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 Honorable Mr Jeremy Hunt MP, Secretary of State for Health Richmond House, 78 Whitehall, London, SW1A 2NS
1	**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 27th December 2012 I commenced an investigation into the death of Katie Louise Davies, 21 years, born on 9th October 1991. The investigation concluded at the end of the inquest on 22nd May 2014. The medical cause of death was 1a Massive Cerebral Venous Sinus Thrombosis. The conclusion of the inquest was Katie Louise Davies died as a consequence of Cerebral Venous Thrombosis arising from a combination of naturally occurring inflammatory bowel disease and the use of oral contraception.
4	**CIRCUMSTANCES OF THE DEATH** 1. Katie Louise Davies died at the Royal Albert Infirmary, Wigan on the 26th December 2012. 2. Katie was using oral contraception and in the summer of 2012 she was diagnosed as suffering from Crohn's Disease, which is an inflammatory bowel disease. She was prescribed Humira by injection for the treatment of Crohn's Disease. 3. On the 22nd December 2012 the deceased started to feel unwell whilst shopping at the Trafford Centre, Manchester and, later the same day, she attended at the Accident and Emergency Department at the Royal Albert Edward Infirmary, Wigan with a history of severe headache and vomiting. She had a CT scan which revealed a Cerebral Venous Sinus Thrombosis and the diagnosis was confirmed by a CT venogram on the following day.

When the CT venogram confirmed the diagnosis the deceased was referred to the Regional Centre for Medical Neurosciences at Salford Royal Hospital, Salford for advice in relation to treatment of the Cerebral Venous Sinus Thrombosis and further advice as to whether the deceased should be transferred to the Regional Centre at Salford Royal Hospital for treatment

4. The Neurology Registrar at Salford Royal Hospital supported by the Consultant Neurologist on call, advised treatment with low molecular weight Heparin and Warfarin, as anticoagulant treatment, with regular neurological examinations including fundoscopy and visual fields.

   The advice was that the deceased should be treated at the District General Hospital namely the Royal Albert Edward Infirmary in Wigan and the Regional Unit at Salford Royal Hospital should be contacted for further advice if needed. The purpose of regular neurological examinations was to observe the patient for signs of neurological deterioration. Further advice was given that the deceased should be referred to the visiting Neurologist at the Royal Albert Edward Infirmary, Wigan

5. On the 24th December 2012 the Regional Centre for Medical Neurosciences at Salford Royal Hospital was contacted by a Clinician from the Royal Albert Edward Infirmary, Wigan in relation to whether the deceased should be discharged from hospital as there were no available Neurologists visiting the Hospital for two weeks. The Neurology Registrar at Salford Royal Hospital was informed by the Clinician that the deceased remained clinically stable without any neurological deterioration and the Registrar advised that the deceased should remain in Hospital at Wigan until her symptoms settled and until she was on a therapeutic warfarin dose.

6. The deceased remained at the Royal Albert Infirmary, Wigan and, although she showed some signs of deterioration on the 25th December 2012, her observations were stable until she was found unresponsive on the 26th December 2012 at 7.20am when she had a cardiac arrest and 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. In the course of investigations at the Royal Albert Edward Infirmary, Wigan, in relation to the failure of Doctors to respond to contact by use of the internal bleeper system during the deceased's admission, it was discovered that there were two

blind or blank spots within the precincts of the Hospital, where bleepers could not be activated. The blind or blank spots were previously unknown but were rectified so that bleepers can now be activated within all precincts of the Hospital.

Evidence was given that it is believed that similar problems may exist at other Hospitals in the United Kingdom and Hospitals may be unaware of the existence of blind or blank spots within the Hospital.

I have concerns that if blind or blank spots exist within Hospitals that there would be a delay in the response of Clinicians to emergencies and patients requiring urgent treatment and in my opinion there is a risk that future deaths will occur unless action is taken.

ii. Expert evidence was considered at the Inquest from a Consultant Neurosurgeon at Salford Royal Hospital and Consultant Neurologists from London Edinburgh and Liverpool. The Experts agreed that, on the balance of probabilities, the deceased would have died when she did irrespective of her management after her admission to the Royal Albert Edward Infirmary, Wigan on the 22nd December 2012.

However, evidence was given that in parts of the United Kingdom, and in particular in London and Cambridge, the management of patients diagnosed with Cerebral Venous Sinus Thrombosis involved the transfer patients from a District General Hospital to a Regional Neuroscience Centre, as soon as reasonably practicable after a confirmed diagnosis to, allow the patient to receive treatment in a Regional Centre where Specialties and Sub-Specialties exist, including Consultant Neurosurgeons, Consultant Neurologists and Consultant Neuroradiologists together with appropriate resources and facilities available on a 24 hour a day 365 day year basis.

The evidence confirmed that the treatment of Venous Thrombosis or Venous Stroke is different to the treatment of Cerebral Artery Thrombosis or Cerebral Stroke. The Experts agreed that the treatment of Cerebral Venous Sinus Thrombosis requires initial anticoagulation treatment and monitoring with regular neurological examinations and neurological observations and, where there is a significant deterioration, invasive procedures should be considered including Thrombolysis, Thrombectomy or Clot Extraction and Craniectomy, which can only be carried out at a Regional Neuroscience Centre.

iii. Following the deceased's death, a full investigation in relation to the treatment of patients with Cerebral Venous Sinus Thrombosis was conducted by [redacted], Consultant Neurologist and Clinical Director of Medical Neurosciences at Salford Royal Hospital who, together with [redacted], Consultant

	Neurologist Specialising in Cerebrovascular Diseases has produced a policy and guidelines for the assessment and management of adult patients with Cerebral Venous Thrombosis in Greater Manchester, a copy of which is attached hereto. The document is extensive and refers to the expectation that all patients suffering Cerebral Venous Thrombosis will be transferred from the District General Hospital to the Regional Medical Neuroscience Centre after a confirmed diagnosis of the condition to enable the patient to have the benefit of the Specialties, resources, facilities and invasive procedures only available at the Regional Centre. The evidence at the Inquest indicated that policies and guidelines similar to those produced by [redacted] do not exist in many parts of the United Kingdom. In my opinion, there is a risk that future deaths will occur unless action is taken to review the policy and guidelines for the assessment, management and treatment of patients suffering Cerebral Venous Thrombosis in all parts of the United Kingdom. 2. I request you to consider the above concerns and to carry out a review with regard to the following:- i. The bleeper systems in all Hospitals in the United Kingdom to consider whether blind spots or blank spots exist within the precincts of Hospitals to ensure coverage of all areas of each Hospital by the local bleeper system to enable response and appropriate action by Clinicians in relation to bleeper calls at all times. ii. The policy and guidelines for the assessment, management and treatment of patients diagnosed with Cerebral Venous Thrombosis in all areas of the United Kingdom, particularly with regard to the diagnosis of the condition and the transfer of patients from a District General Hospital to a Regional Medical Neuroscience Centre, as soon as practicable, after a confirmed diagnosis to enable patients to have the benefit of the Specialties, resources, facilities and invasive procedures, which are only available at Regional Centre.
6	**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 1st August 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] Wigan, Wrightington & Leigh NHS Trust Salford Royal NHS Foundation Trust [redacted] Sheffield Teaching Hospitals NHS Foundation Trust 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 6th June 2014**	**Signed** **Alan Peter Walsh**