	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. The Royal College of Obstetricians and Gynaecologists 10-18 Union Street, London Bridge, SE1 1SZ 2. The Royal College of Paediatrics and Child Health 5-11 Theobald's Road London WC1X 8SH 3. NICE – National Institute for Health and Care Excellence National Institute for Health and Care Excellence Level 1A, City Tower Piccadilly Plaza Manchester M1 4BT
1	**CORONER** I am Alan Anthony Wilson Senior Coroner for **Blackpool & Fylde**
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. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** The death of Sienna Scarlett Monterio, on 6th April 2022 at Blackpool Victoria Hospital was reported to me and I opened an investigation, which concluded by way of an inquest on 15th September 2023. I determined that the medical cause of Sienna's death was **1 a 1 a Fetal-maternal haemorrhage** In box 3 of the Record of Inquest I recorded as follows: **Sienna Monteiro was born in hospital in Blackpool on 6th April 2022. Earlier that morning, her Mother rang the hospital to report a lack of fetal movements and was appropriately asked to attend the maternity day unit, arriving within 30 minutes.**

	There had been no noticeable fetal movements since the previous evening. It is likely that a fetal-maternal haemorrhage had occurred during the previous afternoon or early evening, and at around the time her Mother was admitted to hospital Sienna would have been experiencing some mild hypoxia. **Upon being triaged, and with a concerning CTG trace, plans were made for Natalie to go the delivery suite for continued observations. Sienna was delivered by way of an emergency caesarean section at 10.18 hours. Sienna was pale and was handed to the neonatal team and she was given ventilation breaths. A Consultant Paediatrician attended when Sienna was four minutes old. Sienna remained on the delivery unit so she could be stabilised prior to her transfer to the neonatal unit for ongoing care, which would have included establishing IV access through an umbilical cord catheter. There were difficulties in trying to intubate Sienna. At around 77 minutes of age, there was no detectable heart rate. CPR was commenced but after 20 minutes of resuscitation with no cardiac output, this was stopped when there were no apparent signs of life and death was confirmed at 11.59 hours that morning. A subsequent paediatric post – mortem report revealed Sienna died due to a severe fetal – maternal haemorrhage, which occurs when there is a passage of fetal blood into the maternal circulation. Prior to Sienna being born, there had been no clear indication of a fetal – maternal haemorrhage. In part due to what appeared to be effective lung inflation, and a reassuring heart rate, the extent of fetal compromise was not fully appreciated. Sienna suffered a delayed collapse from which she could not be resuscitated, caused by significant blood loss and hypoxia. The blood loss needed to be replaced if she was to respond to ventilation. This fetal – maternal haemorrhage was a very rare occurrence as there had been incomplete haemodynamic recovery by the time Sienna was born. Given the circumstances at the time, there was nothing the clinical team could have done to avoid the fatal outcome.** In addition to the above, I wish to note that I made the following findings: • That investigation revealed no significant failings in the antenatal care received, nor in relation to the obstetric care provided; • That earlier attendance at the hospital once a reduction in felt movement was suspected would not have altered the outcome; In box 4 of the Record of Inquest I determined that Sienna died due to: **Natural causes**
4	**CIRCUMSTANCES OF THE DEATH** In addition to the contents of section 3 above, the following is of note: In advance of the inquest, the court received a maternity investigation report from the Healthcare Safety Investigation Branch [HSIB] which included the following finding: *"Paired cord blood gas samples were taken at the time of birth of the Baby. The blood gas analyser was not set to analyse the haemoglobin. This prevented other possible causes for the Baby's condition being considered and possibly corrected."* At the end of that report, this recommendation was made: *"The Trust to ensure a blood gas analyser with an Hb (haemoglobin) measurement facility is available in all neonatal resuscitation settings to support the provision of clinical information, and to optimise decision making processes and clinical care."* Despite the fact that in Sienna's case I found that it did not contribute to her death, nevertheless, having considered the evidence received at inquest, I have a concern that this issue may pose a risk in future.

	Haemoglobin is the protein in red blood cells that carries oxygen to the body's organs and tissues. If a blood test reveals that haemoglobin levels are lower than normal this is known as anaemia. [independent Obstetrics & Gynaecology witness] told the court that although in his experience the blood gas analyser facility is usually turned on, he had recently been involved in a significant piece of work analysing maternity incidents within another hospital trust and found that it is variable whether this function is turned on or not; [independent Consultant Neonatologist] echoed comments, and said he that rather than having to rely on clinical observation only, were clinicians to have this blood gas analyser data in the event of a low haemoglobin level in the blood cord gas, this may provide additional insight. He went on to say that personally, he could see no potential disadvantage in having the Hb measurement being readily available in the cord blood gas from a clinical perspective; The court also received some helpful information from Blackpool Teaching Hospitals NHS Foundation Trust on this issue which included the following: • that cord blood haemoglobin analysis is not a standard requirement and does not form part of the Newborn Life Support (NLS) process; • that according to guidance from The British Journal of Haematology, the current position is that cord blood testing is not regulated or included in the Newborn Life Support (NLS) process at a national level and that there remain concerns regarding the reliability of samples tested by the blood gas analyser; • that against this background nationally, from a local perspective the Trust in Blackpool are considering whether there may be steps that can be taken locally, despite there being no national requirement for the same, to use cord blood sampling as a screening tool to assist in ongoing treatment. The Trust add they are acutely conscious that no snap decision should be made and that careful consideration is given to the matter such that the Trust can be reassured that any changes made locally are both safe and appropriate in the clinical setting. As Senior Coroner for this coroner area, I regard that approach as reassuring. However, having considered all of the above, I have determined that I have a duty to write this report.
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 could occur unless action is taken. In the circumstances it is my statutory duty to send the report: The **MATTER OF CONCERN** is as follows. – I have conducted a complex inquest into the death of newborn baby in a maternity setting. The evidence included input from independent expert witnesses, senior consultant paediatricians from the hospital trust. Having reviewed the circumstances surrounding Sienna's death, the Healthcare Safety Investigation Branch [HSIB] found that at the time of birth the blood gas analyser was not set to analyse the haemoglobin level.

	The HSIB very clearly state that in the absence of this data, this *"prevented other possible causes for the Baby's condition being considered and possibly corrected."* The HSIB has also recommended this facility is available in all neonatal resuscitation settings to support the provision of clinical information, and to optimise decision making processes and clinical care. Sienna was born following an urgent caesarean section, and died within two hours of delivery. Those who work in this area inevitably have to make urgent, life-saving decisions and in the most challenging of circumstances, and it seems to me that there is a lack of clarity on this issue which needs to be addressed. In the absence of such clarity, a baby may die from a preventable cause which is not appreciated by clinicians in the absence of data which would have highlighted a low haemoglobin level in the blood cord gas. It appears that in some trusts, this data will be readily available, but not in others. If [redacted] comment above is correct, there may be different practices within the one trust. The court has been told that cord blood testing is not regulated or included in the Newborn Life Support (NLS) process at a national level. It appears as though the hospital trust in Blackpool is considering this issue appropriately, and this may reflect the picture nationally. The HSIB states this data may assist in identifying other possible causes for a baby's condition being considered, and possibly corrected. [redacted] expresses the view that he sees no potential disadvantage in having the Hb measurement being readily available in the cord blood gas from a clinical perspective. I have therefore concluded that there is risk of future deaths and that I therefore have a duty to write this report. I do not seek to be prescriptive about what should now happen, and that is not the purpose of this report. I simply raise the concern. It may be the recipients of this letter feel the issue is one which is being addressed , but it would be remiss of me not to raise this concern should Sienna's inquest provide assistance.
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. Given the approaching holiday period I have extended this period to 12th November 2**023**. I, the coroner, may extend the period further. 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] [Parents of Sienna] • The Director of North West Neonatal Operational Delivery Network • Medical Director of Blackpool 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	16/09/2023 Signature__________ A Wilson ______________ Alan Anthony Wilson Senior Coroner **Blackpool & Fylde**