REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **Mr Peter Herring, Chief Executive, Sherwood Forest Hospitals NHS Foundation Trust**
1	**CORONER** I am (Mrs) Heidi Connor, assistant coroner for the coroner area of Nottinghamshire.
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 18 July 2016 I commenced an investigation into the death of Sheila Stokes, aged 83. The investigation concluded at the end of the inquest on 21 November 2016. The medical cause of death was : 1a Retroperitoneal haemorrhage 1b Ruptured abdominal aortic aneurysm I recorded a narrative conclusion as follows : Sheila Stokes was diagnosed with a large abdominal aortic aneurysm by ultrasound. Vascular surgeons knew about this on 16 July 2015. There was delay in arranging appointments, CT scanning, discussion at MDT meeting, and in sending key information to the manufacturers of a proposed custom-made graft. These delays contributed directly to her death at home on 26 January 2016, following rupture of her aneurysm. If a finalised plan for her graft had been agreed with the manufacturer any time up to 2 November 2015, then she is likely to have undergone life-saving surgery.
4	**CIRCUMSTANCES OF THE DEATH** Mrs Stokes was referred to vascular surgeons at Kings Mill Hospital with a clear diagnosis of a 7.3 cm abdominal aortic aneurysm on 16 July 2015. She was given an urgent appointment to see a vascular surgeon. The appointment was on 27 July 2015. She did not attend, but the family have said that no appointment letter was sent. The trust could not show evidence that it was sent. No letter was sent to the patient or GP following the non-attendance in July 2015. She was given a further appointment on 14 September. It was accepted by the witness, [redacted] (consultant vascular surgeon) that when Mrs Stokes saw his colleague, [redacted] on 14 September, that a CT was requested urgently because Mrs Stokes was a smoker, she had hypertension and the aneurysm was large. He told us that 15% of aneurysms rupture per annum. This view was reached even before a CT was performed. There were clearly risk factors present for rupture of this aneurysm from the start. The CT scan was carried out on 22 September. A RAD alert appears to have been sent by the radiologists, but there was no evidence that this was received or acted upon by the vascular surgery team.

We heard that the radiology report was available on 28 September. All aneurysms are discussed at MDT meetings at QMC. Mrs Stokes' scan findings were discussed at an MDT meeting on 16 October 2015. It was noted that this was a complex aneurysm, and it was decided that Mrs Stokes would need a custom-made graft. The plan was that this would be made by Cook (UK) Ltd.

I find the following to be the key dates in this matter :

16 July 2015	Referral received by vascular surgeons. Large aneurysm had been seen on ultrasound – for urgent appt.
27 July	Pt did not attend. No evidence that appointment letter was sent, or of chaser letter to patient or GP thereafter.
14 September	Patient attended – for urgent CT.
22 September	CT ; RAD alert sent by radiologist. No evidence of this being received or acted upon.
28 September	CT report available
16 October	Case discussed at MDT. For custom-made graft.
20 October	[redacted] telephoned Cook to notify them of this patient.
27 November	Cook representative attended QMC (after a further MDT meeting) and waited while CDs of the scans were produced so that they could start to consider the graft.
3 December	Cook sent a preliminary plan to [redacted]
30 December	Family raised concerns about delay. An email was sent from [redacted] to [redacted] , stating "now she is becoming symptomatic and due to caring for her elderly husband (which includes picking him up when he tumbles to the floor), this lady is convinced that she is putting her 7.6cm [sic] aneurysm under strain".
30 December	Chaser email from Cook to [redacted]
2 January 2016	10.41 [redacted] forwarded the email from [redacted] (30 Dec) to [redacted] (amongst others). 12.11 [redacted] emailed Cook to ask them to proceed with the graft
8 January	Cook produced final plan
11 January	[redacted] signed off the final plan
26 January	Mrs Stokes died.

11 January 2016 was the date on which Cook was effectively given the 'green light' to produce the graft. There was some some initial confusion about how the scans would be sent to Cook, resulting in a delay of 5 weeks between initial contact and the scans being received by Cook.

I note with some concern the wording of letters and emails sent around the time of these events. [redacted] email of 2 January 2016 (referred to above) states :

"I have spoken to [Mrs Stokes] and explained that her graft needs to be tailor made for her aneurysm and that's the delay."

By that date, her large aneurysm had been diagnosed 5 and a half months earlier, and a decision had been made (at the MDT) that a custom-made graft would be needed 2 and a half months earlier. No response had been given to Cook's first proposed plan for the graft, sent a month earlier.

No mention has been made of delay by the trust, even after Mrs Stokes' death – in morbidity and mortality meeting minutes, or in statements and documents produced for this investigation. The tenor of [redacted] statements clearly cites manufacturer delay

	as the central issue. On its kindest interpretation, there has been a complete failure to recognise key areas of delay and administrative errors. On a less kind interpretation, there has been an attempt to disguise the real reasons for this delay. This concerns me greatly, taking into account the trust's duty of candour and the responsibility of clinicians to assist coroners in their enquiries. Applying the longest time estimates suggested in evidence, ie 8 weeks to manufacture the graft and a further 4 weeks to arrange the surgery, I have calculated that, if Cook had been given the 'green light' to manufacture the graft at any time up to 2 November 2015, then Mrs Stokes would, on the balance of probabilities, have undergone surgery and survived. In reaching my conclusions, I have taken account of the fact that the aneurysm was a complex one, and that not every aneurysm is immediately life-threatening / requires emergency surgery. There were however clear risk factors in Mrs Stokes' case which made delay more significant. The extent of delay by the hospital in this case is stark, and it is clear that this has played a clear and direct part in Mrs Stokes' death. I find that there was no delay on the part of Cook in these matters. It would appear that they were proactive both in planning and in chasing for and obtaining the scans they needed to plan the graft.
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. There has been delay at almost every stage of these events. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – 1. Review of administrative systems for contacting and following up patients who DNA appointments – with such correspondence to becopied to their GPs. 2. System for ensuring RAD alerts are received and acted on timeously. 3. Vascular surgeons based at both KMH and NUH should consider having a clear agreed protocol for obtaining custom-made grafts – to include such matters as : a. A clear pathway for contacting and sending scan results to manufacturers. b. Limited no of consultants dealing with these cases. c. Clear timetable between first contact with manufacturer and final sign off – with responsibility of a named consultant to ensure there is no delay. d. Advising and updating patients on these timescales. 4. Adequacy of the trust's investigation of these events – in particular the morbidity and mortality meeting discussion, which was incomplete, and does not refer to delay by the trust at all. 5. Nature and content of the witness statements provided to the coroner, which again refer only to delay by the manufacturer, which is clearly not the central issue in this case.
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 3 February 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. Family of Mrs Stokes 2. [redacted], Medical Director, KMH 3. NUH vascular surgery team 4. Head of legal services at KMH and NUH 5. Cook (UK) Ltd, via their legal representative. I am also under a duty to send the Chief Coroner a copy of your response. For the avoidance of doubt, only Mr Herring is required to respond to this report. 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	**9 December 2016**