Regulation 28: Prevention of Future Deaths report

Norman Joseph Pirie (died 5.10.2018)

	THIS REPORT IS BEING SENT TO: **Dr Alastair Chesser** **Chief Medical Officer** **Barts Health** **Royal London Hospital** **Whitechapel Road** **London E1 1BB**
1	**CORONER** I am: Edwin Buckett Assistant Coroner Inner North London Poplar Coroner's Court 127 Poplar High Street London E14 0AE
2	**CORONER'S LEGAL POWERS** I make this report under the Coroners and Justice Act 2009, paragraph 7, Schedule 5, and The Coroners (Investigations) Regulations 2013, regulations 28 and 29.
3	**INVESTIGATION and INQUEST** On 12th October 2018 Senior Coroner Hassell began an investigation into the death of Norman Joseph Pirie who died aged 90 on the 5th October, 2018 at the Royal London Hospital. The investigation concluded at the end of the inquest on 17th January 2019 conducted by myself, Assistant Coroner Edwin Buckett. I made a determination at inquest that the deceased died as a result of a major haemorrhage (causing a cardiac arrest) which in turn was caused as a result of an operation which took place on the 4th October, 2018 at the Royal London Hospital.
4	**CIRCUMSTANCES OF THE DEATH**

	The deceased had an abdominal aortic aneurysm which was previously repaired with a stent graft in 2011. At CT scan carried out on the 20th June, 2018 revealed a leak around the stent and a decision was made to offer the deceased an elective procedure to extend the seal zone, with a cuff and to anchor the stent. On 4.10.2018, the deceased underwent this procedure at the Royal London Hospital under general anaesthetic. During the course of the procedure, a device known as an RX1-28-43 Zenith Renu AAA Ancillary Graft Main Body Extension ("the cuff device") manufactured by Cook Medical of Bloomington, Indiana, USA was used. The black trigger wire relating to the device was released successfully. However attempts to deploy the super renal stent part of the device, by advancing the top cap inner cannula, were not successful. This meant that the super renal stent did not deploy properly. It would also appear that somehow the white trigger wire mechanism was partially released prematurely. The effect of this was to cause the whole device to remain adrift, in the body, with no prospect of pulling it out, the way it had gone in. The only option open to the surgical team was to proceed to open surgery to remove all parts of the device as a matter of urgency. During the course of the open surgery which then followed, a major haemorrhage occurred as a consequence of removing the device. This led to a subsequent cardiac arrest post operation and death at about 3am on the 5.10.2018. The cuff device was being used outside of the Instructions For Use ("IFU") provided by the manufacturer, in that there was a 68-degree angulation of the infra-renal neck in the way it had been used, whereas the instructions permit a maximum of 60-degrees. The effect of this, is to make it more difficult for the super renal stent to deploy properly.

	The device was found to be in proper working order when examined by the manufacturer after the operation and there is no evidence of a defect in the device. Norman died as a result of the consequences of the open surgery carried out on the 4.10.2018 the requirement for which was caused by the failure of the cuff device during the procedure.
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. Evidence was given by medical staff at the Royal London Hospital that: 1. The original procedure on the 4.10.2018 an elective procedure; 2. The cuff device was used at a 68-degree angle and this was known to be outside the IFU of the manufacturer which permitted an angle of up to 60-degrees as a maximum; 3. That it was normal procedure on occasions to exceed the permitted maximum stated by the IFU for such devices; 4. Using the cuff device in that manner was taking a calculated risk although this was not an emergency life-saving operation; 5. If a cuff device failed to deploy during the procedure or was deployed prematurely the only option is to proceed to open surgery which carries with it a high risk of mortality, in excess of 50%. 6. The manufacturer Cook Medical had been contacted by the hospital after the event. Cook Medical had inspected the device used at the time of the deceased's procedure and found it to be in satisfactory working order. I am concerned that: (a) Cuff devices are being used in non-emergency procedures in a way that is contrary to the IFU limits set down by the manufacturers of those devices; and

	(b) In such circumstances, this increases the risk that the devices do not deploy as expected, as a result of which remedial open surgery has to be urgently performed which carries with it a high risk of death.
6	**ACTION SHOULD BE TAKEN** In my opinion, action should be taken to prevent future deaths and I believe that you and/or 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 **19th March 2019**. 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 following. • HHJ Mark Lucraft QC, the Chief Coroner of England & Wales • [redacted], on behalf of the family of Norman Pirie 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	**DATE 18.1.2019 SIGNED BY ASSISTANT CORONER EDWIN BUCKETT**