

Strictly Private and Confidential

HSE Ref: 51227, Case 9a

Final report of an investigation conducted into the circumstances surrounding the care, management and treatment delivered to the patient at the Hospital during the period of her antenatal care from 31st October 2007 to 7th March 2008 the date of the patient's admission to the hospital at 30 weeks gestation.

First Draft Report: November 2016

Investigators: Ms. Deirdre Carey & Ms. Aideen Quigley, Quality & Patient Safety Department, Acute Hospitals Division

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Preface

This report has been prepared following a detailed systematic analysis of the events around the birth of your baby. Your clinical charts and other documentation have been reviewed. All possible key personnel involved at the time of your baby's birth, along with yourselves, were interviewed. The information from the documentation reviews and the interviews was collated and summarised into this systems analysis review report. This report outlines a detailed chronology of the events, key causal factors of the events (if found) and additional incidental findings. In its conclusion, the report has made recommendations to improve practice so that the likelihood of similar adverse events happening again can be reduced where possible.

I would like to unreservedly apologise for failings in the care provided to you and your baby. I am fully committed to implementing the recommendations and will ensure that there is a clear process for the communication of the work that is being undertaken for those who wish to be kept informed.

I would also like to apologise for the prolonged period it has taken to complete this review. I recognise the extreme frustration and additional upset this has caused and I am very sorry for it.

Dr. Pat Nash Chief Clinical Director Saolta University Health Care Group.

Acknowledgement

The investigation team would like to thank the patient and her husband for their participation in this investigation. The willingness of the patient to share her experience was invaluable in allowing this investigation to learn from her experience and in helping to make recommendations to improve the systems and processes in place at the hospital related to the delivery of Maternity Services.

The investigators would also like to thank all of the staff who participated in this investigation for their invaluable contribution to the process.

Glossary of Terms

Term	
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.
AMI	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/
Anoxic	Anoxic - relating to or marked by a severe deficiency of oxygen in tissues or organs (reference: http://www.thefreedictionary.com/anoxic)
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: <u>http://www.webmd.com/a-to-z-guides/antibody- tests</u>)
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. http://www.merriam-webster.com/dictionary/apgar%20score
ΑΡΤΤ	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).
Artificial Rupture of Membranes (ARM)	An artificial rupture of the foetal membranes is usually performed to stimulate or accelerate the onset of labour (reference: http://medical-dictionary.thefreedictionary.com/amniotomy)
Assisted Birth	An assisted birth (sometimes called an instrumental or operative vaginal birth) uses instruments (either forceps or ventouse) that are attached to your baby's head so that s/he can be pulled out (reference: http://www.babycentre.co.uk/pregnancy/labourandbirth/labourcomplications/ assisteddelivery/).
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 wh seems to be sustained into later childhood. (references: Edwards, AD; Brocklehurst, P; Gunn, AJ; Halliday, H; Juszczak, E; Levene, 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 da 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 af hypothermia for neonatal encephalopathy". New England Journal of Medicin 366 (22): 2085–92. Guillet, R; Edwards, AD; Thoresen, M; CoolCap Trial Group (2011). "Seven eight-year follow-up of the CoolCap trial of head cooling for neonatal 	M; ta". ter ne
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 tis injury after moderate hypothermia in neonates with hypoxic-ischaemic encephalopathy: a nested substudy of a randomised controlled trial". Lance neurology 9 (1): 39–45. Robertson, NJ; Nakakeeto, M; Hagmann, C; Cowan, FM; Acolet, D; Iwata, Allen, E; Elbourne, D et al. (2008). "Therapeutic hypothermia for birth	et O;
asphyxia in low-resource settings: a pilot randomised controlled trial". Lan 372 (9641): 801–3.	cet
Baseline Foetal Heart Rate (FHR)Baseline foetal 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 else the baseline is considered indeterminate. In cases where the baseline 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. It the baseline FHR is more than 160 beats per minute, it is termed tachycard	f dia.
Baseline FHR Variability Baseline FHR variability is based on visual assessment and excludes sinusor patterns. Variability is defined as fluctuations in the FHR baseline of 2 cycle 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 base FHR in association with a uterine contraction, with the time from onset of th 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 to the auterine contraction, with the time from onset of the deceleration to 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. T 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 lasts less than 2 minutes from onset to return to baseline. When variable	es eline che ned tion its ent f he
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 Commo Language When Describing Electronic Fetal Monitoring. Rev Obstet Gyneco 2008 Spring; 1(2): 56-60 (Available from: http://medical- dictionary.thefreedictionary.com/premature+labor). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).	

BP	Blood Pressure
BPD	Biparietal diameter, the diameter of the fetal head as measured from one
DFD	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)
Breech	Breech means that the baby is lying bottom first or feet first in the womb
Diecen	(uterus) instead of in the usual head first position. In early pregnancy, breech
	is very common. As pregnancy continues, a baby usually turns naturally into
	the head first position. Between 37 and 42 weeks (term), most babies are
	lying head first ready to be born. Three in every 100 (3%) babies are breech
	at the end of pregnancy (reference: http://www.rcog.org.uk/womens- health/clinical-guidance/breech-baby-end-pregnancy).
C&S	Culture and Sensitivity
Caesarean	There are two types of Caesarean Sections: the classical Caesarean Section,
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 (reference http://www.news-medical.net/health/Cesarean-Section-
	Types.aspx)
Cardiopulmon	Cardiopulmonary resuscitation involves physical interventions to create
ary	artificial circulation through rhythmic pressing on the patient's chest to
Resuscitation	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
Cardiotocogra	In medicine (obstetrics), cardiotocography (CTG) is a technical means of
phy	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
Cephalic	as an electronic fetal monitor (EFM). A cephalic presentation is a situation at childbirth where the foetus is in a
Presentation	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
Conclose	Card Number 73-133179. p. 322–2)
Cerclage	Stitch around the cervix in an attempt to close it and keep it closed to prevent miscarriage or preterm delivery.
Cervix	Neck of the Womb
Chorioamioniti	Chorioamnionitis is a condition that can affect pregnant women. In this
S	condition, bacteria infects the chorion and amnion (the membranes that
	surround the fetus) and the amniotic fluid (in which the fetus floats). This can
CMM	lead to infections in both the mother and fetus.
CMM CNM	Clinical Midwife Manager Clinical Nurse Manager
Coliform(s)	Coliform(s) is a term often applied to a broad group of Gram negative bacilli
	before they are fully identified to species level by the Microbiology laboratory.
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 (Reference: http://www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html).
	State Claims Agency (2009). The State Claims Agency Clinical Indemnity
	Scheme Incident Notification Requirements. Available form

	http://www.stateclaims.ie/ClinicalIndemnityScheme/publications/2009/SCACI
Cord blood Ph	SIncidentNotificationReqs.pdf [accessed 7th March 2013]. A low pH (less than 7.04 to 7.10) means there are higher levels of acids in the
Cora bioda Ph	baby's blood. This might occur when the baby does not get enough oxygen
	during labor (Reference: http://www.plm.pib.gov/modlinoplus/oncy/article/003403.htm)
CRL	http://www.nlm.nih.gov/medlineplus/ency/article/003403.htm). Crown-rump length: The fetal crown rump length (CRL) is defined as the
CRL	longest length excluding the limbs & yolk sac. It is the measurements
	between the top of the head to the area above where the legs
	begin.(reference: http://www.babymed.com/fetus-crown-rump-length-crl-
	measurements-ultrasound).
CRP	C-Reactive Protein, a measure of inflammation
СТG	CTG is a technical means of recording the foetal 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 foetal monitoring: update on definitions, interpretation, and research guidelines Obstet Gynecol (2008) 112:661-666) A 'Normal' CTG is indicated when all four features (foetal heart rate, baseline variability, acceleration and deceleration of the foetal 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, Midland Regional Hospital at Portlaoise: Foetal Heart Monitoring in the Maternity Department. Approval date: April 2011)
сх	Cervix
Cytotec	Cytotec makes the uterus contract and expel the pregnancy tissue (reference:
cytotec	http://www.whcoso.com/index.cfm/fuseaction/site.content/type/index.cfm/fuseaction/site.content/mode/dtl/type/45105/post/61678.cfm)
Doppler	This technique uses reflected sound waves to measure blood flow in different
Sonography	parts of the baby's body. Doppler assessment of the placental circulation
	assists screening for impaired placentation and its complications of pre-eclampsia, intrauterine growth restriction and perinatal
	death.
E. coli	<i>E. coli (Escherichia coli)</i> is one of several types of Gram negative bacilli
	bacteria that normally inhabit the intestine of humans. Some strains of <i>E. coli</i>
	are capable of causing disease under certain conditions.
ECG	Electrocardiogram
EDD	Estimated Date of Delivery
EEG	Electroencephalogram
Electronic	In medicine (obstetrics), cardiotocography (CTG) is a technical means of
Fetal Monitor	recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions
(EFM)	(-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)
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)
Endotracheal	Endotracheal intubation is the insertion of a tube into the trachea for purposes
Intubation	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 (reference : http://medical-
F actor	dictionary.thefreedictionary.com/intubation)
Entenox	Entenox 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)

Epidural	Epidural analgesia is a central nerve blockade technique, which involves the
Analgesia	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 (reference:
	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)
ESBL	Extended-Spectrum Beta-Lactamases ESBL-producing bacteria are bacteria
	that produce enzymes that may break down commonly used antibiotics.
EFW	Estimated Foetal Weight
External	External Cephalic Version is when pressure is put on the tummy to try to turn
Cephalic Version	the baby into a head-down (cephalic) position (reference:
version	http://www.nhs.uk/conditions/pregnancy-and-baby/pages/breech- birth.aspx#close).
FH	Foetal Heart
FHR	Foetal Heart Rate
Foetal	Foetal biometric parameters are various antenatal ultrasound measurements
Biometric	that are used to indirectly assess the growth and well being of the foetus and
Parameters	in assessing dates - gestational age (reference:
	http://radiopaedia.org/articles/fetal-biometric-parameters)
Foetal	An abnormally slow fetal heart rate, usually below 100 beats/min. Ref Mosby's
Bradychardia	Medical Dictionary, 8th edition. © 2009, Elsevier.
Full Blood	Full Blood Count (FBC) is used as a broad screening test to check for such
Count (FBC)	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).
Fetal Scalp	An electrode that is attached to the baby's scalp and connected to the CTG
Electrode	machine so that a trace of the fetal heart can be recorded electronically
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).
Galfer FA	Galfer FA capsules contain two active ingredients, ferrous fumarate and folic
	acid. Ferrous fumarate is a form of iron and folic acid is a member of the B
	group of vitamins.(reference: <u>http://www.netdoctor.co.uk/diet-and-</u> nutrition/medicines/galfer-fa.html#ixzz38IT4hwU0).
GBS	Group-B Streptococcus
GDS Gram negative	Gram negative bacilli are a type of bacteria. The name is derived from a type
bacilli	of staining called Gram staining where these particular bacteria do not retain
	the stain. This is characteristic of bacteria having a cell wall surface more
	complex in chemical composition than the gram-positive bacteria.
GTT	Glucose Tolerance Test
Hartmann's	Solutions of electrolytes are given intravenously, to meet normal fluid and
Solution	electrolyte requirements or to replenish substantial deficits or continuing losses, when the patient is nauseated or vomiting and in unable to take
	adequate amounts by mouth. Hartmann's Solution contains sodium chloride
	0.6%, sodium lactate 0.25%, potassium chloride 0.04%, calcium chloride
	0.027% (reference: British National formulary 2009).
H1N1	Swine influenza virus
Haemoglobin	A conjugated protein, consisting of haem and the protein globin, that gives
(Hb)	red blood cells their characteristic colour. It combines reversibly with oxygen
	and is thus very important in the transportation of oxygen to tissues
	(reference: <u>http://www.thefreedictionary.com/haemoglobin</u>). Low levels of haemoglobin in pregnancy can indicate anaemia (reference:
	http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438&np=459&id
	= 2759 # hae moglobin)

Haemagglutin	Haemagglutination inhibition test is a serologic technique useful in testing for
ation inhibition test	certain unknown soluble antigens. The unknown antigen is mixed with a
Inhibition test	known agglutinin. If a reaction occurs, the agglutinin can no longer adhere to the cells or particles that carry its corresponding antigen, and the unknown
	antigen is thus identified (reference: http://medical-
	dictionary.thefreedictionary.com/agglutination-inhibition+test)
HDU	High Dependency Unit
HR	Heart rate
HSE	Health Service Executive
Нурохіс	Hypoxic Ischemic Encephalopathy has many causes and is essentially the
Ischemic	reduction in the supply of blood or oxygen to a baby's brain before, during, or
Encephalopath	even after birth. It is a major cause of death and disability, occurring in
y · · ·	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.
ICU	Intensive Care Unit
Intermittent	Intermittent auscultation employs listening to foetal heart sounds at periodic
Auscultation	intervals to assess the foetal heart rate (FHR) using either a Pinard
	stethoscope or a hand held (Doppler) devise (reference: Regional Maternity Department MRH Mullingar and MRH Portlaoise Foetal Heart Monitoring in the
	Maternity Department. Approval date: April 2011)
IOL	Induction of Labour is a method of artificially or prematurely stimulating
	childbirth in a woman (Reference: National Collaborating Centre for Women's
	and Children's Health 2008 Clinical Guideline; Induction of Labour RCOG
	Press London)
Iron	Routine iron supplementation is a common practice for preventing iron
supplements	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.
Ischial spines	Ischial spines are two relatively sharp posterior bony projections into the
	pelvic outlet from the ischial bones that form the lower border of the pelvis
	(reference http://medical-dictionary.thefreedictionary.com/ischial+spines).
	The spines are the narrowest part of the pelvis and they are natural
	measuring point for the delivery progress. If the presenting part of the baby
	(the head, shoulder, buttocks or feet) lies above the Ischial spines, the foetal
	position is reported as a negative number from -1 to -5 (each number is a centimetre). If the presenting part lies below the Ischial spines, the station is
	reported as a positive number from $+1$ to $+5$. The baby is said to be
	'engaged' in the pelvis when it is even with the Ischial spines at 0 station
	(reference: http://www.umm.edu/ency/article/002060.htm)
K2 Fetal	K2 Fetal Monitoring Training System is an interactive computer based training
Monitoring	system covering a comprehensive spectrum of learning that can be accessed
Training	over the internet. (Reference:
System	http://www.k2ms.com/products/fetal_monitoring_training_system_online.htm I#2).
Labour	The first stage of labour is the process of reaching full cervical dilatation. This
(stages)	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 deceleration. The second stage is the delivery of the infant. The third
	and deceleration. 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).

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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)
Lithotomy	Lithotomy position in which the patient is on their back with the hips and
Position	knees flexed and the thighs apart. The position is often used for vaginal
	examinations and childbirth (reference:
	http://www.medterms.com/script/main/art.asp?articlekey=25628)
LFTs	Liver Function Tests are used to evaluate how well the liver is working (liver
-	function) (reference:
	http://www.nlm.nih.gov/medlineplus/ency/article/003436.htm).
LMP	Last Menstrual Period
Left	The occiput (back of baby's scull) faces posteriorly (behind) and towards left.
occipitoposterior (LOP)	
Macerated	A macerated stillbirth is defined as having degenerative skin changes as
Stillbirth	recorded by the delivering clinician and is presumed to have occurred 12
	hours or more before delivery. A recent (fresh) stillbirth is defined as having
	no such skin changes and is presumed to have occurred within 12 hours of
	delivery, usually in labour (reference:
	http://journals.lww.com/greenjournal/Fulltext/2011/05000/Determinants_of_
M (Stillbirth_in_Zambia.18.aspx)
Mané	The next morning
МСН	The average amount of hemoglobin in the average red cell. MCH is particularly
	important when testing for anaemia. <u>http://www.babymed.com/laboratory-</u> values/mean-corpuscular-hemoglobin-mch-whole-blood-during-pregnancy)
МСУ	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 foetal
	distress in labour, but not universally so (reference:
	http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf)
Membrane	A membrane (cervical) sweep is a vaginal examination during which a finger is
(Cervical)	used to sweep the neck of the womb to try to separate the membrane from
Sweep	the cervix. This can encourage the body to release a hormone called
	Prostaglandins that work to soften and thin the cervix which might encourage
	labour to start naturally in the next 48 hours (reference:
Meninges	http://nhslocal.nhs.uk/story/features/membrane-sweeps-and-inductions). Meninges are the three membranes that enclose the vertebrate brain and
Renniges	spinal cord: the pia mater, arachnoid, and dura mater (reference:
	http://www.thefreedictionary.com/Meninges).
MOET	Managing Obstetric Emergencies and Trauma
MRSA	Multidrug Resistant <i>Staphylococcus aureus</i>
MSU test	Midstream Urine test
Multigravida	A woman who has 2 or more pregnancies.
NaCl	Sodium Chloride contains sodium chloride 0.9% (reference: British National
	Formulary 2009).
NAD	No Abnormality Detected
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: <u>http://www.medfriendly.com/neutrophil.html</u>
Newborn	Newborn hypoxic-ischaemic brain injury differs from injury in the adult brain

hypoxic-	in several ways: NMDA receptor toxicity is much higher in the immature brain.
ischaemic	Apoptotic mechanisms including activation of caspases, translocation of
brain injury	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.
	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
Nuchal	Nuchal Translucency is the collection of fluid under the skin at the back of the
Translucency	baby's neck. The nuchal is measured using ultrasound when the foetus is
	between 11 weeks and 13 weeks plus six days gestation. All foetuses will have
	some fluid; those with Down's Syndrome have an increased amount
	(reference:
	http://www.bmihealthcare.co.uk/treatment/treatmentsdetail?p_name=1%20-%20Nuchal%20translucency%20scan%20(11-
	13%20weeks)&p_treatment_id=415.
Occiput	The most common position for a baby during labour is head down with the
Posterior	back of the head (occiput) facing the front of the mother (anterior). When the
Position	back of the head is facing the back of the mother (posterior) the baby's
-	position is called Occiput Posterior (reference:
	http://www.birthingnaturally.net/birth/challenges/posterior.html)
0&G	Obstetrics and Gynaecology
O/E	On examination
(O)EWS	(Obstetric) Early Warning Score
Operative	Operative vaginal delivery refers to the application of either forceps or a
vaginal	vacuum device to assist the mother in effecting vaginal delivery of a fetus.
delivery	Ali U and Norwitz E, 2009, Vacuum-Assisted Vaginal Delivery Rev Obstet
	<i>Gynecol.</i> Winter; 2(1): 5–17.
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 nullip's os, for a first pregnancy, or a multip's os for subsequent pregnancies.
	http://www.netdoctor.co.uk/ate/pregnancyandchildbirth/205040.html#ixzz31
	WTIfpx9
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
PCR	Polymerase Chain Reaction
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_peri
	natal/en/
PET	Pre-eclamptic toxaemia (PET) is also called Toxemia of Pregnancy or
	pregnancy induced hypertension. This is a syndrome that develops after the 20th week of pregnancy. It is characterized by:
	•Persistent high blood pressure at or above 140/90mmHg.
	•Edema or swelling of the feet and ankles.
	•Proteinuria or presence of protein in the urine.
	Edema is usually the first sign to occur followed by high blood pressure and
	then by proteinuria. Ref: http://gynaeonline.com/PET.htm

PGE2	Prostaglandin E_2
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)
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 foetal head is the presenting part. Breech presentation: presentation of the foetus during birth in which the upper back part of the foetal 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 foetal 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
Prostaglandin	Any of a group of naturally occurring, chemically related fatty acids that stimulate contractility of the uterine and other smooth muscle (Reference: The Free Dictionary. Available from http:medical-dictionary the free dictionary.com prostaglandin)
РТТ	PTT (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 PTT 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 PTT 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).
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/)
Resuscitated Stillbirth	Resuscitated Stillbirth is where an infant is stillborn and, following active resuscitation, a heart beat is detected, the birth is required to be registered as a livebirth. If the infant subsequently dies up to 28 days of age registration as a neonatal death is necessary (Reference: Perinatal Society of Australian New Zealand (Perinatal Mortality Group) (2009) Clinical Practice Guidelines for Perinatal Mortality. Available from http://www.stillbirthalliance.org.au/doc/Section_1_Version_2.2_April_2009.pd f [accessed 8th March 2013].
SBAR	Situation, Background, Assessment, Recommendation.
Show	A 'show' is the passage of small quantities of blood-tinged mucus from the vagina at the onset of labour (reference: http://medical- dictionary.thefreedictionary.com/premature+labour)
Smear Test	A screening test for precancerous and cancerous cells on the cervix. This simple test is done during a routine pelvic exam and involves scraping cells from the cervix (reference: http://medical- dictionary.thefreedictionary.com/smear+test).
Sonicaid	Hand held ultrasound monitor that is used to detect fetal heart rate

SCBU	Special Care Baby Unit
SpR	Specialist Registrar
SROM	Spontaneous Rupture of Membranes
Stages of Labour	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 deceleration. The second stage is the delivery of the infant . The third stage of labour is the passage of the placenta (reference: <u>http://www.umm.edu/pregnancy/000126.htm#ixzz1x0x7XMI5</u>).
STAT	Medication given immediately as a single dose
Stillbirth	The definition recommended by WHO for international comparison is a baby born with no signs of life at or after 28 weeks' gestation. (http://www.who.int/maternal_child_adolescent/epidemiology/stillbirth/en/)
SVD:	Spontaneous Vaginal Delivery: a vaginal birth occurring without the mechanical assistance of obstetric forceps or vacuum aspirator. (reference Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)
Sweep	A membrane (cervical) sweep is a vaginal examination during which a finger is used to sweep the neck of the womb to try to separate the membrane from the cervix. This can encourage the body to release a hormone called Prostaglandins that work to soften and thin the cervix which might encourage labour to start naturally in the next 48 hours (reference: http://nhslocal.nhs.uk/story/features/membrane-sweeps-and-inductions).
Syntocinon	Syntocinon is administered to induce or augment labour, usually in conjunction with amniotomy (surgical rupture of the foetal membrane to induce labour) (reference British National Formulary 2008).
Syntometrine	An injection of Syntometrine is given in the third stage of labour, just after the birth of the child to facilitate delivery of the placenta and to prevent postpartum hemorrhage by causing smooth muscle tissue in the blood vessel walls to narrow, thereby reducing blood flow. (reference: http://www.netdoctor.co.uk/pregnancy/medicines/syntometrine.html)
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 (reference: http://medical-dictionary.thefreedictionary.com/Systolic+blood+pressure)
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	U&E 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. (reference: 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
UBAC	Unassisted Birth after Caesarean
VE	Vaginal Examination
Ventouse Delivery	An apparatus sometimes used to assist the delivery of a baby, consisting of a cup which is attached to the fetal head by suction, and a chain by which

	traction can be exerted in order to draw out the baby <u>http://dictionary.reference.com/browse/ventouse</u> Ventouse, also known as vacuum-assisted vaginal delivery or vacuum extraction (VE), is a method to assist delivery of a baby using a vacuum device. It is used in the second stage of labour if it has not progressed adequately. It may be an alternative to a forceps delivery and caesarean section. It cannot be used when the baby is in the breech position or for premature births. eMedicine - Vacuum Extraction : Article by John P O'Grady Retrieved March 3 rd 2015 http://emedicine.medscape.com/article/271175-overview Vacca, Aldo (2009). Handbook of Vacuum Extraction in Obstetric Practice, 3rd edition. Vacca Research.
Wessermann Reaction	Wessermann Reaction is diagnostic test for syphilis involving the fixation or inactivation of a complement by an antibody in a blood serum sample (reference: http://www.thefreedictionary.com/Wassermann+reactions)
Vx	Vertex

1.0 Executive Summary

In February 2015, a decision was made to commission a full review of the Maternity Service at this hospital; the decision was made on the basis of a preliminary review that was completed the previous December i.e. December 2014. An integral part of the full review that was commissioned was a review of the care of the women who were the subject of the preliminary review and of a number of other women's cases that were identified following conclusion of the preliminary review.

This is the report of the investigation conducted into the care of one of the affected women referenced above. The investigation examined the circumstances surrounding the care, management and treatment delivered to the woman at the hospital during the period of her antenatal care from 31st October 2007 to 7th March 2008 date of the patient's presentation and admission to the hospital at 30 weeks gestation.

The aim of the investigation was to:

- Undertake a review of the patient's perinatal care (from their presentation for care at the Maternity Unit to their immediate postnatal care). In addition the investigation will include a review of the initial neonatal care provided to the patient's baby. The investigation will focus on:
 - **a.** Establishing the factual circumstances leading up to the adverse perinatal event.
 - **b.** Identifying any key causal factors that may have occurred.
 - **c.** Identifying the contributory factors that led to the key causal factors.
 - **d.** 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 investigation was carried out by:

- Deirdre Carey, Quality Patient Safety, Acute Hospitals Division
- Aideen Quigley, Quality Patient Safety, Acute Hospitals Division

As part of this investigation; independent expert validation of the draft investigation report was sought by the Investigation Team from the Review Team that was established to conduct the full Review of the Maternity Service at the hospital as outlined in the Terms of Reference attached in Appendix 1 of this report.

The purpose of validating the first draft report was to ensure that:

• The investigation was robust, thorough and fair and that it was carried out in line with the requirements of the HSE Guidelines for the Systems Analysis of Incidents (August 2016)

That the findings and recommendations contained in the report that related to clinical issues were appropriate and reasonable and that they were aligned to the relevant clinical standards and practices in place at the time of the events described in the report.

At the time of the events described in this report the patient was a 27 year old woman who had two previous pregnancies. The patient's obstetric history included a previous miscarriage at 10 weeks and a delivery of a baby girl in 2006 by ventouse¹ extraction.

At 23.08hrs on 7th March 2008, the patient presented and was admitted to the labour ward from home at 30 weeks gestation with a history of pressure pains and decreased foetal movement that evening. The patient was assessed and examined. It has been documented the " CTG^2 tracing showed reduced variability³, uterus was tense and sore to touch. There was no PV^4 bleed".

The patient was commenced on oral antibiotics due to signs and symptoms of UTI⁵. The patient was transferred to the floor within the Maternity Unit.

At 01.50 on 8th March 2008, the patient was advised to go to the labour ward as she was having pressure pains and spotting⁶.

At 03:00hours, the patient had a lot of PV bleeding, a scan was carried out and showed there was no fetal heart beat and very sadly confirmed an intrauterine death (IUD).

The patient was taken to theatre for an Emergency Lower Segment Caesarean Section $(LSCS^7)$

A concealed placental abruption⁸ was identified during the Caesarean Section.

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. In this context the Investigation Team sought and was provided

¹ Ventouse, also known as vacuum-assisted vaginal delivery or vacuum extraction (VE), is a method to assist delivery of a baby using a vacuum device. It is used in the second stage of labour if it has not progressed adequately. It may be an alternative to a forceps delivery and caesarean section. It cannot be used when the baby is in the breech position or for premature births.

² 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. (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 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. (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.thefreedictionary.thefreedictionary.com/premature+labor). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).

PV - Per Vaginam (Latin) meaning via/ through the vagina (Reference: Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier) ⁵ Urinary tract infection

 $^{^{6}}$ Staining, streaking or blood spotting noted on underwear or sanitary protection (RCOG 2011c)

⁷ 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. LSCS - 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 (reference http://www.newsmedical.net/health/Cesarean-Section-Types.aspx)

Placental abruption is defined as complete or partial separation of a normally situated placenta, before the delivery of the fetus. (RCOG 2011a) Concealed Placental Abruption: The blood fails to trickle down and collects between the placenta and the uterine wall. The enlarging blood clot further dissects out the placenta from its bed and placental separation can occur over a large area. This is a serious type of placental abruption. (Reference: gynaeonline.com/placental abruption.

with specialist clinical input related to certain clinical/technical issues that arose during the course of the investigation.

The aim of the investigation is to establish the facts in relation to the care and treatment that the patient received by the hospital on her admission on 7th March 2008 and to consider whether any Key Causal Factors were identifiable. Key causal factors are defined as issues that arise in the process of delivering and managing health services which the investigators consider had an effect on the eventual harm.

The investigation identified one Key Causal factor:

Failure to consider and recognise the signs and symptoms of a placental abruption on the patient's admission at 30 weeks gestation and intervene to deliver the baby

In place in Hospital 1 since 2008:

- 1. K2⁹ training implemented at end of 2014
- The following areas of training are mandatory fields for Midwifery staff, Obstetric Consultants and Obstetric NCHD's¹⁰
 - a. CTG
 - b. K2
 - c. PROMPT (Practical Obstetric Multi-Professional Training)
- 3. Polices Procedures and Guidelines (PPPG's) reviewed on an ongoing basis at local meeting attended by midwives and doctors
- 4. Multidisciplinary twice daily safety huddle/pause
- 5. Triggers for escalation clearly identified, such as link Instrumental Deliveries link with Consultant on Call
- 6. A Clinical Midwife Manager2 is rostered 24/7 in the labour ward
- 7. Implementation of clinical hand-over, twice daily in the labour ward and Maternity unit which includes documentation and sign off
- 8. The introduction of the National Maternity Healthcare Record
- Guideline & Procedure for the Management of Antepartum Haemorrhage (APH), Revision No:4, Oct 2015

⁹ Encompassing all the established and award winning content of the K2 Fetal Monitoring Training System, the Perinatal Training Programme is an interactive computer based training system covering a comprehensive spectrum of learning that can be accessed over the internet, anywhere, ¹⁰ Non Consultant Hospital Doctors

This investigation identified the following recommendations:

Recommendation 1

It is recommended that routine audits are undertaken of training records and the results of such audits are subject to review by the relevant governance committee.

Recommendation 2

Ensure that all staff are aware of adhere to the HSE Standards and Recommended Practices for Healthcare Records (2007 amended May 2011). In addition it is recommended that routine audits of compliance with the Standard are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Recommendation 3

It is recommended that routine audits of compliance with the 'Guideline & Procedure for the Management of Antepartum Haemorrhage (APH), Revision No: 4 Oct, 2015' are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

2.0 Methodology

This investigation was undertaken using the methodology for incident investigations outlined in the HSE Guideline for System Analysis Investigation¹¹ of Incidents 2016. This approach is an internationally recognised methodology for investigating adverse incidents in healthcare.

Prior to commencement of the investigation; consent was sought and gained from the patient to allow the Review Team (as outlined in the Terms of Reference for the Review: Appendix 1) to access her healthcare records.

This systems analysis investigation of the patient's case was carried out by the Investigation Team named in this report on behalf of the Review Team.

Details provided in this report have been obtained from a review of the relevant documentation and interviews with the patient and relevant personnel. Timings are based on records and the patient's and staff's recollection(s).

While carrying out this investigation the investigators examined relevant literature and documentation including the following:

- The patient's maternity healthcare record
- Relevant policies, procedures and guidelines
- Relevant literature including Clinical Guidelines and peer reviewed articles (References for the literature referred to in the report including policies, procedures and guidelines are available in Section 10.0 of the report).

In addition interviews were undertaken with staff members involved in the patient's care during the period covered by the scope of the Terms of Reference for the investigation.

A total of 5 people were interviewed as part of the investigation.

Those interviewed included:

- Staff Midwife1 was interviewed on the 29th August 2016
- Staff Midwife2 was interviewed on the 23rd May 2016
- Staff Midwife3 was interviewed on the 23rd May 2016
- Obstetric Registrar was interviewed on the 24th May 2016 & phone interview on 13th
 October 2016
- Consultant Obstetrician was interviewed on the 24th May 2016

¹¹ 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.

The investigation team met with the patient and her husband on 16th May 2016.

The interviews were conducted by the two investigators; 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.

All information gathered during the documentation, literature review and interview stages of the investigation process were treated confidentially. Information gathered was maintained securely.

On completion of the interview and documentation/literature review process a draft report was prepared; 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 correct any erroneous information contained in the report and to enhance the factual accuracy of the information contained in the report.

The patient and her partner were provided with a copy of the Draft Chronology Section of the report for their comments.

The draft report identified recommendations to address those issues which were identified as incidental findings. Feedback was sought to ensure that the recommendations identified were a) specific, b) measurable, c) achievable, d) realistic and e) timely as far as was reasonably practicable.

On this basis the Final Report of the investigation was developed.

Limitations to the investigation:

The investigators acknowledge the length of time that has elapsed since this event. As a result, the only method the staff could recall the sequence of events was solely from the patient's healthcare records.

3.0 Background to the Incident

11th October 2007

The patient, a 27yr old lady was referred by her General Practitioner (GP) to Consultant Obstetrician1's Antenatal Outpatient Clinic at Hospital 1 by a letter of referral. This letter was received by Hospital 1 on 17th October 2007. The letter outlined the following information: Antenatal 1st visit: Antenatal examination: Antenatal care routine Date: 11/10/2007 Last menstrual period (LMP): 06/08/2007 Expected date of delivery (EDD): 11/05/2008 Duration of pregnancy: 9.6 Number of pregnancies: 3 Number of deliveries: 1 Maternity number: Menstrual cycle: normal Hospital: Hospital 1 Blood: taken Weight: 59kg BMI: Systolic blood pressure: 130 Diastolic blood pressure: 69 Fundus (uterus): Urine: negative Comments: Outreach Clinic Site B Medical History: Epilepsy 31st October 2007

The patient attended the Antenatal Outpatient Clinic in Hospital 1. The following has been documented in the patient's healthcare records under <u>ANTE-NATAL RECORD</u> Date of booking: 31/10/2007 L.M.P: 6/8/07 If referred by Doctor: blank Estimate Date of Delivery: 14/05/08 by dates Name and Address: GP details outlined It was documented the patient had past medical history of epilepsy and was not on any medication by choice over the past two years. The last seizure was in June 2007. The patient did not have any seizure in the last pregnancy. It is also noted the patient had no allergies and was taking Folic acid¹² at that time.

The following is documented under heading *Previous Obstetrical History:*

- 1998 miscarriage in first trimester¹³
- 2006 vacuum delivery of a girl at term

The following was documented in the section titled "The history of this pregnancy" -Gestation¹⁴ by dates =12weeks +1 day. The patient was complaining of N+V (Nausea and Vomiting) at that time. It has been documented under "Result of Special Examination" – "Done by GP-Pt will bring to next visit". It is not clear what this refers to.

The following has been documented on the proforma at the Antenatal Outpatient Clinic visit-

FUNDAL HEIGHT¹⁵: It is outlined the patient's fundal height was 12 weeks and equal to dates

GIRTH: -

PRES (baby Presentation)¹⁶:

F.H - The foetal heart rate was documented as $+^{17}$

B/P: Blood pressure: 128/65 milligrams of mercury (mmHg)

OEDEMA: NIL

URINE (Urinalysis): ¹⁸ NAD¹⁹

WEIGHT: 57kgs

HB: blank

COMMENTS: -

The plan of care at that time was documented that the patient was to return to her GP in 8 weeks and to the Antenatal Outpatient Clinic in 18 weeks.

¹² Folic acid, another form of which is known as folate, is one of the B vitamins. It is used as a supplement during pregnancy to prevent neural tube defects. It is also used to treat anaemia caused anaemia caused by folic acid deficiency.

¹³ Pregnancy is measured in trimesters from the first day of last menstrual period, totalling 40 weeks. The first trimester of pregnancy is week 1 through week 12, or about3 months. The second trimester is week 13 to week 27. And the third trimester of pregnancy spans from week 28 to the birth.

¹⁴ Pregnancy

¹⁵ Fundal height is the height of the fundus of the uterus, measured in centimetres from the top of the symphysis public 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-

¹⁶ Presentation of foetus: that part of the foetus lying over the pelvic inlet; the presenting body part of the fetus. **Vertex (VX) presentation**: ¹⁶ Presentation of foetus: that part of the foetus lying over the pelvic inlet; the presenting body part of the fetus. **Vertex (VX) presentation**: presentation or the foetal 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 foetal 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) Head presentation of the foetus during birth in which the upper back part of the foetal head is the presenting part. **Breech presentation:** presentation of the foetal buttocks or feet in labour; the feet may be alongside the buttocks (complete breech p.); the legs may be extended against

⁷ Is a test that evaluates a sample of urine. Urinalysis is used to detect and assess a wide range of disorders, such as urinary tract infection, kidney disease and diabetes. Urinalysis involves examining the appearance, concentration and content of urine.

¹⁹ NAD - Nothing Abnormal Detected

The patient was also seen by the midwife at this appointment for the first trimester visit. The documentation indicates that the following topics on the antenatal proforma were discussed with the patient:

Effects of pregnancy on your body

Nutrition in pregnancy

General exercise

Smoking status

Alcohol intake

Pelvic floor exercises discussed

Information on infant feeding

Social worker referral

Birth plan discussed

Analgesia in labour

Impending signs of labour

Reasons for coming into hospital apart from labour i.e SROM²⁰, Bleeding

The following laboratory results are in the patient's healthcare records dated 12th October 2007, 15th October 2007 and 16th October 2007. These were requested by the patient's GP on 11th October 2007. These results appear to have been sent to Hospital 1 on 6th March 2008.

Full Blood Count (FBC)²¹

Blood Group

Antibody Screen²²

Rubella²³

HIV antibody test²⁴

Hepatitis B²⁵

The patient's haemoglobin (HB) and blood group are noted by their GP. On this occasion these are as follows:

HB: 12.1 g/dl (reference range 12-15).

Blood group: O Rhesus positive with no atypical antibodies present.

Following the Antenatal clinic visit, the examining doctor wrote to the patient's GP, letter dated 1st November 2007. S(he) thanked the GP for referring the patient to Consultant

¹ Not detected

²⁰ SROM – Spontaneous rupture of membranes

²¹ 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: <u>http://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test</u>). ²² 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-zguides/antibody-tests) ²³ Exceeds 15 IU/mL. This level of antibody suggests immunity and is generally accepted as sufficient to protect against primary rubella virus

infection and congenital rubella virus infection.

²⁵ Not detected

Obstetrician's1 Antenatal Outpatient Clinic and was satisfied to share the patient's care with them. S(he) outlined in the letter that on this visit general and systemic examinations were unremarkable; that booking investigations were taken and that ultrasound confirmed the patient's dates.

5th March 2008

The patient attended her second Antenatal Outpatient Clinic appointment. The following has been documented on the proforma at the Antenatal Outpatient Clinic visit-

<u>FUNDAL HEIGHT</u>: It is outlined the patient's fundal height was 30 weeks gestation and equal to dates

<u>GIRTH:</u> -<u>PRES</u>: Baby presentation, it is difficult to decipher the entry <u>F.H</u> -<u>B/P: Blood pressure:</u> 120/70 milligrams of mercury (mmHg) <u>OEDEMA:</u> -<u>URINE:</u> Protein + MSU²⁶ (mid-stream urine)√. <u>WEIGHT</u>: 66kgs <u>HB</u>:-<u>COMMENTS</u>:

It was documented that the patient was to return to her GP in three weeks; and to the Antenatal Outpatient Clinic in six weeks.

The report of the MSU sample date 5th March 2008 within the patient's healthcare records showed the following result:

Microscopy	
Pus, cells	Nil
Red cells	Nil
Organisms	Nil
Casts	Nil
Epithelial Cells	Nil
Debris	+
Bacterial count	< 10,000 cfu's/ml (negative)
Urine Culture	No significant growth

²⁶ MSU: Midstream urine

4.0 The chronology of events has been established as follows:

The sections in italics are direct entries from the patient's healthcare records.

Friday 7th March 2008

23:08hours

It has been documented in the patient's healthcare records by Staff Midwife1; the patient 27yr old lady presented to the labour ward within the maternity unit²⁷ at 30 weeks gestation²⁸ with a history of pressure pains and decreased foetal movement that evening. The patient felt nauseous during this time. There was good foetal movement earlier that day.

At interview, the patient informed the investigators she had pains from about 17:00hours that evening and went to the hospital about 20:00hours. The patient informed the investigators the midwife wasn't happy with her colour. The Midwife asked the patient's sister about her colour, she was quite yellow. The patient's sister indicated she is not normally that colour.

Through feedback, the patient indicated that it was her recollection that she had pain in her stomach, and that she did not have pressure pains and or decreased foetal movement.

At interview, Staff Midwife1 indicated s (he) does not recall commenting on the patient's colour, but outlined s(he) was definitely concerned about the patient.

At interview, Staff Midwife1 indicated to the investigators the night was particularly busy. S(he) received a handover from the day shift; this included an overall report on the patients and the patient's who were coming up to labour. S(he) re-called being told about this patient.

Through feedback on the first draft report, the patient indicated that she was not present for the day shift and Staff Midwife1 was the first staff member she met.

The patient's clinical observations were documented as follows:

- Blood pressure: 135/77 milligrams of mercury (mmHg)
- Pulse rate: 91 beats per minute
- Temperature: 36.7 degress Celsius.

²⁷ There are 33 beds (antenatal and postnatal sections) and 4 delivery single rooms (labour ward) in the maternity unit in Hospital 1. The labour ward is a ward off the main antenatal and postnatal sections.
²⁸ Pregnancy

The patient's HB²⁹ (haemoglobin) was recorded as 12.1g/dl. The report in the patient's healthcare records indicated the FBC³⁰ sample was taken on 11th October 2007.

Urinalysis³¹ showed moderate amount of protein³² & leucocytes³³.

The following has been documented in the patient's healthcare records by Staff Midwife1:

"On palpation, Good size baby, long lie Cephalic³⁴ Variability³⁵ reduce, period like pains" It has been documented in the patient's healthcare records by Staff Midwife1 -

"Cephalic now was breech³⁶ earlier CTG³⁷ commenced"

23:18hours

The following has been documented in the patient's healthcare records by Staff Midwife1:

"Variability reduced uterus tense and sore to touch. No PV³⁸ bleed"

23:20hours

The following has been documented in the antenatal notes in the patient's healthcare records by the Obstetric Registrar–

"CTG satisfactory, Vital signs, frequency of urination, ++ leucocytes, MSU³⁹

Scan – cephalic FH⁴⁰ \checkmark

- Fundal placenta
- AFI^{41} \checkmark

23:30hours

It has been documented by Staff Midwife1; the patient was seen and scanned by the Obstetric Registrar, the patient was for admission and for oral antibiotics.

²⁹A 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: <u>http://www.thefreedictionary.com/haemoglobin</u>). Low levels of haemoglobin in pregnancy can indicate anaemia (reference: <u>http://www.thefreedictionary.com/haemoglobin</u>). Low <u>http://www.cyh.com/haelthtopics/healthtopicdetails.aspx?p=438&np=459&id=2759#haemoglobin</u>)

³⁰ 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: <u>http://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test</u>).

³¹ Urinalysis is a test that evaluates a sample of urine. Urinalysis is used to detect and assess a wide range of disorders, such as urinary tract infection, kidney disease and diabetes. Urinalysis involves examining the appearance, concentration and content of urine.
³² Low levels of protein in urine are normal. Small increases in protein in urine usually aren't a cause for concern, but larger amounts may indicate

³² Low levels of protein in urine are normal. Small increases in protein in urine usually aren't a cause for concern, but larger amounts may indicate a kidney problem. Evidence of infection. If either nitrites or leukocyte esterase — a product of white blood cells — is detected in your urine, it may be a sign of a urinary tract infection. (Reference: Mayo Clinic)

³³ White blood cells

³⁴ 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) ³⁵ 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. (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: <u>http://medical-dictionary.thefreedictionary.com/premature+labor</u>). <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172(</u>).

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/). ³⁶ 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. ³⁷ Cardiotocography (CTG) is a technical means of recording the foetal heartbeat and the uterine contractions during pregnancy, typically in the

³⁷ Cardiotocography (CTG) is a technical means of recording the foetal heartbeat and the uterine contractions during pregnancy, typically in the third trimester. (Reference: Macones GA, Hankins GD, Spong CY, et al

 ³⁸ PV - Per Vaginam (Latin) meaning via/ through the vagina (Reference: Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)
 ³⁹ MSU-Midstream Urine

⁴⁰ FH – Foetal heart

⁴¹ Amniotic Fluid Index

At interview, the Obstetric Registrar indicated the reason s(he) commenced Amoxicillin was that this was as a result of his/her diagnosis the patient had a UTI⁴². The patient complained of the following symptoms: Lower abdominal pressure, frequent urination, and the patient had leucocytes in a urine sample. Also, the Obstetric Registrar indicated a UTI is very common in pregnancy. It has been recorded in the patient's "Maternity/Paediatric Drug Record Sheet" that the patient received Amoxicillin⁴³ 500mgs orally at that time.

23:30hours

It has been documented in the patient's healthcare records by Staff Midwife1 -

"Cephalic now was breech⁴⁴ earlier CTG⁴⁵ commenced"

The plan of care was as follows-

- To admit the patient
- For oral antibiotics

At interview, Staff Midwife1 indicated the patient was brought back to the floor.

Through feedback, the patient outlined that she does not recall that she was informed at any point that she had a urinary tract infection. The patient also indicated that she has no recollection of being given any medication upon admission to the maternity ward or labour ward.

The report of the mid-stream urine sample dated 7th March 2008 within the patient's healthcare records showed the following result:

Microscopy		
Pus cells	20	/mm^3
Red cells	20	/mm^3
Organisms	Nil	
Casts	Nil	
Epithelial Cells	Nil	
Debris	Nil	
Bacterial count	10,000 -100,000 cfu's/ml (Equivocal) ⁴⁶	
Urine Culture	Mixed Growth	

At interview, the patient indicated she was admitted to the ward. The pain was getting worse. After about 30-45 minutes she went to the bathroom. She was bleeding; she

⁴² UTI: Urinary tract Infection

 ⁴³ Antibiotic used to treat susceptible infections (including urinary-tract infections, otitis media, sinusitis, uncomplicated community acquired pneumonia, salmonellosis, oral infections). Dose 500 mg every 8 hours, increased if necessary to 1 g every 8 hours, increased dose used in severe infections. (Reference – BNF, June 2016)
 ⁴⁴ 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

⁴⁴ 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.
⁴⁵ Cardiotocography (CTG) is a technical means of recording the foetal heartbeat and the uterine contractions during pregnancy, typically in the

⁴⁵ Cardiotocography (CTG) is a technical means of recording the foetal heartbeat and the uterine contractions during pregnancy, typically in the third trimester. (Reference: Macones GA, Hankins GD, Spong CY, et al

⁴⁶ Neither positive nor negative, there is a mixed bacterial growth and the red cell and white cell counts are low, suggests contamination in the specimen rather than a confirmed UTI.

went to the nurses' station in the labour ward. A different midwife was there. She said the labour rooms were very busy and to go back to the ward and wait until a delivery room became available. The patient told her about the pain again. She said it was probably the early stages of labour. The patient informed the nurse that she was only 30 weeks. She was told to go back to her room and that someone would come to get her when a room was available.⁴⁷

 $^{^{\}rm 47}$ Due to the inability to contact staff members this entry has not been verified

Saturday 8th March 2008

00:30hours

The following has been documented in the mother's report in the patient's healthcare records by Staff Midwife2 –

"Panadol x 2 given for backache"

01:50hours

The following has been documented in the mother's report in the patient's healthcare records by Staff Midwife3 –

"Rang call bell having pressure pains. Had been out to toilet ? Spotting on wiping. Advised to go to L/W^{48}

At interview, the patient indicated the pain was getting worse. She was curled up in a ball in the bed. She went to the toilet again; there was a lot of blood. She again went to the nurses' station in the labour ward. The patient's recollection is that the midwife that originally admitted the patient put her on a chair and informed another midwife that "this is the lady I was not happy with earlier".

Through feedback on the final draft report, the patient indicated her recollection was that she was asked by the midwives, on her second time to the labour ward, "when did she start bleeding?" She told the midwives it was about an hour ago. They asked why she had not come down sooner and she said she did but had been sent back to the maternity ward.⁴⁹

Through feedback, Staff Midwife1 indicated that s(he) has no recollection of asking the patient "when did she start bleeding?" and or asking the patient why she did not go to labour ward sooner.

Through feedback, the patient indicated her recollection was that she never rang a bell for assistance and that she was not advised to go to the labour ward; the patient indicated that she recalled that she went to the labour ward based on her own decision. The patient outlined her recollection was that she was left for a few hours on the maternity ward without being checked on or monitored in any way before going to the labour ward herself.

At interview, the patient outlined she was brought into a labour room. The patient recalled that the midwives tried desperately to find a heartbeat. They could not find a heartbeat. They called the doctor. The patient recalled that the midwives informed her that her baby had passed away and she would have to have a caesarean section. The patient asked the midwives to contact her husband. The patient's husband recalled that

⁴⁸ L/W – Labour Ward

⁴⁹ Due to the inability to contact staff members this entry has not been verified

he was contacted via telephone; that he was not told what was wrong but that he was asked to come to the hospital.

03:00hours (entry of time clarified at interview)

The following has been documented in the antenatal continuation section in the patient's healthcare records by the Obstetric Registrar –

"Called to review P/V bleeding C/O^{50} → Abdominal Pain Vital signs $\sqrt{}$ Abd⁵¹ very tense & hard Scan no foetal heart beat $O/A^{52} CX^{53} - 2cms$

At interview and through feedback on the first draft report; the patient indicated her recollection was that she was not informed by the Obstetric Registrar that s(he) was about to carry out an examination. The patient indicated her recollection was that the pain was severe.

At interview, the Obstetric Registrar indicated that his/her recollection was that everyone was in a state of distress at the time and understands why the patient would be upset.

At interview, the Obstetric Registrar indicated all the patient's signs were satisfactory until the bleeding commenced.

No time recorded

The following has been documented in the antenatal notes in the patient's healthcare records, there was no signature -

*History as above Abdomen stony hard PV bleeding ++ Scan confirmed IUD*⁵⁴ *For Emergency LSCS*⁵⁵

03:28hours - retrospective note

The following has been documented in the antenatal continuation sheet in the patient's healthcare records by Staff Midwife1 –

"Report in retrospect after days off

Down to LW. Fresh bleeding on pad

⁵⁰ C/O - Complaining of

⁵¹ Abd - Abdomen

⁵² O/A- On examination

 $^{^{53}}$ CX- Cervix (Neck of the womb)

⁵⁴ IUD – Intrauterine death

⁵⁵ 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. *LSCS* - 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 (reference http://www.news-medical.net/health/Cesarean-Section-Types.aspx)

Unable to hear FH with CTG. Obstetric Registrar called $\sqrt{^{56}}$ Bloods \sqrt{IV} cannula"⁵⁷

There was a copy of the consent form in the patient's healthcare records signed by the patient and the Obstetric Registrar. This outlined the Obstetric Registrar explained the following:

- 1. Caesarean section delivery through the abdomen
- 2. Intended benefits safe delivery of mother and baby
- 3. Serious or Frequently occurring risks
 - Haemorrhage (C/S 5:1000 births, vaginal birth 7:1000 births)
 - Infection, antibiotics may be given during and following surgery. (C/S 6:1000 births, vaginal birth 4:10000 births)
 - Painful wound or delayed wound healing.
 - Damage to surrounding organs bladder, bowel very rare. (C/S 1:1000 births, vaginal birth 3:1000)
 - Thrombosis and pulmonary embolism (serious blood clot) Anti coagulation therapy if given to patients at risk.

(It is noted on the form that the statistics are taken from 2004 NICE Guidelines UK)

The form outlined additional procedures may be required and states the following:

- Blood for transfusion is available at all times and may be required in an emergency
- Hysterectomy for severe bleeding very rare (C/S 8:10000, vaginal birth 1:10000).

An entry on the Pre-Operative/Intra-Operative and recovery room record by Staff Midwife1 outlined the patient received premedication⁵⁸ at 16:05hours⁵⁹. The Pre-Medications were not recorded.

Other sections on this record are as follows, requiring circle Yes or No

- Consent signed: Not completed
- Proposed Operation: LSCS⁶⁰
- Food/drink last consumed: 18:00hours
- Intravenous Therapy: Yes circled

⁵⁹ Query should read 04:05hours

 $[\]frac{56}{\sqrt{-}}$ complete

⁵⁷ A peripheral IV cannula is a small plastic tube that is inserted through the skin into one of the small veins in your hand or arm. They are used to give many different types of medications, for example antibiotics or fluids. (Reference www.buckshealthcare.nhs.uk)

⁵⁸ Administration of drugs before anesthesia to allay apprehension, produces sedation, and facilitate the administration of anesthesia. (Reference: www.medicaldictionary.thefreedictionary.com/pre-medications)
⁵⁹ ourse should need 04:051

⁶ 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 (reference http://www.news-medical.net/health/Cesarean-Section-Types.aspx)

- Cortisone Therapy: No circled
- Other drugs given: No circled
- Identity band: Yes circled
- Dentures removed: not completed
- Urinalysis Last passed urine Time: not completed
- Weight: not completed
- Dental caries crowns/bridges: not completed
- Jewellery removed: not competed
- Drug/Food Allergies: NKA⁶¹
- Group and X Match: not completed
- Rhesus Factor: not completed
- Hx of previous Back injury/problem: not completed
- Subcutaneous Heparin Type: not completed
- Visited by Clergyman: not completed
- Operation site marked: not completed
- Care of valuables as per policy: not completed
- Nail Polish: No circled
- Any prosthesis : No circled
- Any Contact Lens: No circled
- Bath: No circled
- Skin Prep: not completed
- Gown: not completed
- Section To Theatre with patient: not completed

The form does not outline who completed the form and who accompanied the patient to theatre.

04:10hours

An entry completed on the Nurses Operation Record Sheet outlined the patient entered the anaesthetic room –Theatre 1 at that time.

At interview, the patient's husband recalled that he was brought into the operating theatre and told that their baby had passed away. He recalled that he was then brought into theatre to see his wife and he was then taken to wait outside the theatre. He recalled that the midwife kept him updated with regards to the progress of events. He was advised it would be awhile before his wife would be out of theatre.

04:25hours

An entry completed on the Nurses Operation Record Sheet outlined the patient entered the theatre at that time.

⁶¹NKA- No known allergies

The following has been documented in the Operating Chart in the healthcare record by the Obstetric Registrar -

Operating Chart

"Operation: EMCS⁶²

Indication: Concealed Pl Abruption⁶³

There was no entry beside heading Thrombophylaxis⁶⁴ and Antibiotics

The following has been documented in the Operative Note by the Obstetric Registrar –

Operative Notes

GA⁶⁵

Lower transverse skin incision

L.S.C.S \rightarrow Baby (IUD) Large retroplacental⁶⁶ haematoma⁶⁷

Blackish discoloration of the uterus, Repair uterus 3 layers, Redivac⁶⁸ \checkmark

Abdominal wall 4 layers skin subcuticular

Few interrupted skin stitches due to oozing blood

2 ampoules Haemobate⁶⁹ intraoperativelv⁷⁰

The following post operative instructions were recorded by the Obstetric Registrar as the plan of care for the patient -

Fluids.....IL Hartmans⁷¹ 18hrs

Drugs......4 Units of Blood

2 Units Fresh frozen plasma⁷² Zinnat⁷³

⁶² Emergency Caesarean section

⁶³ The blood fails to trickle down and collects between the placenta and the uterine wall. The enlarging blood clot further dissects out the placenta from its bed and placental separation can occur over a large area. This is a serious type of placental abruption. ttp://gynaeonline.com/placental_abruption.htm#sthash.s6CXUtwg.dpuf 64

Any preventive measure or medication that reduces the likelihood the formation blood clots. of of (Reference:http://medicaldictionary.thefreedictionary.com/thromboprophylaxis)

⁶⁵ GA - General anaesthetic

⁶⁶ Behind the placenta, or between the placenta and the uterine wall. ref="http://medicaldcictionary.thefreedictionary.com/retroplacental">retroplacental

A localized mass of extravasated (discharge or escape) blood that is relatively or completely confined within an organ or tissue, a space, or a potential space; the blood is usually clotted (or partly clotted), and, depending on its duration, may manifest various degrees of organization and decolorization. Reference: "http://medical-dictionary.thefreedictionary.com/hematoma">hematoma

⁶⁸ Redivac- Is a thin PVC tube that is placed in the cavity (hole) created when tissue is removed during surgery. Its purpose is to remove the fluid that collects after an operation from your body. The end of the tubing that is outside your body will be attached to a plastic measuring Bottle. © 2013 Guy's and St Thomas' NHS Foundation Trust

⁶⁹ Carboprost / Haemobate, Carboprost is a man-made oxytocic medication that mimics the action of a naturally occurring chemical called prostaglandin F2 alpha. Oxytocic medications have the effects of oxytocin, which causes contractions during labor and controls bleeding after childbirth. Carboprost works on prostaglandin F receptor sites in uterine muscle to increase contractions and induce labor. Dosage for post partum haemorrhage 250micrograms/1ml solution for injection ampoules (Reference: BNF June 2016) 70

Pertaining the to period during surgical procedure. href="http://medicalа <a

dictionary.thefreedictionary.com/intraoperative">intraoperative ⁷¹ Solutions of electrolytes are given intravenously, to meet normal fluid and electrolyte requirements or to replenish substantial deficits or continuing losses, when the patient is nauseated or vomiting and in unable to take adequate amounts by mouth. Hartmann's Solution contains sodium chloride 0.6%, sodium lactate 0.25%, potassium chloride 0.04%, calcium chloride 0.027% (reference: British National formulary 2009).

⁷² Plasma is the fluid portion of the **BLOOD**, in which the formed elements (blood CELLS) are suspended. Plasma is to be distinguished from **SERUM**, which is plasma from which the FIBRINOGEN has been separated in the process of clotting. Called also blood plasma. adj., adj plasmat'ic, plas/mic. Of the total volume of blood, 55 per cent is made up of plasma. It is a clear, straw-colored liquid, 92 per cent water, in which are contained plasma PROTEINS, inorganic salts, nutrients, gases, waste materials from the cells, and various hormones, secretions, and enzymes. These substances are transported to or from the tissues of the body by the plasma. It is Plasma obtained from blood donors is given to persons suffering from loss of blood or from shock to help maintain adequate blood pressure. Since plasma can be dried and stored in bottles, it can be transported almost anywhere, ready for immediate use after addition of the appropriate fluid. Plasma can be given to anyone, regardless of blood type. Fresh Frozen Plasma (FFP) - Separated plasma, frozen within 6 hours of collection, used in byonovidemia and coagulation factor deficiency. but Virgendicitionary come (Frept) - from the prospinate mass. hypovolemia and coagulation factor deficiency. http://medicaldictionary.thefreedictionary.com/Fresh+frozen+plasma

Drain.....for 48hours Catheter..... for 24hours

Repeat bloods for Haemoglobin⁷⁴ (HB), Coagulation⁷⁵ (Coag) Screen and urea & electrolytes⁷⁶ (U/E)

At interview, the Obstetric Registrar indicated there are 3 types of placental abruption. This case was a concealed abruption⁷⁷. It is the most severe type. The patient had a large placental haematoma⁷⁸. The womb was dark due to bleeding between the muscles. Placental abruption complicated by coagulopathy⁷⁹ is very rare and the onset is sudden.

The other 2 types of abruption are revealed abruption⁸⁰ and combined abruption⁸¹

The "Maternal Summary" proforma was completed as follows:

⁷³ Zinnat/Zinacef (Cefuroxime)Antibiotic- dose 750 mg every 6-8 hours; increased if necessary up to 1.5 g every 6-8 hours, increased dose used for severe infections (Reference BNF June 2016)

⁷⁴ 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 (reference:

http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438&np=459&id=2759#haemoglobin)

Blood test to measure blood's ability to clot and the amount of time it takes to do so.

⁷⁶ U&E 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. (reference: http://www.patient.co.uk/health/nephrotic-syndrome-leaflet)
77 The blood fails to trickle down and collects between the placenta and the uterine wall. The enlarging blood clot further dissects out the placenta

from its bed and placental separation can occur over a large area. This is a serious type of placental abruption. (Reference : gynaeonline.com/placental_abruption."

A localized mass of extravasated (discharge or escape) blood that is relatively or completely confined within an organ or tissue, a space, or a potential space; the blood is usually clotted (or partly clotted), and, depending on its duration, may manifest various degrees of organization and decolorization. Reference: "http://medical-dictionary.thefreedictionary.com/hematoma">hematoma

⁷⁹ A disorder in which blood is either too slow or too quick to coagulate (clot). Reference: "http://medical- <a href="http://medical- dictionary.thefreedictionary.com/coagulopathy">coagulopathy

⁸⁰In this type of placental abruption, the bleeding that occurs behind the placenta (retroplacental haemorrhage) trickles down between the membranes and the <u>uterine walls</u> to be revealed at the <u>vaginal opening</u>. Since there is no collection of blood behind the placenta, separation of the placenta from the uterus is usually less than in the other types. This is a mild type of placental abruption http://gynaeonline.com/placental_abruption.htm#sthash.s6CXUtwg.dpuf ⁸¹ In this type, part of the blood trickles down and part collects behind the placenta. Like the concealed type, this is also a dangerous type of

placental abruption as the blood clot continues to dissect out the placenta from the placental bed. http://gynaeonline.com/placental_abruption.htm#sthash.s6CXUtwg.dpuf

Hospital Name: Hospital 1 Hospital Number: Completed Consultant: Consultant Obstetrician GP Name: Not completed Address: Not completed Phone No: Not completed

Mother's name:	completed
DOB:	completed
Age:	completed
Marital Status:	Married
Telephone:	Completed
Mobile:	Completed
E.D.D ⁸² :	14/05/2008

GP & Antenatal	
PARITY:	1+1
BLOOD GROUP:	0 Rh Positive
ANTIBODIES:	No
RUBELLA – Status:	RUBELLA IMMUNE
Hb. – (most recent:	12.1
result	
H.I.V. Status:	H.I.V. antibody negative
VDRL Status:	Negative
Hep B Status:	Negative
Hep C Status:	Unknown
Sickle Cell Status:	Test – Not indicated
PAST OBSTETRIC Hx ⁸³ :	Specify: Ventouse ⁸⁴ x 1, Miscarriage x 1
MEDICAL Hx.	Specify: Epilepsy, Not on meds by Choice last seizure June 07
ALLERGIES:	No Known Allergies
Patient booked in Hospital1:Yes	
TYPE OF CARE:	Combined GP/A/N Clinic
ETHNIC ORIGIN:	Caucasian
Main maternal:	Antepartum haemorrhage
Diseases or conditions	
Affecting fetus or Infan	
Comments – A/N:	Yes, Admitted with abdominal pain @ 30weeks and reduced fetal
	movements

Emergency LSCS
EMERGECNY L.S.C.S
Placenta Praevia / Abruption
Spinal

 $^{^{82}}$ EDD- Expected date of delivery

EDD- Expected date or delivery
 83 Hx-History
 84 Ventouse/Vacuum assisted vaginal delivery - an apparatus used to assist the delivery of a baby, consisting of a cup which is attached to the fetal head by suction, Reference: "http://medical-dictionary.thefreedictionary.com/ventouse"

<u>Third stage</u> TRANSFERRED TO:

ICU: PPH – For observation

Comments – Labour/3rd: Yes; Blood transfusion x 3 in ICU

Baby Details SURNAME: DATE/TIME - DELIVERY: MODE of DELIVERY: NUMBER OF BABIES BORN: SEX: **GESTATION:** WEIGHT? (Kgs): TYPE of BIRTH: TIME OF DEATH: I.D. Bands: PLACE of BIRTH: TRANSFERRED TO: COMMENTS: Baby – MRN⁸⁵: Completed by:

Completed 08/03/2008 04:30:00 EMERGECNY L.S.C.S Singleton FEMALE 30 1.6 STILLBIRTH INTRA-PARTUM Yes Hospital Grieving Room. Yes, Fresh Stillbirth xxxxx Staff Midwife

 $^{^{85}}$ MRN-Medical Record Number

At interview, the patient's husband indicated he sat with their baby girl following her delivery at 04:30hours. He recalled a midwife checked on him a couple of times during the night.

05:20hours

It has been documented in the patient's healthcare records the patient left the operating theatre at that time and was transferred to the recovery room.

An unsigned entry in the recovery room record outlined the following were in situ-

- Oxygen 40% via mask
- An ECG monitor
- Pulse oximetry⁸⁶
- Automatic B.P⁸⁷

Wound Observations: Mepore⁸⁸

It was not recorded what time the patient left the recovery room and the time the patient was transferred to the Intensive Care Unit (ITU).

06:00hours

It has been documented in the patient's healthcare records the patient was transferred to the Intensive Care Unit (ITU) from the recovery room following caesarean section. The patient developed PPH⁸⁹ - coagulopathy⁹⁰. The patient's vital signs/clinical observations were stable. The patient was awake and self ventilating. The patient received 2units Red Blood Cells (RBC) and 2unis of Fresh Frozen Plasma⁹¹ (FFP) in theatre due to 2litre blood loss. The patient had PCA⁹² for analgesia, PCA prescription was prescribed as follows:

DRUG	MG(milligram)	CONC	BOLUS	LOCKOUT	Prescribed	Date
		(mg/ml)	(mg)	(mins)	by	
Morphine ⁹³	100	2	1	6	completed	8/3
Zofran ⁹⁴	8					

⁸⁶ Device, usually attached to the earlobe or fingertip that measures the oxygen saturation of arterial blood by sensing and recording capillary pulsations. Reference "http://medical-dictionary.thefreedictionary.com/pulse+oximeter">pulse oximeter 87 B.P – Blood Pressure

⁸⁸ Mepore is a self-adhesive absorbent dressing that has an absorbent wound pad located centrally on a piece of apertured, non-woven polyester fabric coated with a layer of an acrylic adhesive. The wound pad is made of a viscose nonwoven coated with a polyolefin layer to give a smooth surface and render it low-adherent. The polyester backing makes the product permeable and highly flexible, allowing it to conform well to body contours. The dressing is protected by two pieces of overlapping release film which are easy to remove and allows for aseptic application. *tp://www.dressings.org/Dressings/mepore.html* ⁸⁹ PPH-Post partum haemorrhage

⁹⁰ A disorder in which blood is either too slow or too quick to coagulate (clot). Reference: "http://medical- coagulopathy ⁹¹ Fluid portion of the BLOOD, in which the formed elements (blood CELLS) are suspended. Of the total volume of blood, 55 per cent is made up of

plasma. It is a clear, straw-colored liquid, 92 per cent water, in which are contained plasma PROTEINS, inorganic salts, nutrients, gases, waste materials from the cells, and various hormones, secretions, and enzymes. These substances are transported to or from the tissues of the body by the plasma. Reference "http://medical-dictionary.thefreedictionary.com/fresh+frozen+plasma">fresh frozen plasma

⁹² PCA-Patient Controlled Analgesia. It is a method of pain management that allows patient to decide when you will get a dose of pain medicine. With this type of pain treatment, a needle attached to an intravenous (IV) line is placed into vein; a computerized pump attached to the IV allows to release pain medicine by pressing a hand-held button.

⁹³ Opioid analgesia

⁹⁴ Zofran / Ondansetron 8mgs/4ml solution - Prevention of postoperative nausea and vomiting

The patient also had intravenous fluids as charted and 40% oxygen for 6hours.

06:00-08:00hours

The following has been documented in the Intensive Care (ITU) critical care nursing care plan and flow sheet under the following headings-

<u>Respiratory</u>

The patient's respiratory rate and oxygen saturations were monitored on 4litres of oxygen.

Oxygen saturations⁹⁵: 99%

Respiratory rate: 21 per minute

<u>Cardiovascular</u>

The patient's blood pressure, heart rate, rhythm and temperature were monitored.

Heart rate: 92 beats per minute

Blood pressure: stable

Urinary output – satisfactory

The patient's $HB^{96} = 7.4$, the patient required 2units of Red Blood cells each over 2hours.

The patient's clinical observations ranged within the following parameters during the blood transfusions:

- Blood pressure: 110/60 130/30mmHg
- Pulse rate: 72 94 guesstimate beats per minute (bpm)
- Respiratory rate: 20resps per minute recorded once
- Temperature: 36.5degress celsius

Medication was administered as prescribed.

Pain/sedation/sleep

PCA was effective

Hygiene/mobility

The patient's skin integrity was good. The patient's bandage and dressing on her wound was dry and intact.

<u>Elimination</u>

The patient had moderate PV loss.

⁹⁵ Amount of oxygen bound to hemoglobin in the blood expressed as a percentage of the maximal binding capacity. Reference "http://medicaldictionary.thefreedictionary.com/oxygen+saturation"

 ⁹⁶ 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 (reference: http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438&np=459&id=2759#haemoglobin)

Neurological

The patient's $GCS^{97} = 15/15$

Psycho-social

It is recorded that the patient's husband was present; and that the midwife spoke to both the patient and her husband about seeing their baby

Nutrition

It was recorded that the patient was "nil by mouth" at that time, and that intravenous fluids were in progress

Communication

It was recorded that the patient's dignity and privacy were maintained. The nursing staff recorded that they explained all procedures to the patient.

08:00hours

The patient was seen on the morning ward round. The following has been documented in the patient's healthcare records:

"Tx⁹⁸ to date: 4 units FFP

4 units RBC

Patient is looking well

Vitals: BP 120/50

PR 80

Apyrexial 36.3 degress Celsius

Sats 99%

Patient feeling weak

Resp: Clear, not able to decipher next word

Legs soft

Ρ 1.Continue RBC's

2. Repeat blds FBC Coag and fibrinogen

U&E

 $LFT's^{99}$

at 13:00

3. Review for return to maternity tonight if bloods improved

4. TEDS¹⁰⁰

08:00hours assessment and evaluation

The following has been documented in the Intensive Care (ITU) critical care nursing care plan and flow sheet under the following headings-

⁹⁷ GCS - Glascow Coma Scale - A scale for measuring level of consciousness, especially after a head injury, in which scoring is determined by three factors: the ability to open the eyes, verbal responsiveness, and motor responsiveness, maximum score of 15. "http://medical-dictionary.thefreedictionary.com/Glasgow+Coma+Scale">Glasgow Coma Scale ⁹⁸ Tx - Treatment

⁹⁹ LFT's – Liver function tests

¹⁰⁰ Thrombo-oembolic deterrent stockings

Respiratory

It has been documented the oxygen therapy was discontinued at that time. The patient was slightly chesty but had good air entry. Physiotherapy was arranged. The patient appeared flushed.

Oxygen saturations on room air: 99%

Respiratory rate: stable

Cardiovascular

It was recorded that the patient required minimum intervention but needed continuous monitoring. The patient's blood pressure, heart rate, rhythm and temperature were monitored.

- Heart rate: 90 120beats per minute
- Blood pressure: 140/73
- Temp: 36.3 *degress Celsius*

It was recorded that the patient had TED stockings applied

Medication administered as prescribed.

Pain/sedation/sleep

PCA in progress

It was recorded that the patient's intravenous cannula tissued¹⁰¹, the PCA was changed to cannula in the patient's right hand.

Hygiene/mobility

It was recorded that the patient required minimum assistance. The patient's dressing was intact.

Elimination

It was recorded that the patient had urinary catheter and redivac drain. The patient had 2 episodes of moderate PV loss. The patient had lasix 20mgs ¹⁰² with good diuresis¹⁰³.

<u>Neurological</u>

It was recorded that the patient's GCS - 15/15

Psycho-social

It was recorded that the patient's husband visited. The midwife spoke with the patient regarding visiting her baby. The patient visited pastoral care, support was provided.

Nutrition

It was that the patient had intravenous fluids in progress and was allowed sips as tolerated.

¹⁰¹ Occurs when fluid infuses into the tissues surrounding the veni-puncture site. This sometimes happens when the tip of the catheter slips out of the vein, the catheter passes through the wall of the vein, or the blood vessel wall allows part of the fluid to infuse into the surrounding tissue ¹⁰² Loop diuretic, dosage initially 20–50 mg, then (by intramuscular injection or by intravenous injection or by intravenous infusion) increased in

steps of 20 mg every 2 hours if required, doses greater than 50 mg given by intravenous infusion only; maximum 1.5 g per day. (Reference: BNF June 2016) ¹⁰³ Increased excretion of urine (Ref=http://medical-dictionary.thefreedictionary.com/dieresis)

Communication

It was recorded that the patient's dignity and privacy were maintained, that the nursing staff explained all the procedures and that the patient was a little tearful at times during the day.

18:00hours

The nursing staff contacted the Obstetric Registrar in relation to the patient's FBC¹⁰⁴ results: platelets¹⁰⁵ low and increase WCC¹⁰⁶. The Obstetric Registrar did not make any changes to the patient's treatment at that time. The patient remained in the ITU for 24hours. The plan of care-

- Patient was allowed to eat and drink •
- Discontinue intravenous fluids

20:00hours assessment and evaluation

The following has been documented in the Intensive Care (ITU) critical care nursing care plan and flow sheet under the following headings-

Respiratory

It has been documented the patient's chest was clear and no wheeze or cough was noted.

• Oxygen saturations on room air: 99%

Cardiovascular

It was recorded that the monitor showed normal sinus rhythm¹⁰⁷

- Heart rate: 72beats per minute 0
- Blood pressure: stable 0
- It was recorded that the patient's blood pressure was low at 6am = 96/47mmHq

It was recorded that medication was administered as prescribed.

Pain/sedation/sleep

It was recorded that the patient was using the PCA when required; and that this was providing adequate pain relief and that the patient slept for long periods

Hygiene/mobility

It was recorded that the patient's dressing was intact. The patient found it difficult to remain on her side

¹⁰⁴ 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: tp://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test). ¹⁰⁵ Platelets are the cells that circulate within the blood and bind together when they recognize damaged blood vessels. When a cut occurs; the

platelets bind to the site of the damaged vessel, thereby causing a blood clot. (Reference: Johns Hopkins Bayview Medical Center) ¹⁰⁶ White Cell Count

¹⁰⁷ The normal heart rhythm whose pacemaker is in the sinoatrial node and whose conduction through the atria, atrioventricular node, and ventricles is unimpaired. The interval between complexes is regular, the ventricular rate is 60 to 100, there are upright P waves in leads I and II, a negative P wave in lead AVR, a P-R interval of 0.12 to 0.20 sec, and one P wave preceding each QRS complex. (Reference:medical-dictionary.thefreedictionary.com/normal+sinus+rhythm)

<u>Elimination</u>

It was recorded that the patient's urinary output was decreased since intravenous fluids were discontinued, the redivac drain drained minimum amount and that the patient had no episode of PV bleeding overnight.

<u>Neurological</u>

It was recorded that the patient's GCS – 15/15

<u>Psycho-social</u>

It was recorded that the patient's family visited and spoke with the patient over the phone.

<u>Nutrition</u>

It was recorded that the patient was not hungry and that oral fluids to be encouraged. <u>Communication</u>

It was recorded that the patient was very quiet but restful and that she spoke about the baby.

Sunday 9th March 2008

08:00hours assessment and evaluation

The following has been documented in the Intensive Care (ITU) critical care nursing care plan and flow sheet under the following headings-

Respiratory

The patient was self ventilating on room air. The patient had no cough noted and her chest appeared clear.

Oxygen saturations on room air: 98%

Cardiovascular

It was recorded that the monitor showed normal sinus rhythm. The patient's blood pressure, heart rate, rhythm and temperature were monitored.

- Heart rate: 77 beats per minute
- Blood pressure: 104/77 0
- Temp: Apyrexial

It was recorded that medication was administered as prescribed.

It was recorded that the patient was commenced on Galfer¹⁰⁸ 1 capsule twice daily subsequent to the ward round. The plan of care was if the patient's HB¹⁰⁹ was below 8.0g, the patient required a blood transfusion.

At **13:00hours**, it was recorded that the laboratory contacted the ITU and outlined the patient's HB=7.5g/dl (range 11.8-14.8) and that the patient had cross-match¹¹⁰ blood sample taken for 2units RBC.

At 16:30hours, it was recorded that the first unit RBC commenced and was transfused at 19:25hours. The patient's temperature increased to 37.5 degress Celsius.

Pain/sedation/sleep

It was recorded that the patient was on PCA and that she was using it effectively Hygiene/mobility

It was recorded that the patient's dressing was intact.

It was recorded that the doctor reviewed the patient's wound on the ward round and advised placing mepore dressing only to the patient's wound.

 $^{^{108}}$ Treat iron deficiency anaemia, 1 capsule twice daily - therapeutic dose (Reference: BNF June 2016)

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

 http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438&np=459&id=2759#haemoglobin
 110
 A laboratory test done to confirm that blood from a donor and blood from the recipient are compatible.

 (reference: anaemia

<u>Elimination</u>

It was recorded that the patient had urinary catheter and redivac drain, that the patient had minimum PV loss. The urinary catheter and redivac drain were removed following the ward round. The patient passed urine following removal of the catheter.

<u>Neurological</u>

It was recorded that the patient's GCS – 15/15

<u>Psycho-social</u>

It was recorded that the patient's husband phoned during the morning and that he made arrangement to visit the pastoral care services at the hospital.

<u>Nutrition</u>

It was recorded that the patient tolerated light meals.

Communication

It was recorded that the patient's dignity and privacy were maintained and that the nursing staff explained all the procedures to the patient.

19:50hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records, that the patient was transferred to the maternity unit in a wheelchair by nursing staff, that the patient mobilised to the toilet with assistance, that the patient was using the PCA with good effect and was pain free, that the patient's mepore dressing on the wound was dry and intact, that the patient sat out for a period of time, that Lochia¹¹¹ was minimal and that the patient was for a second unit of blood. It was recorded that the the patient's clinical observations prior to the transfusion were as follows-

- Heart rate: 100beats per minute
- Blood pressure: 100/59
- Temp: 38.3 degrees Celsius

It was recorded in the "Continuation Report Sheet" section of the healthcare records that the patient's temperature was 37.6 degrees celsius in ITU.

The nursing staff contacted the Obstetric Registrar. S/he decided to -

- Commence Zinacef¹¹² IV¹¹³ TDS (three times daily)
- To hold the transfusion until the following morning following administration of the first dose of the antibiotic.

22.20hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient's clinical observations were as follows:

• Temperature = 37.2 degrees celsius

¹¹¹ The normal discharge from the uterus

¹¹² Used for susceptible infections due to Gram-positive and Gram-negative bacteria, in surgical prophylaxis. Dosage - 750 mg IV every 6-8 hours; increased if necessary up to 1.5 g every 6-8 hours (Reference: BNF June 2016

¹¹³ Intravenous

• Pulse rate=88bpm

It was recorded that the wound dressing was dry and intact, that the patient's lochia and micturition were normal, that the PCA¹¹⁴ was effective at that time and the patient was tearful.

¹¹⁴ Patient controlled analgesia

Monday 10th March 2008

06:20hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient was apyrexial (36.7 degrees Celsius), that intravenous antibiotics were given as prescribed and that the the intravenous cannula was patent.

07:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient was feeling much better.

10:00hours

It has been documented in the section of the healthcare records that the patient's wound was clean and dry that the patient was using PCA as required, that lochia and micturition¹¹⁵ were reported as normal, that the patient's clinical observations were stable, and that the patient was seen by the Consultant Obstetrician. It has been documented that the patient required FBC¹¹⁶ and that she was query for discharge the next day.

13:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records, the patient received solpadol x 2 for pain at this time and that intravenous $Zinacef^{117}$ 750mgs intravenous was administered as charted.

18:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient felt well and had no complaints.

The patient's clinical observations were recorded as follows:

- Blood pressure: 121/62mmHg
- Heart rate: 81bpm
- Temp:36.7degress Celsius

It has been documented that Galfer¹¹⁸ was administered. The patient continued to use the PCA, that the patient required an FBC the next day and that the patient was not for a blood transfusion at that time and was query for transfusion pending FBC result.

22:00hours

It has been documented in the patient's healthcare records that the patient's temperature was 37degress Celsius and that her pulse rate was 82bpm¹¹⁹, that the

¹¹⁵ The discharge of urine from the bladder; urine from the kidneys is passed in spurts every few seconds along the ureters to the bladder, where it collects and later is passed to the outside via the urethra. Called also urination and voiding.

¹¹⁶ 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: tp://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test).
¹¹⁷ Used for susceptible infections due to Gram-positive and Gram-negative bacteria, in surgical prophylaxis. Dosage - 750 mg IV every 6-8 hours; increased if necessary up to 1.5 g every 6-8 hours (Reference: BNF June 2016)

¹¹⁸ Treat iron deficiency anaemia, 1 capsule twice daily - therapeutic dose (Reference: BNF June 2016)

¹¹⁹ bpm-beats per minutes

patient was feeling weak postnatally, that the patient received Difene¹²⁰ 100mgs PR for pain and that she was using the PCA. It has been documented that the patient was not able to tolerate Galfer and that she needed Feospan¹²¹.

22.30hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that Zinacef 750mgs IV was administered at this time.

¹²⁰Difene contains diclofenac sodium as the active ingredient which is a non-steroidal anti-inflammatory drug (NSAID) Used in post-operative pain, dosage: Adult, 0rally 75-150mgs daily in 2-3 divided doses, per rectum 75-150mgs in divided doses. (Reference: BNF June 2016)
¹²¹ Used in iron deficiency anaemia, dosage: 1-2 capsules daily, can be opened and sprinkled on food (Reference: BNF June 2016)

Tuesday 11th March 2008

06:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records the patient slept well, that the patient was apyrexial at that time and that the patient's pulse rate = 90bpm¹²². The PCA¹²³ was removed. This was not recorded on the PCA chart. It was recorded that Difene 50mgs was administered orally and that IV Zinacef 750mgs was given also.

09:30hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records the patient was seen by Consultant Obstetrician2 and their team on the ward round and that the patient was "*well*" at that time.

Unable to decipher time

It has been documented in the "Continuation Report Sheet" section of the healthcare records the patient was postnatally well at that time and that she was advised in relation to natural suppression of lactation, that the patient's lochia and micturition were normal; the wound was clean and healthy, legs NAD¹²⁴. TEDS¹²⁵ in situ, the patient declined analgesia, was apyrexial¹²⁶, had FBC taken that morning.

12:30hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient's $HB^{127} = 8.9 \text{ g/dl}$ (Reference range 11.8-14.8) and that the doctor was aware of the result and was satisfied there was no need for transfusion at that time.

14:45hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that Zinacef 750mgs IV was given as charted along with solpadol for soreness.

15:15hours

It has been documented in the "Continuation Report Sheet" section of the healthcare that spatone an iron supplement was given.

19:10hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient declined analgesia, that she wished to go home the following day for the baby's funeral, and that she was for Zinacef IV that night.

¹²² Bpm-beats per minute

¹²³ Patient Controlled analgesia

¹²⁴ NAD – no abnormalities detected

¹²⁵ TEDS-Thrombo-embolic deterrent stockings

¹²⁶ Normal temperature

¹²⁷ 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: <u>http://www.thefreedictionary.com/haemoglobin</u>). Low levels of haemoglobin in pregnancy can indicate anaemia (reference: <u>http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438&np=459&id=2759#haemoglobin</u>

23:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient was well overall, that she was apyrexial, that Difene 50mgs was given for soreness, and that the patient's wound was clean and healing. It was recorded that IV Zinacef 750mgs was administered as charted. The patient was for discharge home the following morning for the baby's funeral.

Wednesday 12th March 2008

06:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient slept relatively well, that IV Zinacef 750mgs was administered as charted, that the patient declined pain relief and that the IV cannula¹²⁸ was removed.

09:00hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records the patient was postnatally well, that the patient's wound was clean and healing and that she was query for removal of sutures. It was documented in the "Continuation Report Sheet" section of the healthcare records that the patient was complaining of left calf pain. It has been documented, that the patient's left calf pain did not appear swollen and that the patient was for review on the ward rounds. It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient was been documented in the "Continuation Report Sheet" section of the healthcare review on the ward rounds. It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient received difene¹²⁹ 100mgs (per rectum) for soreness and that the patient was advised with regards to 6 week check up and to take iron.

09:30hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient was seen by a member of the obstetric team who outlined the following:

The patient was well, was mobilising well. The patient's clinical observations/vitals were normal. On examination, the patient's abdomen was soft, wound was clean and dry, and that there was no obvious swelling or erythema¹³⁰, or tenderness of the left calf. It was documented in the "Continuation Report Sheet" section of the healthcare records that the plan was to discharge the patient home and for her to be followed up at the Outpatient Clinic in 6 weeks

10.10hours

It has been documented in the "Continuation Report Sheet" section of the healthcare records that the patient's sutures were removed, that the patient received solpadol and a prescription was given. The section "Discharge Planning" in the "Patient Assessment Form" was not completed.

¹²⁹ Difene contains diclofenac sodium as the active ingredient which is a non-steroidal anti-inflammatory drug (NSAID). Used in post-operative pain, dosage: Adult, Orally 75-150mgs daily in 2-3 divided doses, per rectum 75-150mgs in divided doses. (Reference: BNF June 2016) ¹³⁰ Partners of the still active data with a fill active fill active data with a fill active fill active data with a fill active fill active fill active fill active fill active data with a fill active fill a

¹²⁸ A peripheral IV cannula is a small plastic tube that is inserted through the skin into one of the small veins in your hand or arm. They are used to give many different types of medications, for example antibiotics or fluids. (Reference <u>www.buckshealthcare.nhs.uk</u>)

¹³⁰ Redness of the skin caused by congestion of the capillaries in the lower layers of the skin. It occurs with any skin injury, infection, or inflammation. (Reference: medical-dictionary.thefreedictionary.com/erythema)

5.0 Aftermath of Incident

The patient and her husband received pastoral care whilst the patient was an inpatient. Following the patient's discharge home the patient was seen within six weeks by Consultant Obstetrician1 in the Out Patients Department on 21st April 2008.

Through feedback, the patient advised that her recollection of this appointment was that she and her husband waited at this clinic for over an hour surrounded by expectant mothers. She recalled that when she and her husband were about to leave the outpatient clinic they were offered a separate room to wait in.

Through feedback on the draft report, Consultant Obstetrician1 outlined that his/her recollection was the clinic that occurred on 21st April 2008 was a gynaecological clinic; the only patients present would have gynaecological issues or be recently delivered by caesarean section. However, there were not any expectant mothers present on that occasion.

Through liaising with Hospital1, the investigators identified there was a morning antenatal clinic on the 21st April 2008 under another Consultant Obstetrician.

A discharge summary was sent to the patient's GP "General Practitioner Report" proforma dated 26th April 2008 as follows:

General Practitioner Report"

Hospital Name	: completed	Mother name	e : completed
Hospital Number	: completed	DOB	: completed
Consultant	: completed	Age	: completed
GP Name	: completed	Home addres	ss:completed

Antenatal/Labour/third stage			
PARITY:	1+0		
BLOOD GROUP:	O RH POSITIVE		
TYPE OF CARE:	Combined G.P. /A.N Clinic		
RUBELLA – Status:	RUBELLA IMMUNE		
H.I.V. Status:	H.I.V. antibody negative		
ONSET of LABOUR:	Emergency LSCS		
Emergency LSCS-:	Placenta Praevia/Abruption		
Indication			
MODE OF DELIVERY:	EMERGECNY L.S.C.S.		
Pain Relief/Anaes:	Spinal		
Comments-Labour/3 rd :	Yes, Blood transfusion x 3 in ICU		
Stage			
Comments – A/N:	Yes; Admitted with Abdominal pain @ 30 weeks and reduced Fetal		
	Movements		

<u>Baby 1 – Delivery Re</u>	Baby 1 – Delivery Report		
DATE/TIME –Delivery:	08/03/2008 04:30:00		
MODE OF DELIVERY:	EMERGECNY L.S.C.S.		
GESTATION:	30		
NUMBER OF BABIES:	Singleton		
BORN			
TYPE of BIRTH:	STILLBIRTH		
SEX:	FEMALE		
WEIGHT? (Kgs):	1.6		
Comments:	Yes, Fresh Stillbirth		

<u>Baby 1 – Discharge Report</u>	
Main disease/ Condition of Infant:	NAD ¹³¹
Autopsy performed:	No
Cause of Intrapartum Death:	Unknown
Cause of Neonatal Death:	
Date/Time of Baby's death:	08/03/2008
Sensitive Case:	Death of Child
Comments:	Yes

¹³¹ No abnormalities detected

Mother PostNatal		
Discharge date:	12/03/2008	
Post-natal Haemoglobin:	Discharge Hgb: 8.9	
Rubella Vaccine:	Not indicated	
Anti D Immug:	Not indicated	
Perineum:	Intact	
Abdominal Wound:	Other Clean & healing, sutures removed	
P/N Problems:	Other	
Medication on Discharge:	Analgesia, Iron	
Appointments/Review:	G.P – Follow –up; P/N Clinic: Hospital 1	
Comments:	Yes, Tenderness on L calf Reviewed by SHO ¹³² - NAD	

¹³² Senior House Officer

6.0 Key Causal Factors, Contributory Factors & Linked Recommendations

Key Causal Factors are issues that arose in the process of delivering and managing health services which the investigators considered had an effect on the eventual adverse outcome.

The examination of the circumstances surrounding the care, management and treatment delivered to the patient at Hospital 1 from the date of her antenatal care of 31st October 2007 to 7th March 2008 date of the patient's admission to the hospital at 30 weeks gestation identified the following Key Causal Factor:

Failure to consider and recognise the signs and symptoms of a placental abruption on the patient's admission at 30 weeks gestation and intervene to deliver the baby

Several epidemiologic¹³³ chort studies have found that abruption complicates approximately 1% of deliveries (Annath CV et al 1999).

The risk factors for placental abruption include:

- cigarette smoking
- Multiple gestations
- hypertension¹³⁴
- Mild and severe preeclampsia¹³⁵

(Obstet Gynecol 2006)

At interview, the Obstetric Registrar outlined the patient did not have any risk factors when s(he) assessed and examined the patient on admission.

The Key Causal Factor identified was analysed by the investigators to identify the 'Contributory Factors'.

Contributory Factors are considered to be the hazards and potential causes of harm, if not mitigated (through appropriate recommendations being put in place).

¹³³ Epidemiology is the study and analysis of the patterns, causes, and effects of health and disease conditions in defined populations. It is the cornerstone of public health, and shapes policy decisions and evidence-based practice by identifying risk factors for disease and targets for preventive healthcare. ¹³⁴ Abnormally high blood pressure

¹³⁵ Preeclampsia is a pregnancy complication characterized by high blood pressure and signs of damage to another organ system, often the kidneys. Preeclampsia usually begins after 20 weeks of pregnancy in a woman whose blood pressure had been normal. Even a slight rise in blood pressure may be a sign of preeclampsia (Mayo Clinic)

The list of Contributory Factors outlined within the Contributory Factors Framework were used to analyse the Key Causal Factor identified by this investigation is included in Appendix 2 of this report.

The following section of this report analyses the Key Causal Factor and the contributory factors identified.

Individual (Staff) Factors

Knowledge and skills/competence – education, training, supervision

At interview, Staff Midwife1 informed the investigators s(he) has been working in the area of obstetrics over 15yrs.

At interview, the Obstetric Registrar outlined s(he) has been working in Hospital 1 16years, s(he) is now a Consultant Obstetrician in Hospital 1.

At **23:08hours** on 7th March 2008, it has been documented in the patient's healthcare records by Staff Midwife1; the patient 27yr old lady presented to the labour ward within the maternity unit¹³⁶ at 30 weeks gestation¹³⁷ with a history of pressure pains and decreased foetal movement that evening. The patient felt nauseous during this time. There was good foetal movement earlier that day.

23:18hours

The following has been documented in the patient's healthcare records by Staff Midwife1:

"Variability reduced uterus tense and sore to touch. No PV¹³⁸ bleed"

The severity of symptoms depends of the location of the abruption, whether it is revealed¹³⁹ or concealed¹⁴⁰ and the degree of the abruption. (Obstet Gynecol 2006)

The uterus is frequently tender and may feel hard on palpitation. Backache may be the only symptom, especially when the placental location is posterior. (Obstet Gynecol 2006)

At interview, Staff Midwife1 indicated to the investigators s(he) remembers thinking it was a concealed abruption as the abdomen was tense, hard and the pain the patient was describing. Staff Midwife1 informed the investigators the tense and hard abdomen in particular alerted him/her, s(he) did CTG tracing as s(he) thought the patient was abrupting.

¹³⁶ There are 33 beds (antenatal and postnatal sections) and 4 delivery single rooms (labour ward) in the maternity unit in Hospital 1. The labour ward is a ward off the main antenatal and postnatal sections.

¹³⁷ Pregnancy

¹³⁸ PV - Per Vaginam (Latin) meaning via/ through the vagina (Reference: Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)

¹³⁹ Revealed – Blood tracks between the membranes, and escapes through the vagina and cervix. (Yinka O et al (2006))

¹⁴⁰ Concealed - blood collects behind the placenta, with no evidence of vaginal bleeding, this type is less common (Yinka O et al (2006))

At interview, the Obstetric Registrar outlined the patient complained of the following symptoms: Lower abdominal pressure, frequent urination, and had leucocytes in a urine sample. The Obstetric Registrar indicated a UTI is very common in pregnancy. At interview, the Obstetric Registrar indicated the reason s(he) commenced Amoxicillin at that time was as a result of his/her diagnosis the patient had a UTI¹⁴¹.

The microbiology report on the patient's urine sample from the laboratory outlined the followina:

Microscopy		
Pus cells	20	/mm^3
Red cells	20	/mm^3
Organisms	Nil	
Casts	Nil	
Epithelial Cells	Nil	
Debris	Nil	
Bacterial count	10,000 -100,000 cfu's/ml (Equivocal ¹⁴²)	
Urine Culture	Mixed Growth	

The differential diagnosis includes all causes of abdominal pain and bleeding. These include placenta previa¹⁴³, appendicitis, urinary tract infections, preterm labour, fibroid degeneration, ovarian pathology and muscular pain. (Obstet Gynecol 2006)

The Clinical expert (Obstetrician) nominated from the membership of the Clinical Review Team indicated; an abruption should have been considered. It is of significant importance that a tense tender uterus should be considered to be an abruption until proven otherwise.

The diagnosis of abruption is a clinical one and the condition should be suspected in women who present with vaginal bleeding or abdominal pain or both, a history of trauma, and those in who present in otherwise unexplained preterm labour. (Obstet Gynecol 2006)

The following has been documented in the patient's healthcare records by Staff Midwife1:

"On palpation, Good size baby, long lie Cephalic¹⁴⁴ Variability¹⁴⁵ reduced, period like pains"

 $^{^{141}}$ UTI: Urinary tract Infection

¹⁴² Neither positive nor negative, there is a mixed bacterial growth and the red cell and white cell counts are low, suggests contamination in the specimen rather than a confirmed UTI. ¹⁴³ Placenta previa is a condition that occurs during pregnancy when the placenta is abnormally placed, and partially or totally covers the cervix.

⁽Reference: medical-dictionary.thefreedictionary.com/placenta+previa)

 $^{^{144}}$ 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)

¹⁴⁵ 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. (reference: Robinson B. (2008) A Review of NICHD

A subsequent entry was documented in the patient's healthcare records by Staff Midwife1 -

"Cephalic now was breech¹⁴⁶ earlier CTG¹⁴⁷ commenced"

A variety of fetal heart rates have been described in association with abruption. There may be recurrent late¹⁴⁸ or variable declarations¹⁴⁹, reduced variability, bradycardia¹⁵⁰, or a sinusoidal¹⁵¹ fetal heart rate pattern. (Obstet Gynecol 2006)

The Clinical expert (Midwifery) nominated from the membership of the Clinical Review Team indicated the CTG on admission was very worrying, there was reduced variability. In any minute there is supposed to be variability of more/greater than 5 beats per minute.

At interview, the Obstetric Registrar outlined one cannot rely on CTG at 30 weeks, it is not active.

The Clinical expert (Obstetrician) indicated the key is to keep the CTG tracing going so changes can be recognised if the situation deteriorates; especially in this case where reduced fetal movements had been reported.

The CTG was discontinued while non-reassuring and the patient was transferred to the floor in the maternity unit.

At interview, Staff Midwife1 outlined to the investigators s(he) recalled the labour ward was particularly busy on that night and that s(he) would have kept the patient in the labour ward if there were enough beds.

In place in Hospital 1 since 2008:

- 1. K2¹⁵² training implemented at end of 2014
- 2. The following areas of training are mandatory fields for Midwifery staff, Obstetric Consultants and Obstetric NCHD's¹⁵³
 - a. CTG

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: <u>http://medical-dictionary.thefreedictionary.com/premature+labor</u>). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).

 $^{^{146}}$ 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.

Cardiotocography (CTG) is a technical means of recording the foetal heartbeat and the uterine contractions during pregnancy, typically in the third trimester. (Reference: Macones GA, Hankins GD, Spong CY, et al

¹⁴⁸ Uniform, repetitive, periodic slowing of FHR with onset mid to end of the contraction and nadir more than 20 seconds after the peak of the contraction and ending after the contraction.

¹⁴⁹ Variable, intermittent periodic slowing of the FHR with rapid onset and recovery. Time relationships with contractions cycle are variable **and** they may occur in isolation, sometimes they resemble other types of decelerations patterns in timing and shape 150 100-109bpm

¹⁵¹ A sinusoidal fetal FHR pattern is defined as a pattern of fixed, uniform fluxuations of the FHR that creates a pattern resembling successive geometric sine waves. It frequently is described as undulating and smooth and is characterized by the absence of variability. ¹⁵² Encompassing all the established and award winning content of the K2 Fetal Monitoring Training System, the Perinatal Training Programme is

an interactive computer based training system covering a comprehensive spectrum of learning that can be accessed over the internet, anywhere, ¹⁵³ Non Consultant Hospital Doctors

- b. K2
- c. PROMPT (Practical Obstetric Multi-Professional Training)
- Polices Procedures and Guidelines (PPPG's) reviewed on an ongoing basis at local meeting attended by midwives and doctors
- 4. Multidisciplinary twice daily safety huddle/pause
- 5. Triggers for escalation clearly identified, such as link Instrumental Deliveries link with Consultant on Call
- 6. A Clinical Midwife Manager2 is rostered 24/7 in the labour ward

Recommendation

It is recommended that routine audits are undertaken of training records and the results of such audits are subject to review by the relevant governance committee.

Team Factors

Verbal & Written Communication – Adequate handover & management plan

At interview, the Obstetric Registrar indicated his/her rationale to admit the patient was for observation further to his/her assessment and examination.

There was no evidence of handover in the patient's healthcare records from the staff in the labour ward to the staff on the floor in the maternity unit. There was no written care plan or management plan for the staff receiving the patient outlining what observations or monitoring was required for the patient.

In place in Hospital 1 since 2008:

- 1. Implementation of clinical hand-over, twice daily in the labour ward and Maternity unit which includes documentation and sign off
- 2. The introduction of the National Maternity Healthcare Record

Recommendation

Ensure that all staff are aware of adhere to the HSE Standards and Recommended Practices for Healthcare Records (2007 amended May 2011). In addition it is recommended that routine audits of compliance with the Standard are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Team Factors

Supervision & seeking help – willingness of junior staff to seek help

At **23:20hours on 7th March**, the following was documented in the antenatal notes in the patient's healthcare records by the Obstetric Registrar–

"CTG satisfactory, Vital signs, frequency of urination, ++ leucocytes, MSU¹⁵⁴

Scan – cephalic FH¹⁵⁵ \checkmark

- Fundal placenta
- $AFI^{156} \sqrt{}$

At interview, the Obstetric Registrar indicated the scan was normal. On his/her examination the patient did not have any risk factors.

The Clinical expert (Obstetrician) nominated from the membership of the Clinical Review Team indicated on a scan at that stage, a clot can be difficult to see. There may not even be a clot, instead there maybe blood tracking which will not be evident on a scan.

¹⁵⁴ MSU-Midstream Urine

¹⁵⁵ FH – Foetal heart

¹⁵⁶ Amniotic Fluid Index

The ultrasonographic appearance of abruption depends to a large extent on the size and location of the bleed as well as the duration between the abruption and the time the ultrasound examination was performed. (Nyberg et al, 1987)

Importantly, a negative ultrasound does not rule out an abruption. (Glantz et al, 2002)

At interview, the Obstetric Registrar indicated his/her rationale to admit the patient was for observation further to his/her assessment and examination. It is noted by the investigators there is no record in the patient's healthcare records outlining that the Obstetric Registrar at that time discussed the patient with the Consultant - on - call, seek advice or assistance.

In place in Hospital 1 since 2008:

- 1. Implementation of clinical hand-over, twice daily in the labour ward and Maternity unit which includes documentation and sign off
- Guideline & Procedure for the Management of Antepartum Haemorrhage (APH), Revision No: 4, Oct 2015

Recommendation

It is recommended that routine audits of compliance with the 'Guideline & Procedure for the Management of Antepartum Haemorrhage (APH), Revision No: 4 Oct, 2015' are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Most cases of placental abruption cannot be predicated or prevented. (Obstet Gynecol 2006)

However, in some cases, maternal and infant outcomes can be optimised through attention to the risk and benefits of conservative management, ongoing evaluation of fetal and maternal well-being, and through expeditious delivery where appropriate. (Obstet Gynecol 2006)

7.0 Incidental Findings and Linked Recommendations

Incidental findings are issues identified in the course of the investigation which did not impact on the outcome but are system development issues.

Incidental Finding 1 - Incomplete and inconsistent documentation

Legible, timely and complete patient records are a critical component of communication between members of the multidisciplinary team. All professionals rely upon thorough records to ensure that they are properly informed prior to making their own clinical intervention.

In conducting this systems analysis the review of the healthcare record revealed incidences of poor legibility throughout the clinical content of the healthcare record and on occasions the documentation was not in line with the HSE Code of Practice for Healthcare Records 2007 amended in 2011.

- Some entries and signatures were difficult to decipher which made it difficult and sometimes impossible to identify the note and the healthcare professional.
- Entry with no signature.
- There were gaps in the documentation from:
 - \circ 11:30 hours 7th March 00:30 hours 8th March 2008
 - \circ 00:30hours 01:50hours 8th March 2008
 - o 01:50hours 03:00hours on 8th March 2008
- There was no evidence of handover in the patient's healthcare records from the staff in the labour ward to the staff on the floor in the maternity unit.
- There was no written care plan or management plan for the staff receiving the patient outlining what observations or monitoring was required for the patient.

The investigators note the National Maternity Healthcare Record has been introduced in Hospital 1.

Recommendation

Ensure that all staff are aware of adhere to the HSE Standards and Recommended Practices for Healthcare Records (May 2011). These standards replaced the HSE Standards and Recommended Practices for Healthcare Records (2007) that were in place in 2008. In addition it is recommended that routine audits of compliance with the Standard are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Incidental Finding 2 - Communication with the patient

At the meeting with the investigators on 16th May 2016, the patient's recollection was that she felt she was not being listened to and that her symptoms were not being taken seriously.

It is outlined in "National Institute for Health and Care Excellence", Guideline 190, (2007) amended in 2014 that the woman is in control, is listened to and is cared for with compassion.

Recommendation

It is recommended that the hospital should ensure that all policies, procedures and guidelines within the maternity unit include section that reflects "that the woman is in control, is listened to and is cared for with compassion". It is recommended that patient satisfaction surveys are carried out and the results of such surveys are subject to review by the relevant governance committee

Incidental Finding 3 –Follow up appointments

Through feedback on the draft chronology, the patient and her husband advised that her recollection of the 6 week follow up appointment was that she and her husband waited at this clinic for over an hour surrounded by expectant mothers. She recalled that when she and her husband were about to leave the outpatient clinic they were offered a separate room to wait in.

Recommendation

The Hospital should ensure that appropriate follow up appointments in these circumstances are held in a private and quiet area with protected time to ensure that there are no interruptions.

8.0 Urgent Follow up Required Post Investigation

Follow up for the implementation of the recommendations of this Incident/Complaint Investigation

In order to ensure that the recommendations contained in this report are implemented as expediently as is reasonably practicable it is of the utmost importance that the hospital develops an Action Plan to agree a schedule of prioritisation of the recommendations of this report and to further agree the named person who will take responsibility for advancing specific recommendations.

9.0. Summary of Recommendations

Recommendation 1

It is recommended that routine audits are undertaken of training records and the results of such audits are subject to review by the relevant governance committee.

Recommendation 2

Ensure that all staff are aware of adhere to the HSE Standards and Recommended Practices for Healthcare Records (2007 amended May 2011). In addition it is recommended that routine audits of compliance with the Standard are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Recommendation 3

It is recommended that routine audits of compliance with the 'Guideline & Procedure for the Management of Antepartum Haemorrhage (APH), Revision No: 4 Oct, 2015' are developed and carried out and the results of such audits are subject to review by the relevant governance committee.

Recommendation 4

It is recommended that the hospital should ensure that all policies, procedures and guidelines within the maternity unit include section that reflects "that the woman is in control, is listened to and is cared for with compassion". It is recommended that patient satisfaction surveys are carried out and the results of such surveys are subject to review by the relevant governance committee.

Recommendation 5

The Hospital should ensure that appropriate follow up appointments in these circumstances are held in a private and quiet area with protected time to ensure that there are no interruptions.

10.0 References

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Hospital 1, Guidelines & Procedure for the Management of Antepartum Haemorrhage (APH) (Rev. 4, 2015)

Health Service Executive; Guideline for Systems Analysis Investigation of Incidents; Ref NIMLT 0010 (2015)

Health Service Executive, Standards and Recommended Practices for Healthcare Records Management V3.0 (2007 amended May 2011)

National Institute for Health and Care Excellence, Intrapartum care: care of healthy women and their babies during childbirth, Clinical Guideline 190, 2007 amended 2014

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Appendices Appendix I – Terms of Reference

Review of the Maternity Services at Portiuncula Hospital, Ballinasloe (PHB) and of a number of adverse perinatal events between 2008 and November 2014

Terms of Reference:

Introduction

A Preliminary Review into the care of 7 women who had adverse perinatal events between February and November 2014 at Portiuncula Hospital, Ballinasloe was undertaken in December 2014 by Dr. Geraldine Gaffney, Prof. Declan Devane and Ms Dawn Johnston. The results of this preliminary Review were reported on the 19th Jan 2015.

Scope of the Review

It has been decided on the basis of the preliminary Review completed in December 2014 to commission a full Review of the Maternity Service at Portiuncula Hospital, Ballinasloe. This Review will include as an integral part of it, the review of the care of the women who were the subject of the Preliminary Review.

A number of other similar cases have been identified since the Preliminary Review was concluded and it has been decided that they will be included in this new Review. The total number of cases to be covered by the Review is anticipated to be in the region of 12.

Review Team

A Review Team has been appointed to undertake the overall Review. They will be assisted in their work in relation to the Review of the individual cases, by a systems analysis investigation which will be conducted on their behalf by experienced systems analysis investigators. These reports will be available to the Review Team as key inputs to their work.

Review Commissioner

This Review is being commissioned by the Chief Clinical Director, Saolta University Health Care Group.

The final report will be provided to the Group CEO and Board of Saolta University Health Care Group and the HSE's National Director for Acute Hospitals.

Purpose of the Review

The purpose of the Review is to:

Part 1: Review of maternity services at Portiuncula Hospital

- 1. Review the perinatal care provided by PHB maternity unit including the findings of the analysis of the perinatal care in the cases covered by this Review.
 - **a.** Identify the extent, if any, of deficiencies in the process and outcome of care.
 - **b.** Identify any patterns that would have wider implications for the safety of services delivered during the time period in question.
- 2. Review, the wider delivery of services at PHB maternity unit during the time period in question.
- 3. Examine the extent to which the corrective measures that were put in place during the Preliminary Review and the audits of their implementation, address any deficiencies identified in items 1 and 6 of these Terms of Reference.
- 4. Examine the implementation of national HSE policies in relation to patient safety, risk management, incident management, reporting, investigation and open disclosure, to ascertain the extent that they were:
 - **a.** In place in the PHB maternity unit, and
 - **b.** Followed in the cases comprehended by this Review, and
 - c. Managed and escalated appropriately by the Saolta Group
- 5. Arising from the findings from 1 to 5 above, recommend any actions necessary to improve the safety and quality of services at;
 - a. PHB maternity unit
 - **b.** Other maternity units in the Saolta University Health Care Group and across the country

Part 2: Review of individual cases

- 6. Undertake a review of the perinatal care (from their presentation for care at PHB maternity unit to their immediate postnatal care) provided to the women who were the subject of the preliminary Review and those agreed additional cases. In addition this review will include the initial neonatal care provided to the babies born. In particular it will focus to
 - **a.** Establishing the factual circumstances leading up to the adverse perinatal event in each of the individual cases.
 - **b.** Identifying any key causal factors that may have occurred.
 - **c.** Identifying the contributory factors that led to the key causal factors.

(Should any immediate safety concerns arise during the course of the Review the Chair

of the Review Team will convey the details of these safety concerns to the Commissioner as soon as possible)

Membership of the Review Team

Professor James Walker (Chair): Professor of Obstetrics in the University of Leeds.

Professor Sean Daly: Elected Master of the Coombe Hospital in 1998: Mastership 1999-2005: Head of Perinatal Medicine in Coombe Hospital 2005-2010

Dr Paul Hughes: Obstetrician & Gynaecologist, Kerry

Dr Elaine Madden: Head of Midwifery and Gynaecology at the South Eastern Trust (Belfast)

Ms Rachel Conaty: Assistant Director of Midwifery and Nursng at the National Maternity Hospital in Holles Street, Dublin from 2008 to 2015..

Professor Eugene Dempsey: Consultant Neonatologist at Cork University Maternity Hospital and Professor of Paediatrics at University College Cork.

Dr Adrienne Foran: Consultant Neonatologist, Rotunda Hospital

Ms Breda Shiel Kerans: service user representative on the Maternity Services Steering Group

Should the Review Team require further external independent input, the Chair of the Review Team will discuss this with the Commissioner.

Support for the Review Team

The Review Team will;

- Be afforded the assistance of all relevant 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).

Review methodology

The Review will follow the HSE Investigation policy and will be cognisant of the rights of all involved to privacy and confidentiality; dignity and respect; due process; and natural and constitutional justice. The Review will commence immediately and will be concluded in the shortest timeframe necessary to achieve the purpose of the Review. It is anticipated that a maximum of 5 month will be required.

Following completion of the Review, an anonymised draft report will be prepared by the Review Team outlining the 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.

As part of the overall Review individual Investigation Reports into the care of each of the women will also be produced and shared with the women/partners concerned.

The anonymised version of the full Review report will also be shared with the women involved and may be published. This report may also be the subject to Freedom of Information requests.

Communications

A named individual within the Saolta group, will be appointed for the purpose of communicating information pertaining to the Review to the family/staff member(s) affected by and/or involved in the adverse events which are the subject of the Review.

Dr. Pat Nash

Chief Clinical Director, Saolta University Health Care Group

Appendix 2: Framework of Contributory Factors

Factor Types Contributory Factor (i.e. potential causes related to each key causal factor and incidental finding)

Individual affected/harmed

- Condition (complexity & seriousness)
- Language and communication
- Personality and social factors
- Psychological, existing mental health condition, stress

Task and Technology Factors

- Task design and clarity of structure
- Availability and use of protocols, policies, standards
- Policies etc. relevant, unambiguous, correct and realistic
- Availability and accuracy of test results
- Decision-making aids
- Individual (Staff) FactorsKnowledge and skills
 - Competence education, training, supervision
 - Physical, psychological and mental health illness

Team Factors

- Verbal communication
- Written communication
- Supervision and seeking help
- Team structure (leadership, congruence, consistency etc.)

Work Environmental Factors

- Staffing levels and skills mix
- Workload and shift patterns
- Administrative and managerial support
- Environment Physical and cognitive.
- Design, availability and maintenance of equipment

Organisational & Management Factors

- Organisational structure
- Financial resources and constraints
- Policy, standards and goals
- Quality & Safety culture and priorities

Institutional Context Factors

- Economic and regulatory context
- National health service executive
- Links with external organisations

Strength of	Category of Control	Comments/ Examples
Strongest 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. Examples of controls may be to stop providing service; discontinue a particular procedure; discontinue use of a particular product, service or piece of equipment. <i>If hazard elimination is</i> <i>not successful or practical, the next control measure is</i> <i>substitution.</i>
	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. Ensure that administrative policies, procedures and guidelines are in place Ensure staff are appropriately trained in these Monitor compliance with policies, procedures and guidelines through audit If no administrative procedure is available the next control measure is work practice controls.
Weakest Control	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. <i>Work Practice</i> <i>controls should be only considered after all the previous</i> <i>measures have been considered and found to be</i> <i>impractical or unsuccessful</i>

Appendix 3: Hierarchy of Hazard Controls