REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **(1) NHS England and NHS Improvement** **(2) National Institute for Health and Care Excellence (NICE)** **(3) Department of Health and Social Care** **(4) British Cardiovascular Intervention Society**
1	**CORONER** I am, Rachel Galloway, Assistant Coroner for the Coroner Area of Manchester City.
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
3	**INVESTIGATION and INQUEST** On the 2nd July 2019 an investigation was commenced into the death of **Stuart Clarke**, aged 82 years, born on the 15th October 1936. The investigation concluded following the inquest on the 22nd October 2019. The Medical Cause of Death was: 1a Pulmonary Oedema 1b Left Ventricular Dysfunction II Complications of Aortic Valve Procedure, Coronary Artery Disease and Hypertension. The conclusion at the inquest was: Narrative Conclusion: Stuart Clarke died as a consequence of naturally occurring disease, exacerbated by complications arising out of an aortic valve procedure.
4	**CIRCUMSTANCES OF THE DEATH** 1. In February 2018, Stuart Clarke presented at his GP with symptoms of breathlessness. However, it was not until the 25th June 2019 (16 months later) that Mr Clarke finally underwent necessary Transcatheter Aortic Valve Implantation (TAVI) at Wythenshawe Hospital. 2. Evidence was heard from the Consultant Cardiologist at Wythenshawe Hospital, who carried out the TAVI procedure on the 25th June 2019. She confirmed that this overall pathway from onset of symptoms to treatment in Mr Clarke's case was unacceptably long. In the event, Mr Clarke did not recover following the procedure on the 25th June 2019 and his condition declined, leading to his death at Wythenshawe Hospital on the 27th June 2019.

	In evidence, the Consultant Cardiology expressed the view that – had the procedure been carried out in a timelier manner – the outcome *might* have been different for Mr Clarke. She could not say if the outcome would have been different on the balance of probabilities. 3. The Consultant Cardiologist explained that the normal patient journey would involve referral by the GP to the local hospital. In the present case, Mr Clarke was referred to Cardiology at Royal Oldham Hospital. It is then for the local hospital (in this instance, Royal Oldham Hospital) to refer to the tertiary centre (in this case, Wythenshawe Hospital) for specialist assessment. Mr Clarke was not seen at Wythenshawe Hospital until January 2019. It then took a further 5 months for his suitability for TAVI to be confirmed and then for the procedure to take place.
5	**CORONER'S CONCERNS** During 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. During the inquest, evidence was heard that: By the time that Mr Clarke underwent the TAVI procedure on the 25th June 2019 he had deteriorated and was significantly less well than he had been in the months following his initial presentation to his GP in February 2018. During the course of the inquest, I heard that steps are being taken at local level to ensure more timely intervention in similar cases. However, I was concerned that there remain no national guidelines for referral from primary care to secondary care and/or from secondary care to tertiary care for patients with known valve disease.
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 **Monday 6th January 2020**. I, the assistant 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 the following Persons: (1) [redacted] – Wife of Mr Clarke (2) [redacted] – Daughter of Mr Clarke (3) Medical Director - Manchester University NHS Foundation Trust (4) Medical Director – The Pennine Acute Hospitals NHS Foundation Trust (5) MFT Heart and Lung Clinical Standards Group

	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 assistant coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**Dated** 6th November 2019
	Signed:  **Rachel Galloway** HM Assistant Coroner