk that future deaths could occur from *Mycobacterium chimaera* infection acquired during cardiac surgery. These relate to a perceived inaccuracy in the risk estimate of "1 person in every 5,000" published by PHE in 2017 in its guidance to primary and secondary care providers and on its website. In summary, this inaccuracy is stated as stemming from:

- (i) being based on data from 2017 and not updated data, and
 - (ii) being based on data which reflects only those patients who are reported to PHE as having died of *Mycobacterium chimaera* infection.
- 2) In relation to the above, the Coroner has requested (in summary):
- (i) a review of all data held to date with a recalculation of the incidence of infection and dissemination of the consequential risk assessment through updated guidance and website information, and
 - (ii) consideration as to the optimal investigative basis for formulating this risk assessment.

Inaccuracy in calculation of *Mycobacterium chimaera* infection risk

- 3) With regard to the concern in paragraph (1)(ii) above, we would like to clarify to the Coroner that these risk calculations were not based solely on risk of death but in fact based on risk of infection associated with this type of surgery, namely heart-valve surgery performed on bypass. As such, data collection was not restricted to patients reported to PHE as having died of *Mycobacterium chimaera* (*M. chimaera*) infection.
- 4) In responding to the potential threat posed by transmission of *M. chimaera* from contaminated heater cooler units (“**HCUs**”) used in open-heart surgery, PHE established a surveillance system to capture data on all cases (not just cases resulting in death) potentially arising as a result of open-heart surgery performed in the UK. PHE continues to collate and publish information on newly diagnosed cases and associated deaths. This can be found on:

<https://www.gov.uk/government/collections/mycobacterial-infections-associated->

[with-heater-cooler-units.](#)

- 5) With regard to the concern in paragraph (1)(i) above, this risk was estimated to support the nationwide patient notification exercise mounted in 2017. The risk estimate is not inaccurate; it refers to an estimated risk of *Mycobacterium chimaera* (*M. chimaera*) infection for patients who underwent NHS surgery between 2007 and 2015. Based on cases reported to PHE to date, the risk for patients undergoing surgery during that period remains unchanged at 1 in 5000.

Proposed actions to be taken

- 6) With reference to the proposed updating of risk estimates referred to in paragraph (2)(i) above, PHE has continued to monitor changes in risk, utilising cases reported to PHE coupled with numbers of patients undergoing heart-valve surgery in NHS hospitals derived from Hospital Episode Statistics. This has shown a continued decline in risk with successive years of surgery since 2014. The most recent date of surgery for cases identified to date is February 2017. Therefore there have been over four years of cardiac surgery performed in the United Kingdom without a further case of *M. chimaera* identified to date.
- 7) With reference to paragraph (2)(ii) above and given that the current methodology includes surveillance data not just restricted to deaths, the respondent bodies believe the established mechanism provides a reasonable means for ongoing monitoring of risk and that a revised or alternative investigative basis is not required.
- 8) PHE accepts that information on the risks of infection should be more widely disseminated to inform patients' decision-making, and for clinical awareness. An

updated risk assessment was undertaken by PHE in November 2019 and submitted to an international medical conference with a view to publication of an article in a medical journal. An extract from the conference abstract book is attached at Exhibit PHE1¹. The advent of the COVID-19 pandemic resulted in the cancellation of the conference and delayed completion of the publication.

- 9) PHE will further update the risk estimates and ensure that these are published by September 2021. The respondent bodies will thereafter cascade these updated risk estimates to healthcare professionals involved in informing and consenting patients or investigating and diagnosing these infections, namely consultant microbiologists and cardiothoracic surgeons. This will be achieved through our respective clinical networks.
- 10) In relation to the updating of the guidance for healthcare providers, we would like to make the Coroner aware that NHS England assumed responsibility for management of the *M. chimaera* incident in October 2016. PHE and SCTS worked with NHS England to support the patient notification exercise launched in February 2017, including the development of guidance for healthcare providers.
- 11) With specific reference to the inclusion of the 1 in 5000 risk estimate on PHE's website, whilst the risk estimate was produced by PHE, we believe this information is in fact found on the NHS website (which is not controlled by PHE):
<https://www.nhs.uk/conditions/mycobacterium-chimaera/>

¹ The ECCMID Abstract Book from which the extract is taken can be downloaded from the following website:
https://www.escmid.org/escmid_publications/eccmid_abstract_book/

- 12) Given the transfer of responsibility for management for the incident, we will forward this request for the further updating of guidance and to the need to update the NHS website to NHS England to agree responsibilities and a timetable for updating.

Exhibit PHE1



Abstract Book 2020

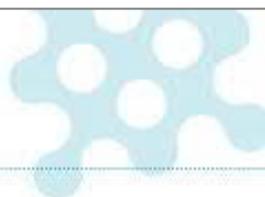
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Abstracts 2020



Abstract 4328

Global outbreak of *Mycobacterium chimaera* infections in cardiac surgery patients: tracking risk through ongoing surveillance in the UK

¹Public Health England, London, United Kingdom, ²Public Health Wales NHS Trust, Cardiff, United Kingdom, ³NHS Highland, Inverness, United Kingdom, ⁴Health Protection Scotland, Glasgow, United Kingdom, ⁵Public Health Agency Northern Ireland, Belfast, United Kingdom

Background: Global distribution of *Mycobacterium chimaera* contaminated heater cooler units used in open-heart surgery has resulted in one of the most widespread multicenter hospital outbreaks described to date, with cases documented in 13 countries spanning 4 continents. Prospective monitoring established in 2015 by Public Health England in collaboration with Devolved Administrations informed UK risk mitigation strategies. We assess changes in risk since implementation of these measures, including enhanced device decontamination, advice on theatre positioning and patient notification of early signs and symptoms.

Methods: Following initial retrospective case finding, laboratories were requested to report prospective cases meeting our case definition - *Mycobacterium chimaera* endocarditis, surgical site infection or disseminated infection within 10 years of cardiopulmonary bypass (cardiothoracic surgery, extracorporeal membrane oxygenation or other procedure involving heater cooler units). Risk to patients in England was quantified using denominators derived from NHS Digital Hospital Episode Statistics.

Results: 45 *Mycobacterium chimaera* outbreak cases have been identified to date in the UK. Patients had undergone surgery in 22 cardiac centres, including 2 private facilities. Most (39) had heart valve surgery, the remainder coronary artery bypass or aortic graft surgery. The earliest case underwent surgery in 2007 and the most recent in 2016. Median interval between surgery and microbiological diagnosis was 23 months (<1 month to 68 months) with a decrease from 27 to 12 months from 2007-11 to 2016. Analysis of data from England indicated a crude risk of 0.19 per 1000 patients undergoing heart valve surgery from 2007 to 2018 [1 in 5000]. Assuming a 5y period of risk, incidence peaked in 2014 at 1.48 cases per 10,000 person-years of follow-up, with significant decrease from 2014 to 2018 (RR=0.51, 95% CI 0.31-0.84). To date, just over half (25) of cases have died, with deaths within 1y of diagnosis (n=16) dropping between 2007-11 and 2016.

Conclusions: Whilst cases linked to this global outbreak continue to be diagnosed in the UK, risk estimates suggest a substantial reduction since the implementation of control measures in 2015. With limited effectiveness of treatment, outcomes for patients remain very poor, highlighting the devastating impact of this unique outbreak.

Presenter email address: [REDACTED]