REGULATION 28: REPORT TO PREVENT FUTURE DEATHS.

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Mr Jeremy Hunt, Secretary of State for Health, Department of Health.** 2. [redacted] **Chair, National Institute for Health and Care Excellence** 3. [redacted] **Vice President of Clinical Quality, Royal College of Gynaecologists and Obstetricians**
1	**CORONER** I am Miss Sara Lewis, Assistant Coroner, for the coroner area of City of Manchester.
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	**INQUEST** On 5 June 2013 an inquest was opened into the death of Isa Riaz Mushtaq aged 3 days old and who died on 29 May 2013. The inquest concluded on 1 September 2014. The medical cause of death was: 1a. Hypoxic ischaemic encephalopathy, myocardial ischaemia The death of Isa Riaz Mushtaq was due to Natural Causes.
4	**CIRCUMSTANCES OF THE DEATH** The mother of the deceased became pregnant in August 2012. Her estimated date of delivery was 18 June 2013. On 29 May 2013 at 13:25 hours the mother of the deceased attended the ante natal unit at 37 weeks and 1 day gestation with a history of reduced fetal movement over the previous two days. A cardiotocograph (CTG) was commenced. She was reviewed by a registrar at approximately 1510 hours and reported that she had felt no fetal movement during the CTG. The CTG was classed as suspicious with reduced variability. The mother was advised to eat and drink as this may stimulate fetal movement, with a plan to review the CTG after 30 minutes. At 15:40 it was noted by the midwife that the variability was still reduced and the registrar was asked to review. The registrar attended at 15:50 hours when it was noted that the variability was still reduced and the plan was to give intravenous fluids and transfer her to the labour ward. At 16:00 there was a fetal bradycardia. The emergency buzzer was pulled. The fetal heart was 70 beats per minute. At 16:03 hours, two consultants arrived. It was noted that the CTG demonstrated reduced variability for over 50 minutes and a prolonged deceleration. A decision was made for a grade 1 caesarean section. At 16:15 a midwife noted that she was unable to auscultate the fetal heart. Isa Riaz Mushtaq was delivered at 16:18 hours. There was no heart rate for 7 minutes but then resuscitation succeeded. It became evident that Isa Mushtaq had not recovered from the bradycardia – asystole episode and demonstrated severe hypoxic ischaemic encephalopathy. He died on the third neonatal day. An internal investigation of the incident noted that clinicians were to some extent relying

	on NICE guidelines as to how to categorise CTG during labour. There is no equivalent NICE guidance in relation to antenatal CTG interpretation and therefore there is no rigorous system for antenatal monitoring of fetal heart trace. This is a national issue rather than a local one.
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. – In clinical practice the fetal CTG continues to be a source of problems, both in interpretation and in what degree of action should be taken. This is particularly the case for antenatal (non labour) CTG's since there has not been the same clarification that was provided for electronic intrapartum fetal monitoring by specific NICE guidance. Currently there is no detailed national guidance on antepartum CTG assessment and therefore no guidance as to the circumstances in which CTG changes or abnormalities require urgent delivery. For example, the following problems with antenatal CTG interpretation may arise:- (i) Should change of position or intravenous fluids be used in the same way as in labour (ii) What role can be given to iced water drinks or dietary intake to stimulate fetal changes (iii) At what stage should intervention should be made and with what urgency in the absence of decelerations. (iv) What significance should be attached to reduced variability and what action should be taken in the absence of decelerations (v) What significance should be attached to the absence of accelerations where there is reduced variability. Reliance on the NICE guidance for intrapartum CTG monitoring to interpret antenatal CTG features is of limited value because: (i) It is not intended for such use and therefore such practice is arguably not evidence based (ii) It is much more common for fetal heart traces not to look normal during labour (in the region 20 -30 % outwith normal parameters) therefore the significance of such abnormal traces may not be the same in labour as compared to when identified antenatally. (iii) Only a very small percentage of antenatal CTG's are not normal. (iv) There is no recourse to fetal blood sampling for an antenatal CTG, so that if suspicions persist about lack of fetal well-being there is no way of assessing fetal acid-base balance. St Mary's Hospital has now developed its own local guidance for the management of suspected abnormal antenatal CTG in order to mitigate risk. In the absence of uniform, detailed national guidance on antepartum CTG abnormalities St Mary's hospital has implemented a procedure of early consultant involvement where there are persisting features of unusual CTG. There should be a review to consider whether national guidance on antepartum CTG monitoring and interpretation where there are abnormalities or unusual features would lead to safer, evidence based management of such cases.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and 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. 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] and also to the LOCAL SAFEGUARDING BOARD. I have also sent it to [redacted] Consultant Obstetrician, St Mary's Hospital, Central Manchester Foundation NHS Trust who may find it useful or of interest. 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** 24. IX .14 **SIGNED BY CORONER**