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.** Chief Executive, Wrightington, Wigan & Leigh NHS Trust, Wigan Lane, Wigan **2.** Chief Executive, Eschmann SISK Group, Eschmann Equipment, Peter Road, Lancing, West Sussex **3.** Chief Executive, Medicines and Healthcare Products Regulatory Agency, Adverse Incident Centre, 151 Buckingham Palace Road, Victoria, London
	CORONER I am Alan Peter 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 11th April 2013 I commenced an investigation into the death of Kenneth Smalley, 67 years. The investigation concluded at the end of the inquest on 5th December 2013. The medical cause of death was 1a) Sepsis and Traumatic Laceration of Spleen, 1b) Explantation of Aortic Graft and Aortoduodenal Fistula Repair, 1c) Abdominal Aortic Aneurysm, 2) Ischaemic Heart Disease. The conclusion of the Inquest was Kenneth Smalley died as a consequence of a combination of sepsis arising from an infected aortic graft and an aortoduodenal fistula and a laceration of the spleen, being a recognised complication of abdominal surgery on a background of naturally occurring disease.
4	**CIRCUMSTANCES OF THE DEATH** 1) Kenneth Smalley died at the Royal Albert Edward Infirmary, Wigan on the 28th March 2013. 2) The deceased was known to suffer from naturally occurring Ischaemic Heart Disease prior to his death. 3) In 1997 the deceased had an Aortic Graft to repair an Abdominal Aortic Aneurysm. 4) On the 2nd March 2012 the deceased had an Appendectomy to treat Acute Gangrenous Appendicitis. 5) On the 26th March 2013 the deceased was admitted to the Royal Albert Edward Infirmary, Wigan with back pain and right loin pain and a CT

scan identified a large Aortic Aneurysm and an Aortoduodenal Fistula with clinical evidence of an infection relating to the Aortic Graft.

6) On the 27th March 2013 the deceased had surgery to explant the Aortic Graft and repair the Aortoduodenal Fistula. The surgery was conducted in Operating Theatre 6 at the Royal Albert Edward Infirmary, Wigan by Mr [redacted] Consultant General and Vascular Surgeon and the surgery was commenced at 0915hours. The surgery was completed at 1752hours and the deceased was transferred to the Intensive Care Unit at the hospital at around 1800hours.
7) The surgery was conducted on an operating table with a handheld control unit (handset) both manufactured by the Eschmann Group. The handset is used for adjusting the operating table during the course of surgery and the handset has a bracket to enable it to be hooked onto the side of the operating table during surgery.
8) During the course of the surgery, at or about 12noon, the Surgeon requested the adjustment of the operating table for the height to be lifted to assist the next phase of the surgery. The Anaesthetic Practitioner on duty for the surgery picked up the headset, which she found on the floor of the Operating Theatre and she pressed the button to lift the operating table but there was no movement of the table. She released the button and asked other members of the Theatre team whether they could operate the handset. Suddenly, without any buttons being pressed on the handset, the operating table started to move, tilting the table into a steep head down position, referred to as the Trendelenburg position. The emergency stop button on the handset was pressed but without effect and the table continued to move until it stopped in the Trendelenburg position. The deceased was held in place by members of the surgical team including the Surgeon and the Anaesthetist to prevent him falling from the table and the deceased did not fall from the table or move from his previous position on the table during the malfunction of the table. Despite several attempts to straighten the table it was not possible to do so and the deceased was moved to a replacement operating table, which was brought from an adjacent operating theatre, for the surgery to continue. When the deceased was moved to the replacement table the surgery was recommenced and there was no change in his vital observations as a consequence of the malfunction of the operating table.
9) Following the malfunction of the operating table there was no evidence of bleeding, particularly from the spleen, until approximately 4 hours later when, during the latter part of the surgery, the Surgeon became aware of some bleeding around the spleen. The Surgeon identified multiple small lacerations on the surface of the spleen which the Surgeon concluded was a result of traction and/or retraction during surgery. In order to try and save the spleen the Surgeon packed the area with Vicryl mesh and Surgesel in an attempt to control the bleeding. Prior to concluding the surgical procedure, the Surgeon washed the deceased's abdomen with Saline and on review of the spleen noted that the bleeding had stopped.
10) At 2030hours on the 27th March 2013 the deceased was examined by Mr [redacted] the Surgical Consultant on call after he was found to by tachycardic, hypotensive and acidotic with a drop in his Haemoglobin level. A Laparotomy was carried out at 2045hours on the same day

	when 1.5 litres of blood and a clot was noted inside the abdominal cavity with active bleeding from the spleen. The spleen was removed by a Splenectomy, the bleeding was controlled and drains were inserted. The deceased was transferred to the Intensive Care Unit but he continued to deteriorate, in spite of maximum inotropic support and fluid management, and he died.
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) During the inquest evidence was heard that i) The damage to the spleen was unlikely to have been due to the malfunctioning of the operating table. ii) During the surgery the operating table moved uncontrollably without operation of the handset until it stopped in the Trendelenburg position. iii) The handset was last serviced by the Eschmann Group on the 14th December 2012 when no defects were identified but after that date the handset had been opened at some point. The handset is not a serviceable item and the handsets are replaced as sealed units only and are not repairable. The opening of the handset can compromise the seal that protects the circuit board and the button contacts from fluid ingress. There was evidence of tarnish on the handset Trendelenburg button electrical contacts within the handset indicating possible moisture ingress at this point. iv) The handset had been left on the floor of the Operating Theatre and not in the correct position on the side of the operating table. The bracket to attach the handset to the side of the operating table was missing at the time of inspection after the incident. v) The handset emergency stop button should stop the movement of the operating table at all times but on this occasion the emergency stop button did not cause the operating table to stop. The Eschmann Group confirmed that the emergency stop button is not isolated from the circuit board within the handset nor within the handset itself to ensure that it operates separately from other functions within the headset. vi) Over the last 5 years the Eschmann Group has recorded 6 other incidents of unrequested powered table movement in relation to operating tables with 4 incidents where no fault was found and the issue could not be replicated. One incident was traced to handset damage and one incident traced to possible fluid ingress into a circuit board. In the case of the incident relating to the deceased no explanation could be given for the malfunction of the operating table other than possible fluid ingress but there was no evidence of fluid on the floor of the Operating Theatre at

the time of surgery and the table had functioned without incident in relation to surgical procedures on previous days.

vii) The Royal Albert Edward Infirmary has similar operating tables with similar handsets in the Hospital but no review has been carried out by the Hospital in relation to those operating tables and handsets, particularly as to whether the handsets have been opened with damage to the seals.

viii) Whilst pre-operation checks of equipment are conducted by Surgical and Theatre teams at the Hospital prior to each surgical procedure, the checks do not appear to cover the position of the handsets or whether the handsets had previously been opened or subjected to tamper. Training and Auditing are required in relation to such matters.

ix) The incident was reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) who conducted an investigation but the conclusions of the investigation and any guidance has not been shared with the Wrightington, Wigan & Leigh NHS Foundation Trust. There appeared to be very little, if any, contact between the MHRA, the Eschmann Group and the Wrightington, Wigan & Leigh NHS Foundation Trust to enable the sharing of information for lessons to be learned and actions to be taken.

(2) I have concerns with regard to the Wrightington, Wigan & Leigh NHS Foundation Trust in relation to

i) The function of operating tables and handsets particularly the review of all operating tables and handsets used at the Hospital following the incident on the 27th March 2013.

ii) Pre-operation checks of equipment particularly the function of handsets attached to operating tables with particular attention to the general condition of the handsets, the seals, and the position of the handsets at the side of the operating table to avoid the handsets being placed on the floor of the Operating Theatre to reduce the risk of fluid ingress.

iii) The procedures relating to inspection of operating tables and handsets used at the Hospital particularly to identify any damage to the handsets to ensure the immediate replacements of any damaged handsets.

iv) The training of staff in relation to pre-operative checks of equipment in the operating theatres at the Hospital with emphasis on operating tables and handsets including the correct positioning of the handsets with effective auditing of such inspections.

(3) I have concerns with regard to the Eschmann Group in relation to a review of the operation of handsets attached to operating tables in view of the number of unexplained and uncontrolled movements of operating tables with particular reference to the isolation of the emergency stop button on the handsets to ensure that the emergency stop button operates in all circumstances whether there is damage to other parts of the handset.

(4) I have concerns with regard to the Medicines and Healthcare Products Regulatory Agency in relation to contact with all interested Agencies following an investigation to ensure the sharing of information with all interested Agencies particularly to enable lessons to be learned and

	corrective action to be taken as soon as possible.	
	ACTION SHOULD BE TAKEN In my opinion urgent action should be taken to prevent future deaths and I believe 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 13th February 2014. 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 [redacted] The son of Kenneth Smalley. 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** **19th December 2013**	**Signed** **Alan P Walsh**