REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **NHS England** **NHS National Patient Safety Alerting Committee**
1	**CORONER** I am Janine Wolstenholme, Assistant Coroner, for the coroner area of West Yorkshire (Eastern)
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 12 November 2020 an investigation was commenced into the death of Dumile Daniel Thompson, aged 49 years, who died on 31 October 2020. The investigation concluded at the end of the inquest on 5 July 2023. The medical cause of death was 1a) Hypoxic Brain Injury with myoclonic status epilepticus 1b) Ramipril Induced Angiodema II End stage renal failure requiring dialysis, hypertensive heart disease. The conclusion was a narrative conclusion, reflecting the circumstances of the death as set out below.
4	**CIRCUMSTANCES OF THE DEATH** Mr Thompson was a man of African-American origin. He suffered a reaction to recently prescribed Ramipril medication and developed angioedema on 23 October 2020. He attended hospital at around 09.15hr. ACE Inhibitor induced angioedema was confirmed following assessments by the emergency department he was referred to an ENT consultant who commenced treatment with a plan to admit to ITU and set a low threshold for intubation upon deterioration. Following reassessment by an ITU consultant it was determined admission to that unit was not required and admission to a high observation unit was appropriate. ACE Inhibitor angioedema is a rare event and the limited knowledge of its trajectory, including the potential for rapid deterioration in circumstances where Mr Thompson appeared to be improving, offered false reassurance at a number of points in care namely, there was no request for specialist input from immunology, the potential for an alternative medication regime was therefore not considered, there was no clear plan for ongoing monitoring requirements, and he was not admitted to ITU. At approximately 20.20hr he was seen by an A&E doctor because of a report of increased swelling, which was the first report of a deterioration since admission. This should have prompted a request for reassessment by a specialist in airway compromise who would likely have attended promptly and noted the decline in Mr Thompson's condition. Shortly after 20.35hr Mr Thompson suffered a respiratory collapse which caused a catastrophic brain injury and passed away several days later when life support was withdrawn.

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. The evidence, including that of Independent experts in Immunology and Adult Critical Care and Anaesthetics, highlighted that: • National Guidance and training for front line/emergency staff did not, and still does not, include specifics about the various types of angioedema (histamine/bradykinin mediated), the risk factors, and the diverging treatment pathways, including the need for speciality medicine input with certain types of angioedema. • NICE does not currently publish guidance or a clinical knowledge summary on emergency management of angioedema. • Those treating Mr Thompson on 23 October 2020 in the A&E department were therefore not aware of the complexity and fickle nature of ACE Induced angioedema, including the potential speed of deterioration in symptoms, even after what appeared to be initial improvement. • ACE Inhibitor angioedema is more common, up to four to five times more, in individuals of Black African or African Caribbean origin. This increased risk factor is not published in the BNF. • The NICE recommendation about using ARB as the preferred choice of medication in patients of Black African or African Caribbean origin is not highlighted in BNF, notwithstanding the BNF is the go-to source for medication management, contraindications, and cautions. It also came to light that Mr Thompson had transferred geographical areas such that clinicians were unable to access his previous medical records to determine why ARB's, an alternative to ACE Inhibitors, had been preferred by clinicians on a previous occasion. His now treating clinicians were unable to access this information because such records are not readily available to, or shared with, clinicians in a different area/Trust. The reason for this is not entirely clear and was thought to be related to data protection though there is nothing to suggest Mr Thompson withheld his consent, or would have done so.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and 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 Thursday 28 September 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 • Mr Thompson's wife • Leeds Teaching Hospitals NHS Trust • Medicines and Healthcare Products Regulatory Agency • Royal College of Emergency Medicine 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	**2nd August 2023** **Janine Wolstenholme** **Assistant Coroner**