Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NIMLT 51615 NIMS 16238316

FINAL Report

Investigation of an Incident conducted into the circumstances surrounding the care, management and treatment delivered to Mrs X and her Baby Aaron at Hospital S1 during the period of the 19th November 2015 to the 4th May 2016; to include her Baby's transfer and admission to Hospital S2 following delivery on the 4th May 2016 to the 9th May 2016 inclusive.

Strictly Private and Confidential

Investigation Commencement and Completion Dates: The investigation commenced on the 28th November 2016 and was completed on the 19th March, 2020.
The reviewers who undertook this investigation: Ms Deirdre O'Keeffe, Quality Improvement Division, HSE (Investigation Lead and Chairperson). Dr. Francois Gardeil, Consultant Obstetrician and Clinical Expert. **Commissioner:** Hospital Manager.

Date: 27th May 2020

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Glossary of Terms and Acronyms

ADOM	Assistant Director Of Midwifery
ALP	An Alkaline phosphatase test measures the amount of the enzyme ALP in the blood. ALP is made mostly in the liver and in bone with some made in the intestines and kidneys. It also is made by the placenta of a pregnant woman.
AFI	Amniotic Fluid Index
Amnisure ROM™ test	The Amnisure ROM™ test is approved for the diagnosis of rupture of membranes (ROM). Ref: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2744034/
Antepartum	Antepartum - occurring or existing before birth; "the prenatal period"; "antenatal care" (reference: http://www.thefreedictionary.com/Antepartum)
Antibodies	Antibody tests are done to find certain antibodies that attack red blood cells. Antibodies are proteins made by the immune system. Normally, antibodies bind to foreign substances, such as bacteria and viruses, and cause them to be destroyed (reference: http://www.webmd.com/a-to-z-guides/antibody-tests)
Apgar score	An objective score of the condition of a baby after birth. This score is determined by scoring the heart rate, respiratory effort, muscle tone, skin colour, and response to a catheter in the nostril. Each of these objective signs receives 0, 1, or 2 points. An Apgar score of 10 means an infant is in the best possible condition. The Apgar score is done routinely 60 seconds after the birth of the infant. A child with a score of 0 to 3 needs immediate resuscitation. The Apgar score is often repeated 5 minutes after birth, and in the event of a difficult resuscitation, the Apgar score may be done again at 10, 15, and 20 minutes. Ref: http://www.medicinenet.com/script/main/art.asp?articlekey=2303 Apgar Score: an index used to evaluate the condition of a newborn infant based on a rating of 0, 1, or 2 for each of the five characteristics of colour, heart rate, response to stimulation of the sole of the foot, muscle tone, and respiration with 10 being a perfect score. Ref: http://www.merriam-webster.com/dictionary/apgar%20score
APTT	Partial Thromboplastin Time is used when someone has unexplained bleeding or clotting. Along with the PT test (which evaluates the extrinsic and common pathways of the coagulation cascade), the aPTT is often used as a starting place when investigating the cause of a bleed or thrombotic (blood clot) episode. It is often used with recurrent miscarriages which may be associated with anticardiolipin or antiphospholipid antibodies. The aPTT and PT tests are also sometimes used as pre-surgical screens for bleeding tendencies, although numerous studies have shown that they are not useful for this purpose Reference; http://www.labtestsonline.org.uk/understanding/analytes/aptt/tab/test.
Baby Cooling / Brain Hypothermia	Brain Hypothermia, induced by cooling a baby to around 33 °C for three days after birth, is a treatment for hypoxic ischemic encephalopathy. It has recently been proven to be the only medical intervention which reduces brain damage, and improves an infant's chance of survival and reduced disability. Hypothermic neural rescue therapy is an evidence-based clinical treatment which increases a severely injured full term infant's chance of surviving without brain damage detectable at 18 months by about 50%, an effect which seems to be sustained into later childhood. (references: Edwards, AD; Brocklehurst, P; Gunn, AJ; Halliday, H; Juszczak, E; Levene, M; Strohm, B; Thoresen, M; Whitelaw, A; Azzopardi, D. (2010). "Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischaemic encephalopathy: synthesis and meta-analysis of trial data". BMJ (Clinical research ed.) 340: c363. Shankaran, S; Pappas, A; McDonald, SA; Vohr, SR; Hintz, SR; Yolton, K; Gustafson, KE; Leach, TM; Green, C et al. (2012). "Childhood outcomes after hypothermia for neonatal encephalopathy". New England Journal of Medicine 366

	(22): 2085–92. Guillet, R; Edwards, AD; Thoresen, M; CoolCap Trial Group (2011). "Seven- to eight-year follow-up of the CoolCap trial of head cooling for neonatal encephalopathy.". Pediatr Res 71 (2): 205–9. Rutherford, M; Ramenghi, LA; Edwards, AD; Brocklehurst, P; Halliday, H; Levene, M; Strohm, B; Thoresen, M et al. (2010). "Assessment of brain tissue injury after moderate hypothermia in neonates with hypoxic-ischaemic encephalopathy: a nested substudy of a randomised controlled trial". Lancet neurology 9 (1): 39–45. Robertson, NJ; Nakakeeto, M; Hagmann, C; Cowan, FM; Acolet, D; Iwata, O; Allen, E; Elbourne, D et al. (2008). "Therapeutic hypothermia for birth asphyxia in low-resource settings: a pilot randomised controlled trial". Lancet 372 (9641): 801–3.
Base Excess	Together with the bicarbonate, the base excess gives you an indication of the metabolic component of the blood gas results. A positive base excess means excess base, i.e. a metabolic alkalosis, whereas a negative base excess means reduced base, i.e. a metabolic acidosis.
Baseline FHR Variability	Baseline FHR variability is based on visual assessment and excludes sinusoidal patterns. Variability is defined as fluctuations in the FHR baseline of 2 cycles per minute or greater, with irregular amplitude and inconstant frequency. These fluctuations are visually quantitated as the amplitude of the peak to trough in beats per minute. By visual assessment, acceleration is defined as an apparent abrupt increase in FHR above baseline, with the time from the onset of the acceleration to the acme of less than 30 seconds. Late deceleration is defined as an apparent gradual decrease and return to baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. Early deceleration is defined as an apparent gradual decrease and return to the baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. Variable deceleration is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline. When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol, 2008 Spring; 1(2): 56-60 (Available from: http://medical-dictionary.thefreedictionary.com/premature+labor). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).
Baseline Fetal Heart Rate (FHR)	Baseline fetal heart rate is the average fetal heart rate (FHR) rounded to increments of 5 beats per minute during a 10-minute segment, excluding periodic or episodic changes, periods of marked variability, or baseline segments that differ by more than 25 beats per minute. In any given 10-minute window, the minimum baseline duration must be at least 2 minutes, or else the baseline is considered indeterminate. In cases where the baseline is indeterminate, the previous 10-minute window should be reviewed and utilized in order to determine the baseline. A normal FHR baseline rate ranges from 110 to 160 beats per minute. If the baseline FHR is less than 110 beats per minute, it is termed bradycardia. If the baseline FHR is more than 160 beats per minute, it is termed tachycardia.
BHCG	Beta Human Chorionic Gonadotrophin (Pregnancy Hormone)
BP	Blood Pressure
BPD	Biparietal diameter, the diameter of the fetal head as measured from one parietal bone to the other. The measurement is useful in dating the pregnancy and estimating fetal weight after about 13 weeks of pregnancy. (reference: The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company. Published by Houghton Mifflin Company).

BPS	Biophysical Profile Score
Bradycardia	Bradycardia is a slow heart rate usually defined as less than 60 beats per minute (reference: http://www.medterms.com/script/main/art.asp?articlekey=2515)
BW	Birth Weight
C&S	Culture and Sensitivity
Caesarean Section	There are two types of Caesarean Sections: the classical Caesarean Section, and the Lower Segment Caesarean Section. The classical section involves a midline longitudinal incision which allows a larger space to deliver the baby. The Lower Segment Caesarean Section, more commonly used today, involves a smaller transverse cut which results in less blood loss and is easier to repair (ref: http://www.news-medical.net/health/Cesarean-Section-Types.aspx)
Cardiopulmonary Resuscitation	Cardiopulmonary resuscitation involves physical interventions to create artificial circulation through rhythmic pressing on the patient's chest to manually pump blood through the heart, called chest compressions, and usually also involves the rescuer exhaling into the patient (or using a device to simulate this i.e. an ambu bag and oxygen mask) to ventilate the lungs and pass oxygen in to the blood, called artificial respiration
Cardiotocography	In medicine (obstetrics), cardiotocography (CTG) is a technical means of recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions (-toco-) during pregnancy, typically in the third trimester. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM).
Cephalic Presentation	A cephalic presentation is a situation at childbirth where the foetus is in a longitudinal lie and the head enters the pelvis first; the most common form is the vertex presentation where the occiput (back part of the head or skull) is the leading part (Reference: Hellman LM, Pritchard JA. Williams Obstetrics, 14th edition, Appleton-Century-Crofts (1971) Library of Congress Catalogue Card Number 73-133179. p. 322–2)
Cervix	Neck of the Womb
CIS	The Clinical Indemnity Scheme (CIS) was established in 2002, in order to rationalise pre-existing medical indemnity arrangements by transferring to the State, via the Health Service Executive (HSE), hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks. (Ref: http://www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html). State Claims Agency (2009). The State Claims Agency Clinical Indemnity Scheme Incident Notification Requirements. Available from http://www.stateclaims.ie/ClinicalIndemnityScheme/publications/2009/SCACISIncidentNotificationReqs.pdf .
Commissioner	The commissioner of an investigation differs across the health system, but it is typically the senior accountable officer in a service, directorate or care group that commissions an investigation of a clinical or non-clinical incident.
Cord blood ph	A low pH (less than 7.04 to 7.10) means there are higher levels of acids in the baby's blood. This might occur when the baby does not get enough oxygen during labor (Ref: http://www.nlm.nih.gov/medlineplus/ency/article/003403.htm).
CRL	Crown-rump length: The fetal crown rump length (CRL) is defined as the longest length excluding the limbs and yolk sac. It is the measurements between the top of the head to the area above where the legs begin. (Ref: http://www.babymed.com/fetus-crown-rump-length-crl-measurements-ultrasound).
CRP	C-Reactive Protein, a measure of inflammation
CTG	CTG is a technical means of recording the fetal heartbeat and the uterine contractions during pregnancy, typically in the third trimester. (Reference: Macones GA, Hankins GD, Spong CY, et al. The 2008 National Institute of Child

	Health and Human Development workshop report on electronic fetal monitoring: update on definitions, interpretation, and research guidelines Obstet Gynecol (2008) 112:661-666). A 'Normal' CTG is indicated when all four features (fetal heart rate, baseline variability, acceleration and deceleration of the fetal heart rate and frequency and strength of contractions as recorded by the attending healthcare professional) fall within the reassuring category i.e. they fall within the normal ranges as outlined on page 16 of this report. A 'Suspicious' CTG is when one feature falls within the nonreassuring category and the remainder are reassuring. A 'Pathological' CTG is when two or more features fall within the nonreassuring category or one or more features fall within the abnormal category (Ref: Regional Maternity Department, Midland Regional Hospital at Hospital S1: Fetal Heart Monitoring in the Maternity Department. Approval date: April 2011)
CX	Cervix
CXR	Chest X-Ray
DC	Discharge
E. coli	E. coli (Escherichia coli) is one of several types of Gram negative bacilli bacteria that normally inhabit the intestine of humans. Some strains of E. coli are capable of causing disease under certain conditions.
ECG	Electrocardiogram
ECMO	Extracorporeal membrane oxygenation (ECMO), also known as extracorporeal life support (ECLS), is an extracorporeal technique of providing prolonged cardiac and respiratory support to persons whose heart and lungs are unable to provide an adequate amount of gas exchange or perfusion to sustain life.
ED	Emergency Department
EDD	Estimated Date of Delivery
EEG	Electroencephalogram
Effacement	Effacement relates to the softening and shortening of the cervical canal from about 3cm long to less than 0.5cm long. (Reference: National Collaborating Centre for Women's and Children's Health 2008 ClinicalGuideline; Induction of Labour RCOG Press London)
EFW	Estimated Fetal Weight
Electronic Fetal Monitor (EFM)	In medicine (obstetrics), cardiotocography (CTG) is a technical means of recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions (-toco-) during pregnancy, typically in the third trimester. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM)
Endotracheal Intubation	Endotracheal intubation is the insertion of a tube into the trachea for purposes of anesthesia, airway maintenance, aspiration of secretions, lung ventilation, or prevention of entrance of foreign material into the airway; the tube goes through the nose or mouth. (Ref: http://medical-dictionary.thefreedictionary.com/intubation)
Entonox	Entonox is used as an analgesia and can be self administered using a demand valve which is popular in obstetric practice (Reference: British National Formulary 2009)
EPAU	Early Pregnancy Assessment Unit
Epidural Analgesia	Epidural analgesia is a central nerve blockade technique, which involves the injection of a local anaesthetic, with or without an opioid into the lower region of the spine close to the nerves that transmit painful stimuli from the contracting uterus and birth canal. Ref: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009234.pub2/pdf .
ERPC	ERPC is an evacuation of retained products of conception (reference: http://www.nhs.uk/Conditions/Miscarriage/Pages/Treatment.aspx)
External Cephalic Version	External Cephalic Version is when pressure is put on the tummy to try to turn the baby into a head-down (cephalic) position Ref: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/breech-

	birth.aspx#close).
Fetal Scalp Electrode	An electrode that is attached to the baby's scalp and connected to the CTG machine so that a trace of the fetal heart can be recorded electronically
FHHR	Fetal Heart Heard and Regular
FHH	Fetal Heart Heard
FHR	Fetal Heart Rate
Fetal Biometric Parameters	Fetal biometric parameters are various antenatal ultrasound measurements that are used to indirectly assess the growth and well being of the foetus and in assessing dates - gestational age Ref: http://radiopaedia.org/articles/fetal-biometric-parameters)
Fetal Bradychardia	An abnormally slow fetal heart rate, usually below 100 beats/min. Ref Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.
Full Blood Count (FBC)	Full Blood Count (FBC) is used as a broad screening test to check for such disorders as anaemia, infection, and many other diseases. It is actually a panel of tests that examines different parts of the blood (reference: http://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test).
Fundal Height	Fundal height is the height of the fundus of the uterus, measured in centimetres from the top of the symphysis pubis to the highest point in the midline at the top of the uterus. Fundal height is measured at each prenatal visit with large blunt callipers or with a tape measure. From the twentieth to the thirty-second week of pregnancy the height in centimetres is equal to the gestation in weeks (reference: http://medical-dictionary.thefreedictionary.com/fundal+height).
Governance	The system by which organisations direct and control their functions and relate to their stakeholders in order to manage their business, achieve their missions and objectives and meet the necessary standards of accountability, integrity and propriety (HSE, 2006).
GP	General practitioner
GS	Gestational sac
GTT	Glucose Tolerance Test
Haemoglobin (Hb)	A conjugated protein, consisting of haem and the protein globin, that gives red blood cells their characteristic colour. It combines reversibly with oxygen and is thus very important in the transportation of oxygen to tissues (reference: http://www.thefreedictionary.com/haemoglobin). Low levels of haemoglobin in pregnancy can indicate anaemia. (ref: http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438andnp=459andid=2759#haemoglobin)
HCO_3	Bicarbonate - a salt of carbonic acid (containing the anion HCO3) in which one hydrogen atom has been replaced; an acid carbonate.
HDU	High Dependency Unit
HFOV	High frequency oscillation ventilation
HR	Heart rate
HSE	Health Service Executive
Hypoxic Ischemic Encephalopathy	Hypoxic Ischemic Encephalopathy has many causes and is essentially the reduction in the supply of blood or oxygen to a baby's brain before, during, or even after birth. It is a major cause of death and disability, occurring in approximately 2-3 per 1000 births and causing around 20% of all cases of cerebral palsy. Hypoxic ischemic encephalopathy (HIE) is a condition that occurs when the entire brain is deprived of an adequate oxygen supply, but the deprivation is not total. While HIE is associated in most cases with oxygen deprivation in the neonate due to birth asphyxia, it can occur in all age groups, and is often a complication of cardiac arrest. Busl, K. M., Greer, D. M., "Hypoxic-ischemic brain injury: pathophysiology, neuropathology and mechanisms". NeuroRehabilitation. 2010 Jan;26(1):5-13. Allen K, Brandon D, 2011, Hypoxic Ischemic Encephalopathy: Pathophysiology and Experimental Treatments, Newborn Infant Nurs Rev. September 1; 11(3): 125–

	133.
Incident:	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. (Adapted from WHO (2009) and doh (2010), HSE Quality and Risk Taxonomy (2009)). Incidents include adverse events which result in harm; and Near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention. Incidents can be clinical or non-clinical and include incidents associated with harm to: ▪ Our patients, staff and visitors ▪ The attainment of HSE objectives ▪ HSE ICT systems ▪ Data security e.g. Data protection breaches ▪ The environment Incidents include complaints which are associated with harm and as such these complaints are Mrs reported incidents.
Intermittent Auscultation	Intermittent auscultation employs listening to fetal heart sounds at periodic intervals to assess the fetal heart rate (FHR) using either a Pinard stethoscope or a hand held (Doppler) device.
IOL	Induction of Labour is a method of artificially or prematurely stimulating childbirth in a woman (Ref:National Collaborating Centre for Women's and Children's Health 2008 Clinical Guideline; Induction of Labour RCOG Press London)
Iron supplements	Routine iron supplementation is a common practice for preventing iron deficiency (ID) and iron deficiency anemia (IDA) in pregnancy, because the dietary iron intake of pregnant women often does not meet the recommended dietary intake (reference: http://www.ajcn.org/content/83/5/1112.full.pdf).
ISBAR	Identify, Situation, Background, Assessment, Recommendation.
K2 Fetal Monitoring Training System	K2 Fetal Monitoring Training System is an interactive computer based training system covering a comprehensive spectrum of learning that can be accessed over the internet. (Ref: http://www.k2ms.com/products/fetal_monitoring_training_system_online.html#2
Key Causal Factors	Issues that arose in the process of delivering and managing health services which had an effect on an eventual adverse outcome.
Labour (stages)	The first stage of labour is the process of reaching full cervical dilatation. This begins with the onset of uterine labour contractions, and it is the longest phase of labour. The first stage is divided into three phases: latent, active, and descent of the presenting part. The second stage is the delivery of the infant. The third stage of labour is the passage of the placenta Reference: http://www.umm.edu/pregnancy/000126.htm#ixzz1x0x7XMI5 .
LFTs	Liver Function Tests are used to evaluate how well the liver is working (liver function) (ref: http://www.nlm.nih.gov/medlineplus/ency/article/003436.htm).
Liquor	Liquor is amniotic fluid within the amniotic cavity produced by the amnion during the early amniotic period and later by the lungs and the kidneys. Amniotic fluid protects the embryo and foetus from injury. (Reference: Dorland's Illustrated Dictionary 31ed)
LMP	Last Menstrual Period
Mané	The next morning
MCH	The average amount of hemoglobin in the average red cell. MCH is particularly important when testing for anaemia. http://www.babymed.com/laboratory-values/mean-corpuscular-hemoglobin-mch-whole-blood-during-pregnancy)
MCV	Mean Corpuscular Volume measures the size of an average red blood cell. Low mean corpus volume can be associated with anemia, thalassemias, iron deficiency and Shahidi-Nathan-Diamond syndrome. High mean corpus volume can be caused by vitamin B12 deficiency, impaired vitamin absorption, hyperthyroidism, celiac disease and deficient enzymes (reference: http://www.babymed.com/laboratory-values/mean-corpuscular-volume-mcv-whole-blood-during-pregnancy)

Meconium	Meconium is the greenish-black sticky material passed from the baby's bowels after birth. In some instances, the foetus will pass meconium into the amniotic fluid while still in the womb, indicated by the presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so. Reference: http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf
Meninges	Meninges are the three membranes that enclose the vertebrate brain and spinal cord: the pia mater, arachnoid, and dura mater (reference: http://www.thefreedictionary.com/Meninges).
MRSOPA	Describes the maneuvers performed during NRT when there is ineffective ventilation: - Mask is tightly applied to the face - Re-position the head into the "sniffing" orientation - Suction the nares and the pharynx - Open the mouth - Pressure of PPV can be increased to a max of 40 cm H2O - Alternate airway, i.e. ET, should be considered and planned for
MOET	Managing Obstetric Emergencies and Trauma
MSU	Midstream sample of urine
NaCl	Sodium Chloride solution contains sodium chloride 0.9% (reference: British National Formulary 2009).
NAD	Nothing Abnormal Detected
NCHD	Non consultant hospital doctor
Neutrophil	A neutrophil is a type of mature (developed) white blood cell that is present in the blood. White blood cells help protect the body against diseases and fight infections (reference: http://www.medfriendly.com/neutrophil.html)
Newborn hypoxic-ischaemic brain injury	Newborn hypoxic-ischaemic brain injury differs from injury in the adult brain in several ways: NMDA receptor toxicity is much higher in the immature brain. Apoptotic mechanisms including activation of caspases, translocation of apoptosis-inducing factor and cytochrome-c release are much greater in the immature than the adult. The inflammatory activation is different with less contribution from polymorphonuclear cells and a more prominent role of IL-18 whereas IL-1, which is critical in the adult brain, is less important. The anti-oxidant system is underdeveloped with reduced capacity to inactivate hydrogen peroxide. Ref: Wang, X.; Carlsson, Y.; Basso, E.; Zhu, C.; Rousset, C. I.; Rasola, A.; Johansson, B. R.; Blomgren, K. et al. (2009). "Developmental Shift of Cyclophilin D Contribution to Hypoxic-Ischemic Brain Injury". Journal of Neuroscience 29 (8): 2588–96. Ferriero, DM (2004). "Neonatal brain injury". The New England Journal of Medicine 351 (19): 1985–95.
NIMLT	National Incident Management and Learning Team
Nocte	At night
O&G	Obstetrics and Gynaecology
O/E	On examination
Occiput Posterior Position	The most common position for a baby during labour is head down with the back of the head (occiput) facing the front of the mother (anterior). When the back of the head is facing the back of the mother (posterior) the baby's position is called Occiput Posterior. (ref: http://www.birthingnaturally.net/birth/challenges/posterior.html)
Os	The OS is the outlet of the cervix, which will stretch during labour from two to three millimetres up to ten centimetres to allow baby to emerge. Once the birth process has occurred, the OS changes in size and shape. The two descriptions given to the appearances are either a nulliparous os, for a first pregnancy, or a multiparous os for subsequent pregnancies. Ref:

	http://www.netdoctor.co.uk/ate/pregnancyandchildbirth/205040.html#ixzz31WTlfpx9
Para	Para is a woman who has produced one or more viable offspring, regardless of whether the child or children were living at birth (reference: http://medical-dictionary.thefreedictionary.com/para).
Partogram	A partogram provides an instant picture of the labour and its progress
Perinatal	The World Health Organisation defines the perinatal period as commencing at 22 completed weeks (154 days) of gestation and ending seven completed days after birth. http://www.who.int/maternal_child_adolescent/topics/maternal/maternal_perinatal/en/
ph	A figure expressing the acidity or alkalinity of a solution on a logarithmic scale on which 7 is neutral, lower values are more acid and higher values more alkaline. A low pH (less than 7.04 to 7.10) means there are higher levels of acids in the baby's blood. This might occur when the baby does not get enough oxygen during labor (Reference: http://www.nlm.nih.gov/medlineplus/ency/article/003403.htm)
PMHX	Previous Medical History
PPROM	Preterm Pre-labour Rupture of Membranes
PPV	Positive Pressure Ventilation
Presentation	Presentation of foetus: that part of the foetus lying over the pelvic inlet; the presenting body part of the fetus. Vertex (VX) presentation: Head presentation of the foetus during birth in which the upper back part of the fetal head is the presenting part. Breech presentation: presentation of the fetal buttocks or feet in labour; the feet may be alongside the buttocks (complete breech p.); the legs may be extended against the trunk and the feet lying against the face; or one or both feet or knees may be prolapsed into the maternal vagina. Cephalic presentation: presentation of any part of the fetal head in labour, whether the vertex, face, or brow. (reference: The American Heritage® Medical Dictionary, 2004 Published by Houghton Mifflin Company; Medical Dictionary for the Health Professions and Nursing © Farlex 2012)
Primagravida	Woman pregnant for the first time
PV	Per Vaginam (Latin) meaning via/ through the vagina (Reference: Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)
RCOG	Royal College of Obstetricians and Gynaecologists
Resuscitaire	A resuscitaire is a device which combines an effective warming therapy platform along with the components needed for clinical emergency and resuscitation (reference: http://www.draeger.ae/AE/en_US/products/neonatal_care/)
SBAR	Situation, Background, Assessment, Recommendation.
SCBU	Special Care Baby Unit
Serious incident	An incident that resulted in death or serious harm.
Show	A 'show' is the passage of small quantities of blood-tinged mucus from the vagina at the onset of labour (ref: http://medical-dictionary.thefreedictionary.com/premature+labour)
SROM	Spontaneous Rupture of Membranes
Syntocinon	Syntocinon is administered to induce or augment labour, usually in conjunction with amniotomy (surgical rupture of the fetal membrane to induce labour) (reference British National Formulary 2008).
Systems Analysis Investigation	A systems analysis investigation is a structured investigation that aims to identify the systems cause(s) of an incident or complaint and the actions necessary to eliminate the recurrence of the incident or complaint or where this is not possible to reduce the likelihood of recurrence of such an incident or complaint as far as possible. Healthcare services carry out incident investigations using systems analysis to find out what happened, how it happened, why it happened, what the organisation can learn from the incident and what changes the organisation should make to prevent it happening again.

Systolic Blood Pressure	Systolic blood pressure is the pressure exerted on the bloodstream by the heart when it contracts, forcing blood from the ventricles of the heart into the pulmonary artery and the aorta (ref:http://medical-dictionary.thefreedictionary.com/Systolic+blood+pressure)
TAS	Trans Abdominal Scan
Term	The normal duration of pregnancy is approximately 37 – 42 weeks, with the estimated due date at 40 weeks or 280 days from the first day of the last menstrual period (reference: http//www.uptodate.com/contents/post-term pregnancy-beyond-the-basics)
U&E	UandE is the abbreviation used for urea and electrolytes. These are a group of blood tests to measure the levels of salts in the blood (such as sodium and potassium), as well as the urea and creatinine levels, which show the kidney function as they are waste products. (ref: http://www.patient.co.uk/health/nephrotic-syndrome-leaflet)
U/S	Ultrasound. A pregnancy ultrasound is an imaging test that uses sound waves to create a picture of how a baby is developing in the womb. It is also used to check the female pelvic organs during pregnancy. http://www.medicinenet.com/script/main/art.asp?articlekey=9509
USS	Ultrasound Scan
VE	Vaginal Examination
Vx	Vertex

Executive Summary

This report presents the findings of a methodological investigation into an incident relating to the circumstances surrounding the care, management and treatment delivered to Mrs X and her infant son Aaron while under the care of staff at Hospital S1 from the 19th November 2015 until Baby Aaron's delivery at 01:31[1] hours on the 4th May 2016. The investigation focused primarily on Mrs X's antenatal care and intrapartum[2] care however, in order to complete the chronology the Investigation Team believed it to be beneficial to document the events leading up to Baby Aarons death on the 9th May 2016.

Mrs X was a healthy young woman. She had quit smoking when she became pregnant. The only risk factor was a BMI above 30. The expected date of delivery from the date of the last period, confirmed by early scan was the 4th June 2016.

On the 4th February 2016, at 22 weeks, Mrs X was referred by her GP to hospital S1 because of palpitations and frequent episodes of breathlessness when walking. She was assessed by the obstetrics team and also by physicians. Blood tests were normal. An electrocardiogram, an echocardiogram and a 24-hour monitoring of the blood pressure were entirely normal.

On the 29th February 2016, at 26+ weeks, Mrs X presented to hospital S1 with a complaint of spasmodic upper abdominal pains and vomiting. An abdominal ultrasound scan was performed on the 2nd March 2016, which revealed the presence of gallstones with possible cholecystitis. Mrs X was reviewed by the surgical team. It was decided to manage her conservatively with anti-acid medications and a plan for review 6 months later as an outpatient was made. Symptoms settled and Mrs X was discharged home on the 3rd of March with arrangements for review in the antenatal clinic on the 18th March 2016.

Mrs X attended the clinic as planned on the 18th March 2016 at 28+ weeks. She was chesty and had flu like symptoms. She was prescribed an antibiotic (Augmentin). Because Augmentin didn't agree with her, her GP subsequently prescribed Amoxycillin instead. A glucose tolerance test (GTT) performed on the 16th March 2016 was normal, excluding gestational diabetes.

Mrs X was reviewed in the antenatal clinic on the 1st April 2016 and again on the 15th April 2016. On that date she complained of back pain radiating down both legs.

On Friday the 29th April 2016, at 35 weeks, Mrs X complained of reduced fetal movements when seen in the clinic for a scheduled appointment. She said at interview that she had noticed her bump had increased in size suddenly at 34 weeks and felt rock-solid. The Braxton-Hicks contractions had also become more frequent and painful. A scan showed marked increase in the amniotic fluid volume and bilateral dilatation of the fetal kidneys. A request for urgent assessment in the feto-maternal unit of hospital S2 (a large Maternity Hospital with specialist neonatal services) was faxed at 13.26 hours. In addition, on the 29th April 2016, for the first time in her pregnancy, the presence of protein was detected in a sample of urine. Because of that, and despite a blood pressure within normal limits, PET bloods were sent as there was a suspicion of pre-eclampsia.

On Sunday the 1st May 2016, Mrs X presented to hospital S1 at 11.55 hours feeling very unwell. She complained of abdominal discomfort and painful contractions. She was admitted for observation and discharged home the following day, bank holiday Monday the 2nd May 2016.

Mrs X presented again to the Maternity Admission Unit in hospital S1 at 12.30 hours on Tuesday the 3rd May 2016. She had woken up at 02.45 hours with severe pains. She was admitted to hospital S1

[1] The time of delivery is taken from Mrs X's interview and the Obstetric Registrar entry on the surgical sheet. The disparity in relation to the time of delivery is addressed later in the report under incidental findings
[2] Intrapartum care refers to the events occurring during labor or delivery.

and administered the first dose of steroids at 15.00 hours.

CTG Interpretation Summary

- On the 3rd May 2016 a CTG with the times 22.32 hours to 22.55 hours (35 3/7 weeks gestation) shows the baseline fetal heart rate as 140-150 bpm, with normal variability and accelerations are present. There are no significant decelerations. There are no regular contractions. This is considered to be a normal CTG tracing.

- On the 3rd May 2016 the CTG trace between 23.13 hours and the 4th May 2016 at 00:45 hours shows the baseline fetal heart varies from 130 to 150 bpm, with normal variability and accelerations are present. Shallow variable declarations to 120 bpm are present at 23.33 hours, 23.36 hours, 23.54 hours, 00.01 hours and 00.04 hours. There are two more substantial decelerations at 00.16 hours to 70 - 80 bpm for 1.5 minutes and at 00.20 hours to 100bpm for 1 minute. There are irregular contractions. This is considered to be a suspicious CTG tracing.

- On the 4th May 2016 the CTG tracing from 00.51 hours to 01.02 hours shows the baseline fetal heart rate is initially 140 bpm, with reduced variability, and a prolonged deceleration occurred at 00.55 hours to 80 bpm until 01.02 hours. There are irregular contractions. This is a pathological CTG.

- On the CTG trace on the 4th May 2016 between 01.02 hours and 01.25 hours, the fetal heart rate is difficult to establish, but generally varies from 110 bpm to 140 bpm. It is not possible to determine timing of decelerations. This is a pathological CTG.

Baby Aaron was born in poor condition at 01:31 hours on the 4th May 2016; he was flat and unresponsive and was immediately transferred to the resuscitaire[3] where efforts were made to resuscitate him.

The Investigation Team identified that there had been two failed attempts to intubate Baby Aaron during resuscitation following delivery; there is no clinical documentation stating why the Paediatric Registrar was unable to intubate Baby A. Consultant Paediatrician C was contacted at approximately 01:35 hours, arrived in Theatre at 01:45 hours, assessed the situation and successfully intubated Baby Aaron at 01:51 hours.

At 05:00 hours Baby Aaron was transferred to a large Dublin Maternity Hospital (Hospital S2). Sadly, following intensive intervention Baby Aaron passed away at 01:40 hours on the 9th May 2016 while under the care of the neonatal team in Hospital S2.

Mrs X and her husband raised concerns related to the antenatal and intrapartum care delivered to Mrs X and the care and treatment delivered to Baby Aaron following delivery.

Based on these concerns an investigation of the incident was commissioned by Hospital Manager, Hospital S1, Health Services Executive (HSE).

From the outset Mrs X requested that Baby Aarons name be used throughout the report rather than be anomyised.

The Investigation Team acknowledge that even if Mrs X's care had all been carried out effectively, it is accepted that this would not necessarily have changed the ultimate outcome for Baby Aaron BUT the issues identified during the course of this investigation MUST be rectified to ensure that they do not recur as the care delivered to Mrs X and Baby Aaron in hospital S1 is at best

[3] A resuscitaire is a device which combines an effective warming therapy platform along with the components needed for clinical emergency and resuscitation (reference: http://www.draeger.ae/AE/en_US/products/neonatal_care/).

suboptimal and potentially dangerous and such deficits would not have lessened the problems for Baby Aaron.

Aim

The aim of this investigation as outlined in the terms of reference (Appendix A) was to establish whether there were any failures in relation to the care and management received by Mrs X and Baby Aaron during her admission to Hospital S1.

Purpose

The purpose of this investigation was to:

- Establish the factual circumstances leading up to the incident
- Identify any key causal factors that may have occurred
- Identify the contributory factors that caused the key causal factors
- Recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably practicable.

The reviewers who undertook this investigation were:

- Ms Deirdre O'Keeffe, Quality Improvement Division, HSE (Investigation Chairperson).
- Dr. Francois Gardeil, Consultant Obstetrician/Gynaecologist and Clinical Expert, Wexford General Hospital.

Forum[4] Nominated Consultant Obstetrician/Gynaecologist to the Investigation Team to review the Healthcare Record, CTG Tracing and validate the investigation report findings:

- External Expert Consultant Neonatologist/Paediatrician– Confirmed Nomination 16th May 2017.
- External Expert, Clinical Midwifery Manager, Labour Ward– Confirmed Nomination 16th May 2017.
- External Expert, Resuscitation Trainer and Neonatal Clinical Nurse Manager Neonatal Unit,– nominated 26th July 2017.

The Investigation Report was quality assured by an external specialist in the field of Midwifery and Nursing, at the request of the Investigation Team.

Nominated support to the external review team:

The commissioner identified the Quality and Patient Safety Manager to provide assistance to the external review team for the purposes of collating relevant policies and guidelines, healthcare records and to identify the names of staff involved in the care and treatment of Mrs X.

The Investigation Team wished to include Mrs X in the investigation process at an early stage in order to inform the review findings in a full and meaningful way.

This report outlines all of the discussion with Mrs X within the chronology and this information was considered in detail in the final report.

While the scope of the investigation relates to the timeframe from the 19th November 2015 until

[4] Where external expert input is required by the review team the HSE National Incident Management and Learning Team (NIMLT) will request a nominee from the Forum of Irish Postgraduate Training Bodies to secure an External Independent Expert to input to the HSE investigation

the 4th May 2016, in order to complete the chronology of events the Investigation Team took the view that it was essential to consider the healthcare records relating to the care and treatment Baby Aaron while under the care of clinicians at Hospital S2. An amended Terms of Reference was agreed on the 17th August 2017 by the Safety Incident Management Team.

In relation to the issues and concerns identified by Mrs X related to her care and management and that of Baby Aaron within hospital S1 for the period covered by this investigation, the investigation identified three Key Causal Factors.

The Three Key Causal Factors identified;

1. **Failure by staff in hospital S1 to effectively communicate on several occasions with each other, Mrs X, her husband and hospital S2;**
2. **Failure by staff to anticipate the potential severity of Baby Aaron's condition at delivery.**
3. **Failure by staff to complete and document all the required steps in the sustained neonatal resuscitation in this case within a desirable time-frame, including failure to assign a scribe to provide a full and accurate recording of the resuscitation efforts provided.**

In respect of the Incidental Findings the Investigation Team identified that elements of care provided fell well below an acceptable level. These incidental findings if not addressed have the potential to cause serious harm to patients.

The Investigation Team has made a number of recommendations to address the findings that have been identified during the investigation as contributing to the key causal factors related to this incident. These recommendations are made to address the risks associated with each contributory factor or hazard identified by the investigation using the hierarchy of hazard control measures as per the HSE Guidance document on conducting a systems analysis investigation (2012).

Summary of Recommendations

Recommendation 1 *(Hierarchy of Hazard Controls - Administrative Procedure):*
That a formal and agreed policy and procedure for the communication of information between the Obstetrician Gynaecology Consultant staff related to patients seen in the Antenatal Clinic and referred for admission to the Maternity Department is developed and implemented within 3 months of this report being finalised and that monitoring of the implementation of the procedure is incorporated into the routine audit schedule of the Department.

Recommendation 2 *(Hierarchy of Hazard Controls - Administrative Procedure):*
Remind all Health Care Practitioners of HIQA standards, HSE policies and procedures, HSE standards and recommended practices for healthcare records management (May 2011) and guidelines regarding communication, standards of the regulatory bodies such as the Irish Medical Council and the Nursing & Midwifery Board of Ireland. The Hospital Management must decide, in conjunction with the lead clinicians and Director of Midwifery, if retraining is required; what needs to be audited; how often and what sanctions may be considered in light of further breaches and how is that communicated to staff. Implement within 6 months of this report being finalised.

Hospital Response to Recommendation 2: Communication guidelines and escalation policies are in place. Communication policies and procedures are incorporated into the induction programmes of midwifery and medical staff. Non adherence to regulatory guidance standards is a matter for each practitioner and their line manager. Performance and disciplinary procedure applies.

Recommendation 3 *(Hierarchy of Hazard Controls - Administrative Procedure):*
Full implementation of the;
- *NCEC Clinical Handover Guideline in Maternity Services and the;*
- *Irish Maternity Early Warning System (IMEWS), which contain the communications tool ISBAR (identify, situation, background, assessment and recommendation);*
- *and the Patient Safety Pause, and checklists such as those published by the World Health Organization (WHO) in surgery and childbirth.*

and audit within 3 months of this report being finalised and follow-up on audit findings.

Hospital Response to Recommendation 3: Ongoing education of existing and new staff in relation to ISBAR, Clinical Handover Guideline. Patient Safety Pause implemented.

Recommendation 4 *(Hierarchy of Hazard Controls - Administrative Procedure):*
Hospital S1 as a priority must work with the Hospital Group to ensure all pregnant women have access to a fetal anomaly scan should the wish to avail of one. This recommendation must be communicated to the NWIP (National Women's and Infants Programme) in terms of available funding (if funding is required).

Hospital Response to Recommendation 4: This has been implemented. An anatomy scanning service is in place for all women. Second ultrasonographer is currently undertaking an MSc and training in the CWIUH.

Recommendation 5 *(Hierarchy of Hazard Controls - Administrative Procedure):*
That the HSE's National Acute Hospitals Division confirm CTG training as a mandatory training requirement for all Obstetrics and Gynaecology Medical Staff and Midwives. The frequency of this training is to be established in accordance with best practice. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner

Recommendation 6 *(Hierarchy of Hazard Controls - Administrative Procedure)*
That Hospital S1 conduct an audit of compliance with the guideline Mandatory K2 Fetal Monitoring Training (PHOG019) including the requirement to participate in and complete CTG training in a given twelve month period. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner and non-compliance is to be addressed within 3 months of the audit.

Hospital Response to Recommendation 6: Mandatory K2 training in place annually for all obstetric and midwifery staff. Mandatory In addition CTG study day attendance mandatory for all midwifery staff bi-annually

Recommendation 7 *(Hierarchy of Hazard Controls - Administrative Procedure)*
That systems and processes are established, up to and including the disciplinary process, within each National Division to ensure compliance with mandatory training. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Recommendation 8 *(Hierarchy of Hazard Controls - Administrative Procedure):*
Develop a hospital group networked maternity/neonatal referral guidelines and patient pathways

*which must include criteria to ensure equitable access to the service based on clinical need across the hospital group**.** This is a national requirement. There is a need for each Hospital Group to have to develop separate pathways especially when most traffic is to one of the 3 Dublin maternities whether for feto- maternal consultation or neonatal consultation. There is a need to specifically address urgent referrals such as in Mrs X's case during the out of hours (a Friday afternoon of a bank holiday weekend and during nights). Implement within 6 months of this report being finalised.*

Recommendation 9: *(Hierarchy of Hazard Controls - Administrative Procedure)*
As recommended in the National Maternity Strategy Hospital S1 must ensure that multi-disciplinary training takes place at each hospital/unit within their network. This should include at the very least CTG interpretation, NRP, Stable & PROMPT, Communication, Clinical Handover, IMEWS and ISBAR training. The Hospital management in conjunction with the Clinical leads (in Obs and Neo) and Director of Midwifery should;
1) set a standard for frequency of such training in the absence of a nationally agreed one;
2) devolve responsibility/oversight of this to a named person/ group;
3) specify requirement for quarterly training logs of the MDT to be reviewed by the maternity and neonatal service and remedial action to be taken in cases of non- compliance with attending training and/or compliance with the standard of care and communication up to and including invoking of disciplinary process if and when required.
Implement within 6 months of this report being finalised.

Hospital Response to Recommendation 9: Maternity Guideline Committee has developed a suite of guidelines to address the most common obstetric emergencies. The committee has developed the guidelines from a MDT perspective.

Recommendations – Incidental Findings

Recommendation 10: *(Hierarchy of Hazard Controls - Administrative Procedure)*
Hospital S1 must have in place a Guideline in place for the follow-up of abnormal diagnostic results. This must take cognisance of the appropriateness of the request in line with clinical presentation.

Recommendation 11: *(Hierarchy of Hazard Controls - Administrative Procedure)*
The unit at Hospital S1 should ensure that they have in place, guidelines for the 10-12 most common obstetric complications within 6 months of this report being finalised and that they continue to build on these. These should include both the obstetric and midwife components of care; by way of example

- *Monitoring of the fetal heart*
- *SROM*
- *SROM with clear liquor in women at term in spontaneous labour with a well engaged fetal head and satisfactory fetal heart rate and no other discernible problems and is not the potential emergency,*
- *meconium stained liquor,*
- *history of significant polyhydramnios and other potential fetal / maternal complication etc.*

Recommendation 12: *(Hierarchy of Hazard Controls - Administrative Procedure)*
Hospital S1 must have in place a guideline for the management of CORD AND MATERNAL BLOOD SAMPLING and deviations from practice must be reported and managed appropriately. All staff should perform these techniques in accordance with the Hospital Group Standard Infection Prevention guideline. The Acute Hospitals Division should ensure that this recommendation is circulated to all relevant hospital groups for implementation.

Recommendation 13: *(Hierarchy of Hazard Controls - Administrative Procedure)*
Hospital S1 must ensure that 'Debriefing' following a neonatal resuscitation is in place and

implemented. There must be a process in place to ensure that critical incident debriefing is made available to all staff involved (including porters where they were involved etc) within 72 hours of a critical incident and that there is a SOP in place to ensure the procurement and provision of same and a means to release all staff involved where at all possible. Lesser events may be dealt with by informal debriefing within unit level but again management of the Unit should have a SOP in place to ensure that this is routinely offered to all staff members involved irrespective of discipline / rank. Finally, the Hospital must ensure that it has in place, an Employee Assistance Programme whereby staff members can easily self-refer for free and confidential counselling on a 24/7/365 basis.

The HSE HR (local, regional, national) should review the effectiveness of this programme and modify as required, This aspect is particularly important in that ? 2 of the staff members interviewed appear tp have explained that they no longer work at this unit although the reasons why, do not appear to have been explored or noted as relevant to this Investigation.

Hospital Response: A Debriefing service is offered following a critical incident in the maternity department. This is facilitated through the employee assistance and counselling service. This service is automatically arranged by a senior line manager in the event of a critical incident. This service was offered following this incident but unfortunately staff did not avail. Local debrief also took place at the time and takes place in these circumstances to support staff.Employee assistance and counselling services are advertised across the hospital and form part of the support mechanism. A standard operating procedure is to be divised (SOP).

Recommendation 14: *(Hierarchy of Hazard Controls - Administrative Procedure)*
The Unit at S1 must have a policy for call taking. All calls should be logged and reviewed on an on-going basis by the shift leader so it is known who is expected in and to be able to go back and audit advice given. There should be an agreed SOP to guide and monitor this practice of advice

Apology

On behalf of the Hospital, I would like to thank you both for your engagement with this investigation process and acknowledge your contribution to this final report. I understand that this was a difficult and demanding process for your family.We apologise for the length of time this review has taken and for you to receive a copy of this report.

I accept the investigators findings and we apologise sincerely for this and for your overall experience in our services. The process of addressing the key care delivery issues will continue to have my full support so that the hospital will avoid these poor elements of care occurring in the future.

An action plan is being finalised which I will closely monitor, along with the Maternity Governance Committee, to ensure all of the outstanding recommendations made in this report are implemented.I have attached an update from the hospital (Appendix N) on how the recommendations have been addressed to date.

Please be assured that the experience of you, your husband and Baby Aaron will significantly contribute to how we work to improve our care pathways into the future. Progress has been made to develop a more established maternity clinical network which is contributing to how we work to improve our care pathways. A significant change to the service includes the introduction of a foetal anomaly scanning service for all women, one of the first regional hospitals in this country to do so.

The recommendations will be shared with the National Women and Infants Health Programme to ensure learning across all maternity services.

General Manager

Acknowledgement

The Investigation Team greatly appreciated the willingness of Mrs X and her husband to share their experience with us. This was invaluable in carrying out the review and in the development of the recommendations.

It is the sincere hope of the Investigation Team that this investigation has addressed all of the issues that Mrs X and her husband have sought.

The commissioner of this report and the senior clinical staff interviewed for this review outlined that all safety incidents within their services should be comprehensively investigated within a reasonable timeframe. They wished to identify and learn from any lessons that might help to prevent any further incidents of this nature and help improve the reporting and investigation of similar serious events in the future.

The Investigation Team would also like to acknowledge the co-operation of the HSE staff we met with as part of the investigation.

Methodology

The investigation was undertaken using the methodology for incident investigation as outlined in the HSE Guideline for the Systems Analysis Investigation[5] of Incidents (August 2016).

Systems analysis is an internationally recognised methodology for investigating adverse incidents in healthcare. A systems analysis investigation is a structured investigation that aims to identify the systems cause(s) of an incident or complaint and the actions necessary to eliminate the recurrence of the incident or complaint or where this is not possible to reduce the likelihood of recurrence of such an incident or complaint as far as possible.

Healthcare services carry out incident investigations using systems analysis to find out what happened, how it happened, why it happened, what the organisation can learn from the incident and what changes the organisation should make to prevent it happening again.

From the outset Mrs X and her husband wished to use Baby Aaron's name throughout the report, as they did not want the term 'Baby X' used when referring to Aaron as this was considered to be very impersonal.

In consideration of anonymisation, throughout this report where staff are referred to as he or she, that does not necessarily indicate their gender.

While carrying out this investigation the reviewers examined relevant documentation and information including the following:

- Mrs X's relevant healthcare records from Hospital S1 and Private Clinic Healthcare Records
- Baby Aaron's Healthcare records from Hospital S1
- Baby Aaron's Healthcare records from Hospital S2 (Chronology is contained in Part 2 of External Expert Consultant Report in Appendix C)
- All relevant Radiology Examinations from Hospital S1 and Hospital S2
- On call roster for Consultant Staff April and May 2016
- Rapid System Quality Control, Service Reports for Analyser 1& 2, Maintenance logs for May 2016.
- Calibration Reports: RAPIDLab 1200, Device Events History: Labour Ward (04/05/16), C Diagnostics Ltd: Service level Agreement dated 08/09/2014
- Laboratory Standard Operating procedure for Blood Gas Analyser 2017 (Revision No. 1) -0ut of scope.
- Rapid System Blood Gas Analyser RAPIDLab 1200 Training records, Dated 2013
- Guideline, Fetal Blood sampling by Obstetric Medical Team, Dated May 2016 (NO indication whether this was pre or post 4th May 2016).
- K2 (CTG) and Blood Gas Training records and log at the time of this incident (Appendix E).
- Resuscitation Algorithm NRP Neonatal resuscitation (Appendix F)
- Letter from National Devices Lead (Appendix G)
- Model of Care for Neonatal Services in Ireland, 2015, HSE and RCPI (Appendix J)
- Letter outlining Referral process to Hospital S2 (Appendix H)
- Referral Form used at Hospital S1 (Appendix I)
- Access to Baby Aaron's post-mortem report
- Two National Incident Management System Reporting Forms dated the 4th May, 2016 and the 10th May, 2016.

[5] A systems analysis investigation is a structured investigation that aims to identify the systems cause(s) of an incident or complaint and the actions necessary to eliminate the recurrence of the incident or complaint or where this is not possible to reduce the likelihood of recurrence of such an incident or complaint as far as possible. Healthcare services carry out incident investigations using systems analysis to find out what happened, how it happened, why it happened, what the organisation can learn from the incident and what changes the organisation should make to prevent it happening again.

Additional Documentation Considered By the Investigation Team

- A detailed statement was provided by Mrs X and her husband
- Relevant Policies, Procedures and Guidelines from Hospital S1

In addition interviews were undertaken with Mrs X who was accompanied by her husband and sister. Staff involved in Mrs X's antenatal and perinatal care were also interviewed as part of this investigation process.

A total of 14 people were interviewed as part of the investigation. Those interviewed included:

Family Members Interviewed

- Mrs X and her Husband Mr X Interviewed on 21 December 2016
- Mrs X's Sister on 21 December 2016 accompanied Mrs X for interview

Clinical Staff

- Consultant Obstetrician and Gynaecologist A Interviewed on 21 December 2016
- Consultant Obstetrician and Gynaecologist B Interviewed on 21 December 2016
- Consultant Paediatrician C Interviewed on 21 December 2016
- Midwife M1– Hospital S1 – Interviewed on 21 December 2016
- Midwife M2– Hospital S1 – Interviewed on 21 December 2016
- Midwife M3– Hospital S1 – Interviewed on 21 December 2016
- Midwife M4– Hospital S1 – Interviewed on 21 December 2016
- Midwife M5– Hospital S1 – Interviewed on 21 December 2016

The Investigation Team in conjunction with the clinical experts met with Mr and Mrs X on the 9th August 2017 as part of the investigation process.

The family requested to meet with the Clinical Experts with the Investigation to provide their account of the chronology.

In addition to meeting with the family the Clinical Experts assigned to the investigation process identified that it would be beneficial to their analysis of the chronology of events to meet with relevant staff involved in the perinatal care and treatment of Mrs X.

The Investigation Team therefore identified the following staff invited to be re-interviewed on the 4th of October 2017:

Staff re-interviewed included:

- Consultant Paediatrician C, Hospital S1 - Interviewed on the 4th October 2017
- Midwife M1, Hospital S1 – Interviewed on the 4th October 2017
- Midwife M2, Hospital S1 – Interviewed on the 4th October 2017
- Midwife M3, Hospital S1 – Interviewed on the 4th October 2017
- Special Care Baby Unit Nurse M4, Hospital S1 - Interviewed on the 4th October 2017
- Special Care Baby Unit Nurse, M5 Hospital S1 – Interviewed on the 4th October 2017

Additional Staff interviewed:

- Midwife M6, Hospital S1 - Interviewed on the 4th October 2017
- Midwife M5, Hospital S1 - Interviewed on the 4th October 2017
- SHO Paediatrics, Hospital S1- Interviewed on the 4th October 2017

The Investigation Team worked in collaboration with the clinical experts in relation to specific clinical aspects and issues highlighted by the overall systems analysis investigation process.

The input of the clinical experts was sought by making a request to the HSE National Incident and Learning Management Team (NIMLT) and Forum of Irish Postgraduate Medical Training Bodies (the 'Forum') who sought the relevant nominations from the following faculties:

- Faculty of Obstetricians and Gynaecologists at the Royal College of Physicians of Ireland.
- Faculty of Paediatrics (sub-speciality neonatology) at the Royal College of Physicians of Ireland.

Clinical Experts Assigned to the Investigation

- Dr. Francois Gardeil Consultant Obstetrician and Gynaecologist, Wexford General Hospital
- External Expert, Consultant Neonatologist,
- External Expert, Midwifery Expert,
- External Expert, Clinical Nurse Specialist in Neonatal Resuscitation,

Appointment of an Independent Expert in Obstetrics and Gynaecology (To form part of the Investigation Team)

As a result of the request from the NIMLT to the Institute of Obstetricians and Gynaecologists Royal College of Physicians through the 'Forum' for an Obstetric nomination, Dr. Francois Gardeil was assigned to undertake the review of Mrs X's healthcare record and provide a report to the Investigation Team.

In November 2016 Dr Gardeil was provided with a copy of Mrs X's healthcare record relating to Mrs X's antenatal outpatient attendances and admissions to Hospital S1, all sections of the CTG and fetal heart trace prior to and during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Aaron was born. Dr. Gardeil's report is available in Appendix B.

Appointment of an Independent Clinical Expert in Neonatology

As a result of the request from the NIMLT to the Institute of Paediatricians Royal College of Physicians through the 'Forum' for a neonatology nomination, External Expert Consultant Neonatologist was assigned to undertake the review of Baby Aaron's healthcare record from Hospital S1.

Independent Clinical Experts were sought by the Investigation Team and at the request of the family. The family outlined their concern at the length of time required to source experts for an investigation and this must become a more efficient process.

In July 2017 Expert External Consultant was provided with a copy of Mrs X's and Baby Aaron's healthcare records from Hospital S1 including a copy of the record relating to Mrs X's antenatal outpatient attendances and all sections of the CTG and fetal heart trace during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Aaron was born.

Expert External Consultant report was received by the Investigation Team on the 11th May 2018 and is included in this report (Appendix C: Part 1 and 2).

Following interviews carried out by the Investigation Team on 21st December 2016 Consultant Paediatrician C requested that a Neonatologist should be present for his interview. Consultant

Paediatrician C was therefore re-interviewed on the 4th October 2017 as previously described.

Mr and Mrs X also requested to meet the Investigation Team with the external expert Consultant so that they could provide an account of their recollections of the events leading up to Mrs X's delivery of Baby Aaron.

In addition the external expert Consultant deemed it beneficial to meet with the family and relevant staff to inform his report for the investigation. The Investigation Team also attended this meeting and recorded the minutes of the meeting.

In line with fair procedures it was therefore deemed appropriate to afford all relevant staff an opportunity to meet with the External Expert Consultant should they wish to provide him with an account of events in addition to their earlier interview with the Investigation Team on the 4th October 2017.

Appointment of an Independent Clinical Expert in Neonatology Resuscitation

As a result of the request to the Hospital Group for a neonatology resuscitation nomination, External Expert was assigned to undertake the review of Baby Aaron's healthcare record from Hospital S1.

In July 2017 External Expert was provided with a copy of Mrs X's and Baby Aaron's healthcare records from Hospital S1 including a copy of the record relating to Mrs X's antenatal outpatient attendances and all sections of the CTG and fetal heart trace during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Aaron was born.

External Expert's report was received by the Investigation Team on the 13th December 2017 and is included in this report (Appendix D).

Mr and Mrs X also requested to meet the Investigation Team with External expert neonatal rescucitation so that they could provide an account of their recollections of the events leading up to Mrs X's delivery of Baby Aaron.

In addition External Expert neonatal rescucitation deemed it beneficial to meet with the family and relevant staff to inform her report for the investigation. The Investigation Team also attended this meeting and recorded the minutes of the meeting on the 4th October 2017.

In line with fair procedures it was therefore deemed appropriate to afford all relevant staff an opportunity to meet with External Expert should they wish to provide him with an account of events in addition to their earlier interview with the Investigation Team on the 4th October 2017.

Appointment of an Independent Clinical Expert in Midwifery

External Expert Midwifery is an external midwifery expert sourced by the Dublin Midlands Hospital Group to review the midwifery care for this investigation.

In July 2017 External Expert was provided with a copy of Mrs X's healthcare records from Hospital S1 including a copy of the record relating to Mrs X's antenatal outpatient attendances and all sections of the CTG (COPIES) and fetal heart trace during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Aaron was born. At the request of External Expert Midwifery, the original CTG trace was provided for review.

External Expert Midwifery report was received by the Investigation Team on 9th January 2018 and is included in this report (Appendix E).

The Interview Process

Prior to the interviews taking place each Investigation Team member received a paginated set of clinical records along with the Investigation Terms of Reference. It was possible for each Investigation Team member to identify potential staff to be interviewed and questions that needed to be asked.

The interviews were conducted by all members of the Investigation Team. Additional interviews were conducted by the investigation team and included all clinical expert nominees at the request of some staff and the family. The interviews were conducted in a manner that aimed to ensure that the optimal levels of information were obtained whilst ensuring that the individuals being interviewed were treated with dignity and respect.

The Terms of Reference for the review were provided to all interviewees prior to their attendance at interview.

In addition as the review was carried out using a systems analysis methodology, everyone interviewed received information about the interview process and systems analysis investigations.

All information and documentation gathered during the investigation and interview process were treated confidentially. Information gathered was maintained securely, electronic documents were password protected and codes have been used to replace the names of individuals involved in the incident. The review team received consent from Mrs X to access all her healthcare records relevant to this investigation.

The Investigation process was conducted in a manner that was respectful of the rights of all to privacy and confidentiality. The Investigation process has been carried out in accordance with natural justice and fair procedures.

Each individual interviewed was informed in advance of the interview and that notes would be taken of the discussions at the interviews for the purpose of ensuring accuracy. The interviews were used as an opportunity to establish the facts of the incident, to clarify information for the Investigation Team and as an opportunity for parties involved in the incident to present information to the Investigation Team. If staff had any concerns about the interview process, they were invited to communicate these concerns to the interviewers or to the investigation commissioner.

Each individual interviewed was advised that they could bring their personal written account of the incident which could be used as an Aide Memoire by the interviewee or could be submitted to the Investigation Team for consideration.

In advance of the interviews all parties were informed of their entitlement to be accompanied at interview. In order to ensure the confidentiality of the interview process for all involved, accompanying individuals not employed by the HSE were asked to sign a confidentiality agreement. Prior to the interviews each individual was informed of the opportunity to review their interview transcript and the draft report whereby they would have an opportunity to review and comment on/check the factual accuracy of the draft report.

On completion of the interviews the relevant sections of the Draft Report was shared with all of those individuals who were interviewed as part of the investigation to ensure that the report was factually accurate; amendments were made to the Draft Report following receipt of submissions by all parties.

The Final Draft Report identified recommendations to address those issues which were considered by the Investigation Team to have contributed to the serious adverse event and feedback was sought on the recommendations identified. On this basis the Final Report of the investigation was developed and submitted to the commissioner Hospital Manager, Midlands Regional Hospital.
Prior to finalising the report Mrs X and her husband requested that Baby Aaron be identified by name in the final report.

Limitations to the investigation:

The events that were the subject of this investigation occurred in May 2016; when the investigation commenced the Paediatric Registrar who was involved in the resuscitation of Baby Aaron no longer worked within the jurisdiction.

The Investigation Team made contact with the Paediatric Register and invited him to participate in the investigation. The Terms of Reference, a letter of invite and a number of questions that the investigation team required a response to in order to complete the chronology were issued to the Paediatric Registrar via e-mail and documented were password protected.

Unfortunately despite efforts the staff member informed the investigation team that he remembered the combined note he made with the Paediatric NCHD and agreed with the records. However regarding the answering of the questions he was unable to recall those specific events, therefore his documentation was all that could be used.

Background to this Investigation

Details provided in this report have been obtained from the review of relevant documentation as listed on page 26 of this report; and on the basis of interviews with relevant staff and Mrs X and her husband.

Wednesday 7th October 2015

No Time

Mrs X first attended her GP on the 7th October 2015 as her last menstrual period (LMP)[6] was the 29th August 2015. This was a planned pregnancy for Mrs X and her husband. A pregnancy test carried out and had routine pregnancy blood tests carried out by her GP on the 7th October 2015 which suggested Mrs X was in the early stages of pregnancy. The pregnancy test was positive. The blood tests were normal; blood group A Positive[7], Rubella immune, VDRL (test for syphilis) negative and negative serology for Hepatitis B and HIV infection. Mrs X was referred by her GP to Consultant Obstetrician and Gynaecologist A for her first booking visit.

Thursday 14th October 2015

Mrs X attended a scheduled GP visit as part of her combined antenatal care.

Thursday 29th October 2015

It is documented in a GP Practice referral letter by the Practice Nurse that Mrs X was referred to Hospital S1 on the 29th October 2015 for antenatal care under the combined ante natal programme. This referral letter included the following details:

- This was Mrs X's first pregnancy
- Mrs X was estimated to be 5 weeks gestation
- Mrs X had no previous miscarriages
- Pregnancy test was carried out on the 7th October 2015
- LMP (Last menstrual period) 29th August 2015
- EDD (Estimated date of delivery) 4th June 2016
- Blood Pressure: 116/77
- Urine – Negative for evidence of infection
- Weight: 78.5 kgs
- Oedema: Nil

It is also documented on this referral form that Mrs X's next GP visit was due on the 14th October 2015 next obstetrician visit due 18th November 2015. Mrs X had no vomiting or headaches, she experienced occasional abdominal cramps, no pv bleeding, she was taking folic acid, stopped cigarettes, had occasional palpations, no chest pains, and an occasional cough. On examination the following was captured on the referral:

- pulse 74
- temp 37,

[6] LMP: last menstrual Period

[7] Blood types are either A, B, AB, or O, and Rhesus (Rh) positive or negative. Both the mother and baby may experience problems if their blood types are different, or if the mother has antibodies that will react with factors on the baby's blood cells .
(Reference: http://www.labtestsonline.org.uk/understanding/wellness/pregnancy/first-antibody).

- heart normal,
- chest clear
- abdomen soft
- Urinalysis normal
- BCHG positive

Plan

Observe, if any other abdominal pains and/or any PV bleeding, stat review, repeat Urinalysis and BHCG 1/52 with nurse and Antenatal bloods, if chest pains/dizziness, or worsening of palpitations/Shortness of breath: stat review.

This was Mrs X's first pregnancy. All blood tests were considered normal; blood group A Positive[8], Rubella immune, VDRL (test for syphilis) negative and negative serology for Hepatitis B and HIV infection. Mrs X was then referred by her GP to Consultant Obstetrician and Gynaecologist A for her first booking visit on the 4th November 2015.

Mrs X had her first visit (the booking visit) at the antenatal clinic at Hospital S1 on the 19th November 2015. Ms X was a healthy young woman. She had quit smoking when she became pregnant.

On the 19th November 2015 at the booking visit Mrs X gave the 29th August 2015 as the first day of her last menstrual period (LMP). A pelvic ultrasound scan carried out confirmed Mrs X's gestation dates to be accurate. On this basis her estimated date of delivery (EDD) was calculated and agreed to be the 4th June 2016. Consultant Obstetrician and Gynaecologist A performed the scan which confirmed viability, and measurements of the fetus were consistent with 14 weeks and 3 days gestation based on the LMP.

[8] Blood types are either A, B, AB, or O, and Rhesus (Rh) positive or negative. Both the mother and baby may experience problems if their blood types are different, or if the mother has antibodies that will react with factors on the baby's blood cells. (Reference: http://www.labtestsonline.org.uk/understanding/wellness/pregnancy/first-antibody).

Chronology of Events[9]

Details provided in the chronology have been obtained from a review of the relevant documentation, medical records and interviews with the relevant personnel. Timings are based on records, Mrs X and her husband and relevant staff recollections.

Thursday 19th November 2015

No Time Midwife M1 Entry

It is documented in Mrs X's healthcare records that Mrs X attended a scheduled antenatal booking clinic in hospital S1. The following is documented by a Midwife M1 under:

Under **Current Pregnancy** it is documented:

- Gravida: 1
- Para: PO+0

Under **Menstrual History** it is documented**:**

- Length of cycle: 28-30 days
- Regular
- Contraception yes
- Planned pregnancy
- LMP: 29th August 2015
- EDD 4th June 2016

Under **Problems (E.g. Bleeding, vomiting, PV discharge, haemorrhoids, varicose veins, oedema, urinary symptoms, visual disturbance or any other problems)** it is documented that:

Mrs X had a scan with Consultant Obstetrician and Gynaecologist A in a private capacity at 10+2 gestation. This ultrasound Scan was noted to be normal.

Under **Medication** it is documented:

- Post conception Pregnacare tablets

Under **Physical Examination** it is documented:

- Baseline weight: 77.4kgs
- Height: 155.5cm
- Body mass index: 32

Under **Risk Factor Assessment** it is documented

- No risk factors identified on the checklist containing 41 potential risk factors:

Under **Obstetric History** it is documented:

Pregnancy problems / complications: PRIMIP (primiparous - Giving or having given birth for the first time)

[9] Bold Italics used throughout the chronology of events section indicate direct quotes from medical records and all interviewees

Under **Social History** it is documented that:

- Mrs X did not have a family social worker. Not required.
- There were no on-going problems at present.

Under **Medical History** it is documented:

- Hypertension – No
- Cardiac Disease - No
- Respiratory - No
- Gastro intestinal - No
- Renal - No
- Bowel - discomfort for 2 years under other
- Haematological - No
- Metabolic disorders e.g. PKU No
- Endocrine - No

Under **Mental Health** it is documented:

- History of anxiety. Never medicated, well at present.
- Substance misuse – no
- Cigarettes – Quit smoking

Other

- Neurological - No
- Infection History – No
- Connective Tissue Disorder - No
- Anaesthetic Risk – No
- Allergies – No NKDA (No Known Drug Allergies)
- Gynaecological History - No
- Last Smear - ? 2011 Normal
- Would you accept a blood transfusion in case of an emergency? Yes

Under **Previous History** it is documented:

- Mrs X had no previous history

Under **Partner History/ Family History** it is documented:

- Adopted: Partner/husband

Under **Mother** it is documented:

- No Family history to report.

Other conditions

It is documented by Midwife M1 that Mrs X's father has haemochromatosis. Mr X's mother had a renal transplant and Mr X also has a hearing disability.

Under the section **Record of Antenatal Visits** it is documented:

- Para: PO+0
- EDD 4th June 2016
- Age 29 years old
- Rhesus status: 0 Positive

- Date/Time: 19th November 2015
- Gestation by agreed date: 14+2
- Maternal Pulse 70
- BP 126/64
- Routine Bloods and GTT @ 28/40
- HB 15.2 g/dL (14th October 2015)
- Booking bloods done by GP (Midwife M1)
- Pregnancy Risk assessment for Gestational Diabetes
- Booking BMI ≥30kg/m^2

It is documented in the healthcare records that a Glucose tolerance test offered and accepted by Mrs X.

Pregnancy Information given to Mrs X

1. Protecting You and Your Baby – Your First Antenatal Visit Leaflet
2. Information pack given which includes Folic Acid supplementation
3. Food hygiene, including how to reduce the risk of a food acquired infection
4. Nutritional supplements
5. Useful telephone numbers and websites

Under Smoking during Pregnancy it is documented by Midwife M1 that Mrs X quit Smoking.

Under Alcohol Consumption during Pregnancy it is documented by Midwife M1 that no alcohol consumption advised.

Midwife M1 completed the Infant Feeding Antenatal checklist completed: Advised to attend Breast feeding antenatal classes.

Friday 4th December 2015

No Time

Mrs X attended Consultant Obstetrician Gynaecologist A antenatal clinic on the 4th December 2015 for her first booking ante-natal clinic appointment where an ultrasound scan indicated at this point that she was 13 weeks and 4 days gestation, confirming her estimated date of delivery (EDD) as 4th June 2016.

It is documented by Consultant Obstetrician and Gynaecologist A in Mrs X's Record of Antenatal Visits contained within Mrs X's healthcare record under;

Comments/Findings:

- Maternal BP: 135/71
- Pulse: 97
- Urine: NAD
- Nuchal Translucency Screening[10] was carried out and was normal
- To return to her GP in 4 and 8 weeks' time
- Adequate Liquor noted on the ultrasound scan.

[10] Nuchal translucency (amount of fluid behind the neck of the fetus on ultrasound) carried out at 11 – 13+6 weeks

Friday 1st – 5th January 2016

Mrs X informed the Investigation Team that she had a chest infection over 3 week period and as a result attended her GP on the 5th of January, at this visit Mrs X's GP prescribed her Clonamox for one week.

Thursday 4th February 2016

No Time - GP Visit and Referral Letter to Hospital S1

On the 4th February 2016 Mrs X presented to her GP complaining of intermittent worsening palpitations, which was of concern to the GP and required a referral to the maternity assessment Unit in hospital S1 for further investigation. An ECG and bloods were carried out on the day. The Echo and 24 hour heart monitor[11] were arranged for later date.

15:05 Hours – MAU Hospital S1

It is captured in the healthcare records that Mrs X presented to Hospital S1 at 15:05 hours.

Obstetric SHO Entry

Mrs X presented to the Maternity Assessment Unit (AMU) following her GP review. It is documented in Mrs X's healthcare record by the Obstetric SHO (Senior House Officer)[12] that Mrs X was:

- 29 years old
- Parity 0+0
- Gestation 22 weeks
- Onset of regular contractions
- Show - NO
- Membranes Intact
- Mrs X had no surgical history.

Under Medical History it is documented by SHO that:

- History of Anxiety which has not been present for 2 years
- Query Mrs X has a heart murmur as a teenager with no follow-up required.
- Vital signs as per IMEWS Chart: = 0
- Urinalysis: Trace protein and Trace Leukocytes
- No Oedema
- For review by medical team on call.
- Discussed with Mrs X's presentation with Medical Registrar on call who review Mrs X
- Possibly for an ECHO.

Midwife M6 Entry

According to an entry by Midwife M6 in the healthcare record there was no requirement for a vaginal examination.

- Obstetric history Primip (First time pregnant)
- Reason for Presentation to MAU: GP referral with heart palpitations. It was documented that Mrs X experienced frequent episodes of breathlessness when walking.
- No Current Medications

[11] Results of echo and heart monitoring were normal.

[12] An SHO is a trainee doctor.

- Plan of care/Management: Obstetric SHO reviewed Mrs X. The Medical Registrar was contacted and will also review Mrs X. On examination Mrs X's abdomen was soft and non- tender.
- Fundus was in line with dates
- Overall Mrs X feels well

It is also documented by Midwife M6 that on Abdominal Palpation the size of uterus is in line with gestation dates.

16:00 Hours Medical Registrar On-Call Entry

It is documented in Mrs X's healthcare record by the Medical Registrar A on call that he was asked to review Mrs X.

The Medical Registrar A on call documented the following:

- 22 weeks pregnant
- Present complaint of palpations for 3 weeks
- chest pain reported
- Feels shortness of breath on exertion
- GP possibly identified a murmur on chest auscultation
- Not on regular medication

On Examination

- Looks well
- Not dyspnoeic
- Thyroid not enlarged
- BP 123/83
- Heart Rate 89 regular
- Sat 99% on R/A
- Chest no crackles no wheeze
- Good air entry bilaterally

CVS - Normal

- Soft systolic heart murmur

No ankle oedema

Plan

- Do ECG and Echo
- For a 24 hour Holter Monitor
- Check Thyroid Function Test
- Can be discharged medically.

16:35 Hours Obstetric SHO Entry

It is documented by the Obstetric SHO that Mrs X had gone for an ECG. Thyroid Function Tests were carried out and sent to the laboratory.

16:50 Hours Obstetric SHO Entry

It is documented by the Obstetric SHO in the healthcare record that Mrs X had an ECG performed and that the Medical Registrar on call was requested to review.

The Investigation Team considers that there is no apparent follow up of this recommended action. It is not clear how one can ensure that actions are implemented or if reviewed and not required, this should be documented.

Saturday 20th February 2016

On the 20th February 2016 Mrs X had a Private 26 week Anomaly Scan with Consultant Obstetrician Gynaecologist A at his private clinic. The findings of this scan revealed a normal fetus however it was noted at the time of the scan that Baby Aaron's bladder did not empty over the 30 minute scan period.

A follow up appointment was made for two weeks' time in Hospital S1 outpatient clinic.

During the feedback process Mrs X stated that a fetal anomaly scan was not available in Hospital S1 and at no time was she informed that anything '*could possibly be wrong'*.

Mrs X stated during the feedback process that it is so important for a mother to be prepared for what is to come; if the anomaly scan was available it can prepare parents. Mrs X stated that she did not go for the anomaly scan for any particular reason, it was not routine and therefore was not offered. Mrs X elected to attend Consultant Obstetrician and Gynaecologist A privately to have this anomaly scan carried out as she wanted the best care for her baby.

No Time

Mrs X informed the investigation team that she attended for a private 26 week Anomaly Scan with Consultant Obstetrician and Gynaecologist A at his private clinic.

> *'I attended Hospital S1 and Consultant Obstetrician and Gynaecologist A as a public patient. The findings included everything was normal with baby except the baby's bladder did not empty over the 30 minute scan period. A follow up appointment was made for two weeks' time in hospital S1 outpatient clinic. Mrs X had an appointment every two weeks from this date until the baby was born; baby was scanned at each appointment. At every appointment Consultant Obstetrician and Gynaecologist A said that the bladder was always full but was not distending further. He thought that the bladder was releasing slowly. Over next 1-2 appointments he noted that the right kidney was dilated. Fluid around the baby was normal. Consultant Obstetrician and Gynaecologist A informed me that he was not concerned and would look for a second opinion if he was. He also said that the extent of the problem would not be known until the baby was born'.*

Friday 26th February 2016

No Time

It is documented in the healthcare record that Mrs X attended for her routine antenatal appointment in Hospital S1.

It is documented by the NCHD that;

- Agreed Gestation: 26 weeks
- Fundal height (cm) 27 D
- Presentation/Lie: Cephalic

- AFI[13] (Amniotic Fluid Index) – Normal (to be measured in cm – but measurement not recorded)
- Fetal movement: yes
- Fetal Heart Heard: Yes
- BP recorded: 125/67
- Urine Nothing Abnormal Detected

Comments: Fetal Movement Good and antenatal classes booked. Pregnancy going well.

- Fetal Bladder on scan contains 30-33 mls urine
- Mrs X to return in 2 weeks to GP and Hospital in 3 weeks

Mrs X outlined during the feedback process that;

> *'The following week I was due to go to the hospital following week. He (Consultant Obstetrician and Gynaecologist A) actually had a colleague (Another Obstetrician) scan me this day, and this Obstetrician said everything is fine. Consultant Obstetrician and Gynaecologist A wanted to see me himself, so this Obstetrician brought Consultant Obstetrician and Gynaecologist A to see me and they had a disagreement about the bladder empting on a 20 to 30 minute cycle.*
>
> *Consultant Obstetrician and Gynaecologist A stated this needs to be watched and that he would keep an eye on it.*
>
> *At every appointment Consultant Obstetrician Gynaecologist A said that the bladder was always full but was not distending further: He thought that the bladder was releasing slowly. Over next 1-2 appointments he noted that the right kidney was dilated. Fluid around the baby was normal. Consultant Obstetrician Gynaecologist A informed Mrs X and her husband that he was not concerned and would look for a second opinion if he was. He also said that the extent of the problem would not be known until the baby was born'.*

Monday 29th February 2016

19:00 Hours

Mrs X outlined that she had been complaining of complaining of spasmodic upper abdominal pain since 19:00 hours.

23:30 Hours Midwife Entry

The Review risk factor assessment Sheet and Documented Significant Events was completed by the Midwife:

It is documented by the Midwife in the healthcare record that Mrs X presented to the Maternity Assessment Unit at Hospital S1 complaining of spasmodic upper abdominal pain since 19:00 hours. The healthcare records state:

[13] An AFI between 8-18 is considered normal. Median AFI level is approximately 14 from week 20 to week 35, when the amniotic fluid begins to reduce in preparation for birth. An AFI < 5-6 is considered as oligohydramnios. The exact number can vary by gestational age. AFI is the score (expressed in cm) given to the amount of amniotic fluid seen on ultrasonography of a pregnant uterus. To determine the AFI, doctors may use a four-quadrant technique, when the deepest, unobstructed, vertical length of each pocket of fluid is measured in each quadrant and then added up to the others, or the so-called "Single Deepest Pocket" technique.

- Obstetric history – 26 weeks and 3 days gestation
- Reason for referral: history of spasmodic upper abdominal pain since 19:00 hours this evening and vomiting.
- Not on medications

Under **Surgical History** it is documented: History Bowel discomfort x 2 years

No medications and NKDA (No known drug allergies)

Under **Obstetric History** it is documented that Mrs X was 26 weeks 3 days gestation.

Under **Reason for Presentation to MAU** it is documented: History of spasmodic upper abdominal pain since 19:00 hours this evening and vomiting.

Under **Current Medications** it is documented; Nil

Under **Plan of Care/Management** it is documented: 26 weeks 3 days. A/P Fundus is in line with dates, longitudinal line possibly cephalic, Fetal heart heard with Sonicaid at 149 beats per minute. Vital signs mother: Temp – 36.1 ℃, Pulse 78, BP 127/78, Oxygen Saturations: 98%; Respiratory 17 per minute.

- Urinalysis normal accept for a trace of blood.
- Plan to see Registrar and SHO bleeped to review.

Tuesday 1st March 2016

Mrs X outlined at interview that on the 1st March 2016 Mrs X was admitted to Maternity Assessment Unit, Hospital S1 due to extreme abdominal stomach pain and was kept in as an inpatient for four days and the findings were that the gallbladder was the cause. She was prescribed Ranitidine 150mg for remainder of pregnancy

01:10 Hours Obstetric NCHD Review

It is documented by the Obstetric NCHD that s/he was called to review Mrs X. The documentation completed by the Obstetric NCHD indicates the following:

- Primagravida
- 26 weeks 3 days
- Complaining of upper abdominal spasmodic pain and has had similar pain before
- History of gastritis
- History of nausea and vomiting
- No urinary symptoms
- Opening bowels regularly
- Fetal movements felt
- No vaginal loss
- On examination complaining of upper abdominal pain
- Fundus in line with dates
- IMEWS = 0
- Examination: tenderness upper abdomen and epigastrium
- Fetal Heart heard with sonicaid
- Urine clear
- Diagnosis reflux symptoms secondary to growing uterus
- Plan to commence antacid, analgesia, carry out a Full Blood Count, C-reactive protein (CRP), Urea and Electrolytes, Liver Function Tests
- Obstetric Registrar informed to review.

02:30 Hours Midwife Entry

It is documented by a Staff Midwife that she received Mrs X from the MAU, Mrs X's history noted, and she was transferred to bed and sleeping at present.

07:00 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X's IMEWS was recorded as 0. Mrs X reported upper abdominal pain this morning and was given analgesic. No vaginal loss. Mrs X reported that she urinated 2-3 times during the night and awaiting urine sample.

08:10 Hours Midwife Entry

It is documented by the Midwife completing the night duty shift that she informed day staff to review with the Obstetric Team as bloods may need to be repeated.

10:00 Hours Midwife Entry

It is documented by the Midwife on day duty that Mrs X's IMEWS =0

- Fetal Movement Felt and Fetal Heart auscultated at 141 beats per minute with hand Doppler for 1 minute.
- Pain has settled
- No nausea no vomiting
- No PV loss reported

- For team review
- Possibly repeat bloods

10:00 Hours Ward-round Obstetric NCHD

The Obstetric NCHD documented the following in Mrs X's healthcare record during the obstetric ward round;

- 26 weeks pregnant
- Patient complaining of abdomen pain
- Full Blood Count normal
- Abdomen: Soft and tender
- Plan: Ultrasound scan of abdomen booked
- Discussed with the radiology department and USS of abdomen to be done tomorrow morning.
- Nil by mouth from midnight
- Avoid fatty foods / sauces
- For Liver Function Tests and amylase[14] blood tests.

13: 15 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X received Ranitidine[15] 150mgs as charted.

14:00 Hours Midwife Entry

[14] A blood amylase test is used to help diagnose and monitor acute pancreatitis and sometimes to diagnose and monitor chronic pancreatitis and other disorders that may involve the pancreas. A blood amylase test may be ordered when a person has symptoms of a pancreatic disorder.

[15] Ranitidine, sold under the trade name Zantac among others, is a medication that decreases stomach acid production. It is commonly used in treatment of peptic ulcer disease, gastroesophageal reflux disease. There is also tentative evidence of benefit for hives. It can be taken by mouth, by injection into a muscle, or into a vein.

The Midwife on Duty documented that Mrs X was getting good relief post ranitidine, pain has eased. Mrs X is for repeat bloods and Ultrasound scan of abdomen in the morning and fast overnight.

16:00 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X continues to get good relief from Ranitidine and declining analgesia. IMEWS = 0, no abdominal pain, no PV loss. Fetal movement felt. Fetal heart auscultated at 149 beats per minute with hand held Doppler for 1 minute and Maternal pulse recorded as 79 bpm.

18:00 Hours Midwife Entry

The Midwife on Duty documented that Mrs X feels that pains in ribs particularly the right side have increased, feeling slightly nauseous, declining antiemetic. IV perfalgan (paracetamol) given as charted. No abdominal pain. No PV loss. Blood results ALT raised 69 and Obstetric Registrar aware.

19:00 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X feels much better post Perfalgan. IMEWS =0. Nausea has settled. Pain has reduced. Fetal Movement Felt and fetal heart auscultated at 151 bpm with hand held Doppler for 1 minute.

22:50 Hours Obstetric Registrar Entry

The Obstetric Registrar documented that s/he woke Mrs X to review her and that Mrs X was admitted 29th February 2016 for upper abdominal pain. The Obstetric Registrar documented that;

- Gestation recorded as 26 weeks 4 days.
- Abdomen soft and tender.
- Fundus equal to dates.
- Lie longitudinal
- Fetal Heart Rate recorded for 1 min with the sonicaid 150 bpm.
- No bleeding, no pains, voiding well.
- No epigastric pain this pm.
- IMEWS = 0.
- Fast for 24 hours for Abdominal Ultrasound Scan in the morning.

Wednesday 2nd March 2016

01:00 Hours Midwife Entry

It is documented by the Midwife that Mrs X was given a zantac (Ranitidine) tablet as charted with a small sip of water.

03:00 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X was antenatally well. No Pain no PV loss. No concerns voiced by Mrs X.

06:50 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X is antenatally well this am. IMEWS =0. Fetal movements felt. Fetal Heart Rate recorded as 140 bpm via sonicaid. Mrs X is fasting for USS. No issues voiced.

09:35 Hours Obstetric SHO Entry

It is documented by the Obstetric SHO that Mrs X is gestation 26 weeks 4 days.

- Admitted with spasmodic upper abdomen pain. Pain improved by 50 %.
- Fetal Movement felt. No PV loss IMEWS= 0
- Currently fasting
- On panadol and ranitidine twice daily
- USS today
- Review post ultrasound of abdomen

09:35 Hours Midwife Entry

The Midwife on duty documented that the fetal heart was 140 bpm on auscultation for 1 minute, IMEWS = 0, Maternal Pulse 100, Fetal movement felt, No PV loss, fasting for Ultrasound Scan (USS).

No Time

Mrs X attended the radiology department for an Ultrasound Scan of her abdomen.

16:30 Hours Obstetric SHO Entry

The Obstetric SHO recorded the USS result in Mrs X's healthcare record which reflected the below findings.

Formal Radiology Report – Consultant Radiologist C

*'**Indication**: Pregnant Patient Admitted with right Upper Quadrant Pain. Tender RUQ (Right Upper Quadrant). To Exclude Gallstones Please.*

Images by sonographer with retrospective workstation review.

Technically challenging examination, interposed bowel gas/body habitus. Limited views of pancreas appear unremarkable. Limited views of liver. ….1.6 x 1.0 cm echogenic lesion in the right lobe of the liver. There is at least one mobile calculus within the gallbladder. CBD measures 2.3 mm. Both Kidneys and spleen are unremarkable. No free fluid demonstrated. Impression:

6. *Cholelithiasis without demonstrated imaging features of acute complication. Appearances would not preclude a clinical diagnosis of acute cholecystitis, nor indeed, other GI condition, if clinical assessment convincing.*
7. *Incidental small probable right hepatic haemangioma, single follow-up focused sonography in 4.5 months once post-partum, could be reassuring'.*

The Investigation Team note that the repeat ultrasound was not followed up on i.e. Mrs X did not have a repeat USS as set out above.

16:35 Hours Obstetric SHO Entry

The Obstetric SHO documented that s/he discussed the USS findings with the Registrar on call;

- Plan needs review by surgical on call.
- Discussed with surgical team on call who agreed to review patient.

16:46 Hours ECG Print

ECG carried out and a copy of the ECG trace available in the healthcare record is suggestive of Normal Sinus Rhythm.

18:40 Hours Midwife Entry

The Midwife on duty noted the following in the healthcare records. Mrs X was feeling a little better this evening, 'discomfort' awaiting surgical review, Fetal Heart recorded as 146 bpm on auscultation for 1 minute. Fetal Movement Felt; maternal pulse recorded as 84;

No Time Surgical Registrar On Call Entry

It is documented by the Surgical Registrar on call that s/he reviewed Mrs X and included the following commentary in the healthcare record;

- 30 year old 24 weeks pregnant
- Complaining of acute right upper quadrant pain and vomiting. Colicky in nature. Settled before admission, had a previous similar attack.
- WCC 13 (Neutraphilia)
- CRP 19
- ALT 60
- On Examination: Abdomen soft; Distended by pregnant uterus; Tender RUQ
- USS suggestive of Cholelithiasis[16] with features of acute cholecystitis
- Plan Repeat bloods mane will review tomorrow.

21:40 Hours Midwife Entry

The Midwife on duty documented in the healthcare that Mrs X was seen by Surgical Registrar as above; the plan was for repeat bloods mane. The Midwife on duty also documented in the healthcare that Mrs X feels well at present, no acute pain but has mild dull back pain. In addition the Midwife on duty documented in the healthcare that Mrs X was given Paracetamol 1g PO (Orally), a warmer blanket given, Fetal Movement Felt, no PV bleeding, no SROM, Fetal heart heard with Doppler for I min recorded as 146 bpm and the Maternal pulse recorded as 80 bpm. Mrs X was advised to rest and the call bell at hand.

Thursday 3rd March 2016

02:30 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X is sleeping on and off. Warming blanket aiding back pain somewhat. Fetal movement felt. Fetal Heart heard using Doppler and recorded as 154 bpm. Maternal pulse recorded as 84 bpm. Ranitidine 150 mgs PO given as due.

06:30 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X was complaining of trapped wind. Possibly constipation this am. Last bowel motion was 2 days ago. Will try breakfast and discuss with team on round possibly for laxative.

Assessment and Vital Signs were recorded as follows:

[16] Cholelithiasis involves the presence of gallstones, which are concretions that form in the biliary tract, usually in the gallbladder. Choledocholithiasis refers to the presence of 1 or more gallstones in the common bile duct (CBD).

- IMEWS = 0
- Fetal Movement Felt
- Fetal Heart rate = 136 bpm
- Maternal Pulse = 71 bpm

09:00 Hours Obstetric SHO Entry

It was documented by the Obstetric SHO that;

- Mrs X is 26 weeks 5 days gestation
- No complaints, feeling much better
- Waiting for surgical review
- Continue same management
- Hoping to go home after surgical review.

09:09 Hours Obstetric SHO Entry

The Obstetric SHO documented that Mrs X had an USS on 2nd March 2016. There was a mobile calculus measuring 2.3mm identified. Mrs X had a dull pain. Fetal movement felt, there was no PV loss. IMEWS recorded as 0. Await surgical review, repeat bloods for FBC, CRP, U+E's, LFT's.

12:25 Hour Midwife Entry

It is documented by the Midwife on Duty that;

- Fetal heart was recorded as 145-150 bpm on auscultation for 1 min,
- Maternal pulse 66,
- Mrs X appears a lot better, some discomfort today but not the same extent as before,
- Panadol 1 g given
- IMEWS = 0
- Awaiting FBC

No Time Surgical RV (Surgeon F on Take)

It is documented by a member of the Surgical Team in the healthcare record that Mrs X was admitted with RUQ (Right Upper Quadrant) pain and;

- LFTs where stable, CRP = 56, WBC= 8.0
- USS Stable
- Pain free
- Plan analgesia
- Discharge
- Review in OPD surgical clinic in 6 months.

16:20 Hours Obstetric SHO Entry

The Obstetric SHO documented that Mrs X is well today with some epigastric discomfort. The Surgical team reviewed her and they are happy for her to go home.

Plan:

- For surgical OPD in 6 months
- Plan
- Fit to go home from an obstetric point of view
- Antenatal clinic appointment for 18th March 2016

- To continue ranitidine 150 mgs BD (twice daily) and Gaviscon

16:20 Hours Midwife Entry

It is documented by the Midwife on duty that Mrs X's IVC (Intravenous cannula) removed d/c (Discharged) home.

Wednesday 16th March 2016

No Time

There is a Sticker GTT (Glucose Tolerance Test) completed signed by Midwife dated 16th March 2016.

In addition the following is documented in the healthcare record;

- Vital Signs recorded as: BP 110/73 P: 107
- Urine NAD (Nothing abnormal detected)

The Investigation Team consider that Mrs X was tachycardic with pulse of 107 but nothing appears to have been done about it. The TPR should be done as one holistic assessment even on rechecking one abnormal parameter.

Friday 18th March 2016

Mrs X outlined at interview that she had extreme flu symptoms and Consultant Obstetrician A prescribed Augmentin. Mrs X was bed bound for a week and went to her GP as Augmentin was not agreeing with her, Amoxicillin was prescribed instead.

No Time NCHD and Consultant Obstetrician and Gynaecologist A Review

Mrs X attended for a routine antenatal clinic appointment in Hospital S1 and was review by an Obstetric NCHD. The NCHD clinical note states the following;

- Gestation agreed: 28+6
- Presentation /lie: Vx (Vertex[17])
- BP = 110/73 P= 107
- Urine NAD
- Feeling very unwell, very chesty since yesterday, very sore and has flu like symptoms.
- Baby moving very well.
- Taking pregnacane daily

Mrs X was tachycardic again with pulse of 107.

Scan carried out by Consultant Obstetrician and Gynaecologist A

Consultant Obstetrician and Gynaecologist A also documented the following in the healthcare record following the scan;

- EFW (Estimated Fetal Weight) 2-8 pounds
- Adequate Liquor
- There is slight dilatation of the pelvis in the right kidney
- Bladder is full

[17] Vx = cephalic, Ceph means the baby's head down

Dr. Gardeil outlined for the investigation that mild renal dilatation is a relatively common finding on fetal ultrasound scans and would not give rise to concern at this stage of the pregnancy.

Mrs X was also reviewed by Consultant Obstetrician and Gynaecologist A who advised the Investigation Team that he was keen to keep a close eye on the patient and to see her himself even though patient was a public patient.

At this visit Consultant Obstetrician and Gynaecologist A also documented that he would review her again at her next antenatal visit.

The Investigation Team consider that it is not documented what was explained to Mrs X and why.

Friday 1st April 2016

No Time

Mrs X attended for a routine antenatal clinic appointment in Hospital S1 and was review by an Obstetric NCHD. The NCHD clinical note states the following;

- Agreed Gestation 30 weeks
- BP: 119/73
- Maternal Pulse: 96 bpm
- Urinalysis Positive for ketones
- Oedema: No

Comments made by NCHD:

- On the 1st March 2016 Mrs X had a USS of gallbladder
- On antibiotics for Chest Infection
- Weight 81kgs
- Advised re movements and be aware of patterns
- Well, no complaints,
- USS shows cephalic,
- Fetal Heart and fetal movement
- Adequate Liquor
- See again in 2 weeks

Friday 15th April 2016

No Time

Mrs X attended for a routine antenatal clinic appointment in Hospital S1 and was reviewed by an Obstetric NCHD. The NCHD clinical note states the following;

- Gestation by agreed date: 33 weeks
- Presentation Lie/Engagement Vx (Vertex)
- BP: 125/75
- Urine: NAD
- Weight: 83.7kgs
- Fetal Movements good, advised to monitor
- Abdominal USS small right hepatic haemangioma seen and cholelithiasis
- c/o palpations yesterday and of back pain radiating down both legs
- Fetal Movement Felt and advised to monitor

- Not taking Iron and unable to provide urine sample for routine testing.

Antenatal Scan done which notes the following;

- Adequate Liquor
- Safe placenta
- Small dilatation of pelvis in right kidney

The Investigation Team note that the use of phrase "*safe placenta*". It is an unclear statement; possibly relates to location but if so, the location should be identified, this is not a usual phrase and could lead to confusion.

Consultant Obstetrician and Gynaecologist A confirmed at interview that Mrs X was seen by the Obstetric NCHD on the 15th April 2016 visit and Consultant Obstetrician and Gynaecologist A joined the review as he wanted to assess Mrs X. Consultant Obstetrician and Gynaecologist A advised the Investigation Team that from 26 weeks Mrs X was seen by the most senior person and stated, Mrs X had a GTT as her BMI was high, there were a few complications such as gallstones, flu. Otherwise, everything else was normal until 33 weeks.

According to Dr. Gardeil the first abnormal finding on scan was made at 28 weeks and 6 days, on the 18th of March 2016. Consultant Obstetrician and Gynaecologist A noted a slight dilatation of the pelvis of the right kidney with a full bladder and normal amniotic fluid volume that would indicate normal fetal renal function. The same findings were noted, again by Consultant Obstetrician and Gynaecologist A, on the 15th of April 2016 at 33 weeks. Mild renal dilatation is a relatively common finding and doesn't, in the absence of other abnormalities, warrant referral to a feto-maternal medicine specialist.

During the feedback process Mrs X stated that she informed the Obstetric NCHD that Consultant Obstetrician and Gynaecologist A wished to review her at every visit. Therefore at this particular visit the Obstetric NCHD went to the adjoining room in the clinic to speak with Consultant Obstetrician and Gynaecologist A. Consultant Obstetrician and Gynaecologist A came into the clinic room where Mrs X was lying. The Obstetric NCHD proceeded to scan Mrs X again and Consultant Obstetrician and Gynaecologist A observed the ultrasound scanner screen. Consultant Obstetrician and Gynaecologist A informed Mrs X that the bladder had not emptied and was always full at each scan carried out. This was the reason he wished to review Mrs X at every visit. Mrs X outlined as it happened she was returning to the clinic anyway in two weeks, so there was no requirement to increase the frequency of visits.

Mrs X recounted at interview that by 32-33 weeks her bump had grown, and she was experiencing Braxton hicks however not regularly; Mrs X stated that they were intense but not painful and she was not in any discomfort at this time.

Friday 22nd April 2016

Mrs X stated by the 22nd April 2016 (Gestation approximately 34 weeks), she recorded Braxton hicks 20 minutes apart from between 8pm-12pm. Mrs X outlined that the Braxton hicks were '*up high*', and she had a '*pulsation feeling'* in her bump. Mrs X's outlined her '*bump would completely tighten up as if it was a spasm and the Braxton hicks were intense and irregular'*; this was the only time she recorded the Braxton hicks. By week 34 Mrs X had an appointment to see her GP, the discomfort of bump was very uncomfortable, gradually it became unbearable and her GP advised from a measurement of her bump that she was having a big baby.

Mrs X stated at interview that it was '*this particular week that everything completely changed'* for her particularly from the 22nd April 2016. Within a few days Mrs X stated she felt completely different. Her bump had increased significantly, she just thought that she was growing, she felt fine but how she was feeling physically had completely changed.

Mrs X informed the Investigation Team through the feedback process that it was not until week 34 that her bump had increased in size drastically suddenly and it was then that she began experiencing more intense Braxton Hicks on a regular basis.

Friday 29th April 2016

No Time Recorded

Mrs X attended for a routine antenatal clinic appointment in Hospital S1 and was reviewed by the Obstetric NCHD E who documented the following:

- Gestation by agreed 35 weeks
- Fundal height 33cm
- Presentation Lie Cephalic
- Fetal Movement: Ticked
- Fetal Heart Rate: Ticked
- BP 130/81
- Maternal Pulse: 78
- Urinanalysis: Normal with the exception of Protein +1
- Midstream Specimen of Urine (MSU) sent to the lab
- C/O (Complaining of) movements overall reduced. CTG commenced
- CTG reassuring

08:40 Hours

Urinalysis Report timed at 08:40 hours contained within the healthcare record includes the following results:

- Glucose Negative
- Bilirubin Negative
- Ketones Negative
- SG 1.025
- BLD Negative
- PH 7.0
- Protein 1+
- UBG 3.2 umol/L
- NIT Negative
- Leu Negative

No Time

Mrs X outlined during the feedback process that she reported more intense Braxton Hicks and reduced movements for almost two weeks at this visit. She reported increased pressure and feeling very uncomfortable, her bump *'was now rock solid and had grown drastically suddenly'*. Mrs X outlined that the Obstetric NCHD E informed her that the lack of movements was due to increased amniotic fluid.

It is documented in the healthcare record by the Obstetric NCHD E that an USS Scan was carried out at the visit. The results documented in the healthcare record include the following:

- Fetal Weight of 2.360 kgs
- Amniotic fluid index (AFI) > 48 (Increased)
- Urgent Referral to Antenatal Unit in the Hospital S2 done

Mrs X informed the Investigation Team that during the scan the Obstetric NCHD E found both Baby Aarons kidneys were now dilated and diagnosed polycystic kidney, hydronephrosis, polyhydramnios, and recommended an urgent more detailed anomaly scan in the Hospital S2. Mrs

X also stated that the NCHD E also mentioned a possible blockage somewhere in Baby Aaron. (Mrs X also highlighted that this was the first mention of fluid level and second kidney dilation and possible blockage elsewhere and also it was the first indication of a serious problem).
Mrs X recalled the following at interview:

> *'Following the scan the Obstetric NCHD E went into the adjoining clinic room to discuss the scan finding with Consultant Obstetrician and Gynaecologist A. The Obstetric NCHD E explained that there was a lot of fluid, polyhydraminos, that there was an issue with the kidneys, she never mentioned echogenic bowel, and said that "this means you may have your baby in a more specialised unit". She then referred me to the Hospital S2 for a second opinion and anomaly scan. I was not aware that the referral was urgent at this time and none of the staff appeared concerned. Obstetric NCHD E also suggested that I would have to wait for appointment due to May Bank Holiday weekend. However she said that she would send*
>
> *the fax straight away and mark it as urgent. The referral was filled in there and then and marked URGENT'.*

The reason documented for the referral on the 'External Referral Form' completed by the Obstetric NCHD E (in Consultation with Consultant Obstetrician and Gynaecologist A) included, possible bilateral renal hydronephosis and possible polycystic kidney renal, possible bladder anomaly.

It was confirmed at interview by Consultant Obstetrician and Gynaecologist A that he had serious concerns about the Ultrasound Sound findings;

> *'Severe problems were noted on ultrasound at approximately 35 weeks gestation. There was severe polyhydraminous, the amniotic fluid index (AFI) was 48cm. This was a significant change compared to the AFI at the previous antenatal clinic visit. Bilateral hydronephrosis could not be ruled out. In such cases when abnormal findings such as severe polyhydraminous are noted on ultrasound, it is normal to ring or fax the Hospital S2 for Foetal Assessment and a fax referral was sent that day for an urgent appointment. She was asked to return to the antenatal clinic (in Hospital S1) in one week in anticipation that the Hospital S2 would have reviewed her in the intervening period'.*

The Investigation note that these concerns were not addressed in the healthcare record, one would expect that any advice provided to Mrs X should have been captured and with a clearly documented plan of care in the event of any issues relating to the wellbeing of Mrs X and her unborn baby. If there was to be no such plan of care this should have been equally documented. The Investigation Team consider this to be a serious omission in terms of communication.

Dr. Gardeil outlined for the investigation that a member of the team should have communicated with hospital S2 to establish that status of the referral and indeed speak with a member of the team. Mrs X should have been informed of the plan, as it stands it appears that there was inaction and this is unsafe.

09:49 Hours Midwife M1 Entry

It is documented by Midwife M1 in Mrs X's antenatal records that Mrs X attended for a CTG in the ANC at hospital S1. Mrs X had a CTG which specified the following:

- baseline rate 150bpm.
- Reassuring CTG.
- Accelerations present.
- No decelerations.
- Opinion normal[18] CTG.

[18] A 'Normal' CTG is indicated when all four features (fetal heart rate, baseline variability, acceleration and deceleration of the fetal heart rate and frequency and strength of contractions as recorded by the attending healthcare professional) fall within the reassuring category i.e. they fall within the normal ranges as outlined on

It is also documented by Midwife M1 that Mrs X's maternal pulse was 70 bpm, membranes were not ruptured at this time, there was no liquor and Mrs X was documented correctly as being 35 weeks gestation. Midwife M1 also documented the reason for CTG was to assess fetal wellbeing due to reduced fetal movements.

Mrs X recalled at interview;

> *'the Midwife decided to do CTG due to my concerns of lack of movement felt and due to discomfort all over my abdomen. CTG showed contractions. There was protein in my urine. I was sent for bloods to be checked for pre-eclampsia. These Blood Results are not in the Chart'*.

Again the investigation team notes that important blood results were not available for review in the healthcare record.

According to Dr. Gardeil, very importantly, blood samples that had been obtained in the antenatal clinic on the 29th of April 2016 showed abnormal liver function with AST of 119 and ALT of 294 U/L respectively. Whatever the cause of abnormal liver function in pregnancy is, it is associated with poor outcome. The blood results were signed off and ticked 'abnormal' by a doctor but this additional risk factor doesn't seem to have been taken into account by caregivers in the peripartum period. Given that Ms X was not in established labour there was no possibility of performing fetal blood sampling to out rule hypoxia.

13:26 Hours Referral Faxed to Hospital S2

Fax receipt contained within the healthcare record indicates that the referral for the anomaly scan was sent at 13:26 hours.

The Investigation Team consider the communication surrounding Mrs X's visit on the 29th April 2016 and subsequent UUS findings to be collectively significant failures in communication. There was no advice provided to Mrs X based on the interviews with Consultant Obstetrician and Gynaecologist A given the USS findings or documented in the healthcare record. It is the opinion of this investigation team that it was wholly unsatisfactory to assume that someone would even pick up the fax in Hospital S2 on a Friday afternoon. It is the opinion of this investigation team that this referral should have been followed up by a phone call from the referring clinician.

It is the opinion of this investigation team that there is no documented evidence of an appropriate plan of care. This investigation Team consider this finding to be a serious shortcoming in terms of safeguarding Mrs X and her Baby (Aaron) and placed Mrs X and Baby Aaron in a position of unnecessary risk.

Complete healthcare records are a mandatory requirement to ensure that all staff caring for both mother and baby have a clear understanding of any untoward findings and plans to manage and/or address the emergent issues.

Sunday 1st May 2016

15:30 Hours

In a summary provided to the Investigation Team at interview Mrs X outlined that she attended

page 16 of this report. A 'Suspicious' CTG is when one feature falls within the non-reassuring category and the remainder are reassuring. A 'Pathological' CTG is when two or more features fall within the non-reassuring category or one or more features fall within the abnormal category (reference: Hospital S1: Fetal Heart Monitoring in the Maternity Department. Approval date: April 2011).

Hospital S1 at 15:30 hours due to feeling very unwell and extreme discomfort all over her abdomen and irregular contractions.

16:45 hours

It is documented by a member of staff on duty that on the 1st May 2016 at 16:45 hours Mrs X presented to hospital S1 with abdominal discomfort and a history polyhydramnios.

18:00 Hours Obstetric SHO Entry

The Obstetric NCHD on duty documented that Mrs X presented:

- with abdominal discomfort,
- felt her abdomen was tight all over,
- needs to be upright as this is the only comfortable position.

- Known polyhydraminos and was advised to attend *'ASAP'* if any concerns.
- Urgent referral sent to Hospital S2 for anomaly scan due to increased AFI and query bladder / kidney issues.

The Obstetric NCHD's clinical assessment included the following:

Background

- Para 0+0
- 0 Rhesus Positive
- Rubella Immune, serology negative
- No known drug allergies
- Medical History of palpitations in the past
- Surgical history nil
- Pregnancy history to date
- 22/40 (weeks pregnant out of 40 weeks) investigated for palpitations
- 26/40 upper abdominal pain
- Inflamed gallbladder
- 28/40 GTT Negative
- IMEWS = 0

There is a set of observations documented on the IMEWS chart that are dated for the 1st May 2016 but these are not timed.

The Obstetric NCHD also documented that on palpation the fundus is greater than dates, tense abdomen, no pain on palpation of same, cannot feel much movement, very subtle as indicated by Mrs X, last felt yesterday evening, there was no PV loss or bleeding and the plan was documented to wait for the Obstetric Registrar to review Mrs X.

Mrs X outlined that;

> *'CTG done by midwife, Baby fine, Contractions showing up to level 70, Scan performed at 6:30 hours (Checked Placenta and findings were normal), Amniotic Fluid Levels were reported as being 48cm, Overall opinion from the doctor was that everything was fine. The Doctor spoke to Consultant Obstetrician and Gynaecologist A twice on the phone about my scan and whether or not I was to be kept in. It was decided to keep me in for monitoring due to reduced foetal movements. The Doctor also mentioned the possibility of placental abruption if waters were to break due to high volumes of amniotic fluid. Approximately 6 CTG's were done from Sunday to Monday morning: All Reported Normal. Contractions were showing up on each CTG. They were unable to get a trace most of the time on my side but they were able while I was lying on my back. My husband and I asked the medical team on many occasions from Sunday to Tuesday about the referral*

> *for the scan to Hospital S2 and if they had heard back about it. Each time the team members reported hearing nothing. The referral was never followed up at anytime'.*

Consultant Obstetrician and Gynaecologist A informed the investigation that he was not on call the weekend of the 1st May 2016 or in the hospital when Mrs X was admitted. Consultant Obstetrician and Gynaecologist A outlined that this phone call from the NCHD was not to give a plan of action for this admission. Consultant Obstetrician and Gynaecologist A outlined that the on-call Consultant Obstetrician and Gynaecologist would put a plan in place for Mrs X's emergency admission.

The Investigation Team note that there is no record of this conversation in the healthcare record other than the phone call being made, again this is considered to be a serious communication failure. Given that Mrs X was known to Consultant Obstetrician and Gynaecologist A, in that she was booked under his care, attended him in his private rooms for a private anomaly scan and that he had ensured that he personally reviewed her on most occasions in the public antenatal clinic, it is the opinion of this investigation team that it is surprising that he would have adopted such a hands off approach in terms of management of Mrs X's plan of care on a bank holiday weekend particularly in light of all of the abnormal findings.

The investigation team note that there is no evidence in the healthcare record that the concerns relating the previous USS were discussed in terms of a plan of care or indeed why the urgent referral sent to Hospital S2 on the 29th April 2016 was not being followed up on.

The Investigation Team consider that there were a number of missed opportunities to contact hospital S2 to seek advice and guidance. It is the opinion of this investigation team that this lack of action is wholly unacceptable.

During the feedback process Mrs X stated that;

> *'Bank Holiday weekend as an excuse is a disgrace. Please include in your report that this was an emergency situation and should have been responded to in 72 hours'.*

19:00 Hours Obstetric Registrar Entry

Mrs X was reviewed by the Obstetric Registrar who documented the following in the healthcare record;

- 35 weeks 2 days (Gestation)
- Polyhydramnios
- Not feeling Fetal Movements
- GTT offered
- Abdomen painful distension
- Urine NAD
- Doppler normal
- Consultant Obstetrician and Gynaecologist A informed
- Significant polyhydramnios
- Referred for second opinion in Hospital S2
- Plan to admit and observe.
- If ok home tomorrow.

23:10 Hours Midwife M7 Entry

Midwife M7 on duty documented that on palpation the fundus was larger for gestation dates due to polyhydramnios. Longitudinal lie with cephalic presentation Fetal Heart was recorded at 152 bpm. Fetal movement difficult for Mrs X to feel sometimes, feels a flick to her abdomen. It is also documented Midwife M7 in the healthcare record that Mrs X commenced on CTG as per doctor's recommendation.

23:05 Hours Midwife M7 Entry

Midwife M7 documented that Mrs X reports having Braxton Hicks for the last couple of days. CTG discontinued at 23:50 Hours.

23:50 Hours Midwife M7 Entry

Midwife M7 reviewed and documented her interpretation of the CTG;

- CTG reassuring 145 bpm
- Variability greater > 10
- Accelerations present
- Decelerations none

Midwife M7 also recorded that the membranes not ruptured, Normal CTG, Mrs X reports tightenings, having some for the last couple of weeks not painful and all 4 features present (See Table 1).

Mrs X recounted that on Sunday she had irregular contractions which were occurring every 20-30 minutes and sometimes they were closer together, they were intense and she recalled she was feeling unwell and weak due to pain caused by the tightness and extreme discomfort.

Table 1: CTG Classification/Decision Tool[19]

Feature	Baseline Fetal Heart Rate (Beats per minute)	Variability (Beats per minute)	Decelerations	Acceleration
Reassuring	110 – 160	≥5	None	Present
Non-Reassuring	100 – 109 161 – 180	<5 for 40-90 minutes	Typical variable decelerations with over 50% of contractions occurring for over 90 minutes Single prolonged decelerations for more than 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	<100 >180 Sinusoidal pattern >10 minutes	<5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged decelerations for more than 3 minutes	

Monday 2nd May 2016 – Bank Holiday

01:35 Hours Midwife M7 Entry

It is documented by the Midwife M7 on duty that the Doctor was contacted and asked to review the CTG. The Plan was for a repeat CTG in the am.

Midwife M7 requested the on call Doctor to review the CTG as Mrs X had reported tightenings and because the Doctor had requested the CTG to be carried out.

06:30 Hours

A set of observations have been documented on the IMEWS chart. It would appear that these relate to the 2nd May 2016, however the entry is not dated.

[19] **Baseline fetal heart rate** is the average fetal heart rate (FHR) rounded to increments of 5 beats per minute during a 10-minute segment, excluding periodic or episodic changes, periods of marked variability, or baseline segments that differ by more than 25 beats per minute. In any given 10-minute window, the minimum baseline duration must be at least 2 minutes, or else the baseline is considered indeterminate. In cases where the baseline is indeterminate, the previous 10-minute window should be reviewed and utilized in order to determine the baseline. A normal FHR baseline rate ranges from 110 to 160 beats per minute. If the baseline FHR is less than 110 beats per minute, it is termed **bradycardia**. If the baseline FHR is more than 160 beats per minute, it is termed *tachycardia*. **Baseline FHR variability** is based on visual assessment and excludes sinusoidal patterns. **Variability** is defined as fluctuations in the FHR baseline of 2 cycles per minute or greater, with irregular amplitude and inconstant frequency. These fluctuations are visually quantitated as the amplitude of the peak to trough in beats per minute. By visual assessment, **acceleration** is defined as an apparent abrupt increase in FHR above baseline, with the time from the onset of the acceleration to the acme of less than 30 seconds. **Late deceleration** is defined as an apparent gradual decrease and return to baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. **Early deceleration** is defined as an apparent gradual decrease and return to the baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. ***Variable deceleration*** is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline. When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol. 2008 Spring; 1(2): 56-60 (Available from: http://medicaldictionary thefreedictionary.com/premature+labor). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).

06:40 Hours Midwife M7 Entry

It is documented by the Midwife M7 that the CTG was commenced with permission. FHR was recorded at 148 bpm. Maternal Pulse was 83 bpm. Nil complaints voiced by Mrs X and fetal movements felt.

07:10 Hours Midwife Entry

It is documented in the healthcare record by the Midwife on duty that the *'CTG shows no accelerations for 30 minutes….repeat CTG post breakfast'.*

07: 35 Hours Midwife Entry

The Midwife on duty documented that the CTG was recommenced, the Fetal Heart rate was recorded at 144 bpm and the CTG was considered reassuring based on the following;

- Baseline rate 140
- Variability 5-10
- Accelerations yes
- Decelerations no
- Normal CTG: Ticked

09:00 Hours Midwife M2 Entry

It is documented by the Midwife M2 that Mrs X was seen by the Obstetric SHO. It is documented that Locum Consultant Obstetrician and Gynaecologist B would scan Mrs X.

11:00 Hours Midwife Entry

It is documented by the Midwife M2 that Mrs X was seen by Locum Consultant Obstetrician and Gynaecologist B and the plan is for Mrs X to go home and await appointment for scan in Hospital S2 and for Antenatal clinic appointment Friday.

No Time Consultant Obstetrician and Gynaecologist B Entry in Antenatal OPD Visit Form

Mrs X informed the Investigation Team during the feedback process that Locum Consultant Obstetrician and Gynaecologist B discharged Mrs X early on Monday 2nd May (bank holiday) as the CTG's were normal.

It is documented in the healthcare record by Locum Consultant Obstetrician and Gynaecologist B that an USS was carried out indicating an echogenic dilated pelvis in the right kidney, refer to Hospital S2. Locum Consultant Obstetrician and Gynaecologist B discharged Mrs X.

According to Dr. Gardeil there is, as always, overlap between maternal and fetal complications during pregnancy;

> *'Ms X and her baby were monitored closely during the pregnancy with a total of 8 visits to hospital S1 antenatal clinic, 2 visits to consultant A private rooms and at least 4 visits with the GP. Outpatient scanning was performed at 6 of the antenatal visits and twice in the private rooms; at 10+ weeks for dating and at 25 weeks on the 20th of February 16 as an anomaly scan, which included 3D imaging.*
>
> *The first anomaly noted on scan was on the 18th of March when consultant A noted a slight dilatation of the pelvis of the right kidney with a full fetal bladder and normal amniotic fluid volume. The same findings were noted at 33 weeks, on the 15th of April.*

On Friday the 29th of April 16, a scan done in the clinic showed marked polyhydramnios with an AFI of 48. The same day an urgent referral to the scan department at hospital S2 for a second opinion was faxed.

Ms X had 2 scans while an in-patient. On the 1st of May, Doppler studies of the umbilical artery were performed and were normal. On the 2nd of May, consultant B performed another scan. In addition to the previously noted dilated pelvis of the right kidney, a short femur and echogenic bowels were noted. These findings can be associated with fetal abnormality.'

The Investigation Team consider that there is no evidence at the point of discharge as to whether Consultant Obstetrician and Gynaecologist B discussed Mrs X's care with Consultant Obstetrician and Gynaecologist A to determine next steps in terms of a plan of care. The Investigation Team consider that this again constitutes another failure in communication.

It is the opinion of this investigation team that senior clinical staff placed far too much reliance on the fact that they believed Mrs X would not be accepted as a patient by hospital S2 without even consulting with hospital S2 prior to coming to this conclusion, and appeared satisfied that Mrs X would be reviewed in hospital S2 before her next antenatal visit on the 6th May 2016. This approach is unsafe and again placed Mrs X and her unborn Baby Aaron in a position of unnecessary risk. This was of course further compounded by the lack of any documented plan of care.

According to Dr. Gardeil Consultant Obstetrician and Gynaecologist B does not explain his/her action(s) or decision making in relation to the clinical oversight of Mrs X's condition whilst an inpatient that weekend. Notwithstanding that there was no documentation regarding the findings, discussion and actions of the 29th April 2016, it is surprising that there appears to be little discussion with Mrs X in relation to why she was in hospital or what had predated this admission only days beforehand in relation to a blood test result, Ultrasound examination findings, urinalysis results, raised blood pressure, clinical signs and symptoms including those of polyhydramnios.

Whilst it may be routine for a Midwife to follow up on a referral, all staff would or ought to have known that a faxed urgent referral at lunch time on a bank holiday Friday provides no assurance that it will be seen by a human being in less than 72 hours over a bank holiday weekend and the consultant on call ought to have enquired into its status where there was an on-going concern which is a failure communication.

It is the opinion of Dr. Gardeil Mrs X's presentation was not normal, this is a lady that was booked under consultant led care from the outset, and despite developing significant problems during pregnancy her care was fragmented and inadequate in the days leading up to the delivery of Baby Aaron.

It is the opinion of this investigation team that the communication between the consultants and the woman and between the consultants and the NCHDs and Midwives and, between the medical staff of S1 to the USS Dept and/or on-call consultant Obstetrician was substandard in all respects.

11:00 Hours Midwife M2 Entry

It is documented by Midwife M2 that the CTG was applied prior to discharge.

11:58 Hours Midwife

It is documented by a midwife that the CTG discontinued at approximately 11:58 hours and reviewed by a senior midwife. To come in again if Mrs X had any concerns. The CTG Review contains the following:

- Baseline rate 145bpm
- Variability 5 bpm or more
- Accelerations present
- Decelerations none
- Maternal Pulse 70
- Normal CTG - ticked

In relation to Mrs X's urgent referral, Consultant Obstetrician and Gynaecologist B stated during the interview process that Mrs X was not her patient and that;

> *'Hospital S1 patients are referred to Hospital S2 with Polyhydramnios. Mrs X was greater than 48cm which is huge. She was going to go to Dublin that week. She should have got an appointment, this is a problem. "Urgent referral" seen by 72 hours maximum. A patient 34/35 weeks gestation, Hospital S2 will not take it; I did not feel she needed to go now. She was seen on 29/04/2016 and also 15/04/2016 when she was 33 week, at that stage she may not have been polyhydramnois. She was at 35 weeks but what happened between 15/04 & 29/04, I do not know'.*

During the feedback process Mrs X stated;

> *'The urgent referral was not followed up at any time and should have been within a 72-hour period. Due to a bank holiday weekend the urgent referral was not looked into. 'My Blood Pressure was elevated, there was a significant increase in fluid, protein in the urine, abdominal pain, reduced urine output as previously unable to provide sample. Dizziness and reported dots in front of eyes. I had an elevated abnormal liver function test, possible sudden weight gain. Polyhydramnios at 48cm. All Ignored. Given the effects of pre-eclampsia on a baby and mother if left untreated. All signs and symptoms ignored'.*

Consultant Obstetrician and Gynaecologist B stated at interview that the Midwife would normally follow-up on the referral and she normally follows up on her own referrals made. It is unacceptable to assume that the Midwives would follow-up on a referral while Consultant Obstetrician and Gynaecologist B would however follow-up on her own referrals. This can only lead to confusion and must be addressed to ensure a formal process in place for referral follow-up.

The Investigation Team considers that Consultant Obstetrician and Gynaecologist B does not explain his/her action(s) or decision making in relation to the clinical oversight of Mrs X's condition whilst an inpatient that weekend. It is the opinion of this investigation team that there was no documentation regarding the findings, discussion and actions of the 29th April 2016 during this admission, it is surprising that there appears to be little discussion with Mrs X in relation to why she was in hospital or what had predated this admission only days beforehand in relation to a blood test result, Ultrasound examination findings, urinalysis results, raised blood pressure, clinical signs and symptoms including those of polyhydramnios.

It is the opinion of this investigation team that whilst it may be routine in hospital S1 for a Midwife to follow up on a referral, all staff would or ought to have known that a faxed urgent referral at lunch time on a bank holiday Friday provides no assurance that the referral will be seen by anyone in hospital S2 in less than 72 hours over a bank holiday weekend and the consultant on call ought to have enquired into its status where there was an on-going concern.

The Investigation Team considers this to be a serious deficit in care, i.e. lack of communication with Hospital S2 in terms of establishing the status of the referral and next steps and informing Mrs X of what decisions where being made in relation to her care or in this case the lack of any verbal and written plan/decision.

No Time

On Monday afternoon while at home Mrs X outlined that she had a mucus discharge, no blood so she contacted the Maternity Assessment Unit and described her symptoms. Mrs X recalled that the midwife at the time was not concerned as there was no blood or change in the pain. Although Mrs X felt rested she still had discomfort and continued having irregular contractions.

Mrs X stated at interview that on the night of the 2nd May and morning of the 3rd of May, although she felt rested she still had discomfort and continued having irregular contractions.

The Investigation Team note that there was no available Midwife record of that call. The unit should have a record any calls The Investigation Team consider that all calls are logged and reviewed on an on-going basis by the Midwife shift leader so it is known who is expected in etc and to be able to go back and audit advice given. There should be an agreed SOP to guide and monitor this practice of advice.

Tuesday 3rd May 2016

02:45 Hours

Mrs X stated at interview that by Tuesday morning her contractions had changed;

> *'I woke up with lower abdominal cramping along with back cramping and leg cramping and tightening in upper abdominal area at 2:45am. Contractions occurred every 20 minutes and lasted 1minute. The contractions progressed down to 10 minutes apart lasting one minute each.*
>
> *At 7:25am and 7:44am – I had more discharge of mucus. I rang Maternity at 8:30am and was told if concerned to come in. I had a bloody show at 10:34am and went to the hospital straight away. I kept a record of her contractions on my iphone until I was in MAU'.*

The below contains a record of contractions provided by Mrs X:

> *2:45am 3:57am 4:21am 5:08am 5:26am 5:42 am 6:50am 7:10am 7:25am 7:44am 7:57am 8:27am 9:01am 9:17am 9:26am 09:40am 09:54am 10:07am 10:14am 10:24am 10:34am 10:49am 11:00am 11:13am 11:29am 11:34am*

During the interview process Consultant Obstetrician and Gynaecologist A was asked why the referral was not followed up on; to which he replied that the plan was to contact Hospital S2 on Tuesday 3rd May to follow up on the urgent appointment in the foetal assessment unit of Hospital S2, however when Mrs X represented on Tuesday 3rd of May at 11:30, she was admitted and kept in from there on to determine if she was in labour or not and to monitor foetal wellbeing; and therefore the referral was not followed up on.

At interview Consultant Obstetrician and Gynaecologist A stated that Mrs X's waters broke at 9:45pm on 3rd May and the patient started having labour pains; there was no opportunity then for the patient to go to Hospital S2.

It is the opinion of the Investigation Team based on the interview with Consultant Obstetrician and Gynaecologist A that it was the intention of Consultant Obstetrician and Gynaecologist A to follow up on the urgent referral sent to Hospital S2 however it is not documented as to why it was not followed up on.

Mrs X was admitted to the hospital mid- morning on the 3rd May 2016, but did not rupture her membranes until about 11 hours later so one could argue that Hospital S2 should have been contacted in the am, given the reason for the urgent referral together with the presenting signs and symptoms, and that there was time to liaise with a tertiary hospital and consider the most

appropriate management for Mrs X at that point.

09:00 Hours

According to the hospital S1 on call rota Consultant Obstetrician and Gynaecologist A was on-call on Tuesday the 3rd May 2016 from 09:00 hours.

11:30 Hours Midwife M7 Entry MAU Assessment sheet

It is documented by the Midwife M7 on duty in the Maternity Assessment Unit at Hospital S1 that Mrs X was having pains once every 5 minutes. It is also documented by Midwife M7 that Mrs X is awaiting an appointment for a fetal anomaly scan in Hospital S2. The FHR is recorded as 147 bpm. Mrs X is currently on Ranitidine tablets.

- Lie longitudinal
- Presentation cephalic
- Reason for attendance: assess fetal well being
- Plan for Obstetric Registrar to review.
- Urinalysis: Trace Ketones and small amount of blood

During the interview process Midwife M7 stated that the assessment unit is open 24 hours a day 7 days a week for patients to attend. Staff can be a *'floater'* at night if it is not busy. During the day there are 2 midwives on duty. Midwife M7 also stated that the on call Registrar admitted Mrs X and she was complaining of pain and she was for dexamethasone 2 injections 24hrs apart.

12:30 Hours

Mrs X outlined that she waiting in MAU until 12:30;

> *'History given to midwife…Midwife performed CTG - Findings were that baby was fine and contractions were showing up. I highlighted to the midwife that the contractions on Sunday were different as they were more uncomfortable up high. I felt they had changed due to my bump dropping, however I now had contractions in my lower abdomen and back along with upper abdomen.*
>
> *No Ultrasound was performed. Cervix was checked for dilation by Obstetric NCHD who reported the lining of cervix was very thick. A high vaginal swab was performed. I was advised to stay in and wait for a bed. I felt the baby's movement were less and less over the last few days and voiced my concerns but I was reassured by the doctors it was because I had so much fluid'.*

According to Dr. Gardeil it would not be unusual to experience reduced fetal movement with the increased fluid due to polyhydraminos, however it is not clear from the healthcare records that this was explored appropriately, even if it is just to provide Mrs X the assurance that Baby Aaron was well at that time. There is no acknowledgment that the reduced fetal movement was taken into consideration by staff which gives rise cause for concern in terms of recording clinical presentation, plan of action and the rationale for same. This could be perceived as a failure to monitor Mrs X appropriately.

12:32 Hours

Using times that were visible on a segment of a CTG trace in the healthcare record and then by working backwards on the segments, it seems that a CTG was commenced at about 12:32 hours. Insofar as the fetal heart rate can be interpreted from this CTG trace, the investigation team considers this CTG reassuring and normal.

12:35 Hours IMEWS Chart

Mrs X's BP is recorded as 132/92.

The investigation notes that the diastolic blood pressure was 92mm Hg, which constitutes a yellow trigger. On this occasion the yellow trigger was not documented as a trigger and was noted to be 0, this is incorrect and should have been documented as 1.

The blood pressure measurement should have been repeated within an hour but it was not rechecked until 15.00 hours.

Dr. Gardeil outlined that it is not clear from the records whether this was in fact communicated to another member of staff to be rechecked. In any event there is no repeat BP carried out and this constitutes another failure in communication.

13:30 Hours Obstetric NCHD Entry

The Obstetric NCHD documented that Mrs X self-referred to the MAU;

- Complaining of abdominal tightenings since last night. Experienced a show with some blood. Still complaining of tightening's and irregular
- Had paracetamol at home only 1 tablets at 09.30 hours today. CTG satisfactory overall
- Toco some uterine activity noted
- On examination well-comfortable U/A NAD
- Abdomen soft and non-tender F>D
- Speculum / vaginal examination to assess
- Cervix close os
- Scanty mucous discharge and light blood on speculum
- Known polyhydraminos
- Patient awaiting USS in Hospital S2
- Impression not in labour at present
- Plan admit for observation
- Betamethasone x 2
- Will inform Consultant Obstetrician and Gynaecologist A
- Analgesia

Midwife M7 stated during the interview process that;

> *'We would go over to handover from the assessment unit to the antenatal ward'.*

13:30 Hours

The Investigation Team considers that Mrs X was reviewed at 13:30 hours, based on this review by the NCHD, it would appear the IMEWS chart was not reviewed by the NCHD. This was a missed opportunity.

The Investigation Team would have expected that if a patient was being reviewed by a member of the medical team that the IMEWS chart should have been reviewed for the purposes of a complete clinical assessment and escalate any concerns to staff.

14:30 Hours

As noted in the healthcare records a CTG was commenced and discontinued at 14.30 hours.

Antenatal CTG Performa completed by Midwife M7 contains the following information;

CTG assessment carried out by Midwife M7: Normal CTG All 4 features reassuring)

- Baseline Rate (bpm) 140bpm
- Variability 10bpm
- Accelerations increased 165 bpm
- Decelerations none
- Maternal pulse 87
- Membranes not ruptured
- Gestation 35 weeks 3 days

Mrs X informed the Investigation Team that she was;

> *'given an injection for lung surfactant in or around 2:30pm, Admitted to ward at approximately 3pm. The midwife documented the plan as – to be monitored'.*

Dr. Gardeil outlined that Mrs X's labour could be considered to have started at 12.30 hour on the 3rd of May 2016. Ms X was having pains at 35 weeks and 3 days and presented to the Maternity Assessment Unit. A CTG was commenced and discontinued at 14.30 hour. Vital signs were checked at 12.35 hour and recorded on an Irish Maternity Early Warning System (IMEWS). The diastolic blood pressure was 92mm Hg, which constitutes a yellow trigger. Blood pressure measurement should have been repeated within an hour but it was not rechecked until 15.00 hour: again a yellow trigger because of a diastolic pressure of 91 mm Hg was not escalated.

15:00 Hours IMEWS Chart (2 hours 25 minutes post previous raised BP)

Mrs X's BP is recorded as 137/91; Maternal heart rate was recorded as 90 bpm. IMEWS yellow trigger was noted to be 1.

The Investigation Team again considers that this second *'yellow trigger'* due to a diastolic pressure of 91 mm Hg was not escalated, nor has this finding been communicated to another member of staff to be escalated. This constitutes another failure in communication and a failure to take the necessary actions (deviations from the norm, failure to follow up and failure to take the necessary actions).

On this occasion the IMEWS yellow trigger was noted to be 1, this was a correct assessment.

16:00 Hours

Mrs X was transferred from the MAU by Midwife M7 to the Antenatal ward. Midwife M8 received the care of Mrs X.

16:00 Hours Midwife M8 Entry

It is documented by the Midwife M8 on duty that she admitted Mrs X to the ward and orientated her to ward, bed bell and controls.

Plan:

- 2nd betamethasone to be given at 15:00 hours 4/5/16.
- IMEWS
- Consultant Obstetrician and Gynaecologist A aware of admission.

At interview Midwife M8 stated that Mrs X came from the assessment room, and that she didn't remember her. Midwife M8 informed the Investigation Team that she was to repeat the IMEWS trigger but was unable to recall where she was.

During the interview process Midwife M8 stated that she went to the ward at 16:00 hours and would have checked the IMEWS at 16:00 hours.

There is no documented evidence in the healthcare to suggest that the IMEWS was repeated at 16:00 hours. The Investigation Team note that the observation columns of the IMEWS chart was full following the 15:00 hours entry, this required the commencement of a new IMEWS chart.

16:00 Hours – 17:57 Hours

Mrs X outlined at interview that;

> *'I recorded my Contractions as follows until visiting hours: 15:59pm 16:10pm 16:20pm 16:39pm 16:44pm 16:51pm 17:00pm 17:15pm 17:18pm 17:27pm 17:40pm 17:57pm*
>
> *At 6pm I asked a midwife (M8) to assist putting on a tens machine to help with the contractions. The midwife asked me to wait until after her dinner break. I was not happy with this and after the midwife returned from her dinner she offered to put the tens machine on, at which point I told her I would wait for my sister who was a Physio to come in to do it instead. No observations were taken or CTG performed between 3pm and 10pm'.*

At interview Midwife M8 stated that she would help Mrs X and never refuse any request like that.

18:00 Hours – 20:09 Hours

Mrs X outlined at interview that;

> *'I went for a walk. Felt a lot of pressure had contractions about every 10 minutes, also more mucus came: 18:45pm 19:00pm 19:18pm 19:53 20:09pm'.*

The Investigation Team note that there is no further entry made in the healthcare record by Midwife M8.

20:30 Hours

Midwife M6 informed the Investigation Team at interview that she commenced her night shift at 20:30 hours. On night duty the unit has 30 beds divided into 2 sections and Midwife M6 stated that she received the care of half the ward that night.

Midwife M6 stated at interview that;

> *'I write an ISBAR for each patient when I take over care. I like to have a plan for each patient. I performed a routine antenatal assessment and performed Mrs X's clinical observations. I noted there was a yellow trigger from that day that wasn't rechecked. Mrs X reported feeling no fetal movements at this time, so I arranged for Mrs X to go to the labour ward for a CTG and obstetric registrar review. I informed the shift leader and the shift leader brought Mrs X to the labour ward for review. There was a yellow trigger at 3pm. I don't recall this, but if I forgot to recheck it was because I was worried and was getting the registrar to review. I was not on duty at 3pm, I commenced shift at 20:30. I was unaware of a yellow imews trigger that day until I looked at Mrs X chart that night. The last imews entry that day was the last imews entry box on the imews chart, I needed to obtain a new imews chart to write on. I was concerned about Mrs X fetal movements and arranged for Mrs X to go to labour ward for registrar review. When I reviewed Mrs X chart, I noted my imews entry was not present in the chart'.*

21:45 Hours - Approximately

Consultant Obstetrician and Gynaecologist A stated at interview that;

> *'Her waters broke on 3rd May and the patient started having labour pains. There was no opportunity then for the patient to go to* Hospital S2*'.*

Based on the healthcare record entries Mrs X had a SROM at 22:45 hours.

The Investigation Team wish to highlight that Consultant Obstetrician and Gynaecologist A states that because of the ruptured membranes and labour pains, Mrs X couldn't be transferred out of hospital S1, however Mrs X had already been an inpatient for the previous 10 hours so why was that not considered beforehand. It is not sufficient to state that she went into labour hence she could not be transferred. Again is unsatisfactory.

22:00 Hours

Mrs X stated during the interview process while reading from her aide memoire that by;

> *'no observations were taken or CTG performed between 3pm and 10pm'.*

The Investigation Team acknowledge that Mrs X believed that she should have been reviewed more closely considering previous findings from USS and other investigations i.e. urinalysis showing evidence of protein, raised LFT's; there is no documented plan for Mrs X in the healthcare record nor is there any attempt to reassure Mrs X if the plan was not to monitor her for this period between 3pm and 10pm including any rationale as to why she did not require monitoring. Healthcare staff need to consider that expectant mothers need support and reassurance that everything is going well, particularly if there is any suggestion that an unborn baby maybe at risk. Again, the Investigation Team considers this is a failure in communication.

Mrs X documented the following in her aide memoire;

> *'After 10pm the midwife (M6) took my blood pressure, I reported no foetal movements.*

The investigation team note that Midwife M6's entry in the notes timed 22.10 hours indicated that vital signs were normal (IMEWS=0) but the values of the vital signs checked are not documented. This is again a failure to monitor and act in accordance with IMEWS requirements and contributes to the failure to communicate (deviations from the norm, failure to follow up and failure to take the necessary actions).

At interview Mrs X stated that;

> *'I feel and know that Aaron was in distress long before that point (waters breaking), even in the days leading up to it for instance. Given the day, the fact that there were 7 hours without Aaron being monitored. Nobody can know what happened in those 7 hours, whether he did go into distress or whether that is what pushed the fact that my waters did break. I know how I felt at that time. I know the pressure that I was under, even to walk. I knew what was coming. With hindsight now understand, the feeling. It was my first birth, my first time, I didn't know at that time, pressure is pressure, it is good whatever. But those seven hours, is this something that has to be looked at? We don't know how he was in those seven hours'.*

22:10 Hours – Midwife M6 Entry

It is documented by the Midwife M6 on duty that;

- IMEWS 0

- Fundus>dates
- Polyhydramnios
- c/o abdomen soft non tender
- FHR at140bpm with sonicaid for 1 minute
- Using TENS for pains
- Not distressed, reports mucus discharge
- Commenced CTG
- Registrar review

During the feedback process Mrs X stated that she was;

> *'was admitted with high blood pressure and protein in urine. Bloods from Friday 29th of April showed abnormal liver function with elevated levels. Bloods were not repeated at any time between admissions Sunday-Monday. High risk patient should have been monitored on a continuous basis, however Mrs x was not attended to for a period of 7 hours in which IMEWS should have been repeated'.*

The Investigation Team again note the Mrs X's raised LFT's were not repeated and no rationale provided in the Healthcare Record as to why they were not repeated. This constitutes sub-optimal care.

During the feedback process Midwife M6 outlined that;

> *'On reviewing Mrs X notes, it was then that I noted my IMEWS entry was not present in file. A new IMEWS chart was commenced at 22:10 as last entry of IMEWS before this was in last column of previous IMEWS chart. The IMEWS is documented as 0 in clinical notes. IMEWS was performed as part of routine antenatal examination at 22:10 hours as documented via ISBAR'.*

22:30 Hours Approximately

During the feedback process Mrs X stated that*;*

> *'2 hours after change of shift[200] Midwife M6 attended to me. I was brought to the labour ward for a CTG with shift leader Midwife M3 as I had not been monitored since admission, it is documented in the healthcare record the CTG was commenced due to 'Mrs X's complaints'; I had not complained, the CTG had been organised once it was noted by midwife that I had not been monitored for a period of time. I had the same complaints at admission as I did over the previous four days. I was brought to the labour ward for CTG with the senior midwife (M3) and my blood pressure was up. I told Midwife M3 the last foetal movements I felt were that morning'.*

22:32 Hours

Based on the CTG trace in the healthcare record Mrs X was commenced on a CTG tracing again at 22:32 hours, following transfer to the labour ward.

The Investigation Team note that the Antenatal CTG Proforma which contains an assessment of each CTG only contains the time that the CTG was reviewed (which appears to be in close proximity to the time the CTG was discontinued) as opposed to capturing a start and stop time.

Mrs X outlined that when she was an inpatient during all her admissions that all CTGs were carried out at the bedside;

> *'the time was 22:20hours. Why on this occasion WAS I transferred to the labour ward*

[20] Shift change occurs at 20:00 hours for night duty.

especially for a CTG to be carried out by the shift leader…. CTG was not carried out at bedside as usual, for a reason? The Shift leader carried out CTG not midwife, for what reason!!! The Register asked to review for a reason'.

Midwife M3 Shift Leader outlined that Mrs X complained of lack of movement and that she was available to carry out the CTG and was trained in carrying out a CTG.

The Investigation Team consider that to bring Mrs X to Labour Ward for her CTG and Obstetric review was appropriate, as she could get 1:1 care there given her gestation, presenting signs and symptoms, polyhydramnios, reduced fetal movements, raised BP, previous abnormal USS findings, previous abnormal blood results and she would need a comprehensive Obstetrics & Gynaecology review. Notwithstanding this correct decision, it is the opinion of this investigation team that Mrs X was never informed of the rationale for any action taken nor was this plan documented in the healthcare record constituting another failure in communication.

22:40 Hours Midwife

It is documented by Midwife on duty that Mrs X brought to labour ward for CTG as she is complaining of reduced fetal movements.

- Fundus >dates due to polyhydramnios
- Longitudinal lie cephalic FHHR[21] 146bpm
- CTG commenced
- Mrs X stated she finds it difficult to feel FM since having polyhydramnios
- BP 145/103
- P 70
- T36.6
- RR 18
- SpO2 98%
- No headache
- No complaints of upper abdomen pain
- Or epigastric pain
- Did have spots in front of her eyes today but felt it was because she was bending over.
- No visual disturbances and awaiting urinalysis post CTG

The Investigation Team note following a review of the IMEWS chart it is noted there is one yellow trigger and one pink trigger. Based on the instruction highlighted at the top of the IMEWS chart;

Contact appropriate doctor for early intervention if the woman triggers one PINK or two Yellow zones at any one time.

At interview Midwife M6 stated;

'I brought Mrs X to labour ward for obstetric review. Vaginal examinations in preterm cases are performed by the registrar. My practice would be to always perform an abdominal palpation before commencing a CTG to ascertain fetal position. I auscultated the fetal heart and commenced a CTG to assess fetal wellbeing'.

22:45 Hours

Mrs X informed the Investigation Team at interview that;

'By 10:45pm my waters broke while going to the toilet. It is documented as Grade 1 Meconium, I saw that my waters were a light green in colour from the pad placed on the floor to clean up the waters that had dripped from me when I had to get up to open the

[21] FHHR – Fetal Heart Heard and Regular

bathroom door. Midwife looked into the toilet to observe the waters. She appeared to be concerned. High volumes of waters went into the toilet and continued to come for the next hour. Contractions stopped after waters broke noticed my stomach deflated rapidly and could see the outline of my baby more to my right side'.

The Investigation Team note that it is documented later in the healthcare record that Mrs X's waters broke at 23:10 hours. It maybe that it was at that time the staff member documented the event.

22:50 Hours Midwife M6 Entry

It is documented by Midwife M6 on duty that the rechecked BP was 125/76. Mrs X had not felt movement since this am. The NCHD was informed.

22:50 Hours

It would appear that the CTG which was commenced at approximately 22:32 hours was discontinued at 22:50 hours.

22:54 Hours NCHD Entry

It is documented by the NCHD that;

- Patient not able to feel much of fetal movements
- CTG satisfactory
- BP noted
- Plan Reassure / continue observations
- Can go back to ward

22:55 Hours Midwife Assessment of CTG

- Baseline Rate 145
- Variability >5
- Accelerations present
- Decelerations none
- Opinion normal CTG[22]
- Maternal Pulse: 70bpm
- Contractions: 0
- Membranes ruptured no
- Action for review by NCHD

Following these entries it is not clear whether Mrs X was transferred back to the antenatal ward for on-going monitoring by a midwife or whether she remained in the labour ward. Either way this is not documented.

Mrs X did confirm during the feedback process that she returned to the antenatal ward following her CTG.

23:05 Hours
Mrs X informed the Investigation Team at interview that;

[22] A 'Normal' CTG is indicated when all four features (fetal heart rate, baseline variability, acceleration and deceleration of the fetal heart rate and frequency and strength of contractions as recorded by the attending healthcare professional) fall within the reassuring category i.e. they fall within the normal ranges as outlined on page 16 of this report. A 'Suspicious' CTG is when one feature falls within the nonreassuring category and the remainder are reassuring. A 'Pathological' CTG is when two or more features fall within the nonreassuring category or one or more features fall within the abnormal category (reference: Regional Maternity Department, Hospital S1: Fetal Heart Monitoring in the Maternity Department. Approval date: April 2011).

'I was brought to the labour ward and set up on CTG. Midwife M3 was concerned and told me the foetal pulse had dropped'.

23:10 Hours Midwife M6

It is documented by Midwife M6 that Mrs X activated the 'call bell', SROM Grade 1 meconium noted and Mrs X was to be transferred to labour ward.

At interview Midwife M6 stated;

'I informed the shift leader and the shift leader brought Mrs X to the labour ward for review. On returning from the labour ward, Mrs X went to the toilet and activated the call bell. On answering the call bell, I noted liquor[23] on the floor and in the toilet. The liquor was meconium stained. I informed the shift leader that I would be transferring Mrs X back to the labour ward for continuous monitoring due to the meconium stained liquor. I noted a substantial amount of meconium stained liquor, I brought Mrs X immediately to the labour ward for CTG Monitoring and obstetric review. I auscultated the FH at 110bpm and commenced a CTG with consent to assess fetal being following rupture of membranes and the noted meconium stained liquor. I noted the maternal pulse was high on commencing the CTG. Mrs X was awaiting obstetric Registrar review, as the registrar was currently attending another delivery in the labour ward. The shift leader was informed immediately. I handed over care in labour ward shortly after 23:27hours.

The Investigation Team note that Mrs X returned to the ward in the interim period. The investigation team were informed that the maternity ward and the labour ward are part of one continuous corridor in S1 so transfer in and out is a relatively short transfer/ movement.

During the feedback process Midwife M6 stated that the;

'Time of SROM: 23:10- This is the time of SROM documented contemporaneously. Mrs X was on CTG in labour ward until 22:50. There was no delay in transferring Mrs X to labour ward for continuous CTG monitoring and obstetric registrar review post SROM'.

I brought Mrs X to labour ward post SROM for continuous monitoring and review by registrar as soon as possible. The heart rate was auscultated at 110bpm and a CTG was commenced to assess fetal wellbeing post auscultation. The CTG was normal at this time. My practice is to always perform an abdominal palpation before the auscultation the fetal heart as part of an abdominal examination. This includes before commencing a CTG. CTG was normal Mrs X was brought to labour ward for continuous monitoring and registrar review'.

23:14 Hours Midwife M6

CTG commenced with consent to asses fetal wellbeing. Assessment findings and action:

- FHHR pre CTG @ 110 bpm
- maternal pulse high 122bpm
- Good volumes of Meconium 1 draining mild pains
- For continuous CTG and Obstetric Registrar to review on labour ward

At interview Midwife M6 stated that;

[23] A good liquor volume is a reassuring sign that the fetus has not been subjected to chronic hypoxia in the antenatal period. If no liquor is seen in labour, this can pose a serious risk to the wellbeing of the fetus and the safe assumption must be that there is oligohydraminos/anhydramnios i.e. a reduction or absence of liqour.

'I brought Mrs X to labour ward for obstetric review. Vaginal examinations in preterm cases are performed by the registrar. My practice would be to always perform an abdominal palpation before commencing a CTG to ascertain fetal position. I auscultated the fetal heart and commenced a CTG to assess fetal wellbeing'.

During the feedback process Mrs X stated that she was concerned over the colour of the meconium.

'I noted that it was a lot darker. Also how it was still draining meconium coloured water over next two hours. Also please look into the fact that large volumes of waters can dilute meconium'.

During the interview process Midwife Shift Leader M3 stated that Mrs X was brought to the labour ward with Spontaneous Rupture of Membranes (SROM) by Midwife M6, who connected Mrs X to a CTG machine at 23:14 hours.

23:14 Hours – CTG Commenced

A review of the CTG tracing provided indicated that this CTG was commenced at approximately 23:14 hours.

23:27 Hours Midwife M6

At interview Midwife M6 stated that she handed over care in labour ward shortly after 23:27hours.

Midwife M6 documented the maternal pulse at 106bpm. Midwife M6 noted that Mrs X anxious now and reassurance given, Mrs X was to be reviewed by the Obstetric Registrar and the Shift leader was made aware.

23:30 Hours

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

23:39 Hours Midwife M3 Healthcare Record Entry

Midwife M3 on duty documented that Mrs X's pads changed, Meconium Grade 1 draining in large volumes. The NCHD was informed of the meconium grade 1. The fetal heart was recorded as 152bpm.

23:39 Hours

During the interview process Midwife Shift Leader M3 stated that she took over the care of Mrs X at 23:39 hours and informed the Registrar of Mrs X's admission.

Midwife M3 stated during the feedback process that;

'The CTG was very reassuring with no abnormal features. Reassuring me that there was no evidence that there was a cord pro-lapse. On taking over care of Mrs. X, I requested a registrar review, whom I know to be nearby and whom I knew would carry out a vaginal exam. I felt that it was unnecessary for me to perform a VE when I knew the registrar would be performing a VE also especially as there was no evidence of a cord prolapse. It is common practice, that registrars carryout vaginal examinations on pre-term women. I explained that if a registrar was not available and I thought for one moment that a cord pro-lapse was a possibility, I would of course have had the experience to examine her, if required. I did in fact, immediately recognize the abnormal features of the CTG, documented and escalated them appropriately. It is also my opinion that the other midwives caring for Mrs. X did in fact, immediately recognized abnormal features of the

CTG, documented and escalated them appropriately'.

23:40 Hours Midwife M6 Entry

Midwife M6 on duty documented that Mrs X returned to bed. There was loss of contact on CTG. It was difficult to auscultate the fetal heart when Mrs X is lying on her side. No problems auscultating fetal heart while in the semi recumbent position, the CTG was considered reassuring and Mrs X was awaiting NCHD review.

During the feedback process Midwife M6 stated that;

> *'Mrs X was not left unattended in the Labour Ward… I stayed providing 1:1 care until I handed over the care of Mrs X care directly to the shift leader in Labour Ward room 1 after this time. I then proceed back to my caseload on the ward'.*

23:40 Hours

Mrs X informed the Investigation Team at interview that;

> *'At 23.40pm unprovoked loss of contact and difficult to auscultate heartbeat'.*

During the feedback process Mrs X stated that at midnight she was reviewed by the Registrar due to loss of contact while on the CTG between 23:31 hours and 23:41 hours, Consultant Obstetrician and Gynaecologist A was contacted and advised to leave Mrs X for 2 hours and induce, then both unprovoked decelerations occurred at 00:13 hours. Mrs X also stated that she stood up out of bed for 4-5 minutes to be changed while on the CTG, Mrs X outlined that this does not explain the extend of the loss of contact. This period of time co-insides with the decision for the Midwife M3 requesting the Obstetrician Registrar to review Mrs X. Mrs X outlined that there must have been a reason why the registrar was called. Was it because of the loss of contact or that the loss of contact led to concern.

The Shift Leader Midwife M3 during the feedback process stated that;

> *'It is my understanding, that Mrs X was continually monitored from 23:14 with no break in CTG monitoring'.*

According to External Expert, Midwifery;

> *In my opinion from 23.43 hrs the baseline rate was 150bpm, variability > 5, no accelerations and subtle late decelerations slow to recover followed by a deceleration recovering to baseline @ 00.20hrs. Uterine activity appears to be recorded on the CTG."Tightenings 2:10 mins short on palpation" documented by Midwife on retrospective note (pg 121). Fetal movements appear to be recorded on the CTG. The maternal pulse recorded on the CTG fluctuates from 80-120bpm. CTG from 00.20hrs to delivery decision time @ 01.00hrs baseline 150-155bpm with period of increased variability @ 00.52hrs followed by further bradycardia @ 00.56hrs. Whilst acknowledging Midwifery staff concerns over the CTG particularly around the decelerations @ 00.15hrs and 00.56hrs with appropriate call for Obstetric Registrar review, there appears to be a delayed recognition of a pathological CTG.*

During the feedback process Midwife M3 stated that the;

> *'External Expert Midwifery opined that there "there appears to be a delayed recognition of a pathological CTG". I would strongly disagree with this statement, as the midwifes immediately escalated their concerns to the Registrar, who then immediately escalated their concerns to the consultant, which is clearly documented and which clearly shows that there was no delay in the recognition of a pathological CTG'.*

Dr Gardeil outlined that shallow variable declarations to 120 bpm are present at 23.33 hours and 23.36 hours.

Wednesday 4th May 2016

00:00 Hours

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

Mrs X described at interview that by 00:00 hours her contractions had started again.

00:00 Hours

During the interview process Midwife Shift Leader M3 stated that Mrs X was reviewed by the Registrar and was found not to be in labour. The CTG was normal. The Consultant Obstetrician and Gynaecologist A was informed, plan was to repeat VE in two hours and for Oxytocin if not progressing.

00:00 Hours NCHD Entry

The Obstetric NCHD documented that s/he was asked to review Mrs X. The NCHD documented that Mrs X had a history of leaking fluid at 23.30 hours 3rd May 2016, yellow tinge noted, and meconium grade 1, no pain at present and that a CTG was in progress.
Clinical assessment record by the NCHD included:

- VE (Vaginal Examination) to assess: Cervix 1 cm dilated and Vertex – 2-3
- Lots of liquor

The NCHD recorded that Consultant Obstetrician and gynaecologist A was contacted and recommended to leave Mrs X for 2 hours, VE to assess in 2 hours, syntocin infusion, inform neonatology unit.

Mrs X outlined at interview that at 12:00am contractions started again.

00:10 Hours

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

00:13 Hours Midwife M2 Entry

During the feedback process Mrs X stated that there was no specific midwife monitoring her continuously.

Midwife M2 on duty documented that she was monitoring Mrs X while assisting also in Labour Ward 3 as Midwife M3 shift leader was called to the MAU.

00:13 Hours

During the interview process Shift leader M3 stated that she was called to the MAU for an emergency and had to leave the labour ward.

00:15 Hours Midwife M2 Entry

Midwife M2 on duty documented that the CTG beeping in labour ward and documented a deep

deceleration unprovoked down to 70 bpm for 1.5 minutes and that the Obstetric Registrar was called to review. Midwife M2 also recorded a 2nd unprovoked deceleration for 30 seconds and Mrs X was changed to the left lateral position.

Mrs X informed the investigation team that;

> *'my cervix was checked around 12:15am by NCHD AF who reported 0.5cm dilation. I asked the midwife (M3) about what the meconium in her waters would mean and she explained that there are 3 stages and she was not concerned. NCHD AF spoke to Consultant Obstetrician A who advised to monitor until 2am at which point I was to be induced. Between 12am and 12:30am CTG Foetal Heartbeat showed signs of distress. Midwife (M2l) told parents if it happens again I would be brought for an emergency section'.*

Mrs X informed the Investigation Team at interview that;

> *'At 00.15am (4th May 2016) - unprovoked deceleration to 70 for 1.5 mins;*

Consultant Obstetrician and Gynaecologist A informed the Investigation Team during the interview that the CTG became non-reassuring at 00.15 hours on Wednesday and the Midwife called Consultant Obstetrician and Gynaecologist A as he was on call Tuesday night/Wednesday a.m. Consultant Obstetrician and Gynaecologist A stated that he was informed that there was an episode of foetal bradycardia but this had recovered. Consultant Obstetrician and Gynaecologist A stated that he advised staff to keep the patient under close observation and to inform him if any other bradycardia was noted and to keep the team and the patient on standby for potential C Section. Consultant Obstetrician and Gynaecologist A was planning to come to assess the patient but when he was informed bradycardia was recovered and CTG was reactive, his plan to come straight if anymore abnormalities on the CTG'.

1.20 Hours

Mrs X informed the Investigation Team at interview that;

> *'At approximately 00.20am – unprovoked deceleration to 70-80 for 30 seconds, slow to recover, NCHD was informed, it was decided to continue monitoring'.*

00:20 Hours NCHD Entry

The NCHD called to review Mrs X documented the following in the healthcare records;

- Review unprovoked decelerations x 2
- FH 70-80 bpm for 1.5 minutes
- Slow to recover
- Recover now baseline 150 bpm
- Reduced variability
- No accelerations
- VE (Vaginal Examination) Cx (Cervix) 1 cm dilated, effaced, Vx – 3
- Plenty of yellow tinge liquor noted
- Contraction 2:10
- Plan continuous CTG monitoring
- IV cannula/FBC/Group and Hold
- Will inform Consultant Obstetrician and Gynaecologist A

00:20 Hours NCHD Entry

- Consultant Obstetrician and Gynaecologist A contacted

- Continuous CTG monitoring
- If further deceleration to call Consultant Obstetrician and Gynaecologist A asap.

Mrs X informed the Investigation Team at interview that;

> *'The midwives documented foetal heart distress between time of waters breaking and the time of c-section preparation (11pm and 1:00am)*

In light of the previous USS findings on the 29th April 2016, gross polyhydraminos, proteinuria and raised LFT's and belief by both Consultant O&G A and B that Baby Aaron could in fact be born in poor condition suggests firstly that Mrs X should have been monitored prior to 22:00 hours and secondly the decision to operate should have been made sooner according to Dr. Gardeil. The Investigation Team consider these decelerations to be very concerning indicating a degree of fetal distress. The actual time the decision was made to proceed to surgery is not clear and this does not lend itself to establishing whether Mrs X was prepared and operated on within the appropriate time frame. Again the Investigation Team consider this to be sub-optimal.

Mrs X recorded the timing of her contractions as follows:

> *'12:05 am 12:11am 12:15am 12:19am 12:23 am 12:32am 12:35am'*

Midwife M3 shift leader stated at interview;

> *'One of these accounts is described at 23:40 as unprovoked loss of contact and difficult to auscultate heartbeat. I do not believe this to be an episode of fetal distress as this loss of contact occurred during maternal repositioning and it is documented that the fetal heart was easily auscultated while Mrs X was in a semi-recumbent position but was not easily auscultated while she was in the left lateral position'.*

Mrs X stated that she was;

> *' informed that there could be a problem with Aaron'.*

Shift Leader Midwife M3 during the feedback process stated;

> *'At 00:15 hours there was a further unprovoked deceleration… The decision at this time was to contact the consultant if there were any further decelerations'.*

It is Dr. Gardeil's opinion that there was a delay in acting on the abnormal CTG's and the decision to operate could have occurred before 01:00 hours. Dr. Gardeil also outlined that this may not have altered the tragic outcome for Baby Aaron, but is important to highlight for the purposes of learning from adverse events.

During the feedback process Midwife M3 stated that the;

> *'Mrs X claims the midwives documented five accounts of fetal heart distress.*
>
> *23:14 FH 110bpm (The normal FH is 110bpm to 160bpm) therefore this cannot be described as an episode of Fetal distress.*
>
> *23:40 Mrs X describes an unprovoked loss of contact; this loss of contact was provoked by Mrs X moving to the left lateral position. This is clearly documented in the chart. Once Mrs X returned to a semi-recumbent position the fetal heart became easier to record. I would argue that this also cannot be described as an episode of fetal distress'.*

During the feedback process Consultant Obstetrician and Gynaecologist A submitted a statement from another Consultant Obstetrician who was sourced by his representation which he agrees with:

> *"In my opinion, there was no absolute clinical requirement to decide to proceed with emergency caesarean delivery at 00:20am on May 4, 2016 based on the CTG tracing at that time. … In my opinion, the CTG tracing at this time should have been categorised as suspicious, because of this one non-reassuring feature. Such variable decelerations are quite common in the setting of PPROM and early labour in the preterm setting. While some obstetricians might proceed with emergency caesarean section in response to variable decelerations and meconium-stained amniotic fluid at 35 weeks' gestation, in my opinion, many other obstetricians would maintain continuous fetal heart rate monitoring in such a clinical situation and defer a decision on emergency caesarean delivery until further non-reassuring features develop. I therefore would not be critical of the deferral of the decision to proceed with caesarean delivery in this case until the next fetal heart rate abnormality at 00:58 am."*

00:22 Hours Shift Leader Midwife M3

At interview Shift Leader Midwife M3 stated that;

> *'When I returned to the labour ward from the MAU, the registrar was already present and the consultant had already been informed, the plan was to call the Consultant again if there were any further decelerations. At this point [00.22] the SHO inserted an IV line and sent bloods to the lab'.*

00:22 Hours (Retrospective note written at 04:00 Hours) Midwife M2

Midwife M2 on duty documented that she returned to Labour Ward from MAU. The NCHD present following prolonged deceleration. Consultant Obstetrician and Gynaecology A informed of CTG by NCHD;

Plan:

- To call Consultant Obstetrician and Gynaecology A if any further decelerations. NCHD called to insert IV line and take bloods. FH 145 bpm
- Mec 1 draining
- Maternal pulse 80 bpm
- C/O mild tightenings only
- No analgesia required.

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

During the interview process Midwife M2 stated;

> *'at 00:15 hours I heard Mrs X's CTG machine beeping, I noted a deceleration on the CTG and called the Obstetric Registrar-on-call to review Mrs X. A second deceleration occurred on the CTG when the Registrar was present, but the CTG recovered'.*

00:35 Hours Shift Leader Midwife M3

At interview Shift Leader Midwife M3 stated that at 00.35 hours, she was called to another emergency in the MAU.

00:35 Hours Midwife Entry

The Midwife documented that she is relieving Midwife M3 as she is called to MAU for emergency.

Note taken of events to date;

- FH 147 bpm
- Tightenings 2:10
- Mec 1 draining

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

CTG Interpretation (23.16 hours – 00.45 hours) On the 3rd May 2016 the CTG trace between 23.13 hours and the 4th May 2016 at 00:45 hours shows the baseline fetal heart varies from 130 to 150 bpm, with normal variability and accelerations are present.

Shallow variable declarations to 120 bpm are present at 23.33 hours, 23.36 hours, 23.54 hours, 00.01 hours and 00.04 hours. There are **two more substantial decelerations at 00.16 hours to 80 bpm for 1.5 minutes** and - **at 00.20 hours to 100bpm for 1 minute**.

There are irregular contractions. This is considered to be a **suspicious CTG tracing**.

00:45 Hours Midwife Entry

It is documented in the healthcare record that Mrs X mobilised out to toilet.

During the feedback process Midwife M2 outlined that Mrs X went to the toilet at 00.46 hours and returned from the toilet at 00.51 hours, the CTG was recommenced.

00:50 Hours (Approximately)

Mrs X informed the Investigation Team at interview that;

> *'Mrs X recounted that Baby Aaron went into distress, Baby had an unprovoked deceleration down to 80 bpm for 4 minutes. The red button was pressed at 12:50am. I was fully prepped for section before 1:00am but midwives told me they were waiting on* Consultant Obstetrician and Gynaecologist A's *go ahead which I found distressing. While waiting I was moved to the trolley in the hall of ward'.*

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

Midwife M2's feedback is at variance with Mrs X's recollection of the call bell being activated at 00:50 hours, and stated that she would not have activated the call bell at 00:50 hours while Mrs X was in the toilet and the CTG was not in progress at this time.

Mrs X recounted at interview that;

> *'After I was prepped for section I was told by Midwife M3 that they were waiting on the go ahead from Consultant Obstetrician A if they were going ahead. This was quiet distressing, there was a wait, Midwife M2 moved me to the hall where a trolley awaited to bring me to Theatre, there was still a wait, at which point Midwife M2 said that she was not waiting and brought me straight to theatre at this point'.*

Mrs X informed the Investigation Team at interview that;

CTG shows at 00:54 Unprovoked Deceleration continuous for 8 minutes until 01:02/ 01:03 when

Mrs X moved to trolley.

During the feedback process Midwife 3 stated that the;

> *'It is documented in the report that Mrs X stated the call bell was activated at 00.50. This is incorrect as Mrs X was in fact in the toilet at this time and returned from the toilet at 00.51, as per the clinical records and the CTG was recommenced'.*

00:56 Hours

During the feedback process Midwife M2 and M3 outlined that there was no deceleration at 00.50 hours and at 00:56 hours there was a further deceleration and the emergency bell was activated. This timeline is very clear from the CTG trace.

Consultant Obstetrician and Gynaecologist A informed the Investigation Team during the interview that a second episode of bradycardia happened approximately 30 minutes later and he was notified and advised for emergency C section; and he was on his way to come to the hospital and arrived by 01:10 a.m as documented in the health care record. When patient was on her way to Theatre. The arrangements for the emergency C section were made once the decision to proceed was progressed immediately there was no delay. The registrar delivered the baby. A loose cord was present around the baby's neck but not obstructing and the Paediatric Team took over the care of the baby.

The Investigation Team note that the bradycardia mentioned above is in fact a prolonged deceleration lasting 7 minutes.

Midwife Entry

It is documented in the healthcare record by the Midwife that Mrs X returned from toilet passed a good amount of urine. The CTG was commenced and the Fetal Heart was recorded at 155bpm. At 00:56 Hours FH dropped 80 bpm call bell activated and a second midwife was present. The NCHD was called to review and Consultant Obstetrician and Gynaecologist A phoned. VE by Midwife M10 to establish progress in labour;

- Cervix thick
- Effacement 0.5 cm long
- Consistency Firm/medium
- Dilation 1 cm
- Relationship to Ischial Spines -3
- Liquor Meconium stained
- FHR 90 bpm

00:58 Hours Midwife Entry

It is documented by the Midwife on duty that the NCHD was present and Mrs X was prepared for theatre and;

- Deceleration x 6 minutes
- Anaesthetist informed
- Theatre Informed
- Nursing admin informed
- SCBU informed
- Reg and SHO called.
- Drug Prescription and administration record: 1litre hartmanns commenced

The investigation team note that following a review of the CTG trace, this deceleration lasted 7

minutes not 6 minutes as recorded above.

Mrs X outlined during the feedback process that she is aware that the midwives documented five accounts of foetal heart distress between time of waters breaking and the time of c-section preparation (11pm and 1:00am)

00:56 Hours

During the feedback process Midwife M2 outlined that at 00:56 hours there was a further deceleration and the emergency bell was activated. Midwife M2 outlined that this timeline is very clear from the CTG trace.

00:58 Hours

During the feedback process Midwife M2 outlined that preparations for the c-section began at 00:58 hours

00:58 Hours

During the feedback process Midwife M3 stated that;

> *'I answered the emergency bell at Mrs. X room at 00:58. 3 minutes later, I transferred Mrs X to the portable monitor to aid CTG monitoring enroute to theatre. 4 minutes later, Mrs. X received her pre-op medication. I know the decision to transfer to theatre was already made as the trolley was in the labour ward. This could only happen if an emergency caesarean- section had been called as the trolley comes from theatre. Once Mrs X was on the trolley, she was immediately transferred to theatre. No authorization to go to theatre is required at this point.*

It is unclear from the healthcare records when the discussion to operate was made again leaving a gap in terms of adhering to guidelines relating to timelines between the decision to operate to time of surgery.

01:00 Hours

Based on the CTG trace in the healthcare record the CTG continued to record the fetal heart rate and uterine activity.

Mrs X informed the Investigation Team at interview that;

> *'I was fully prepped for section before 1:00am but midwives told me they were waiting on* Consultant Obstetrician and Gynaecologist A's *go ahead which I found distressing. While waiting I was moved to the trolley in the hall of ward'.*

The Investigation Team consider that it is important to be able to ascertain the time of decision to deliver. This should be clear in the healthcare record. It is not documented as such in the Healthcare record but the Midwife began to prepare Mrs X for surgery at 00.58 hours. The NCHD mentions it at 01.00 and Consultant Obstetrician and Gynaecologist A concurs at 01.10hrs. Then the standard (RCOG- UK) is to deliver within 30 minutes of that whereas USA standards (ACOG) is to deliver within 20 minutes. Investigation Team consider that there must be a clearly documented decision to deliver time called in order to prevent delay and the standard can then be audited with a view to improving quality and safety.

The Investigation Team acknowledge that preparation for surgery does take time considering the patient requires the following; catheterisation, bloods, checklist, transfer, mobilising the required team, anaesthetic to safely perform surgery. From the records it would appear that this was being done prior to 01:00 hours, however the decision to deliver is not clear hence it is almost impossible to establish whether the process was timely. The Investigation Team consider that the decision to

proceed to c-section should have been carried out earlier.

Dr Gardiel outlined that considering Mrs X's full clinical presentation and CTG findings, he would have planned to carry out a c-section at 00:00 hours.

01:00 Hours Obstetric NCHD Entry

Timeline is very important more importantly the amount of time Aaron was in distress. From 00:54 CTG shows Aaron did not recover.

The NCHD documented that he was called to review Mrs X another episode of an unprovoked decelerations slow to recover 80 bpm x 4 minutes;

- VE no change
- Consultant Obstetrician A contacted to review
- Patient is prepped for emergency c-section
- FBC/GandH
- Consented
- Anaesthetist informed
- Theatre staff informed
- Portable continuous CTG monitoring

01:00 Hours

Paediatric Nurse P5 informed the Investigation Team at interview; at approximately 01:00 hours she received a call stating that Mrs X was going for an emergency c-section for fetal distress and decelerations. Paediatric Nurse P5 informed the Investigation Team at interview that she understood Mrs X was 35 weeks and 3 to 4 days gestation with polyhydramnois with fetal bowel and renal issues.

Following the phone call Paediatric Nurse P5 informed the Investigation Team at interview that she went straight to the operating theatre. SCBU Nurse P5 informed the Investigation Team that the Paediatric Registrar, Paediatric NCHD along with Midwives M2 and M3 were present in Theatre when she arrived. Paediatric Nurse P5 stated that she performed the emergency pre checks which included the following tasks:

- Warmer turned on
- Towels preheated
- Suction working and pressure 100 mm/hg
- Suction catheter 10F attached and kept meconium aspirator ready
- Oxygen checked and all tubing connected
- Oxygen flow turned to 4-5 litres, , neopuff[24] connected and neopuff pressure mask 18/4
- Term and Pre- term mask ready
- Blender 40%,
- Pulse-oximeter[25] –checked and working and probe ready
- Laryngoscope – working and blade size 2 ready
- Endotracheal tube – size 2.5 and 3 ready and stylet

[24] Neopuff®: is a flow controlled, pressure limited mechanical device specifically designed for neonatal resuscitation. Breaths are delivered by occluding a T piece.

[25] Pulse oximetry is a noninvasive method for monitoring a person's oxygen saturation (SO2). Though its reading of SpO2(peripheral oxygen saturation) is not always identical to the more desirable reading of SaO2 (arterial oxygen saturation) from arterial blood gas analysis, the two are correlated well enough that the safe, convenient, noninvasive, inexpensive pulse oximetry method is valuable for measuring oxygen saturation in clinical use. In its most common (transmissive) application mode, a sensor device is placed on a thin part of the patient's body, usually a fingertip or earlobe, or in the case of an infant, across a foot.

- Carbon dioxide detector ready
- Medication: Adrenaline and Narcan , NaCl 0.9% kept ready

CTG Interpretation (00.51 hours to 01.02 hours)

On the 4th May 2016 the CTG tracing from 00.51 hours to 01.02 hours shows the baseline fetal heart rate is initially 140 bpm, with **reduced variability**, and **-a prolonged deceleration occurred at 00.55 hours to 80 bpm until 01.02 hours lasting 7 minutes**.

There are irregular contractions. This is a pathological CTG.

01:03 Hours Midwife Entry

Transferred to portable monitor FH recovered 132 bpm. During the feedback process Mrs X outlined that this timeline noted here between 01:03 – 01:13 also confirms her account of events in waiting to go for a c-section and in waiting on Consultant Obstetrician and Gynaecologist A's go ahead. Mrs X stated that she believes 10 minutes was wasted and this is very important to her and her husband.

01:05 Hours Midwife Entry

- Sodium Citrate given IV
- Ranitidine given by NCHD
- Theatre checklist completed by Midwife

01:10 Hours Midwife Entry

Consultant Obstetrician and Gynaecologist A arrives agrees with plan by Obstetric NCHD for emergency c-section and the FHR is recorded as 125 bpm.

01:10 Hours Consultant Obstetrician and Gynaecologist A Entry

The following is documented by Consultant Obstetrician and Gynaecologist A in the healthcare record regarding Mrs X;

- 35 weeks 3 days. P0+0
- SROM at 23:10 hours
- Meconium grade 1
- Polyhydramnios
- Was referred to the Hospital S2
- Dilated renal pelvis and echogenic bowel
- Three unprovoked dips for emergency c-section.
- Consent
- Theatre staff and anaesthetist.

01:13 hours Midwife Entry

Mrs X was transferred to Theatre on a trolley and the Fetal Heart was recorded as 140bpm.

Midwife M3 Shift Leader Delivery stated that;

'We all went together to the Operating Theatre to scrub and take the baby to resus.

Midwife M2[26] knew Mrs X.

Mrs X stated that the timeline noted here between 01:03 – 01:13 also confirms her account of events in waiting to go for a c-section and in waiting on Consultant Obstetrician and Gynaecologist A's go ahead. Mrs X stated that 10 minutes was wasted and this is very important to them as a family.

01:17 Hours Midwife M2 Entry

Mrs X arrived in theatre FH is recorded as 150 bpm, Pre-operative Nursing care record completed by Midwife, Monitoring applied ECG NIBP Oximetry.

Mrs X stated at interview that it is documented in the chart that;

> *'a decision to do an emergency section at 01.10am and that 'knife to skin' was 01.28am. I arrived in theatre at 01:17am'.*

01:20 Hours Midwife M2 Entry

Midwife M2 documented that the Spinal Anaesthetic was inserted.

01:24 Hours Midwife M2 Entry

Midwife M2 documented that the CTG discontinued and the FH 138 bpm

CTG Interpretation (01.02 hours and 01.25 hours)

On the CTG trace on the 4th May 2016 between 01.02 hours and 01.25 hours, the fetal heart rate is difficult to establish due to multiple loss of contact, but generally **varies from 110 bpm to 140 bpm**. It is not possible to determine timing of decelerations due to loss of contact. This CTG is **pathological CTG**.

01:28 Hours Midwife M2 Entry

Midwife M2 documented 'Knife to skin'.

01:30 Hours Midwife M2 CTG Review carried out

- Baseline rate 145 bpm
- Variability 5
- Accelerations present
- Decelerations related to uterine tightenings
- Meconium 1
- MP 80
- Contractions 1:10

Delivery and Resuscitation

There is a disparity relating to the time of birth in the healthcare records by staff. The family outlined during the feedback process that Baby Aaron was born at 01:31 hours, and this is extremely important to them.

[26] The investigation Team became aware that Midwife M2 knew Mrs X personally

In addition the caesarean section form which was completed by the Obstetric Registrar who deliver Baby Aaron note the time of delivery to be at 01:31 hours.

01:30 Hours

At interview Midwife M3 informed the Investigation Team that she was present before Baby Aaron was born at 01:31 hours. Midwife M3 Shift leader outlined that Baby Aaron was born extremely flat, and that they were; '*very surprised, everyone was present, it wasn't expected'.*

Midwife M3 Shift leader stated that Baby A was limp, not responsive, had no respiratory effort, the Paediatric NCHD was on her right side and palpated the heart rate to be less than 60. Midwife M3 Shift leader stated that she didn't recall any Meconium, grade 1 possibly. Midwife M3 Shift leader brought Baby Aaron to the resus area.

According to Midwife M3 Shift leader at interview the Paediatric Consultant B was contacted, the Paediatric Registrar provided IPPV while Midwife M3 Shift leader provided chest compressions. Midwife M3 outlined that the Paediatric Registrar repositioned Baby Aarons head as he was at the head of the resusitaire.

01:30 Hours NCHD Entry (Entry retrospectively highlighted)

The Paediatric NCHD documented in the healthcare record that he was called to emergency caesarean section, gestation 35 weeks 3 days and that the Baby was born flat with poor respiratory effort and poor tone, the Heart rate less than 60 bpm.

01:30 Hours Midwife Entry

Caesarean section operation form completed by Obstetric Registrar X – this is a retrospective entry as it refers to blood gases taken later than 01:30 hours.

- Indication: Abnormal CTG / Unprovoked decelerations.
- Robson Category: 1
- Technique
- Pfannenstiel[27] ticked
- Uterine incision Transverse ticked
- Operative difficulties Preterm, cord around neck x 1 loose meconium in cord noted.
- Uterine closure Vicyl 1 x 2 layers
- Indwelling catheter
- Blood loss 600mls
- Cord gases: 1st 2 samples clotted
- Venous ph: 7.336
- Base excess: -1.3
- Innohep 4,500 iu s/c od x 5/7

01:30 Hours Midwife M3 Entry

Midwife M3 documented in the healthcare records that a live infant male born at 01:30 hours. Baby experienced difficulties when born, the heart rate very low, some compressions given by paediatrics and Baby Aaron was ventilated in theatre, Oxygen saturations were not satisfactory. Baby Aaron was transferred to SCBU and every step in process of babies care explained to mum and dad by midwives and theatre team. Baby checked by theatre nurse and midwife.

01:30 Hours Midwife Entry M3 Shift Leader

[27] Pfannenstiel-Kerr incision or pubic incision is a type of abdominal surgical incision that allows access to the abdomen. It is used for gynecologic and orthopedics surgeries, and it is the most common method for performing Caesarian sections

It is documented in the Healthcare records by Midwife M3 that;

> *'Delivery of newborn male infant – flat at birth. Paeds SHO and Peads Registrar present in theatre. HR check by Paeds SHO' less than 60 bpm'. PPV given by Paeds reg. Instructed to commence chest compressions. One round of chest compressions performed by me. Paeds SHO took over compressions. Paediatrician contacted via switch to come urgently. Night nursing admin officer present, resuscitation continues'.*

01:30 Hours

At interview the Paediatric NCHD stated that he was on a 6 month training rotation in Hospital S1 and was present at the birth of Baby Aaron and that the Paediatric Registrar was also present;

> *'I received a message that there was an emergency c-section and get there very quickly,*

01:31 Hours Caesarean Section Operation Form

There is a disparity in the times entered into the healthcare records regarding Baby Aarons time of birth.

On the Caesarean Section Operation Form it is documented by the Obstetric Registrar that;

- Decision time for the c-section was 01:10 hours
- Time of delivery was 01:31 hours.
- Cephalic[28] presentation
- Grade 1 meconium
- Cord around the neck once was loose
- Evidence of meconium noted on the baby and on the cord
- Regarding the cord gases it is documented that the 1st two arterial samples were clotted.

This delivery time of 01:31 hours is in line with Mrs X's recollection of events.

It is important to ensure that all staff use the same source for recording time otherwise this is a source of error. Clocks should be synchronised in the Labour Ward and Theatre.

01:31 Hours

Mrs X informed the investigation team at interview that;

> 'Baby Aaron *was delivered at 1:31am. Baby Aaron when born was floppy, blue in colour and made no respiratory effort, heart rate was 60 and sats were 50%.*
>
> *Baby Aaron was resuscitated for 10 minutes and 44 seconds. Consultant Obstetrician and Gynaecologist A was standing at the door in his coat after Baby Aaron was born observing. Consultant Paediatrician C was not present when Baby Aaron was born and did not arrive to the theatre for 15 minutes after he was born. I was told by Midwife (M3) that they were waiting for him. Baby Aaron was in theatre while I was there for up to an hour before he was brought to SCBU. Following delivery, Baby Aaron received two rounds of chest compressions. Two trials of intubation failed in the first 10 minutes. Compressions continued for the next 5 minutes until Consultant Paediatrician C arrived. It is in the file that the*

[28] A cephalic presentation or head presentation or head-first presentation is a situation at childbirth where the fetus is in a longitudinal lie and the head enters the pelvis first; the most common form of cephalic presentation is the vertex presentation where the occiput is the leading part (the part that first enters the birth canal). All other presentations are abnormal (malpresentations) which are either more difficult to deliver or not deliverable by natural means

difficulty was due to large volumes of secretions which caused intubation to fail. It took approximately three- four hours to successfully ventilate Baby Aaron. Consultant Paediatrician C spoke with my husband and Baby Aaron's Aunt and said that it was very difficult ventilation. He thought this was because Baby Aaron's lungs were so stiff and also said that he thought that there was a blockage in his bowels. He said that there was no chromosomal abnormality. He also said that there was a lack of oxygen to the brain and a 60% chance that he may have a brain injury and that Baby Aaron may die. I felt like there was a wait and see approach taken. I think when it comes to something like this and actually looking at everything that is involved and all the factors that are involved, that we can only learn from that overall point of view. I know 100% what my experience was and what I was feeling at that time. I also understand protocols and procedures and so on. But I was high risk. There was a 7 hour period there, nobody can say yes/no or different about whether Aaron was in distress at that time'.

At interview Dr. Gardeil advised Consultant Obstetrician and Gynaecologist A that Mr X was upset that Consultant Obstetrician and Gynaecologist A was there at the delivery of Baby Aaron, but did nothing to help. In response, Consultant Obstetrician and Gynaecologist A stated that he was ready to intervene if any problem arose during the C Section procedure but he observed that the registrar was efficient and delivered the baby very quickly. The Paediatric team took over the care of the baby. Consultant Obstetrician and Gynaecologist A observed the registrar during suturing of the C Section incision and this was completed efficiently. Good haemostasis was achieved. A cord pH was done immediately after delivery and it was normal.

The healthcare record states that the time of birth was 01.30 hrs and Mrs X and the Obstetric registrar state that it was 01.31hrs. If the times were from the same source and there is an error, the unit should develop a Standard Operating Procedure (SOP) stating who is to call the time of birth and using what means. The clocks in use in theatre and labour ward should be synchronised. The management of the maternity unit at Hospital S1 should review these aspects and ensure that all procedures in respect of this are clear and followed consistently.

Investigation Team understand that Mrs X and the Obstetric Register obtained the time from the clock on the wall in theatre. There should be no discrepancy in time recording. This must be addressed locally to ensure accuracy.

Any discrepancy irrespective of the amount of time is indicative of unsafe processes.

Between 01:30 – 01:40 Hours Paediatric Nurse P5 Entry

Paediatric Nurse P5 stated during the feedback process that she supported the resuscitation. Baby Aaron was born at 01:30 hours and was limp and apnoeic at birth. Paediatric Nurse P5 stated that following Baby Aarons delivery Baby Aarons head was positioned, his airway was suctioned while being stimulated, all done quickly by both the Paediatric Nurse P5 and the Paediatric Registrar.

Paediatric Nurse P5 stated at interview that there was still no respiratory effort; IPPV was commenced by the Paediatric Registrar with an initial pressure of 18/5; Pulse oximeter was connected; The heart rate and oxygen saturation was checked, HR<60, the Oxygen saturation was recorded as 55%. Paediatric Nurse P5 stated that corrective measures performed, mask changed to term size, seal ensured, head repositioned, suctioned, pressure increased to 20/5, Oxygen increased to 100% and IPPV recommenced by neo-puff with oxygen flow 4-5 litres and pressure of 18/4 with minimal chest rise (MRSOPA performed) in line with the NRP guidelines.

At interview Paediatric Nurse P5 stated that the Baby was reassessed, Heart rate still less than 60 bpm, chest compressions commenced and IPPV continued. Baby reassessed. HR still less than 60 and Oxygen was less than 60%(Saturation / Blend.)

Paediatric Nurse P5 stated the Paediatric Registrar cleared the airway by suctioning again,

repositioned the head and ensured mask was sealed well.

The appears to be a disparity in recollections of staff and what is documented in the healthcare record relating to Baby Aarons heart rate;

At interview Paediatric Nurse P4 stated that Baby Aarons heart rate was reported to her as being 30 bpm.

01:30 Hours Paediatric Registrar Entry (Entry retrospectively highlighted) relating to the time between 01:30 Hours and 01:40 Hours

The Paediatric Registrar documented the following retrospectively in the healthcare records that he was called to emergency c-section at 35 weeks 3 days gestation for fetal distress and declaration. Baby born flat with poor respiratory effort and poor tone. Heart rate less than 60 beats per minute. IPPV and chest compressions started for 10 minutes until heart rate was above 100 bpm. Two trials of ET intubation with CO2 detector, No colour change so pulled out.

IPPV continued for another 5 minutes until Consultant Paediatrician B arrived to intubate and suction the tube until colour change. First dose of surfactant was given 200mg/kg, second does 100mg/kg;

- Bolus of normal saline 10ml/kg given twice.
- Two IV lines secured on the hands and one on the right foot.
- X-Ray – carried out for tube position and for lung expansion.
- Baby Aaron received IV Penicillin and IV Gentamicin
- O Rh Negative blood 10ml/kg given
- Blood for FBC, Urea and Electrolytes, Culture
- Baby ventilated on 02 Saturations 100%, Pressure 35/5, Rate 50
- Transport team contacted for transfer to Hospital S2.

The Investigation Team note that there is no reference to the presence of meconium on the baby, secretions and the administration of adrenaline. There was no resuscitation proforma in place. In addition there was no scribe.

01:34 Hours Approximately

Paediatric Nurse P5 stated at interview that she assisted the intubation by giving cricoid pressure and handing over equipment to the Paediatric Registrar who attempted the 1st intubation which failed with a size 3 ET tube. Following this failed attempt at intubation IPPV with chest compressions was recommenced.

At interview the Paediatric NCHD stated that Baby Aaron was born at 01:31 hours;

- The Apgar scores were as follows (2 @1, 2@5, 3@10).
- Suctioning was performed initially along with simultaneous stimulation of the baby as no meconium was visible.
- This was a very sick baby
- The Paediatric register did the initial bagging as the senior person
- I palpated the initial heart rate as less than 60 beats per minute
- The baby was on the Resusitaire
- The baby was very blue, flat and unresponsive, no respiratory effort
- Neonatal resuscitation was commenced which included IPPV (neopuff) with bag and mask - was started by the Reg with pressures of 20/5 along with chest compression.
- I can't recall meconium
- Saturation monitor was applied by the nurse not me, who was present from delivery.
- Normal saline given at 01.31 hours -Whoever arrived tried to clarify amounts.

During the feedback process the Paediatric NCHD stated that:

'the time of 01:31 is incorrect although I cannot be sure of the correct time, the time recorded on the Drug Chart is 0145 as per the report'.

01:34 Hours Approximately

At interview the Paediatric NCHD stated that;

'The Paediatric Registrar tried to intubate at 3 mins of life and after that the Consultant Paediatrician B *arrived. I wasn't personally doing IPPV [29] – there didn't appear to be much chest rise. I didn't have anything to do with IPPV. I didn't listen for air entry. The nurse commenced compressions and I took over at 1 min of life. 30 seconds of bagging had been in process;*

- *HR more than 60 and less than 100.*
- *HR did come up but not sure by how much*
- *2 attempts to intubate.*
- *IV access carried out by me between compressions.*
- *Cord gases taken.*
- *There was no standard resus sheet.*
- *There was a scribe as a clarification was sought regarding the amount of fluids I gave the baby.*
- *10mls and 12 mls (separate amounts).*
- *Don't recall the oxygen saturation.*
- *Pressure was at 18'.*

During the feedback process the Paediatric NCHD stated that there was a scribe available until at least 10 minutes of life.

Notwithstanding this there is no evidence to support that there was a dedicated scribe for the first 10 minutes.

01:34 Hours

At interview Consultant Paediatrician B outlined that he received a crash call at 01:34 hours from theatre, he was on call and was called urgently at around 01:35 hours., at 1 min old the baby was described as being pale in colour and cyanosis, floppy/hypotonic, from the time of delivery until he arrived and intubated the baby, the baby was gasping.

The Investigation Team note the inconsistency regarding Baby Aarons respiratory effort. There is reference to the fact that Baby Aaron had no respiratory effort versus Baby Aaron was gasping up to 4 minutes of age.

01:39 Hours Approximately

At interview the Paediatric Nurse P5 stated that the second attempt to intubate was unsuccessful and IPPV and chest compressions continued.

01:40 Hours Approximately

Paediatric Nurse P5 informed the Investigation Team at interview that at 10 minutes of age Baby Aarons heart rate increased to over 100 bpm, but oxygen stats were still less than 60%. At this point chest compressions were stopped and IPPV continued.

Again, the Investigation Team note that there is no reference to why the intubation attempts failed

[29] Intermittent positive-pressure ventilation (IPPV) is the process of manually or mechanically ventilating a patient that is apnoeic or dyspnoeic. IPPV is a simple and effective method of ventilation

and whether there was prolonged suctioning due to secretions.

01:41 Hours Approximately

Paediatric Nurse P5 stated that Paediatric Nurse P4 arrived at 01:41 and increased the flow of Oxygen to 8 litres and changed the mask to preterm mask, the heart rate was above 100 and the oxygen saturation was still less than 60%.

Time Period from 01:30 Hours – 01:41 Hours - Resuscitation[30]

It has been identified that the first 10 minutes of Baby Aaron's resuscitation has not been appropriately recorded. The Investigation Team was informed that there was no scribe available until 11 minutes of birth.

There is no record that Baby Aaron received Adrenaline[31] during the course of his resuscitation for the heart rate which was below 60 bpm and the rationale for not administering adrenaline is not documented.

It is the opinion of this Investigation Team that there are many unknowns regarding the resuscitation particularly in the first 11 mins. This is crucial and the Investigation Team consider that at best the resuscitation efforts appear suboptimal. The initial resuscitation steps were completed but full documentation is not available over the first 11 minutes. A sick baby had not been anticipated to this degree, the resuscitation effort recording was disorganised, no records for some elements and no recall. Inconsistent information was provided. However, the investigation

Team understands that even if the Resuscitation effort had been well planned and delivered, there is no guarantee that intubation will always be successful on first attempt. The availability of a scribe for the entire resuscitation along with a resuscitation recording tool would have avoided these unknowns.

The External Expert Consultant outlined that the paediatric expertise available in a unit such as Hospital S1 cannot be expected to match a Unit in a large tertiary referral centre such as hospital S2. The level of expertise available in hospital S2 is greater than that in a level 1 hospital. The investigation concludes that it is not possible to establish whether the outcome could have been different for Baby Aaron if he had been born in hospital S2 given his later poor response to the intensive care measures undertaken at hospital S2.

01:41 Hours Approximately

Paediatric Nurse P4 stated at interview that she arrived at 11 minutes following the delivery of Baby Aaron, Paediatric Nurse P4 stated that s/he received a call from Midwife M3 who was the shift leader on the night of the 3rd May 2016, requesting that s/he to go to theatre immediately.

Paediatric Nurse P4 stated at interview that on arrival to the Operating Theatre Baby Aaron was flat,

[30] The resuscitation of babies at birth is different from the resuscitation of all other age groups, and knowledge of the relevant physiology and pathophysiology is essential. However, the majority of babies will establish normal respiration and circulation without help. Ideally, someone trained in newborn resuscitation should be present at all deliveries

[31] The adrenergic effect of adrenaline increases coronary artery perfusion during resuscitation, enhancing oxygen delivery to the heart. In the presence of profound unresponsive bradycardia or circulatory standstill, 10 micrograms/kg (0.1 ml/kg 1:10,000) adrenaline may be given intravenously. Further doses of 10 – 30 micrograms/kg (0.1 – 0.3 ml 1:10,000) may be tried at 3 – 5 - minute intervals if there is no response.

The Registrar, SHO, Shift Leader M3 and Midiwfe M2 were all in attendance. The Registrar was attempting intubation and the SHO was carrying out chest compressions at the time. Paediatric Nure P4 also stated that she asked for a report and Baby Aarons heart rate was reported to her as 30 beats per minute. Paediatric Nure P4 stated that she requested that the mask be changed to a pre-term baby mask.

Paediatric Nurse P4 also stated at interview that;

> *'I immediately put the Oxygen flow up to 8-10cm. The blender was at 100% Oxygen. I put the Oxygen Saturation probe on the Baby..'.*

Paediatric Nurse P4 also stated at interview that that when she arrived the saturation probe was not recording, and she could not see a reading.

The investigation note that the above is not captured in the Healthcare record.

01:41 Hours

Paediatric Nurse P5 informed the Investigation Team at interview that;

> *'baby was delivered at 01:30, baby was born flat, apnoeic, baby was pale and dusky, there were no spontaneous breaths, the doctors filled in the apgar score, 2@1, 2@5, 3@10.*
>
> *Registrar commenced SATS monitor, H/rate check. Started giving CPR, Midwife M3 was on the right giving compression. Registrar was carrying out IPPV with OXIGEN on Baby Aaron. H/rate < 60, I was getting stuff for intubation. Tapes and CO_2 director. Started to intubate baby – first attempt failed continued IPPV. Staff Nurse arrived and increased oxygen pressure from 5 to 8. Tried to intubate but second attempt failed; started cardiac compressions. Baby Aaron at 10 minutes of age; HR >100. SATS mid 50's Cardiac compressions stopped. I was standing on left side with bolus of saline as per Registrars orders. Consultant Paediatrician B arrived – Baby Aaron was intubated on first attempt, HR up to 104. SATS 60 at this stage'.*

During the feedback process SCBU Nurse P5 wished to highlight that all steps were correctly followed including the corrective measures (MRSOPA), both term and preterm mask were tried on Baby Aaron by the team and that there was definitely an improvement in the heart rate by 10 minutes of age.

01:41 Hours

At interview the Paediatric NCHD stated that;

- The pressure was increased during the initial 15 minutes of resus.
- Bag and mask – (effective resus)
- In terms of medications – HR did not come up quickly.
- Compressions for 10 minutes
- APGARS done by myself, nurse and Reg
- 10 minutes HR above 100 bpm.

01:41 Hours – 01:45 hours

At interview Paediatric Nurse P5 stated that the Paediatric NCHD inserted cannula in Baby Aaron's left hand and that she assisted, the 1st saline bolus of 22 mls was ordered by the Paediatric Registrar and administered to Baby Aaron between 11 minutes and 15 minutes of age.

Paediatric Nurse P4 stated at interview that she asked Midwife M 3 shift leader to scribe at 11 minutes of age when Paediatric Nurse P4 arrived in theatre.

01: 45 Hours NCHD

At interview the Paediatric NCHD stated that;

- Bolus of saline given at 01:45 hours
- Two boluses of 22mls of NaCl 0.9% (10ml/kg) were administered.
- Two IV lines were secured in theatre.
- Umbilical vein- I assisted prior to transfer and Reg put in 2nd line
- As part of the NRP you should use the umbilical vein
- I gave a bolus – not sure when it was given (it was completed at 14 mins of age.
- First dose of Surfactant was given in theatre at a dose of 200mg/kg.
- Blood was also ordered in theatre on advice of Consultant Neonatologist.

Details relating to 01:30 Hours until Baby Aaron was transferred to SCBU / Retrospective statement on resuscitation in theatre of Baby Aaron

A statement dated 25/05/16 completed shortly after the events of the 4th May 2016 was made available to the investigation team which was signed by both the Paediatric Registrar and Paediatric NCHD is contained below, the Investigation Team note that this retrospective record is 21 days after the resuscitation. It is not clear from the statement why the decision was made to detail the following as part of an incident reporting process;

> *'Called to Emergency CS, We arrived before the delivery of the baby, with a gestational age of 35+3 with a background of polyhydramnios and renal pelvis dilatation on antenatal scans. Equipment checked including Resuscitator, Suction, Neopuff and laryngoscope. Indication for C/S was for foetal distress. A baby boy was born @ 0130 flat with low Apgar scores (2 @1, 2@5, 3@10). Suctioning was performed initially along with simultaneous stimulation of the baby as no meconium was visible. The baby had poor respiratory effort and poor tone. The baby's HR was less than 60 bpm. Neonatal resuscitation was commenced which included IPPV (neopuff) from the start with pressures of 20/5 along with chest compression. Saturation always remained below 60%, two trials of intubation with size 3.5 ET tube were performed, but there was no change in colour with the capnogram. We continued the IPPV until the On Call Consultant arrived and he put the ET tube size 3 but he required suctioning of the ET tube until the colour changed on the capnogram, IPPV continued after intubation but the lungs were very stiff, so we have to go high on the pressure of the circuit to 30/8, still stiff so highest is 35 PEEP was tried and continued on that until transferred to SCBU. Two IV lines were secured in theatre. Two boluses of 22mls of NaCl 0.9% (10ml/kg) were administered. First dose of Surfactant was given in theatre at a dose of 200mg/kg. Blood was also ordered in theatre on advice of Consultant Neonatologist.*
>
> *On arrival in SCBU, baby was connected to the ventilator with FiO2 of 100% with pressure of 35/5 and rate of 50. Second of surfactant administered via ET at 100mg/kg. Bloods performed for FBC, Renal, Blood Group and Blood Culture. IV Benzylpenicillin (50mg/kg) and IV Gentamicin (5mg/kg) also administered at this time. 22mls of RBC transfused in SCBU. Chest XRay performed on 3 occasions'.*
>
> *(LOCUM REGISTRAR)*
> *(PAEDS NCHD)*
> *TO DR. CONSULTANT PAEDIATRICIAN – (Hospital S1)*

The Investigation Team note that while the above retrospective statement (relates to the events following Baby Aarons delivery on the 4th May 2016, which was written 21 days later is the first time any staff member has referred to and documented that Baby Aarons lungs were thought to be 'stiff'. This retrospective letter was not included in the healthcare records originally and formed part of the incident form.

The Investigation Teams considers that a structured proforma covers the important aspects of a neonatal resuscitation.

During the feedback process on the chronology the Paediatric Registrar stated that;

> *'I do remember my combined notes on that morning...So I definitely agree with whatever was written there. Regarding the event document that you want me to complete, it's been more than one and a half year since the delivery. I will be lying if I can recall those specific events, so my documentation will be your best bet…'.*

01:45 Hours

At interview Paediatric Nurse P5 stated that IPPV continued until the Paediatric Consultant B arrived at 01:45 hours.

01:45 Hours

Paediatric Nurse P4 stated at interview that when Paediatric Consultant B arrived the baby was given the first dose of Surfactant and 2 bolus doses of NACL.

At interview Consultant Paediatrician B outlined that he arrived at the Theatre at 01:45 hours and discovered that the paediatric team present had been unable to intubate Baby Aaron since delivery at 01:30 hours. He notes Baby Aaron had a bruise on his sternum from compressions. The HR when he arrived was 128 bpm. He had no respiratory effort. Regarding spontaneous respirations – the baby had very poor respiratory effort and was gasping when I arrived at 01:45 hours. I started assessing the heart with a stethoscope in OT and the resus equipment used. I was not feeling the umbilical cord. Meconium was present in the liquor. Meconium green colour on the body. When I intubated there was no meconium. Started IPPV, Consultant Paediatrician B read from his notes in the HCR. The baby was quiet;

- 1st attempt to intubate failed ? time (No time noted)
- Neo-puff in OT
- Max pressure was pre-set at a low level
- Baby's chest was not going up.
- Whatever pressure is set – we don't adjust: 20/22
- Saturations at 50% on my arrival
- 100% O2 on
- When I ventilated - I could see a rise and fall of the chest.

01: 51 Hours

At interview Paediatric Consultant B stated the neopuff was unable to oxygenate Baby Aaron, chest compressions were carried out prior to his arrival, and he intubated Baby Aaron at 01: 51 hours, Baby Aaron was 20 minutes old; Baby Aaron had a good response and he received the 1st dose of surfactant in theatre, he was stabilised.

At interview Paediatric Consultant B stated that in terms of recording the resus it is usually the paediatric nurses who write on a piece of paper and write notes. There is now a change to this practice and a resuscitation form has been developed.

Consultant Paediatrician B informed the Investigation Team that;

> *'at 01:45 hours I arrived, 01:51hrs I intubated, no sufficient respiratory effort, gasping, pale floppy, cyanosed, 2 peripheral IV access lines were inserted theatre by the Paediatric Registrar or Paediatric NCHD; there was No adrenaline given as the Heart Rate was over 60 (this would fit with established Neonatal Resuscitation Guidelines), 2 Bolus doses of surfactant were given; the Baby was still pale on arrival, O negative blood was on hand in case it was required. Baby very pale, no FBC at that time hence Group and cross match for 0 RH negative and a blood transfusion was given at advice of Hospital S2 at 22 mls per 1 hour. The capillary refill was 3*

minutes.

Consultant Paediatrician B informed the Investigation Team that he moved quickly into intubating Baby Aaron and was in contact for advice with the neonatologist in Hospital S2. Consultant Paediatrician B stated that there were a lot of secretions and the ventilation of Baby Aaron was monitored very closely.

01:51 Hours Entry

Consultant Paediatrician B at interview while reading from the healthcare records stated that he successfully intubated Baby Aaron at approximately 01:51 hours.

Consultant Paediatrician B explained at interview that he knew he was definitely 'in' when the CO2 rate detector turned 'yellow'.

Consultant Paediatrician B was advised that a Nurse, in her interview, had highlighted that the size of the mask used was not appropriate for the size of the infant.

At interview Paediatric Consultant B stated that as he increased the pressure, there is an increase of the chest rising and falling. He believed they were dealing with pulmonary hypoplasia due to the increase BP, pre ductal BPHM.

Paediatric Consultant B documented in a retrospective entry that Baby Aarons colour remained pale and slight pink. It is not clear what time this aspect of the entry relates .i.e. on arrival at 01:45 hors or post intubation at 01:51 hours.

Again the Investigation Team note that the retrospective entries are challenging in developing a concise and accurate chronology of events.

The issue of pulmonary hypoplasia was not documented in the healthcare records.

Based on an entry in the healthcare records by the Paediatric Registrar a chest x-ray was requested to confirm the ET tube positioning and lung expansion.

01:51 Hours

At interview Paediatric Nurse P5 stated that Paediatric Consultant B successfully intubated Baby Aaron with a size 3 ET tube which was taped at 8 cm, the HR was 124 bpm, Oxygen saturation was coming up to 66% with 100% oxygen supply.

01:55 hours

At interview Paediatric Nurse P5 stated at 01:55 hours a 2nd bolus dose of NACL was given.

Prior to 02:06 hours

At interview Midwife M3 Shift Leader stated that she took the first arterial sample from the umbilical cord for analysis, but it was Midwife M2 who processed the sample. Midwife M3 Shift Leader stated that she was unable to say with certainty that the sample clotted, as she was not there.

The Investigation Team identified a 66 minute time lapse between the result of the first venous cord sample and the arterial cord sample following Baby Aarons delivery. The Investigation Team identified that Mrs X delivered Baby Aaron at 01:31 hours and the first venous cord sample was processed with a result timed at 02:06 hour, as the first arterial cord sample was clotted a 2nd arterial cord blood sample was processed with a result timed at 03:12hr

At interview Midwife M3 Shift Leader stated that Midwife M2 took the second arterial cord sample, and this would explain the time lapse.

At interview Midwife M3 Shift Leader stated Baby A had cord blood gases taken that were normal. These were done on 2 different machines[32].

The Investigation Team was informed that both arterial and venous samples can be run on both machines simultaneously or on one machine consecutively.

Midwife M2 informed the Investigation Team during the interview process that the first arterial sample clotted and therefore she took a second sample hence the time lapse; after securing the second arterial cord sample Midwife M2 informed the Investigation Team that she stopped to talk to Mrs X in theatre briefly and then went to process the second arterial sample.

Staff informed the Investigation Team that they received formal training on the use of the blood gas machines used in Hospital S1.

During the resuscitation process Midwife M2 informed the investigation Team that there was no scribe for the resuscitation. Midwife M2 stated that she would have taken notes initially, but abandoned due to other tasks.

Staff informed the Investigation Team that at the time of the birth there was no standard resuscitation record template for use by midwives however following this incident Hospital S1 has created a record proforma for resuscitation documentation which is in use for all paediatric resuscitation procedures for all staff.

02:06 Hours – Cord Blood Gases Site Venous:

It is documented in the Healthcare record Paediatric Nurse P4 that the Cord Blood Gas results are as follows. Based on the interviews conducted the arterial sample had clotted and was repeated.

- pH: 7.336
- pCO2: 6.38
- p02: 2.44
- HCO3: 25
- BE: -1.3

02:10 Hours P5

At interview Paediatric Nurse P5 stated that the 1st dose of surfactant was given by the Paediatric Registrar via the ET tube.

02:06 Hours

Midwife M2 stated at interview that Midwife M3 shift leader took the first set of samples:

→ *1st Arterial was clotted,*
→ *2nd Arterial, went back to get a second sample (The machines are side by side)*
→ *Then I spoke with Mrs X, delayed in getting back to process second sample.*
→ *Once I got the sample I processed it'.*

The investigation noted a 66 minute time lapse between samples. Delays in sampling blood from the umbilical cord or the placental surface artery can result in abnormal findings due to the deterioration of the gas parameters over time and may not reflect the condition of the baby at birth. It is therefore recommended that blood gases for assessment of acid base status should be taken as soon as possible

[32] The identical Blood Gas Machines are on the Labour ward and are side by side

after delivery from the umbilical cord artery. These later samples according to the External Expert Consultant cannot be relied upon, and it is unclear why staff would continue beyond 1 hour to seek an umbilical arterial sample from the placenta. This would not be in keeping with best practice.

Midwife M2 informed the Investigation Team at interview that the blood gas machines are situated in the labour ward which is on the next floor up from the theatre; it only takes a couple of minutes to go from the Operating Theatre to the machines on the labour ward.

According to Dr. Gardeil, It is best practice that paired (arterial and venous) cord samples should be obtained immediately after delivery and processed without delay using the same machine. In this case, the venous sample was analyzed 36 minutes after delivery. The arterial samples are more difficult to obtain than the venous ones. The first 2 arterial blood samples clotted. A third sample was obtained and analyzed 1 hour and 42 minutes after delivery. The midwife operator stated at interview that she could not recall a significant delay in processing the arterial sample.

02:25 Hours

Paediatric Nurse P5 stated that the 2nd IV cannula was sited in Baby Aaron in the Special Care Baby Unit in Hospital S1 prior to transferring Baby Aaron to Hospital S2. Paediatric Nurse P5 stated that a resus sheet is now in place along with 10 minute neonatal drills.

The Investigation Team identified that the Blood Gas Machine in the labour ward can measure plasma lactate[33] levels however a different cartridge is required. In summary the External Expert Consultant outlined the following in relation to the Cord Gases. Cord bloods from umbilical arteries and vein were obtained in theatre. The first 2 arterial samples clotted and had to be repeated. The venous sample was analysed at 02.06 hour with a Rapidsystem machine ID 1240-18225. The pH was
7.336 with a base excess of – 1.3 mmol/L. The arterial sample was not analyzed until 03.12 hour, by the same midwife, using a different Rapidsystem ID 1240-18080. First blood gas which was taken at 02.26 hours showed pH 6.67 pCO2 17.33 kPa PO2 2.5kPa. This showed significant respiratory failure and a respiratory acidosis. The above recorded low oxygen saturations despite ventilatory support and 100% inspired oxygen concentration at the time of are consistent with a critically ill infant with likely persistent pulmonary hypertension of the newborn (PPHN).

The External Expert Consultant stated that the second blood gas taken reported at 03.38 hours p H 6.98 PCO2 12.02 kPa pO2 3.5 kPa Base excess -10 mmol/L. result consistent with respiratory failure but improved. On the 04/05/16 following this gas ventilation settings were adjusted and at 04.30 hours the ventilator set rate was 60 BPM (the sheet does not state time after gas result that this change was made, I note nursing records are taken at 30 minute intervals at this point. Consultant Paediatrician B's note refers to an increased rate of 60 BPM but does not state the time this change was made after the second gas. This second gas on the baby suggests that adequate ventilation was being achieved (lower PCO2) but the predominant feature is continuing hypoxia (low pO2) secondary to PPHN.

According to the External Expert Consultant it is not evidence-based practice to continue to secure repeat arterial blood gases after 40 minutes post-delivery. Any delay with analysis leads to a decrease or potential change in the original pH values and, therefore, it is probable the pH's would have been slightly higher if the samples had been analysed without delay. Therefore the ABG's cannot be relied upon.

Consultant Paediatrician B (Retrospective Entry at 04:19 Hours)

Consultant Paediatrician B documented that he was called at 01:34 hours and arrived in theatre at 01:45 hours. Baby Aaron had no/poor respiratory effort. Started chest compressions, Intubated Baby Aaron size 3 tube, APGAR 3 at 15 minutes. Consultant Paediatrician B explained to the family about hypoxic brain injury baby required active resuscitation.

Dr. Gardeil asked Consultant Obstetrician A to help answer questions the family have as to;

1. why was it impossible to oxygenate the baby after labour? Dr. Gardeil referred to the fact that there were 2 attempts to intubate the baby and the fact that the mask was not the correct size for a premature baby.
2. was it possible that the resus was not undertaken in a competent way?
3. was it possible that the resus was undertaken very competently but for some reason there was a problem with the baby's lungs and, thus the baby couldn't absorb oxygen.

Consultant Obstetrician A outlined that he did not have an answer for these queries.

> *'Consultant Obstetrician and Gynaecologist A added that the first deceleration was followed by a recovery and therefore at that point a section was not needed. Consultant Obstetrician and Gynaecologist A had advised the registrar that if a second deceleration occurred the patient should be prepared for Category 1 C Section and this was what happened. There was no delay in arranging the procedure when the deceleration occurred the second time. Furthermore, the cord pH was normal at birth'.*

02:45 Hours

At interview Paediatric Consultant B stated that Baby Aaron's oxygen saturations were between 70% and 75%; Baby Aaron was connected to an SLE ventilator and checks for cold light to rule out a pneumothorax were carried out; PH test was yellow, HB 22.1 which was taken most likely after infusion because baby was so pale.

The investigation notes that there is a disparity in relation to staff recollections and what is documented in the healthcare record regarding Baby Aarons heart rate following delivery. Paediatric Nurse P4 stated at interview that the heart rate was reported as 30 bpm, however it is documented in the healthcare record that the heart rate was less than 60 bpm.

02:45 Hours SCBU

At interview Paediatric Consultant B stated that intraveneous antibiotics were given to Baby Aaron, the Ventilation settings were at a respiration rate of 56. Oxygen saturations increased to 90%. Moderately good job and outcome despite attempts, the HR increased to 128 bpm .The resus team efforts were satisfactory. The Cord bloods were essentially were normal. The lungs did not work. There was no critical intrapartum event identified.

At interview the Paediatric NCHD outlined that he did not see Baby Aaron after he was transferred to SCBU. He outlined that he was asked to do the transfer letter and his role ceased when Baby Aaron went to SCBU.

02:45 Hours

Paediatric Nurse P4 stated at interview that Baby Aaron was transferred to the SCBU at 02:45 hours. Surfactant 240mgs was then given in SCBU.

03:44 Hours

The is a medical imaging report contained within the healthcare records state that a chest x-ray was carried out on Baby Aaron at 03:44 hours that states that the ET was in place with the tip at

the right main bronchus which needs to be repositioned. The NG tube was noted to be correctly positioned.

There is no reference to lung expansion.

The Investigation Team note that it is not clear from the healthcare records whether the ET was repositioned however a follow-up chest x-ray indicated that the ET was correctly positioned.

04:06 Hours

At interview Paediatric Consultant B stated that intraveneous antibiotics were given to Baby Aaron, the Ventilation settings were at a respiration rate of 56. Oxygen saturations increased to 90%.When the transport team arrived

- transport team – SpO2 77%
- Inotropes – no – BP 80/46
- Acceptable BP's
- Pulmonary hyperplasia – Reg or SHO giving pressure through neo-puff
- Hospital S2 transport team arrived.

04:10 Hours

Neonatal transport team arrived to transfer Baby Aaron including a doctor. Consultant Paediatrician B stated that the Umbilical lines were placed by the neonatal transport team.

04:15 Hours Midwife Entry

It is documented by the Midwife in the healthcare records that Mrs X was stable, vital signs were satisfactory and she was ready for transfer to maternity ward but would be kept in recovery room until Baby was transferred from SCBU to the Hospital S2. It is also documented by the Midwife that the family were present, and Mrs X had no complaints of pain and was comfortable.

05:40 Hours Midwife Entry

As recorded in the healthcare records by the Midwife, Mrs X's vitals rechecked, remained stable. Mrs X was noted to be comfortable. Mrs X's family were present with Mrs X at all times.

06:00 Hours Midwife Entry

It is documented by the Midwife in the healthcare records that Mrs X was transferred into wheelchair and brought to SCBU with a midwife and was later transferred back to ward room 28 from SCBU.

06:05 Hours

There is a medical imaging report contained within the healthcare records state that a chest x-ray was carried out on Baby Aaron at 06:05 hours that states that the ET tube and NG tube were correctly positioned.

The investigation notes that the time of this chest x-ray is after Baby Aaron was transferred to hospital S2.

07:00 Hours approximately

Baby Aaron transferred to the Hospital S2. Infant Referral History Form contains the following information:

- Baby Aaron born 4th May 2016 at 01:30 hours
- Birth Weight: 2.25 kgs
- Gestational age: 35 weeks 3 days
- Reason for referral: On-going care
- Time decision to transfer: 02:30 Hours
- Problems during current pregnancy: Scan showed renal dilatation and echogenic bowel.
- Referral for anomaly scan sent 29th April 2016.
- Scan on the 29th April 2016 carried out in the Antenatal Clinic showed polyhydramnios and renal dilatation

- Type of Labour: Not in Labour
- Type of Delivery: Emergency caesarean section, Meconium 1, non-reassuring CTG
- Rupture of membranes 23:10 hours
- Signs of fetal distress – Decelerations
- Antenatal steroids given at 15:00hours on 3rd May 2016

Details of Resuscitation: No/Poor Respiratory effort, flat at birth, HR<60 bpm, chest compressions for 10 minutes, 2 attempts at intubation unsuccessful, intubated by consultant, Surfactant 200mg/kg given, transferred to SCBU;

- Admission temperature 36.8 degrees Celsius
- Lowest blood sugar 3.6 mmol/l
- Largest base deficit -6.0

Under **General** it is documented
- Colour Pale
- Trauma on chest due to compressions

Under **Cardiovascular** system it is documented
- HR 155
- BP 80/40
- Capillary Refill Time < 3-4 minutes

Under **Respiratory** system it is documented
- Respiration rate 60
- SaO2 Pre-ductal: 80% Post Ductal: 76% Fi02 100%
- Intubated – Yes is circled
- ET ventilation
- ET tube size 3.0 at 8cm
- Ventilation mode: SIMV
- Inspiratory Time 0.40
- Surfactant Yes 1st dose at 02:11 hours 2nd Dose at 03:36 hours

Under **Gastro Intestinal System** it is documented: NG tube in place

Investigation Results – Blood Tests

Blood Gases				
Date	4th May 17	4th May 17	4th May 17	4th May 17
Time	**02:06**	**02:19**	**03:12**	**03:38**
Site	Venous	Capillary	Arterial	Capillary
pH	7.336	6.677	7.250	6.981
pCO2	6.38	>17.33	6.69	12.02
pO2	2.44	2.5	1.97	3.5
HCO3	25	-	21.5	21.3
BE	-1.3	-	-6.0	-10
Haematology				
Date	4th May 17			
Time	04:32			
Hb	22.1			
HCT	0.71			
WCC	64.13			
Platelets	144			
Clotting				
Blood group				

O Negative Infusion – 10mls per kg (Blood Transfusion)

Under **Treatment** it is documented;

Drug	**Dose**	**Route**	**Last Given**
0.9% NaCl	22mls	IV	01:45
0.9% NaCl	22mls	IV	01:55
Surfactant	440mg	IV	02:11
Surfactant	240mg	IV	03:36

It is also documented by the Midwife that; '*Infant seen by mother and Photos given to mother, Religious Rites – Blessing'.*

Mrs X outlined during the feedback that they were not given photos, they were asked by the midwife to take photos on their own mobile phone.

Hospital S1 Referral letter to Neonatologist in Hospital S2

> *Many thanks for accepting care of this baby. He was born at 35 weeks 3 days by emergency c-section due to fetal deceleration which was prolonged. At birth there was no respiratory effort, heart rate was below 60 bpm, IPPV was initiated and due to no increase in heart rate chest compressions were commenced. Intubation was attempted twice but there were large volumes of excretions. Rounds of chest compressions continued until 10 minutes of life until heart rate was greater than 100bpm. IPPV (Intermittent Positive Pressure Ventilation) was continued. Consultant Paediatrician B intubated at around 15 minutes of life. There is no significant colour change after intubation and suctioning. Surfactant Bolus of 10 ml/kg was given by 2 doses. He was stabilised and transferred to SCBU, there 22mls of o negative blood was transfused on advice of Consultant Neonatologist. The recovery team arrived and placed an umbilical vein catheter. Morphine 220mcg was administered. Bloods performed and results attached with referral to Hospital S2.*

Mrs X recounted at interview that;

> *'The neonatal team from the Hospital S2 were on the way. It took the team approximately three hours to stabilize Baby Aaron for transport. He was taken to the Hospital S2 at 7:30am'.*

Entry No Time Consultant Obstetrician and Gynaecologist Entry

Baby Aaron transferred to Hospital S2 by ambulance.

07:40 Hours Midwife Entry

It is documented in the healthcare records that Mrs X was;

> *'admitted to ward from recovery. IMEWS 0. Care as per care pathway. Baby has arrived at the Hospital S2. Wound dressing clean and dry. Method of hand expressing discussed with Mrs X, as asked same. Tolerating PO fluids – declined tea and toast. Family with Mrs X at present. Good family support. Advised Mrs X to inform staff if any concerns. Clear urine draining in catheter bag'.*

09:00 Hours Midwife Entry

It is documented in the healthcare records that Mrs X's wound dressing intact and;

- IMEWS = 0
- IV fluids in progress
- Catheter draining concentrated urine.
- Intravenous (IV) paracetamol given at 08:00 hours with good effect.
- Mrs X aware of Baby Aaron has arrived in the Hospital S2 and that provisions will be made for discharge to Hospital S2.
- Mrs X and family eager to speak with Consultant A.

09:30 Hours Healthcare Record Entry

It is documented in the healthcare records that Mrs X was administered Innohep as prescribed; Pads changed Lochia minimal.

No Time

Mrs X recounted at interview that;

> *'Each consultant came to my room the following morning one by one. Consultant Obstetrician and Gynaecologist A was asked by my sister if the outcome of Baby Aaron's delivery would have been any different if Baby Aaron was delivered in Hospital S2. His reply was "NO" that "Baby Aaron more than likely had a chromosomal anomaly and anomalies of his lungs and this would have happened regardless".*

10:45 Hours Midwife Entry

The following is documented in the healthcare record by the Midwife on duty;
Attended to Mrs X as her mother came to the office saying she was feeling unwell and had pain in her abdomen. Very pale on inspection. No PV loss. Became unresponsive for 2 seconds. Emergency call bell rang. Assistance came straight away BP 58/34. 2 midwives and a doctor attended.

11:00 Hours Midwife Entry

It is noted in the healthcare record by the Midwife on duty that Mrs X was feeling improved post unstable episode;

- IMEWS=0.
- 1L hartmanns IV infused
- 500 mls gelofusion infused.
- FBC to lab.
- PV loss minimal.
- Seen by the Doctor.

11:00 Hours Doctors Entry

There is an entry in the healthcare record by the Obstetric NCHD on duty that s/he was asked to review Mrs X and came within 2 minutes to Mrs X. Mrs X feeling better following an episode of not feeling well with loss of consciousness (LOC) and was unresponsive for a few seconds;

- BP 112/64 PR 75
- No PV bleeding seen
- Gelofusion IV given
- Pt on Hartmann Infusion 1l over 125 mls/hour

Plan agreed at the time included the monitoring of vitals and an FBC was taken.

11:15 Hours

Mrs X and her husband outlined at interview that Mr X met with the SCBU nurse and an NCHD in Hospital S2 when he arrived at 11:15am in the Neonatal ICU. Mr X recalled that Baby Aaron was stable after his journey. There was a drop in Baby Aaron' sats after being changed from one ventilator to another. Mr X was informed by staff that the first 24 hours were critical. As a family they outlined they were so hopeful that everything would be ok. Mr X outlined that his memory was hazy due to trauma at this time. What was meant to be a joyous occasion had been shattered in minutes.

11:25 Hours Midwife Entry

IMEWS 0 feeling much improved

11:35 Hours NCHD Entry

Review of Mrs X feeling well;

- IMEWS 0
- BP Normal PR 68 mins
- No bleeding
- On hartmanns 125ml/hour
- Planned transfer to Hospital S2

Plan: Hospital S2 Obstetrician Informed, check FBC, if FBC ok transfer to Hospital S2.

No Time Midwife Entry

- IMEWS 0
- HB 8.7 g/dl

It is documented in the healthcare record by the Midwife that she was requested to meet with Mrs X, to offer support and assistance following transfer of her Baby Aaron to Hospital S2, she

contacted Hospital S2 ICU and was informed that Baby Aaron was stable at the time but remained critical. Spoke with Mrs X and her mother and support offered. Mrs X was awaiting transfer to the Hospital S2.

12:25 Hours

Haemoglobin Results

HB: 01:02 Hours = 13.0 g/dl
HB: 11:51 Hours = 8.7 g/dl

The NCHD documented that s/he would discuss with Registrar who will discuss with Obstetric Consultant.

There is no follow-up documented in relation to this conversation again leaving a gap in terms of decision making and treatment for abnormal findings.

Consultant Obstetrician and Gynaecologist A outlined that he was not concerned about the low HB.

The investigation team note that if the NCHD did discuss this with the Registrar or indeed the Consultant the action or rationale for inaction is not documented.

12:45 Hours Midwife Entry (Retrospective note)

It is documented in the healthcare records by a Midwife on duty that she contacted Hospital S2 at 10.30 am and requested a post natal bed for Mrs X as agreed with Consultant Obstetrician in Hospital S2 and Consultant Obstetrician and Gynaecologist A. Hospital S1 to please send a copy of notes.

12:45 Hours NCHD Entry

The Obstetric Registrar on duty documented that s/he was informed about Haemoglobin pre op and post op and was asked to contact Consultant Obstetrician and Gynaecologist A. The Registrar also documented that Consultant Obstetrician and Gynaecologist A was on his way to review Mrs X.

13:00 Hours Consultant Obstetrician and Gynaecologist A Entry

It is documented in the healthcare record by Consultant Obstetrician and Gynaecologist A that Mrs X had a Hb 8.7 g/dl, she was noted to be, clinically well, stable vitals, IMEWS 0, no bleeding noted. The plan documented by Consultant Obstetrician and Gynaecologist A was to prepare for Mrs X's transfer to Hospital S2. Consultant Obstetrician and Gynaecologist A also recorded that the family had asked them if early discovery of congenital anomalies and transfer to Hospital S2 would make a difference.

Consultant Obstetrician and Gynaecologist A documented that the care given was adequate, and only massive polyhydraminos was found in the last USS and on the 29th April an urgent referral went to hospital S2 for fetal assessment and Mrs X was subsequently admitted with pain and had a SROM.

It is the opinion of this Investigation Team that there should have been a follow up telephone call to hospital S2 on the Friday of the referral given the AFI result and the high risk that Mrs X could have an SROM or go into early labour with an increased risk of cord prolapse with a prem baby, non-engaged presenting part and significant polyhydramnios. Indeed there is a valid argument that Mrs X should have been admitted to hospital S1 Friday 29th April 2016 after the clinic visit for monitoring and observation in view of these risks while staff actively communicated with hospital S2 following the referral. There is no guarantee that Hospital S2 would have recommended admission at that time. In-addition the basis for discharge on Monday when Mrs X had self-

presented on the Saturday 30th April 2016 and that she had felt the need to contact the hospital again that Monday pm. When Mrs X presented on Tuesday am, there was then ample opportunity for the team to contact Hospital S2 to follow up on the urgent referral given the admissions and telephone contact within the preceding 96 hours. Whether all of this could have been achieved before Mrs X went into labour that evening and had an SROM (Spontaneous Rupture of Membranes) is unclear.

The omissions/ commissions in this case have been viewed as contributory factors by the investigation team.

13:15 Hours Midwife Entry

Ambulance control contacted for the transfer of Mrs X to the Hospital S2. Routine transfer.

13: 20 Hours Midwife Entry

Ambulance booked for 5th May to transfer Mrs X to Hospital S2.

13:25 Hours Midwife Entry

No ambulance available today.

13:30 Hours Midwife Entry

The Midwife on duty documented that there was a difficulty getting ambulance and therefore Nursing administration was contacted.

13:45 Hours Midwife Entry

It is documented in the healthcare records by the Midwife that a private ambulance company was contacted following Director of Midwifery approval.

15:00 Hours

It is noted in the healthcare records that an Ambulance was ready to pick up Mrs X in 30 minutes.

15:15 Hours Midwife Entry

Mrs X's sister concerns re delays in getting an anomaly scan in Hospital S2. The Midwife informed Mrs X's sister to make her concerns known using YSYS (Your Service Your Say).

The Investigation Team consider whilst it is appropriate to advise patients and their families to use Your Service Your Say (YSYS), this should not preclude a staff member from LISTENING to that issue and following up on it internally also.

17:00 Hours

Mrs X while reading from her prepared aide memoire at interview stated;

> *'I arrived by ambulance at 5pm to the Hospital S2. Dr Y informed us that Baby Aaron had an infection that he suffered in utero. Baby Aaron had persistent pulmonary hypertension. Baby Aaron's lungs were small. They scanned Baby Aaron's kidneys and Kidneys and Bladder were normal. An MRI scan showed that the brain could be considered normal for 35 weeks. He doesn't know what happened in the four hour period in Hospital S1 but that there was a lack of oxygen to the brain in those four hours. Baby Aaron had Metabolic Acidosis. Baby Aaron had not made any respiratory effort himself and he wasn't in any pain. Baby Aaron's oxygen levels dropped every night in NICU'.*

(Note the above scan performed was actually an on-site cranial ultrasound not an MRI).

Hospital S2 Chronology

While the scope of the investigation relates to the timeframe from the 19th November 2015 until the 4th May 2016, in order to complete the chronology of events the Investigation Team took the view that it was essential to consider the healthcare records relating to the care and treatment Baby Aaron while under the care of clinicians at Hospital S2 in order to provide a clear sequence to his medical treatment and decision making.

Wednesday 4th May 2016

08:00 Hours

Admission time at hospital S2 08:00 hours as documented in the transport documents.

10.19 Hours

Contained in the healthcare records is a Radiology report and findings by Consultant Radiologist;

CXR report 04/05/16 10.19 hours reported on 04/05/16: ET tip is at T1 The NG tube is in the stomach. Presumed UVC catheter has tip at T10 in the midline. This is slightly low and should be used with caution. Further lines and leads overlie the patient. A density in the right axilla is presumably artefactual. The heart size is normal. The lungs show a non-specific hazy opacification that in the correct clinical context could represent RDS. There is no apparent consolidation. In the abdomen the bowel gas pattern is unremarkable.

08.05 hours

Baby Aaron was admitted in hospital S2 on PAS system at 08.05 hours.

10.30 Hours

It is documented in the healthcare records by the Neonatology SpR X that hospital S1 details documented from transfer letter and handover;

- DOL 1
- BW 2.25 kg
- Em LSCS 35 weeks 3/7 gestation, resuscitation in Hospital S1 noted, Apgar scores 2 at 1 min, 2 at 5 mins, 3 at 10 mins. Cord pHs detailed.
- Medication including surfactant and Iv fluid boluses recorded as given there,
- Hospital S1 gases noted last at 05.45 hours prior to TF pH 7.135, pCO2 9.9 (kPa), pO2 2.6 (kPa), Bicarb 25, BE -4.0

Assessment and treatment as follows
- Intubated, ventilated, now on HFOV MAP 18, Amplitude 32, Hz 10, FiO2 100%.
- Preductal oxygen Saturations Preductal 91%, post ductal 79%, Good Air entry bilaterally, POCT gas pH 7.376, pCO2 4.37, pO2 3.74.
- CVS no arterial access at time, on inotropes milrinone 0.33 mls/hr, adrenaline 0.3 mcg/kg/minute
- POCT ECHO very poor function, large PDA, severe PPHN with complete right to left shunt present. No urine output, but baby had passed at birth.
- Sedated morphine 10/mcg/kg (hr)
- Total fluids 65mls/kg/day dextrose 10% with infusions.
- GI abdomen distended, soft, no audible bowel sounds,

- Haem: Hb 22(g/dl), White cell count 64(,000), platelets 144(,000), had received O Rh neg blood in hospital S1.
- Metabolic sodium 135 mmol/l, glucose 4,0 mmol/l
- Microbiology amoxicillin day,1 cefotaxime day1, gentamycin held ?renal issue
- Ward Round Consultant Neonatologist F review arterial access, for formal renal and cranial Ultrasounds
- Hold gentamycin, needs FBC and CRP, CFAM (aEEG) when stable, target non-invasive BP, mean > 45 mmHg.
- From reports Capillary blood gas taken 04/05/16 10.45 hours pH 7.376 pCO2 4.37 kPa pO2 3.74 kPa bicarbonate 19.6 mmol/L base excess -4.8 mmol/L lactate 3.7 mmol/L Glucose 4.0 mmol/L ionised calcium 0.97 mmol/L.

13.35 Hours

It is documented in the healthcare record that Baby Aaron underwent a Cranial and abdominal US as outlined in formal radiology report dated 04/05/16 at 13.35 hours.

Cranial ultrasound: The corpus callosum is present. Normal appearance of the ventricular system. The periatrial white matter appears heterogenous and marginally more echogenic than the adjacent choroid plexus. Are there any clinical concerns about a hypoxic ischaemic injury? No other brain parenchymal abnormality noted. No intraventricular haemhorrage observed.

Urinary tract ultrasound: Exam performed on the first day of life. The bladder appears unremarkable. No dilatation of the distal ureters observed.

The left kidney measures 4.2 cm in long axis. The right kidney measures 4 cm in long axis. Cortical medullary differentiation appears age appropriate with no focal renal abnormality noted and no pathological upper tract dilatation observed on the first day of life.

Impression: I note that the periatrial white matter appears heterogenous and marginally more echogenic than the adjacent choroid plexus. Are there any clinical concerns about a hypoxic ischaemic injury? A urinary tract ultrasound on the first day of life shows no abnormality.

Findings discussed at the bedside with Consultant Neonatologist F and Doctor Z

15.40 Hours Neonatologist F Consultant Entry

The following is documented in the healthcare record by Neonatologist F;

> *'Transfer from Hospital S1, maternal history, birth details and resuscitation recorded including suspected fetal anomalies on antenatal scans in hospital S1…noted an improvement in oxygen saturations to 85% in transport on Nitric Oxide 20 ppm, PIP 35/PEEP 5 cms H2O'.*

Condition on admission to hospital S2 NICU

Neurology; very little spontaneous movement, occasionally triggers ventilator breaths, withdrawal to pain, hypotonic.

CVS invasive blood pressure reading approximately 45 mmHg on inotropes. Neonatologist F records point of care echo , 4 chamber view, no obvious Ventricular septal defect or Transposition of the Great Arteries, very poor function globally, minimal tricuspid regurgitation (poor function), large Patent ductus arteriosus with mostly right to left shunt, aortic arch seen, no total anomalous venous drainage seen.

Serum lactate levels have reduced from 3.7 to 2.7 mmol/l
Impression of poor function and severe Persistent Pulmonary Hypertension of the newborn.

Lungs/ventilation baby had required increased PIP pressure; changed then to Sensormedics (oscillator ventilator) iNitric Oxide 20 (ppm), 10 Hz, amplitude reduced from 34 to 30, mean airway pressure 19 cms/H2O, due to improving blood gases.

Renal/urinary tract, baby had passed small amount of urine, renal and bladder ultrasound look essentially normal (there had been antenatal scan concerns about the kidneys). Fluids 65mls/kg/24 hours, dextrose 10%, blood glucose levels normal. Haematology, he notes that baby was very bruised on chest, legs and hands, that baby had received O neg blood (in hospital S1)

In relation to the above bruising, the External Expert Consultant informed the investigation team that such bruising can cause significant alarm for parents which is due to the resuscitation process which required intravenous cannulation, blood taking. It would have been helpful if the Neonatology staff had documented the possible cause of this bruising in order to establish whether the bruising was due to cannulation of both the hand and feet or from any chest compressions.

Medications

Baby Aaron was noted to be on Amoxicillin and Cefotaxime because of the meconium grade 1 at delivery (in a preterm baby, to cover possible listeriosis infection in baby).

Baby Aaron was noted to be on Adrenaline 0.3mcg/kg/min, Vasopressin 0.0003 units/kg/minute, Milrinone 0.5 mcg/kg/min, Morphine 10 mcg/kg/hr.

Clinical impression 35 weeks gestation infant, critically ill, failed postnatal newborn transition and severe PPHN, suspected sepsis (infection), no obvious congenital abnormality, hypotensive with global myocardial (muscle) dysfunction. Neonatologist F notes a guarded prognosis in view of possible hypoxic ischaemic perinatal event.

Plan continue HFOV, blood gases 4 to 6 hourly to monitor response, continue inotropes, start hydrocortisone IV 2.5 mgs/kg/body weight (in view of hypotension and already on high inotropes), cardiologist review tomorrow. Continue antibiotics, keep baby NPO, parents have been informed. Reports Arterial blood gas 04/05/16 15.15 hours pH 7.357 pCO2 3.57 kPa pO2 7.81 kPa Bicarb 18.3 mmol/L BE -8.0 mmol/L Lactate 2.7 mmol/L Glucose 3.5 mmol/L Ionised calcium 1.06 mmol/L Calculated oxygenation index = 36 at this time 15.15. OI is abnormal and above 30 which represents cardio-respiratory failure, consideration was given that day to ECMO centre contact.

22.31 Hours Neonatology SpR K Healthcare Record Entry

The following is documented by the Neonatology SpR K on duty;

- Night-time review note
- History as before
- Severe PPHN
- Prolonged resuscitation post birth which included chest compressions, severe respiratory acidosis noted at 1 hour of age
- Ischaemic changes on cranial ultrasound today (brain injury signs)

Currently

Intubated, ventilated HFOV settings are mean airway pressure 24 cms H2O, amplitude 32, frequency 10 Hz, FiO2 100%, preductal oxygen saturations 70%, post ductal 82% (MW comment both are subnormal particularly for this degree of support and baby is in hospital S2 NICU for last 14 hours at this point)

Neonatology SpR K notes poor air entry, that baby has been re-suctioned for secretions, on nitric oxide 20 ppm, latest gas at 20.56 hours pH 7.28, pCO2 5, pO2 4.9, bicarbonate 18, base excess -7.7, lactate 1.9 mmol/l ionised calcium 1.05

Cardiac assessment

No murmurs on examination, baby becoming oedematous, heart rate high at 178 beats per minute, blood pressure satisfactory at 70/31 mean arterial blood pressure 54 mmHg, on adrenaline 0.4 mcg/kg/min, vasopressin 0.0004 units/kg/min, both Adrenaline and Vasopressin increased, on Hydrocortisone IV.

GI nil noted new save anus patent, some staining of meconium today.

Renal he notes urine passed in hospital S1, minimal urine output, normal electrolytes, normal renal ultrasound, continue present management.

Neurology, sedated on morphine 10 mcg/kg/min, no seizures seen, not breathing with ventilator (rate)

Infectious disease; CRP 1.3 (negative), raised White cell count 60,000, on cefotaxime and amoxicillin, no growth yet on cultures.

He records the Consultant Neonatologist P review and plan which is to provide paralysis medication with Pancuronium IV, to increase the sedation - Morphine to 20 mcg/kg/hr, repeat his chest xray, insert a urinary catheter, to add in another inotrope Noradrenaline, if mean blood pressure falls below 55 mmHg.

22.54 Hours Chest X-Ray Report

Contained in the healthcare record is a CXR report containing the following information; 04/05/16 at 22.54 hours reported on 05/05/16

ET Tube tip at T3, the tip of NG tube is not included in the stomach. Further lines and leads overlie the patient. Presumed UV catheter has tip at the level of T10. Presumed artefact is again identified over the right axilla. The heart size is normal. There is no focal collapse or consolidation in the lungs. Signed off by Consultant Radiologist

23:00 Hours Consultant Neonatologist P Entry

It is documented in the healthcare records by Consultant Neonatologist P that Baby Aarons desaturation noted with low paO2 4.5 kPa on gas.

History as above, severe PPHN, cranial ultrasound suggestive of hypoxic injury, currently oxygen desaturation with ventilator and baby's breathing dysynchronous, post suctioning of endotracheal tube,. Plan is to commence muscle relaxant, she records a sequential increase in mean airway pressure on ventilator from 19 up to 23 cms H2O. Chest xray shows hyperinflated lung fields to 9 and half posterior rib markings, a slightly bell shaped chest noted on the CXR (a sign of pulmonary hypoplasia). MAP reduced to 21.5 cmsH2O, nitric oxide 20 ppm, she noted a lower mean arterial blood pressure from high 40s to low 50s mmHg, baby to have noradrenaline if mean BP falls to 40s (consistently), Consider epoprostenol at 10 nanogs/kg/min (subsequently commenced), increase glucose infusion rate as baby now receiving comparatively little dextrose (once infusions included). Consultant Neonatologist P documents that s/he updated baby's parents on his current clinical deterioration. Vasopressin increased to 0.0005 unit/kg/minute. Note mentions potential future discussion with ECMO team regarding retrieval if baby fails to respond but that due to gestation and weight, that baby is likely not to be accepted for ECMO.

Repeat blood gas 04/05/16 20.56 hours ABG result pH 7.28 pCO2 5.24 pO2 4.9 Bicarb 18.0 BE -7.7 Lactate 1.98 ionised calcium 1.05

Oxygenation index on this gas and ventilation settings at 20.56 hours. OI = 59 severely abnormal (normal usually < 20) note worsening result despite increased supports.

Thursday 5th May 2016

Mr and Mrs X recounted at interview that;

> *'On Thursday the 5th May 2016 my husband and I were asked to come to NICU. Neonatologist F and The Neonatal Nurse advised that Baby Aaron was being considered for ECMO in Sweden. If we agreed they would see if Sweden would consider Baby Aaron a suitable candidate. Alternatively Baby Aaron would stay in NICU but chances of survival were low.*
>
> *Neonatologist F used the term "brain dead" in reference to Baby Aaron. He communicated about the possibility of death.*
>
> *Sweden refused ECMO and the reasons were:*
> 1. *Baby Aaron was not a suitable candidate*
> 2. *Baby Aaron had experienced a brain injury in Hospital S1 and Neonatologist F referred to four hour period of difficult intubation.*
> 3. *Baby Aaron would more than likely die during the transportation or in Sweden.*
> 4. *EEG was showing a moderate abnormality of brain activity.*
>
> *Baby Aaron's oxygen levels dropped every night in NICU. Aaron stayed in Hospital S2 for active intervention which continued up until he died. Aaron's chances of survival were given by the consultants in NICU to be 50/50'.*

10.08 Hours

Baby Aaron underwent a Cranial ultrasound, which was reported on 05/05/16. Corpus callosum present. Ventricles are unremarkable. The periatrial white matter remains rather echogenic, but has not changed in the interval 22 hours. There are no new findings. Signed by Consultant Radiologist

10.25 Hours Neonatology SpR AL Entry Time Entry

Consultant Neonatologist F ward round note is documented by Neonatology SpR A;

Parents updated, baby on maximal support, No real improvement overnight despite increasing supports, baby remains critical.

Improving left ventricular function but worsening PPHN on echocardiogram (today), underfilled (ventricle) so given intravenous fluid boluses. CFAM (EEG) to be performed today, MRI head to be booked for 7 to 10 days but not for requisition forwarding yet (presumably reflecting the critical condition and that MRI would require off-site transfer and baby (was)very critical at the time).Pancuronium iv to be given to baby if unsettled but after aEEG performed (to avoid drug interference). Wean morphine to 15 microg/kg (says nanograms).

Consultant cardiology review today. Change fluids to 10% dextrose iv and add calcium and potassium to the fluids. Increase milrinone to 0.75 mcg/kg/minute. If needs a third IV bolus (today) to be given fresh frozen plasma as a volume expander.

Antibiotics, stop cefotaxime, continue meropenem, amoxicillin and acyclovir.
Samples (to be sent) for herpes simplex PCR (viral panel) enterovirus, urine for CMV.

12.30 Hours Neonatology SpR AL Entry

The Neonatology SpR AL documented the following in the healthcare record;

Seen by Neonatology SpR AL day of life 2, ex 35 3/7 at birth infant now 35 4/7, birth weight 2.25 kg, baby has not been weighed.

Issues 1, Severe PPHN 2. Cardiac dysfunction 3. Oliguria 4. Hypocalcaemia 5. White matter injury on cranial ultrasound 6. Query Sepsis (CRP 1.3, White cell count 60,000)

Currently

- Respiratory - intubated and ventilated. HFOV MAP 18 cms H2O, Amplitude 33, FiO2 100%, oxygen saturations were preductal 77%, post 71%, oxygenation deteriorated overnight, increased sedation and paralysis medication added, mean AP increased to 24 cms H2O.
- Maximal inotropic supports
- Adrenaline 1mcg/kg/min, noradrenaline 0.1 mcg/kg/min, milrinone 0.75 mcg/kg/min, sildenafil 0.03 mg/kg/hr, vasopressin 0.005 mcg/kg/min hydrocortisone IV. Mean BP 49-55 (satisfactory).
- POCT echo this morning showed large PDA, left ventricular function slightly improved, worsening PPHN, underfilled (heart), 2 boluses of normal saline given, milrinone increased.
- Drugs/sedation sedated morphine 15 mcg/kg/hr, (weaned from 20), given pancuronium iv overnight, minimal baby response to stimulus, CFAM aEEG commenced.
- Fluids:urine output 1.4 mls/kg/hr (low)
- GI abdomen not distended, bowels not opened.
- Total fluids 80 mls/kg/day of which 20mls/kg (available for) maintenance.

Hematology, Hb 18.8 g/dl on POCT gas, FBC 05/05/16 Hb 23.1, platelets 157,000, WCC 59.3. She notes O neg blood transfused post delivery in hospital S1 and that a bolus of plasma has been given.

Microbiology, CRP 1.3, WCC fell from 60 to 59.5, day 2 of amoxicillin, cefotaxime and gentamycin stopped. Commenced meropenem overnight.

Impression 1. Severe PPHN worsening oxygenation 2. Abnormal cranial Ultrasound
Plan as per ward round, increase vasopressin.
Report blood gas 05/05/16 10.15 hours pH 7.35 pCO2 2.68 pO2 5.48 bicarb 16.5 BE -10.1 Lactate 1.95

Oxygenation index at time of this gas with MAP of 19.5 and FiO2 100% OI = 53 still very abnormal despite increased supports.

No Time Cardiology Consultant O Entry

Cardiology Consultant O recorded the following in the healthcare records and noted the update from the Consultant Neonatologist F;

- Echo cardiogram findings, No evidence of structural abnormality, very large PDA, note biventricular hypertrophy, mild tricuspid regurgitation, note mild hypoplasia of the branch pulmonary arteries.
- Conclusion dilated PDA, borderline pulmonary artery dimensions, biventricular hypertrophy with normal venous structures, query prenatal pulmonary hypoplasia, no evidence of structural cardiac anomaly. Biventricular cardiac function surprisingly good in view of the PPHN (degree). Not all features seen typical of PPHN, query pulmonary hypoplasia. No structural abnormality, spoke to Consultant Neonatologist F post echocardiogram.

12.10 Hours

A CXR was performed on 05/05/16 at 12.10 hours report reported on 05/05/16; Compared with 04/05/16 showed;

ET at T3, NG tube tip is in the stomach. Umbilical catheter has tip at level of T10. The heart size is

normal. The lung parenchyma remains relatively clear. No pleural fluid or pneumothorax seen. Signed by Consultant Radiologist.

16.00 Hours

A CXR and PFA was performed on 05/05/16 16.00 hours showed;

The ET tube is in left main bronchus and there is collapse of the left lung. I understand from discussion with Consultant Neonatologist F (16.45 hours) that the tube has already been re-sited. The NG tube is in the stomach. UVC has tip in the midline at T10, which is slightly low. There is a urinary catheter. Right lung remains relatively clear. The abdomen is gasless, there is no free air. Signed by Consultant Radiologist.

17.13 Hours Consultant Neonatologist F Summary of the Day.

Consultant Neonatologist F documented the following in the healthcare records;

Baby Aaron's condition deteriorated since last night, remains in critical condition, with severe PPHN, query cause, query pulmonary hypoplasia, relative hypotension, cardiorespiratory failure

Neurology examination: no spontaneous movement, on morphine 15mcg/kg/hr, aEEG discontinuous trace, moderately abnormal.

Lower margin 5mV, higher margin 25mV, no documented seizures.

CVS relative hypotension, desaturates if mean BP below 55mmHg, heart function improved since yesterday, but severe PPHN with marked right to left flow/shunt, minimal tricuspid regurgitation, biventricular hypertrophy, Cardiology Consultant O opinion noted.

Chest good air entry bilaterally, lungs appear small (on CXR and ECHO) but parenchyma looks unremarkable, ETT withdrawn by 1.5 cms, Oxygenation index is 46 (very abnormal).

Fluids (needed additional fluid boluses of normal saline and FFP) to maintain a supra-normal BP to keep preductal oxygenation saturation above 85%. Urine output now.

Antibiotics same as per Neonatology SpR AL note, viral PCR sent (blood), blood cultures and PCRs pending.

17.24 Hours

A CXR was performed on 05/05/16 17.24 hours reported on 06/05/16 revealed;

The ET tube is now at T2. There has been near complete re-expansion of the left lung. The NG tube tip is in the stomach. UV catheter still has tip at the level of T10 which is low. Apart from some residual volume loss in the left lung, the lung parenchyma is relatively clear. No pleural fluid or pneumothorax seen. Signed off by Consultant Radiologist

17.50 Hours

Patient examined heart rate increased at 211 beats/min, invasive BP mean 69 mmHg, mildly cyanosed, good bilateral air entry.

Consultant Neonatologist F notes discussion with the ECMO (extra corporeal membrane oxygenation) centre in Karolinska, Sweden, Aaron's condition was discussed in detail, the possible "functional" pulmonary hypoplasia and perinatal hypoxia (pO2 < 3 kPa for 4 hours) meant that he is not suitable for ECMO treatment.

Consultant Neonatologist F notes discussion with Mr and Mrs X that Baby Aaron is in a critical condition, has reached maximal therapies, that they are aware of same, plan is to continue ICU support and hope that he will improve.

Consultant Neonatologist F documented the following;

- Plan for next 24 to 48 hours: continue HFOV and nitric oxide 40 PPM,
- Continue inotropic support and sildenafil
- Liberalise fluid total/day to 130 mls/kg/24 hours
- Do viral PCR panel
- Request serum ammonia (metabolic test)
- Discuss appropriate genetic testing (due to prior transfusion given in hospital S1)
- Continue CFAM monitoring.

Friday 6th May 2016

9.57 Hour Neonatology Registrar S Entry

The following is documented during a ward round by the Neonatology Registrar S;

- Document inotropes amount (fluids)
- Minimal handling
- No boluses IV at present
- Point of care echo today
- Keep mean BP above 70 mmHg (high level)
- Might be for hyperbaric chamber treatment (to be discussed prior to same with baby's parents)
- Continue same management
- Discuss with Pharmacist about increased drug concentrations to enable less fluids to be given IV.
- Do Chest xray
- Get ready for trial of ?other ventilation mode? Later
- Report Blood ABG 06/05/16 09.22 hours pH 7.24 pCO2 4.75 pO2 3.55 Bicarb 14.8 BE -11.5 Lactate 5.4
- Oxygenation index with MAP of 24 cms H2O and FiO2 100% OI = 80 which is showing a marked deterioration and failure to respond to treatment. (likely incompatible with survival).
- 06/05/16 11.43 hours Dr K S Registrar
- Day of life 3.
- History noted as previous Late preterm,
- RDS, severe PPHN, 1 dose of surfactant yesterday, cardiac dysfunction, on full inotropic support, query pulmonary hypoplasia, rest of antenatal history noted as previously. Antenatal steroids given.

Medications

- Antibiotics: Amoxicillin day 3, Meropenem day 2, Aciclovir day 2 of treatment.
- Drugs: Noradrenaline 0.08 nanogram/kg/min, Adenosine 50 mcg/kg/min, Milrinone 0.75 mcg/kg/min, Adrenaline 4.1 mcg/kg/min, Vasopressin 0.005 units/kg/min, Epoprostenol 20 nanog/kg/min, sildenafil 0.03mcg/kg.
- Total fluids 161 mls/kg/day

Current assessment: critically ill baby, sedated, incubator, oedematous, skin pink pale, haematoma on his forearm and antecubital fossa.

Ventilation: HFOV Mean airway pressure 24 cms H2O, amplitude 55, freq 8.9 Hz, FiO2 100%,

inhaled nitric oxide 40 ppm.

- CVS heart rate 166-195, mean BP 71 mmHg
- Urine output 1.92 mls/kg/day (low)
- Abdomen nil new noted.
- CNS unchanged sedated on CFAM continuous.

Plan as per Ward round, secretions for viral respiratory panel, do new ammonia blood sample, he spoke to NVRL (national viral reference laboratory) about specimens sent or being sent to check best sampling methods eg serology, secretions, stool or swabs for specific tests, and for the NVRL to prioritise same.

11.27 Hours Chest X-Ray

A CXR was performed on 06/05/16 11.27 hours Reported on 06/05/16 and compared with 5/5/16 CXR recorded the following;

The ET tube tip is at T1. The NG tube tip is in the stomach. Umbilical catheter has tip at the level of T 10 which remains low. The heart seems a little larger than previous, this may be projectional. The lung parenchyma remains relatively clear. I wonder if there is a very small right pleural effusion. Subcutaneous oedema is increasing. Signed off by Consultant Radiologist

Saturday 7th May 2016

02.30 Hours Neonatology SpR AL Entry

The Neonatology SpR AL documented that s/he was called to review Baby Aaron for low oxygen saturations and blood pressure readings. She noted baseline during the day: mean BP 73 mmHg, oxygen saturations were 79-81 5 (low for this degree of support). Maximal inotropic supports, mean airway pressure 24 cms H2O. At 02.30 acute oxygen desaturation to 60s (%), mean BP had fallen to 45 mmHg. No change in infused drugs noted, given hydrocortisone IV, checked that air entry good on auscultation, extensive oedema, urine output now 4-5 mls/kg/hr. Discussion with consultant on duty, to increase noradrenaline and vasopressin infusions, discontinue flolan (epoprostenol), do chest xray now. Bolus of normal saline IV 20 mls/kg body weight commenced, mean airway pressure increased to 26 cms H2O, mean BP improved to 65-70 mmHg, oxygen saturations recovered.

02:51 Hours Chest X-Ray

A CXR was performed on CXR report 07/05/16 report at 15.17 hours on CXR taken at 02.51 hours per next reported on 09/05/16; Comparison with 06/05/16 revealed;

The endotracheal tube is at T1 level. A nasogastric tube is noted in the body of the stomach. An umbilical venous catheter is noted in the midline at T9 endplate level. The cardiothymic silhouette does not appear enlarged. Atelectasis evident in the medial basal segments of the left lower lobe and to a lesser extent middle lobe. Lung volumes are greater than on the prior day's radiograph. Small bilateral pleural effusions persist (greater on the right in the left). The degree of cutaneous body wall oedema appears broadly similar to prior imaging. Signed by Consultant Radiologist.

03.25 Hours Neonatology SpR Entry

The Neonatology SpR AL noted CXR showed small left pneumothorax, no lung field hyperinflation. Point of care echocardiogram by Consultant Neonatologist F no pneumopericardium noted, wean Mean airway pressure to 22 cms H2O, observe response.

02.30 Hours Consultant Neonatologist F (Retrospective Entry at 08:30 Hours)

Consultant Neonatologist F documented the following in the healthcare records;

Called to bedside at 02.30 hours due to severe desaturations to SaO2 60s (%) and low mean BP 45, chest x-ray tiny left pneumothorax, decrease mean airway pressure to 19 cms H2O, increase vaspopressin to 0.002 units/kg/min, noradrenaline to 1.0 mcg/kg/min, temporary improvement only noted and oxygen saturations only back to 75%.

Paralysing agent IV suxamethonium tried as baby breathing spontaneously (eg dysynchronous with ventilator), no improvement and mean airway pressure put back to 23 cms H2O.

Consultant Neonatologist F concludes, overall remains critically ill with guarded prognosis, worsening oxygenation despite being on such high limits of ICU care.

Report blood ABG 07/05/16 07.17 hours pH 7.261 pCO2 4.09 pO2 4.49 Bicarb 15.1 BE -11.8 Lactate 4.58 ionised calcium 0.99

Oxygenation index at this time with MAP 20 and FiO2 100% OI = 67, OI remains very abnormal, only marginally improved.

03.25 Hours Neonatology SpR Entry

The Neonatology SpR AL noted CXR showed small left pneumothorax, no lung field hyperinflation. Point of care echocardiogram by Consultant Neonatologist F no pneumopericardium noted, wean Mean airway pressure to 22 cms H2O, observe response.

11.47 Hours Neonatology SpR Entry

The Neonatology SpR K documented the following in the healthcare record;

Ward round Consultant Neonatologist F; plan for day. Reduce morphine to 10 mcg/kg/min, check cranial ultrasound has been requested, inotropes as follows, adrenaline increased to 4.3 mg/kg/min, noradrenaline to 1.2 , epoprostenol stopped, order FFP bolus of 20 mls/kg iv and administer same, reduce nitric oxide to 20 ppm, give bicarbonate correction over 6 hours, , repeat blood tests as ordered, supplement sodium IV, continue amoxicillin, meropenem, acyclovir, if repeat ammonia sample > 100, contact metabolic team, send plasma amino acid sample with next blood sampling, check blood and urine for ketones (metabolic), genetics blood sample (query pretransfusion taken in Hospital S1 so to be sent to genetics lab for array CGH). Weight of baby now 2.67 kg (working weight)

Query nonketotic hyperglycinaemia and sulphate oxidase deficiency (query)? (metabolic disorders)

15.00 Hours Consultant Neonatologist F Entry

Consultant Neonatologist F notes further deterioration in baby, low oxygen saturations to 58%, heart rate 167 BPM, mean BP 69 mmHg, there is a tiny left pneumothorax no signs of tension pneumothorax, not suitable for chest drainage. Consultant Neonatologist F documented that he had spoken directly about the metabolic results to date with the metabolic consultant on-call, opinion of the metabolic team is that the raised ammonia levels of 163-164 do not represent a primary metabolic disorder but reflect Aaron's level of illness at this time.

15.17 Hours Chest X-Ray

A CXR was performed on 07/05/16 taken at 15.17 reported on 09/05/16; Comparison with prior exam 7th May 2016 at 02.51 hours revealed;

ET tube at C7 level. NG in the body of the stomach. The cardiothymic silhouette does not appear enlarged. Small lung volume patchy consolidation evident in the right middle lobe, lingual and to a lesser extent medial basal segment of the left lower lobe. The pulmonary vascularity appears within normal limits. Small bilateral pleural effusions noted which appear larger on the right than the left. The degree of cutaneous body wall oedema appears similar to prior imaging. Signed off by Consultant Radiologist

22.30 Hours Neonatology SpR Entry

Neonatology SpR documented the following in the healthcare records;

Present weight 2.695 kg working weight is 2.67 kg. previous history noted and medications listed. Only changes in medication are noted the addition of one dose of furosemide diuretic, bicarbonate correction had been given, one dose of suxamethonium, one bolus of fresh frozen plasma IV, total fluids at 161 mls/kg/day.

Impression critically ill baby: PPHN, on maximal ventilatory and inotropic support.

HFOV MAP 20 cms H2O, Amplitude 63, freq 8 Hz, FiO2 100%. Oxygen saturations were 79/76 (note were lower at 14.00 hours 67/73)

- Mean BP 71 mmHg at present.
- Urine output 5.6 mls/kg/hr
- Abdomen no changes, CNS baby is sedated.

Impression: He notes critically ill background of borderline oxygen sats 76-79-80 with episodes of desaturation noted periodically to 60-58 %, blood tests plan for sampling noted.

Mrs X outlined at interview that on the 7th of May;

> *'my husband and I were called into NICU and were told that Baby Aaron' sats were at 50% and had remained so for a few hours and therefore were told to ring family and get them there as soon as possible because Baby Aaron wasn't going to last. We were offered some time alone in the parent's room. We left to go back to my room to prepare to say goodbye to Baby Aaron and grieve. My husband and I were very upset at Baby Aaron's incubator, we thought we were there to say goodbye. Dr informed us that Baby Aaron's sats had improved and there was another option. I was very confused by this and asked "what does this mean are you saying there is hope?" "We are here to say goodbye to our son because we were told this is it". Dr was surprised by this and requested that we meet him in my room and to discuss something privately. This was extremely distressing for us as it seemed to be a constant yo-yo from one extreme to another, having no hope to all of a sudden Baby Aaron having a chance at life.*
>
> *Dr and the SCBU Nurse came to my room and explained that Baby Aaron's Oxygen levels had improved again and now there were 3 options of care.*
>
> - *Stay on current ventilator*
> - *"Comfort Option" which was a change of ventilator to allow us to hold our baby with a hope that his sats may improve which has been seen in previous cases of Persistent Pulmonary Hypertension. But Baby Aaron could also pass this way.*
> - *Try High pressure chamber... This was a risk to Baby Aaron's life as he could pass at any stage from the change of ventilator to transport or during the treatment in the pressure chamber.*
>
> *Dr said that if there was a positive result in the chamber that Baby Aaron more than likely did not have hypoplastic lungs and he would know within 5 minutes of being in the chamber because Baby Aaron' lungs would not respond. He also said that pulmonary hypoplasia could only be confirmed on autopsy.*
> *Aaron went to the Chamber and survived all obstacles his sats were improving throughout the evening.*

Sunday 8th May 2016

No Time

There is a morning note completed by Neonatology SpR AL Neonatology Registrar S which includes the following;

Ward round Consultant Neonatologist F plan: reduce hydrocortisone dosage to 3 mgs/kg, change maintenance fluids to 15% dextrose iv, do bloods full blood count and check urea and electrolyte sample result, do chest xray today, after ward round try conventional ventilation (call bio-engineer to support same), continue iv antibiotics and acyclovir for 7 day course, continue same inotrope dosages, do cranial ultrasound tomorrow and working weight = 2.67 kg for the baby.

Report ABG 08/05/16 07.29 hours pH 7.266 pCO2 4.25 pO2 3.64 Bicarb 15.2 BE -11.1 Lactate 5.6 ionised calcium 1.16

Oxygenation index at this point with MAP 20 and FiO2 100% OI = 67.

10.50 Hours Chest X-Ray

A CXR was performed on 08/05/16 10.50 hours reported on 09/05/16; Comparison : prior exam May seventh 2016 showed;

ET tube at T2 level. NG in the body of the stomach. The cardiothymic silhouette does not appear enlarged. Small areas of patchy consolidation evident in both lungs. The degree of cutaneous body wall oedema appears unchanged from prior imaging. An umbilical catheter is noted just to the right of the midline at T10 level. Signed by Consultant Radiologist

14.00 Hours Consultant Neonatologist F Entry

Consultant Neonatologist F documented the following in the healthcare record;

Day 5 now 36 weeks gestation corrected age. Working weight 2.69 kg

Background 1. 35 3/7 born/critically ill since birth 2. PPHN likely due to pulmonary hypoplasia 3. Biventricular myocardial dysfunction 4. Suspected infection query viral 5. Thrombocytopenia 6. Perinatal stress/failed transition.

CNS/Cranial ultrasound mild periventricular hyper-echogenicity, baby is reacting to handling today, with some (facial) grimacing seen. Sedated on morphine.

Ventilation settings: HFOV MAP 20 8 Hz amplitude 65 FiO2 100% inhaled nitric oxide 30 ppm
Last gas arterial pH 7.23, pCO2 4.86 kPa, Base excess -11.4 paO2 3.53 kPa (low), lactate 5.55 mmol/l increased, glucose 4.3 mmol/l.

CVS Consultant Neonatologist F notes falling BP despite support, invasive mean BP now 68 mmHg, desaturated to 58% in last hour, adrenaline increased to 5 mg/kg/min, vasopressin increased to 1.1 units/kg/min

Consultant Neonatologist F did point of care echo difficult study to do but PDA query closed which may be worsening PPHN, since Thursday, disimproved function seen, signs of bi-atrial overload
Total fluids 140-160 mls/kg/day depending on drug doses, urine output now increased to 11 mls/kg/hr, normal glucose 4.3 mmol/l

Inotropes/meds: milrinone 0.75, adrenaline 5.0, noradrenaline 1.2, vasopressin 0.00067?, sildenafil IV infusion, Prostin 5 microg/kg/min, caffeine 20 mgs/kg/dose given, adenosine IV, morphine, meropenem, amoxicillin. (note prostin has been commenced)

Liver jaundiced high serum bilirubin of 330 micromol/l on phototherapy.
Consultant Neonatologist F concludes baby's general condition is worsening and speaks to both parents with 3 options offered on baby's treatment after detailed discussion.

1. Pro-active offer course of hyperbaric treatment in national hyperbaric treatment centre based in Dublin (if he can tolerate transport there and back).
2. Redirection to comfort care, no escalation and allowing out for "kangaroo care".
3. Withdrawal of current life support.

Parents opted for trial of hyperbaric, Consultant Neonatologist F notes that this treatment is physiologically plausible but is a potential treatment option.

15.00 Hours Consultant Neonatologist F Entry

Baby Aaron is changed to conventional non-oscillatory ventilation (for the transport) of PIP 40 and PEEP 6 cms H2O IT 0.4 seconds, FiO2 100%, rate 60 breaths/minute tolerated with saturations 62-71%. Inhaled nitric oxide 30 ppm.

20.15 Hours Consultant Neonatologist F Entry

Consultant Neonatologist F documented the following summary of hyperbaric chamber treatment session in the healthcare record;

Baby Aaron was transported to treatment centre on settings above, only difference was inhaled nitric oxide of 20 ppm in this note, on arrival there oxygen saturations 64% preductal, exposed to 2 ATA pressure (10 meters depth), improved oxygen saturations to 89%, noted 1 hour at 2 ATA, overall time 2 hours, transported back stable.

On arrival back in hospital S2 on same ventilation and nitric oxide settings, oxygen saturation readings are preductal 83%, post ductal 58 %.

Plan. Do ABG, chest xray, blood for urea and electrolytes, increase adrenaline dose as low mean BP of 52 mmHg, start levosimentin infusion (to potentiate inotropes)

Report Blood ABG 08/05/16 19.53 hours pH 7.201 pCO2 4.67 pO2 3.08 Bicarb 12.9 BE -13.6 Lactate 5.4 ionised calcium 0.92

Oxygenation index result on MAP 21 cms H2O and FiO2 100% OI = 93. This shows no improvement after hyperbaric chamber treatment and remaining on maximal supports. (MW comment, this result is not compatible with survival).

Consultant Neonatologist F advised parents that in his opinion on the basis of the clinical course and findings that this likely means pulmonary hypoplasia (which is) not compatible with baby's long term survival.

19.44 Hours Chest X-Ray

A CXR was performed on 08/05/16 19.44 hours reported on 09/05/16; Report Comparison prior exam at 10.50 showed;

ET tube at D2 level. NG in the body of the stomach. The cardiothymic silhouette does not appear enlarged. Pulmonary vascularity appears within normal limits. Small volume consolidation is noted projected posterior to the left ventricle. Small bilateral pleural effusions are evident. The degree of cutaneous oedema is marked and appears unchanged in the interval since the last exam. Signed by Consultant Radiologist.

No Time noted

Blood gas on return to hospital S2 pH 7.201 pCO2 4.67 pO2 3.08 HCO3 12.9 base excess -13.5 glucose 5.4 lactate 5.2, ionised calcium 0.92 low potassium of 1.62 mmol/l for lab urea and electrolytes.

Monday 9th May 2016

Mrs X outlined at interview that;

> *'Baby Aaron went to the Chamber and survived all obstacles his sats were improving throughout the evening. Baby Aaron's chances of survival were given by the consultants in NICU to be 50/50. Baby Aaron stayed in the Hospital S2 for active intervention which continued up until he died.*
>
> *However later that night Baby Aaron passed away at 1:40am on the 09/05/2016. He did die in my arms.*
>
> *It was the first time I held him. We were asked if we want to hold him when he was dying. The coroner's report mentioned it was a clot that had caused Aaron's passing at the end'.*

01.00 Hours

According to an entry in the healthcare record Consultant Neonatologist M was called urgently to the NICU.

Consultant Neonatologist M Entry (Timed at a later time of 02:00 Hours)

Consultant Neonatologist M records emergency call to hospital at 01.00 hours for baby, arrival at 01.16 hours.

Consultant Neonatologist M noted; Background of suspected pulmonary hypoplasia and severe PPHN noted. Baby had bradycardia at 00.59 hours, suctioned, given multiple doses of adrenaline (however he notes that baby already on significant dose of iv adrenaline already), given PPV by neopuff device, heart rate low at 60 beats per minute, good chest lift noted (not an endotracheal tube problem as tube was in the airway and moving chest on bagging) Transillumination showed suspected pneumothorax seen previously on chest xray (suspected extension of pneumothorax). Adrenaline dose increased, given chest compressions, needle thoraco-centesis of left side performed and 60 mls of air withdrawn, no improvement in his heart rate or oxygen saturations seen in response to these measures. Parents called to bedside, after 15 minutes of attempted resuscitation, parents were advised that further resuscitation efforts futile. Baby Aaron was handed to his parents to hold at 01.30 hours and death was certified at 01.40 hours.

Neonatology SpR Retrospective Note (Timed at a later time of 06.11 Hours)

Neonatology SpR recorded that s/he was called to Baby Aaron at bedside due to acute bradycardia and hypotension and attended immediately, low heart rate 80 BPM, mean BP 40-45 mmHg, preductal oxygen saturations were in low 60s%. Team present. Increased inotropes adrenaline to 8.5 mls/hr, (5.3 Mmcg/kg/min from 5 mcg/kg/min), vasopressin increased to 6.5 mls/hr (0.0073 units/kg/min from 0.0067) no response noted.

Baby Aaron received manual ventilator breaths, consultant and radiographer called. Disconnected from ventilator and given neopuff breaths PIP 40 PEEP 6 cms H2O pressures, FiO2 100%, good chest rise noted but less good air entry heard on left side compared to right side of the chest. Heart rate now 60-80 BPM, mean BP 30s mmHg, oxygen saturations were deteriorating 40s to 30s%. ETT position checked to be in position with laryngoscope, oropharynx suctioned.

Endotracheal tube suctioned and thick mucus obtained, brief improvement in heart rate to 100 BPM, no improvement in BP or oxygen saturations.

Total of 7 boluses of adrenaline given 0.3 mls/kg. Chest transilluminated, left chest area of lucency, needle thoracocentesis performed by Consultant Neonatologist M, drained 60 mls air. Continued deterioration and chest compressions commenced, parents attended approx. 01.30 hours and then given to mother to hold in arms at 01.30 hours, Baby Aaron died at 01.40 hours.

01:40 Hours

Sadly Baby Aaron died at 01.40 hours.

Summary Opinion of Hospital S2 Chronology

Baby Aaron's care in opinion of the Investigation Team was satisfactory while under the care of the team of specialists at hospital S2, he had appropriate intensive care treatment in the Hospital S2 NICU, he had a degree of severe PPHN which did not respond to treatment. His Chest x-rays did show a somewhat bell-shaped chest (indicative of possible pulmonary hypoplasia), coupled with his echocardiogram findings and his clinical condition his death was felt to be caused by pulmonary hypoplasia and severe PPHN.

The decision by the ECMO centre in Sweden to decline him for ECMO treatment fits with their admission criteria and matches other ECMO centres in this regard. We do not believe that ECMO treatment would have been successful or curative in his case and he was born prematurely and had low birth weight which would have worsened outcomes further. No bacterial or viral infections were identified on tests prior to or after death. There were some results documented above suggesting a possible primary or secondary metabolic abnormality. At no time did Aaron have a normal oxygenation index during his course in NICU and this would be in keeping with the underlying functional pulmonary hypoplasia and PPHN identified clinically by the team of specialists.

Section 3: Aftermath of Incident

Following Baby Aarons death in Hospital S2 an investigation was commissioned following the family's concerns. The findings of this investigation are contained within this report.

Following a review of the healthcare records and interviews with staff in the aftermath of this incident the External Expert Consultant Neonatologist that it would be of importance to this investigation to consider the port mortem (PM) findings to ensure that all aspects of the incident could be considered and made available to the family.

In a follow-up report to the investigation team External Expert Consultant Neonatologist outlined the following having reviewed the post mortem report:

> *'I have been provided with copy of the post-mortem report on a confidential basis by the Dublin City Coroner, having reviewed the PM findings, in my opinion there should have been more clinico-pathological correlation (between the pathologist and the neonatologists) made on the basis of baby's clinical course taken together with the autopsy findings.*
>
> *This is a case of severe unremitting persistent pulmonary hypertension of the newborn (PPHN) causing the death of baby Aaron based on my clinical review of the Hospital S2 and Hospital S1 charts with the post-mortem findings.*
>
> *There is no evidence that the consultant pathologist in this case sought further clarification from the Neonatology team or the Consultant Neonatologist F around the PM conclusion of mild pulmonary hypoplasia, the consultant pathologist (A) did however seek appropriate second opinions from two other consultant pathologists on the histological findings. I think that such clinico-pathological discussion (with the Neonatology Team) should occur and in my opinion would enhance and certainly not detract from the coronial process'.*

Thursday 16th June 2016

My sister and I attended my 6 week check-up which was a meeting we were unaware of at Hospital S1 with Consultant Obstetrician and Gynaecologist A, the Director of Midwifery (was called in) and Hospital S1 Quality and Safety Manager. Consultant Obstetrician and Gynaecologist A went through my notes and was asked the following questions:

- *What level of monitoring did I receive antenatally, being seen every 2 weeks at the outpatient clinic.*

According to Dr Gardeil the frequency of monitoring was appropriate. There was no requirement to repeat the CTG on the 3rd May 2016.

- *Was I a high risk patient?*

Mrs X was informed on the 29th April 2016 that she was a high risk patient.

According to Dr Gardeil Mrs X was monitored appropriately and in line with best practice however there was a requirement to repeat the IMEWS, which was not done.

The Investigation Team consider that Mrs X was a high risk patient. There is a requirement for a Maternity Network Referral Guideline to ensure that there is a clear understanding of what patients are to be transferred and those patients that will be accepted by the tertiary referral centre, and the timeframes for transfer. Patients must be informed of this process.

Section 4: Key Causal Factors, Contributory Factors, Incidental Factors and Linked Recommendations

In line with current thinking and best practice for the development of safety management systems in healthcare settings this investigation used a systems analysis approach in undertaking the overall review of the care and treatment Mrs X received while under the care of staff at Hospital S1 from the 19th November 2015 until Baby Aarons delivery on the 4th May 2016; including Baby Aarons transfer to hospital S2 until the 9th May 2016.

The investigation focused primarily on Mrs X's antenatal care and intrapartum[34] care however in order to complete the chronology the Investigation Team believed it to be beneficial to document the events leading up to Baby Aarons death on the 9th May 2016.

The aim of this investigation as outlined in the terms of reference was to establish whether there were any failures in relation to the care and management received by Mrs X on admission on the 4th May 2016.

The Key Causal Factors identified;

1) Failure to effectively communicate on several occasions with each other, with Hospital S2, Mrs X, her husband and neonatology;

2) Failure by Staff to anticipate the potential severity of Baby Aaron's condition at delivery.

3) Failure by staff to complete and document all the required steps in the sustained neonatal resuscitation in this case within a desirable time-frame, including failure to assign a scribe to provide a full and accurate recording of the resuscitation efforts provided.

Key causal factors are defined by the NIMLT 0010; Guideline Title: Guideline for the Systems Analysis Investigation of Incidents; Revision No: 3, Approval Date: August 2016[35] as issues that arise during the process of delivering and managing health services that are considered by the investigation team to have had an effect on the eventual adverse outcome.

This investigation endeavored to specify the factors that contributed to the occurrence of the three Key Causal Factors utilising the framework of influencing / contributory factors outlined in the 2015 Safety Incident Investigation Policy.

The Investigation Team acknowledge that even if Mrs X's care had all been carried out effectively, it is accepted that this would not necessarily have changed the ultimate outcome for Baby Aaron BUT the issues identified during the course of this investigation MUST be rectified to ensure that they do not recur as the care delivered to Mrs X and Baby Aaron in hospital S1 is at best suboptimal and potentially dangerous and such deficits would not have lessened the problems for Baby Aaron.

The Investigation Team identified that Mrs X and her husband did not have a clear understanding

[34] Intrapartum care refers to the events occurring during labor or delivery

[35] The NIMLT 0010; Guideline Title: Guideline for the Systems Analysis Investigation of Incidents; Revision No: 3, Approval Date: August 2016 Available at: http://www.hse.ie/eng/about/QAVD/Incident-Management/HSE-Systems-Analysis-Investigation-Guidelines-Part-1-and-Part-2.pdf

of the rationale for Mrs X's plan of care following her assessment in the antenatal clinic on the 29th April 2016 and the urgent referral for further assessment to hospital S2 or indeed her subsequent admissions to Hospital S1 up to the point of Baby Aarons delivery.

In-addition Mrs X was concerned in relation to the difficult resuscitation of Baby Aaron following delivery. It took 20 minutes for Baby Aaron to be intubated following delivery with little or no explanation provided to the family as to why intubation was difficult, particularly as the Consultant Paediatrician intubated Baby Aaron within minutes of arrival.

Dr. Francois Gardeil carried out a review of the healthcare record in relation to obstetric clinical care. It is the opinion of Dr. Gardeil and the investigation team that both this report must with read in conjunction with his report and the key casual factors identified by the investigation team.

It is the objective of the HSE that service users should be supported optimally to gain an accurate understanding of their care and management; including understanding of the reason(s) for their admission, transfer and discharge to and from care.

It is the opinion of this investigation team that the failure to achieve this objective with regard to Mrs X's care is considered to be the adverse outcome in this case.

Key Causal Factors are issues that arose in the process of delivering and managing health services which had an effect on the eventual adverse outcome.

Three Key Casual Factors were identified in this regard.

Contributory factors are defined as "the causes of harm in the incident being investigated". They are also considered to be hazards and potential causes of harm, if not mitigated through the implementation of appropriate recommendations. The list of contributory factors outlined within the Contributory Factor Framework used to analyse the Key Causal Factors identified is included under Appendix K of this report.

All recommendations must be audited and the findings of such audits acted upon.

Key Causal Factor 1:

Failure to effectively communicate on several occasions with each other, Mrs X, her husband and Hospital S2.

In respect of key causal factor 1; Mrs X attended for an antenatal appointment on the 29th April 2016, and was reviewed by the Obstetric NCHD. At this visit the Obstetric NCHD carried out an ultrasound scan which identified severe polyhydraminos and fetal anomalies which included dilated kidneys and echogenic bowel. The Obstetric NCHD in consultation with Consultant Obstetrician and Gynaecologist A advised Mrs X that Baby Aaron may need specialist attention and faxed an urgent referral at lunchtime (Friday of a Bank Holiday) for a second opinion and fetal anomaly scan to hospital S2. The Investigation Team believe that the decision to refer to hospital S2 for further assessment and a fetal anomaly scan was the correct decision on the 29th April 2016.

Notwithstanding this the team failed to communicate with hospital S2 to establish firstly, whether the referral was received by any staff in hospital S2 and secondly, enquire as to the status of this referral with a view to agreeing a review date, a plan of action or no action. It is possible having reviewed the healthcare record that one could form the opinion that there was a degree of tardiness in relation to the management of this referral on the part of the hospital S1 team.

It is the opinion of External Expert Consultant Neonatologist that the clinical team should have

telephoned hospital S2, and it is not sufficient to make an assumption that hospital S2 would not accept Mrs X because she was more than 32/33 weeks gestation is unacceptable. The rationale for not telephoning hospital S2 should also have been documented.

During the interview process Mrs X outlined that Consultant Obstetrician and Gynaecologist A informed her that he was not concerned and if he was he would look for a second opinion, and went on to say that when it comes to the kidney's these issues can rectify itself following delivery. In addition Mrs X stated that she was informed the extent of the problem would not be known until the Baby was born.

At interview Consultant Obstetrician and Gynaecologist A and B both stated that the scan carried out on the 29th April 2016 identified *'serious problems'*. However this concern is not evident in the healthcare record, nor is there any documentation setting out the advice (if any) that was provided to Mrs X at the visit on the 29th April 2016 should any issues arise. In-addition there is no documented plan of care.

Mrs X presented to hospital S1 on the 1st May 2016 and was admitted due to reduced fetal movement and was subsequently discharged on the 2nd May 2016. Again on the 2nd May 2016 it was noted in the healthcare record that staff were waiting on the appointment from hospital S2.

During the feedback process Mrs X stated that she was;

> *'was admitted on the 1st May 2016 with high blood pressure and protein in urine. Bloods from Friday 29th of April showed abnormal liver function with elevated levels. Bloods were not repeated at any time between admissions Sunday-Monday'.*

There is no documentation in the healthcare record whether the clinical team considered these results to be significant and if there was a plan to repeat these bloods. Consultant Obstetrician and Gynaecologist A did not consider these abnormal bloods to be problematic.

It is surprising that Consultant Obstetrician and Gynaecologist A took such a hands-off approach over the bank Holiday weekend, having previously reviewed Mrs X at all earlier antenatal visits. There is evidence that Consultant Obstetrician and Gynaecologist A was contactable by phone when Mrs X was admitted on the 1st May 2016 as the Obstetric NCHD on-duty referred to calling Consultant Obstetrician and Gynaecologist A but did not expand as to the purpose of this communication. In-addition Consultant Obstetrician and Gynaecologist A informed the investigation team at interview that he would expect Consultant Obstetrician and Gynaecologist B (the on call obstetrician on duty) to develop the plan of care for Mrs X.

Consequently it seemed that the senior clinical staff who managed Patient X's care following her admission to the Maternity Unit were unsure as to the reason(s) for the patient's admission and of treatment plan(s) in place or being considered following the earlier assessment of the patient.

While it would appear staff were aware of the clinical circumstances around Mrs X's admission on the 3rd May 2016 and the urgent referral to hospital S2 which was faxed on the 29th April 2016, the investigation team notes that there were no documented attempts to seek clarity at this point from hospital S2 in relation to further management and a plan of care for Mrs X and delivery of Baby Aaron.

During the feedback process Mrs X stated that she was;

> *'considered a high risk patient who should have been monitored on a continuous basis, however I was not reviewed by a Midwife for a period of 7 hours after admission on the 3rd May 2016, during which time the IMEWS should have been repeated'.*

The investigation team consider that Mrs X should have been communicated with appropriately in

relation to the monitoring or indeed as in this instance the lack of, if only to alleviate any anxiety or concern. Mrs X is now left with the experience that something may have been missed and therefore the appropriate action not taken.

In relation to Mrs X's feedback, Mrs X wanted to be able to make a reasoned choice based on relevant information about the advantages and disadvantages of all the possible courses of action (including taking no action).

During the interview process Consultant Obstetric and Gynaecologist A and B outlined that they did not expect Mrs X to be reviewed over the Bank Holiday weekend in hospital S2 but would be seen before the following Friday 6th May 2016, one week after the referral, in-advance of her scheduled antenatal appointment on the 6th May 2016.

Mrs X was assessed by the locum Consultant Obstetrician and Gynaecologist B who sent her home early on Monday the 2nd May 2016 (bank holiday) as CTG's were considered to be normal. There was no suggestion documented in the Healthcare record as to what action should have been taken in light of such serious findings i.e. regarding a return to hospital S1 given that Mrs X was waiting on an urgent referral to a tertiary unit to check for a potentially serious condition in her unborn baby and already had evidence of polyhydramnios in pregnancy. Nor was there any discharge advice provided to Mrs X to safe guard not only the wellbeing of Mrs X but also that of her unborn Baby.

The External Expert Consultant outlined for the investigation that there were on-call staff available in hospital S2 over this bank-holiday weekend that would have discussed Mrs X's case with the clinical team in hospital S1 and; would have assisted with devising a plan of care or indeed recommend Mrs X for transfer based on the outcome of discussions. As it stands there is no documentation regarding findings, discussions and actions suggestive serious lapses in care.

The investigation team considers that senior clinical staff should have documented a clear plan of care for the delivery of Baby Aaron and whether delivery should occur in hospital S1 or hospital S2, a Tertiary Referral Centre which has a full spectrum of neonatal specialist services[36]. Hospital S1 does not have this full spectrum available locally as it is a local level 1 hospital which provides routine neonatal care to term infants.

The External Expert Consultant stated that the tertiary referral centre (hospital S2) has a primary function to provide specialised care to infants who are critically unwell. Most of the workload is concentrated on very preterm infants, unwell term infants, and infants with major congenital malformation. Tertiary care is about the activity, not the place. It is a facility where healthcare professionals have the necessary knowledge, training and experience to deliver intensive care to small infants.

The Investigation Team note that 'The Model of Care for Neonatal Services in Ireland'[37], HSE, 2015

[36] Level 1 (local) neonatal units provide routine neonatal care to term infants, and special care to infants ≥32 weeks gestation. Infants of 30-31 weeks gestation can be cared for in Level 1 units if the appropriate staffing complement is available, i.e. 1:2 high dependency nursing ratios, middle grade and consultant staff.
Level 2 (regional units) provide routine neonatal care to term infants, special care, high dependency care and short-term ventilation to infants >27 weeks gestation.
Level 3 (tertiary units) provide the full spectrum of neonatal care to term and pre-term infants who are critically unwell. There should be sufficient clinical throughput to maintain clinical skills and expertise, with a minimum of 100 infants BW <1500g and/or 100 infants requiring assisted ventilation / CPAP.

[37] The Model of Care for Neonatal Services in Ireland, HSE 2015 addresses the delivery of neonatal services in Ireland, and the integration between tertiary (Level 3), regional (Level 2) and local (level 1) neonatal units. It proposes how the three categories of the neonatal service should function. It describes how the current neonatal services operate nationally. It outlines how neonatology should change and advance with reference to best international practice. It provides a vision for the future of neonatology and describes how that vision can be implemented. It proposes the blueprint for a neonatal model of care for Ireland. The model is guided throughout by the triad of Quality, Access and Cost.

does not provide sufficient guidance in relation to categories of referrals and timeframes. There was no maternity network guideline in place within the Hospital Group that set out the necessary detail for a referral to a tertiary referral centre for specialist opinion or support irrespective of the category of referral. Notwithstanding, this it was not that lack of referral categories and timeframes that lead to the communication failings but the lack of communication between staff.

In line with the National Maternity Strategy 2016, women should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Every opportunity should be taken to provide the woman and her partner or other relevant family members with the information and support they need.

The investigation team also identified a number of failures in relation to IMEWS i.e. abnormal observations with no follow-up, if not addressed through a robust audit process could pose a risk to patients.

Mrs X outlined during the feedback process that she wanted to be able to make a reasoned choice based on relevant clinical information regarding the advantages and disadvantages of all the possible courses of action (including taking no action) in terms of Baby Aaron's delivery as she was communicated with.

Mrs X outlined a concern that she was not offered an opportunity to be transferred to a tertiary hospital capable of providing optimal perinatal care, despite the uncertainty about the timing of the delivery of Baby Aaron and despite the uncertainty of the need for specialist neonatal care. Mrs X outlined she will never know whether the outcome for Baby Aaron would have been different following a transfer for delivery.

Team Factors I- (Verbal & Written Communication) – Plan of care

It is the opinion of this investigation team that Mrs X was not communicated with appropriately regarding any possible risk to Baby Aaron and was therefore not afforded the opportunity to make an informed decision regarding her perinatal care and treatment in partnership with her healthcare professionals; particularly as a possible risk to Baby Aaron had been identified.

The Investigation Team consider that there was no plan of care documented or indeed communicated. The lack of any plan to follow up on the referral between the 29th April 2016 and the 3rd May 2016 is a significant lapse in the care provided to Mrs X irrespective of the outcome in this case. The Investigation Team having reviewed the healthcare record believe that Mrs X should have been offered admission on Friday 29th April 2016; in the absence of this the other recourse was to ensure the discharge on Monday the 2nd May 2016 occurred following a discussion with hospital S2 particularly as there was no follow up on the referral at any point.

During the interview process Consultant Obstetrician and Gynaecologist A and Consultant Obstetrician and Gynaecologist B did not provide any information that clearly outlined they informed Mrs X of their concerns or indeed developed a plan of care in partnership with Mrs X and her Husband.

Consultant Obstetrician and Gynaecologist A did not expect the urgent referral; to be acted on within 72 hours and believed that Mrs X would have been seen within a week. The Investigation Team believe this approach to an urgent referral to be wholly unsatisfactorily from a patient experience perspective and also unsafe considering the findings identified on the 29th April 2016.

Mrs X was consequently admitted on the 1st May 2016, and on the 2nd May 2016 (Bank holiday Monday) Consultant Obstetrician and Gynaecologist B rescanned Mrs X, who outlined similar concerns previously identified on the 29th April 2016 scan. At interview Consultant Obstetrician and

Gynaecologist B outlined serious concerns regarding the scan and findings. However again the Investigation Team consider that there was another missed opportunity to contact hospital S2 rather than just assuming that Mrs X would be called for review after the bank holiday weekend and before her next antenatal appointment scheduled for the 6th May 2016.

In-addition there is no evidence that Consultant Obstetrician and Gynaecologist A and B discussed these findings to agree a plan of care and follow-up on the status of the referral or contact hospital S2 to seek a second opinion. Mrs X was in hospital for 11 hours on the 3rd May 2016 before her SROM providing ample opportunity to link with hospital S2.

According to the External Expert Consultant staff were available in hospital S2 to discuss Mrs X's case and inform the development of a careplan. It is unsatisfactory to assume that hospital S1 would not accept Mrs X as an admission on the basis of her gestation of 35 weeks without first consulting with the team in hospital S2.

The Investigation Team consider there were multiple opportunities between the 29th April and 3rd may 2016 to communicate with hospital S2 regarding a plan of care rather than assuming Mrs X would be reviewed in hospital S2 before the end of the week, and; contact the Paediatric Consultant on duty to discuss any concerns relating to the birth of Baby Aaron to ensure the on call team were appropriately prepared.

At no time were Mrs X and her husband informed of the plan of care regarding the delivery of Baby Aaron. Mrs X and her husband at interview stated that they believe pregnancy care should have been transferred to Hospital S2. Mrs X expressed regrets she did not present herself to Hospital S2 over the bank holiday weekend. She believes she was not told her pregnancy had become high- risk with fetal complications to be expected that may place Baby Aaron in a position of risk. As a result she was unable to make an informed decision in relation to her on-going perinatal care.

Recommendation 1 ***(Hierarchy of Hazard Controls - Administrative Procedure):***

That a formal and agreed policy and procedure for the communication of information between the Obstetrician Gynaecology Consultant staff related to patients seen in the Antenatal Clinic and referred for admission to the Maternity Department is developed and implemented by the end of Q2 2019 and that monitoring of the implementation of the procedure is incorporated into the routine audit schedule of the Department.

Task and Technology Factor 1 – Verbal and Written Communication Referral Process

It is important to state that the referral made in the method that it was in order to seek a second opinion, was deficient with or without a guideline. It is likely that the fax machine was unsupervised after lunch time on a Bank Holiday weekend; fax machines are generally located in admin offices which may or may not be manned during lunchtime. Not to make a telephone call to the department /hospital on call consultant at any time in light of such abnormal findings could be viewed as a significant deficit and not to do so at this time, potentially even more so.

The fact that there was no guiding policy is not an excuse to not use common sense. There will never be a time when there is a Policy Procedure Protocol Guideline (PPPG) for absolutely every eventuality. Both the NCHD and Consultant Obstetrician and Gynaecologist A were aware of the findings on USS and it appears that neither ensured the adequacy of the referral at that time.

On the 1st May 2016 following Mrs X's admission to hospital S1, the Obstetric SHO on duty documented that he made contact with Consultant Obstetrician and Gynaecologist A to gain further insight into Mrs X's clinical presentation and status of the referral to hospital S2. Following this conversation there is no detailed plan documented in relation to a plan of care for this high risk pregnancy, nor is there any clarity as to the status of the referral irrespective of a bank holiday weekend.

According to the External Expert Consultant there are on call senior clinical obstetric staff available in hospital S2 to discuss any high risk case should the need arise. Therefore, the instruction should have been for the on-call team in hospital S1 to contact hospital S2.

There is no documented evidence to indicate what the next steps in care were for Mrs X and Baby Aaron in terms of referral for further assessment or indeed if the clinical situation was to change suddenly.

Following a review carried out by Consultant Obstetrician and Gynaecologist B on the 2nd May 2016, Consultant Obstetrician and Gynaecologist B informed the investigation Team at interview that these new scan findings were concerning. Consultant Obstetrician and Gynaecologist B informed the investigation at interview that she was uncertain as to what had happened over the previous 3 weeks as the polyhydraminos was so severe. This opinion is not documented in the healthcare record. The information contained within the healthcare record did not reflect this level of concern that Consultant Obstetrician and Gynaecologist B voiced at interview. Again, Consultant Obstetrician and Gynaecologist B had an opportunity as the senior decision maker to contact hospital S2. The investigation note that if senior clinical staff had concerns regarding the potential for Baby Aaron to require specialist treatment following delivery this was not documented in the healthcare records.

The Investigation Team were informed Consultant Obstetrician and Gynaecologist B that an urgent referral means that a patient would be reviewed within 72 hours. Again, the investigation Team considers that one may not 72 hours to wait for a specialist review. This timeframe must be addressed in terms of unnecessary delays, particularly if a patient should be transferred that day for a review/opinion. In relation to the follow-up of the urgent referral Consultant Obstetrician and Gynaecologist B also outlined that the midwives would normally follow-up on the referrals and she normally follows up on any referrals she sends herself. Again the Investigation Team consider that the inaction identified is unacceptable and place Mrs X and Baby Aaron in a position of unnecessary risk.

As outlined in the chronology it is unacceptable to assume the Midwives would normally follow up on an obstetric referral; this is not an acceptable justification in these circumstances.

Mrs X presented on the 3rd May 2016 and was admitted to Hospital S1 and subsequently had an SROM later that day at approximately 22:45 hours. Consultant Obstetrician and Gynaecologist A outlined that the reason the urgent appointment in Hospital S2 was not progressed was directly related to her admission on the 3rd and SROM the night of the 3rd May 2016.

Nevertheless, it is the opinion of the Investigation Team that staff at Hospital S1 should have followed up on the urgent referral as there was no indication at the point of Mrs X's presentation at 11:30 hours on the 3rd May 2016 that Mrs X would go into labour, nor is there any documentation in the healthcare record to establish why the referral was not followed up on in conjunction with a plan a care.

The Investigation Team consider that follow-up on any urgent referral is important for several reasons; including ensuring proper treatment continuation of the initial condition identified; identification of a full and proper diagnosis; management of treatment failures and possible complications which may result as a consequence of any underlying disorders.

The Investigation Team were informed that the expectation was that Mrs X would be seen within a week of the referral being sent to hospital S2 at which point she would be seen again in clinic. It would appear that there was no contingency plan in place should Mrs X go into labour before the referral was acted upon.

The Investigation Team consider that the approach lacked structure, in that there was no evidence that hospital S2 received the referral and no evidence that anyone individual from hospital S1 had responsibility to follow up on the status of the referral, even though Mrs X had repeatedly enquired as to the status of the referral.

The investigators are cognisant that the Maternity Strategy, 2016 states the requirement for Hospital Groups to develop a plan to ensure that all maternity hospitals/units within their network provide all pregnant women with access to dating and anomaly scans. This will include a clearly defined referral pathway to an expert in foetal health medicine, where clinically indicated by a scan.

Mrs X stated that she asked repeatedly on the day of the 3rd May 2016 about the status of the referral and was informed by staff that it was being followed up on. This was not documented by staff.

The investigation identified that any follow-up on the referral is not documented in the healthcare record, nor is there any documentation captured with respect to any conversation to hold on the referral due to Mrs X's admission on the 3rd April 2016 and the possibility that she may go into labour.

Hospital S2 were asked to provide insight into the referral process with respect to urgent referrals and whether Mrs X could have been referred for delivery of Baby Aaron in hospital S2 (Appendix K).

Consultant Obstetrician and Gynaecologist A outlined that Hospital S1 does not routinely transfer patients to hospital S2 except for delivery before 33 weeks. The expectation is that the baby will be delivered in the treating hospital, however referrals for fetal assessment and anomaly scans are still processed and acted on.

Mrs X and her husband stated at interview that while they were aware an urgent referral was faxed to Hospital S2 on the 29th April 2016, they were not of the understanding that clinical staff did not expect the referral to be acted upon as it was a bank holiday weekend.

Mrs X outlined that her opinion is irrespective of whether the outcome would have been different following transfer to Hospital S2. However Mrs X believes that Baby Aaron would have received prompt specialist treatment by neo-natal staff on Hospital S2.

There is an increased risk of many abnormalities in the event of polyhydramnios and the Investigation Team would expect that all staff would be aware of this and would be prepared for fetal anomalies e.g. trachea oesophageal fistula etc even if that was not an outcome in the end and whether or not there were any CTG abnormalities.

During the feedback process Midwife M3 that;

> *'at every point of care staff were aware of the risks of Ms X's high-risk pregnancy. We were aware of her polyhydramnios, possible abnormalities on her previous scans and her prematurity. Mrs X was continuously monitored following her SROM. Every single deviation from the norm was immediately escalated to the obstetric registrar who appropriately escalated it to the obstetric consultant. It should also be noted the that some preparations for theatre were made by the midwives prior to the official decision for an emergency section by the medical team, which shows their insight into Mrs X's high risks and also shows their experience in dealing with high risk labours, especially that of Mrs X. The midwives did in fact anticipate problems at birth for baby Aaron. This is proven by the fact the midwives had a full paediatric resuscitation team present, which included Paediatric SHO, Registrar and Special Care Nurses'.*

Notwithstanding the above staff did not document their concerns in the context of Mrs X's USS findings.

Sadly, Baby Aaron died as a result of severe hypoxic ischemic encephalopathy on the 9th May 2016 in Hospital S2 following his transfer on the 4th May 2016. It is unclear why the brain injury happened and what underlying anomaly led to complications in pregnancy and the poor condition of Baby Aaron in the neonatal period.

The Investigation Team considers that multidisciplinary communication and bi-directional transfer of care between professionals and between care pathways should be seamless.

At all stages, the need and rationale for consultation with another professional, or the transfer to a different care model, should be discussed with the woman. Some high-risk mothers and babies may be referred to a medical or multidisciplinary team clinic where an individualised, agreed, multidisciplinary, multispecialty care plan is agreed in order to ensure that the woman's care is appropriately integrated and structured.

Mrs X was booked under consultant led care from the outset and despite that and despite developing significant problems in her pregnancy; her care was both fragmented and inadequate particularly in the last week prior to delivery. The communication between the consultants and Mrs X and between the consultants and the NCHDs and Midwives and, between the medical staff of S1 to the USS Dept and/or on-call consultant O&G was substandard in all respects. This was not a woman booked under another model of care that was not referred to Consultant led care by Midwives.

Dr Gardeil outlined for the investigation that insofar as possible, all care pathways should support the normalisation of pregnancy and birth. However, as the needs of the mother and/or baby may change at any stage during the pregnancy, our services must be responsive to ensure that the increased need is identified quickly and that the mother is placed in the correct care pathway.

In summary the Investigation Team consider that there is a lot of not taking responsibility especially by senior clinical staff. Particularly stating that Midwives follow up on some referrals and she follows up on her own shows a poor understanding of team work or of obstetric/ consultant led care in high risk cases and does not make sense. It is not acceptable not to follow up on something both Consultants viewed as very serious and or concerning even if that were to be a clear direction to either a Midwife or a NCHD to follow up. At various levels in all sizes of maternity hospitals, this type of query in this type of clinical scenario would ordinarily be undertaken by either a Registrar in Obstetrics or the consultant directly but in any case the Consultant does not seem to have raised a query as to the status of the referral or sought to enhance same.

Mrs X's clinical picture was not normal. Mrs X was in the consultant led care model of care, i.e. to the assisted model of care (as per National Maternity Strategy 2016) and may have required full specialist care. She should have been referred and that referral should have been effective in terms of seeking a timely and appropriate response whether or not the results of which may have necessitated a transfer of her care to S2 antenatally for delivery and neonatal support. The suggestion of supporting normalisation of birth in such a scenario is misleading if it fails to recognise what must be done in the first instance to ensure the safety and wellbeing of mother and fetus/ baby.

Recommendation 2 (Hierarchy of Hazard Controls - Administrative Procedure):
Remind all Health Care Practitioners of HIQA standards, HSE policies and procedures and guidelines regarding communication, standards of the regulatory bodies such as the Irish Medical Council and the Nursing & Midwifery Board of Ireland. The Hospital Management must decide, in conjunction with the lead clinicians and Director of Midwifery, if retraining is required; what needs to be audited; how often and what sanctions may be considered in light of further breaches and how is that communicated to staff.
Implement within 6 months of this report being finalised.

Task and Technology Factor 2 - Non adherence to IMEWS escalation pathway

The IMEWS is a critical communication tool in the healthcare setting. The Investigation Team identified a number of errors and omissions in paper-based early warning scores used in hospital S1.

As outlined in the chronology there was a yellow trigger on IMEWS which was not followed up on. Following Mrs X's admission on the 3rd May 2016, the IMEWS chart contained an elevated blood pressure of 132/92 which was not repeated in line with best practice, the midwife documented 'IMEWS=0' instead of 1. This 1 yellow trigger recorded at 12.35 hours on the 3rd of May required a repeat full set of observations after 30 minutes and before 60 minutes.

The next IMEWS=1 was recorded was at 15:00 hours on the 3rd May 2016 which documented an elevated BP of 137/91, again this required a repeat set of observations in line with best practice. Following the completion of the observations at 15:00 hours, a new IMEWS chart was required as the existing chart was now full.

Although a midwife documented 'IMEWS=0' at 22:10 hours, the actual figures for the vital signs are not documented on the IMEWS chart.

On the 3rd may 2016 again, the next IMEWS recorded by a midwife is at 22:40 hours, this does detail the vital signs on the chart. The 2 IMEWS triggers found at 22:40 hour were appropriately escalated.

In-addition to the above Mrs X stated that her pain score was also incorrect, her pain was never 0, and she had at all times voiced this.

Staff during the interview and feedback process did not provide an explanation in relation to these deviations.

The Irish Maternity Early Warning System (IMEWS) has been developed and introduced for the early detection of life threatening illness in pregnancy and postnatal period following an investigation into a serious adverse event. This HSE investigation detailed the following recommendation:

> *'Prompt introduction of a Maternity Early Warning Scoring Systems Chart for patients with pregnancy complications in gynaecology wards. This should be followed by a compliance audit. The chart should indicate a monitoring coupled with an escalating nursing, medical and multidisciplinary response'.*

According to Dr Gardeil the purpose of the IMEWS clinical practice guideline[38] is to improve the management of the pregnant patient between confirmed pregnancy and 6 weeks postpartum. They are designed to guide clinical judgement but not replace it. In individual cases a healthcare professional may, after careful consideration, decide not to follow a guideline if it is deemed to be in the best interests of the woman.

There is evidence in the chronology of events that staff did not adhere to these guidelines, deviations relate to the following;

[38] CLINICAL PRACTICE GUIDELINE, The Irish Maternity Early Warning System (IMEWS) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland and Directorate of Clinical Strategy and Programmes, Health Service Executive Version 1.1 Date of publication: July 2014, Guideline No.25 Revision date: July 2017

1. Incomplete observation sets
2. Observation sets that should have led to a repeat set of observations
3. Alerting score incorrectly calculated resulting in no trigger to repeat observations.
4. Incorrect pain scores

As stated in the National Maternity Strategy, patient safety training and education of healthcare professionals have not kept pace with advances in patient safety, or with workforce requirements. The introduction of patient safety in health professional training for maternity care is therefore necessary and timely. In addition, the Strategy recommends the implementation of multidisciplinary patient safety tools to minimise risk and patient safety incidents.

These include the NCEC Clinical Handover Guideline in Maternity Services and the Irish Maternity Early Warning System (IMEWS), which contain the communications tool ISBAR (identify, situation, background, assessment and recommendation) and the Patient Safety Pause, and checklists such as those published by the World Health Organization (WHO) in surgery and childbirth.

Recommendation 3 *(Hierarchy of Hazard Controls - Administrative Procedure):*
Full implementation of the;
- *NCEC Clinical Handover Guideline in Maternity Services and the;*
- *Irish Maternity Early Warning System (IMEWS), which contain the communications tool ISBAR (identify, situation, background, assessment and recommendation);*
- *and the Patient Safety Pause, and checklists such as those published by the World Health Organization (WHO) in surgery and childbirth.*

and audit within 3 months of this report being finalised and follow-up on audit findings.

Task and Technology Factors 3 (Decision-making aids)

Consultant Obstetrician and Gynaecologist A and B both agreed that the findings on the scan carried out on the 29th April 2016 warranted an urgent referral for fetal assessment and an anomaly scan along with a second opinion. At the time of this incident fetal anomaly scans were not available in Hospital S1 and the normal fetal ultrasound has limitations in relation to identifying fetal anomalies.

The National Maternity Strategy published in 2016 recommended that;

> *'Safety and quality capacity is developed across the maternity service to ensure that each network and service has a defined patient safety and quality operating framework'.*

Dr Francois Gardeil outlined for the investigation that the introduction of fetal anomalies scans for all pregnant women is a priority for the National Women ' and Infant Programme tasked with implementation of the Maternity Strategy and; good progress is being made allocating resources to units not yet offering routine scans.

The National Maternity Strategy is very clear that all women must have equal access to standardised ultrasound services and, therefore, the issue of anomaly scanning is a priority issue for the newly established HSE National Women and Infants Health Programme (NWIHP).

An early priority for the Programme is to develop clinical guidance regarding routine detailed scans at 20 weeks. Work has been on-going with the six Hospital Groups to assist in increasing access to anomaly scans for those units with limited availability.

Specific Actions in the National Maternity Strategy Implementation Plan include:

- Seek details from each maternity network on the resources required (ultrasonographers

and ultrasound machines) to provide access for 100% of pregnant women to dating and anomaly scans.

- Seek the additional resources required to improve access to dating and anomaly scans.

- Develop a plan to ensure that all maternity hospitals/units within their network provide all pregnant women with access to dating and anomaly scans. This will include a clearly defined referral pathway to an expert in foetal health medicine, where clinically indicated by a scan. It will also include the training and development of ultrasonographers.

Action taken since these events:

The Investigation Team have been informed that fetal anomaly scans are now available in hospital S1.

Recommendation 4 (Hierarchy of Hazard Controls - Administrative Procedure):
Hospital S1 as a priority must work with the Hospital Group to ensure all pregnant women have access to a fetal anomaly scan should the wish to avail of one. This recommendation must be communicated to the NWIP (National Women's and Infants Programme) in terms of available funding (if funding is required).

Task and Technology Factor 4 - Delayed Recognition of Abnormal CTG

On the 3rd of May 2016, a CTG was commenced at 12.34 hours and continued until 14.30 hours. It was signed off by a midwife as normal and reviewed by the obstetric registrar who noted it was 'satisfactory overall'.

Mrs X outlined her concern during the investigation process that she remained unmonitored prior to the delivery of Baby Aaron for a period of 7 hours between 15:00 hours and 22:00 hours while under the care of staff at hospital S1 on the 3rd May 2016. During this time Mrs X outlined that she cannot know whether Baby Aaron would have displayed signs of fetal distress during this time.

A repeat CTG was performed on the same day because Mrs X complained of an absence of movement; this CTG, commenced at 22.30 hour and continued until 22.55 hour was reviewed by the obstetric registrar and noted to be satisfactory.

Mrs X outlined during the feedback process that the aforementioned is incorrect. This CTG was only performed as there was a change in shift at 20:00 and when the midwife approached her at 22:00 hours, she noted Mrs X's file was not with Mrs X and that she had not been monitored or checked for several hours.

Mrs X also stated during the feedback process that despite her continuous complaints at this time she was sent back to her room to rest and within 5 minutes of leaving ward her membranes ruptured.

Mrs X also stated during the feedback process that there was a delayed recognition of abnormal CTG, and that the standard of the machinery used was not up to standard and should have been recalled 9 years ago and again 4 years ago.

The Investigation Team confirmed with hospital management that all CTG equipment is fit for purpose and up to standard and that all Field Safety Notifications in relation to CTG machines have been fully complied with.

The Investigation Team note from the healthcare records that the CTG was recommenced at approximately 23.15 hours, following spontaneous rupture of the membranes. There were periods of loss of contact recorded from 23.30 hours to 23.42 hours approximately, probably due to the fact that Ms X was standing out of bed at the time.

The Investigation Team are unable to establish whether Baby Aaron would have showed some degree of fetal compromise prior to 22:30 hours.

Mrs X outlined during the feedback process that the aforementioned is incorrect 'Loss of contact' was not due to me standing. There was nothing normal about CTG's up until 00:14 hours.

CTG Interpretation Summary

- On the 3rd May 2016 a CTG with the times 22.32 hours to 22.55 hours (35 3/7 weeks gestation) shows the baseline fetal heart rate as 140-150 bpm, with normal variability and accelerations are present. There are no significant decelerations. There are no regular contractions. This is considered to be a normal CTG tracing.

- On the 3rd May 2016 the CTG trace between 23.13 hours and the 4th May 2016 at 00:45 hours shows the baseline fetal heart varies from 130 to 150 bpm, with normal variability and accelerations are present. Shallow variable declarations to 120 bpm are present at 23.33 hours, 23.36 hours, 23.54 hours, 00.01 hours and 00.04 hours. There are two more ssubstantial decelerations at 00.16 hours to 80 bpm for 1.5 minutes and at 00.20 hours to 100bpm for 1 minute. There are irregular contractions. This is considered to be a suspicious CTG tracing.

- On the 4th May 2016 the CTG tracing from 00.51 hours to 01.02 hours shows the baseline fetal heart rate is initially 140 bpm, with reduced variability, and a prolonged deceleration occurred at 00.55 hours to 80 bpm until 01.02 hours. There are irregular contractions. This is a pathological CTG.

- On the CTG trace on the 4th May 2016 between 01.02 hours and 01.25 hours, the fetal heart rate is difficult to establish, but generally varies from 110 bpm to 140 bpm. It is not possible to determine timing of decelerations This is however a pathological CTG.

The prolonged deceleration occurred at 00.55 hours (which lasted for 7 minutes), prompted the decision to perform an emergency caesarean section. Transfer to a transport CTG machine took place at 01.03 hours.

The fetal heart rate was around 140 bpm a few minutes before the knife to skin recorded time of 01.28 hours.

Dr. Gardeil outlined that the decision to proceed to surgery should have been made before 01:00 hours given the clinical picture and Baby Aaron visible distress on CTG. Dr. Gardeil outlined there was no reason to delay.

During the feedback process Consultant Obstetrician and Gynaecologist A disagreed with the above, stating that there was no delay. It is the opinion of this investigation team that action should have been taken earlier to deliver Baby Aaron at least 30 minutes earlier. While an earlier c-section may have not altered the outcome, the purpose of a systems analysis investigation is to recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably possible.

Baby Aaron was born flat and in poor condition with no respiratory effort. It appears that staff did not expect Baby Aaron to be born in such poor condition.

The Investigation Team established during the investigation process that since July 2013 an

electronic Perinatal Training Programme has been mandatory in Hospital S1. The training requirement is to complete all modules within a twelve month period, as a rolling programme.
On the 18th July 2013 a Senior Nursing and Midwifery Manager wrote to Midwives identifying that the electronic Perinatal Training Programme (CTG Training) was mandatory from that point onward and in addition to this there was also a mandatory requirement for Midwives to:

- Take part in annual CTG training
- Take part in Obstetric emergency drills
- Attend CTG review meetings (3 per year minimum)
- Complete the required electronic Perinatal Training Programme
- Read all current policies, procedures and guidelines

Following the introduction of the mandatory electronic Perinatal Training Programme compliance reports relating to attendance are retained and monitored. Monitoring covers both Midwives and NCHDs (Non-Consultant Hospital Doctors) and once the report is produced it is the responsibility of the Clinical Lead for Obstetrics and Gynaecology to follow-up non-compliance with Medical staff and the Senior Midwifery Manager to address non-compliance with Midwifery Staff.

A guideline titled: Mandatory K2 Fetal Monitoring Training (PHOG019) was provided to the investigation team. This guideline was issued in November 2013. In addition to the above, since January 2016, on each Monday morning in Hospital S1, the caesarean sections from the previous week are reviewed.

All of the CTGs relating to the sections done from the labour ward are discussed. At this meeting, there is also the opportunity to discuss CTGs in cases that were not delivered by caesarean section.

As set out in the National Maternity Strategy Implementation Plan a review existing models of education to develop a national standard approach is underway. This review will include the Centre of Midwifery Training CME which provides professional development, skills training including CTG training to the three maternity hospitals in Dublin and be carried out in conjunction with ONMSD.

In order to answer a specific question posed by the family in relation to a specific CTG machine in use at Hospital S1 the Investigation Team sought the opinion of the National Medical Devices Lead. The National Medical Devices lead informed the Investigation that the HSE received an update from the HPRA on the interactions with the manufacturer of the Cardiotocography (CTG) monitor and steps taken to address concerns that had been raised.

The HPRA have advised the following in relation to the sequence of events: Avalon Fetal monitors are CE marked medical devices on the market in Europe. Philips Healthcare issued communications in October and December 2009 to users of these devices in Ireland highlighting the known limitations inherent to ultrasound fetal heart rate monitoring and providing advice on the appropriate use of these devices. In addition there was a software revision applied to all these devices in Ireland and Philips Healthcare confirmed to the HPRA in November 2011 that the software revision had been completed in all Irish centres. The HPRA monitored the completion and effectiveness of these communications and the software revision. These medical devices were not recalled in Europe or USA as a result of this issue. The use of the word 'recall' is FDA terminology used in communications for either a device correction or a removal depending on the action in the USA. The HPRA has monitored the incident and complaint rates nationally, on a European level and internationally and at no time identified the need for additional regulatory action.

Mrs X stated during the feedback process on the final draft report that:

> *'After reviewing the report we are not happy with the factual accuracy of the technical response in regards to the Philips Avalon monitors recall/notification… there was a recall notification made by the manufacturer with regards to the functioning of the ctg monitors used on me while in labour with Aaron and prior to my membranes rupturing. I have personally checked the serial numbers and they were in fact part of the recall notification.*

The manufacturer gave a number of checks that needed to be followed by staff should the monitors be continued to be in use and should it alert to the doubling of maternal heart rate.

In regards to my ctgs being called suspicious between 11/12:20 we feel this is also misleading and not factually accurate as we feel the phrasing should be changed as suspicious leads to the belief that caution was in place, however they were abnormal and this was ignored. We also wish to address the final ctg which was on the portable monitor. This ctg was pathological! Between 01:03am and 01:17 I was not in theatre! There was no reassuring ctg trace since 00:51 until knife to skin 00:28! This was also alerting staff to the doubling of heart rate, therefore the heart rate which is mentioned on numerous occasions between 01:03 and 01:28 is more than likely mine, using the said heart-rate and reappearing that as an explanation, is implying that Aaron was not in trouble and the ctg was not readable due to movement! Also considering that no staff member checked to see if it was the fatal heart rate or not. Please include scbu nurse outline of events also, she arrived 11 minutes of age, she was told Aaron's heartrate was 30bpm, she changed the mask size to a smaller fitting size, as the one being used was to big, she increased the oxygen pressure up to 8-10 litres, and within 30 seconds Aaron's heart-rate was up to 90-100 beats per minute and SpO2 probe then began to respond. We don't understand as to why this was not done sooner or prior to the scbu nurse arriving!'.

According to National Medical Devices lead response there was actually no recall / no issue of the CTG equipment and no issue of it being not fit for purpose. Training records are available in Appendix E for staff relating to CTG training.

Recommendation 5 *(Hierarchy of Hazard Controls - Administrative Procedure):*
That the HSE's National Acute Hospitals Division confirm CTG training as a mandatory training requirement for all Obstetrics and Gynaecology Medical Staff and Midwives. The frequency of this training is to be established in accordance with best practice. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Recommendation 6 *(Hierarchy of Hazard Controls - Administrative Procedure)*
That Hospital S1 conduct an audit of compliance with the guideline Mandatory K2 Fetal Monitoring Training (PHOG019) including the requirement to participate in and complete CTG training in a given twelve month period. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner and non-compliance is to be addressed within 3 months of the audit.

Recommendation 7 *(Hierarchy of Hazard Controls - Administrative Procedure)*
That systems and processes are established, up to and including the disciplinary process, within each National Division to ensure compliance with mandatory training. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Task and Technology Factors 5 - (Availability and Use of Protocols)

The Investigation Team established that there was no written Maternity Network policy for the transfer of maternity patients from hospital S1 to hospital S2 (Tertiary Referral Maternity Hospital).

Notwithstanding this, absence of a guideline should not deter staff from making direct contact with hospital S2. The introduction of a guideline will support the clinical team in the decision making process. The investigation team believe there was a failure by the local team to make direct contact irrespective of a guideline being in place. One would ordinarily expect to make direct

contact in such circumstances given the urgency and coupled with the fact that this was a bank holiday weekend. A guideline may have aided/ guided practice but its presence does not necessarily ensure correct action.

The Investigation Team note that the 'Model of Care for neonatology services in Ireland' does not articulate a clear pathway for patients. This has the potential to cause ambiguity in terms of the process and responsibilities of the care providers, in addition will cause unnecessary anxiety for families while waiting for further assessment. There should be a standardised approach to care and treatment with algorithms and guidelines available for common neonatal conditions.

Mrs X was clearly unaware of the plan of care for her Baby or indeed her own care or indeed the absence of one. In-addition Mrs X was not informed of the timelines to be seen by a specialist in hospital S2. Had the mother been fully informed in terms of the referral process, she too would/ could have communicated that to new staff she was meeting in the two admissions that followed the findings of Friday 29th April 2016. Mrs X presented on two occasions to hospital S1 after her antenatal visit on the 29th April 2016.

The first time was on the 1st May 2016 when she was admitted and subsequently discharged on the 2nd May 2016. Mrs X presented for a second time on the 3rd May 2016, complaining of a mucus discharge and cramping pains. There were a number of opportunities to discuss plans surrounding the delivery of Baby Aaron.

Recommendation 8 (Hierarchy of Hazard Controls - Administrative Procedure):
*Develop a hospital group networked maternity/neonatal referral guidelines and patient pathways which must include criteria to ensure equitable access to the service based on clinical need across the hospital group***.**

This is a national requirement. There is a need for each Hospital Group to have to develop separate pathways especially when most traffic is to one of the 3 Dublin maternities whether for feto-maternal consultation or neonatal consultation. There is a need to specifically address urgent referrals such as in Mrs X's case during the out of hours (a Friday afternoon of a bank holiday weekend and during nights). Implement within 6 months of this report being finalised.

Key causal Factor 2:

Failure by Staff to anticipate the potential severity of Baby Aaron's condition at delivery.

In respect of Key Causal Factor 2; Based on Mrs X's clinical profile and emerging concerns i.e. gross polyhydraminos, raised LFT's and abnormal fetal USS , the investigation team consider that staff should have anticipated Baby Aaron being born in poor condition. Having a resuscitation team available is standard practice when a mother is to undergo an emergency C-Section. However from 35 weeks Mrs X's pregnancy was not going to be uneventful. The lack of appropriate written and verbal communication relating to Mrs X care and treatment has led this investigation team to believe that Staff at delivery did not anticipate how unwell Baby Aaron would be at delivery.

Patient Factors (Condition & Complexity)

Shortly before mid-night on the 3rd May 2016 non-reassuring features were evident on Baby Aarons fetal heart tracing, with decelerations and reduced variability.

Baby Aaron was born at 01:31 hours on the 4th May 2016 by emergency c-section, he was flat and unresponsive. Resuscitation proved very challenging, with two failed attempts with intubation. The Consultant Obstetrician and Gynaecologist A outlined at interview that Baby Aarons lungs were very 'stiff' hence the difficult intubation.

Following resuscitation Baby Aaron was transferred to a large Dublin Maternity Hospital (hospital S2) which has a wide spectrum of neonatal specialist services. Baby Aaron died on the 9th May 2016.

Mrs X outlined during the feedback process that;

> *'If possible we would like the cause of death put into the report. Aaron's cause of death was found through the inquest and was "Renal Vein Thrombosis, acute and chronic hypoxia, mitochondrial myopathy.'*

According to External Expert Consultant;

> *'This is a case of severe unremitting persistent pulmonary hypertension of the newborn (PPHN) causing the death of Baby Aaron based on my clinical review of hospital S2 and S1 charts with the post-mortem findings.*

Team Factors I- (Verbal & Written Communication)

It is the opinion of this Investigation Team, that it is the responsibility of the treating obstetrician to arrive at, and explain, the best possible plan of care for a pregnant woman particularly in light of any serious antenatal findings. This will assist staff caring for a woman to anticipate any potential problems in the delivery room.

The plan of care should be informed through discussion(s) in relation possible outcomes and courses of action and involves the various members of the perinatal team, who each bring a different expertise and perspective, as well as the pregnant woman and her partner/husband if she chooses.

If there is doubt about the outcome or the correct action, or if the discussion with the parents has been inconclusive, best practice is to provide support; this is also in keeping with professional guidelines.

Mrs X was in hospital for over 11 hours prior to the delivery of Baby Aaron providing ample time to put the appropriate supports in place. Instead the resuscitation of Baby Aaron was disorganised with far too many unknowns. Baby Aaron was very clearly compromised at birth, and intubation proved very challenging for the Paediatric Registrar, with two failed attempts. Baby Aaron was successfully intubated at 01:51 hours following the arrival of the Paediatric Consultant C at 01:45 hours.

There is no evidence that Consultant Obstetrician and Gynaecologist A discussed the potential challenges with Mrs X's delivery with the Paediatric Consultant C.

It is policy in hospital S1 to have the paediatric SHO at an emergency c-section. Notwithstanding this the Investigation Team must consider that both Consultant Obstetrician and Gynaecologist A and B voiced concerns at interview that Baby Aaron could be born very unwell. The Investigation Team considers that there was an opportunity to request the presence of the Paediatric Consultant at the delivery.

What is evident is that Baby Aaron did experience a hypoxic event either before or after delivery.

During the feedback process Mrs X stated that;

> *'It is clear that the appropriate level of expertise was not available to effectively manage Baby Aaron's resuscitation. The 2 unsuccessful attempts at resuscitation and the lack of supporting documentation further reiterates this for us'.*

According to the External Expert Consultant Neonatologist assigned to the investigation stated the specialist support available in Hospital S1 cannot be compared to the specialist supports available in a Level 3 (tertiary units) that provide the full spectrum of neonatal care to term and pre-term infants who are critically unwell. Particularly with respect to the necessary resuscitation support required for Baby Aaron following delivery; this is evident particularly in light of the delay in intubation.

The Model of Care for Neonatal Services in Ireland[39], HSE, 2015 states that Neonatal resuscitation is an essential function of all units providing acute neonatal services, and should be standardised and improved.

In-addition The Model of Care for Neonatal Services in Ireland, HSE, 2015; Neonatal services should be integrated across hospital groups to form clinical networks, with each unit clear about the services provided and appropriately resourced. Neonatal resuscitation is an essential function of all units providing acute neonatal services, and should be standardised and improved.

Recommendation (See Recommendation 8)

[39] The Model of Care for Neonatal Services in Ireland, HSE 2015 addresses the delivery of neonatal services in Ireland, and the integration between tertiary (Level 3), regional (Level 2) and local (level 1) neonatal units. It proposes how the three categories of the neonatal service should function. It describes how the current neonatal services operate nationally. It outlines how neonatology should change and advance with reference to best international practice. It provides a vision for the future of neonatology and describes how that vision can be implemented. It proposes the blueprint for a neonatal model of care for Ireland. The model is guided throughout by the triad of Quality, Access and Cost

Key Causal Factor 3:

Failure by staff to complete and document all the required steps in the sustained neonatal resuscitation in this case within a desirable time-frame, including failure to assign a scribe to provide a full and accurate recording of the resuscitation efforts provided.

In relation to Key Causal Factor 3 Staff present at delivery did not capture the difficulties that presented from his perspective, leaving far too many unknowns. There was no standard proforma for capturing important resuscitation information in hospital S1. The lack of appropriate documentation left too many unknowns for the family in relation to the resuscitation of Baby Aaron

Task and Technology Factor 1 - Written communication (Incomplete/absent information)

Absence of comprehensive documentation relating the first 10 minutes of the neonatal resuscitation lead to the recall of scant details as scribing only commenced at 11minutes of age.

Documentation of the neonatal resuscitation event was mostly captured retrospectively as there was no scribe available from the beginning.

Following delivery Baby Aaron's Apgar scores were documented as follows;

- 1 minute = 2
- 5 minutes = 2
- 10 minutes = 3

Dr. Gardeil outlined that normally the Apgar score is from 7 to 10 following delivery. Infants with a score between 4 and 6 have moderate depression of their vital signs while infants with a score of 0 to 3 have severely depressed vital signs and are at great risk of dying unless actively resuscitated.

Baby Aarons heart rate at delivery was noted to be less than 60 bpm, central cyanosis developed and Baby Aaron was hypotonic (floppy) and unresponsive.

According to Dr Gardeil most fetal hypoxia occurs during labour (i.e. intrapartum hypoxia), and may result in poor breathing at birth. This is further compounded if the Baby is not rapidly resuscitated.

Baby Aaron failed to establish adequate, sustained respiration after delivery (gasps only) based on the healthcare records. Therefore Baby Aaron failed to breathe well at birth.

Following a review of the chronology and interviews with staff the Investigation Team identified a discrepancy in relation to when chest compressions were started and when intravenous access was sought. During the interview process the Paediatric SHO present at the beginning of Baby Aarons resuscitation stated that chest compressions may have started at 1 minute of life. The Paediatric Nurse P 5 outlined that compressions may have commenced at 2-3 minutes of life.

Staff did confirm at interview that compressions continued between intubation attempts.

During the resuscitation of Baby Aaron it is evident that staff followed a series of actions taken to establish normal breathing, heart rate, colour, tone and activity in Baby Aaron in line with the Neonatal Resuscitation Programme (NRP) 6th Edition Guidelines which were in use at hospital S1 at the time of this incident (Algorithm See appendix F).

Following a review of the retrospective healthcare entries regarding Baby Aarons resuscitation, it would appear that all the relevant equipment was at hand including medications such as adrenaline. Baby Aaron was delivered at 01:31 hours, however 2 failed intubated attempts by the Paediatric Registrar resulted in Baby Aaron not being successfully intubated until 01:51 hours. Based on the documentation within the healthcare records that resuscitation attempts were somewhat successful as Baby Aarons heart rate did rise above 100bpm.

The Consultant Paediatrician B carried out a successful intubation at 01:51 hours.

Following a review of the NRP Guidelines, adrenaline[40] is indicated if the heart rate is less than 60 beats per minute after one minute of chest compressions. During the investigation process Consultant Paediatrician B indicated that adrenaline was not given as the heart rate was over 60 bpm, however the rational for this was not documented by staff following the resuscitation. Baby Aarons heart rate did not rise above 60 bpm until after 10 minutes of resuscitation.

A good heart rate is the best indicator of adequate ventilation and oxygenation during resuscitation.

The first 10 minutes of the resuscitation is not comprehensively documented by the Paediatric Registrar. The exact reasons for the 2 failed intubation attempts are not documented by the Paediatric Registrar nor is the rationale for not administering adrenaline.

The Paediatric Registrar outlined during the feedback process outlined that his notes are all that he *'can go by'*.

During the interview process Consultant Paediatrician B thought the difficult intubation was as a direct result of Baby Aaron's lungs being *'so stiff'*.

A review of the healthcare records and process in place for neonatal resuscitation identified that there was no proforma to capture key points in the neonatal resuscitation process. This allows for concise information to be captured. The accurate timing of every intervention and medication administered is essential. At the end of the resuscitation, the team must complete and sign one agreed record of the event.

Based on the findings contained within this report the Investigation Team considers that neonatal resuscitation should be standardised and improved across all units following the findings of this report.

The Investigation Team were informed of recent improvements in this area in Hospital S1 which include a resuscitation proforma and 10 minute resuscitation drills for staff.

Investigation Team wish to highlight the potential for local variations in neonatal resuscitation practice which could impact on newborns in both the short and long term. Increased standardisation within and between the hospital groups' neonatal services would go some way to ameliorate this potential problem.

The External Expert Consultant in his report for the investigation stated that the initial steps were appropriate in resuscitation; there was an initial heart rate. PPV was provided with mask/Neopuff and the improvement in the heart rate at 10 minutes suggested the PPV and

[40] 1:1000 adrenaline gives 1 mg/ml. Therefore 1 ml of 1:10 000 adrenaline gives 0.1 mg while 0.5 ml gives 0.05 mg. A dose of 0.25 ml/kg of 1:10 000 adrenaline gives 0.025 mg/kg. It has been suggested that 0.5 ml/kg may be given via an endotracheal tube if it is not possible to access an intravenous route.
If the infant has a good heart rate and is centrally pink, but still does not breathe, consider giving naloxone (Narcan) if the mother has received an opiate analgesic (pethidine or morphine) in the 4 hours before delivery.

chest compressions must have been somewhat effective during this period. The undetectable oxygen saturations levels with pulse oximeter noted at 10 minutes suggested a severely compromised infant with respiratory failure at that point however.

In conclusion NCHD's and locum staff rotate frequently and as a result may be exposed to wide variation in resuscitation protocols and practices throughout their training, potentially creating confusion and a lack of clarity concerning best practice.

The National Maternity Strategy states that;

> *'The Irish Multidisciplinary Obstetric Emergency Training (IMOET) group examined the extent of multidisciplinary training in Ireland and found that although some training was on-going, it was inconsistent and not in accordance with HIQA or HSE recommendations. Fostering and developing a culture of cooperation is essential to strengthening the maternity service and in that regard, multidisciplinary training within the maternity workforce is recommended.*
>
> *Such training should take place in a number of ways, including on-site, in clinical settings and within third level institutions etc. It is critically important that all maternity staff have the appropriate skills to deal with a deteriorating mother and baby. The IMOET skills course provides and maintains the knowledge base to care for the deteriorating mother and has a significant role to play in strengthening the capability of the maternity service.*
>
> *The Strategy therefore proposes that such training should be included on all relevant undergraduate and postgraduate curricula'.*

The Investigation Team note that engagement with all relevant training and education institutes to review programmes to enhance the multi-disciplinary nature and quality and safety focus is underway.

It is critically important that all maternity staff have the appropriate skills to deal with a deteriorating mother and baby. The IMOET skills course provides and maintains the knowledge base to care for the deteriorating mother and has a significant role to play in strengthening the capability of the maternity service.

The National Maternity Strategy therefore proposes that such training should be included on all relevant undergraduate and postgraduate curricula.

Changes in practice since this event.

Resuscitation recording sheets are in use and drills and skills in neonatal resuscitation occur frequently.

Recommendation 9: (Hierarchy of Hazard Controls - Administrative Procedure)
As recommended in the National Maternity Strategy Hospital S1 must ensure that multi-disciplinary training takes place at each hospital/unit within their network. This should include at the very least CTG interpretation, NRP, Stable & PROMPT, Communication, Clinical Handover, IMEWS and ISBAR training. The Hospital management in conjunction with the Clinical leads (in Obs and Neo) and Director of Midwifery should;
1) set a standard for frequency of such training in the absence of a nationally agreed one;
2) devolve responsibility/oversight of this to a named person/ group;
3) specify requirement for quarterly training logs of the MDT to be reviewed by the maternity and neonatal service and remedial action to be taken in cases of non- compliance with attending training and/or compliance with the standard of care and communication up to and including invoking of disciplinary process if and when required.
Implement within 6 months of this report being finalised.

Incidental Findings

During the course of this investigation other issues were identified that serve to highlight areas for system improvement and these will be discussed in the report under the heading 'Incidental Findings'. Following an analysis of the chronology, this investigation identified the following **9 Incidental Findings:**

i. Failure to follow up on an abnormal blood test result
ii. Delay in intravenous cannulation
iii. Incomplete clinical assessment
iv. Confusion regarding processing of cord bloods
v. Absence of a debriefing following resuscitation either formal or informal manner.
vi. Variation in Timings for baby Aarons Delivery

Incidental Finding 1: Failure to Follow-up on an Abnormal Blood Test results and Ultrasound Results

There is evidence of a raised Liver Function Test that was not acted upon during the antenatal period. This is a significant shortfall in communication and places both mother and baby in a position of unnecessary risk.

Mrs X outlined during the feedback process that;

> *'The bloods which were "apparently overlooked" could have highlighted a severe on-going problem. This accompanied with high blood pressure, protein in urine are direct serious signs of concern. The seriousness of the above is not addressed, approached or mentioned. In fact all incidental findings are excused and not directly addressed within this report'.*

In addition and importantly, blood samples that had been obtained in the antenatal clinic on the 29th April showed abnormal liver function with AST of 119 and ALT of 294 U/L respectively. Whatever the cause of abnormal liver function in pregnancy is, it is associated with poor outcome.

The blood results were signed off and ticked 'abnormal' by a doctor but this additional risk factor doesn't seem to have been taken into account by caregivers in the peripartum period. As outlined in the chronology there was also an abnormal USS abdomen which was not repeated as requested on the formal report 6 months later.

Dr. Gardeil outlined that these results in his opinion are suggestive of a problem with Baby Aaron. In-

addition Mrs X had a low HB 8.7 g/dl on the 4th May 2016. It is not documented whether this was ever followed up on i.e. action or rationale for inaction.

Recommendation 10: (Hierarchy of Hazard Controls - Administrative Procedure)
Hospital S1 must have in place a Guideline in place for the follow-up of abnormal diagnostic results. This must take cognisance of the appropriateness of the request in line with clinical presentation.

Incidental Finding 2: Delay in Intravenous Cannulation

The investigation considers that it would also have been prudent to establish venous access and take blood samples given the high-risk situation. Cannulation was not performed until 00.20 hour on the 4th of May 2016.

Incidental Finding 3: Incomplete Clinical Assessment

It is preferable to limit Vaginal Examination's in general and particularly in premature babies and or premature Prelabour ROM. Therefore, it would often be the registrar or Consultant who would undertake same. However, as the FH was abnormal and especially in the case of polyhydramnios, this is a clinical emergency and an abdominal and Vaginal examination should be undertaken immediately to out-rule cord prolapse and or to relieve pressure on cord by a presenting part if this has occurred and this should be done by the midwife if the registrar or Consultant is not present at that immediate time. This is only one in a series of actions/ considerations to safe guard the baby.

Following spontaneous rupture of the membranes at 23.10 hour on the 3rd of May, it is the opinion of the investigation team that the attending midwife should have performed abdominal and vaginal examinations to rule out cord prolapse which is more likely to happen in cases of polyhydramnios.

The Nursing & Midwifery Board of Ireland has published the Code of Conduct (2014), the Scope of Practice (2015) and the Practice Standards for Midwives (2015). The HSE Clinical Programmes have published a series of 30 + guidelines for clinical practice, common scenarios and there are many others done by NICE and/or the RCOG. These can all be used to support staff in delivering safe care.

During the feedback process Midwife M3 stated that the;

> *'On taking over care of Mrs X at 23:39, she had been a SROM for 29 minutes. The CTG was normal at this time and had been progress since 23:14. A vaginal examination was performed at 00:00 by the registrar prior to any abnormalities. Of course if there had of been any abnormalities on the CTG following the SROM, I would have immediately performed a vaginal examination as I am very experienced with dealing with cord prolapses. This paragraph implies that there was an abnormal CTG following a SROM and a vaginal examination was not performed, this is not the case'.*

Recommendation 11: (Hierarchy of Hazard Controls - Administrative Procedure)
The unit at Hospital S1 should ensure that they have in place, guidelines for the 10-12 most common obstetric complications within 6 months of this report being finalised and that they continue to build on these. These should include both the obstetric and midwife components of care; by way of example

- *Monitoring of the fetal heart*
- *SROM*
- *SROM with clear liquor in women at term in spontaneous labour with a well engaged fetal head and satisfactory fetal heart rate and no other discernible problems and is not the potential emergency,*
- *meconium stained liquor,*
- *history of significant polyhydramnios and other potential fetal / maternal complication etc.*

Incidental Finding 4: Confusion Regarding the Processing of Cord Bloods

Dr Gardeil outlined for the Investigation Team that it is best practice that paired (arterial and venous) cord samples should be obtained immediately after delivery and processed without delay using the same machine. In this case, the venous sample was analyzed 36 minutes after delivery. The arterial samples are more difficult to obtain than the venous ones.

The Investigation Team identified that the first 2 arterial blood samples clotted. A third sample was obtained and analyzed 1 hour and 42 minutes after delivery. The midwife operator stated at interview that she could not recall a significant delay in processing the arterial sample.

Cord bloods from umbilical arteries and vein were obtained in Theatre. The first 2 arterial samples clotted and had to be repeated. The venous sample was analysed at 02.06 hour with a Rapidsystem machine ID 1240-18225. The pH was 7.336 with a base excess of – 1.3 mmol/L. The arterial sample was not analyzed until 03.12 hour, by the same midwife, using a different Rapidsystem ID 1240-18080.

First blood gas which was taken at 02.26 hours showed pH 6.67 pCO2 17.33 kPa PO2 2.5kPa. This showed significant respiratory failure and a respiratory acidosis. The above recorded low oxygen saturations despite ventilatory support and 100% inspired oxygen concentration at the time are consistent with a critically ill infant with likely persistent pulmonary hypertension of the newborn (PPHN).

The External Expert Consultant stated that the second blood gas taken reported at 03.38 hours p H 6.98 PCO2 kPa pO2 3.5 kPa Base excess -10 mmol/L. result consistent with respiratory failure but improved. On the 04/05/16 following this gas ventilation settings were adjusted and at 04.30 hours the ventilator set rate was 60 BPM (the sheet does not state time after gas result that this change was made, I note nursing records are taken at 30 minute intervals at this point.) Consultant Paediatrician B's note refers to an increased rate of 60 BPM but does not state the time this change was made after the second gas. This second gas on the baby suggests that adequate ventilation was being achieved (lower PCO2) but the predominant feature is continuing hypoxia (low pO2) secondary to PPHN.

According to the External Expert Consultant it is not evidence based practice to continue to secure repeat arterial blood gases after 40 minutes post-delivery. Any delay with analysis leads to a decrease in pH values and, therefore, it is probable the pH's would have been slightly higher if the samples had been analysed without delay. Therefore the ABG's cannot be relied upon.

It is, however, possible that Baby Aaron suffered from a lack of oxygen at some stage during the pregnancy, however this lack of oxygen may have also occurred following delivery.

According to Dr Gardeil if the cord gases results can be relied upon, the delay in delivering Baby Aaron is extremely unlikely to have caused his hypoxic encephalopathy and ultimate death. There is a need, however to establish, with the help of the bioengineering staff, the calibration history of the machines and explore the possibility that time was wrongly set up on the machine used to analyse the arterial sample.

Dr Gardeil outlined for the Investigation Team that the cord bloods gases obtained after delivery indicates that Baby Aaron didn't suffer from oxygen deprivation in the hours before his birth.

It is, however, crucial to establish the servicing/calibration history of the machines used for analysis in this case and also explore the possibility that timing of the machine used for the arterial sample may have been incorrect.

Although Baby Aaron had very low Apgar scores, which is unusual with normal cord blood gases results, it is likely that severe oxygen deprivation occurred after delivery due to impossibility to

deliver oxygen effectively through the lungs during the resuscitation process.

The External Expert Consultant stated for the investigation that;

> *'I am somewhat concerned at the discrepancy between the venous report (02.06 hours) arterial blood gas (03.12 hours) report times; this represents a difference of over 1 hour, specimens processed by Midwife M2. This taken with the operating surgeon's note which stated the first 2 (arterial ?) samples were clotted, I am inclined to take the venous gas as definite (written by the surgeon/obstetrician into the operation form at the time) but I am unsure about reliability of the umbilical arterial sample because of a possible delay in processing same. The umbilical venous sample was normal'.*

Midwife M3 stated during the feedback process that;

> *'The 1st Arterial Sample Clotted……." I took the 1st arterial sample form the cord, but Midwife M2 processed the sample. I cannot say with certainty that the sample clotted, as I was not there. Midwife M2 took the second Arterial sample, but this would explain the time lapse. The laboratory staff maintains and calibrates the machines*
>
> *Could the machine time be out, I do not think so. There was a delay in processing the second arterial sample'.*

Midwife M2 outlined during the interview process that she cannot be certain why there was a delay other than the first sample was clotted and a second sample had to be retrieved, however she did stop briefly to talk to Mrs X while she was still in Theatre prior to processing the second sample. Midwife M2 also outlined that the machines are only a few minute's walk from the Theatre so there is no delay in getting to the machines in the Labour Ward.

In order to establish whether there may have been a technical issue with the Blood Gas machines the Investigation Team requested evidence of the local process in place at the time regarding the use and calibration of the Rapidlab 1200 Blood gas analysers.

The Investigation Team were informed by the local Laboratory Manager at Hospital S1, that Hospital S1 has two identical Siemens Rapidlab 1200 Blood gas analysers in the Labour Ward and the following points are relevant;

- The analysers are password protected and can only be used by trained personnel.
- Each analyser is supported by a UPS (Uninterrupted power supply) in the event of power failure.
- Calibration occurs automatically at prescribed intervals and requires no operator action. A full calibration occurs every 8 hours. A one point calibration occurs every 30-60 minutes depending on sensor drift. There is an automatic lock out following a failed calibration.
- Internal quality control samples are measured at 8 hour intervals at 3 levels. These were all within range during period 4-5th May 2016. QC results from both analysers can be compared. Records available.
- External Randox quality control samples are measured monthly and results are compared externally with results from over 100 other sites that use identical analysers. These were all within range in the April 2016 sample. QC results from both analysers can be compared.
- A comprehensive service contract with 'C' Diagnostics was in place for both analysers during 2016. Records available.
- Laboratory staffmaintain the analysers daily and analysers are monitored remotely via an electronic link from the laboratory. The analysers were operating normally on 4-5th May 2016. Records available.

- Maternity staff are trained in the correct use of the analysers, training records are available.

Based on the Blood Gas Analyser training records at hospital S1 Midwife M2 and Midwife M3 received training on the 19th November 2013; there is no indication that this is mandatory training requiring refresher training every 2 to 3 years. Staff receive an access code to use the machines once trained, evidence of this was provided to the Investigation Team.

The investigation believes that if staff are not frequently using the machines that it may prove challenging to maintain the appropriate competency level.

The Investigation Team identified that the local procedure for the operation of the Blood Gas Analyzer is for laboratory use only and does not contain a specific section for staff education and training.

The Investigation were provided with a Guideline titled "Fetal Blood Sampling by Obstetric Medical Team" dated May 2016.

Recommendation 12: (Hierarchy of Hazard Controls - Administrative Procedure)
Hospital S1 must have in place a guideline for the management of CORD AND MATERNAL BLOOD SAMPLING and deviations from practice must be reported and managed appropriately. All staff should perform these techniques in accordance with the Hospital Group Standard Infection Prevention guideline. The Acute Hospitals Division should ensure that this recommendation is circulated to all relevant hospital groups for implementation.

Incidental Finding 5: Absence of a Debrief for Staff

According to the staff involved in the resuscitation of Baby Aaron, Baby Aaron was born in unexpectedly poor condition. It is inconceivable to think that staff walked away after the resuscitation and were not affected, particularly as the resuscitation attempt was extremely difficult. Following the delivery of Baby Aaron a debriefing which is an essential component of resuscitation did not take place in either formal or informal manner. This would have provided an opportunity for all staff to share their thoughts on the events of the 4th May 2016, and capture additional valuable learning. Staff outlined at interview would have liked the opportunity to discuss the case and no counselling was offered nor did any staff request it.

Recommendation 13: *(Hierarchy of Hazard Controls - Administrative Procedure)*
Hospital S1 must ensure that 'Debriefing' following a neonatal resuscitation is in place and implemented. There must be a process in place to ensure that critical incident debriefing is made available to all staff involved (including porters where they were involved etc) within 72 hours of a critical incident and that there is a SOP in place to ensure the procurement and provision of same and a means to release all staff involved where at all possible. Lesser events may be dealt with by informal debriefing within unit level but again management of the Unit should have a SOP in place to ensure that this is routinely offered to all staff members involved irrespective of discipline / rank. Finally, the Hospital must ensure that it has in place, an Employee Assistance Programme whereby staff members can easily self-refer for free and confidential counselling on a 24/7/365 basis. The HSE HR (local, regional, national) should review the effectiveness of this programme and modify as required, This aspect is particularly important in that 2 of the staff members interviewed appear to have explained that they no longer work at this unit although the reasons why, do not appear to have been explored or noted as relevant to this Investigation.

Incidental Finding 7: Confusion with terminology

At a visit on the 15th April 2016, the use of the phrase "safe placenta" is an unclear statement. Possibly relates to location but if so, the location should be identified, this is not a usual phrase and could lead to confusion.

Incidental Finding 8: Telephone Log

On the 2nd May 2016, Mrs X stated she made contact with Hospital S1 regarding a mucous discharge following her discharge earlier that day. There was no available MW record of that call.

Recommendation 14: (Hierarchy of Hazard Controls - Administrative Procedure)
The Unit at S1 must have a policy for call taking. All calls should be logged and reviewed on an on-going basis by the shift leader so it is known who is expected in and to be able to go back and audit advice given. There should be an agreed SOP to guide and monitor this practice of advice.

Incidental Finding 9: Responses to Complaint/Concern

Staff member referred family to YSYS while Mrs X was an inpatient in hospital S1.

Whilst it is appropriate to advise patients and their families to use Your Service Your Say (YSYS), this should not preclude a staff member from LISTENING to that issue and following up on it internally also.

See Appendix N for Hospital S1 Response to all recommendations.

Addendum External Expert, Consultant Neonatologist – Clarification regarding National Incident Report forms and Oxygen supply. Date 15/03/20

The review team was requested in December 2019 to review a request raised by the family in relation to specific NIMS documentation. The 2 NIRF forms are NIMS record numbers 16238316 dated 04/05/16 and 16244639 dated 10/05/16. The specific concern was the reference on NIRF form 16244639 in relation to oxygen not being switched on. Briefing documents dated 11/08/16 and 18/08/16 also refer to these NIRF forms. These forms had not been provided to the review team previously.

Following this the review team requested the forms and all accompanying documentation. The review team further required and received written confirmation that the MRHP was not in possession of any other documents relevant to investigation NIMLT 51615 or the specific NIRF forms. I can confirm that the review team has received full written confirmation from MRHP that there are no outstanding documents.
The review team has reviewed all the documents, original chart records, the interviews with the staff present during the resuscitation, these interviews were conducted by the review team on 20/12/16 and 04/10/17.

The NIMS record number 16238316 report form initially completed makes no reference at all to any oxygen issue, this was completed 04/05/16.

The supplied incident ref 16238316 and the relevant claim abstract forms do not contain any reference to the verbal report of a potential issue around oxygen supply.

NIMS record number 16244639 completed on 10/05/16 makes reference to a verbal report by a staff member to senior midwifery management as does the attached incident abstract form ref 16244639.

Forms logged by QPS MRHP.

Both NIMS form 16238316 and NIMS form 16244639 were completed sometime after the resuscitation and the senior staff completing the forms had not been present for any part of the baby's resuscitation.
There are 2 dated incident briefings held ref 16238316 and 16244639/51615 on 11/08/16 and 18/08/16. These reports suggested the need for further investigation as agreed with the family and arising from same our NIMLT 51615 review team and the investigation were then commissioned by the CEO MRHP.

The review team conducted detailed interviews with staff on 20/12/16 and 04/10/17 having previously met the family. The Nurse P4 present at resuscitation referred to in form 16244639 was interviewed both on 20/12/16 and 04/10/17.

The stated objectives of the staff interviews held on 04/10/17.

1. To clarify what happened during the first 10 minutes of the baby's life, in relation to the heart rate, respiratory effort, oxygen saturations, colour, secretions, duration of IPPV, prior to commencing chest compressions. Initial pressure(s) used and what corrective steps (MRSOPA) were taken. Time of first and second intubation.

2. To present questions raised by the parents.

NIMLT 51615 15/03/20 Addendum to report

3. To give staff the opportunity to recall in their own words the event. To clarify their role, and actions they performed during the event and the baby's response to an intervention during the resuscitation.

4. AAP/AHA 6th edition guidelines for Neonatal resuscitation applied and were they implemented?

SN P4 was consistent in he/r interview record of 04/10/17 only that s/he increased the flow to 8-10 litres during the resuscitation, there was no record of the oxygen being switched off. This was further corroborated by P4 in her reply to our team of 21/11/19 when asked if the oxygen had been switched off, P4 stated specifically that s/he had no further addition on the subject to he/r interview statements of 20/12/16 and 04/10/17. SN P5 in he/r notes and at interview on 04/10/17 stated clearly that she had checked all the resuscitation equipment in OT prior to the birth and that the Neopuff device was fully working. SN P5 also stated that the flow checked by her was set initially at 5 litres/min and this corroborates with P4's statement that s/he increased flow to 8-10 litres/min after her arrival at 11 minutes. These 2 paediatric nurses P4 and P5 are consistent around these points and a full reading of all the staff interviews conducted by the review team found no evidence that the oxygen supply was switched off only that the flow was later increased by P4.

Therefore the review team having reviewed the newly supplied documentation and after consideration of the medical records and the comprehensive interview records of staff interviews already held are satisfied:

1. That the production of the above NIMS documents after the completion of the review has not altered the conclusions set out in our report on NIMLT 51615.
2. That the reference in NIRF form 16244639 to the oxygen supply or flow being switched off, we are now satisfied after careful review, that this suggestion has not been in any way substantiated and is therefore not correct.
3. That the review team had satisfactorily conducted a comprehensive investigation of all the aspects of the baby's resuscitation as stated above in the objectives set out prior to the interviews on 04/10/17.
4. This addendum is to be attached to the final report.

Yours sincerely,

Consultant Neonatologist/Paediatrician
IMC.

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Appendix A: 51449 Terms of Reference Version 1 and Version 2

Terms of Reference NIMLT 51615 Version 1 Introduction

These are the terms of reference for an investigation commissioned by the General Manager hospital S1 into the circumstances of the care, management and treatment of Mrs X and her new born baby at hospital S1. The investigation will consider the antenatal care provided to Mrs X, the circumstances of the birth of her baby, the care management and treatment of her baby, until the baby was transferred to the hospital S2 on the 4th of May 2016.

Purpose

The purpose of this investigation is to:

- Establish the factual circumstances of Mrs X's and her newborn baby's care, management and treatment during this timeframe
- Identify any incident that may have occurred during this timeframe
- Identify any key causal factors that may have occurred
- Identify the contributory factors that caused the key causal factors
- Recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably practicable.

Scope of the Investigation/Review

The time frame of this investigation/review will be the period from Mrs X's first Antenatal visit at hospital S1 on the 19th November 2015 to the 4th of May 2016.

The Investigation Team

The Members of the investigation are:

- Ms. D. O'Keeffe, General Manager for Quality and Safety Quality Improvement Division, Investigation Chairperson
- Dr. Francois Gardeil, External Consultant Obstetrician

In addition the investigation team will seek the opinion of a Consultant Neonatologist and Senior Midwife:

1. To answer specific clinical or technical questions and;
2. To validate that the final draft report prepared by the Investigation Team is clinically/technically accurate and addresses the clinical/technical issues highlighted appropriately.

Through the Investigation Commissioner the investigation team will:

- Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Investigation Team will convey the details of these safety concerns to the Commissioner, General Manager as soon as possible.

Investigation method

The investigation will follow a systems analysis methodology as per HSE Guidelines for the Systems Analysis of Incidents (2015) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures.

The investigation will commence on early September 2016 and will be expected to last for a period of approximately four months, provided unforeseen circumstance does not arise. Note: The HSE

Guideline for the Systems Analysis Investigation of Incidents (2015) indicates that the target for completion of an investigation report is 4 months or less, from the date the Terms of Reference is agreed.

Following completion of the investigation, an anonymised draft report will be prepared by the investigation team outlining the chronology, findings and recommendations. All who participated in the investigation will have an opportunity to give input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Investigator will ensure that the Investigation team apply a quality assurance process to ensure compliance of the investigation process with the systems analysis guidelines prior to the delivery of the final report to the Investigation Commissioner. The Investigation Commissioner will seek assurance that the quality assurance process has been completed.

The anonymised Report may be published. There is currently no specific legislation and common law dealing with the protection of individual data, confidential data, data disclosed on the basis of confidence etc and no guarantee can be given by the HSE that information received as part of an incident investigation will be protected from legal discovery or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Investigation Commissioner.

The Investigation Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred implement the recommendations of the investigation report.

The Investigation Commissioner is responsible for communicating nationally applicable recommendations to the relevant National Director(s) for national implementation.

Communication Strategy for the Investigation

A communication strategy will be determined and Ms. D. O'Keeffe General Manager for Quality and Safety Quality Improvement Division will be appointed by the hospital for the purpose of communicating information pertaining to the investigation to the family of Mrs X.

Reference:

– HSE Safety Incident Management Policy (2014 and any subsequent revisions)
- HSE Guideline for Systems Analysis Investigation of Incidents(2015)

Terms of Reference Version 2 (Amendment[42] 10 August 2017)
NIMLT 51615

Introduction

These are the terms of reference for an investigation commissioned by the General Manager in the Midland Regional Hospital at Hospital S1 into the circumstances of the care, management and treatment of Mrs X and her new born baby at Hospital S1. The investigation will consider the antenatal care provided to Mrs X, the circumstances of the birth of her baby, the care management and treatment of her baby, until the baby was transferred to the Hospital S2 Women and Infants University Hospital on the 4th of May 2016.

Purpose

The purpose of this investigation is to:

- Establish the factual circumstances of Mrs X's and her newborn baby's care, management and treatment during this timeframe
- Identify any incident that may have occurred during this timeframe
- Identify any key causal factors that may have occurred
- Identify the contributory factors that caused the key causal factors
- Recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably practicable.

Scope of the Investigation/Review

The time frame of this investigation/review will be the period from Mrs X's first Antenatal visit at Hospital S1 on the 19th November 2015 to the 9th of May 2016.

The Investigation Team

The Members of the investigation are:

- Ms. D. O'Keeffe, General Manager for Quality and Safety Quality Improvement Division, Investigation Chairperson
- Dr. Francois Gardeil, External Consultant Obstetrician

In addition the investigation team will seek the opinion of a Consultant Neonatologist, a Senior Midwife and Senior Neonatal Nurse:

1. To answer specific clinical or technical questions and;
2. To validate that the final draft report prepared by the Investigation Team is clinically/technically accurate and addresses the clinical/technical issues highlighted appropriately.

The nominated experts to the Investigation Team include:

1. External Expert Consultant Neonatologist and Paediatrician
2. External Expert, Clinical Midwife Manager
3. External Expert, Clinical Nurse Manager, Neonatal Unit and neonatal resuscitation facilitator

Through the Investigation Commissioner the investigation team will:

- Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.

- Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Investigation Team will convey the details of these safety concerns to the Commissioner, General Manager as soon as possible.

Investigation method

The investigation will follow a systems analysis methodology as per HSE Guidelines for the Systems Analysis of Incidents (2015) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures.

The investigation will commence on early September 2016 and will be expected to last for a period of approximately four months, provided unforeseen circumstance does not arise. Note: The HSE Guideline for the Systems Analysis Investigation of Incidents (2015) indicates that the target for completion of an investigation report is 4 months or less, from the date the Terms of Reference is agreed.

Following completion of the investigation, an anonymised draft report will be prepared by the investigation team outlining the chronology, findings and recommendations. All who participated in the investigation will have an opportunity to give input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Investigator will ensure that the Investigation team apply a quality assurance process to ensure compliance of the investigation process with the systems analysis guidelines prior to the delivery of the final report to the Investigation Commissioner. The Investigation Commissioner will seek assurance that the quality assurance process has been completed.

The anonymised Report may be published. There is currently no specific legislation and common law dealing with the protection of individual data, confidential data, data disclosed on the basis of confidence etc and no guarantee can be given by the HSE that information received as part of an incident investigation will be protected from legal discovery or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Investigation Commissioner.

The Investigation Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred implement the recommendations of the investigation report.

The Investigation Commissioner is responsible for communicating nationally applicable recommendations to the relevant National Director(s) for national implementation.

Communication Strategy for the Investigation

A communication strategy will be determined and Ms. D. O'Keeffe General Manager for Quality and Safety Quality Improvement Division will be appointed by the hospital for the purpose of communicating information pertaining to the investigation to the family of Mrs X.

Reference:

- HSE Safety Incident Management Policy (2014 and any subsequent revisions) HSE Guideline for Systems Analysis Investigation of Incidents (2015)

Appendix B: Report Dr. Francois Gardeil, Consultant Obstetrician and Gynaecologist, Wexford General Hospital, Wexford

HOSPITAL S1 REVIEW NIMLT 51615: Received 9th January 2018

This is a draft of the review of the case from a obstetrics perspective.

Ms X was a 29 year old first time mother who underwent delivery by emergency caesarean section at 01.30 hour on the 4th of May 2016 at hospital S1. A male infant weighing 2,255g was born in poor condition and required intensive resuscitation before transfer to tertiary referral hospital S2. Sadly, Baby Aaron passed away at 5 days of age on the 9th of May 2016.

Antenatal period:

1 **Maternal complications:**

Ms X was a healthy young woman. She had quit smoking when she became pregnant. The only risk factor was a BMI above 30.

The expected date of delivery from the date of the last period, confirmed by early scan was the 4th of June 2016.

On the 4th of February 16, at 22 weeks, Ms X was referred by her GP to hospital S1 because of palpitations and frequent episodes of breathlessness when walking. She was assessed by the obstetrics team and also by physicians. Blood tests were normal. An electrocardiogram, an echocardiogram and a 24-hour monitoring of the blood pressure were entirely normal.

On the 29th of February 16, at 26+ weeks, Ms X presented to hospital S1 with a complaint of spasmodic upper abdominal pains and vomiting. An abdominal ultrasound scan was performed on the 2nd of March, which revealed the presence of gallstones with possible cholecystitis. Ms X was reviewed by the surgical team. It was decided to manage her conservatively with anti-acid medications and a plan for review 6 months later as an outpatient was made. Symptoms settled and Ms X was discharged home on the 3rd of March with arrangements for review in the antenatal clinic on the 18th of March.

Ms X attended the clinic as planned on the 18th of March at 28+ weeks. She was chesty and had flu like symptoms. She was prescribed an antibiotic (Augmentin). Because Augmentin didn't agree with her, her GP subsequently prescribed Amoxycillin instead. A glucose tolerance test (GTT) performed on the 16th of March was normal, excluding gestational diabetes.

Ms X was reviewed in the antenatal clinic on the 1st of April and again on the 15th of April 16. On that date she complained of back pain radiating down both legs.

On Friday the 29th of April, at 35 weeks, Ms X complained of reduced fetal movements when seen in the clinic for a scheduled appointment. She said at interview that she had noticed her bump had increased in size suddenly at 34 weeks and felt rock-solid. The Braxton-Hicks contractions had also become more frequent and painful. A scan showed marked increase in the amniotic fluid volume and bilateral dilatation of the fetal kidneys. A request for urgent assessment in the feto-maternal unit of hospital S2 was faxed at 13.26 hour. In addition, on the 29th of April, for the first time in pregnancy, the presence of protein was detected in a sample of urine. Because of that, and despite a blood pressure within normal limits, PET bloods were sent as there was a suspicion of pre-eclampsia.

On Sunday the 1st of May 16, Ms X presented to hospital S1 at 11.55 hour feeling very unwell. She complained of abdominal discomfort and painful contractions. She was kept for observation and discharged home the following day, bank holiday Monday the 2nd of May.

Ms X presented to the Maternity Admission Unit in hospital S1 at 12.30 hour on Tuesday the 3rd of May. She had woken up at 02.45 hour that day with severe pains. She was admitted to the ward and administered the first dose of steroids at 15.00 hour.

What happened subsequent to that last admission will be discussed under 'peripartum events'

2 **Fetal complications:**

There is, as always, overlap between maternal and fetal complications during pregnancy.

Mrs X and her baby were monitored closely during the pregnancy with a total of 8 visits to hospital S1 antenatal clinic, 2 visits to consultant A private rooms and at least 4 visits with the GP. Outpatient scanning was performed at 6 of the antenatal visits and twice in the private rooms; at 10+ weeks for dating and at 25 weeks on the 20th of February 16 as an anomaly scan, which included 3D imaging.

The first anomaly noted on scan was on the 18th of March when consultant A noted a slight dilatation of the pelvis of the right kidney with a full fetal bladder and normal amniotic fluid volume. The same findings were noted at 33 weeks, on the 15th of April.

On Friday the 29th of April 16, a scan done in the clinic showed marked polyhydramnios with an AFI of 48. The same day an urgent referral to the scan department at hospital S2 for a second opinion was faxed.

Ms X had 2 scans while an in-patient. On the 1st of May, Doppler studies of the umbilical artery were performed and were normal. On the 2nd of May, consultant B performed another scan. In addition to the previously noted dilated pelvis of the right kidney, a short femur and echogenic bowels were noted. These findings can be associated with fetal abnormality.

Peripartum period:

This can be considered to have started at 12.30 hour on the 3rd of May 2016. Ms X was having pains at 35 weeks and 3 days and presented to the Maternity Assessment Unit. A CTG was commenced and discontinued at 14.30 hour. Vital signs were checked at 12.35 hour and recorded on an Irish Maternity Early Warning System (IMEWS). The diastolic blood pressure was 92mm Hg, which constitutes a yellow trigger. Blood pressure measurement should have been repeated within an hour but it was not rechecked until 15.00 hour: again a yellow trigger because of a diastolic pressure of 91 mm Hg was not escalated. A midwife's entry in the notes timed 22.10 hour indicated that vital signs were normal (IMEWS=0) but the values of the vital signs checked are not documented.

At 22.10 hour the midwife noted that Ms X was using a TENS machine for pain relief and didn't appear to be distressed. However, Ms X was concerned that her baby was not moving. She was transferred to the labour ward at 22.40 hour for monitoring. Blood pressure was elevated at 145/101 mm Hg. There were 2 triggers, 1 yellow and 1 pink and although the blood pressure rechecked at 22.50 hour was normal at 125/76 mm Hg, an appropriate request for review by the on-call Obstetric team was made. Ms X returned to the antenatal ward at approximately 22.55 hour, after medical review. At 23.10 hour Ms X called the bell and informed a midwife that her waters had broken while going to the toilets. Meconium grade 1 was noted and Ms X was transferred again to the labour ward in a timely fashion.

A CTG was commenced but, although the maternal pulse was high at 102 bpm, the maternal temperature was not recorded. No examination, abdominal and/or vaginal is documented. Intravenous access with insertion of a cannula was not performed. The obstetric registrar on-call was informed at 23.39 hour and reviewed Ms X at 12 midnight. A vaginal examination revealed that the cervix had started to shorten and was 1 cm dilated. The registrar informed Consultant A who advised that a repeat vaginal examination should be performed 2 hours later and advised that the neonatal unit staff should

be informed.

On the 4th of May, at 00.15 hour, a midwife noted that the fetal heart rate had become abnormal with 2 marked decelerations. The obstetric registrar was informed and reviewed Ms X at 00.20 hour. The registrar noted the earlier decelerations and also noted that there was decreased variability and absence of accelerations. A vaginal examination revealed that the cervix was still 1 cm dilated. The registrar instructed that a cannula for intravenous access should be inserted and blood sample taken in anticipation of a delivery by emergency caesarean section. Consultant A was informed over the phone and advised to continue close monitoring.

At 01.00 hour, the registrar was called by a midwife because of further fetal heart rate abnormalities. The decision was made to deliver baby by caesarean section and preparation for same were started. It appears intravenous access and taking of blood samples had been initiated at 00.20 hour. Ms X was transferred to a portable monitor at 01.03 hour and administered antiacid medications at 01.05 hour. Consultant A was present in the labour ward at 01.10 hour.

A spinal anaesthesia was given at 01.20 hour and Baby Aaron was born at 01.30 hour, 30 min after the decision to deliver. Pediatric SHO and registrar were in theatre at the time of delivery. The paediatric consultant on-call arrived at 01.45 hours.

Baby Aaron was born with a heart rate below 60 bpm and no respiratory effort. Apgar scores were 2 at 1 minute, 2 at 5 minutes and 3 at 10 minutes.

Cord bloods from umbilical arteries and vein were obtained in theatre. The first 2 arterial samples clotted and had to be repeated. The venous sample was analysed at 02.06 hour with a Rapidsystem machine ID 1240-18225. The pH was 7.336 with a base excess of – 1.3 mmol/L. The arterial sample was not analyzed until 03.12 hour, by the same midwife, using a different machine, Rapidsystem ID 1240-18080.

OPINION

1. **The CTG's:**
   There was no CTG performed when Ms X was admitted at 26+ weeks on the 29th of February 2016. On the 3rd of May 16, a CTG was commenced at 12.34 hour and continued until 14.30 hour. It was signed off by a midwife as normal and reviewed by the obstetric registrar who noted it was 'satisfactory overall'.

   A repeat CTG was performed on the same day because Ms X complained of absent fetal movements; this CTG, commenced at 22.30 hour and continued until 22.55 hour was reviewed by the obstetric registrar and noted to be satisfactory.

   The CTG was commenced again at 23.15 hour, following spontaneous rupture of the membranes. There were periods of loss of contact from 23.30 hour to 23.42 hour approximately, probably due to the fact that Ms X was standing out of bed at the time. The CTG was essentially normal until a bradycardia occurred at 00.14 hour on the 4th of May, lasting for 6 minutes. A further prolonged bradycardia occurred at 00.56 hour, prompting the decision to perform an emergency caesarean section. Transfer to a transport CTG machine took place at 01.03 hour. The transfer CTG is difficult to interpret due to loss of contact. The fetal heart rate was around 140 bpm a few minutes before the knife to skin recorded time of 01.28 hour.

   The review team believe that the decision to deliver Baby Aaron by caesarean section should have been made before 01.00 hour. The CTG became abnormal at 00.14 hour with a prolonged bradycardia. Although the fetal heart rate recovered to a normal baseline at 00.20 hour, this was concerning in the context of a high-risk pregnancy and the presence of meconium. Passage of meconium pre-term is more significant and more suggestive of fetal compromise than it is at term or post dates.

In addition and importantly, blood samples that had been obtained in the antenatal clinic on the 29th of April showed abnormal liver function with AST of 119 and ALT of 294 U/L respectively. Whatever the cause of abnormal liver function in pregnancy is, it is associated with poor outcome. The blood results were signed off and ticked 'abnormal' by a doctor but this additional risk factor doesn't seem to have been taken into account by caregivers in the peripartum period. Given that Ms X was not in established labour there was no possibility of performing fetal blood sampling to out rule hypoxia. If the decision to deliver Baby Aaron had been made at around 00.20 hour, he would probably have been born before 01.00 hour.

All CTG's performed before the 4th of May were reassuring. The review team contend that the fetal heart rate was appropriately monitored at all times. In particular, there was no indication to perform a repeat CTG on the 3rd of May until Ms X voiced her concerns about lack of fetal movements.

1 **Cord blood gases:**

It is best practice that paired (arterial and venous) cord samples should be obtained immediately after delivery and processed without delay using the same machine. In this case, the venous sample was analyzed 36 minutes after delivery. The arterial samples are more difficult to obtain than the venous ones. The first 2 arterial blood samples clotted. A third sample was obtained and analyzed 1 hour and 42 minutes after delivery. The midwife operator stated at interview that she could not recall a significant delay in processing the arterial sample.

The values of blood gases were normal and comparisons between venous and arterial values make sense. Delay with analysis leads to a decrease in pH values and, therefore, it is probable the pH's would have been slightly higher if the samples had been analysed without delay.

Normal values of cord blood gases are believed to exclude oxygen deprivation in labour. It is, however, possible that Baby Aaron suffered from a lack of oxygen at some stage during the pregnancy.

If the cord gases results can be relied upon, the delay in delivering Baby Aaron is extremely unlikely to have caused his hypoxic encephalopathy and ultimate death. There is a need, however to establish, with the help of the bioengineering staff, the calibration history of the machines and explore the possibility that time was wrongly set up on the machine used to analyse the arterial sample.

2 Neonatal resuscitation:

A paediatrician/ neonatologist and a neonatal resuscitation Nurse Specialist are reviewing the initial resuscitation process in hospital S1 and subsequent care of Baby Aaron in hospital S2 before death at the age of 5 days.

There is limited midwifery documentation of the initial resuscitation and no midwifery input in Baby Aaron's records. Overall, however, the midwifery and obstetric documentation of care was very good with contemporaneous, narrative entries individualised, descriptive and unambiguous.

3 Care given to Ms X:

The IMEWS was not escalated in line with best practice. Because of 1 yellow trigger recorded at
12.35 hour on the 3rd of May a full set of observations should have been repeated after 30 and before 60 minutes. Although a midwife documented 'IMEWS=0' at 22.10 hour, the actual figures for the vital signs are not documented. The 2 IMEWS triggers found at 22.40 hour were appropriately escalated.

Following spontaneous rupture of the membranes at 23.10 hour on the 3rd of May, it is the

opinion of the review team that the attending midwife should have performed abdominal and vaginal examinations to rule out the possibility of cord prolapse which is more likely to happen in cases of polyhydramnios. It would also have been prudent to establish venous access and take blood samples given the high-risk situation. Cannulation was not performed until 00.20 hour on the 4th of May.

KEY CAUSAL FACTOR(S)

Key causal factors are defined as issues that arise during the process of delivering and managing health services that are considered by the investigation team to have had an effect on the eventual adverse outcome. The adverse outcome in this case is the death of Baby Aaron at the age of 5 days.

Baby Aaron died as a result of severe hypoxic ischemic encephalopathy. It is unclear at this stage of the review when and why the brain injury happened. The autopsy report may help to find an underlying anomaly that led to complications in pregnancy and the poor condition of Baby Aaron in the neonatal period.

Ms X and her husband believe the cause of death can only be established by the Coroner. They want the investigation team to focus solely on possible concerns regarding the management of Ms X and her unborn baby during pregnancy and resuscitation process in hospital S1.

Important issues include the timing of Baby Aaron's delivery and the place of his birth.

Timing of delivery:

Despite the complications that arose in late pregnancy the investigation team contend that there was no reason to deliver Baby Aaron before the 4th of May 2016. On that day, however, the team contend that a decision to proceed to an emergency caesarean section should have been made around 00.20 hour rather than 40 minutes later at 01.00 hours, due to fetal heart rate abnormalities and the presence of meconium in the context of a high-risk pregnancy. There was delayed recognition of a pathological CTG.

The cord bloods gases obtained after delivery indicates that Baby Aaron didn't suffer from oxygen deprivation in the hours before his birth. It is, however, crucial to establish the servicing/calibration history of the machines used for analysis in this case and also explore the possibility that timing of the machine used for the arterial sample may have been incorrect.

Although Baby Aaron had very low Apgar scores, which is unusual with normal cord blood gases results, it is likely that severe oxygen deprivation occurred after delivery due to impossibility to deliver oxygen effectively through the lungs during the resuscitation process.

It is impossible to know what the outcome would have been if Baby Aaron had been delivered soon after the first abnormalities were noted on the CTG. It is, however, not possible to say that delayed recognition of a pathological CTG is a Key Causal Factor in this case given the apparently normal pH values.

Place of delivery:

The first abnormal finding on scan was made at 28 weeks and 6 days, on the 18th of March 2016. Consultant A noted a slight dilatation of the pelvis of the right kidney with a full bladder and normal amniotic fluid volume that would indicate normal fetal renal function. The same findings were noted, again by consultant A, on the 15th of April at 33 weeks. Mild renal dilatation is a relatively common finding and doesn't, in the absence of other abnormalities, warrant referral to a feto-maternal medicine specialist.

The decision to refer Ms X to the scan department of hospital S2 for a second opinion was made on Friday, bank holiday, the 29th of April 2016, due to marked polyhydramnios and other new features on

scan that included a short femur and echogenic bowel. This referral for a second opinion was appropriate. New scan findings were concerning.

Ms X and her husband believe pregnancy care should have been transferred to hospital S2. Ms X expressed regrets she did not present herself to hospital S2 over the bank holiday weekend. She believes she was not told her pregnancy had become high- risk with fetal complications to be expected.

It is impossible to know what the outcome would have been if Baby Aaron had been delivered in hospital S2. It is, however, extremely unlikely that a decision would have been made to deliver Baby Aaron prematurely before the 4th of May, because of reassuring CTGs.

Neonatologist and specialist neonatal resuscitation nurse will provide an opinion regarding the conduct of initial resuscitation in hospital S1. They have been asked whether, in their opinion, the outcome could have been different if delivery had taken place in a tertiary referral hospital.

In summary, from an obstetrical and midwifery perspective no clear Key Causal Factor has been identified. Care Delivery Issues have been identified.

CARE DELIVERY ISSUES

- Non adherence to IMEWS escalation pathway
- Delayed recognition of abnormal CTG
- Incomplete documentation
- Apparent overlooking of an abnormal blood test result
- Delay in intravenous cannulation
- Incomplete clinical assessment
- Confusion regarding processing of cord bloods

All the above to be detailed in report and recommendations to be made.

Appendix C: Report External Expert, Consultant Neonatologist (Part 1)

Report on Baby Aarons care while in Hospital S1

04/02/18
Department of Paediatrics and Newborn Medicine
External Paediatric Dept.
Tel: +353 XXXXXX: Fax. : +353 XXXXXXX

Interim Expert report on NIMLT 51615

Baby Aaron
Date of Birth 04/05/16
Date of Death 09/05/16

Dear Ms O'Keeffe,

I am writing this medical report on the neonatology care provided to Baby Aaron , infant of Mrs X born at Hospital S1, on 04/05/16 who died at Hospital S2 Dublin on 09/05/16 some days following his transfer there for further care on day 1 of life 04/05/16. This report is based on the medical notes provided to me which include the Maternal Chart of Mrs X, the infant notes of baby Aaron from Hospital S1, I also requested a copy of the infant chart for Aaron from the Hospital S2 as a substantial amount of intensive care was subsequently received there prior to his death. The focus of this review by the team originally was to review the total care provided to Mrs X and her son Aaron at Hospital S1, I had requested the scope of the review be broadened to include the care at Hospital S2 as it might provide information relevant to his illness and treatment at Hospital S1 so as to enhance any findings or recommendations. The members of the review group also had access to direct interviews with the family and staff involved with the exception of the Paediatric registrar on duty at the time of birth. Some staff interviews had pre-dated my involvement in this review and because of this a repeat set of staff interviews were necessitated to address questions on neonatal care as no paediatrician/neonatologist expert was present for the first set of staff interviews. I have also requested a copy of the post-mortem from the Dublin City Coroner's office and her office has agreed to issue me the final copy when available. I would like to note that my report is therefore limited by these two factors (lack of the post-mortem report and no interview with the paediatric registrar involved) and I do not recommend that any final report be issued by the review group without access at least to the post-mortem report for Baby Aaron. This report is therefore an interim report on my part.

I will list my chronology of events and include my commentary with a final summary based on the medical notes and the interviews held. Reference will be made to the maternal chart (M) and the baby notes (B) from Hospital S1.

Maternal Care prior to birth where relevant.

29/04/16 13.26 hrs p24-5 (M). External referral form and copy of fax sent to Hospital S2 from Antenatal Clinic on 29/04/16 at 13,26 hrs. This refers to bilateral renal hydronephrosis and query polcystic kidney. This request is also referred on p 108(M) in that a second opinion had been requested from the Hospital S2.

29/04/16 p 42 (M). Antenatal visit record of consultation and that urgent referral had been sent to the Hospital S2 on that day.

13.30 hrs 03/05/16 p114 (M) records admission note for Mrs X as self referral from home at 35 5/7 gestation EDD 04/06/16 and the Obstetric Doctor's assessment at the time. Polyhydramnios was noted, she was deemed not in labour at present and admitted for observation. Betamethasone second dose is recorded as being administered lower on same page at 16.00 hrs.

04/05/16 p 266(M). Laboratory report 04/05/16 00.49 hrs : maternal blood group was O Rhesus positive, antibody screen negative.

04/05/16 00.56 hrs p 122 (M) records progress to date in labour and that meconium stained liquor was noted.

00.58 hrs 04/05/16 Same page records a decision to proceed to LSCS in note and that Theatre, Dr I, nursing administration and SCBU (Special care baby unit) were informed of the possible impending delivery by LSCS.

01.10 hrs 04/05/16 p 123 (M) Consultant Obstetrician A attended and agreed with the plan by Obstetric Registrar for LSCS. Decision to proceed with LSCS at this time.

01.17 hrs 04/05/16 p123-124(M) Mrs X's arrival in OT and spinal in situ

01.20 hrs, knife to skin at 01.28 hrs and delivery of the baby at 01.30 hrs. Note (by MW notes that baby was flat at birth, that the paediatric SHO and paediatric registrar were present in the theatre at the time. Heart rate recorded as "less than 60" beats per minute by the SHO. PPV given by, (midwife who completed this note) and that she performed 1 round of chest compressions after she had been instructed to perform same by the paediatric registrar. She records that urgent call sent to Consultant Paediatrician to attend. Resuscitation continues and Consultant Paediatrician arrives at 01.45 hrs

04/05/16 p 171(M) note at 02.30 hrs records grade 1 staining of liquor, normal placental appearance with 3 cord vessels seen.

04/05/16 p 192 (M) I cannot read time of entry. Caesarean Section operation form completed by the operating obstetric Registrar records indication for LSCS was abnormal CTG and unprovoked prolonged decelerations. Baby was preterm 35+3 days gestation, cord (loose) around the neck and that there was evidence of meconium in the cord. Blood loss estimated at 600 mls. Of note the first 2 cord samples (arterial) were clotted in the arterial blood gas section of the operator form , (umbilical) venous pH was
7.336 with Base excess of _1.3, no (umbilical) arterial recorded at this point.

04/05/16 P 43 (B) and P 192(M) I am somewhat concerned at the discrepancy between the venous report (02.06 hrs) arterial blood gas (03.12 hrs) report times, this represents a difference of well over 1 hour, specimens processed by Nurse. This taken with the operating surgeon's note which stated the first 2 (arterial ?) samples were clotted, I am prepared to take the venous gas as definite (written by the surgeon/obstetrician into the operation form at the time) but I am unsure about reliability of the umbilical arterial sample because of the serious delay in processing same. The umbilical venous sample was normal. I have reviewed the S.O.P (standard operating procedures) in place for cord gas analysis at institutions where I have worked and the evidence-based literature in

relation to cord gas sampling and the timing of processing. Most SOPs recommend a delay of no more than 30 minutes to processing such samples and I have concluded that the delay in arterial cord pH sampling in this case is unacceptable and therefore no credence should be given to this arterial sample. There is a delay of over 1 hour 40 minutes recorded from baby's birth to the results being obtained . *Reference Arch Dis Child 2006 A Lynn, P Beeby. Cord and placental arterial gas analysis: the accuracy of delayed sampling. F 281-285*

04/05/16 p 193(M) further note on this page by the operating surgeon that presentation was cephalic, cord around the neck X 1 loose, meconium grade 1 (liquor) noted on the baby and the umbilical cord. Flat baby given to Paeds (team).

04/05/16 P188-9(M). Peri-operative nursing care record was completed. This describes that every step in process of baby's care was explained to baby's parents at the time.

04/05/16 p 2-3 (M) Midwife records birth notification, birth weight 2.255 kg, Apgar scores were 2 at 1 minute, 2 at 5 minutes, 3 at 10 minutes and that baby was transferred to the Hospital S2 on ventilation.

04/05/16 P 195(M) 04.15 hrs Maternal notes Midwife records that the baby will be transferred to the Hospital S2. 6.00 hrs Mrs X is recorded as visiting the SCBU to see Aaron.

04/05/16 p 208 (M) and P 19 (B).. Neonatal record sheet copy records time of birth as 01.30 hrs, time of intubation as 01.51 hrs, that baby received mask and PPV, intubation, suction under direct vision and chest compressions. Umbilical cord gases, no time given, record arterial as pH 7.25 BE -6.0, venous pH 7.336 BE -1.3. Curosurf (surfactant) also recorded as being given after the resuscitation. Breakdown of Apgar scoring reveals scores 1 for heart rate and colour at 1 minute, unchanged at 5 minutes, at 10 minutes now scores 2 for heart rate and 1 for colour, total Apgar score = 3.

06/05/16 p 267 (M) Laboratory report of high vaginal swab sent 03/05/16 - reported and signed by staff 06/05/16 normal flora.

23/05/16 p 207 (M) GP letter refers to Baby Aaron's death and ? pul hypoplasia as a possible cause.

16/06/16 11.15 hrs p 304-310 Records a meeting between Consultant Obstetrician A and Mrs X with her sister with a detailed discussion of Mrs X's antenatal, intrapartum and postnatal care.

22/06/16 p 291 (M) discharge letter states that baby Aaron died in Hospital S3 (incorrect, he died in Hospital S2) this also refers to pulmonary hypoplasia.
Paediatric section

Aaron's birth weight recorded at time of birth 2.25 kg (9^{th} to 25^{th} centile).
Head circumference recorded as 35 cms (91^{st} to 98^{th} centile)

04/05/16 01.30 07.00 hrs p41-2 (B). records those at the resuscitation. Paed Reg, Paeds SHO and Nurse were present in OT at the time of birth at 01.30 hrs. maternal details, gestation of infant, antenatal scans showed renal dilatation, echogenic bowel and polyhydramnios. Emergency LSCS for fetal distress and decelerations. No

respiratory effort at birth. "Flat at birth", she records resuscitation from this point. Further clarification at interview, her recollections agreed with the notes

04/05/16 p 12-3. (B) Transfer letter and interview. Paeds SHO records details at birth, no respiratory effort, he recorded heart rate as less than 60 BPM (at interview he could not recall an exact figure for HR but definitely less than 60 beats per minute). IPPV commenced and due to low heart rate chest compressions were commenced. He records there were 2 intubation attempts but there were large volumes of secretions (no times for the intubation attempts given in the letter). At interview Paeds SHO did remember that the first intubation attempt as being approximately at 3 minutes of life, not sure of timing of second attempt.

04/05/16 P 123-4. (M) Midwife records time of birth as 01.30 hrs and that she performed chest compressions, one round of same at the request of the Paediatric registrar. She confirms that Consultant Paed had arrived at 01.45 hrs. At interview she recalled that the paediatric SHO assessed heart rate as less than 60 BPM initially but she had little role after the first round of CPR.

04/05/16 04.06hrs P 35(B). Paediatric registrar note. Paed Reg notes no respiratory effort/poor tone in baby and heart rate less than 60 beats/minute. He also records IPPV and chest compressions continued over a 10 minute period until heart rate over 100 beats/minute. This notes records 2 intubation attempts but CO2 detectors (should change if successful) did not change so tubes removed during this period of life (first 10 minutes) but no specific times recorded for the attempts.

O4/05/16 P 41 (B) 01.20 hrs Staff Nurse records IPPV continued from age 10 minutes until Dr T arrived at 01.45.

04/05/16 04.19 hrs P37-40 (B) Consultant Paed records being called urgently at 01.34 hrs and arriving at 01.45 hrs at age 15 minutes of life. He assigns an Apgar score of 3 at this time, he confirms that heart rate on his arrival was 128 beats/minute.

04/05/16 P 41(B) Staff nurse records arrival of three staff "shortly" but no times given. Staff nurse at interview stated that she arrived at approximately 11 minutes of age, then the registrar, SHO and Nurse were actively resuscitating the infant, a second intubation attempt was in progress, SHO was doing chest compressions, she said that the oxygen saturations were not recording.

Nurse changed the face mask and increased the flow on the blender. She also took over chest compressions and noted an increase in heart rate at this point. At interview the other persons interviewed and their notes suggested that the heart rate was above 100 beats/minute by 10 minutes so there is a question/discrepancy as to the exact times mentioned between her and the other staff present. It appears that she asked another member of nursing staff to scribe the interventions from this point.

04/05/16 01.45 hrs p 37-9. Consultant Paed notes that on his arrival at 01.45 hrs he assessed baby as heart rate 128/minute, colour was pale /cyanosed, no respiratory effort, hypotonic, no grimace (response), he assigned Apgar score of 3. He appears to have given (continued) the Positive Pressure Ventilation initially with a mask, adjusted jaw position (MR SOPA adjustments as per NRP), oxygen saturations were 50% per his note, he increased the Peak Inspiratory Pressure (on the nNeopuff), he then intubated with a size 3.0 ETT.

04/05/16 01.45 hrs P 41(B) and P 66(B) Intravenous fluids chart. Nurse also records a bolus of normal saline (10 mls/kg) being given at this time, a second bolus of 10 mls/kg normal saline at 01.54 hrs. Bolus of IV dextrose 10% 6 mls given also to avoid hypoglycaemia during resuscitation.

04/05/16 01.51 P 41-2. (B) Consultant Paed is recorded as intubating the infant at 01.51 hrs by Nurse. Surfactant first dose given at 02.16 hrs in this note. She records blood glucose as 3.8 mmol/L, infant temperature at 02.15 hrs as 36.8 degrees, increasing to 37.4 degrees at 01.34 hrs so hypothermia was avoided.

04/05/16 02.45 hrs P 41 (B) Baby transferred to SCBU. See record sheet SCBU P 52 (B) admission vital signs : heart rate 150 beats/minute, Blood pressure 80/40 mean 53 mmHg, blood glucose 3,8 mmol/L, very abnormal oxygen saturations of preductal 75%, post ductal 71%. Ventilation settings were PIP 36, PEEP 4, set rate 50 BPM, FiO2 100%. First blood gas which was taken at 02.26 hrs showed pH 6.67 pCO2 17.33 kPa PO2 2.5kPa. This showed significant respiratory failure and a respiratory acidosis. The above recorded low oxygen saturations despite ventilatory support and 100% inspired oxygen concentration at the time of are consistent with a critically ill infant with likely persistent pulmonary hypertension of the newborn (PPHN).

04/05/16 02.48 hrs P 87 (B) c. Chest Xray shows ETT and NG in good position. Lungs appear clear. No significant lung abnormality identified eg pneumothorax or meconium aspiration seen. It is important to realise that PPHN does not require an abnormal chest Xray to occur, changes in lung and vasculature are found at histological level by the pathologist.

04/05/16 03.52 hrs P 53 (B) and P 65(B) 22 mls emergency blood recorded as being administered IV.

04/05/16 03.52-04.52 hrs P 72 (B). Blood was infused over 60 minutes, observations were recorded
04/05/16 03.30 hrs P 42 (B). Second dose of surfactant given

04/05/16 03.34 hrs P 42-3 (B). Second blood gas taken reported at 03.38 hrs pH 6.98 PCO2 12.02 kPa pO2 3.5 kPa Base excess -10 mmol/L. result consistent with respiratory failure but improved. 04/05/16 P 52 (B) Following this gas ventilation settings were adjusted and at 04.30 hrs the ventilator set rate was 60 BPM (the sheet does not state time after gas result that this change was made, I note nursing records are taken at 30 minute intervals at this point.) P 38 (B) Consultant Paed's note refers to an increased rate of 60 BPM but does not state the time this change was made after the second gas. This second gas on the baby suggests that adequate ventilation was being achieved (lower PCO2) but the predominant feature is continuing hypoxia (low pO2) secondary to PPHN.

04/05/16 02.30 hrs P 8-11 Transport team records time of referral to the transport team as 02.30 hrs and that this was the same time 02.30 that a decision for transfer to Hospital S2 was made. I have checked full transport records in Hospital S2 Chart and the transport team were activated at 02.40 hrs, arriving at Hospital S1 at 04.00 hrs on

04/05/16, this would be a reasonable response time.

Transport records agree with the record sheets on P 10 (B) and P 52 (B). baby was on ventilation PIP 36 PEEP 4-5, set rate 60 BPM, FiO2 100%, blood pressure 76/49 mean BP 52 mmHg, preductal oxygen saturations were 77% post ductal 74 %.

04/05/16 04.06 hrs p 42 (B) Nurse records arrival of transport team and that they then inserted an umbilical venous line. Transport team start preparing baby for transport to Hospital S2. Spontaneous movements by the baby noted at this time.

04/05/16 06.00 hrs P 52 (B) and P 43 (B) no change in ventilation settings recorded, blood gas from 05.45 shows some improvement pH 7.135 PCO2 9.9 kPa PO2 2.6 kPa Base excess – 4.0 Bicarb 25.0. Oxygen saturations recorded as 83% preductal and 77 % post ductal, a reasonable improvement from the initial baseline readings but still very abnormal and indicative of severe PPHN. It is difficult to calculate n Oxygenation Index precisely given that the infant gases were capillary but looking at his oxygen saturations and blood gases

04/05/16 03.30 hrs P 59 (B). first doses of penicillin and gentamycin were given IV.

04/05/16 06.00 hrs P 57 (B). Baby had received a bolus of morphine 100 mcg/kg IV and a dose of IM Vitamin K is noted as being administered at 05.00 hrs

04/05/16 06.30 hrs the last set of in-house observations prior to transport the Hospital S2 show:

Oxygen saturations were now 90%, ventilation settings were unchanged, blood pressure was 59/35 mean BP 42 mmHg (adequate). Capillary refill 3-4 seconds, and the baby was then transported to Hospital S2 at 06.45 hrs, arriving in receiving unit at 08.00 hrs on 04/05/16 hrs.

Radiographs/Imaging

O4/05/16 02.48 hrs P87 (B) (c) and P 87(B) (a) I note that first radiograph of chest a 02.48 hrs ETT in good position, lungs clear but an intervening CXR at 03.44 hrs showed ETT was too low and this was repositioned successfully, see below.

04/05/16 06.05 hrs P 86 (B) (b) Radiograph post insertion of UVC taken at 06.05 hrs showed ETT in Good position.

Laboratory results.

P 81 (B) a Full blood count 04/05/16 03.53 hrs shows a satisfactory Hemoglobin 22.1 g/dl, raised white cell count of 53.23 Lymphocytes 23.0, raised neutrophils 26.1 (these are consistent with birth, illness/stress from resuscitation or infection). Platelets 144 normal.
P 81 (B) b Blood group O rhesus positive

P 80 (B) b Urea and electrolyte result 04/05/16 04.09 hrs showed raised potassium of 6.5 mmol/L other electrolytes sodium 135.9mmol/L, Chloride 102 mmol/L, Urea 4.8 mmol/L, CRP 0.30 mg/L were normal. The potassium level is possibly sampling related.

P 80 (B) a Blood culture report no growth

P18-20 (B) Chromosome results on Baby, Clinical Genetics normal array CGH result reported 24/05/16

Summary

Baby Aaron was born by Emergency LSCSat 01.30 hrs on 04/05/16. He was resuscitated by the in-house team and the Consultant Paediatrician was urgently called to assist, arriving from home at 01.45 hrs.

My clinical opinion of his care taking into account his parents' questions is as follows.

1. Aaron was born at 35 3/7 weeks completed gestation by LSCS. Hospital S1 is a Level 1 unit and does deliver and care for babies from 32 weeks gestation. I understand in the opinion of Consultant Obstetrician that this pregnancy was not deemed high risk but a referral to Fetal Medicine had been made on 29/04/16 because of concerns on the antenatal ultrasounds and polyhydramnios. I will defer to my Obstetric colleagues but understand that no high-risk diagnosis was made prior to his birth by Mrs X's Consultant Obstetrician. Mrs X subsequently presented to Hospital S1 on 03/05/16 and went into labour prior to any imaging/assessment appointment at the Hospital S2.
2. A decision was made to proceed to LSCS at 01.10 hrs on 04/05/16 and the appropriate staff were alerted. Paediatric team was present for the delivery.
3. The umbilical cord venous sample was normal, I am concerned at the over 1 hour discrepancy between timing of the venous result mentioned by the operating obstetrician/surgeon and the later arterial blood gas result. I recommend that we accept the venous but not the arterial unless a satisfactory explanation is found.
4. While there is less documentation in both maternal and infant notes on the first 10 minutes of resuscitation, taking the information recorded in the notes and in the interviews the review team conducted with the staff present for the resuscitation it does appear that the NRP guidelines were followed in the first 10 minutes. It would have been better to have had a scribe taking details from birth of the baby, according to interviews this commenced from 10-11 minutes of age. I note that the paediatric registrar on duty was not interviewed by the review team and was not contactable.
5. The initial steps were appropriate in resuscitation; there was an initial heart rate. PPV was provided with mask/Neopuff and the improvement in the heart rate at 10 minutes suggested the PPV and chest compressions must have been somewhat effective during this period. The undetectable oxygen saturations levels with pulse oximeter noted at 10 minutes suggested a severely compromised infant with respiratory failure at that point however.
6. The 2 failed intubation attempts during this resuscitation occur in the context of continued PPV and chest compressions being provided by the team. In the 6Th Edition of the NRP it is recognised that intubations are not always successful and the recommendation is to avoid prolonged intubation attempts (with worsening hypoxia) but that the team should provide PPV with Neopuff and mask if unsuccessful intubation. The staff interviewed did not mention MR SOPA strategies to optimise the mask/Neopuff ventilation, but the paediatric SHO and the Neonatal Nurse present from the birth at interview stated that the NRP was followed but this was not documented by them in the notes in the first 10 minutes but is recorded for later during the resuscitation. This is an area an interview by

the review team with the paediatric registrar on duty would assist greatly. Consultant Paediatrician notes that he made certain adjustments to PPV/Neopuff on his arrival (in line with MR SOPA). In the absence of this, I conclude that the PPV was reasonably effective within the first 10 minutes but clearly an earlier successful intubation would have been better for baby. Subsequent intubation by the consultant at
01.51 hrs did produce a faster improvement than with the PPV/Neopuff according to the records/interviews.

7. Subsequent resuscitation post intubation. I believe that this was appropriate and that care steps were escalated as per NRP from this point and documented in the notes.
8. Decision to request transfer, seek Consultant Neonatologist advice and access the NNTP was made at 02.30 hrs and these decisions were timely and appropriate in my opinion. The mobilisation and response times of the transport team were prompt and acceptable.
9. The SCBU care including monitoring, blood sampling, ventilation, intravascular fluid boluses and imaging were satisfactory and baby's condition was correctly identified as needing tertiary level neonatal care from time of admission to SCBU in Hospital S1. The steps taken by the Hospital S1 team in SCBU produced sufficient improvement in Baby's clinical state to enable his transfer to the HOSPITAL S2 later that morning. Certain modalities of treatment eg Nitric Oxide, HFOV would not be available within a Level 1 unit and the care provided on 04/05/16 was appropriate for this level of unit's expertise, equipment and staffing.
10. At the time of writing I cannot access the post-mortem report as this is not completed and for this reason my report and it's conclusions are limited by this. Aaron's subsequent clinical course after transfer to HOSPITAL S2 centred on his PPHN which was unresponsive to intensive care treatment, he was declined for ECMO, while he had some features to suggest Hypoxic Ischaemic Encephalopathy on EEG and Cranial ultrasound, PPHN was his main problem at the time of his death.

I am happy to update this report following receipt of his post-mortem findings but I am satisfied with the information provided by staff and his parents to enable this interim report.
Yours sincerely

External Expert, MD, MBA (HSM), DCH, FAAP, FJFICMI, FRCPI, FRCPCH
Consultant Neonatologist/ Paediatrician

Report External Expert, Consultant Neonatologist (Part 2)

Report on Baby Aarons care while in Hospital S2

Hospital S2 chronology
Medical summary and chronology of care for Baby Aaron and Mrs X. Date of birth 04/05/16
Admission 04/05/16 08.05 hrs
Discharged/Died 09/05/16 01.40 hrs
I have prepared this detailed chronology of care based on the inpatient medical and nursing notes in the Hospital S2 infant chart for Baby Aaron . I have reviewed the details provided and provided a clear sequence to his medical treatment and decision making.

Baby Aaron

DOB 04/05/16
Admission time CWIUH 08.00hrs per transport documents Admitted on PAS system 08.05 hrs
04/05/16 10.30 hrs
Dr A L SpR
Hospital S1 details documented from transfer letter and handover DOL 1
BW 2.25 kg
Em LSCS 35 weeks 3/7 gestation, resuscitation in Hospital S1 noted, Apgar scores 2 at 1 min, 2 at 5 mins, 3 at 10 mins. Cord pHs detailed.
Medication including surfactant and Iv fluid boluses recorded as given there,
Hospital S1 gases noted last at 05.45 hrs prior to TF pH 7.135, pCO2 9.9 (kPa), pO2 2.6 (kPa), Bicarb 25, BE -4.0
Assessment and treatment as follows
Intubated, ventilated, now on HFOV MAP 18, Amplitude 32, Hz 10, FiO2 100%. Preductal oxygen Saturations Preductal 91%, post ductal 79%, Good Air entry bilaterally, POCT gas pH 7.376, pCO2 4.37, pO2 3.74.
CVS no arterial access at time, on inotropes milrinone 0.33 mls/hr, adrenaline 0.3 mcg/kg/minute POCT ECHO very poor function, large PDA, severe PPHN with complete right to left shunt present. No urine output, but baby had passed at birth.
Sedated morphine 10/mcg/kg (hr)
Total fluids 65mls/kg/day dextrose 10% with infusions. GI
abdomen distended, soft, no audible bowel sounds,
Haem: Hb 22(g/dl), White cell count 64(,000), platelets 144(,000), had received O Rh neg blood in Hospital S1 .
Metabolic sodium 135 mmol/l, glucose 4,0 mmol/l
Microbiology amoxicillin day,1 cefotaxime day1, gentamycin held ?renal issue Ward Round Dr F, review arterial access, for formal renal and cranial Ultrasounds
Hold gentamycin, needs FBC and CRP, CFAM (aEEG) when stable, target non-invasive BP, mean > 45 mmHg.

From reports Capillary blood gas taken 04/05/16 10.45 hrs pH 7.376 pCO2 4.37 kPa pO2 3.74 kPa bicarbonate 19.6 mmol/L base excess -4.8 mmol/L lactate 3.7 mmol/L Glucose 4.0 mmol/L ionised calcium 0.97 mmol/L.

04/05/16 15.40 hrs Dr F consultant note.
Transfer from Hospital S1, maternal history, birth details and resuscitation recorded including suspected fetal anomalies on antenatal scans in Hospital S1.
Transport he noted an improvement in oxygen saturations to 85% in transport on Nitric Oxide 20 ppm, PIP 35/PEEP 5 cms H2O.
Condition on admission to Hospital S2 NICU
Neurology; very little spontaneous movement, occasionally triggers ventilator breaths, withdrawal to pain, hypotonic.

CVS invasive blood pressure reading approximately 45 mmHg on inotropes. He records point of care echo , 4 chamber view, no obvious Ventricular septal defect or Transposition of the Great Arteries, very poor function globally, minimal tricuspid regurgitation (poor function), large Patent ductus arteriosus with mostly right to left shunt, aortic arch seen, no total anomalous venous drainage seen.
Serum lactate levels have reduced from 3.7 to 2.7 mmol/l
Impression of poor function and severe Persistent pulmonary hypertension of the newborn.

Lungs/ventilation baby had required increased PIP pressure, changed then to Sensormedics (oscillator ventilator) iNitric Oxide 20 (ppm), 10 Hz, amplitude reduced from 34 to 30, mean airway pressure 19 cms/H2O, due to improving blood gases.
Renal/urinary tract, baby had passed small amount of urine, renal and bladder ultrasound look essentially normal (there had been antenatal scan concerns about the kidneys)
Fluids 65mls/kg/24 hrs, dextrose 10%, blood glucose levels normal.
Haematology, he notes that baby was very bruised on chest, legs and hands, that baby had received O neg blood (in Hospital S1)
Medications baby on amoxicllin and cefotaxime because of the meconium grade 1 at delivery (in a preterm baby, to cover possible listeriosis infection in baby)
Baby on adrenaline 0.3mcg/kg/min, vasopressin 0.0003 units/kg/minute, milrinone 0.5 mcg/kg/min, morphine 10 mcg/kg/hr.
Clinical impression 35 weeks gestation infant, critically ill, failed postnatal newborn transition and severe PPHN, suspected sepsis (infection), no obvious congenital abnormality, hypotensive with global myocardial (muscle) dysfunction. Dr F notes a guarded prognosis in view of possible hypoxic ischaemic perinatal event.
Plan continue HFOV, blood gases 4 to 6 hourly to monitor response, continue inotropes, start hydrocortisone IV 2.5 mgs/kg/body weight (in view of hypotension and already on high inotropes), cardiologist review tomorrow. Continue antibiotics, keep baby NPO, parents have been informed.
Reports Arterial blood gas 04/05/16 15.15 hrs pH 7.357 pCO2 3.57 kPa pO2 7.81 kPa Bicarb 18.3 mmol/L BE -8.0 mmol/L Lactate 2.7 mmol/L Glucose 3.5 mmol/L Ionised calacium 1.06 mmol/L

Calculated oxygenation index = 36 at this time 15.15. OI is abnormal and above 30 which represents cardio-respiratory failure, consideration was given that day to ECMO centre contact.

04/05/16 22.31 hrs
R K SpR
Nightime review note
History as before
Severe PPHN
Prolonged resuscitation post birth which included chest compressions, severe respiratory acidosis noted at 1 hour of age,
Ischaemic changes on cranial ultrasound today (brain injury signs)

Currently
Intubated, ventilated HFOV settings are mean airway pressure 24 cms H2O, amplitude 32, frequency 10 Hz, FiO2 100%, preductal oxygen saturations 70%, post ductal 82% (MW comment both are subnormal particularly for this degree of support and baby is in Hospital S2 NICU for last 14 hours at this point)
He notes poor air entry, that baby has been re-suctioned for secretions, on nitric oxide 20 ppm, latest gas at 20.56 hrs pH 7.28, pCO2 5, pO2 4.9, bicarbonate 18, base excess -7.7,
lactate 1.9 mmol/l ionised calcium 1.05

Cardiac assessment
No murmurs on examination, baby becoming oedematous, heart rate high at 178 beats per minute, blood pressure satisfactory at 70/31 mean arterial blood pressure 54 mmHg, on adrenaline 0.4 mcg/kg/min, vasopressin 0.0004 units/kg/min, both adrenaline and vasopressin increased, on hydrocortisone IV.
GI nil noted new save anus patent, some staining of meconium today.
Renal he notes urine passed in Hospital S1, minimal urine output, normal electrolytes, normal renal ultrasound, continue present management.

Neurology, sedated on morphine 10 mcg/kg/min, no seizures seen, not breathing with ventilator (rate)
Infectious disease; CRP 1.3 (negative), raised White cell count 60,000, on cefotaxime and amoxicillin, no growth yet on cultures.
He records Dr P consultant review and plan is to provide paralysis medication with pancuronium IV, to increase the sedation morphine to 20 mcg/kg/hr, repeat his chest xray, insert a urinary catheter, to add in another inotrope noradrenaline, if mean blood pressure falls below 55 mmHg.
04/05/16 23.00 hrs Dr P consultant note. Desaturation noted with low paO2 4.5 kPa on gas. History as above, severe PPHN, cranial ultrasound suggestive of hypoxic injury, currently oxygen desaturation with ventilator and baby's breathing dysynchronous, post suctioning of endotracheal tube,. Plan is to commence muscle relaxant, she records a sequential increase in mean airway pressure on ventilator from 19 up to 23 cms H2O. Chest xray shows hyperinflated lung fields to 9 and half posterior rib markings, a slightly bell shaped chest noted on the CXR (a sign of pulmonary hypoplasia). MAP reduced to 21.5 cmsH2O, nitric

oxide 20 ppm, she noted a lower mean arterial blood pressure from high 40s to low 50s mmHg, baby to have noradrenaline if mean BP falls to 40s (consistently), Consider epoprostenol at 10 nanogs/kg/min (subsequently commenced), increase glucose infusion rate as baby now receiving comparatively little dextrose (once infusions included). Dr P documents that she updated baby's parents on his current clinical deterioration. Vasopressin increased to 0.0005 unit/kg/minute. Note mentions potential future discussion with ECMO team regarding retrieval if baby fails to respond but that due to gestation and weight, that baby is likely not to be accepted for ECMO.
Report blood gas 04/05/16 20.56 hrs ABG result pH 7.28 pCO2 5.24 pO2 4.9 Bicarb 18.0 BE -7.7 Lactate 1.98 ionised calcium 1.05
Oxygenation index on this gas and ventilation settings at 20.56 hrs. OI = 59 severely abnormal (normal usually < 20) note worsening result despite increased supports.
05/05/16 10.25 hrs Dr AL SpR
Ward round note. Dr F. Parents updated, baby on maximal support, No real improvement overnight despite increasing supports, baby remains critical.
Improving left ventricular function but worsening PPHN on echocardiogram (today), underfilled (ventricle) so given intravenous fluid boluses. CFAM (EEG) to be performed today, MRI head to be booked for 7 to 10 days but not for requisition forwarding yet (presumably reflecting the critical condition and that MRI would require off-site transfer and baby very critical).Pancuronium iv to be given to baby if unsettled but after aEEG performed (to avoid drug interference). Wean morphine to 15 microg/kg (says nanograms).
Consultant cardiology review today. Change fluids to 10% dextrose iv and add calcium and potassium to the fluids. Increase milrinone to 0.75 mcg/kg/minute. If needs a third IV bolus (today) to be given fresh frozen plasma as a volume expander.
Antibiotics, stop cefotaxime, continue meropenem, amoxicillin and acyclovir. Samples (to be sent) for herpes simplex PCR (viral panel) enterovirus, urine for CMV. 05/05/16 12.30 hrs Dr A L SpR Daytime note
S/B SpR (Dr AL) day of life 2, ex 35 3/7 at birth infant now 35 4/7, birth weight 2.25 kg, baby has not been weighed.
Issues 1, Severe PPHN 2. Cardiac dysfunction 3. Oliguria 4. Hypocalcaemia 5. White matter injury on cranial ultrasound 6. Query Sepsis (CRP 1.3, White cell count 60,000)
Currently
Resp intubated and ventilated. HFOV MAP 18 cms H2O, Amplitude 33, FiO2 100%, oxygen saturations were preductal 77%, post 71%, oxygenation deteriorated overnight, increased sedation and paralysis medication added, mean AP increased to 24 cms H2O.
Maximal inotropic supports
Adrenaline 1mcg/kg/min, noradrenaline 0.1 mcg/kg/min, milrinone 0.75 mcg/kg/min, sildenafil 0.03 mg/kg/hr, vasopressin 0.005 mcg/kg/min hydrocortisone IV. Mean BP 49-55 (satisfactory).
POCT echo this morning showed large PDA, left ventricular function slightly improved, worsening PPHN, underfilled (heart), 2 boluses of normal saline given, milrinone increased.
Drugs/sedation sedated morphine 15 mcg/kg/hr, (weaned from 20), given pancuronium iv overnight, minimal baby response to stimulus, CFAM aEEG commenced.
Fluids:urine output 1.4 mls/kg/hr (low)
GI abdomen not distended, bowels not opened.
Total fluids 80 mls/kg/day of which 20mls/kg (available for) maintenance.

Hematology, Hb 18.8 g/dl on POCT gas, FBC 05/05/16 Hb 23.1, platelets 157,000, WCC 59.3. She notes O neg blood transfused post delivery in HOSPITAL S1and that a bolus of plasma has been given.
Microbiology, CRP 1.3, WCC fell from 60 to 59.5, day 2 of amoxicillin, cefotaxime and gentamycin stopped. Commenced meropenem overnight.
Impression 1. Severe PPHN worsening oxygenation 2. Abnormal cranial Ultrasound Plan as per ward round, increase vasopressin.
Report blood gas 05/05/16 10.15 hrs pH 7.35 pCO2 2.68 pO2 5.48 bicarb 16.5 BE -10.1 Lactate 1.95
Oxygenation index at time of this gas with MAP of 19.5 and FiO2 100% OI = 53 still very abnormal despite increased supports.
05/05/16 Dr O Cardiology Consultant
She noted an update by Dr F
Echo cardiogram findings,
No evidence of structural abnormality, very large PDA, note biventricular hypertrophy, mild tricuspid regurgitation, note mild hypoplasia of the branch pulmonary arteries. Conclusion dilated PDA, borderline pulmonary artery dimensions, biventricular hypertrophy with normal venous structures, query prenatal pulmonary hypoplasia, no evidence of structural cardiac anomaly. Biventricular cardiac function surprisingly good in view of the PPHN (degree). Not all features seen typical of PPHN, query pulmonary hypoplasia. No structural abnormality, spoke to Dr F post echocardiogram.
05/05/16 17.13 hrs Dr F Summary of the day.
Aaron' s condition deteriorated since last night, remains in critical condition, with severe PPHN, query cause, query pulmonary hypoplasia, relative hypotension, cardiorespiratory failure

Neurology examination: no spontaneous movement, on morphine 15mcg/kg/hr, aEEG discontinuous trace, moderately abnormal. Lower margin 5mV, higher margin 25mV, no documented seizures.
CVS relative hypotension, desaturates if mean BP below 55mmHg, heart function improved since yesterday, but severe PPHN with marked right to left flow/shunt, minimal tricuspid regurgitation, biventricular hypertrophy, Dr Franklin's opinion noted.
Chest good air entry bilaterally, lungs appear small (on CXR and ECHO) but parenchyma looks unremarkable, ETT withdrawn by 1.5 cms, Oxygenation index is 46 (very abnormal).
Fluids (needed additional fluid boluses of normal saline and FFP) to maintain a supra-normal BP to keep preductal oxygenation saturation above 85%. Urine output now.

Antibiotics same as per Dr Ls note, viral PCR sent (blood), blood cultures and PCRs pending.
05/05/16 17.50 hrs Patient examined heart rate increased at 211 beats/min, invasive BP mean 69 mmHg, mildly cyanosed, good bilateral air entry.
Dr F notes discussion with the ECMO (extra corporeal membrane oxygenation) centre in Sweden, Aaron's condition was discussed in detail, the possible "functional" pulmonary hypoplasia and perinatal hypoxia (pO2 < 3 kPa for 4 hours) meant that he is not suitable for ECMO treatment.

Dr F notes discussion with Parents that Aaron is in a critical condition, has reached maximal

therapies, that they are aware of same, plan is to continue ICU support and hope that he will improve.
Plan for next 24 to 48 hrs: continue HFOV and nitric oxide 40 PPM, Continue
inotropic support and sildenafil
Liberalise fluid total/day to 130 mls/kg/24 hrs Do
viral PCR panel
Request serum ammonia (metabolic test)
Discuss appropriate genetic testing (due to prior transfusion given in HOSPITAL S1) Continue CFAM monitoring.
06/05/16 09.57 hrs ward round note Dr K Registrar. Document
inotropes amount (fluids)
Minimal handling
No boluses IV at present
Point of care echo today
Keep mean BP above 70 mmHg (high level)
Might be for hyperbaric chamber treatment (to be discussed prior to same with baby's parents)
Continue same management
Discuss with Pharmacist about increased drug concentrations to enable less fluids to be given IV.
Do Chest xray
Get ready for trial of ?other ventilation mode? Later
Report Blood ABG 06/05/16 09.22 hrs pH 7.24 pCO2 4.75 pO2 3.55 Bicarb 14.8 BE -11.5 Lactate 5.4
Oxygenation index with MAP of 24 cms H2O and FiO2 100% OI = 80 which is showing a marked deterioration and failure to respond to treatment. (MW comment likely incompatible with survival).
06/05/16 11.43 hrs Dr K Registrar Day
of life 3.
History noted as previous Late preterm,
RDS, severe PPHN, 1 dose of surfactant yesterday, cardiac dysfunction, on full inotropic support, query pulmonary hypoplasia, rest of antenatal history noted as previously. Antenatal steroids given.
Medications
Antibiotics amoxicillin day 3, Meropenem day 2, acyclovir day 2 of treatment.
Drugs: noradrenaline 0.08 nanog/kg/min, adenosine 50 mcg/kg/min, milrinone 0.75 mcg/kg/min, adrenaline 4.1 mcg/kg/min, vasopressin 0.005 units/kg/min, epoprostenol 20 nanog/kg/min, sildenafil 0.03mcg/kg.
Total fluids 161 mls/kg/day
Current assessment : critically ill baby, sedated, incubator, oedematous, skin pink pale, haematoma on his forearm and antecubital fossa.
Ventilation : HFOV Mean airway pressure 24 cms H2O, amplitude 55, freq 8.9 Hz, FiO2 100%, inhaled nitric oxide 40 ppm.
CVS heart rate 166-195, mean BP 71 mmHg Urine
output 1.92 mls/kg/day (low)

Abdomen nil new noted.

CNS unchanged sedated on CFAM continuous.
Plan as per Ward round, secretions for viral respiratory panel, do new ammonia blood sample, he spoke to NVRL (national viral reference laboratory) about specimens sent or being sent to check best sampling methods eg serology, secretions, stool or swabs for specific tests, and for the NVRL to prioritise same.
07/05/16 02.30 hrs Dr A L SpR
Called to review for low oxygen saturations and blood pressure readings. She noted baseline during the day: mean BP 73 mmHg, oxygen saturations were 79-81 5 (low for this degree of support). Maximal inotropic supports, mean airway pressure 24 cms H2O.

At 02.30 acute oxygen desaturation to 60s (%), mean BP had fallen to 45 mmHg. No change in infused drugs noted, given hydrocortisone IV, checked that air entry good on auscultation, extensive oedema, urine output now 4-5 mls/kg/hr
Discussion with consultant on duty, to increase noradrenaline and vasopressin infusions, discontinue flolan (epoprostenol), do chest xray now.
Bolus of normal saline IV 20 mls/kg body weight commenced, mean airway pressure increased to 26 cms H2O, mean BP improved to 65-70 mmHg, oxygen saturations recovered. 07/05/16 03.25 hrs Dr A L SpR noted CXR showed small left pneumothorax, no lung field hyperinflation. Point of care echocardiogram by Dr F no pneumopericardium noted, wean Mean airway pressure to 22 cms H2O, observe response.
07/05/16 08.30 hrs Dr F consultant note of night summary.
Called to bedside at 02.30 hrs due to severe desaturations to SaO2 60s (%) and low mean BP 45, chest xray tiny left pneumothorax, decrease mean airway pressure to 19 cms H2O, increase vaspopressin to 0.002 units/kg/min, noradrenaline to 1.0 mcg/kg/min, temporary improvement only noted and oxygen saturations only back to 75%.
Paralysing agent iv suxamethonium tried as baby breathing spontaneously (eg dysynchronous with ventilator), no improvement and mean airway pressure put back to 23 cms H2O.
He concludes, overall remains critically ill with guarded prognosis, worsening oxygenation despite being on such high limits of ICU care.
Report blood ABG 07/05/16 07.17 hrs pH 7.261 pCO2 4.09 pO2 4.49 Bicarb 15.1 BE -11.8 Lactate 4.58 ionised calcium 0.99
Oxygenation index at this time with MAP 20 and FiO2 100% OI = 67, OI remains very abnormal, only marginally improved.
07/05/16 11.47 hrs Dr R K SpR note. Ward
round Dr F; plan for day.
Reduce morphine to 10 mcg/kg/min, check cranial ultrasound has been requested, inotropes as follows, adrenaline increased to 4.3 mg/kg/min, noradrenaline to 1.2 , epoprostenol stopped, order FFP bolus of 20 mls/kg iv and administer same, reduce nitric oxide to 20 ppm, give bicarbonate correction over 6 hours, , repeat blood tests as ordered, supplement sodium IV, continue amoxicillin, meropenem, acyclovir, if repeat ammonia sample > 100, contact metabolic team, send plasma amino acid sample with next blood sampling, check blood and urine for ketones (metabolic), genetics blood sample (query pretransfusion taken in Hospital S1 so to be sent to genetics lab for array CGH).
Weight of baby now 2.67 kg (working weight)
Query nonketotic hyperglycinaemia and sulphate oxidase deficiency ? (metabolic disorders)

07/05/16 15.00 hrs Dr F consultant note
He notes further deterioration in baby, low oxygen saturations to 58%, heart rate 167 BPM, mean BP 69 mmHg, there is a tiny left pneumothorax no signs of tension pneumothorax, not suitable for chest drainage. He had spoken directly about the metabolic results to date with the metabolic consultant on-call, opinion of the metabolic team is that the raised ammonia levels of 163-164 do not represent a primary metabolic disorder but reflect Aaron's level of illness at this time.

07/05/16 22.30 hrs Dr R K SpR note
Present weight 2.695 kg working weight is 2.67 kg. previous history noted and medications listed. Only changes in medication are noted the addition of one dose of furosemide diuretic, bicarbonate correction had been given, one dose of suxamethonium, one bolus of fresh frozen plasma IV, total fluids at 161 mls/kg/day.
Impression critically ill baby: PPHN, on maximal ventilatory and inotropic support. HFOV MAP 20 cms H2O, Amplitude 63, freq 8 Hz, FiO2 100%. Oxygen saturations were 79/76 (note were lower at 14.00 hrs 67/73)
Mean BP 71 mmHg at present Urine
output 5.6 mls/kg/hr
Abdomen no changes, CNS baby is sedated.
Impression: He notes critically ill background of borderline oxygen sats 76-79-80 with episodes of desaturation noted periodically to 60-58 %, blood tests plan for sampling noted. 08/05/16 Morning note completed by Dr A L and Dr K
Ward round Dr F plan: reduce hydrocortisone dosage to 3 mgs/kg, change maintenance fluids to 15% dextrose iv, do bloods full blood count and check urea and electrolyte sample result, do chest xray today, after ward round try conventional ventilation (call bio-engineer to support same), continue iv antibiotics and acyclovir for 7 day course, continue same inotrope dosages, do cranial ultrasound tomorrow and working weight = 2.67 kg for the baby.
Report ABG 08/05/16 07.29 hrs pH 7.266 pCO2 4.25 pO2 3.64 Bicarb 15.2 BE -11.1 Lactate 5.6 ionised calcium 1.16
Oxygenation index at this point with MAP 20 and FiO2 100% OI = 67.

08/05/16 14.00 hrs Dr F consultant note, Day
5 now 36 weeks gestation corrected age.
Working weight 2.69 kg
Background 1. 35 3/7 born/critically ill since birth 2. PPHN likely due to pulmonary hypoplasia 3. Biventricular myocardial dysfunction 4. Suspected infection query viral 5. Thrombocytopenia 6. Perinatal stress/failed transition.
CNS/Cranial ultrasound mild periventricular hyper-echogenicity, baby is reacting to handling today, with some (facial) grimacing seen. Sedated on morphine.
Ventilation settings: HFOV MAP 20 8 Hz amplitude 65 FiO2 100% inhaled nitric oxide 30 ppm
Last gas arterial pH 7.23, pCO2 4.86 kPa, Base excess -11.4 paO2 3.53 kPa (low), lactate 5.55 mmol/l increased, glucose 4.3 mmol/l.

CVS he notes falling BP despite support, invasive mean BP now 68 mmHg, desaturated to 58%

in last hour, adrenaline increased to 5 mg/kg/min, vasopressin increased to 0.01 units/kg/min
He did point of care echo difficult study to do but PDA query closed which may be worsening PPHN, since Thursday, disimproved function seen, signs of bi-atrial overload
Total fluids 140-160 mls/kg/day depending on drug doses, urine output now increased to 11 mls/kg/hr, normal glucose 4.3 mmol/l

Inotropes/meds: milrinone 0.75, adrenaline 5.0, noradrenaline 1.2, vasopressin 0.00067?, sildenafil IV infusion, Prostin 5 microg/kg/min, caffeine 20 mgs/kg/dose given, adenosine IV, morphine, meropenem, amoxicillin. (note prostin has been commenced)
Liver jaundiced high serum bilirubin of 330 micromol/l on phototherapy.
He concludes baby's general condition is worsening and speaks to both parents with 3 options offered on baby's treatment after detailed discussion.

1. Pro-active offer course of hyperbaric treatment in national hyperbaric treatment centre based in Dublin (if he can tolerate transport there and back).
2. Redirection to comfort care, no escalation and allowing out for "kangaroo care".
3. Withdrawal of current life support.

Parents opted for trial of hyperbaric, Dr F notes that this treatment is physiologically plausible but is a potential treatment option.

08/05/16 15.00 hrs Changed to conventional non-oscillatory ventilation (for the transport) of PIP 40 and PEEP 6 cms H2O IT 0.4 seconds, FiO2 100%, rate 60 breaths/minute tolerated with saturations 62-71%. Inhaled nitric oxide 30 ppm.
08/05/16 20.15 hrs Dr F consultant note
Summary of hyperbaric chamber treatment session. Transported to treatment centre on settings above, only difference was inhaled nitric oxide of 20 ppm in this note, on arrival there oxygen saturations 64% preductal, exposed to 2 ATA pressure (10 meters depth), improved oxygen saturations to 89%, noted 1 hour at 2 ATA, overall time 2 hrs, transported back stable.
On arrival back in Hospital S2 on same ventilation and nitric oxide settings, oxygen saturation readings are preductal 83%, post ductal 58 %.
Plan. Do ABG, chest xray, blood for urea and electrolytes, increase adrenaline dose as low mean BP of 52 mmHg, start levosimentin infusion (to potentiate inotropes)
Report Blood ABG 08/05/16 19.53 hrs pH 7.201 pCO2 4.67 pO2 3.08 Bicarb 12.9 BE -13.6 Lactate 5.4 ionised calcium 0.92
Oxygenation index result on MAP 21 cms H2O and FiO2 100% OI = 93. This shows no improvement after hyperbaric chamber treatment and remaining on maximal supports. (MW comment, this result is not compatible with survival).
Dr F advised parents that in his opinion on the basis of the clinical course and findings that this likely means pulmonary hypoplasia (which is) not compatible with baby's long term survival.
Blood gas on return to Hospital S2 time ???pH 7.201 pCO2 4.67 pO2 3.08 HCO3 12.9 base excess -13.5 glucose 5.4 lactate 5.2, ionised calcium 0.92 low potassium of 1.62 mmol/l for lab urea and electrolytes.

09/05/16 02.00 hrs Dr M consultant note

Dr M records emergency call to hospital at 01.00 hrs for baby, arrival at 01.16 hrs. Background of suspected pulmonary hypoplasia and severe PPHN noted.
Baby had bradycardia at 01.59 hrs, suctioned, given multiple doses of adrenaline (however he notes that baby already on significant dose of iv adrenaline already), given PPV by neopuff device, heart rate low at 60 beats per minute, good chest lift noted (not an endotracheal tube problem as tube was in the airway and moving chest on bagging) Transillumination showed suspected pneumothorax seen previously on chest xray (suspected extension of pneumothorax). Adrenaline dose increased, given chest compressions, needle thoraco- centesis of left side performed and 60 mls of air withdrawn, no improvement in his heart rate or oxygen saturations seen in response to these measures. Parents called to bedside, after 15 minutes of attempted resuscitation, parents were advised that further resuscitation efforts futile. Baby Aaron was handed to his parents to hold at 01.30 hrs and death was certified at
01.40 hrs.

09/05/16 06.11 hrs Dr A L SpR retrospective note
Called to Baby at bedside at 01.59 hrs due to acute bradycardia and hypotension. Attended immediately, low heart rate 80 BPM, mean BP 40-45 mmHg, preductal oxygen saturations were in low 60s%. Team present.
Increased inotropes adrenaline to 8.5 mls/hr, (5.3 Mmcg/kg/min from 5 mcg/kg/min), vasopressin increased to 6.5 mls/hr (0.0073 units/kg/min from 0.0067) no response noted. Aaron received manual ventilator breaths, consultant and radiographer called. Disconnected from ventilator and given neopuff breaths PIP 40 PEEP 6 cms H2O pressures, FiO2 100%, good chest rise noted but less good air entry heard on left side compared to right side of the chest. Heart rate now 60-80 BPM, mean BP 30s mmHg, oxygen saturations were deteriorating 40s to 30s%. ETT position checked to be in position with laryngoscope, oropharynx suctioned.

Endotracheal tube suctioned and thick mucus obtained, brief improvement in heart rate to 100 BPM, no improvement in BP or oxygen saturations.
Total of 7 boluses of adrenaline given 0.3 mls/kg. Chest transilluminated, left chest area of lucency, needle thoracocentesis performed by Dr M, drained 60 mls air. Continued deterioration and chest compressions commenced, parents attended approx. 01.30 hrs and then given to mother to hold in arms at 01.30 hrs, baby died at 01.40 hrs.
End of medical note.
Summary and reviewer's opinion.
Baby Aaron's care in my opinion was satisfactory, he had appropriate intensive care treatment in the Hospital S2 NICU, he had a degree of severe PPHN which did not respond to treatment. His Chest xrays did show a somewhat bell-shaped chest (indicative of possible pulmonary hypoplasia), coupled with his echocardiogram findings and his clinical condition his death was felt to be caused by pulmonary hypoplasia and severe PPHN. The decision by the ECMO centre in Sweden to decline him for ECMO treatment fits with their admission criteria and matches other ECMO centres in this regard. I do not believe that ECMO treatment would have been successful or curative in his case and he was born prematurely and had low birth weight which would have worsened outcomes further. No bacterial or viral infections were identified on tests prior to or after death. There were some results documented

above suggesting a possible primary or secondary metabolic abnormality. At no time did Aaron have a normal oxygenation index during his course in NICU and this would be in keeping with the underlying functional pulmonary hypoplasia and PPHN identified clinically by Dr F and Dr P Consultant Neonatologists and by Dr F Consultant Cardiologist

I have been provided with copy of the post-mortem report on a confidential basis by the Dublin City Coroner, having reviewed the PM findings, in my opinion there should have been more clinico-pathological correlation made on the basis of baby's clinical course taken together with the autopsy findings.
This is a case of severe unremitting persistent pulmonary hypertension of the newborn (PPHN) causing the death of baby Aaron based on my clinical review of the Hospital S2 and Hospital S1 charts with the post-mortem findings.
There is no evidence that the consultant pathologist in this case sought further clarification from the Neonatology team or the Consultant Dr F around the PM conclusion of mild pulmonary hypoplasia, Dr A did however seek appropriate second opinions from two other consultant pathologists on her histological findings. I think that such clinico-pathological discussion should occur and in my opinion would enhance and certainly not detract from the coronal process.

External Expert, MD, MBA (HSM), DCH, FAAP, FJFICMI, FRCPI, FRCPCH
Consultant Neonatologist/ Paediatrician

02/04/18

Radiology report findings as requested.
CXR report 04/05/16 10.19 hrs reported on 04/05/16
ET tip is at T1 The NG tube is in the stomach. Presumed UVC catheter has tip at T10 in the midline. This is slightly low and should be used with caution. Further lines and leads overlie the patient. A density in the right axilla is presumably artefactual. The heart size is normal. The lungs show a non-specific hazy opacification that in the correct clinical context could represent RDS. There is no apparent consolidation. In the abdomen the bowel gas pattern is unremarkable. Dr AB.
Cranial and abdominal US report 04/05/16 13.35 hrs
Cranial ultrasound: The corpus callosum is present. Normal appearance of the ventricular system. The periatrial white matter appears heterogenous and marginally more echogenic than the adjacent choroid plexus. Are there any clinical concerns about a hypoxic ischaemic injury? No other brain parenchymal abnormality noted. No intraventricular haemhorrage observed.
Urinary tract ultrasound: Exam performed on the first day of life. The bladder appears unremarkable. No dilatation of the distal ureters observed.
The left kidney measures 4.2 cm in long axis. The right kidney measures 4 cm in long axis. Cortical medullary differentiation appears age appropriate with no focal renal abnormality noted and no pathological upper tract dilatation observed on the first day of life.
Impression: I note that the periatrial white matter appears heterogenous and marginally more echogenic than the adjacent choroid plexus. Are there any clinical concerns about a hypoxic ischaemic injury? A urinary tract ultrasound on the first day of life shows no abnormality.

Findings discussed at the bedside with Dr F. Dr Z.
CXR report of xray of 04/05/16 22.54 hrs reported on 05/05/16
ET Tube tip at T3, the tip of NG tube is not included in the stomach. Further lines and leads overlie the patient. Presumed UV catheter has tip at the level of T10. Presumed artefact is again identified over the right axilla. The heart size is normal. There is no focal collapse or consolidation in the lungs. Dr AB

Cranial ultrasound report 05/05/16 10.08 hrs reported on 05/05/16
Corpus callosum present. Ventricles are unremarkable. The periatrial white matter remains rather echogenic, but has not changed in the interval 22 hrs. There are no new findings. Dr AB

CXR 05/05/16 12.10 hrs report reported on 05/05/16 : Compared with 04/05/16 ET at T3, NG tube tip is in the stomach. Umbilical catheter has tip at level of T10. The heart size is normal. The lung parenchyma remains relatively clear. No pleural fluid or pneumothorax seen. Dr AB

CXR and PFA 05/05/16 16.00 hrs
The ET tube is in left main bronchus and there is collapse of the left lung. I understand from discussion with Dr F (16.45 hrs) that the tube has already been re-sited. The NG tube is in the stomach. UVC has tip in the midline at T10, which is slightly low. There is a urinary catheter. Right lung remains relatively clear. The abdomen is gasless, there is no free air. Dr AB

CXR report 05/05/16 17.24 hrs reported on 06/05/16
The ET tube is now at T2. There has been near complete re-expansion of the left lung. The NG tube tip is in the stomach. UV catheter still has tip at the level of T10 which is low. Apart from some residual volume loss in the left lung, the lung parenchyma is relatively clear. No pleural fluid or pneumothorax seen. Dr AB

CXR report 06/05/16 11.27 hrs Reported on 06/05/16
Compared with 5/5/16. The ET tube tip is at T1. The NG tube tip is in the stomach. Umbilical catheter has tip at the level of T 10 which remains low. The heart seems a little larger than previous, this may be projectional. The lung parenchyma remains relatively clear. I wonder if there is a very small right pleural effusion. Subcutaneous oedema is increasing. Dr AB

CXR report 07/05/16 report at 15.17 hrs on CXR taken at 02.51 hrs per next reported on 09/05/16
Comparison with 06/05/16 The endotracheal tube is at T1 level. A nasogastric tube is noted in the body of the stomach. An umbilical venous catheter is noted in the midline at T9 endplate level. The cardiothymic silhouette does not appear enlarged. Atelectasis evident in the medial basal segments of the left lower lobe and to a lesser extent middle lobe. Lung volumes are greater than on the prior day's radiograph. Small bilateral pleural effusions persist (greater on the right in the left). The degree of cutaneous body wall oedema appears broadly similar to prior imaging. Dr Z

CXR report 07/05/16 taken at 15.17 reported on 09/05/16 Comparison
with prior exam May seventh 2016 at 02.51 hrs
ET tube at C7 level. NG in the body of the stomach. The cardiothymic silhouette does not

appear enlarged. Small lung volume patchy consolidation evident in the right middle lobe, lingual and to a lesser extent medial basal segment of the left lower lobe. The pulmonary vascularity appears within normal limits. Small bilateral pleural effusions noted which appear larger on the right than the left. The degree of cutaneous body wall oedema appears similar to prior imaging. Dr Z

CXR 08/05/16 10.50 hrs reported on 09/05/16
Comparison :prior exam May seventh 2016.
ET tube at T2 level. NG in the body of the stomach. The cardiothymic silhouette does not appear enlarged. Small areas of patchy consolidation evident in both lungs. The degree of cutaneous body wall oedema appears unchanged from prior imaging. An umbilical catheter is noted just to the right of the midline at T10 level. Dr Z

CXR performed on 08/05/16 19.44 hrs reported on 09/05/16.
Report Comparison prior exam at 10.50
ET tube at D2 level. NG in the body of the stomach. The cardiothymic silhouette does not appear enlarged. Pulmonary vascularity appears within normal limits. Small volume consolidation is noted projected posterior to the left ventricle. Small bilateral pleural effusions are evident. The degree of cutaneous oedema is marked and appears unchanged in the interval since the last exam. Dr Z.

Appendix D: Report External Expert, Clinical Nurse Specialist in Neonatal Resuscitation

Report of Interviews: Received 13th December 2017

Case NIMLT 51615 conducted on the 4th

November'17.
Interview Panel:

- External Expert; Consultant Paediatrician and Neonatologist,
- Dr Francois Gardeil; Consultant Obstetrician and Clinical Report
- External Expert; Clinical Midwife Manager2.
- External Expert; Clinical Nurse Specialist in Resuscitation

Statement of Interviewer; this is my opinion and my interpretation from the interviews conducted below which I was present for.

Objectives of Interviews;

1. To clarify what happened during the first 10 minutes of the Baby Aaron Life in relation to Heart Rate, Respiratory Effort, Oxygen Saturations, Colour, Secretions, Duration of I.P.P.V .prior to commencing chest compressions. Initial Pressure Used and what corrective steps (MRSOPA) were taken. Time of first and second intubation.
2. To present questions raised by parents.
3. To give staff the opportunity to recall in their words the event. To clarify their role, and actions they performed during the event and the infant's response to an intervention.
4. A.A.P./A.H.A .6th Edition Guidelines for Neonatal Resuscitation applied and were theyimplemented.

Details of Baby: A

- D.O.B . 04/05/2016 @01.31hrs
- Gestation 35+3/40
- Weight 2.25kgs
- Apgar's Score 2@1,2@5,3@10,3@15minutes.
- Transferred by N.T.T. to the N.I.C.U. in the HOSPITAL S2 AT 07.30 hours for further respiratory management.
- Baby passed away on the 09/05/2016 @01.40 .R.I.P.

First Interview

Consultant Paed; Consultant on Duty: Consultant Paed confirmed that he was called urgently at 01.34 hours (4mins after baby was born).

He arrived at 01.45 hours. He observed the infant was receiving I.P.P.V. via neopuff bagging system with pressures of 20-25 cm being administered. Oxygen saturations was 50%.On auscultation heart rate was at 128bpm.

He took over ventilation and increased pressures to 30cms and administered these using a jaw thrust technique.

He successfully intubated Aaron on the first attempt @ 01.51hrs using a Size 3 tube, taped at 8cms at the lip. Secretions in the mouth and oropharynx noted to be clear and normal in amount.

In addition he also excluded the presence of any Pneumothorax. Intravenous Assess had been established by ? paed registrar and Sho and was given first bolus of NACL @ 01.45hrs and was repeated at 01.55hrs.

1st Surfacant of 200 mgs Kg given at 02.16 hours. Baby transferred to Scbu at 1 hour @02.45 hours.

Subsequent Care:

Commenced mechanical ventilation and given intravenous antibiotics. 2ND Surfacant given at 03.30hrs.

Consultant Dr F in Hospital S2 contacted re transfer and accepted baby for on-going care. Blood transfusion given as directed by Dr F.

Neonatal Transport team arrived at 04.06hrs and when infant was stabilized at 07.00hrs they transferred the infant to Hospital S2.

My opinion of interview;

My impression is that he acted appropriately and on arrival he assessed ventilation and noted that the pressures could be increased in order to provide more effective ventilation prior to intubation. He intubated successfully on the first attempt and noted normal volume of clear secretions but no comment was noted on the infants colour. 1st Dose of Surfacant was given to improve ventilation and oxygenation and he also repeated of the NACL bolus.Subsequent care in the SCBU was managed appropriately although umbilical venous and arterial lines were inserted by the neonatal transport team 05.00hrs.

Interview Paed Senior House Officer on Duty. (accompanied by a colleague). He confirmed he was present at the birth of Baby Aaron who he described in his medical transfer letter as being born ''flat at delivery '' with no respiratory effort and a heart rate of < 60bpm .

He informed us that when the infant was born he evaluated the infant's heart rate by umbilical cord palpation and noted it to be less than 60 bpm but the exact number was not estimated. In addition he was unable to recall any subsequent heart rate.

He was also asked to explain what he meant by ''flat'' and this he proceeded to describe: that the infant had no respiratory effort and poor muscle tone .

He was unable to recall if meconium or staining of the skin was present at birth.

He recalled that the nurse midwife from SCBU put on the saturation monitor but did not recall the time or any of the reading during the resuscitation.

Did not recall if corrective steps (MRSOPA) was performed.

Chest compressions he estimated were started at? 1 minute by the midwife.

First Intubation he recalled may have been around 3minutes of age and when the CO2 Detector was connected there was no colour change noted and the tube was removed. He was unable to recall the time of the second intubation attempt but he stressed that IPPV and Chest compressions were continued between intubation attempts.

He remembered that intravenous access was at ? 1min but yet another staff member recalls it was at 11minutes and this would correlate with the giving of the first fluid bolus.

NCHD wrote the medical transfer letter and obtained the information from the notes written by the registrar and consultant on duty after the event.

My opinion of Interview:

He appeared very traumatized by the event but did clarify that the first intubation was around 3 minutes of age and the infant did receive continuous I.P.P.V. and chest compressions for the first 10minutes of life .

Interview with Staff nurse:

Staff Nurse in SCBU who came to assist with Baby Aaron resuscitation and arrived at 11minutes of age.

She confirmed the Registrar, SHO and the SCBU nurse were actively resuscitating Baby Aaron. The SHO was performing chest compressions and the registrar was attempting 2nd intubation. She was informed that the baby was not breathing at birth and the Heart Rate was 30bpm. She also noted on her arrival that the oxygen saturations was not recording at this moment. She observed that the mask size was too big and changed it for a smaller size mask. She also increased the flow in the blender from 5 litres up to 8 litres. Took over chest compressions and then noted after 30seconds the Heart Rate had increased to 90 -100bpm. Oxygen saturations at the time were not recording. In addition she did not recall if staining of the skin was present.

She also noted that the sho sited the Intravenous cannula at around 11 -12mins.

In addition she asked a midwife to start scribing what interventions were taking place.

No debriefing or discussion took place after this event which she found very upsetting and is no longer a member of staff at the hospital.

My opinion of interview:

Paeds nurse took appropriate action when she arrived on the scene by evaluating what was happening and proceeded to make changes to improve outcome.

Interview with SCBU Nurse. Accompanied by CMM2 and INMO REP.

The SCBU Nurse confirmed she was present at the birth of Baby Aaron and noted at birth the infant was '' apnoeic, limp at birth and probably pale /dusky in colour''.

Initial steps in resuscitation were commenced but not documented in medical notes.

Heart Rate noted to be <60 bmp (? 50bpm but not sure) therefore IPPV commenced. She also noted airway had clear secretions. IPPV commenced with a flow of 5 litres and pressures of 18/4 and there was visible chest rise. She did not recall if meconium or staining of the skin was present. She recalls oxygen saturations at ? 2minutes was 50%-60%. Chest compressions were started at 2-3minutes of life and discontinued at 10 minutes.

She was unable to recall time of first intubation but did confirm
Consultant Paediatrician was called at 01.34 and arrived at 01.45hrs . She recalled that post intubation Baby Aaron's heart rate was 128bpm and oxygen saturations 60%-70%.

In SCBU the nurse met with infant's dad and aunty and later mum who visited in a wheelchair.

My opinion on Interview.

SCBU Nurse documentation in the medical notes was very good and all actions were recorded in chronological order except it lacked detail of the first 10 minutes of life. During the interview was not able to elaborate further only confident that the infant received the correct resuscitation procedure and the NRP guidelines were followed and unit protocol was adhered to.

She received no formal debriefing but did have one to one chat with colleague.

During the feedback process SCBU Nurse P5 wished to highlight that all steps were correctly followed including the corrective measures (MRSOPA), both term and preterm mask were tried on Baby Aaron by the team and that there was definitely an improvement in the heart rate by 10 minutes of age.

Interview with Midwife Labour Ward.

Midwife recalled that she was present at the delivery and brought Baby Aaron to the radiant warmer for resuscitation. She noted he was extremely ''flat, limp and no breathing with a poor colour''. She was unable to recall if meconium or staining of the skin was present.

She recalls SHO assessed heart rate <60. She was asked by Reg to perform first round of chest compression but unable to recall the time she started or what the heart rate was at that moment.

My Opinion.

She played a very minor role as she was only involved in the beginning but had poor memory recall of events that took place.

Interview with Midwife in Labour Wd.

She recalls the infant ''was very flat and unresponsive at birth''.

Unable to recall infant's colour or if meconium was present but recall chest compressions were started soon after birth.

She played a minor role in the resuscitation as she was involved with cord blood sampling.
Debriefing not offered or could not remember.

Summary of Resuscitation to Date

D.O.B.: 04.05.2016 @ 1.30 hours
Apgar's Score 2@1 , 2@5. 3@10. 3@15mins
Emergency Cesarean Section for Foetal distress and decelerations.
Present prior at Delivery
Dr R Reg, SHO, SCBU Nurse . Shift Leader.

At Birth
Infant noted to be ''flat'', limp with no respiratory effort.
Colour pale /dusky

Heart Rate <60 (?50) SHO.
Initial Steps commenced but not recorded in notes.

I.P.P.V commenced Flow of 5litires with a P.I.P. 18/5

?1-2 mins of age: Chest compressions commenced

O2 Saturations 50%-60%

3 mins of age: First Intubation attempted unsuccessful – no colour change in CO2 detector. Chest compressions commenced.

4 mins of age: Consultant called urgently .IPPV and Chest compressions continued.

5 mins Apgar Score = 2 (1 Heart rate <100 and 1 for colour)

10 mins Apgar Score = 3 (2 for Heart rate >100bpn and 1 for colour)

11mins of age; Flow increased to 8-10 litres and mask size changed. Intravenous access obtained and first Bolus of NACL given at 01.45 hours.

2ND Intubation attempted which was unsuccessful.

11 min of age; Heart Rate 90-100bpmChest compressions discontinued.

15mins of age; Consultant arrived at 01.45 hours. Pressures increased to 30/5 ,O2 Sats 50%, Heart Rate 128bpm.

Baby Aaron intubated on first attempt Hear Rate 124bpm, O2 Sat's 60%-70%
Repeat bolus of NACL given.

1st dose of Surfactant @02.16 repeated @03.30hrs 1hr-
15mins Transferred to SCBU at 02.45 mins

My conclusion of Interviews.

As one interview by the Registrar remains outstanding it would be unfair of me to comment until all the facts are known. But the following is my impression to date which illustrates that there are still gaps in the details in relation to the first 10 minutes of life. However the ventilation strategy applied enabled the infant's heart rate to increase to 100bpm at 10 minutes of age which would support that their ventilation and chest compressions were effective. One could speculate if the IPPV were increased earlier this may have improved the situation. However, if the increased pressure had caused a pneumothorx would that have compromised the resuscitation further. The Paediatic Nurse did confirm that they were working within their unit protocol in relation to pressures and they did adhere to the 6th Edition Guidelines for Neonatal Resuscitation.

The interviews also clarified to date that oral secretions were within normal limits and meconium and staining of the skin was not an issue.

Documentation of the event was mostly done retrospectively and having no scribe available from the beginning lead to scanty details being recalled as scribing only started at 11minutes of age. Discrepancy also appeared in relation to when chest compressions were started and when intravenous access was sought. However the retrospective documentation was satisfactory and in particular SCBU Nurse notes were comprehensive but lacked detail of the first 10 minutes. SHO present at delivery did not record any comment on the resuscitation.

Debriefing which is an essential component of resuscitation did not take place in either formal or informal manner. Staff would have liked the opportunity to discuss the case and no counselling was offered nor did any staff request it.

Changes in practice since this event.

Resuscitation recording sheet are in use and drills and skills in neonatal resuscitation occur frequently.

External Expert
C.N.S. Resuscitation

Appendix E: Report External Expert, Midwifery

NIMLT 51615. 11/07/2017

As requested, I have reviewed the health care records and original CTG's for mother MRN # 567951 & her baby MRN # 1062561 from a Midwifery perspective with emphasis on care around delivery and initial resuscitation. I have used the HSE Guidelines for the Systems Analysis Investigation of Incidents 2016, HSE Clinical Practice Guideline 2012 "Intrapartum Fetal Heart Monitoring" & NMBI Publications.

Mother

29yr old primigravida booked @ 11^{+5}. EDD 04/06/2016, Dates = Scan. Raised BMI 32. History of anxiety, not medicated. Quit smoking. Combined Ante Natal Care: Obstetric led, hospital based and GP.

04/02/16 @ 22^{+5}: Seen in the Maternity Assessment Unit (MAU). GP referral with palpitations and shortness of breath. No concerns about Midwifery care.

29/02/2016 @ 26^{+2} : Admitted via the MAU with abdominal pain and vomiting. A diagnosis of choleliathesis and acute cholecystitis was made. Whilst an inpatient for 3 days, the fetal heart was auscultated on 14 occasions, mostly by hand held Doppler, but the method of auscultation was not always documented. A CTG was never ordered or recorded (reference query 1).

29/04/2016 @ 34^{+6} : Routine ante natal visit (pg 42). The woman complained of reduced fetal movements and a CTG was done which was normal. The woman's blood pressure was 130/81 mmHg, urine +1 protein and Pre Eclampsia bloods were done. The abnormal results (pg 319) were signed on 03/05/16 (reference query 2). A diagnosis of polyhydramnios and other ultrasound findings prompted an urgent Perinatal Ultrasound referral to be faxed by the Consultant to a tertiary-referral Hospital (reference query 3).

01/05/2016 @ 35^{+1} : 16.24hrs approximately, presented to the MAU with decreased fetal movements and abdominal discomfort. A CTG was performed (pg 280a) but there is no corresponding proforma sticker. Patient admitted. A repeat CTG @ 23.04hrs (pg 287a) has an isolated deceleration @ 23.21hrs which was duly noted and signed off by the Obs Reg with a request for "repeat mane". Uterine activity appears to be recorded on the CTG and narrative entry of patient "reports tightenings, having same for the last couple of weeks not painful" noted (pg 109).

The following morning a CTG (pg 288 a) was done pre and post breakfast which were reviewed by the Obstetric team on ward rounds. A further CTG (pg 283 a) was done prior to discharge which was normal. The antenatal observation record (pg 100) was not completed for this in-patient stay (reference issue 1).

03/05/2016 @ 35^{+3}:

12.30hrs presented to the MAU with "pains 1:5". A CTG was commenced (pg 285a). There was a drop in baseline @ 13.58hrs, the CTG was continued until 14.30hrs when it was signed off by the Obs Reg and "satisfactory overall" (pg 114).

The woman's vital signs were plotted at 12.35hrs on an Irish Maternity Early Warning

System –IMEWS (pg 92).The diastolic blood pressure (BP) 92mmHg was in the yellow zone. Repeat IMEWS was not done until 15.00hrs; again a yellow trigger for diastolic BP of 91 mmHg was not escalated (reference issue 2).There is no documentation to support the Midwife's entry @ 22.10 hrs. "IMEWS = 0" (pg 115).

22.40 hrs. The woman complained of no fetal movement and she was appropriately brought to the Labour Ward for a CTG. IMEWS triggers 1 yellow and 1 red zone and appropriate call for Obstetric review. There were no further IMEWS entries for the remaining stay in the Labour Ward, although a recheck BP was recorded at 125/76 @22.50hrs (pg 116). She returned to the ward after Obs. Reg. review @ 22.54hrs.

23.10hrs. 16 minutes after returning to the ward the women notified staff of a spontaneous rupture of membranes (SROM) "meconium 1 noted". She was returned to the Labour Ward in a timely fashion. The maternal pulse was documented as high - 122bpm @ 23.14 (pg 116). The woman was noted to be anxious at this time, reassurances were given and the maternal pulse returned to 102bpm (pg 117). The maternal temperature was not recorded at this time, as would be indicated by the maternal tachycardia, to out rule pyrexia, an indicator for sepsis (reference issue 2). A full record of maternal vital signs 34 minutes previously noted.

An abdominal palpation was not documented to determine how many fifths palpable the head was abdominally. There was no vaginal examination performed at this time, gestation of 35^{+3} noted. An IV cannula was not sited at this time, as would be best practice in a woman with SROM, preterm and known polyhydramnios, in view of the risk of cord prolapse (reference issue 3).The accompanying Midwife commenced the CTG, informed the shift leader and an Obs review was anticipated. Large volumes of liquor were draining and the Obs. Reg. was informed @ 23.39hrs.

The CTG commenced @ 23.15hrs has periods of loss of contact (pg 284 b & c).It appears the woman was standing out of bed at this time, she was appropriately returned to bed and the contact improved. I would question the entry "CTG reassuring" (pg 117) as it is difficult to determine the baseline at this time.

In my opinion from 23.43hrs the baseline rate was 150bpm, variability > 5, no accelerations and subtle late decelerations slow to recover followed by a bradycardia recovering to baseline @ 00.20hrs. Uterine activity appears to be recorded on the CTG."Tightenings 2:10 mins short on palpation" documented by Midwife on retrospective note (pg 121). Fetal movements appear to be recorded on the CTG. The maternal pulse recorded on the CTG fluctuates from 80-120bpm. CTG from 00.20hrs to delivery decision time @ 01.00hrs baseline 150-155bpm with period of increased variability @ 00.52hrs followed by a prolonged deceleration @ 00.56hrs. Whilst acknowledging Midwifery staff concerns over the CTG particularly around the decelerations @ 00.15hrs and 00.56hrs with appropriate call for Obstetric Registrar review, there appears to be a delayed recognition of a pathological CTG (reference issue 4).

Intravenous access, fluids or taking of bloods was not initiated until requested @ 00.20hrs. Bloods were reserved @ 00.49hrs and IV fluids commenced @ 00.58hrs. As the Dr. was phoned to do this I must assume the Midwives do not cannulate.
The decision for delivery by emergency Caesarean Section was made at 01.00hrs. The category was not classified as recommended by RCOG Guidelines. This can have implications for Midwives using ISBAR although a decision to delivery interval of 30 minutes was achieved. There was a timely transfer to portable CTG and transfer to

theatre. Entries @ 00.15hrs (pg 119) and retrospectively @ 00.20 hrs. (pg 120) capture some of the activity elsewhere in the unit.

The use of Ante natal proforma CTG stickers capturing NICE guidelines for CTG interpretation was used once for the latter admission to the Labour Ward. It was entered retrospectively, understandably due to events in progress. The time on it is 01.30hrs and I would query if this is an error (pg 121)

The post natal period, whilst traumatic for the women did not present any concerns about Midwifery care.

The documentation of care overall was very good with contemporaneous, narrative entries individualised, descriptive and unambiguous. The care provider's sheet (pg 11) was filled in by only 2 staff members providing sample signatures, both Midwives (reference issue 6).

Baby

Baby boy born by emergency Caesarean Section 04/05/2016 at 01.30hrs. Weight 2255g. Gestation 35^{+4}. Apgar score 2@ 1 min. 2 @ 5 mins. 2@ 10mins. 3 @15mins.

There is poor Midwifery documentation of the initial resuscitation (pg 123 mother's record) and no Midwifery input in baby's records (pg 19).Nursing entry on page 188 noted. A heart rate < 60bpm correctly prompts chest compression which initially were performed by the Midwife then the Paediatric SHO took over (pg 123 mother's records.) There is no documented evidence to support MRSOPA as gold standard in AHA NRP Guidelines (reference issue 7).

Best practice would dictate for optimal interpretation paired cord gas samples should be processed without delay. The delivery time was 01.30hrs.

- 02.06hrs Venous cord pH 7.336 Base Excess -1.3
- 03.12hrs Arterial cord pH 7.250 Base Excess – 6.0
- "Rapid system" printouts for these are available to view on page 14 of the baby's record.

The 1st two arterial samples clotted (pg 192 mother's record).

Cord gas results are documented on page 19 of the baby's record.

It would be usual practice to process paired cord samples on the same blood gas analyser. The systems ID on the printouts are different. This leads one to query if they were processed on different machines. Was the time on the machine correct? Do the blood gas analyser machines undergo a regular Quality Control process? (Reference issue 8).

Queries

1. From what gestation are CTG's performed in this hospital.
2. Who has the responsibility to follow up on the results of blood tests ordered from the Antenatal Clinic?
3. Who has the responsibility to follow up on referrals to an extern hospital?
4. Is there a local policy regarding the processing of cord blood samples?

Issues

1. Incomplete documentation.
2. IMEWS escalation pathway not followed.
3. Delay in Intravenous cannulation.
4. Delayed recognition of a pathological CTG.
5. Incomplete documentation.
6. Documentation surrounding neonatal resuscitation.
7. Cord gas analysis.

Recommendations

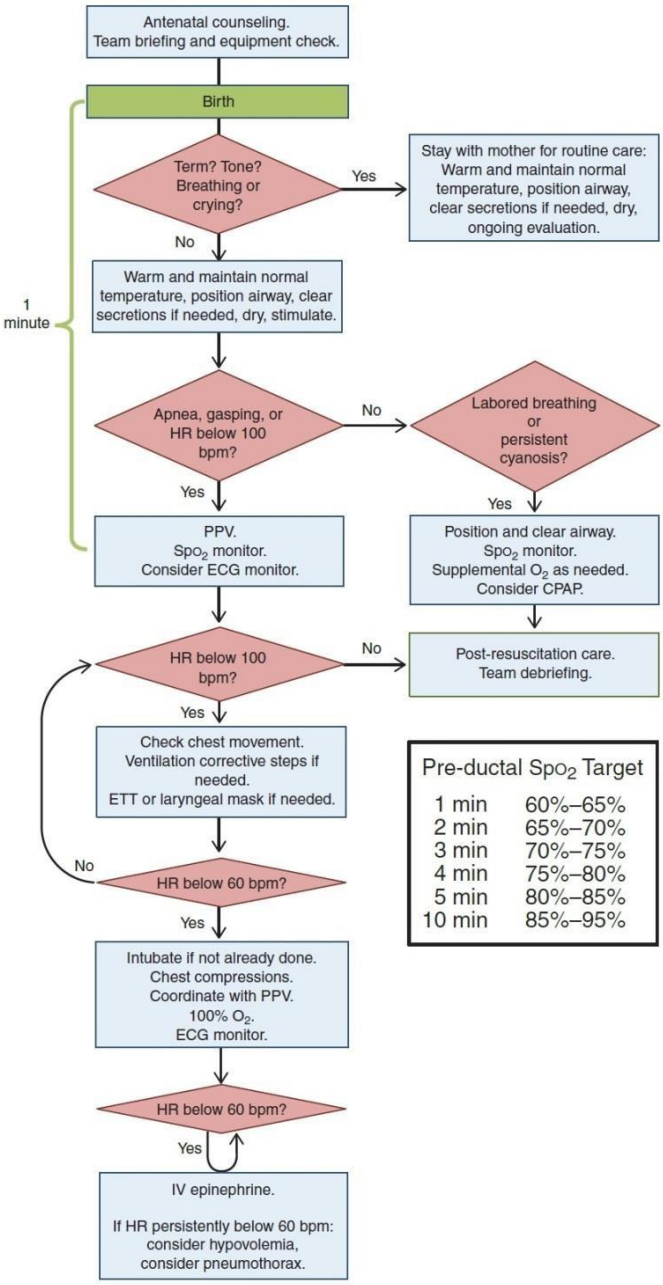
1. Ensure Antenatal Observation Record is completed for every in-patient stay.
2. Adhere to IMEWS escalation guideline.
3. Consider extended practice. Peripheral intravenous cannulation in a timely manner can enhance service provision.
4. Ensure all Midwifery staff keep up to date with CTG interpretation by undertaking relevant continuing professional development.
5. Endeavour to have all Care Providers provide sample signatures on the Identification sheet.
6. Develop a joint Paediatric/ Midwifery neonatal resuscitation record sheet.
7. Develop a guideline regarding the processing of cord blood, if not already in place.

There is evidence to suggest that it may be worth considering when SROM occurs in women at risk of cord prolapse, a full assessment could incorporate abdominal palpation including fifths of the head palpable and possibly vaginal examination (depending on gestation of pregnancy and seniority of Midwife). This is a consideration more for policy makers.

Appendix F: K2 (CTG) Training Records for Maternity Staff and Blood Gas Training Log in Hospital

K2 (CTG) Training Records for Maternity Staff and Blood Gas Training Log in Hospital S1													
Name	***Intrapartum Cardio tocography***	***Antepartum Haemorrhage***	***Postpartum Haemorrhage***	***Uterine Rupture***	***Acid Base and Fetal Physiology***	***Errors & Limitations in Fetal Monitoring***	***Pre-eclampsia***	***Cord Presentation & Prolapse***	***Breech***	***Maternal Collapse***	***Shoulder Dystocia***	***Non-Stress Test***	***Cord Blood Gas***
Cons Obs B	19/04/2015		10/04/2015	10/04/2015	14/04/2015	19/04/2015	13/04/2015						
Midwife M2	28/04/2015	28/04/2015	10/11/2015	10/11/2015	28/04/2015	28/04/2015	28/04/2015	10/11/2015	10/11/2015	10/11/2015	10/11/2015	28/04/2015	
Midwife M1	05/10/2015	11/05/2015		15/11/2015	11/05/2015			16/05/2015	17/09/2015	07/09/2015			
Midwife Shift Leader M3	22/04/2015							03/02/2016		03/02/2016		03/02/2016	
Midwife M7	16/09/2015	16/09/2015			21/04/2015	17/08/2015		16/09/2015	16/09/2015		16/09/2015	16/09/2015	
Midwife M8	01/11/2015	05/10/2015	24/10/2015	29/12/2015	04/05/2015	05/10/2015	10/11/2015	07/01/2016	07/01/2016	02/11/2015	07/01/2016	29/12/2015	
Midwife M6	05/02/2015 & 10/05/2016				05/02/2015 & 17/05/2016								05/02/2015

Appendix G: NRP Resuscitation Algorithm



Appendix H: Report for the National Lead for Medical Devices

Deirdre O Keeffe

Quality & Safety Manager,
Quality Improvement Division,
2nd Floor, HSE Offices,
Model Business Park,
Model Farm Road,
Cork

8th May 2018

Dear Deirdre,
You requested on the 2nd March 2018, on behalf of the incident review team, the following information with respect to the two Siemens Blood Gas Analyser machines located in Hospital S1;

1. The calibration history of the two Blood Gas Analyser (BGA) machines located in Hospital S1 on May the 4th 2016
2. Explore the possibility that the time was incorrectly set up on the machine used to analyse the arterial sample on May the 4th 2016
3. Advise you on what best practice should be in relation to the calibration of cord blood gas machines.

Item 1

The calibration history of the BGA machines located in Hospital S1 on May the 4th 2016

There are 2 x Siemens BGA located in Hospital S1

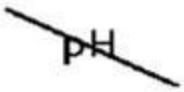
1. Model : RL1240 s/n: 18080 (located in the Labour ward)
2. Model : RL1240 s/n: 18225 (located in the Labour ward)

I contacted the BGA service support manager ,(XX) in order to establish the calibration history of both machines.

From the information I received from Cruinn, both of these BGA's conduct an Automatic Quality Control (AQC) test each day. The activation time each day, in which these AQC checks are conducted, are decided on by hospital department manager and the (AQC) program is then programmed by the Cruinn engineer to reflect this requirement. When the AQC is completed the BGA's automatically sends the results to a QC database via the RapidComm (RComm) Link to the Lab information system (LIS), so the details of the QC results on the 4th May can be retrieved from the Hospital S1 Laboratory Information system (LIS). There are three levels of AQC tests conducted (Level 1, 2 & 3 which are high range, mid range and low range measurements). The range of the parameter tests conducted are as follows;

Parameter	Units	Reporting Range	Resolution
pH	pH	6.000–8.000	0.001
H^+	nmol/L	10.0–1000.0	0.1
pCO_2	mmHg	5.0–250.0	0.1
	kPa	0.67–33.33	0.01
pO_2	mmHg	0–800	0.1
	kPa	0.0–106.67	0.01
pAtm	mmHg	523–800	1
	kPa	69.7–106.6	0.1

Note: in the event that a parameter calibration fails, that parameter will not be available for the test and is highlighted on the analyser screen , example shown below.



Parameter is not available for analysis because the sensor has failed calibration.

Parameter has failed successive calibrations and is unlikely to become available with further calibrations until corrective action is taken.

Parameter is not available for analysis because the parameter failed Required QC or AutomaticQC analysis (the button is yellow).

Parameter is not available for analysis because Required QC was not performed when scheduled (the button is purple).

A calibration check is also conducted by the service engineer as part of the routine service/preventative maintenance checks every 12 months. The details of when these QC checks were carried out in 2016 are as follows;

The calibration of the 2 x RL1240
calibration history for **RL1240 s/n: 18225** on the 8th Feb2016
for calibration history for **RL1240 s/n: 18080** on the 25TH April 2016
for calibration history for **RL1240 s/n: 18080** on the 23rd Aug 2016

With respect to the service/reliability history of the both BGA 's , the service log does not report any corrective maintenance requirements/events during 2016 or a requirement for parameter electrodes to be replaced. Both machines had 100% reliability during 2016.

Routine Service History record

A software upgrade was conducted on the **RL1240 s/n: 18080** on the 25th April 2016 (see record attached to this report)

An annual preventative maintenance check was carried out on **RL1240 s/n: 18080** on the 23rd August 2016 (see record attached to this report)

An annual preventative maintenance check was carried out on **RL1240 s/n: 18225** on the 8th Feb 2016 (see record attached to this report)

A software upgrade was conducted on the **RL1240 s/n: 18225** on the 25th April 2016 (see record attached to this report)

Item 2

Explore the possibility that time was incorrectly set up on the machine used to analyse the arterial sample on May the 4th 2016

I asked Cruinn the following question;

Question

What assurance is provided that the time of day clock is correct on the BGA, in other words how do we know the time on the machine is correct?

Answer

The RL1240 BGA analysers in Hospital S1 are both connected to the Siemens Rapidcomm data manger (on portbackup server 10.168.5.2) and the time on the analysers are synchronised with the server.
The details of the process is as follows;
Set Time (RAPIDPoint 400/405, RAPIDPoint 500, and RAPIDLab 1200 series systems).
Time sent to the BGA's is RAPIDComm server time, which is a windows based embedded operating system.

From the LIS spec:

Time Synchronization Request
The LIS sends a time synchronization request to synchronize the time setting of local systems with the time setting of the LIS. The LIS sends the following message:
Time synchronization request: {CTL_TIME_SET} {aMOD, iIID, aDATE, aTIME}
The aDATE value is in ddMmmYYYY format. The aTIME value is in hh:mm:ss format.
The local system synchronizes its time setting without sending a response to the LIS.
If the local system is currently displaying the Date and Time Setup screen, the LIS command is ignored, and the command is not implemented.
Date/Time Transaction
To determine the local system date and time, the LIS initiates a date/time transaction:
Request time: {TIME_REQ}{aMOD, iIID}
The system responds by sending a data record containing the name and value of the variables aDATE and aTIME:
System time: {TIME_DATA}{aMOD, iIID, aDATE, aTIME}

In conclusion

The time of day displayed on the BGAs and on the test results will always be correct as it synchronised with the server clock and the LIS system

Item 3

Advise you on what best practice should be in relation to the calibration of cord blood gas machines.

Both of these BGA's conduct an Automatic Quality Control (AQC) test each day. The activation time each day in which these AQC checks are conduced are decided on by hospital department manager and the (AQC) program is then programmed by the Cruinn engineer to reflect this requirement. When the AQC is completed the BGA's automatically sends the results to a QC database via the RapidComm (RComm) Link to the Lab information system (LIS), so the details of the QC results can be retrieved from the Hospital S1 Laboratory Information system (LIS).

It is my understanding that Hospital S1 also partakes in an external QC scheme to provide further assurance that the BGA's are functioning correctly. The details of this external QC scheme can be sourced from the Hospital S1 laboratory dept directly.

Regards

Appendix I: Referral Process in place for transferring to Hospital S2

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Re: **Referral policy**

Dear [redacted]

The process for referring patients for fetal medicine advice has changed over time.

The current process is somewhat different from what has been in place in the past therefore it is a little difficult for me to be exact about previous processes. Processes change in order to facilitate service availability.

Since December 2017 anatomy scanning has been carried out at [redacted] I suggest that the algorithm for management from that service is passed on to whoever is looking for the information. In summary all women who book at this hospital are offered an anatomy scan. Should the Sonographer have any concerns regarding the findings at the time of the ultrasound scan these findings are discussed with the Consultant whom the patient is booked. If that Consultant is not available the problem will be discussed with the on call Consultant. It is the Consultant's responsibility to decide whether or not a referral to a tertiary referral centre is required.

From the antenatal clinic should a Consultant decide that there is a significant abnormality that requires a second opinion there is a high risk referral form available. A copy of this form is attached. This form is referred to the high risk clinic at the [redacted] The [redacted] will contact the patient and arrange appointment.

Should a Consultant have a situation that is concerning and where a second opinion is required urgently the Consultant contacts the service at The [redacted] directly.

In very exceptional circumstances the Fetal Medicine services at [redacted] The other large Maternity units. are asked to provide service. The main reason for request for Fetal Medicine service from these hospitals would be to facilitate a patient request. Should anybody wish for any further information please do not hesitate to contact me.

Yours sincerely,

[redacted]

Appendix J Referral form

HIGH RISK EXTERNAL REFERRAL FORM

[redacted] FETAL MEDICINE
[redacted] UNIVERSITY HOSPITAL
Email highriskus@coombe.ie

Office use only
Please place patient's ID label here
Appointment date:
Clinic Code:

DATE OF REFERRAL _____

From : [redacted]

Please PRINT patient details below.

NAME			
ADDRESS			
DOB		CONTACT NO.	
EDD (SCAN)		GESTATION(WKS)	

Please detail reason for Ultrasound request.

Referring Consultant details

NAME	
CONTACT NO	

Please email this referral to: highriskus@[redacted]

Appendix K: NATIONAL CLINICAL PROGRAMME FOR PAEDIATRICS & NEONATOLOGY: MODEL OF CARE FOR NEONATAL SERVICES IN IRELAND

Model of Care

The primary aim of this model of care is to describe the services that should be provided at each level of neonatal unit nationally to inform future service planning and developments, and to eliminate duplication and fragmentation of services.

Neonatal Services in a Level 1 (Local) Unit A local level 1 hospital should provide routine neonatal care to term infants, as follows:

1. The unit should be staffed by consultant general paediatricians who undertake routine newborn care as part of their duties and on-call roster
2. The unit should provide 24/7 cover to the labour ward and operative deliveries
3. There must be established arrangements for prompt, safe and effective resuscitation of babies after birth
4. The unit should provide routine and special care to infants ≥32 weeks gestation onwards. Infants of 30-31 weeks gestation can be cared for in Level 1 units if the appropriate staffing complement is available, i.e. *1:2 high dependency nursing ratios, middle grade and consultant staff.*
5. Infants ≤32 weeks gestation should usually be transferred to a regional or tertiary unit, preferably in-utero – if this is not possible the infant will be transferred after birth by the NNTP if possible
6. Routine care comprises the newborn examination and management of common conditions such as neonatal jaundice
7. Special care should care for infants who are borderline pre-term and require tube feeding, and manage term infants with transient tachypnoea of the newborn
8. Incubator care, monitoring of vital signs, blood pressure and blood gases, venous access, portable x-ray service, and short term ventilation for stabilisation prior to the arrival of the NNTP should all be available
9. The unit should accept retro-transfers from tertiary units when the baby is off CPAP, tolerating feeds and off parenteral nutrition, and usually greater than 1500g in weight
10. There should be access to health and social care professional (HSCP) services – dietetics, pharmacy, physiotherapy, social work, speech and language therapy and occupational therapy

Neonatal Services in a Level 3 (Tertiary) Unit

The primary function of tertiary neonatal units is to provide specialised care to infants who are critically unwell. Most of the workload is concentrated on very preterm infants, unwell term infants, and infants with major congenital malformation. Tertiary care is about the activity, not the place. It is a facility where healthcare professionals have the necessary knowledge, training and experience to deliver intensive care to small infants. Neonatal intensive care requires a high level of attention to detail and the accurate recording of a large bank of physiological data about each infant. Good teamwork is essential, emergencies will occur frequently and doctors and nurses must be able to respond quickly and decisively. There must be a culture of teaching and training, situation awareness and valuing staff. The turnover in tertiary NICUs is high, ranging from 100% for NCHDs to approximately 10% for nursing and HSCPs, and units must be proactive in recognising and addressing this as succession planning, and upskilling new staff will be a constant challenge. Level 3 units should meet the following criteria:

1. The unit should be able to provide the full spectrum of specialised care to critically ill pre-term and term newborn infants
2. There should be sufficient clinical throughput to maintain clinical skills and expertise, with a minimum of 100 infants BW The unit should be able to provide therapeutic cooling The unit should provide parenteral nutrition
3. The unit should be staffed by professionals with the necessary neonatal knowledge, training and experience to undertake complex newborn care, with all professionals clear about their role
4. There must be consultant neonatologist daily presence and on-call cover 24/7, and a separate neonatal on-call roster
5. There should be two grades of trainee neonatal staff at registrar and SHO level in either SpR or BST training schemes
6. The unit should be staffed by skilled neonatal nurses, and it is recommended that at least 70% of nurses should have a neonatal qualification
7. There should be daily paediatric radiology services, with out of hours cover for emergencies
8. There should be consultant microbiologist support with ward round attendance
9. The unit should be staffed by HSCPs with an interest in neonatology, including clinical psychology, dietetics, pharmacy, physiotherapy, social work, speech and language therapy, occupational therapy, and radiographers trained in paediatric diagnostic imaging Clinical engineers should be available daily and out of hours
10. There should be high quality data collection on short- and long-term neonatal outcomes, and units should be members of the Vermont-Oxford collaborative with high quality neurodevelopmental follow-up including a Bayley's developmental assessment profile and early intervention HSCP assessment following discharge to ensure timely intervention received

There should be a standardised approach to care and treatment with algorithms and guidelines available for common neonatal conditions Tertiary centres must coordinate the retinopathy of prematurity (ROP) screening service. Most infants requiring ROP screening will be cared for in tertiary centres. If an infant is transferred to a local or regional unit, or to a paediatric intensive care unit, it is imperative that arrangements for screening are in place. ROP screening can be difficult to coordinate operationally; a recent UK study found that 37.7% of infants were not screened within the optimal time frame.

Appendix L: Framework of Contributory Factors

Sub-Components Underpinning the Framework of Contributory Factors Influencing Practice

- **Patient components**

Contributory factor	Taxonomic components
Condition	Complexity Seriousness
Personal	Personality Language External support Social and family circumstances Disability
Treatment	Know risks associated with treatment
History	Medical Personal Emotional
Staff-patient relationship	Good working relationship

- **Task components**

Contributory factor	Taxonomic components
Availability and use of policies, procedures and guidelines	Procedure for reviewing and updating protocols Availability of protocols to staff Use of protocols Availability of specific types of policies, procedures and guidelines Quality of information included in the policies, procedures and guidelines Accident and incident investigation procedures
Availability and accuracy of test results	Tests done? Disagreements regarding the interpretation of the test results Need to chase up test results
Decision making aids	The availability, use and reliability of specific types of equipment e.g. CTG The availability, use and reliability of specific types of tests (i.e. blood tests) The availability and use of senior clinicians / managers
Task design	Can a specific task be completed by a trained member of staff in adequate time and correctly

- **Individual (staff) components**

Contributory factor	Taxonomic components
Competence	Verification of qualifications Verifications of skills and knowledge
Skills and knowledge	As Above
Physical and mental stressors	Motivation Mental stressors (e.g. the effects of workload, sickness, etc on the individual mental state) Physical stressors (e.g. the effects of workload etc on the individuals physical health)

- **Team components**

Contributory Factors	Taxonomic Components
Verbal communication	Communication between junior and senior staff Communication between professions Communication outside the ward / department, etc Adequate hand over Communication between staff and patient Communication between specialities and departments Communication between staff of the same grade Voicing disagreements and concerns Communication between staff and visitors / patients / relatives / carers
Written communication	Incomplete absent information (i.e. test results) Discrepancies in the notes Inadequately flagged notes Legibility and signatures of records Adequate management plan Availability of records Quality of information in the notes
Supervision and seeking help	Availability of senior staff Responsiveness of senior staff Willingness of junior staff to seek help Responsiveness of junior staff Availability of junior staff
Congruence / consistency	Similar definition of tasks between professions Similar definition of tasks between different grades of staff Similar definition of tasks between same grade of staff
Leadership and responsibility	Effective leadership Clear definitions of responsibility
Staff colleagues response to incidents	Support by peers after incident Support by staff of comparable grades across professions e.g. senior nurse and junior Doctor.

- **Work environment components**

Contributory factor	Components
Administration	Ease of running and review of general administration systems Notes handling
Building an	Maintenance management Functionality (ergonomic assessment e.g. lighting, space, etc)
Environment	Housekeeping Control of physical environment Movement of patients, staff, and visitors between wards or sites
Equipment / supplies	Malfunction / failure / reliability Unavailability Maintenance management Functionality (e.g. ergonomics design, fail-safe, standardisation)
Staffing	(Un)availability
Education and training	Induction Management's influence on training Process Refresher training Provision of training (in general)
Workload / hours or work	Regular rest breaks Optimal workload (neither too high or too low) Involved in non job related duties
Time factors	Delays

- **Organisational and management factors components**

ontributory Factor	Components
Organisational Structure	Hierarchical arrangement of staff Span of control Levels of decision making
Policy, standards and goals	Mission statement and objectives Management arrangements (Functions) Contract services Human resources Financial resources / constraints Information services Maintenance management Task design Education and training policy Policies, procedures and guidelines Facilities and equipment Risk Management (e.g. incident reporting, investigation and analysis Health and safety management (Fire safety, waste management, infection control and occupational health Quality improvement
Risks imported / exported	
Safety culture	Is invoked by other organisational processes and management factors: Attitude to work, safety and others in the workplace Provision of support mechanisms by management for all staff
Financial Resources and constraints	

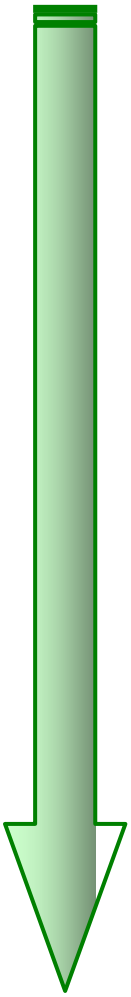
7. Institutional Context

Including:

- Economic and Regulatory Context
- Department of Health and Children
- Health and Information Quality Authority
- Health and Safety Authority
- Clinical Indemnity Scheme
- Links with external organisations

Appendix M: Hierarchy of Hazard Controls

Table 2: Hierarchy of Hazard Controls to support the development of recommendations

Strength of control	Category of control	Comments/Examples
Strongest control  Weakest control	Elimination	The work process or task is redesigned so as to remove the hazard/contributory factor. However, the alternative method should not lead to a less acceptable or less effective process e.g. stop providing service; discontinue a particular procedure; discontinue use of a particular product or service, e.g. stop using a particular type of equipment. *If hazard elimination is not successful or practical, the next control measure is Substitution.*
	Substitution	Replacing the material or process with a less harmful one. Re-engineer a process to reduce potential for 'human error'. *If no suitable practical replacement is available the next control measure is engineering controls*.
	Engineering controls	Installing or using additional equipment. Introduce 'hard' engineering controls, e.g. installation of handling devices for moving and handling people and objects, e.g. Re-engineer equipment so that it is impossible to make errors. *If no suitable engineering control is available the next control measure is administrative procedures.*
	Administrative procedures	Ensure that administrative policies, procedures and guidelines are in place. Ensure staff are appropriately trained in these. Monitor compliance with policies, procedures and guidance through audit. *If no administrative procedure is available the next control measure is work practice controls.*
	Work Practice Controls	This is the last control measure to be considered. Change the behaviour of staff, e.g. make staff wear personal protective equipment, etc. *Work Practice Controls should only be considered after all the previous measures have been considered and found to be impractical or unsuccessful.*

Appendix N: Update from Hospital S1 on recommendations

1. That a formal and agreed policy and procedure for the communication of information between the Obstetrician Gynaecology Consultant staff related to patients seen in the Antenatal Clinic and referred for admission to the Maternity Department is developed and implemented within 3 months of this report being finalised and that monitoring of the implementation of the procedure is incorporated into the routine audit schedule of the Department.

   The Guideline or pathway needs to be formalised by the Maternity Governance Committee.

2. Remind all Health Care Practitioners of HIQA standards, HSE policies and procedures and guidelines regarding communication, standards of the regulatory bodies such as the Irish Medical Council and the Nursing & Midwifery Board of Ireland. The Hospital Management must decide, in conjunction with the lead clinicians and Director of Midwifery, if retraining is required; what needs to be audited; how often and what sanctions may be considered in light of further breaches and how is that communicated to staff. Implement within 6 months of this report being finalised.

   Communication guidelines and escalation policies are in place. Communication policies and procedures are incorporated into the induction and ongoing continuous professional development programmes of midwifery and medical staff. Non adherence to regulatory guidance standards is a matter for each practitioner and their line manager. Performance and disciplinary procedure applies where non-compliance arises.

3. Full implementation of the; - NCEC Clinical Handover Guideline in Maternity Services and the; - Irish Maternity Early Warning System (IMEWS), which contain the communications tool ISBAR (identify, situation, background, assessment and recommendation); - and the Patient Safety Pause, and checklists such as those published by the World Health Organization (WHO) in surgery and childbirth.

   and audit within 3 months of this report being finalised and follow-up on audit findings.
   The department provides ongoing education of existing and new staff in relation all national clinical guidelines pertinent to maternity care which includes ISBAR, IMEWS, Clinical Handover Guideline. The Patient Safety Pause has been implemented. A clinical audit facilitator has been appointed recently to support clinical audit.

4. Hospital S1 as a priority must work with the Hospital Group to ensure all pregnant women have access to a fetal anomaly scan should the wish to avail of one. This recommendation must be communicated to the NWIP (National Women's and Infants Programme) in terms of available funding (if funding is required).

   An Anatomy ultrasound service is in place at Hospital S1 since December 2017. A second ultra-sonographer is currently undertaking a MSc in Ultrasound and training in Hospital S2.

5. That the HSE's National Acute Hospitals Division confirm CTG training as a mandatory training requirement for all Obstetrics and Gynaecology Medical Staff and Midwives. The frequency of this

training is to be established in accordance with best practice. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Mandatory K2 training is in place in Hospital S1 annually for all staff. In addition, CTG study day attendance is mandatory for all midwifery and medical staff bi-annually. A training database is in place and monitored.

6. That Hospital S1 conduct an audit of compliance with the guideline Mandatory K2 Fetal Monitoring Training (PHOG019) including the requirement to participate in and complete CTG training in a given twelve-month period. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner and non-compliance is to be addressed within 3 months of the audit.

   Mandatory K2 training in place annually for all obstetric and midwifery staff. In addition, CTG study day attendance for all midwifery and medical staff bi-annually. A training data base is in place and monitored. This will be included in the hospital's audit programme.

7. That systems and processes are established, up to and including the disciplinary process, within each National Division to ensure compliance with mandatory training. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

   National Divisions and the National Women and Infants Health Programme will need to advise on implementation of this recommendation. Mandatory K2 training is in place in Hospital S1 for all obstetric and midwifery staff.

8. Develop a hospital group networked maternity/neonatal referral guidelines and patient pathways which must include criteria to ensure equitable access to the service based on clinical need across the hospital group. This is a national requirement. There is a need for each Hospital Group to have to develop separate pathways especially when most traffic is to one of the 3 Dublin maternities whether for fetomaternal consultation or neonatal consultation. There is a need to specifically address urgent referrals such as in Mrs X's case during the out of hours (a Friday afternoon of a bank holiday weekend and during nights). Implement within 6 months of this report being finalised.

   Hospital S1 has an existing pathway for referral which is Consultant to Consultant referral to the receiving tertiary hospital for Maternal and/or Neonatal opinion and/or transfer of care.
   The pathway for referral for ultrasound and fetal medicine opinion within the hospital group is by referral form directly to Hospital S2. In the event that the clinician has significant clinical concerns this referral form is followed up by a phone call directly to a fetal medicine expert in Hospital S2 to discuss concerns and expedite an appointment for an opinion. The Hospital Group needs to formalise existing referral pathways.

9. As recommended in the National Maternity Strategy Hospital S1 must ensure that multi-disciplinary training takes place at each hospital/unit within their network. This should include at the very least CTG interpretation, NRP, Stable & PROMPT, Communication, Clinical Handover, IMEWS and ISBAR training. The Hospital management in conjunction with the Clinical leads (in Obs and Neo) and Director of Midwifery should;

1) set a standard for frequency of such training in the absence of a nationally agreed one;
2) devolve responsibility/oversight of this to a named person/ group;
3) specify requirement for quarterly training logs of the MDT to be reviewed by the maternity and neonatal service and remedial action to be taken in cases of non- compliance with attending training and/or compliance with the standard of care and communication up to and including invoking of disciplinary process if and when required. Implement within 6 months of this report being finalised.

Multidiscipinary training records are reviewed by line managers and practice development department. Training schedules for mandatory training are in place. STABLE, PROMPT, NRP, IMEWS and ISBAR training has been in place since 2017.

10. Hospital S1 must have in place a Guideline in place for the follow-up of abnormal diagnostic results. This must take cognisance of the appropriateness of the request in line with clinical presentation.

    Test results are followed up by the team ordering the test. Initial discussions have commenced in relation to formalising a guideline.

11. The unit at Hospital S1 should ensure that they have in place, guidelines for the 10-12 most common obstetric complications within 6 months of this report being finalised and that they continue to build on these. These should include both the obstetric and midwife components of care; by way of example - Monitoring of the fetal heart - SROM - SROM with clear liquor in women at term in spontaneous labour with a well engaged fetal head and satisfactory fetal heart rate and no other discernible problems and is not the potential emergency, - meconium stained liquor, - history of significant polyhydramnios and other potential fetal / maternal complication etc.

    The Maternity Guideline committee has developed a comprehensive suite of guidelines (approximately 45 in number) to address the most common obstetric emergencies. The committee has developed the guidelines from a Multidisciplinary perspective and is not limited to the above clinical scenarios.

12. Hospital S1 must have in place a guideline for the management of CORD AND MATERNAL BLOOD SAMPLING and deviations from practice must be reported and managed appropriately. All staff should perform these techniques in accordance with the Hospital Group Standard Infection Prevention guideline. The Acute Hospitals Division should ensure that this recommendation is circulated to all relevant hospital groups for implementation.

    A Cord pH analysis guideline has been completed and published in Q3 2019 and a guideline for venepuncture is in place.

13. Hospital S1 must ensure that 'Debriefing' following a neonatal resuscitation is in place and implemented. There must be a process in place to ensure that critical incident debriefing is made available to all staff involved (including porters where they were involved etc) within 72 hours of a critical incident and that there is a SOP in place to ensure the procurement and provision of same and a means to release all staff involved where at all possible. Lesser events may be dealt with by informal debriefing within unit level but again management of the Unit should have a SOP in place

to ensure that this is routinely offered to all staff members involved irrespective of discipline / rank.

Finally, the Hospital must ensure that it has in place, an Employee Assistance Programme whereby staff members can easily self-refer for free and confidential counselling on a 24/7/365 basis. The HSE HR (local, regional, national) should review the effectiveness of this programme and modify as required, this aspect is particularly important in that? 2 of the staff members interviewed appear to have explained that they no longer work at this unit although the reasons why, do not appear to have been explored or noted as relevant to this Investigation.

A Debriefing service is offered following a critical incident in the maternity department. This is facilitated through the employee assistance and counselling service. This service is automatically arranged by a senior line manager in the event of a critical incident. This service was offered following this incident but unfortunately staff did not avail. Local debrief also took place at the time and takes place in these circumstances to support staff.
Employee assistance and counselling services are advertised across the hospital and form part of the support mechanism.

14. The Unit at S1 must have a policy for call taking. All calls should be logged and reviewed on an ongoing basis by the shift leader so it is known who is expected in and to be able to go back and audit advice given. There should be an agreed SOP to guide and monitor this practice of advice.

A telephone triage tool was introduced in the maternity department as a quality improvement initiative in Q2 2018.

Incidental Finding 1: Failure to Follow-up on an Abnormal Blood Test results and Ultrasound Results

Initial discussions have commenced in relation to this finding at the Maternity Governance Committee. See also Recommendation 10 above - Test results are followed up by the team ordering the test. Initial discussions have commenced in relation to formalising a guideline.

Incidental Finding 2: Delay in Intravenous Cannulation
The development of a suite of guidelines relating to obstetric complications identifies early cannulation as required by clinical presentation. Considerable investment in training and skills development has taken place in the department since 2016 to equip midwives with cannulation and venepuncture skills.

Incidental Finding 3: Incomplete Clinical Assessment
A range of guidelines for common obstetric emergencies have been developed and published in the period Q3 2018 to Q3 2019, this includes Cord Prolapse.

Incidental Finding 4: Confusion Regarding the Processing of Cord Bloods
A Cord pH Analysis guideline has been developed in line with best practice to support staff in the appropriate management of cord pH samples and timing of analysis.

Incidental Finding 5: Absence of a Debrief for Staff

Critical Incident Stress Management (CISM) is facilitated for all staff following a critical incident, in addition to informal debrief provided by line managers. Employee assistance is also available and availed of by staff as required.

See also Recommendation No. 13 above - A Debriefing service is offered following a critical incident in the maternity department. This is facilitated through the employee assistance and counselling service. This service is automatically arranged by a senior line manager in the event of a critical incident. This service was offered following this incident but unfortunately staff did not avail. Local debrief also took place at the time and takes place in these circumstances to support staff. Employee assistance and counselling services are advertised across the hospital and form part of the support mechanism.

Incidental Finding 7: Confusion with terminology
This will be addressed directly by the Clinical Director with the Healthcare Professional involved.

Incidental Finding 8: Telephone Log
As for Recommendation 14 above -A telephone triage tool was introduced as a quality improvement initiative in Q2 2018.

Incidental Finding 9: Responses to Complaint/Concern
All staff are trained and encouraged to deal with complaints locally in order to address the complaint for the patient promptly. Where resolution cannot be reached it is escalated to the relevant line manager and dealt with in tandem through the complaints procedure as necessary.