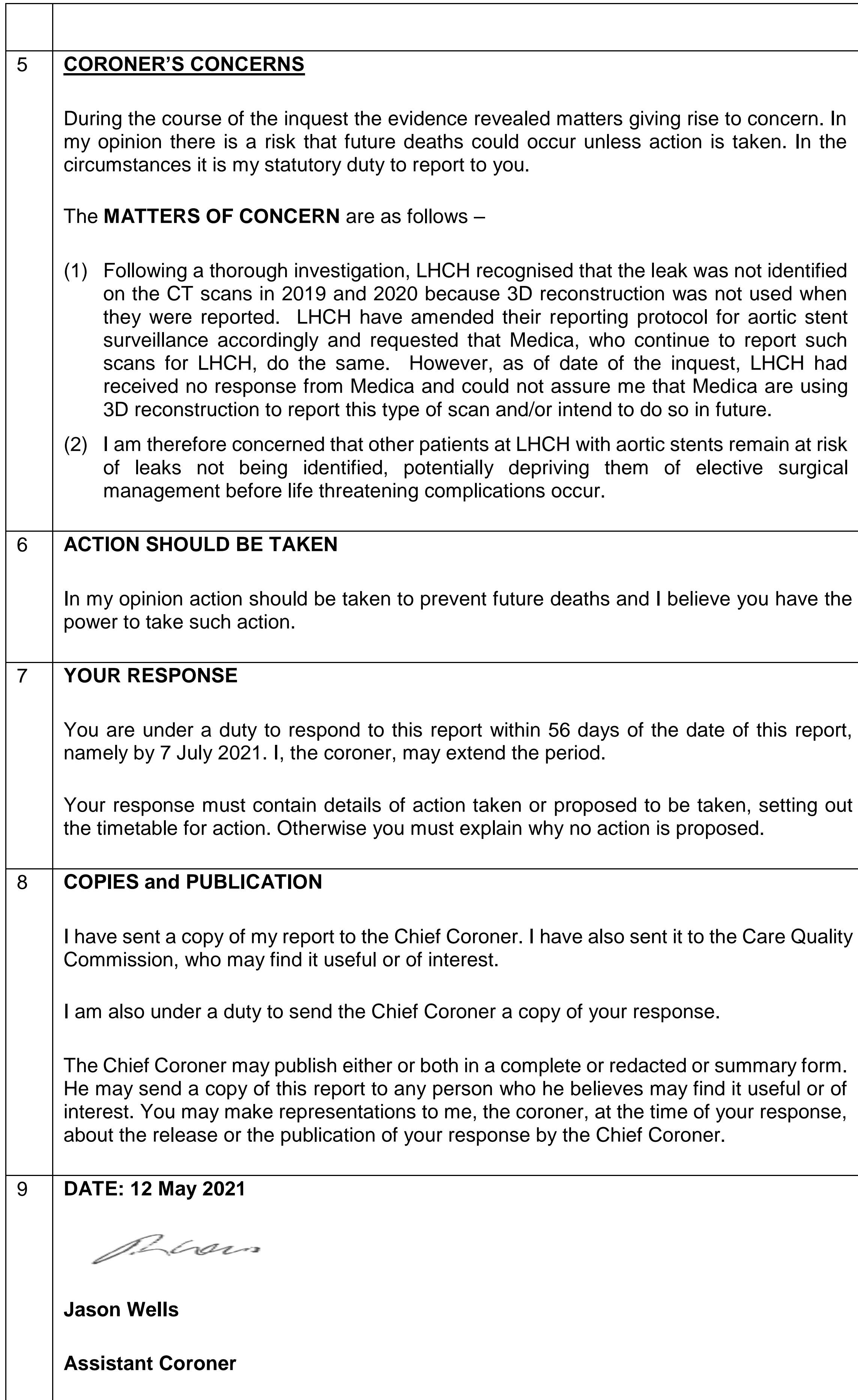
REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **[redacted], Chief Executive, <u>Medica Reporting Limited</u>, 6th Floor, One Priory Square, Hastings. TN34 1EA** **[redacted], Chief Executive, <u>Liverpool Heart and Chest Hospital</u>, Thomas Drive, L14 3PE**
1	**CORONER** I am Jason Wells, assistant coroner, for the coroner area of Manchester South.
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** O 28 September 2020 an investigation was commenced into the death of MARY ANNE MELLOR (dob 25 May 1941). The investigation concluded at the end of the inquest on 4 May 2021. The narrative conclusion of the inquest was: Mary Mellor died on 25 September 2020 at Stepping Hill Hospital from a ruptured thoracic aortic aneurysm caused by a leak from an aortic stent inserted 4 years previously.
4	**CIRCUMSTANCES OF THE DEATH** (1) Mary Mellor (MM) was found to have a mega aorta in 2012, for which she underwent an aortic valve replacement and replacement of the aortic root/ ascending aorta in Manchester. (2) Her disease progressed and in 2016 she underwent staged surgery at Liverpool Heart and Chest Hospital (LHCH) with (i) replacement of the aortic arch and placement of a 'frozen elephant trunk' (FET) stent followed by (ii) thoracic endovascular aortic repair (TEVAR) extension of the FET to seal the stent in the distal aorta. The surgery went well. (3) Thereafter MM underwent annual surveillance with CT scanning. Scans in 2019 (reported by an external agency, Medica) and 2020 (reported at LHCH) were reported as showing 'no leak', but in retrospect both showed a distal leak. 3D reconstruction was not used to report the scans – had it been, the leak would have been identified and further management (elective surgery or conservative measures) could have been discussed/ planned. (4) Whilst the evidence suggested that MM may have declined elective surgery, she was deprived of the opportunity to make an informed decision and of planning for the future. (5) In September 2021 MM became acutely unwell and died of a ruptured thoracic aortic aneurysm, caused by the (unidentified) distal leak from the aortic stent. Emergency surgery would have been associated with significant mortality and morbidity; MM was treated palliatively.



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 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) Following a thorough investigation, LHCH recognised that the leak was not identified on the CT scans in 2019 and 2020 because 3D reconstruction was not used when they were reported. LHCH have amended their reporting protocol for aortic stent surveillance accordingly and requested that Medica, who continue to report such scans for LHCH, do the same. However, as of date of the inquest, LHCH had received no response from Medica and could not assure me that Medica are using 3D reconstruction to report this type of scan and/or intend to do so in future. (2) I am therefore concerned that other patients at LHCH with aortic stents remain at risk of leaks not being identified, potentially depriving them of elective surgical management before life threatening complications occur.
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 7 July 2021. 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. I have also sent it to the Care Quality Commission, 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	**DATE: 12 May 2021** **Jason Wells** **Assistant Coroner**