REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Health Education England** **2. Joint Royal Colleges Ambulance Liaison Committee** **3. British Renal Society** **4. Renal Association** **5. The Vascular Access Society of Britain & Ireland**
1	**CORONER** I am Mr Hassan Shah, Assistant Coroner, for the coroner area of Northamptonshire.
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 7 July 2015 I commenced an investigation into the death of Pamela Keech, aged 82 years. The investigation concluded at the end of the inquest on 9 June 2017. The conclusion of the inquest was as follows: Pamela Keech was declared dead at 07.03 hours on Tuesday 7 July 2015 at Elm Bank Care Home, Northampton Road, Kettering. She died as a result of a catastrophic bleed from her haemodialysis graft site, a rare but recognised complication of this life saving treatment.
4	**CIRCUMSTANCES OF THE DEATH** Pamela Keech was diagnosed with end stage renal failure in 2005. She required haemodialysis as life-saving treatment. The gold standard for delivery of haemodialysis is via an arterio-venous fistula, which is typically formed in the patient's arm. However, assessments showed that Mrs Keech's vasculature would not support such a fistula, an upper limb fistula having previously failed in 2009. Various alternatives were utilised to administer haemodialysis until a femoro-femoral graft was formed in Mrs Keech's leg in 2011. In 2014, Mrs Keech was prescribed the anti-coagulant Warfarin. In January 2015, Mrs Keech underwent a thrombectomy and a jump graft was fitted. On 26th June 2015, Albumin level was low, an indicator of poor prognosis in haemodialysis patients. On Saturday 4th July 2015, Mrs Keech underwent dialysis. Both needle sites were red and leaking fluid; there was a slight bleed at the end; her leg was swollen (not unusual for Mrs Keech); she had a low Albumin level; there was no clear sign of infection (although results that became available on 8th July 2015 confirmed that she was MRSA positive at the access site). On Sunday 5 July 2015, Mrs Keech was conveyed to hospital by ambulance as she was bleeding from her leg in the location of her graft site and was reportedly "covered in

	blood". She was seen in the Accident and Emergency Department where the treating doctor incorrectly believed the bleed was as a result of an operation Mrs Keech had undergone some months previously to treat a fractured neck of femur. There was an open puncture wound on the anterior surface of the thigh which had a trickling bleed during 5 minutes of examination. However, when Mrs Keech's daughter arrived, she explained the bleed had originated from Mrs Keech's graft site and that bleeding following dialysis was not unusual for Mrs Keech. This reassured the doctor, who discharged Mrs Keech given that all of her observations were within normal parameters, save slightly raised CRP (a non-specific marker of inflammation). That first bleed stopped and was not catastrophic. The doctor accepted with the benefit of hindsight that Mrs Keech should have been referred for renal/surgical review, however, this was not known in the department at that time. On the evening of 5 July 2015 Mrs Keech's care home contacted the ambulance service as they had noted a further bleed from Mrs Keech's leg. Mrs Keech was reviewed by an Emergency Care Practitioner who found her to be calm, conscious, alert, breathing, capillary refill less than 2 seconds, normal colour with a history of bleeding. Blood pressure was 170/88, slightly high but within an acceptable range. Temperature was 37.1, slightly raised but not of concern. The Emergency Care Practitioner noted a wound of 1cm on Mrs Keech's leg but it was not clear as to where the wound was. In all likelihood it would have been from the graft access site but the evidence was not clear. The Emergency Care Practitioner knew Mrs Keech had been discharged earlier with a fistula haemorrhage. Observations were normal and the bleeding had stopped, with only a small amount of blood loss. The Emergency Care Practitioner decided that treatment was not required at hospital so provided a bandage and left advice that if a further bleed occurred again then 999 should be contacted. This was a second bleed and was not catastrophic. On Monday 6 July 11.30am Mrs Keech was attended to by an Occupational Therapist at the care home. She noted that the bandage had dry blood on it but it was not clear where the blood had come from. Observations were within the normal range. This was a third mini bleed from the leg and did not prove fatal. At 6.15am on 7 July 2015 Mrs Keech was found unconscious in her bed with a large amount of blood loss from her leg. Mrs Keech was declared deceased at 7.03am. A post mortem examination found that she had died as a result of a catastrophic haemorrhage from the graft site in her leg.
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. – (1) I heard evidence that there is no National Guidance on how to predict and manage a fatal graft/fistula haemorrhage (2) I heard evidence that the risk of developing a fatal haemorrhage from a fistula/graft site is not part of the training requirement for A&E doctors/paramedic carers (3) I am concerned that other patients presenting with bleeds from fistula/graft sites might not be escalated for renal/surgical review before a fatal bleed presents.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisations have the power to take such action as you are responsible for setting the health education requirements for medical professionals and/or disseminating best practice for Renal patients.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 23rd September 2017. 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. Browne Jacobson LLP** **2. Kennedys Law** **3. Wilson Browne** **4. Radcliffes Le Brasseur** 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	**28th July 2017** **Signed -** *Hassan Shah*