REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1.** The Right Honourable Matt Hancock MP, Secretary of State for Health, Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU **2.** [redacted], President, The Renal Association, 3rd Floor, Learning and Research Building, Southmead Hospital, Southmead Road, Bristol BS10 5NB **3.** [redacted], President, British Renal Society, EBS Ltd., City Wharf, Davidson Road, Lichfield, Staffordshire WS14 9DZ **4.** [redacted], President, Intensive Care Society, Churchhill House, 35 Red Lion Square, London WC1R 4SG **5.** Sir David Dalton, The Chief Executive, Salford Royal NHS Foundation Trust, Stott Lane, Salford M6 8HD
1	**CORONER** I am Alan P Walsh, Area Coroner for the Coroner Area of Manchester West.
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 22nd March 2018 I commenced an Investigation into the death of John Waite, 74 years, born on the 21st November 1943. The Investigation concluded at the end of the Inquest on the 10th September 2018. The medical cause of death was: - Ia Haemorrhage from removal of Femoral Dialysis Line, Pneumonia and Acute Kidney Injury due to Rhabdomyolysis. II Ischaemic Heart Disease, Hypertensive Heart Disease and Prophylactic Anti-Coagulation. The conclusion of the Inquest was that John Waite died as a consequence of

	a combination of Pneumonia and Acute Kidney Injury, due to Rhabdomyolysis arising from a long period of time on the floor following an accidental fall, and a Haemorrhage due to a rare but recognised complication of the removal of a Femoral Dialysis Line inserted for the treatment of the Acute Kidney Injury exacerbated by a recognised complication of Prophylactic Anti-Coagulation treatment on a background of naturally occurring disease.
4	**CIRCUMSTANCES OF THE DEATH** 1. John Waite (hereinafter referred to as "the Deceased") died at the Salford Royal Hospital, Eccles Old Road, Salford on the 11th March 2018. 2. On the 25th February 2018 the Deceased, who suffered with naturally occurring Ischaemic Heart Disease and Hypertensive Heart Disease, had a fall in the bedroom at his home address at [redacted], [redacted]. He lay on the bedroom floor for a considerable period of time following the fall before his family found him. He was taken to the Royal Albert Edward Infirmary, Wigan, where he was treated for Rhabdomyolysis with hemofiltration and for Pneumonia with antibiotics. 3. The Deceased required ongoing renal replacement therapy and, on the 6th March 2018, he was transferred to the Salford Royal Hospital, Salford for such therapy. 4. On the 7th March 2018 a right femoral vein dialysis line was inserted as a central venous catheter for haemodialysis treatment and during his time in hospital the Deceased received prophylactic anticoagulation treatment. 5. On the 11th March 2018, the central venous catheter was removed, in accordance with hospital protocols, to prevent infection. At the time the Deceased was the sole occupant of a side room on H3 Ward at the Salford Royal Hospital and the central venous catheter was removed by a Nurse Practitioner in the side room at an uncertain time between 12 noon and 13:00 hours. Following the removal of the central venous catheter, the Nurse Practitioner applied pressure to the site of the catheter for a period of 15 minutes and she sat the Deceased up to a 40-degree angle to enable him to have something to eat. The Nurse Practitioner assisted the Deceased for a few minutes whilst she cut a sandwich for him and to check if he could manage. She left him on his own in the side room whilst he started to eat the sandwich and she left a buzzer next to his left hand. The Nurse Practitioner closed the door behind her when she left the room, as the Deceased was being barrier nursed for infection and the infection control policy required the door to remain closed at all times for infection precautions. The Nurse Practitioner left the side room at approximately 13:10 hours and the Deceased was left on his own in the room at that time. 6. At or about 13:40 hours a Physiotherapist entered the side room for the

purpose of a new patient mobility assessment and when she entered the room she noticed large amounts of blood on the floor covering halfway down the length of the right side of the bed, being the side where the central venous catheter had been removed, and spreading across the floor approximately half a metre out from the side of the bed. The blood had also spread through a sheet and a blanket on the bed in the area where the central venous catheter had been removed. She noticed that the patient was sat up in bed at the time and she completed an emergency crash call on the basis that the Deceased had suffered a cardiac arrest.

The Physiotherapist made a note of the incident in the electronic hospital notes. The author time of the note was recorded as 13:40 hours and the update of the note was recorded as completed at 14:36 hours. The Physiotherapist admitted that she had changed the author time on the electronic system and she confirmed that the electronic system allowed for such a change to take place. She gave evidence that she changed the author time of the note to accord with the time she entered the side room, instead of the time that she authored or made the note.

7. When the cardiac arrest call was made, the cardio arrest procedure commenced immediately but resuscitation was not successful and the Deceased died at 14:08 hours on the 11th March 2018.

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.

The **MATTERS OF CONCERN** are as follows:

1. During the Inquest evidence was heard that: -

   i. A haemorrhage following the removal of a central venous catheter is a rare, but known, complication of the removal of a central venous catheter and the complication has never been seen by many experienced Renal Physicians, including the 3 Renal Physicians giving evidence at the Inquest.

   ii. The Central Venous Catheter Insertion Management and Removal Policy for Short Term Catheters in existence within the Salford Royal NHS Foundation Trust at the time of the death included the fact that pressure should be applied for approximately 5 minutes after removal of the catheter or until bleeding has stopped and a patient should lie flat or supine for 30 minutes after removal of the catheter (if medically safe to do so). The guidelines did not state that a patient requires visual observation for a period of time following the removal of the catheter.

   iii. Following the death of the Deceased the Salford Royal NHS

Foundation Trust has taken action to address the concerns in relation to the Central Venous Catheter Insertion Management and Removal Policy for Short Term Catheters, together with the ongoing training of staff who undertake the removal of catheters and the management of rare complications.

A quick reference guide has been issued to staff by the Hospital in relation to the removal of catheters at the Hospital. The guide requires the patient to remain supine for 30 minutes post removal of the catheter with further bed rest for 2 hours post removal and a visual inspection of the dressing every 5 minutes during the period of 1 hour following the removal. However, the guide does not require constant visual observation for a period of time following the removal of the catheter.

The evidence at the Inquest was that, if there is haemorrhage following the removal of a catheter, blood loss could amount to 200mls every minute so that in the period of 5 minutes between each 5-minute inspection of the dressing, advised by the guidance, one litre of blood could be lost, which could lead to death.

The evidence at the Inquest was that a period of constant visual observation is required for a period of up to one hour following the removal of a catheter to reduce the risk of blood loss rather than simply monitoring by inspecting the dressing every 5 minutes for that period of time.

iv. There are no national guidelines in relation to the removal of central venous catheters, particularly temporary central venous catheters for haemodialysis. The evidence at the Inquest confirmed that the Secretary of State, the Renal Association, the British Renal Society and the Intensive Care Society would be appropriate organisations to consider the issue of a national policy, protocol and guidance relating to the removal of central venous catheters.

v. The evidence of the Physiotherapist in relation to changing the author times of notes on the central computer note system at the Salford Royal NHS Foundation Trust was not believed to be possible by representatives of the Hospital Trust attending the Inquest but the Physiotherapist was adamant, in her evidence, that she changed the times, which was her usual procedure, so that the author time recorded by her represented the time of the action taken by her rather than the time of the note made by her.

2. I request the Secretary of State for Health, the Renal Association, the British Renal Society and the Intensive Care Society to review the policies and protocols in relation to the removal of central venous catheters and to consider the issue of national guidelines relating to the removal of catheters. The review should consider the constant visual observation of a patient for a period of one hour following the removal of the catheter, particularly in view of the extent of blood loss which

	may arise if a patient is left on their own for periods of 5 minutes following the removal of the catheter. 3. I request the Salford Royal NHS Foundation Trust to further review the policy and protocols together with the quick reference guide to consider the constant visual observation of a patient for a period of one hour following the removal of a central venous catheter to prevent extensive blood loss and to prevent future deaths. I acknowledge that a considerable amount of work has been done by the Salford NHS Foundation Trust, but I request a further review to cover the above matters of concern. 4. I request the Salford Royal Hospital to review their information technology systems to prevent the changing of author times of notes on the electronic system because the author times can represent an important time in relation to the treatment and care given to a patient and may be relied upon by healthcare professionals who give treatment and care after the time of a note. The review should also consider whether both the time of the author of the report and the time that appropriate action is taken should be included in the note so that healthcare professionals would have to record both times when completing notes to ensure that there is unequivocal clarity as to the time the action was taken and the time the note was authored.

6	**ACTION SHOULD BE TAKEN** In my opinion urgent action should be taken to prevent future deaths and I believe that 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 Wednesday 21st November 2018. 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 and to the following Interested Persons: - 1. [redacted] Mr Waite's daughter, 4[redacted] 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	**Dated** **26th September 2018**	**Signed** **Alan P Walsh** **HM Area Coroner**