



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Final Report

Investigation of Incident 51449 into the care and treatment provided to Mrs Conroy while under the care of the Maternity Services at Hospital S1 for the delivery of her Baby Róisín on the 14th November 2001.

Investigation Commencement Date:

The investigation commenced on **25th April 2016**

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Completion Date: 9th May 2018

Table of Contents

Glossary of Terms and Acronyms	2
Apology	13
Acknowledgement.....	14
Executive Summary.....	15
Methodology	26
Section 1: Background to this Investigation.....	38
Section 2: Chronology of Events.....	44
Section 3: Aftermath of Incident.....	79
Section 4: Key Causal Factors, Contributory Factors, Incidental Factors and Linked Recommendations	90
Action taken since the time of the events described in this report:	106
Incidental Findings	123
References:	126
APPENDIX A: 51449 TERMS OF REFERENCE	134
APPENDIX B: CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST DISCLAIMER	136
APPENDIX C: REPORT DR. FRANCOIS GARDEIL, CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST, WEXFORD GENERAL HOSPITAL, WEXFORD	137
APPENDIX D: REPORT DR. JOHN F. MURPHY, DEPT. OF NEONATOLOGY, THE NATIONAL MATERNITY HOSPITAL, DUBLIN	141
APPENDIX E: MIDWIFERY REPORT	145
APPENDIX F: CORRESPONDENCE FROM THE MEDICAL COUNCIL	155
APPENDIX G: NURSE/MIDWIFE SCOPE OF PRACTICE DECISION-MAKING FRAMEWORK 2000 (NMBI)	159
APPENDIX H: FRAMEWORK OF CONTRIBUTORY FACTORS	160
APPENDIX I: HIERARCHY OF HAZARD CONTROLS	164

Glossary of Terms and Acronyms

ADOM	Assistant Director Of Midwifery
ALP	An Alkaline phosphatase test measures the amount of the enzyme ALP in the blood. ALP is made mostly in the liver and in bone with some made in the intestines and kidneys. It also is made by the placenta of a pregnant woman.
AFI	Amniotic Fluid Index
Amnisure ROM™ test	The Amnisure ROM™ test is approved for the diagnosis of rupture of membranes (ROM). (Reference: 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: http://www.webmd.com/a-to-z-guides/antibody-tests)
Apgar score	An objective score of the condition of a baby after birth. This score is determined by scoring the heart rate, respiratory effort, muscle tone, skin colour, and response to a catheter in the nostril. Each of these objective signs receives 0, 1, or 2 points. An Apgar score of 10 means an infant is in the best possible condition. The Apgar score is done routinely 60 seconds after the birth of the infant. A child with a score of 0 to 3 needs immediate resuscitation. The Apgar score is often repeated 5 minutes after birth, and in the event of a difficult resuscitation, the Apgar score may be done again at 10, 15, and 20 minutes. (Reference: http://www.medicinenet.com/script/main/art.asp?articlekey=2303) Apgar Score: an index used to evaluate the condition of a new-born 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. (Reference: http://www.merriam-webster.com/dictionary/apgar%20score)
APTT	Partial Thromboplastin Time is used when someone has unexplained bleeding or clotting. Along with the PT test (which evaluates the extrinsic and common pathways of the coagulation cascade), the aPTT is often used as a starting place when investigating the cause of a bleed or thrombotic (blood clot) episode. It is often used with recurrent miscarriages which may be associated with anticardiolipin or antiphospholipid antibodies. The aPTT and PT tests are also sometimes used as pre-surgical screens for bleeding tendencies, although numerous studies have shown that they are not useful for this purpose (Reference: http://www.labtestsonline.org.uk/understanding/analytes/aptt/tab/test).

Artificial Rupture of Membranes (ARM)	An artificial rupture of the fetal membranes is usually performed to stimulate or accelerate the onset of labour (Reference: http://medical-dictionary.thefreedictionary.com/amniotomy)
Baby Cooling / Brain Hypothermia	<p>Brain Hypothermia, induced by cooling a baby to around 33 °C for three days after birth, is a treatment for hypoxic ischemic encephalopathy. It has recently been proven to be the only medical intervention which reduces brain damage, and improves an infant's chance of survival and reduced disability. Hypothermic neural rescue therapy is an evidence-based clinical treatment which increases a severely injured full term infant's chance of surviving without brain damage detectable at 18 months by about 50%, an effect which seems to be sustained into later childhood.</p> <p>(references: Edwards, AD; Brocklehurst, P; Gunn, AJ; Halliday, H; Juszczak, E; Levene, M; Strohm, B; Thoresen, M; Whitelaw, A; Azzopardi, D. (2010). "Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischaemic encephalopathy: synthesis and meta-analysis of trial data". BMJ (Clinical research ed.) 340: c363.</p> <p>Shankaran, S; Pappas, A; McDonald, SA; Vohr, SR; Hintz, SR; Yolton, K; Gustafson, KE; Leach, TM; Green, C et al. (2012). "Childhood outcomes after hypothermia for neonatal encephalopathy". New England Journal of Medicine 366 (22): 2085–92.</p> <p>Guillet, Róisín; Edwards, AD; Thoresen, M; CoolCap Trial Group (2011). "Seven- to eight-year follow-up of the CoolCap trial of head cooling for neonatal encephalopathy.". Pediatr Res 71 (2): 205–9.</p> <p>Rutherford, M; Ramenghi, LA; Edwards, AD; Brocklehurst, P; Halliday, H; Levene, M; Strohm, B; Thoresen, M et al. (2010). "Assessment of brain tissue injury after moderate hypothermia in neonates with hypoxic-ischaemic encephalopathy: a nested substudy of a randomised controlled trial". Lancet neurology 9 (1): 39–45.</p> <p>Robertson, NJ; Nakakeeto, M; Hagmann, C; Cowan, FM; Acolet, D; Iwata, O; Allen, E; Elbourne, D et al. (2008). "Therapeutic hypothermia for birth asphyxia in low-resource settings: a pilot randomised controlled trial". Lancet 372 (9641): 801–3.</p>
Baseline FHR Variability	<p>Baseline FHR variability is based on visual assessment and excludes sinusoidal patterns. Variability is defined as fluctuations in the FHR baseline of 2 cycles per minute or greater, with irregular amplitude and inconstant frequency. These fluctuations are visually quantitated as the amplitude of the peak to trough in beats per minute. By visual assessment, acceleration is defined as an apparent abrupt increase in FHR above baseline, with the time from the onset of the acceleration to the acme of less than 30 seconds.</p> <p>Late deceleration is defined as an apparent gradual decrease and return to baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. Early deceleration is defined as an apparent gradual decrease and return to the baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer.</p> <p>Variable deceleration is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline.</p>

	<p>When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (Reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol, 2008 Spring; 1(2): 56-60 (Available from: http://medical-dictionary.thefreedictionary.com/premature+labor and http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).</p>
Baseline Fetal Heart Rate (FHR)	<p>Baseline fetal heart rate is the average fetal heart rate (FHR) rounded to increments of 5 beats per minute during a 10-minute segment, excluding periodic or episodic changes, periods of marked variability, or baseline segments that differ by more than 25 beats per minute. In any given 10-minute window, the minimum baseline duration must be at least 2 minutes, or else the baseline is considered indeterminate.</p> <p>In cases where the baseline is indeterminate, the previous 10-minute window should be reviewed and utilized in order to determine the baseline. A normal FHR baseline rate ranges from 110 to 160 beats per minute. If the baseline FHR is less than 110 beats per minute, it is termed bradycardia. If the baseline FHR is more than 160 beats per minute, it is termed tachycardia.</p>
BHCG	Beta Human Chorionic Gonadotrophin (Pregnancy Hormone)
BP	Blood Pressure
BPS	Biophysical Profile Score
Bradycardia	<p>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)</p>
C & S	Culture and Sensitivity
Caesarean Section	<p>There are two types of Caesarean Sections: the classical Caesarean Section, and the Lower Segment Caesarean Section. The classical section involves a midline longitudinal incision which allows a larger space to deliver the baby. The Lower Segment Caesarean Section, more commonly used today, involves a smaller transverse cut which results in less blood loss and is easier to repair (Reference: http://www.news-medical.net/health/Cesarean-Section-Types.aspx)</p>
Cardiopulmonary Resuscitation	<p>Cardiopulmonary resuscitation involves physical interventions to create artificial circulation through rhythmic pressing on the patient's chest to manually pump blood through the heart, called chest compressions, and usually also involves the rescuer exhaling into the patient (or using a device to simulate this i.e. an ambu bag and oxygen mask) to ventilate the lungs and pass oxygen in to the blood, called artificial respiration.</p>
Cardiotocography	<p>In medicine (obstetrics), cardiotocography (CTG) is a technical means of recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions (-toco-) during pregnancy, typically in the third trimester. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM).</p>
Cephalic Presentation	<p>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</p>

	the vertex presentation where the occiput (back part of the head or skull) is the leading part (Reference: Hellman LM, Pritchard JA. Williams Obstetrics, 14th edition, Appleton-Century-Crofts (1971) Library of Congress Catalogue Card Number 73-133179. p. 322-2)
Cervix	Neck of the Womb
CIS	The Clinical Indemnity Scheme (CIS) was established in 2002, in order to rationalise pre-existing medical indemnity arrangements by transferring to the State, via the Health Service Executive (HSE), hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks. (Reference: http://www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html). State Claims Agency (2009). The State Claims Agency Clinical Indemnity Scheme Incident Notification Requirements. Available from http://www.stateclaims.ie/ClinicalIndemnityScheme/publications/2009/SCACISIncidentNotificationReqs.pdf
CMM	Clinical Midwife Manager
Commissioner	The commissioner of an investigation differs across the health system, but it is typically the senior accountable officer in a service, directorate or care group that commissions an investigation of a clinical or non-clinical incident.
Cord blood Ph	A low pH (less than 7.04 to 7.10) means there are higher levels of acids in the baby's blood. This might occur when the baby does not get enough oxygen during labor (Reference: http://www.nlm.nih.gov/medlineplus/ency/article/003403.htm)
CRP	C-Reactive Protein, a measure of inflammation
CTG	CTG is a technical means of recording the fetal heartbeat and the uterine contractions during pregnancy, typically in the third trimester. (Reference: Macones GA, Hankins GD, Spong CY, et al. The 2008 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring: update on definitions, interpretation, and research guidelines Obstet Gynecol (2008) 112:661-666) A 'Normal' CTG is indicated when all four features (fetal heart rate, baseline variability, acceleration and deceleration of the fetal heart rate and frequency and strength of contractions as recorded by the attending healthcare professional) fall within the reassuring category i.e. they fall within the normal ranges as outlined on page 16 of this report. A 'Suspicious' CTG is when one feature falls within the non-reassuring category and the remainder are reassuring. A 'Pathological' CTG is when two or more features fall within the non-reassuring category or one or more features fall within the abnormal category.
Cx	Cervix
DC	Discharge
E. coli	E. coli (Escherichia coli) is one of several types of Gram negative bacilli bacteria that normally inhabit the intestine of humans. Some strains of E. coli are capable of causing disease under certain conditions.
ED	Emergency Department

EDD	Estimated Date of Delivery
EEG	Electroencephalogram
Effacement	Effacement relates to the softening and shortening of the cervical canal from about 3cm long to less than 0.5cm long. (Reference: National Collaborating Centre for Women's and Children's Health 2008 Clinical Guideline; Induction of Labour RCOG Press London)
EFW	Estimated Fetal Weight
Electronic Fetal Monitor (EFM)	In medicine (obstetrics), cardiotocography (CTG) is a technical means of recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions (-toco-) during pregnancy, typically in the third trimester. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM)
Endotracheal Intubation	Endotracheal intubation is the insertion of a tube into the trachea for purposes of anesthesia, airway maintenance, aspiration of secretions, lung ventilation, or prevention of entrance of foreign material into the airway; the tube goes through the nose or mouth (Reference : http://medical-dictionary.thefreedictionary.com/intubation)
Entonox	Entonox is used as an analgesia and can be self-administered using a demand valve which is popular in obstetric practice (Reference: British National Formulary 2009)
EPAU	Early Pregnancy Assessment Unit
Epidural Analgesia	Epidural analgesia is a central nerve blockade technique, which involves the injection of a local anaesthetic, with or without an opioid into the lower region of the spine close to the nerves that transmit painful stimuli from the contracting uterus and birth canal. (Reference: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009234.pub2/pdf)
ESBL	Extended-Spectrum Beta-Lactamases ESBL-producing bacteria are bacteria that produce enzymes that may break down commonly used antibiotics.
Fetal Scalp Electrode	An electrode that is attached to the baby's scalp and connected to the CTG machine so that a trace of the fetal heart can be recorded electronically
FHHR	Fetal Heart Heard and Regular
FHH	Fetal Heart Heard
FHR	Fetal Heart Rate
Fetal Biometric Parameters	Fetal biometric parameters are various antenatal ultrasound measurements that are used to indirectly assess the growth and wellbeing of the foetus and in assessing dates - gestational age (Reference: http://radiopaedia.org/articles/fetal-biometric-parameters)
Fetal Bradycardia	An abnormally slow fetal heart rate, usually below 100 beats/min. Reference Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.
Full Blood Count (FBC)	Full Blood Count (FBC) is used as a broad screening test to check for such disorders as anaemia, infection, and many other diseases. It is a panel of

	tests that examines different parts of the blood (Reference: http://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test).
Fundal Height	Fundal height is the height of the fundus of the uterus, measured in centimetres from the top of the symphysis pubis to the highest point in the midline at the top of the uterus. Fundal height is measured at each prenatal visit with large blunt callipers or with a tape measure. From the twentieth to the thirty-second week of pregnancy the height in centimetres is equal to the gestation in weeks (Reference: http://medical-dictionary.thefreedictionary.com/fundal+height).
Governance	The system by which organisations direct and control their functions and relate to their stakeholders in order to manage their business, achieve their missions and objectives and meet the necessary standards of accountability, integrity and propriety (HSE, 2006).
GP	General practitioner
Gram negative bacilli	Gram negative bacilli are a type of bacteria. The name is derived from a type 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
Haemoglobin (Hb)	<p>A conjugated protein, consisting of haem & 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).</p> <p>Low levels of haemoglobin in pregnancy can indicate anaemia (Reference: http://www.cyh.com/healthtopics/healthtopicdetails.aspx?p=438andnp=459andnid=2759#haemoglobin)</p>
HDU	High Dependency Unit
HSE	Health Service Executive
Hypoxic Ischemic Encephalopathy	Hypoxic Ischemic Encephalopathy has many causes and is essentially the reduction in the supply of blood or oxygen to a baby's brain before, during, or even after birth. It is a major cause of death and disability, occurring in approximately 2-3 per 1000 births and causing around 20% of all cases of cerebral palsy. Hypoxic ischemic encephalopathy (HIE) is a condition that occurs when the entire brain is deprived of an adequate oxygen supply, but the deprivation is not total. While HIE is associated in most cases with oxygen deprivation in the neonate due to birth asphyxia, it can occur in all age groups, and is often a complication of cardiac arrest. (Reference: 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, New-born Infant Nurs Rev. September 1; 11(3): 125-133).
Incident:	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. (Adapted from WHO (2009) and doh (2010), HSE Quality and Risk Taxonomy (2009)). Incidents include adverse events which result in harm; & Near-misses which could have resulted in harm, but did not cause

	<p>harm, either by chance or timely intervention. Incidents can be clinical or non-clinical & include incidents associated with harm to:</p> <ul style="list-style-type: none"> • Our patients, staff and visitors; • The attainment of HSE objectives; • HSE ICT systems; • Data security e.g. Data protection breaches; • The environment. <p>Incidents include complaints which are associated with harm & as such these complaints are patient reported incidents.</p>
Intermittent Auscultation	Intermittent auscultation involves listening to fetal heart sounds at periodic intervals to assess the fetal heart rate (FHR) using either a Pinard stethoscope or a hand held (Doppler) device.
IOL	Induction of Labour is a method of artificially or prematurely stimulating childbirth in a woman (Reference: National Collaborating Centre for Women's and Children's Health 2008 Clinical Guideline; Induction of Labour RCOG Press London)
Iron supplements	Routine iron supplementation is a common practice for preventing iron deficiency (ID) and iron deficiency anaemia (IDA) in pregnancy, because the dietary iron intake of pregnant women often does not meet the recommended dietary intake (Reference: http://www.ajcn.org/content/83/5/1112.full.pdf).
ISBAR	Identify, Situation, Background, Assessment, Recommendation.
K2 Fetal Monitoring Training System	K2 Fetal Monitoring Training System is an interactive computer based training system covering a comprehensive spectrum of learning that can be accessed over the internet. (Reference: http://www.k2ms.com/products/fetal_monitoring_training_system_online.html#2)
Key Causal Factors	Issues that arose in the process of delivering and managing health services which had an effect on an eventual adverse outcome.
Labour (stages)	<p>The first stage of labour is the process of reaching full cervical dilatation. This begins with the onset of uterine labour contractions, and it is the longest phase of labour. The first stage is divided into three phases: latent, active, and descent of the presenting part.</p> <p>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).</p>
Left occipitoposterior (LOP)	The occiput (back of baby's skull) faces posteriorly (behind) and towards left.
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).
Liquor	Liquor is amniotic fluid within the amniotic cavity produced by the amnion during the early amniotic period and later by the lungs and the kidneys. Amniotic fluid protects the embryo and foetus from injury. (Reference: Dorland's Illustrated Dictionary 31ed)

LMP	Last Menstrual Period
Mané	The next morning
MCH	The average amount of haemoglobin in the average red cell. MCH is particularly important when testing for anaemia. http://www.babymed.com/laboratory-values/mean-corpuscular-hemoglobin-mch-whole-blood-during-pregnancy)
MCV	Mean Corpuscular Volume measures the size of an average red blood cell. Low mean corpus volume can be associated with anaemia, thalassemias, iron deficiency and Shahidi-Nathan-Diamond syndrome. High mean corpus volume can be caused by vitamin B12 deficiency, impaired vitamin absorption, hyperthyroidism, celiac disease and deficient enzymes (Reference: http://www.babymed.com/laboratory-values/mean-corpuscular-volume-mcv-whole-blood-during-pregnancy)
Meconium	Meconium is the greenish-black sticky material passed from the baby's bowels after birth. In some instances, the foetus will pass meconium into the amniotic fluid while still in the womb, indicated by the presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so (Reference: http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf)
Membrane (Cervical) 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)
MRSA	Multidrug Resistant Staphylococcus aureus
MSU	Midstream sample of urine
NAD	Nothing Abnormal Detected
NCHD	Non consultant hospital doctor
Negligence	Negligence is a failure to exercise the appropriate and or ethical ruled care expected to be exercised amongst specified circumstances. The area of tort law known as negligence involves harm caused by failing to act as a form of carelessness possibly with extenuating circumstances. (Reference: https://www.merriam-webster.com/dictionary/negligence)
Neutrophil	A neutrophil is a type of mature (developed) white blood cell that is present in the blood. White blood cells help protect the body against diseases and fight infections. (Reference: http://www.medfriendly.com/neutrophil.html)
New-born hypoxic-ischaemic brain injury	New-born hypoxic-ischaemic brain injury differs from injury in the adult brain in several ways: NMDA receptor toxicity is much higher in the immature brain. Apoptotic mechanisms including activation of caspases, translocation of apoptosis-inducing factor and cytochrome-c release are much greater in the immature than the adult.

	<p>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. (Reference: Wang, X.; Carlsson, Y.; Basso, E.; Zhu, C.; Rousset, C. I.; Rasola, A.; Johansson, B. Róisín.; Blomgren, K. et al. (2009).</p> <p>"Developmental Shift of Cyclophilin D Contribution to Hypoxic-Ischemic Brain Injury". Journal of Neuroscience 29 (8): 2588–96.</p> <p>Ferriero, DM (2004). "Neonatal brain injury". The New England Journal of Medicine 351 (19): 1985–95).</p>
NIMLT	National Incident Management and Learning Team
Nocte	At night
O&G	Obstetrics and Gynaecology
O/E	On examination
Occiput Posterior Position	<p>The most common position for a baby during labour is head down with the back of the head (occiput) facing the front of the mother (anterior). When the back of the head is facing the back of the mother (posterior) the baby's position is called Occiput Posterior:</p> <p>(Reference: http://www.birthingnaturally.net/birth/challenges/posterior.html)</p>
Operative vaginal delivery	<p>Operative vaginal delivery refers to the application of either forceps or a vacuum device to assist the mother in effecting vaginal delivery of a fetus. Ali U and Norwitz E, 2009, Vacuum-Assisted Vaginal Delivery Rev Obstet Gynecol. Winter; 2(1): 5–17.</p>
Os	<p>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.</p> <p>The two descriptions given to the appearances are either a nulliparous os, for a first pregnancy, or a multiparous os for subsequent pregnancies.</p> <p>(Reference: http://www.netdoctor.co.uk/ate/pregnancyandchildbirth/205040.html#ixzz31WTlfp9)</p>
Para	<p>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).</p>
Partogram	A partogram provides an instant picture of the labour and its progress
Perinatal	<p>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. (Reference: http://www.who.int/maternal_child_adolescent/topics/maternal/maternal_perinatal/en/).</p>
pH	<p>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.</p> <p>(Reference: http://www.nlm.nih.gov/medlineplus/ency/article/003403.htm)</p>

PMHX	Previous Medical History
PPROM	Preterm Pre-labour Rupture of Membranes
PPV	Positive Pressure Ventilation
Presentation	<p>Presentation of foetus: that part of the foetus lying over the pelvic inlet; the presenting body part of the fetus. Vertex (VX) presentation: Head presentation of the foetus during birth in which the upper back part of the fetal head is the presenting part.</p> <p>Breech presentation: presentation of the fetal buttocks or feet in labour; the feet may be alongside the buttocks (complete breech p.); the legs may be extended against the trunk and the feet lying against the face; or one or both feet or knees may be prolapsed into the maternal vagina.</p> <p>Cephalic presentation: presentation of any part of the fetal head in labour, whether the vertex, face, or brow.</p> <p>(Reference: The American Heritage® Medical Dictionary, 2004 Published by Houghton Mifflin Company; Medical Dictionary for the Health Professions and Nursing © Farlex 2012)</p>
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)
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	<p>A resuscitaire is a device which combines an effective warming therapy platform along with the components needed for clinical emergency and resuscitation</p> <p>(Reference: http://www.draeger.ae/AE/en_US/products/neonatal_care/)</p>
SCBU	Special Care Baby Unit
Serious incident	An incident that resulted in death or serious harm.
Show	A 'show' is the passage of small quantities of blood-tinged mucus from the vagina at the onset of labour. Reference: http://medical-dictionary.thefreedictionary.com/premature+labour
Doppler	Hand held monitor that is used to detect fetal heart rate
SpR	Specialist Registrar
SROM	Spontaneous Rupture of Membranes
STAT	Medication given immediately as a single dose
SVD	Spontaneous Vertex Delivery: a vaginal birth occurring without the mechanical assistance of obstetric forceps or vacuum aspirator. (Reference Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier)

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	<p>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.</p> <p>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.</p>
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)
TAS	Trans Abdominal Scan
Term	The normal duration of pregnancy is approximately 37 – 42 weeks, with the estimated due date at 40 weeks or 280 days from the first day of the last menstrual period (Reference: http://www.uptodate.com/contents/post-term-pregnancy-beyond-the-basics)
U&E	UandE is the abbreviation used for urea and electrolytes. These are a group of blood tests to measure the levels of salts in the blood (such as sodium and potassium), as well as the urea and creatinine levels, which show the kidney function as they are waste products. (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. (Reference: http://www.medicinenet.com/script/main/art.asp?articlekey=9509)
USS	Ultrasound Scan
VE	Vaginal Examination
Vx	Vertex

Apology

On behalf of the Health Service Executive, I sincerely apologise to the Conroy family for the failures in care provided to Mrs Conroy while under the care of Maternity Services at Portlaoise Hospital for the delivery of her Baby Róisín on the 14th November 2001.

Portlaoise Hospital and its staff, wish to acknowledge that these deficiencies have had a profound impact on the whole family and on Róisín in particular.

The additional distress caused to the Conroy family by the Hospital's failure, for several years to acknowledge or address these deficiencies was unacceptable and is not what is expected from our services.

The Dublin Midlands Hospital Group, (of which Portlaoise Hospital is part of) will continue to implement the recommendations of this report to improve care provision. Most importantly, the report will be shared with all maternity services and other relevant agencies so that lessons can be learned.

I also apologise for the length of time the investigation process has taken and I wish to acknowledge and thank the Conroy Family for their patience during this difficult process.



Mr Trevor O'Callaghan
Chief Executive Officer
Dublin Midlands Hospital Group

Acknowledgement

The Investigation Team greatly appreciated the willingness of Mr and Mrs Conroy to share their experience with us. This was invaluable in carrying out the investigation and in the development of the recommendations.

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

The commissioner of this investigation outlined that all safety incidents within services should be comprehensively investigated within a reasonable timeframe going forward. This is to ensure we learn from any lessons that might help to prevent any further incidents of this nature.

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

In terms of the findings from this investigation, the Investigation Team would also like to acknowledge the significant challenges faced by doctors, midwives and nurses everyday but the human values which underpin these professions must remain constant as those values underpin the trust which lies at the heart of the staff-patient relationship.

Executive Summary

This report presents the findings of a methodological investigation into an incident relating to the circumstances surrounding the care, management and treatment provided to Mrs Conroy and her infant daughter Baby Róisín at Hospital S1 on 14th November 2001.

Mrs Conroy attended Consultant Obstetrician Gynaecologist A's private clinic for ante-natal care and delivery of her first pregnancy in 2001. The ante-natal care was essentially uncomplicated and at term¹ plus 9 days on 13th November 2001 Mrs Conroy attended a routine antenatal appointment with Consultant Obstetrician and Gynaecologist A, a scan carried out suggested reduced amniotic fluid².

Based on this finding Mrs Conroy was scheduled for admission on 14th November 2001 for induction of labour under the care of Consultant Obstetrician and Gynaecologist A.

On 14th November 2001 following admission to Hospital S1, induction was by way of prostaglandin gel due to an unfavourable cervix and therefore no requirement for an artificial rupture of membranes (AROM)³.

Consultant Obstetrician and Gynaecologist A reviewed Mrs Conroy at 09:00 hours on 14th November 2001 and documented that Mrs Conroy was term + 10 days with diminished liquor, the cervix was unfavourable and he inserted 2mg of Prostin gel vaginally⁴.

Following the administration of prostaglandin gel the C.T.G.⁵ recorded between 09:15 hours and 09:40 hours was considered normal and re-assuring by Dr. Gardeil Consultant Obstetrician and Gynaecologist and Clinical Expert assigned to the Investigation Team. Mrs Conroy was not experiencing contractions at this time and was not considered to be in labour.

Based on the documentation available to the Investigation Team, labour was rapid; Mrs Conroy progressed from 1cm⁶ dilated at 14:00 hours to full dilatation at 15:10 hours (70 minutes).

According to Dr. Gardeil Labour commenced prior to 14:00 hours (possibly as early as 11:00 hours) when Mrs Conroy first complained of strong contractions.

It was established by the Investigation Team that Baby Róisín's intrapartum CTG (cardiotocography) which was re-commenced at 14:14 hours was not a complete CTG⁷. The fetal heart rate (cardio) was recorded however the contraction belt (tocograph) was not attached during labour to electronically monitor and record the contractions.

¹ The normal duration of pregnancy is approximately 37 to 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/postterm-pregnancy-beyond-the-basics>)

² Mrs Conroy attended for a routine antenatal appointment with Consultant Obstetrician and Gynaecologist A on the 13th November 2001 and had a scan carried out which suggested low liquor, based on this finding Mrs Conroy was scheduled for admission on the 14th November 2001 for induction of labour.

³ An artificial rupture of the fetal membranes, usually performed to stimulate or accelerate the onset of labour (Reference: <http://medical-dictionary.thefreedictionary.com/amniotomy>).

⁴ Consultant Obstetrician Gynaecologist A did not review Mrs Conroy again until the following morning on 15th November 2001.

⁵ There is no evidence that the tocograph was attached at this time.

⁶ Mrs Conroy outlined at interview that Midwife M1 informed her that she was 4cm at 14:00 hours following an examination and that she was not considered to be 1cm as stated in the healthcare records. Dr. Gardeil stated that it is highly probable that Mrs Conroy was in fact 4cm by 14:00 hours.

⁷ 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).

From 14:14 hours Baby Róisín's cardiac trace was considered by Dr Gardeil to be non-reassuring suggesting some degree of fetal compromise.

It was retrospectively documented by Midwife M1 on the CTG trace that Consultant Obstetrician and Gynaecologist B was contacted via the local bleep system at approximately 14.32 hours.

The motive for bleeping Consultant Obstetrician and Gynaecologist B was not documented by Midwife M1.

There were no further attempts to contact an obstetrician until approximately 16:25 hours immediately prior to Baby Róisín's delivery⁸.

Dr. Gardeil stated for the investigation that standard practice would be to call a Doctor if the patient is private or if any abnormalities have been identified during labour by the midwife.

Baby Róisín was delivered at 16:32 hours at which point it was noted that the cord was tightly wrapped twice around Baby Róisín's neck, there was no liquor seen until after crowning of Baby Róisín's head which appeared to be old black meconium⁹.

Baby Róisín was born in extremely poor condition, was flat and unresponsive and was immediately transferred to the Resuscitaire¹⁰ where efforts were made to resuscitate her.

The Paediatricians were not called until after the birth of Baby Róisín. According to Dr. Gardeil it is standard practice to call the Paediatricians in advance of a delivery if the baby showed signs of fetal distress in utero.

Baby Róisín had Apgar scores of 1 at 1 minute, 4 at 5 minutes, and 8 at 10 minutes and was given Naloxone at 3 minutes, intubated at 5 minutes.

The cord blood sample at the time yielded a pH value of 7.08¹¹ which is indicative of fetal distress and oxygen deprivation prior to and/or during delivery.

Baby Róisín was administered cardiac compressions because of the initial slow heart rate, she was administered bag and mask ventilation to improve her oxygenation.

In view of her absent respiratory effort she was intubated and given respiratory support and responded to these resuscitation measures. At age 35 minutes she was sufficiently stable to be extubated.

Following resuscitation Baby Róisín was transferred to the Special Care baby Unit (SCBU) where Baby Róisín's clinical and neurological status was monitored.

Abnormal neurological behaviour including seizures was noted and documented. Baby Róisín was treated with intravenous Phenobarbitone.

⁸ It is standard practice to call a Doctor just prior to delivery of a baby.

⁹ Meconium is the greenish-black sticky material passed from the baby's bowels after birth. In some instances, the foetus will pass meconium into the amniotic fluid while still in the womb, indicated by the presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so (Reference: <http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf>).

¹⁰ 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/).

¹¹ Normal Cord PH value in an umbilical arterial sample in a term newborn: PH: 7.18 – 7.38 ; Normal Cord PH umbilical arterial value in a preterm newborn: PH: 7.14 – 7.4

Baby Róisín continued to experience a number of neonatal seizures requiring further intravenous¹² (IV) Phenobarbitone and Clonazepam¹³.

As a result of Baby Róisín's persistent abnormal neurological behaviour the decision was made to transfer her to Hospital S2 (a large Dublin Maternity Hospital) for tertiary neonatal care on the 15th November 2001 at 02:00 hours by ambulance.

While under the care of a Consultant Neonatologist at Hospital S2, Baby Róisín had a cerebral ultrasound indicating echogenicity¹⁴ in the thalami¹⁵ and a diffusion weighted MRI¹⁶ also showed some abnormality in the thalami. This finding is in keeping with acute hypoxic-ischaemia.

Following discharge from Hospital S2 Baby Róisín continued to exhibit some abnormal signs in the form of intermittent abnormal posturing such as head lag and upper limb dyskinesia (involuntary muscle movement).

During the feedback process Mrs Conroy and her husband wished to highlight that they only became aware nine years after Baby Róisín was delivered that an adverse incident occurred on the 14th November 2001.

The family highlighted throughout the process that their experience over the past 16 years is critical to any learning from this incident.

Mrs Conroy and her husband understand based on the feedback from staff during the investigation and previous legal proceedings that medical and midwifery staff involved in the delivery of Baby Róisín were aware at the time that an adverse event had occurred, however the family were not informed.

This became evident for the Investigation Team during the interview process, when Midwife M1 and Midwife M3 stated that they 'pleaded' with Consultant Obstetrician and Gynaecologist A to tell the family that Baby Róisín had been compromised at birth and that this would have serious consequences for Róisín and her family.

At interview Baby Róisín has been described by her parents to be;

'a beautiful young girl trapped in a body that does not work for her, she is a prisoner in her own body, wheelchair bound indefinitely and receiving food daily through an abdominal tube'.

It is the opinion of Dr. Gardeil that this lack of disclosure has had a negative impact on Baby Róisín's life expectancy¹⁷.

¹² Intravenous refers to the process of injecting a solution directly into the vein.

¹³ Phenobarbitone and Clonazepam are regarded as the drugs of choice for the management of convulsions in the neonate.

¹⁴ Echogenicity (EG) of the basal ganglia and thalami region is frequently seen on cranial ultrasonographic (US) images obtained in neonates. In neonates increased EG in this region usually indicates hypoxic-ischemic injury and is associated with serious neurologic diseases or injury.

¹⁵ The thalamus is the large mass of gray matter in the dorsal part of the diencephalon of the brain with several functions such as relaying of sensory signals, including motor signals, to the cerebral cortex, and the regulation of consciousness, sleep, and alertness.

¹⁶ Diffusion-weighted magnetic resonance imaging (DWI or DW-MRI) is the use of specific MRI sequences as well as software that generates images from the resulting data, that uses the diffusion of water molecules to generate contrast in MR images.

¹⁷ During the earlier legal proceedings the family informed the investigation that Baby Róisín's life expectancy was considered to be 29 years at her first assessment by a Clinical Expert assigned by the HSE, and following additional support and treatment Baby Róisín's life expectancy was recalculated as 35 years by the same Clinical Expert.

Dr. Gardeil outlined for the investigation that birth injuries to a baby are very serious and have long term consequences for both the baby and their family. While financial support secured through legal proceedings can provide some level of support to families in ensuring that the child receives an appropriate level of care, however some of the economical expenses experienced by families as a result of physical and social sequelae¹⁸ can rarely be completely quantified.

A review of some international approaches to compensation yielded a number of advancements in countries such as Norway and Sweden.

The Norwegian System of Compensation to Patients (NPE) was established in 1988, with the aim of preventing and compensating for injury to patients, to improve patients' legal protection.

In Norway the NPE¹⁹ is organized as a public body under the Ministry of Health and Care Services. All patient injuries, in the public or private sector, are now considered under the same compensation rules and is funded by the four regional health authorities in Norway.

The distribution between authorities is determined based on each regional health authority's share of compensation payments over the last five years.

Additionally, each hospital pays a certain amount for each case where they have been found liable.

The NPE is a no-fault system. To be eligible for compensation in Norway a patient's injury must have occurred due to or assumed to be a result of an error or omission in diagnosis or treatment, and the patient must also have sustained a financial loss.

Even though something irregular has occurred, the emphasis is not on whether someone is to blame for what happened. This implies that the patient can receive full compensation without anyone being found guilty of negligence.

Negligence in care²⁰ is legally defined as the failure of a physician or other healthcare provider to provide ordinary, reasonable or expected care, with the prudence or skill that would customarily be exercised by other reputable physicians treating similar patients, and which may result in foreseeable harm or injury.

Negligence may be considered to be an act of omission unintentional or intentional, characterized by inattention or thoughtlessness (Segen, 2010).

The family wished to convey to the Investigation Team the indifference they experienced, misleading information and untruths provided to them by staff following Baby Róisín's delivery which has only added to their distress and this must be included in the findings of this report.

The over-riding experience for Mrs Conroy and her husband continues to be '*a lack of compassion, empathy and indifference*' demonstrated by key staff involved in Mrs Conroy's and Baby Róisín's care on the 14th November 2001.

Based on these concerns an investigation of the incident was commissioned by Dr Susan O'Reilly, Dublin Midlands Hospital Group CEO, Health Services Executive (HSE).

¹⁸ Sequelae: a condition which is the consequence of a previous disease or injury.

¹⁹ Reference: <https://www.npe.no/>

²⁰ Reference: <https://medical-dictionary.thefreedictionary.com/negligence>

Aim

The aim of this investigation as outlined in the Terms of Reference (Appendix A) was to establish whether there were any failures in relation to the care and management received by Mrs Conroy during her admission to Hospital S1 on the 14th November 2001.

Purpose

The purpose of this investigation was to:

- Establish the factual circumstances leading up to the incident²¹
- Identify any key causal factors that may have occurred
- Identify the contributory factors that caused the key causal factors
- Recommend actions that will address the contributory factors so that the risk of future harm arising from these factors is eliminated or if this is impossible, is reduced as far as is reasonably practicable.

The reviewers who undertook this investigation were:

- Ms Deirdre O’Keeffe, Quality and Safety Manager, Quality Improvement Division, HSE (Investigation Chairperson).
- Ms Susan Temple, Quality and Safety Manager, Dublin Midlands Hospital Group.

Forum²² Nominated Consultant Obstetrician/Gynaecologist to the Investigation Team to review the Healthcare Record, CTG trace and Continuous Fetal Heart Rate Trace from the 14th November 2001 and validate the investigation report findings:

- Dr Francois Gardeil, Consultant Obstetrician and Gynaecologist and External Independent Clinical Expert, Wexford General Hospital.
- Ms Patricia Hughes, External Independent Midwifery Expert.
- Dr John Murphy, Consultant Neonatologist and Clinical Expert, National Maternity Hospital, Dublin.

At the request of the Family and Investigation Team, the professional and expert opinion of the following individuals was also sought to answer questions posed by the family to inform the findings and recommendations contained within this report. In order for each of these experts to be named in the report, consent was sought to ensure they were all in agreement to be identified:

- Dr. Peter Boylan, Chair of the Institute of Obstetricians and Gynaecologists, Royal College of Physicians, Ireland.
- Mr Ger Flynn, National Clinical Head of Medical Devices, HSE.
- Mr Liam Hackett, National Medical Equipment Advisor Community Services, HSE.
- Mr Ciarán Breen, Director, State Claims Agency, Ireland.
- Mr William Kennedy, Director of Regulation and Professional Standards, Medical Council, Ireland.

²¹ An incident is defined by the HSE Guidelines Guideline for the Systems Analysis Investigation of Incidents; Revision No: 3 (August 2016) as “An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. (Adapted from WHO (2009) and DoH (2010), HSE Quality and Risk Taxonomy (2009)). An event or circumstance which could have, or did lead to unintended harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include Incidents associated with harm to: · patients, service users, staff and visitors · the attainment of HSE objectives · ICT systems · data security e.g. data protection breaches · the environment.”

²² Where external expert input is required by the review team the HSE National Incident Management and Learning Team (NIMLT) will request a nominee from the Forum of Irish Postgraduate Training Bodies to secure an External Independent Expert to input to the HSE investigation.

The commissioner identified an individual to provide assistance to the Investigation Team for the purposes of collating relevant documents, policies and guidelines, healthcare records and to assist with the identification of the staff involved in the care and treatment of Mrs Conroy and Baby Róisín based on entries in the healthcare records.

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

This report outlines all of the discussions with Mrs Conroy and her husband and their feedback within the chronology and this information was considered in detail when collating the final report.

Key Findings of the Investigation

While the scope of the investigation relates to the 14th November 2001, in order to complete the chronology of events the Investigation Team took the view that it was essential to consider the healthcare records relating to Baby Róisín's care and treatment while under the care of the clinical team at Hospital S2.

On examining the timeline from admission on the morning of the 14th November 2001 until Baby Róisín's delivery, which included interviews with Mrs Conroy and her husband along with key staff, the investigation identified two key causal factors and 2 incidental findings.

The Investigation Team believe that the combination of these failures in the care provided to Mrs Conroy and Baby Róisín are causally linked to the fetal hypoxic damage that occurred and Baby Róisín's subsequent diagnosis of dyskinetic cerebral palsy²³.

According to the clinical experts assigned to this investigation there is a lesson to be learnt from this incident about communication, clinical responsibility and teamwork.

In addition to the investigation findings, the family also highlighted a number of issues they wished to have explored by the Investigation Team. While these matters fall outside the scope of this investigation, for the purposes of completeness for the family, the Investigation Team sought the expert opinion of a number of individuals to provide a response for the family.

Summary of Key Causal Factors

Key Causal Factor 1: Failure to perform competently during a high risk labour regarding the;
a) assessment and monitoring of Baby Róisín and;
b) recognition of fetal distress
placed Mrs Conroy and Baby Róisín in a position of unnecessary risk.

Key Causal Factor 2: Failure to demonstrate proper dedication, thoroughness, professional duty and responsibility as set out in professional regulatory guidelines resulted in;
a) a serious absence of the required level of professional communication expected during a high risk labour and;
b) Baby Róisín being catastrophically injured at birth.

In respect of Key Causal Factor 1; The investigation found that Mrs Conroy was a high risk labour requiring an appropriate level of assessment and monitoring in order to reduce or eliminate any unnecessary risk(s) to mother and baby.

It is evident from the chronology that there were a series of deficits in the care provided.

²³ Baby Róisín was subsequently diagnosed with Dyskinetic cerebral palsy (sometimes abbreviated ADCP) is a type of cerebral palsy (CP) primarily associated with damage, like other forms of CP, to the basal ganglia in the form of lesions that occur during brain development due to bilirubin encephalopathy and hypoxic-ischemic brain injury.

These relate to the assessment and monitoring of the condition of Mrs Conroy and Baby Róisín in-utero ranging from minor to serious and grossly deficient from a Midwifery Care and Monitoring of the Condition of Mother and /or Baby in-utero.

The Investigation Team note that there was no pre prostin gel CTG carried out. There was no local policy in place in Hospital S1 at that time in relation to the induction of labour.

It was established through the interview process that it was at least 4 years after this incident before any policy or guideline was developed, suggestive of a lack of a proactive approach to the delivery of evidenced based safe care in this maternity unit.

Dr. Gardeil believes it would have been prudent to have an Induction of Labour guideline in place based on international guidelines which were in use elsewhere in Ireland at the time of this incident.

On the 14th November 2001 Mrs Conroy returned to her single in-patient room following induction of labour shortly before 10:00 hours and was not seen by a midwife again until 11:30 hours (this was at the request of her husband).

There is evidence that Mrs Conroy was experiencing strong contractions from 11:30 hours onwards following the insertion of prostaglandin gel which required continuous fetal heart rate monitoring.

It is not clear from the records from the point of induction who, or if any midwife was providing care for Mrs Conroy.

During the feedback process the family outlined that they believed there to be a number of missed opportunities throughout the morning of the 14th November 2001 to safe guard Baby Róisín.

Mr Conroy stated at interview:

'I had to go out to the corridor at 11:30 hours to wait for a midwife to pass to get something for the pain. At 12:30 hours she was still experiencing really strong contractions so I went to the corridor again and waited for someone.

At 12:45 hours she got some pain relief and she was not reviewed again until 14:00 hours when she was still experiencing very strong contractions'.

Mrs Conroy outlined during the feedback process that;

'I eventually walked down to the labour ward myself because I felt I was going to deliver Róisín, nobody had checked on me to see how things were going, this was around 2pm, Midwife M1 was surprised to see me and asked "what's going on", she examined me and said I was "4 cm and ready to go", but she then appears to have documented that I was only 1cm, which is not correct.'

Based on the healthcare records, continuous fetal heart rate monitoring was not commenced until 14:14 hours on 14th November 2001, even though Mrs Conroy was experiencing strong contractions since 11:00 hours.

The frequency of uterine contractions was not electronically recorded for the entire labour making the interpretation of the trace a challenge, particularly in this case where there is evidence of suspicious findings indicating imminent fetal risk.

Non-reassuring features were evident on the fetal heart tracing from the beginning of the recording at 14:14 hours with decelerations and reduced variability.

Dr Gardeil states for the investigation that it is highly probable that the tracing would have shown abnormalities earlier on if monitoring had been commenced.

Within 14 minutes of commencing continuous fetal heart rate monitoring, the fetal heart rate became pathological with a prolonged bradycardia to 70 beats per minute that lasted for 7 minutes.

After this episode and until delivery the recording of the continuous fetal heart rate shows recurrent decelerations.

The Investigation Team consider it is reasonable to expect that a Midwife would and should have been able to assess the parameters of labour which include the presence, frequency, strength/duration and regularity of contractions using hand palpation plus or minus the use of a CTG monitor. The Definition of a Midwife (ABA 2001) states that;

"she must be able to give the necessary supervision, care and advice to women during pregnancy, labour and the postpartum period.....".

Furthermore the Investigation Team were informed that there were no policies, procedures or guidelines developed or available locally in relation to continuous fetal heart rate monitoring and overall clinical assessment of baby and mother or for the Induction of labour.

Although it was identified that there was limited CTG training available for staff from a company in the UK this training was not mandatory and staff attended on an adhoc basis. Training records were unavailable for 2001 and prior to 2001.

Overall the Investigation Team along with the clinical experts assigned to this Investigation consider that senior staff should have been more proactive in delivering care to Mrs Conroy and Baby Róisín.

In respect of Key Causal Factor 2; There is evidence of a failure to demonstrate proper dedication, thoroughness, professional duty and responsibility as set out in professional regulatory guidelines;

- A. Medical Council guidelines regarding professional conduct and ethics for registered medical practitioners, 1998 and;
- B. Nursing and Midwifery Board of Ireland Guidelines for Midwives, 2001.

The family throughout the investigation process stated that their utmost concern was that they felt '*abandoned*' on 14th November 2001 and they believed this to be a serious ethical failing.

In the context of a training hospital Dr. Gardeil stated that ethical failings which include a failure to demonstrate proper dedication, interest, thoroughness and responsibility are far more grievous than failures relating to clinical decision making²⁴.

Based on the family's feedback, the Investigation Team consider that these ethical failures do violate the ethical standards/guidelines of the discipline and profession and threaten the very basis of the clinical staff and patient relationship (Atwood and Gaines, 1984).

Clinical and or/technical failures given the proper ethical stance are and can be regarded as opportunities to learn, mistakes to be remembered and forgiven (Atwood and Gaines, 1984).

Mrs Conroy and her husband stated that their expectations were two-fold following admission on 14th November 2001; the doctors and midwives were expected to provide care and

²⁴ Robert A. Hahn, Atwood D. Gaines (1984) Physicians of Western Medicine: Anthropological Approaches to Theory and Practice Springer Science and Business Media, 31 Dec 1984 - Social Science

treatment with all the knowledge and skill at their command and secondly that they would not do anything to harm Mrs Conroy or Baby Róisín in any manner.

As set out in the 1998 Medical Council guidelines regarding professional conduct and ethics for registered medical practitioners Doctors must always be guided by their primary responsibility to act in the best interests of their patients, without being influenced by any personal consideration.

In addition Consultant Obstetrician and Gynaecologist A provided Mrs Conroy with a Disclaimer (Appendix B) which was signed by Mrs Conroy at her booking visit, included the following statements;

- While every effort will be made to be in attendance at the delivery this may be physically impossible at the time. No guarantee can be given to attend the delivery.
- When I am unable to attend the delivery a consultant colleague will be available for the delivery.
- Normal Labour and delivery is conducted by a Midwife.

Mrs Conroy and her husband stated that they believe Consultant Obstetrician and Gynaecologist A did not adhere to his own contract as outlined above.

The family believe that;

'this was considered a high risk labour that required oversight from an obstetrician, he was available and chose not to be, he planned the admission and gave me the prostin gel, he did not handover care and this was not a normal delivery to be managed by a Midwife alone, there was no plan to manage the labour'.

Consultant Obstetrician and Gynaecologist A left Hospital S1 on the afternoon of the 14th November 2001 for personal reasons; he did not communicate this to the family. There is no available evidence to suggest Consultant Obstetrician and Gynaecologist A handed over care to another clinician following the induction of Mrs Conroy. Mrs Conroy's labour was considered high risk.

Mrs Conroy and her husband stated at interview that they were unaware that Consultant Obstetrician and Gynaecologist A had left Hospital S1 following Mrs Conroy's induction. As outlined by Dr. Gardeil, Consultant Obstetrician and Gynaecologist A's priority should always have been about the safety of Mrs Conroy and Baby Róisín and his actions that day should not have been determined by any personal consideration.

Consultant Obstetrician and Gynaecologist A did not inform Mrs Conroy or her husband at induction that he would be out of the hospital for a number of hours following her induction or that he had arranged for Consultant Obstetrician and Gynaecologist B to cover in his absence.

There is no evidence available to suggest a handover took place between Consultant Obstetrician and Gynaecologist's A and B; either over the telephone or by another means.

Consultant Obstetrician and Gynaecologist A outlined at interview that he documented this transfer of responsibility to Consultant Obstetrician and Gynaecologist B on the white board in the midwifery station for midwives on duty and labour ward but did not inform the family of the new arrangement. This was considered by Consultant Obstetrician and Gynaecologist A at the time to be an acceptable form of communication in relation to patient handover.

Consultant Obstetrician and Gynaecologist A stated that this practice was in place for more than 20 years in Hospital S1;

'there was no need for formal notification from one consultant to another when one was absent for a day or a few hours'.

It is unclear how Consultant Obstetrician and Gynaecologist B would be aware of this transfer of responsibility which was documented on a whiteboard as she was conducting clinics in a different part of Hospital S1.

Dr. Gardeil outlined for the investigation that this cannot be considered an effective or safe means of communicating clinical responsibility for a high risk patient, particularly as staff were unaware of any white board communication.

The Investigation Team consider that documenting a handover of responsibility on a whiteboard in the context of a high risk labour falls seriously short of what is expected of a treating obstetrician particularly as ineffective communication is a well-recognised contributor to patient harm in hospitals (Lingard et al., 2004).

It would also appear that Midwife M1 was unaware of any whiteboard communication in the labour ward or the Nursing/Midwifery station regarding any the transfer of responsibility as she contacted Consultant Obstetrician and Gynaecologist A at 14:00 hours after he had left Hospital S1. It was only at this point Midwife M1 was made aware that she should contact Consultant Obstetrician and Gynaecologist B.

At approximately 14:32 hours, Midwife M1 documented that she bleeped Consultant Obstetrician B, this is according to the note she made on the CTG paper Consultant Obstetrician B '*contacted on Bleep 04*'.

Based on Midwife M1's interview, it would appear that Midwife M1 made only one attempt to contact a Doctor to relay her concerns regarding the abnormal fetal heart tracing at 14:32 hours. The investigation identified following a review of the healthcare records Midwife M1 did not document the nature of her concerns and did not document that Consultant Obstetrician B attended shortly after 14:32 hours. There is no entry from Consultant Obstetrician B until after delivery (notes regarding repair of an episiotomy).

It is the opinion of Dr. Gardeil, if Midwife M1 recognised fetal heart rate abnormalities; communication of her concerns to an obstetrician failed. If the bleep system was faulty there were other available means of contacting Consultant Obstetrician and Gynaecologist B or, indeed, an obstetric NCHD would have also been available. There is no evidence to suggest on this date that there was a problem with the bleep system.

There are no staff entries in the healthcare record referring to fetal distress.

Where there is reference to the fetal heart rate in the healthcare record, the fetal heart rate is documented retrospectively as being within normal parameters with no reference to any pathological findings. This is in direct conflict with a hand written note, '*Dr... contacted bleep 04*' on the CTG trace shortly after 14:30 hours.

Similarly, there was no documented evidence of any communication with paediatricians prior to the delivery of Baby Róisín despite abnormalities of the fetal heart rate and the noted absence of liquor seen during labour, which constitutes an ominous feature.

Paediatricians were only called after delivery, suggesting that Baby Róisín was not expected to be compromised at birth; albeit the cardiac tracing from 14:14 hours was pathological indicating Baby Róisín was in distress and required immediate intervention.

The paediatric NCHD AB arrived approximately 3 minutes after birth of Baby Róisín and a paediatric registrar 2 minutes later i.e. at approximately 16:37 hours.

Dr. Gardeil stated that it is good practice to have a paediatrician present at the time of delivery for all caesarean sections, all instrumental deliveries, and all normal deliveries where there have been fetal heart rate abnormalities or other abnormalities such as presence of thick meconium or absence of liquor during labour.

In general the Investigation Team observed that nursing and medical entries in Mrs Conroy's healthcare record for the 14th November 2001 were deemed to be extremely poor, in contrast to Baby Róisín's healthcare record in Hospital S1 and Hospital S2 following Baby Róisín's transfer which the Investigation Team consider to be comprehensive.

The standard of record keeping in relation to the labour i.e. history of contractions does not meet the standard of recordkeeping for a Midwife.

This aspect of assessment and documentation and communication comprise a vital part in the care and surveillance of a pregnant and /or labouring woman and are necessary for the safe and on-going planning of care relevant to the factors of pregnancy which are individual to the pregnant woman.

Collectively it is the opinion of the Investigation Team, the recordkeeping and therefore the care provided from about 11.00 hours, demonstrate increasing levels of serious omission of care with time, until the delivery of Baby Róisín is grossly deficient and does not meet the required standards (Nursing & Midwifery Board of Ireland (An Bord Altranais), Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

In conclusion, the family highlighted a clear absence of communication between staff and the family during and after labour which the Investigation Team consider to be extremely concerning.

The family stated at a meeting with the Investigation Team on the 22nd November 2017 that;

'had we only been told the truth on the morning of the 15th November, and not given untruths and misleading information, we could have accepted that people genuinely make mistakes or get it wrong sometimes. Incidents happen, sometimes with serious consequences²⁵. We were held by Consultant Obstetrician and Gynaecologist A that nothing could have been done, no signs that anything was wrong, that there is no way of detecting these things and we were just unlucky, the trace was 'perfect'.

Believing what we were told by Consultant Obstetrician and Gynaecologist A that we were "just unlucky" we tried to do our best for Róisín, meaning we were unable to access the appropriate care for our daughter. It was 9 years later when we found out what really happened and a further 3 years later (12 years in total) before we were able to get the right support for Róisín. We realised that there is really no avenue for individuals to be held to account, particularly if they retire, this investigation is our only recourse now, to find out why everything happened because we did not find out during the legal proceedings.

All the untruth's and misleading information provided to us over a 12 year period ultimately resulted in Róisín being denied the therapies she needed to improve her quality of life and life expectancy '.

Dr Gardeil in his report states that Mrs Conroy was not communicated with clearly, openly and honestly by Consultant Obstetrician and Gynaecologist A and staff at Hospital S1. The family were not informed that an adverse event had occurred in spite of the fact staff were aware.

The lack of disclosure of the adverse event in Dr. Gardeil's opinion will have a profound and lasting impact on the entire family.

Overall the findings of this investigation highlight a poor safety culture and low expectations of accountability in Hospital S1 at the time of this incident.

²⁵ As outlined in the chronology Consultant Obstetrician and Gynaecologist A and Midwife M1 spoke with Mrs Conroy and her husband the morning of the 15th November 2001.

Summary of Incidental Findings

- I. The absence of disclosure of correct information relating to Baby Róisín's condition and issues related to the investigation of adverse incident.
- II. Absence of the Incident Report Form completed in relation to Mrs Conroy's delivery and subsequent catastrophic injury to Baby Róisín.

Summary of additional concerns that the Family wished to have explored and highlighted which fall outside the scope of this Investigation

- I. The requirement to expedite the provision of support for families affected by catastrophic injuries at birth to ensure the best possible outcome for babies.
- II. The inability to progress a complaint about a Doctor through the Irish Medical Council's Preliminary Proceedings Committee²⁶ ("the PPC") if a Doctor removes his/her name from the register prior to the complaint being made irrespective of legacy cases or if the Doctor was registered with the Medical Council at the time of the incident.

Limitations to the Investigation

In terms of an adverse event occurring on 14th November 2001, no incident report form was completed to capture any information and subsequent steps taken to correct any failures in the care delivered to Mrs Conroy and Baby Róisín. Some staff had retired and declined the interview invitation stating that they had no recollection of events 16 years later.

Summary of Recommendations

The Investigation Team has made a number of recommendations to address the factors that have been identified during the investigation as contributing to the key causal factors related to this incident. These recommendations are made to address the risks associated with each contributory factor or hazard identified by the investigation using the hierarchy of hazard control measures as per the HSE Guidance document on conducting a systems analysis investigation (2015).

In developing the recommendations the Investigation Team considered current best practice and carried out a review of the literature informing evidence based practice today.

Recommendations linked to Key Causal Factors

Recommendation 1 (*Hierarchy of Hazard Controls - Administrative Procedure*):

Hospital S1 must develop a local policy adapted from national guidelines with regard to intrapartum fetal heart rate monitoring and ensure appropriate compliance (RCPI/HSE intrapartum fetal heart rate monitoring guideline) and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Action taken since the events described in this report

Response provided from Hospital S1: *The guideline PHOG011 was developed and approved in May 2016 "Fetal heart rate monitoring in labour in the maternity department". The guideline has been fully implemented in the maternity department. This guideline co-exists with the Guideline on Intrapartum care PHOG002 which has also been fully*

²⁶ The PPC is the committee of the Medical Council that looks into and gives initial consideration to complaints about doctors.

implemented in the department. An audit of PHOG011 was completed in November last and no issues were identified from same.

Recommendation 2 (Hierarchy of Hazard Controls - Administrative Procedure):

All Hospital Groups have in place guidelines/protocols adapted from national guidelines with regard to intrapartum fetal heart rate monitoring and ensure appropriate compliance (RCPI/HSE intrapartum fetal heart rate monitoring guideline) and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Recommendation 3 (Hierarchy of Hazard Controls - Administrative Procedure):

The Maternity Unit located in Hospital S1 should develop a local policy adapted from national guidelines with regard to Induction of Labour and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Action taken since the events described in this report

Response provided from Hospital S1: *The Guideline "Management of Antenatal Women admitted for induction of Labour" PHOG022 was developed in 2015 and has been fully implemented in the maternity department. This guideline has been audited since its development and will be re-audited in 2018.*

Recommendation 4 (Hierarchy of Hazard Controls - Engineering controls)

Hospital S1 should ensure the correct application of the CTG machine in all situations where continuous monitoring is required. Managing risks from using equipment is essential for all services, with a focus on factors that intervene with safety, such as the inappropriate use of medical equipment. Issues relating to deviation must be managed and addressed.

Action taken since the events described in this report

Response provided from Hospital S1: *All midwives are trained and competent in the application of CTG monitoring equipment in the department. There is a daily check of CTG equipment function undertaken and a log of these checks is maintained. The maintenance of all CTG machines in the department is scheduled annually. Where faults and maintenance issues are identified, they are communicated to and addressed promptly by the Clinical Engineering team.*

Recommendation 5 (Hierarchy of Hazard Controls - Engineering controls)

Hospital S1 should ensure that all equipment is appropriately maintained and recorded. The recording of this practice must be audited and findings acted on.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department completes a daily check of equipment including the function of CTG monitors as per guideline PHOG013 "Avalon Fetal Monitors". The record of these checks is retained. The inventory of equipment and maintenance programme is retained by the Clinical Engineering department.*

Recommendation 6 (Hierarchy of Hazard Controls - Engineering controls)

The Maternity Unit located in Hospital S1 should ensure the facilities required to carry out fetal blood sampling should be provided at Hospital S1 as a matter of priority.

Action taken since the events described in this report

Response provided from Hospital S1: *There are two fetal blood sampling machines in operation in the labour ward of the maternity department. The machines were installed in October and December 2013. The maternity department provides regular training to midwifery and medical staff on the functionality of the FBS machines and fetal blood sampling kits.*

Recommendation 7 (Hierarchy of Hazard Controls - Administrative Procedure)

The HSE's National Acute Hospitals Division confirm CTG training as a mandatory training requirement for all Obstetrics and Gynaecology Medical Staff and Midwives. The frequency of this training is to be established in accordance with best practice.

This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department ensures that all midwives and obstetricians' have completed K2 fetal monitoring training on an annual basis. A twice yearly report is provided by K2 medical systems to validate this. In addition midwives at the maternity unit must undertake a CTG workshop every 2 years as mandatory training.*

Recommendation 8 (Hierarchy of Hazard Controls - Administrative Procedure)

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

Action taken since the events described in this report

Response provided from Hospital S1: *All midwifery and medical staff are required to complete mandatory annual K2 CTG training online and training records are maintained. This training is complimented with a study day provided every two years at the centre of midwifery education CWIUH for midwives. The record of compliance is overseen by the Director of Midwifery (DoM) and the Clinical lead for obstetrics.*

Recommendation 9 (Hierarchy of Hazard Controls - Administrative Procedure)

That systems and processes are established, up to and including the disciplinary process, within each National Division to ensure compliance with mandatory training. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Recommendation 10 (Hierarchy of Hazard Controls - Administrative Procedure):

The Hospital S1 must remind registrants of their professional values in order to ensure compliance with national regulatory guidelines circulated by the Professional Regulatory Bodies.

Action taken since the events described in this report

Response provided from Hospital S1: *The verification of Annual registration of Midwifery and Nursing staff is overseen by the Assistant Director of Midwifery and Director of Midwifery. The hospital ensures that all staff comply with the requirements of the relevant regulatory bodies to assure individual maintenance of codes of conduct and practice. The Hospital ensures all Medical staff are registered with the Medical Council in the relevant discipline prior to and during employment. The introduction of initiatives such as CBAS-I, What matters to me and Values in action programmes enhance communication and staff engagement.*

Recommendation 11 (*Hierarchy of Hazard Controls - Administrative Procedure*):

Hospital S1 must review the National Healthcare Charter in respect of communicating with patients with a view to ensuring that all staff are aware of the requirements of the Charter.

Action taken since the events described in this report

Response provided from Hospital S1: *The national healthcare charter has been adopted by the hospital. The eight principles of access, dignity and respect, safe and effective services, communication and information, participation, privacy, improving health and accountability are being implemented hospital wide to improve patient experience. This includes open disclosure, patient advocacy services, access and information on the hospital complaints procedure and prompt response to complaints. The hospital has provided training for all staff in relation to customer care programmes and implementing initiatives such as the CBAS I programme to improve our patient experience. These initiatives have been fully implemented in the maternity services.*

Recommendation 12: (*Hierarchy of Hazard Controls - Administrative Procedure*):

That each Hospital Group and Community Healthcare Organisations have a documented escalation process for the escalation of clinical concerns, with clear lines of accountability, operational within their area of responsibility. To be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department has implemented an escalation policy where any staff member may escalate clinical concerns to the Consultant on call to obtain a senior clinical opinion. The midwives in the maternity department have an escalation procedure to the site manager on duty that can escalate to the Assistant Director of Midwifery or Director of Midwifery where senior midwifery opinion is required.*

Recommendation 13: (*Hierarchy of Hazard Controls - Administrative Procedure*):

The ISBAR communication tool should be used when communicating information in relation to deteriorating and/or critically ill patients. Where a situation is deemed to be critical, this must be clearly stated at the outset of the conversation.

Action taken since the events described in this report

Response provided from Hospital S1: *The ISBAR communication tool has been fully implemented in the maternity department. PHOG035 Guideline on communication between healthcare professionals at MRHP maternity department supports the training which has been facilitated by the practice development department reflecting national policies. A clinical handover audit was completed earlier this month.*

Recommendation 14: (*Hierarchy of Hazard Controls - Administrative Procedure*):

That the Guideline on Communication among Health Care Professionals at Hospital S1 introduced in May 2015 (Reference PHOG035) is audited. All non-compliance to be addressed within 3 months of the audit report being finalised. This recommendation must be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *A guideline on communication has been fully implemented and will be audited within 3 months.*

Recommendation 15: (*Hierarchy of Hazard Controls - Administrative Procedure*):

That all Hospital Groups and Community Healthcare Organisations circulate information on the Safety Pause process for implementation in all Wards/Departments. To be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *Clinical handover has been fully implemented. A safety pause is also now being piloted in the maternity department. A time out policy has been fully implemented in the operating theatre.*

Recommendation 16: *(Hierarchy of Hazard Controls - Administrative Procedure):*

Hospital S1 should implement processes to ensure that the consultant obstetrician and gynaecologist on-call is aware of activity levels, potential high-risk situations and staff concerns.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department have fully implemented a daily multidisciplinary handover at nine a.m. The clinical handover policy is used at this meeting using the ISBAR tool. The escalation of care to the Consultant on call, (PHOG005) Guideline for midwives on 'when to refer to the Consultant Obstetrician and/or on call Consultant Obstetrician' has been fully implemented. A clinical activity handover occurs each evening.*

Recommendation 17: *(Hierarchy of Hazard Controls - Administrative Procedure)* Implement the HSE Standards and Recommended Practices for Healthcare Records Management V3.0 (May 2011) and make arrangements for an audit of compliance with this standard (and any subsequent standard) within a six-month timeframe and yearly thereafter.

Action taken since the events described in this report

Response provided from Hospital S1: *The Healthcare records committee meets quarterly. The national guideline has been adopted and is implemented at the hospital. A Healthcare records audit was completed earlier this year.*

Recommendation 18: *(Hierarchy of Hazard Controls - Administrative Procedure)*

Maternity unit S1 needs to ensure the implementation and compliance with all national communication policies, procedures and guidelines and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings.

Action taken since the events described in this report

Response provided from Hospital S1: *The NEWS, IMEWS, PEWS early warning scores have been fully implemented in the hospital. IMEWS and NEWS have been fully implemented in the maternity department and have been audited.*

Recommendation linked to Incidental Findings

Recommendation linked to Incidental Finding 1: *(Hierarchy of Hazard Controls - Administrative Procedure)* Hospital S1 must implement the Open Disclosure Policy (HSE 2013). An audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local Quality and Safety committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Action taken since the events described in this report

Response provided from Hospital S1: *The open disclosure policy has been fully implemented in the maternity department. Any issues arising from open disclosure are addressed promptly.*

Recommendation linked to Incidental Finding 2: (*Hierarchy of Hazard Controls - Administrative Procedure*) There must be prompt notification by all hospitals when an adverse event is identified whether the actual event occurred in that hospital or another, this must be in line with the HSE Safety Incident Management Policy, 2015.

There must be prompt investigation of safety incidents within the acute hospital services in line with HSE Safety Incident Management Guidelines 2015. The service must implement and carry out Audits of Compliance with Safety Incident Management and Systems Analysis Investigation Guidelines (HSE 2015, HSE 2015 respectively).

Key staff must be trained in Safety Incident Management and Systems Analysis Investigation Methodology i.e. Senior Management Teams must be trained in Incident Management and staff assigned to carrying out investigations must receive systems analysis investigation training.

Action taken since the events described in this report

Response provided from Hospital S1: *A culture of incident reporting is supported by the Quality and Patient Safety department and Management in the hospital. Incident forms are completed and recorded on the National Incident Management System (NIMS).*

The Senior Incident Management Team is convened as required to review serious incidents.

Recommendation from additional concerns that the family wished to have explored and highlighted which fall outside the scope of this Investigation

Based on feedback from the family, the investigation considers that a mechanism for reviewing poor professional performance be considered in cases where there are a number of legacy cases against a practitioner who has withdrawn from the register.

The Investigation Team contend that the UK legislation offers the opportunity to investigate legacy issues. This opportunity may be in the interest of the public.

The Investigation Team cannot be prescriptive with respect to how this can be achieved however the adequacy and appropriateness of processes currently in place under existing legislation to consider and/or investigate complaints against a practitioner not on the register does require reflection. A change to the legislation will be required to address this concern.

At the Request of the Commissioner the following has been included in the Report: Quality Improvements at Hospital S1

Governance Developments to Enhance Quality and Safety within the Hospital Group

Integration with the Coombe Women and Infants University Hospital began 2014 and continues, a Memorandum of Understanding was signed off in March 2015. The Clinical Director for Integration has been appointed.

A process of streamlining care pathways has been completed. These care pathways are comparable to the CWIUH.

The Maternity Governance and Maternity Multi-disciplinary Committee meet alternate weeks and oversee the management of the Maternity Services at hospital S1. These committees report into the Senior Management Team.

Hospital S1 has developed a Quality and Patient Safety Action Plan and a Serious Incident Management team is in place and meets as required in hospital S1.

The following committees are also in place:

- Multi-disciplinary Clinical Audit Committee.

- Multi-disciplinary Guideline Development Committee.

Incident Management

The Open Disclosure policy has been fully implemented along with recommendations from National and Local reports. This work is subject to regular audit.

The National Incident Management System was implemented and a process of feedback was put in place.

The Following Training Programmes and Standards have been Implemented:

The Florence Nightingale Leadership Programme for midwifery managers.

- Caring Behaviour Assurance System –Ireland programme has been implemented. This programme engages individuals, teams and Executive Boards in achieving quality and safe care for patients and families and for staff.
- Training needs analysis was carried out and a training plan included mandatory K2 and CTG training
- Tailored customer care programmes were provided for all staff.
- Bereavement education days were provided, by the Irish Hospice Foundation. Bereavement suite was commissioned and completed in early 2018.
- National Standards for Bereavement Care following Pregnancy (August 2016) implemented.

Improving Quality

- Patient/ Staff satisfaction surveys were carried out.
- Staff experience – we seek and value feedback and ideal for improvement, through open forums and staff meetings.

Staffing

A workforce plan has been developed and the filling of vacancies and any additional posts identified is now in progress.

- Two additional Obstetric Consultants and two Neonatologists have been appointed to hospital S1. These are shared posts between the CWIUH and Maternity Services in hospital S1.
- The Director of Midwifery has been appointed in hospital S1.
- A Clinical Skills Facilitator for Maternity has been appointed and is in post.
- Bereavement Support Nurse in place.
- Recruitment of Midwives is on-going.

Methodology

The investigation was undertaken using the methodology for incident investigation as outlined in the HSE Guideline for Systems Analysis Investigation²⁷ of Incidents and Complaints (Nov. 2012). The Investigation Team consisted of a trained experienced investigator, the Hospital Group Quality and Safety Manager and supported by external clinical experts.

Systems analysis is an internationally recognised methodology for investigating adverse incidents in healthcare. The aim is 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.

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

- Mrs Conroy's relevant healthcare records from Hospital S1 and Private Clinic Healthcare Records
- Baby Róisín's Healthcare records from Hospital S1
- Baby Róisín's Healthcare records from Hospital S2
- All relevant Radiology Examinations from Hospital S1 and Hospital S2
- Rosters for Midwifery and Medical Staff
- Obstetric and Gynaecology Clinic Schedules
- Hospital S1 Birth Registration Log
- Relevant literature listed in the Reference Section of Report
- The Use of Electronic Fetal Monitoring: The use and interpretation of cardiotocography in intrapartum fetal surveillance. First published May 2001. Royal College of Obstetricians and Gynaecologists 2001, London.
- National Institute for Health and Care Excellence (NICE). Induction of labour, June 2001.

While carrying out this investigation the Investigation Team requested the following documentation and information:

The Investigation Team discovered that the below records were not available:

- Training records for staff in relation to CTG training around 2001 and before.
- Telephone and Bleep logs relating to the 14th November 2001.
- Medical Device maintenance logs relating to the CTG machine used on Mrs Conroy on 14th November 2001.

Additional Documentation Considered By the Investigation Team

- A detailed statement was provided by NCHD AB in relation to the care and treatment provided to Baby Róisín following delivery in Hospital S1.

Prior to commencement of the investigation consent was sought and gained from Mrs Conroy to allow the Investigation Team to access her healthcare records and Baby Róisín's from

²⁷ 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.

Hospital S1 and S2 in order to complete the chronology for this systems analysis investigation.

In addition permission was sought from Mrs Conroy and her husband to release the relevant healthcare records relating to Mrs Conroy and Baby Róisín to the clinical experts.

Interviews were undertaken with Mrs Conroy who was accompanied by her husband and staff involved in Mrs Conroy's care on the 14th November 2001.

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

Family Members

- Mrs Conroy and her husband Mr Conroy

Clinical Staff

- Consultant Obstetrician and Gynaecologist C - Hospital S3 who previously reviewed this incident – Interviewed 7 June 2016
- Consultant Obstetrician and Gynaecologist A – Hospital S1 – Interviewed 17 August 2016
- Consultant Obstetrician and Gynaecologist Consultant B – Hospital S1 – Interviewed 18 October 2016
- Midwife M1– Hospital S1 – Interviewed on 17 August 2016
- Midwife M2– Hospital S1 – Interviewed on 18 May 2016
- Midwife M3– Hospital S1 – Interviewed on 25 April 2016
- Midwife M4– Hospital S1 – Interviewed on 17 August 2016
- Midwife M5– Hospital S1 – Interviewed on 17 August 2016
- Midwife M6– Hospital S1 – Interviewed on 17 August 2016
- Midwife M7– Hospital S1 – Interviewed on 17 August 2016
- Midwife M8– Hospital S1 – Interviewed on 17 August 2016
- Midwife M9– Hospital S1 – Interviewed on 17 August 2016

Senior Nursing and Midwifery Management were interviewed to establish what systems and processes were in place at the time of the incident in 2001.

Following the initial interview process, additional information had been obtained that required further clarification from staff. Staff invited to be re-interviewed on 24 May 2017 included:

- Consultant Obstetrician and Gynaecologist A – Hospital S1
- Midwife M1– Hospital S1

Statements were also sought and received from the following staff to help complete the chronology:

- Paediatric NCHD AB on duty on the 14th November 2001 and was fully involved in the feedback process.

The Investigation Team met with Mr and Mrs Conroy on four occasions as part of the investigation process.

During the investigation it was identified that there was a variance in recollections and opinions between some clinical and midwifery staff regarding the chronology of events. These variances and opinions were addressed through the feedback process.

The family at all times had a very clear recall of events which did not alter at any point during the investigation process.

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

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

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

Clinical Experts Assigned to the Investigation

- Dr. Francois Gardeil Consultant Obstetrician and Gynaecologist, Wexford General Hospital, Ireland East Hospital Group
- Dr. John Murphy, Consultant Neonatologist, National Maternity Hospital, Ireland East Hospital Group
- Ms Patricia Hughes, External Expert Midwife (Non HSE)

Appointment of an Independent Expert in Obstetrics and Gynaecology

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

In July 2016 Dr Gardeil was provided with a copy of Mrs Conroy's healthcare record including a copy of the record relating to Mrs Conroy's antenatal outpatient attendances, all sections of the CTG and fetal heart trace during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Róisín was born.

Dr. Gardeil's report was received by the Investigation Team on 12th July 2016 and is included in this report (Appendix C).

On 27th July 2016 Consultant Obstetrician and Gynaecologist A requested that Dr. Gardeil be present with the Investigation Team for his interview on 17th August 2016.

Mr and Mrs Conroy also requested to meet the Investigation Team with Dr. Gardeil so that they could provide an account of their recollections of the events leading up to Mrs Conroy's delivery of Baby Róisín. Dr. Gardeil agreed to this request and Mr Conroy met with Dr. Gardeil on 17th August 2016. The Investigation Team also attended this meeting and recorded the minutes of the meeting.

In line with fair procedures it was therefore deemed appropriate to afford all staff an opportunity to meet with Dr Gardeil should they wish to provide him with an account of events in addition to their earlier interview with the Investigation Team.

Midwife M1, M4, M5, M6, M7, M8, M9, and Consultant Obstetrician and Gynaecologist B accompanied by representatives from their respective representative bodies availed of the opportunity to meet with Dr Gardeil.

Appointment of an Independent Clinical Expert in Neonatology

As a result of the request from the NIMLT to the Institute of Paediatricians Royal College of Physicians through the 'Forum' for a neonatology nomination, Dr. John Murphy was assigned to undertake the review of Baby Róisín's healthcare record from Hospital S1.

In November 2016 Dr. Murphy was provided with a copy of Mrs Conroy's and Baby Róisín's healthcare records from Hospital S1 including a copy of the record relating to Mrs Conroy's antenatal outpatient attendances and all sections of the CTG and fetal heart trace during labour along with healthcare records relating to her admission to the Maternity Department up to the time Baby Róisín was born.

Dr. Murphy's report was received by the Investigation Team on the 18th May 2017 and is included in this report (Appendix D).

Appointment of an Independent Clinical Expert in Midwifery

Ms Patricia Hughes is an external midwifery expert sourced by the Dublin Midlands Hospital Group to review the midwifery care for this investigation.

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

Ms Patricia Hughes report was received by the Investigation Team on 31st July 2017 and is included in this report (Appendix E).

The Interview Process

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

The interviews were conducted by the two members of the Investigation Team. Dr. Gardeil was present for interviews with the Investigation Team at the request of one of the clinical staff.

The interviews were conducted in a manner that aimed to ensure that the optimal levels of information were obtained whilst ensuring that the individuals being interviewed were treated with dignity and respect.

The Terms of Reference for the investigation were provided to all interviewees prior to their attendance at interview along with information relating to systems analysis methodology.

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

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

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

Each individual interviewed was informed in advance of the interview and that notes would be taken of the discussions at the interviews for the purpose of ensuring accuracy.

The interviews were used as an opportunity to establish the facts of the incident, to clarify information for the Investigation Team and as an opportunity for parties involved in the incident to present information to the Investigation Team.

If staff had any concerns about the interview process, they were invited to communicate these concerns to the interviewers or to the investigation commissioner.

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

In advance of the interviews all parties were informed of their entitlement to be accompanied at interview. In order to ensure the confidentiality of the interview process for all involved, accompanying individuals not employed by the HSE were asked to sign a confidentiality agreement.

Prior to the interviews each individual was informed of the opportunity to give comments and observations on the sections of a draft report that are relevant to their involvement and to check the factual accuracy of the draft report. Providing comments and observations on draft reports prepared by the Investigation Team is an essential stage in drafting an investigation report in the interest of fair procedures and for the purpose of ensuring that reports are as factually accurate as possible.

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

Staff who requested a copy of their interview transcript were provided with same.

Staff who were not required by the Investigation Team to attend for interview but were involved in Mrs Conroy's care and referred to in the chronology and/or submitted statements were also afforded the opportunity to review and comment on/check the factual accuracy of relevant sections of the draft report.

The Final Draft Report identified recommendations to address those issues which were considered by the Investigation Team to have contributed to the serious adverse event and feedback was sought on the recommendations identified. On this basis the Final Report of the investigation was developed and submitted to the commission Dr. Susan O'Reilly Group CEO, Midlands Hospital Group.

The members of the Investigation Team are not responsible for the service within which the incident occurred and they had no prior involvement in any aspect of the issue being investigated.

The two investigators on the Investigation were internal to the HSE. A Legal Review of the report was undertaken.

The commissioner will communicate the relevant Contributory Factors and associated recommendations that are applicable nationally to the relevant National Director(s) for national implementation.

Prior to finalising the report Mrs Conroy and her husband requested that Baby Róisín be identified by name in the final report and not by 'Baby A'.

Section 1: Background to this Investigation

Mrs Conroy was seen by her GP and had routine pregnancy blood tests on the 4th of April 2001. The following routine blood tests were carried out the results are contained within the healthcare record;

- Full Blood Count²⁸,
- Blood Group A Positive²⁹,
- Rubella immune,
- VDRL (test for syphilis) negative
- negative serology for Hepatitis B and HIV infection.

Mrs Conroy was then referred by her GP to Consultant Obstetrician and Gynaecologist A for her first booking visit.

Mrs Conroy had her first visit (the booking visit) at the antenatal clinic at Hospital S1 on the 3rd of May 2001. She was 31 years of age. This was her first pregnancy. She was in good health, apart from having a diagnosis of asthma which was treated with Ventolin and Becotide inhalers. She was a non-smoker.

On the 3rd of May 2001 at the booking visit Mrs Conroy gave the 28th of January 2001 as the first day of her last menstrual period (LMP) but was not certain about the date, this is not an unusual occurrence. That uncertainty was denoted in the healthcare record using a question mark preceding the date. However, using that date, the expected date of delivery (EDD) was calculated and recorded to be 4th November 2001. Mrs Conroy would have been 13 weeks and 5 days by her original dates.

Mrs Conroy was seen by Consultant Obstetrician and Gynaecologist A on the 3rd May 2001. Consultant Obstetrician and Gynaecologist A performed a scan which confirmed viability, and measurements of the fetus were consistent with 14 weeks and 3 days gestation and not 13 weeks and 5 days based on the LMP³⁰.

On this basis the expected date of delivery was documented by Consultant Obstetrician and Gynaecologist A in her private clinic healthcare records as 29th October 2001.

History taken on this visit as documented in Hospital S1 Healthcare Record

The healthcare records state that;

- Mrs Conroy's LMP (i.e. last menstrual period) was around the 28 January 2001,
- EDD (estimated date of delivery) was the 4th Nov. 2001
- Parity (i.e. no previous pregnancies) 0+0
- Asthma on Becotide and Ventolin
- Allergies Dust/Food
- Rubella is ticked as immune

²⁸ Full Blood Count (FBC) is used as a broad screening test to check for such disorders as anaemia, infection, and many other diseases. It is actually a panel of tests that examines different parts of the blood (Reference: <http://www.labtestsonline.org.uk/understanding/analytes/fbc/tab/test>).

²⁹ Blood types are either A, B, AB, or O, and Rhesus (Rh) positive or negative. Both the mother and baby may experience problems if their blood types are different, or if the mother has antibodies that will react with factors on the baby's blood cells (Reference: <http://www.labtestsonline.org.uk/understanding/wellness/pregnancy/first-antibody>).

³⁰ In practice and because there is an error range with most tests, a woman's dates would not normally be changed based on ultrasound dates unless there was a difference of at least a week or where the woman could not recollect the first date of her LMP. This would be a clinical decision usually made by a senior obstetrician. The accuracy of the scan was and is also determined by the level of training and experience of the person carrying out the scan and the quality of the equipment itself. These factors are unknown based on examination of the Hospital records.

- Blood Group A positive (dated as taken on 5th April 2001)

Under Family History the following is documented in the Hospital S1 Healthcare Record

The records state;

- TPHA/VDRL³¹ Negative
- Under '**Other**' it is documented that Parents are alive and well.

Under Previous Obstetric History the following is documented in the Hospital S1 Healthcare Record

The records state;

- Primigravida³²
- Non smoker
- Height recorded as 5'6 1/2 "
- Haemoglobin 13.0g/dl
- On folic acid tablets

There is no record of subsequent antenatal visits in Mrs Conroy's Hospital S1 healthcare records. Mrs Conroy had elected to be a private patient of Consultant Obstetrician and Gynaecologist A. The private healthcare records were made available to the Investigation Team by Consultant Obstetrician and Gynaecologist A for the purposes of completing the chronology.

Mrs Conroy recalled at interview that she was '*tired*' during the pregnancy and gave up work at around 5 and half months, following an exacerbation of her asthma. She had been working at the time as a care assistant in a Care of the Elderly in patient unit.

Mrs Conroy attended her scheduled antenatal appointments on a regular basis with Consultant Obstetrician and Gynaecologist A in his private consulting rooms. Visits took place at week 23, 30, 34, 37 and 39³³.

The pregnancy appeared to be progressing normally with no cause for concern. Mrs Conroy was seen twice in the private consulting rooms after her expected date of delivery, at Term + 2 days and at Term +9 days.

Based on Mrs Conroy's recollections and the documentation in the healthcare records it would appear that Mrs Conroy had an uncomplicated ante-natal course until the 10th November 2001.

At interview Mrs Conroy stated she was having a shower on the evening of the 10th November 2001 and experienced a '*show*' which she described as a small amount of sticky, jelly-like pink mucus around 18:00 hours.

Mrs Conroy outlined at interview that she believed her waters '*broke*' at this time;

³¹ The Venereal Disease Research Laboratory test (VDRL) is a blood test for syphilis that was developed by the eponymous lab. The VDRL test is used to screen for syphilis (it has high sensitivity), whereas other, more specific tests are used to diagnose the disease. All pregnant women are tested for syphilis to reduce maternal morbidity, fetal loss and neonatal mortality and morbidity due to syphilis.

³² Primigravida (PG), defined as a woman who conceives for the first time, is in a high-risk group. (Reference: <https://www.ncbi.nlm.nih.gov/pubmed/21702258>)

³³ This was and is in keeping with the normal pattern of antenatal care for a first-time mother without additional risks.

'I was very anxious and this played on my mind for a while....I had a 'show' and my waters 'broke', I wanted to get to hospital. I felt the bump had dropped'.

Mrs Conroy and her husband recalled at interview that they left their home shortly after 18:00 hours on the 10th November 2001 to travel to Hospital S1.

At interview Mrs Conroy stated they arrived at Hospital S1 between 18:00 hours and 19:00 hours.

Mrs Conroy recalled entering the maternity ward from the lifts and walked down to the end of a corridor on the maternity unit which was across from the nurse's station. Mrs Conroy recalled getting onto a trolley and a curtain was pulled around her by a member of staff.

Mrs Conroy stated at interview that it was very quiet on the unit at the time and the midwife carried out an internal exam to check to see if Mrs Conroy's waters had broken.

It is documented in Hospital S1 healthcare records by Midwife M5 that Mrs Conroy presented to the maternity department at Hospital S1 at 18:45 hours on Sunday 10th November 2001 with a history of possible rupture of the membranes and irregular contractions.

Mrs Conroy was 6 days overdue. Mrs Conroy was seen by a midwife initially, who;

- took her history,
- carried out an abdominal examination
- recorded that there was "no liquor draining".

Apart from the opening sentence in the admission notes, there is no further reference by Midwife M5 to the presence and evaluation or absence of contractions after her admission and before her discharge home nor is it possible to deduce from the maternal chart how long Mrs Conroy spent in the hospital, whether it was a minimum of one hour, or up to 4 hours or more.

It is not clear whether the irregular contractions were reported by Mrs Conroy on admission or whether they continued after admission. The Investigation Team consider that this is a deficit in the standard of the midwifery recordkeeping. According to the records, Midwife M5 commenced a CTG, recorded Mrs Conroy's vital observations (temperature, maternal pulse and blood pressure - all of which were within normal limits) and performed a vaginal examination on her. The findings recorded do not indicate that Mrs Conroy was in labour at this time.

Although Midwife M5 does not comment further during this episode of care on the presence or absence of contractions, it would have been and is normal practice to consider the use of a sterile speculum examination prior to undertaking a vaginal examination where there is a suggestion of ruptured membranes in advance of labour / onset of contractions to out-rule or confirm rupture of membranes.

The reasons for this include the following;

- 1) it is easier to see liquor if it is present in the vagina using this assessment.
- 2) it can be used to carry out a test such as an Amnicator test which detects variances in the pH balance which can help indicate the presence or absence of amniotic fluid.
- 3) it is important to determine if a rupture of membranes has occurred in a non-labouring woman as once the membranes are ruptured, then the sterile field around the baby has been broken.
- 4) the risk of infection to the baby in the presence of ruptured membranes increases with time. Where liquor is found to be present and there are no contractions, one would

consider avoiding the undertaking of a vaginal examination unless there was concern with the fetal heart rate. So, if the membranes are ruptured and the woman is not contracting then the midwife would alert the obstetrician who would most likely plan to induce labour after a given period.

Based on the entry in the healthcare records there does not appear to have been a consideration of a sterile speculum examination and there may have been contractions but if so, there are no details of these recorded by the midwife.

This standard of record keeping in relation to the history of contractions does not meet the standard of recordkeeping for a midwife. This aspect of assessment and documentation and communication comprise a vital part in the care and surveillance of a pregnant and /or labouring woman and are necessary for the safe and on-going planning of care relevant to the factors of pregnancy which are individual to the pregnant woman.

According to Ms Hughes it is reasonable to expect that a Midwife would and should have been able to assess the parameters of labour which include the presence, frequency, strength/duration and regularity of contractions using hand palpation plus or minus the use of a CTG monitor.

It is documented in Hospital S1 healthcare records by Midwife M5 that she contacted the Consultant Obstetrician and Gynaecologist on-call who instructed the NCHD on call, to review Mrs Conroy³⁴.

The NCHD on duty documented in the healthcare records that he performed an amniotic test (test for the presence of amniotic fluid in the vagina) on Mrs Conroy which was negative and also performed a pelvic ultrasound scan that was reassuring.

The NCHD recorded the following;

- baby was active, had a normal tone and breathing movements were observed, good liquor³⁵.

It is also documented by the NCHD that Mrs Conroy had a rash on her thigh and the NCHD prescribed Daktaort ointment.

Mrs Conroy recalled at interview that:

'A doctor reviewed me and listened to Baby Róisín's heartbeat, a trace was carried out and there were no issues'.

On the 10th November 2001 at 18:45 hours the following information was documented by a Midwife in Mrs Conroy's antenatal form in Hospital S1's Healthcare record following her assessment at the clinic under the following headings:

History and Examination on Admission as Documented in Hospital S1 Healthcare Records by the Midwife M5

Under Reason for admission:

³⁴ It is not clear from the records at what grade this doctor was. It was practice in Hospital S1 to request Hospital doctors to make decisions on care of private patients but where a woman has "a contract" with a consultant for private care, it would be the practice in some hospitals that the Consultant would be informed directly of a woman's admission and presenting signs and symptoms and findings. S/he may then choose to review the woman him/herself or may delegate the duty to the "on duty" doctor(s). Mrs Conroy was "anxious for her baby's wellbeing" and the Doctor had been notified of this.

³⁵ 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).

The records state that;

- Mrs Conroy was admitted with query Spontaneous Rupture Of Membranes (SROM) and irregular Contractions,
- Palpation lie longitudinal³⁶. Presentation Vertex engaged,
- No liquor draining,
- History: Fetal Heart Heard. CTG recorded,
- Temperature normal,
- Pulse 69,
- Blood Pressure 129/63,
- Vaginal examination – OS³⁷ not dilated very posterior,
- NCHD informed,
- Patient anxious to go home and discussed with Consultant Obstetrician and Gynaecologist on Call and instructed NCHD to assess.

During process on the Final Draft Report Mrs Conroy stated that while she was anxious about the baby she was not anxious to go home.

NCHD Entry in Hospital S1 Healthcare Records

The records state that;

- Mrs Conroy was a primigravida
- Complaining of pains and query fluid PV loss
- Not distressed
- CTG perfect
- For Ante Natal Clinic

The NCHD on examination documented, that there appeared to be no liquor draining, the CTG was recorded as being '*perfect*' and Mrs Conroy was discharged home to return as planned on 13th November 2001³⁸ for her antenatal clinic appointment.

On the 13th November 2001 Mrs Conroy attended Consultant Obstetrician and Gynaecologist A's private Obstetric clinic for a routine antenatal review.

It is documented by Consultant Obstetrician and Gynaecologist A in Mrs Conroy's private clinic antenatal healthcare records that he performed a scan that suggested an active baby however there was evidence of diminished liquor.

Mrs Conroy recalled at interview that Consultant Obstetrician and Gynaecologist A carried out an ultrasound scan to estimate her amniotic fluid volume by measuring fluid pockets and two fluid pockets appeared low.

Following the scan Mrs Conroy outlined at interview that she had to insist on being admitted for induction. It is documented by Consultant Obstetrician and Gynaecologist A in the private

³⁶ 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).

³⁷ 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.

Reference: <http://www.netdoctor.co.uk/ate/pregnancyandchildbirth/205040.html#ixzz31WTlfpX9>

³⁸ There was an existing appointment for Mrs Conroy to see Consultant Obstetrician and Gynaecologist A in his private consulting rooms on the 13th of November 2001.

clinic antenatal healthcare record that Mrs Conroy would be admitted to hospital S1 on the 14th November 2001 at 08:00 hours for induction of labour (IOL)³⁹.

Mrs Conroy recalled at interview that;

'I saw Consultant Obstetrician and Gynaecologist A on the 13th November 2001 around 2.30pm. I still noticed mucus and blood for a few days. I explained to him about Saturday, that my waters had broken and following a review I was discharged. The show I had was playing on my mind, I asked to be admitted for induction, and I was worried about my baby. Consultant Obstetrician and Gynaecologist A did not seem concerned, however after I asked he agreed to induce me.

I was concerned about the difference in dates and he said 'baby is fine liquor is low', I felt I was due 28th October 2001 and Consultant Obstetrician and Gynaecologist A gave the 4th November as my due date.

Why was there a discrepancy around my dates? I explained to him about my waters breaking, the show, I went through what happened on the 10th November 2001, he scanned me and showed me 2 pockets that were low in liquor. I was very stressed over the low fluid. I still have a picture in my head of the scan that it looked like half the fluid was gone. I felt something was happening.

I was so upset and was very mindful of myself and counting down to the 14th November 2001; I always felt my first date was correct. I didn't know why there was a discrepancy in my dates, at my second visit to Consultant Obstetrician and Gynaecologist A the date changed to the 4th November 2001, he did not refer to a scan, they all used the 'wheel'⁴⁰ to calculate dates.'

Dr Gardeil stated that the ultrasound scan performed was very reassuring with a Biophysical score⁴¹ of 8/8 and a CTG was noted to be perfect.

According to Ms Hughes, the risk to a baby in-utero rises after 14 days following the expected date of delivery (EDD) and in practice most maternity hospitals in Ireland and elsewhere tend to offer induction of labour from about 10 days following the EDD as logistically, one cannot guarantee that an induction on day 14 will result in the birth on day 14 as the process can take 24- 48 hours.

Mrs Conroy stated at interview that she returned home following her antenatal visit and remained very anxious.

Mrs Conroy told the investigation that at this point she just wanted to be admitted to hospital to have her baby.

³⁹ I.O.L. is Induction of Labour 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).

⁴⁰ A pregnancy wheel is also known as a gestation calculator. This is the small calendar that uses the last menstrual period (LMP) to help determine the due date.

⁴¹ An ultrasound method of evaluating fetal status during the antepartal period based on five variables originating within the fetus, fetal heart rate, breathing movement, gross movements, muscle tone and amniotic fluid volume. It is indicated in cases of postdate pregnancy, maternal hypertension, diabetes mellitus, vaginal bleeding, maternal Rh sensitization, maternal history of stillbirth, and premature membrane rupture (Reference: <http://medical-dictionary.thefreedictionary.com/fetal+biophysical+profile>).

Section 2: Chronology of Events⁴²

Details provided in the chronology have been obtained from a review of the relevant documentation, medical records and interviews with the relevant personnel.

Timings are based on records, Mrs Conroy and her husband and relevant staff recollections.

For the purposes of clarity the Healthcare Records used in the Maternity Unit in Hospital S1 at the time of this incident contained the following;

- Ante Natal Record Sheet – Completed by either a Doctor or Midwife.
- History & Examination on Admission Sheet with Continuation Sheets for additional notes (Antenatal Notes) – for both Medical and Midwifery entries.
- Operation Notes Sheet – for both medical and midwifery entries.
- Special Instructions Sheet – For midwifery entries regarding Fetal Heart Rate, liquor, Moulding, Cervix, Descent, Onset of labour - time, Oxytocin, contraction frequency/timings, medications given, Maternal BP & Pulse, Urine.
- Labour Summary Record - for both medical and midwifery entries.
- Laboratory Results Section.
- Maternal Temperature, Pulse Respiration & Blood Pressure Sheet.
- Nursing Report Sheet – Specifically for midwifery entries.
- Drug Prescription Sheet – medications prescribed by medical staff.

Wednesday 14th November 2001

08:00 Hours (Consultant Obstetrician and Gynaecologist A Schedule for the 14th November 2001)

As outlined in the weekly consultant's schedule, Consultant Obstetrician and Gynaecologist A⁴³ was rostered to undertake a ward round on the labour ward the morning of the 14th November 2001.

08:00 Hours

Midwife M1 stated at interview that she had been contacted by the hospital to do an overtime shift on the labour ward from 08:00 hours until 20:00 hours on 14th November 2001 due to staffing shortages at the time.

Midwife M1 indicated to the Investigation Team at interview that this was a regular occurrence within the maternity unit.

Midwife M1 outlined at interview that she had worked 84 hours night duty the previous week⁴⁴ and was on a week off duty. Midwife M1 was not fatigued at the time and was happy to cover the labour ward that day.

⁴² Bold Italics used throughout the chronology of events section indicate direct quotes from medical records and all interviewees.

⁴³ Consultant Obstetrician and Gynaecologist A also confirmed this to be his schedule at interview.

⁴⁴ It was established during the interview process with Midwife M1 and Senior Management that a week of night duty consisted of 7 consecutive 12 hour night duty shifts which commence on a Monday night and ended the following Monday morning at 8am.

08:00 Hours

At interview Mrs Conroy and her husband stated that they presented to Hospital S1 for a planned induction of labour⁴⁵ under the care of Consultant Obstetrician and Gynaecologist A at 08:00 hours on 14th November 2001.

Mrs Conroy informed the Investigation Team that on arrival her husband went to the admissions office to complete the required admission paperwork and Mrs Conroy proceeded to the nurses' station. Mrs Conroy recalled that there were 2 other women for induction that morning; Mrs Conroy outlined that it appeared to be a busy morning.

There were renovations underway and Mrs Conroy remembered the loud noise of a jackhammer somewhere over head.

Mrs Conroy recalled that the ward was divided into three sections; an antenatal section, post natal section and the labour ward.

At interview Midwife M2 stated;

'I started to admit Mrs Conroy and Midwife M8 took over and admitted Mrs Conroy, we were short staffed at the time and Midwife M1 was called in to cover the labour ward'.

According to an entry in the healthcare records Mrs Conroy was admitted by Midwife M8 for induction of labour to the antenatal Ward in Hospital S1.

No time recorded – Midwife M8 Entry in Ante-Natal Notes

An entry made by Midwife M8 in the healthcare record contains the following information:

'Admitted T +10 for induction. On palpation lie longitudinal, Cephalic presentation⁴⁶. Vertex engaged. FHHR⁴⁷ @ 145Bpm. Microlax TT pr given'.

08:00 Hours – Midwife M8 Entry in the Nursing Report

It is documented in the healthcare record by Midwife M8 that Mrs Conroy was admitted for induction of labour at T+10⁴⁸; the documented findings of the admission assessment are as follows;

- BP 110/77
- P 102
- Apyrexial (Temperature normal)
- Lie – longitudinal Cephalic Presentation.
- Vertex engaged.
- FHHR (Fetal Heart Heard and Regular) @ 145 Bpm (Beats per minute).
- Microlax 2 given PR with consent.

⁴⁵ Induction is the process used to encourage labour to start artificially. Some of these processes involve administration of drugs and all aim to encourage the cervix to shorten and soften with the ultimate aim of dilating (with the help of contractions) in order to allow the baby to be born.

⁴⁶ A cephalic presentation or head presentation or head-first presentation is a situation at childbirth where the fetus is in a longitudinal lie and the head enters the pelvis first; the most common form of cephalic presentation is the vertex presentation where the occiput is the leading part (the part that first enters the birth canal).^[1] All other presentations are abnormal (malpresentations) which are either more difficult to deliver or not deliverable by natural means.

⁴⁷ FHHR – Fetal Heart Heard and Regular

⁴⁸ Term plus 10 days

Based on Midwife M8's entries in the healthcare record there is no indication that she was aware of the concern regarding the reduced liquor or the scan which was carried out the previous day which was suggestive of reduced liquor.

The Investigation Team note that there is no Reference to the presence or absence of membranes or to vaginal loss.

There is no documented plan in respect of further reviews.

The Investigation Team note that the maternal pulse at this time was raised at 102 bpm (this may have been due to anxiety re the process of induction) but it appears to have gone without comment from the admitting Midwife. There is no reference as to how the fetal heart rate was recorded. The Investigation Team established through the interview process that the fetal heart rate was assessed using a hand held Doppler.

At interview Mrs Conroy recalled being escorted to her room, 'number 23' by midwife M8 in the antenatal ward prior to being taken to the treatment room for a clinical assessment and prostaglandin gel insertion by Consultant Obstetrician and Gynaecologist A.

There was no pre prostin CTG carried out⁴⁹.

Ms Hughes Midwifery Expert to the investigation states in her report that it was and is usual practice to assess the fetal heart rate prior to the administration of Prostin by either carrying out a CTG (depending upon the circumstances of the fetus) or to listen in to the fetal heart rate for one minute beforehand. There is no evidence of either action being taken in this case according to examination of the records.

09:00 Hours

On arrival to the antenatal ward, Mrs Conroy stated that she recalled that she was reviewed by Consultant Obstetrician and Gynaecologist A and he informed her again that she had diminished liquor.

Mrs Conroy outlined at interview that on admission her expected date of delivery was again calculated as 40 weeks and 10 days gestation.

09:00 Hours - Entry made by Consultant Obstetrician and Gynaecologist A

It is documented in the healthcare record by Consultant Obstetrician and Gynaecologist A that Mrs Conroy was;

- T+10 (term plus 10 days)
- Diminished liquor
- Cx (Cervix) Unfavourable
- Vx (Vertex) - 3
- Prostin gel 2 mg inserted⁵⁰

According to an examination of the healthcare records there is no plan of care documented by Consultant Obstetrician and Gynaecologist A.

⁴⁹ The Investigation Team were informed by staff interviewed that there were no policies or guidelines developed locally at the time of this incident in relation to continuous cardiotocography (CTG) to electronically monitor babies' heartbeats and wellbeing pre and post prostin gel or during labour, or the escalation/communication of concerns.

⁵⁰ Prostin gel or Prostaglandins are drugs that help to induce labour by encouraging the cervix to soften and shorten (ripen). This allows the cervix to open and causes contractions to start. This drug is a gel which contains a synthetic prostaglandin E2. The exact dose is prescribed by the doctor and determined by how "ready for labour" the cervix is. More than one dose may be needed to induce labour. Repeat doses are given every 6-8 hours approximately to a maximum of 2 doses.

09:00 Hours - Midwife Entry in Nursing Report

It is documented by a Midwife in the healthcare record that Mrs Conroy was seen by Consultant Obstetrician and Gynaecologist A, Prostin Gel 2mgs was inserted vaginally and a CTG⁵¹ was recorded.

Mrs Conroy recalled at interview that;

'No information was really given to me by the midwife or by Consultant Obstetrician and Gynaecologist A at the time'.

Ms Hughes states in her report that there is no reference to presence or absence of membranes or to vaginal loss. There is no documented plan in respect of further reviews.

The Investigation Team consider that a woman admitted for IOL would have usually been asked to remain in bed for up to one-hour post insertion of Prostin to ensure its application and absorption by the cervix, this has not been documented.

09:00 Hours - Midwife Entry on the Special Instruction Sheet contained within the Healthcare Record

It is recorded on the summary page that the first stage of labour began at 09.15 hours. The Investigation Team consider this to be a serious inaccuracy.

Dr. Gardeil outlined for the investigation that Mrs Conroy was not in labour at this point. It is not clear who made this entry and is misleading and incorrect.

Unsigned Entry by a Midwife in Healthcare Record (which is directly under an entry made by Consultant Obstetrician and Gynaecology A) it is documented;

'09:15-09:40 hours – CTG recorded

The Investigation Team contend that this unsigned record stating "CTG recorded" with a time span from 09:15 hours to 09:40 hours does not meet the required standard of recordkeeping⁵².

The Investigation notes that the unsigned entry appears to be "squeezed" into existing notes, suggesting the entry is retrospective. This is a post prostin gel CTG.

09:15 to 09:40 hours

Based on entries in the healthcare record at 09:15 hours continuous fetal heart monitoring (CTG) was commenced and ceased at 09:40 hours.

Dr Gardeil Consultant Obstetrician and Gynaecologist assigned as the clinical expert to the investigation, stated this was a normal and was a reassuring tracing;

'this C.T.G. shows a baseline of approximately 150, normal variability, and no decelerations. This was a 'normal C.T.G'⁵³.

⁵¹ Ms Hughes examined the CTG, and states that there does not appear to have been a Toco transducer in place at that time. This does not meet the required procedure for a CTG which is carried out to measure both the fetal heart rate and the presence of uterine activity, i.e. contractions and their relationship to each other. The Fetal Heart Rate on that tracing appears normal in all respects; baseline, variability, presence of accelerations and no decelerations.

⁵² This does not meet the required standard of recordkeeping in that all entries should be dated, timed (24-hour clock) and signed (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

⁵³ A 'Normal' CTG is indicated when all four features (fetal heart rate, baseline variability, acceleration and deceleration of the fetal heart rate and frequency and strength of contractions as recorded by the attending

There does not however appear to have been a Toco transducer in place at that time. Therefore this trace cannot be considered a CTG trace but rather a cardiac trace of Baby Róisín's heart rate. This does not meet the required procedure for a CTG which is carried out to measure both the fetal heart rate and the presence of uterine activity, i.e. contractions and their relationship to the baby's heart rate.

During the feedback process Consultant Obstetrician and Gynaecologist A stated that after he induced Mrs Conroy he handed care over to the midwives as was the normal practice, the trace at this time was normal.

Consultant Obstetrician and Gynaecologist A stated that the non-written policy in the unit was for the Midwives to manage the labour and call a Consultant Obstetrician and Gynaecologist if they were concerned about a patient; they could communicate directly with a Consultant Obstetrician and Gynaecologist as needed.

The Investigation Team note that the plan of care going forward from Mrs Conroy's first dose of Prostin is not documented by either the Consultant or the Midwife. According to Dr. Gardeil this is a serious omission.

09:40 Hours

Mrs Conroy recalled at interview that she was escorted back to room 23 by Midwife M8 following insertion of the prostin gel and was told to make herself comfortable.

Mrs Conroy outlined during the feedback process that she was not asked to lie down for the hour following the insert of the prostin gel.

11:00 Hours

Mrs Conroy and her husband informed the Investigation Team that they remained in Room 23 and during this time they did not talk to or see a midwife. Mrs Conroy recalled at interview that she was;

'having bad pains and that it was hard to find a midwife to get some pain relief, I remember feeling anxious, my husband went out of the room and finally found a midwife to come in to me. I thought I was in labour, I had pain everywhere'.

The Investigation Team note that there is no record of care provided in the period from 10:00 hours until 11:30 hours.

11.30 Hours – Healthcare record Entry by Midwife M10⁵⁴

It is documented by Midwife M10 in the healthcare record that Mrs Conroy was;

- complaining of strong contractions
- Fetal Heart Heard 138 regular⁵⁵
- PV to assess – 2° consent
- Vertex engaged
- cervix very posterior – unable to reach

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 non-reassuring category and the remainder are reassuring. A 'Pathological' CTG is when two or more features fall within the non-reassuring category or one or more features fall within the abnormal category.

⁵⁴ This level of record keeping does not meet the required standard for midwives in that it is ambiguous and it does not give the full picture to the reader (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10.3.10).

⁵⁵ Consultant Obstetrician and Gynaecologist A outlined at interview that Midwives' would listen to the fetal heart rate every half hour using a Doppler as continuous fetal monitoring was not the practice at the time.

- Advised to take bath
- No hot water – maintenance contacted. No reply from 2 maintenance staff contacted.

It was established during the interview process that the fetal heart rate at this time was recorded using a hand held Doppler⁵⁶ however this is not recorded in the healthcare record.

In addition it is not documented how frequent or regular contractions were, thus not providing sufficient information in relation to how Mrs Conroy's labour was progressing.

According to Ms Hughes even if the Midwife had not placed Mrs Conroy on a CTG monitor, she would have been expected to have palpated those contractions by hand to adequately describe them in terms of frequency and regularity strength/duration and the woman's response to them.

It is not clear from the records whether the Midwife had been called to the bedside by Mrs Conroy or whether she had been doing her rounds.

Mr Conroy provided clarity on why the Midwife reviewed Mrs Conroy during the feedback process by stating;

'I was in and out of the room frequently and couldn't find anyone, so I just waited in the corridor. I waited for a Midwife to pass and stopped her and asked her to review my wife. There was nobody proactively checking my wife'

The Investigation Team consider that Baby Róisín's CTG should have been commenced to assess fetal wellbeing once Mrs Conroy felt strong contractions. This was considered a high risk labour and at this point there was a requirement to monitor the fetal heart rate along with the frequency of contractions⁵⁷.

During the feedback process Consultant Obstetrician and Gynaecologist A stated that following his assessment at 09:00 hours the head was at station -3 and the cervix was unfavourable he did not expect an early onset of labour.

Consultant Obstetrician and Gynaecologist A also stated that he was not made aware of the strong contractions but received a request for pain relief which he regarded as normal.

Dr. Gardeil informed the investigation that an instruction should have been issued by Consultant Obstetrician and Gynaecologist A to check the wellbeing of Baby Róisín at this juncture without necessarily being asked to do so by a Midwife. Particularly as he was present on the labour ward and prescribed analgesia.

Dr. Gardeil stated that this assessment should have been by means of continuous CTG as this was a high risk labour with low liquor.

No Time - Prescription Sheet in Healthcare Record

Consultant Obstetrician and Gynaecologist A has documented and prescribed Cyclimorph 10mgs Intramuscular Injection x 2 doses.

⁵⁶ A Doppler is small hand held device, which looks like a microphone. It is placed against the abdomen and helps the midwife to listen and record the fetal heart rate.

⁵⁷ Retired Midwife M10 declined the invitation for interview and therefore the investigation team were unable to establish why Mrs Conroy was not commenced on the CTG. Relevant extracts were sent to Midwife M10 for comment and feedback.

12:30 Hours – Unsigned Entry by Midwife M10 Entry in the Nursing Report⁵⁸

Midwife M10 documented that Mrs Conroy was seen by Consultant Obstetrician and Gynaecologist A and cyclimorph 10mgs ordered and given at 12:45 hours.

The Investigation Team note that the entry is timed at 12:30 hours and refers to an action relating to 12:45 hours.

During the feedback process Mrs Conroy and her husband were concerned that entries in the healthcare record provided conflicting accounts of the events on the 14th November 2001.

Mrs Conroy and her husband were concerned that the entry is misleading suggesting that Consultant Obstetrician and Gynaecologist A reviewed Mrs Conroy.

Mrs Conroy informed the Investigation Team during the feedback process that they did not see Consultant Obstetrician and Gynaecologist A at 12:30 hours.

As previously outlined the family did not see Consultant Obstetrician and Gynaecologist A following the insertion of the prostin gel. Mrs Conroy stated the next time she saw Consultant Obstetrician and Gynaecologist A was on the morning of the 15th November 2001 at approximately 09:30 hours when he was conducting his scheduled ward round.

At interview Consultant Obstetrician and Gynaecologist A outlined that while he was on the labour ward that morning at approximately 12:30 hours and would have prescribed the pain relief at the Midwives' station, it is likely that the Midwife incorrectly assumed that he reviewed Mrs Conroy.

Consultant Obstetrician and Gynaecologist A stated that he did not recall reviewing Mrs Conroy that afternoon.

12:30 Hours - Entry made by Consultant Obstetrician and Gynaecologist A in the Healthcare Record

The entry in the healthcare record by Consultant Obstetrician and Gynaecologist A indicates that he was aware that Mrs Conroy was having strong contractions and he prescribed cyclimorph 10mgs for the pain, however he did not review Mrs Conroy to establish how her labour was progressing.

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

'Strong Contractions Cyclimorph 10mgs'

In addition Mrs Conroy and her husband have stated that they are '*devastated*' that Consultant Obstetrician and Gynaecologist A did not review Mrs Conroy at the time of this entry to ensure a CTG had been commenced following the onset of labour.

Consultant Obstetrician and Gynaecologist A stated at interview that he was on the labour ward that morning and afternoon and would have prescribed pain relief for Mrs Conroy at the request of midwife.

Consultant Obstetrician and Gynaecologist A outlined that he did not review Mrs Conroy at this time because;

⁵⁸ There are a number of duplicate entries by Midwives in the continuation sheet section of the healthcare records and the midwifery kardex also contained within the healthcare records, these entries tend to vary in content and in some cases are an incorrect account of events which in itself poses a risk to the patient. The investigation considers this duplication of effort to be unnecessary and a wasteful use of valuable time.

'we (obstetricians) did not interfere with the midwives practice and would only review a patient at the midwives' request. That's how things were done then. I believed everything would be fine. With the benefit of hindsight I should have reviewed her.'

During the feedback process Mrs Conroy and her husband outlined that Mrs Conroy was admitted as a private patient under the care of Consultant Obstetrician and Gynaecologist A for the delivery of Baby Róisín. The family understand that there is a clear distinction between the doctors and midwives role. It was their expectation that Mrs Conroy's labour and delivery of Baby Róisín would be managed directly by Consultant Obstetrician and Gynaecologist A and not by the Midwife.

Mrs Conroy and her husband outlined during the feedback process that;

'it was his job/duty to review and care his high risk patient, it was on the chart one hour earlier stating strong contractions, no movement, that should have been alarm bells ringing for him, he stated himself in the records- "strong contractions" and prescribes "pain relief", this was an opportunity missed.'

The Investigation Team consider that although midwives and obstetricians both deliver babies, the similarities stop there, each discipline is educated, licensed and compensated differently resulting in varying public expectations.

The family had an expectation having attended Consultant Obstetrician and Gynaecologist A as a private patient that he would have reviewed Mrs Conroy during the course of the morning particularly as Mrs Conroy was experiencing strong contractions.

Dr. Gardeil agrees with the family's expectation and considers that Consultant Obstetrician and Gynaecologist A should have reviewed Mrs Conroy particularly in light of the fact that he had planned to leave Hospital S1 for a significant period of time and would not be available.

12.30 Hours

It would appear from Mrs Conroy's healthcare record that the last entry made by Consultant Obstetrician and Gynaecologist A was made at 12.30 hours.

At interview Consultant Obstetrician and Gynaecologist A stated that he had to leave to go to a funeral possibility before 14:00 hours.

Any subsequent contact between Midwife M1 and Consultant Obstetrician and Gynaecologist A was over the telephone.

The Investigation Team was unable to establish what time Consultant Obstetrician and Gynaecologist A left Hospital S1 or returned. Consultant Obstetrician and Gynaecologist A however did inform the Investigation Team at interview that he did return later that evening to deliver a primagravida in Hospital S1.

Consultant Obstetrician and Gynaecologist A outlined at interview that Consultant Obstetrician and Gynaecologist B would have known he was gone as there was a white board in the midwives office where he wrote Consultant Obstetrician and Gynaecologist B was covering his clinical workload in his absence.

The Investigation Team enquired how Consultant Obstetrician and Gynaecologist B might be aware of this whiteboard entry. During the feedback process Consultant Obstetrician and Gynaecologist A stated that this was the practice for over 20 years; Consultant Obstetrician and Gynaecologist B would have known she was covering; there were 2 consultant obstetricians, when one consultant was out of the hospital the other consultant covered.

Dr. Gardeil outlined that this to be an unacceptable form of communicating a high risk labour.

Consultant Obstetrician and Gynaecologist A was asked if he informed Mrs Conroy and her husband that he had handed over care to Consultant Obstetrician and Gynaecologist B. Consultant Obstetrician and Gynaecologist A stated at interview that;

'I don't remember but patients are advised at booking that I may not be able to attend the delivery. Patients sign a form (Appendix B). I told the sister and nurses in the labour ward, cyclimorph can help patients progress quickly, I remember Consultant Obstetrician and Gynaecologist B was in clinic. I know that Consultant Obstetrician and Gynaecologist B was in clinic as I had to provide a statement for the legal team so I reviewed the schedule for that time'.

During the feedback process Mr and Mrs Conroy informed the Investigation Team that it was their understanding when they signed the disclaimer form that Consultant Obstetrician and Gynaecologist A would only be unavailable in the event of annual leave or if he was taken up with an emergency situation. Mrs Conroy and her husband outlined that;

'this is an offence to us....he was able to attend but elected not to attend.'

Mrs Conroy and her husband stated that they did not expect Consultant Obstetrician and Gynaecologist A to be unavailable following his decision to admit Mrs Conroy for induction and to not review Mrs Conroy prior to his department from the hospital to attend a funeral.

During the feedback process Mr and Mrs Conroy stated;

'signing the form was in the unlikely event that Consultant Obstetrician and Gynaecologist A being unable to attend the birth i.e. if the birth occurred while he was on holidays and he will assign someone of the same competence level to attend the labour. It was never viewed by us that he would abandon us in preference of a funeral especially as he knew I was high risk and he induced me himself'.

Consultant Obstetrician and Gynaecologist A did not inform Mrs Conroy or her husband that he had planned to leave the hospital at that time.

There is no available evidence that any handover took place in relation to this high risk labour between Consultant Obstetrician and Gynaecologist A and Consultant Obstetrician and Gynaecologist B. Consultant Obstetrician and Gynaecologist B did not recall any handover occurring.

Consultant Obstetrician and Gynaecologist A stated at interview that he would have handed over care to Consultant Obstetrician and Gynaecologist B however he was unable to confirm if this actually occurred and outlined that he would have documented a handover on a whiteboard in the labour ward and midwifery office.

In addition there is no handover documented in Mrs Conroy's healthcare record.

Consultant Obstetrician and Gynaecologist A did not review Mrs Conroy prior to leaving the hospital following her induction of labour, having arranged for her to be admitted that morning for induction.

At interview Consultant Obstetrician and Gynaecologist A outlined that he should have informed Mrs Conroy that he had planned to leave hospital S1 and should have reviewed Mrs Conroy.

Based on Consultant Obstetrician and Gynaecologist A's interview, had Consultant Obstetrician and Gynaecologist A reviewed Mrs Conroy an appropriate plan of care would have been put in

place. Consultant Obstetrician and Gynaecologist A outlined the he planned on being back later that evening⁵⁹.

Consultant Obstetrician and Gynaecologist A outlined that he did not believe at the time Mrs Conroy would progress as quickly as she did and that he believed that he would be back in time later that evening to deliver Baby Róisín. Dr. Gardeil stated for the investigation that this is an unsafe assumption and not in line with the ethical guidelines set out by the Medical Council.

There was no review of Mrs Conroy carried out prior to consultant obstetrician and Gynaecologist A leaving the hospital and therefore no clinical information to form an opinion on how quickly Mrs Conroy would progress.

According to the family's account of events there were so many missed opportunities to prevent harm to Baby Róisín.

Dr Gardeil stated that Consultant Obstetrician and Gynaecologist A had a responsibility to ensure the safety of Mrs Conroy and her unborn baby, having scheduled her for an IOL. Dr Gardeil also stated that there were a number of warning signs which were not managed appropriately which are causally linked to Baby Róisín being born in poor condition.

Untimed/Unsigned Healthcare Record Entry on the Continuation Sheet by Midwife 10

It is documented in the healthcare record by Midwife 10 that Mrs Conroy was given cyclimorph 10mgs at 12:45 hours.

The Investigation Team observed that this unsigned entry appears to be "squeezed" into existing notes, suggesting the entry is retrospective.

12:30 Hours – Entries relating to the time period of 12:30 Hours

During the feedback process Mrs Conroy and her husband outlined their concern regarding the inconsistencies in the midwifery staff entries contained in the healthcare record.

There are duplicate entries in a nursing report and in a healthcare record continuation sheets which are conflicting at times.

The Investigation Team consider this duplication of effort in documentation to be unnecessary and wasteful use of valuable time which should be afforded to direct care of woman and babies and is laden with risk as key factors may fail to be communicated to the entire team as generally only midwives would read the midwifery Kardex whereas all team members review the woman's chart.

The first entry in the healthcare record at 12.30 hours states that Consultant Obstetrician and Gynaecologist A reviewed Mrs Conroy while the second entry at 12.30 hours suggests that Consultant Obstetrician and Gynaecologist A had to be contacted.

Mrs Conroy and her husband stated by 12:30 hours Mrs Conroy was in labour and in a lot of pain, Midwife M10 documented that she contacted Consultant Obstetrician and Gynaecologist A, Mrs Conroy stated she was not reviewed by a Doctor and a CTG was not commenced.

12:45 Hours

Mrs Conroy recalled at interview that by approximately 12:45 hours;

⁵⁹ There is no evidence to suggest that Consultant Obstetrician and Gynaecologist A returned to the hospital that evening to review Mrs Conroy.

'I was in a lot of pain and don't recall seeing Consultant Obstetrician and Gynaecologist A...Nobody was around, my husband couldn't get any help, room 23 was at the end of the corridor, I felt forgotten about...the Midwife came to help and seemed startled and said you appear to be in labour'.

The Investigation Team note that there is no record of any assessment of Mrs Conroy's condition or care provided in the period from 12:45 hours until 14:00 hours.

Following the administration of an opioid, a midwife was/is required to assess its effectiveness and this would or should have been done by 30 minutes after the administration.

Regrettably it is not possible to know from the records if Mrs Conroy was considered at that time to be in labour during the period from 12.45 -14.00 hours due to the absence of documentation.

14:00 Hours

As outlined on Consultant Obstetrician and Gynaecology A's schedule, Consultant Obstetrician and Gynaecology A was due to commence a gynaecology clinic at 14:00 hours in the Outpatients Department in Hospital S1.

14:00 Hours approximately

It was established from the medical roster and Outpatient Department schedule⁶⁰ for the 14th November 2001, that Consultant Obstetrician and Gynaecology B was acting as a locum for another Consultant Obstetrician and Gynaecologist D in Hospital S1 which commenced at 14:00 hours.

Letters issued from Consultant Obstetrician and Gynaecology A's gynaecology clinic regarding patients who had attended were all signed off by either Consultant Obstetrician and Gynaecology B Obstetrician or the Gynaecology NCHD as having been the Doctors who reviewed the attendees indicating that Consultant Obstetrician and Gynaecologist A did not attend the clinic.

14:00 Hours

Mrs Conroy recalled at interview that her husband walked her down to the labour ward where they met Midwife M1, who they recall saying;

'who are you and what's going on, she seemed startled, she then checked me and said you are 4cm and ready to go'.

At this juncture there is still no record of the frequency of contractions, vaginal loss or draining liquor in the healthcare records.

⁶⁰ Consultant Obstetrician and Gynaecologist A's clinic was on the afternoon of the 14th November 2001. The first patient appointment on the PAS (Patient Administration System) was for 13:51 hours and the last appointment time sent to the patients was for a 15:00 hours check in time. It is not possible to give the exact start time of the clinic and the exact end time of the clinic as this was not recorded on the PAS System. In relation to the clinical records the doctors do not normally record the time only the date at an OPD Clinic. 23 patients attended the clinic and 7 patients Did Not Attend the clinic. As there is a team present at the clinic the PAS system is unable to give the number of patients that was seen by each doctor present. However it can be confirmed that Consultant Obstetrician and Gynaecologist A was not present for this Clinic as he had left the hospital. Based on documentation supplied to the investigation team it is evident that Consultant Obstetrician and Gynaecologist B did review a number of Consultant Obstetrician and Gynaecologist A's patients at this clinic while also covering another gynaecologist clinic.

From a review of the healthcare record and staff interviews the Investigation Team identified that Midwife M1 was assigned to Mrs Conroy's delivery in the labour ward and a Student Nurse was present.

14:00 hours – Midwife M1 Entry in Nursing Report

- Distressed ++
- (VE) Cervix very posterior 1cm dilated
- Vertex presentation. No membranes felt. Fetal Heart Heard 142
- Consultant Obstetrician and Gynaecologist A informed – suggested epidural and refused by patient
- May have cyclimorph 10mg
- Same given at 14:20 hours

Dr. Gardeil stated for the investigation that it was highly probable that Mrs Conroy was in fact 4cm dilated by 14:00 hours, which is in keeping with Mrs Conroy's account of events, rather than the 1cm recorded in the healthcare record.

The Investigation Team note that it is not documented in the healthcare how the fetal heart rate was recorded, however during the interview process Midwife M1 outlined that she recorded the fetal heart rate using a hand held Doppler.

During the feedback process Mr and Mrs Conroy requested to know if Consultant Obstetrician and Gynaecologist A was informed of there being no liquor.

Midwife M1 stated at interview that she spoke with Consultant Obstetrician and Gynaecologist A over the telephone regarding Mrs Conroy's status at that time.

At interview Midwife M1 recalled that;

'from the time I saw her (Mrs Conroy) at 2pm there was no liquor seen and during her labour there was no liquor seen, this was alarming, I told Consultant Obstetrician and Gynaecologist A this when I rang him at 2pm'.

Midwife M1 did not document that she informed Consultant Obstetrician and Gynaecologist A that there was an absence of Liquor⁶¹.

Midwife M1 also stated at interview that it is was at this point Consultant Obstetrician and Gynaecologist A informed her to contact Consultant Obstetrician and Gynaecologist B as he was no longer available as he had left the hospital.

In relation to consultant obstetrician cover in Hospital S1, Consultant Obstetrician and Gynaecologist A stated in a formal letter to the Investigation Team during the feedback process that;

'In 2001 there were 2 consultants in the maternity unit to provide 1:2 work in the hospital and 1:2 on call and to provide antenatal and gynaecology clinics both in the hospital and in 2 other locations. When one Consultant was out of the hospital the other consultant covered the hospital i.e. The wards, the labour room and emergencies. As this practice was in place for more than 20 years there was no need for a formal notification from one consultant to the other when one was absent either for a day or a few hours.'

⁶¹ There can be several reasons for no liquor, as follows;

- there is none to drain;
- the head/ presenting part is well down and well applied to the cervix thus blocking drainage or
- the presence of thick meconium may be blocking it.

The Midwives were informed by written notice on a whiteboard in the nursing station and also in the labour ward and usually a verbal notification was communicated to the ward sister.

In this case Consultant Obstetrician and Gynaecologist B who was providing cover that day and had given many years of invaluable locum service for us was aware of the situation as she had been party to it for many years'.

During the feedback process Mrs Conroy and her husband stated that it is clear to them now that a culture of safety did not exist in Hospital S1, because staff should never leave a high risk patient without handing over care and developing an appropriate plan of care.

Mrs Conroy also outlined at interview that a Midwife informed her that she was 4cm dilated and not 1cm as previously documented.

Midwife M1 Entry in Special Instruction Sheet (Retrospective Entry covering a period of time between 14:00 Hours – 17:00 Hours)

There is no entry by Midwife M1 in the healthcare records regarding the absence of liquor⁶² during labour except for a general comment on the special instruction sheet under 14:00 hours to 17:00 hours where it is documented by Midwife M1 retrospectively; 'no liquor'.

Midwife M1 Entry in Nursing Report

Midwife M1 documented that Consultant Obstetrician and Gynaecologist A was informed of the strong contractions, and suggested an epidural⁶³ but this was refused by Mrs Conroy as she did not want the pushing stage⁶⁴ to be difficult.

The investigation notes that there is still no documented record of how frequent those contractions were. A reference such as "strong contractions" on its own is incomplete, ambiguous and unhelpful in assessing a woman's progress in labour.

Dr. Gardeil stated for the investigation that Consultant Obstetrician and Gynaecologist A was aware at this point that Mrs Conroy was experiencing very strong contractions and still made a decision to leave Hospital S1 without reviewing Mrs Conroy to satisfy himself that Mrs Conroy and Baby Róisín were not at risk.

Dr. Gardeil stated that the safety of both Mother and Baby is paramount and must be above all personal considerations.

14:00 Hours – Midwife M1 Special Instruction Sheet contained in the Healthcare Record

It is documented by Midwife M1 that Mrs Conroy was 1cm at 14:00 hours.

14:00 hours – Midwife M1 Entry in Healthcare Record Continuation Notes

- Distressed

⁶² A good liquor volume is a reassuring sign that the fetus has not been subjected to chronic hypoxia in the antenatal period. If no liquor is seen in labour, this can pose a serious risk to the wellbeing of the fetus and the safe assumption must be that there is oligohydramnios/anhydramnios i.e. a reduction or absence of liquor.

⁶³ Epidural analgesia is a central nerve blockade technique, which involves the injection of a local anaesthetic, with or without an opioid into the lower region of the spine close to the nerves that transmit painful stimuli from the contracting uterus and birth canal
(Reference: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009234.pub2/pdf>).

⁶⁴ The pushing stage of labour occurs after the cervix is completely dilated and no longer in front of the baby's head (Reference: http://www.babies.sutterhealth.org/laboranddelivery/labor/ld_push.html).

- Vaginal Examination: Cervix very posterior 1cm dilated.
- Vertex presentation mid cavity.
- No membranes felt.
- Fetal Heart Heard (FHH) 142 beats per minute.
- Consultant Obstetrician and Gynaecologist A informed and suggested epidural.
- Refused by patient.
- May have cyclimorph 10mgs. Same given at 14:20 hours.

During the feedback process Mr and Mrs Conroy outlined that;

'Consultant Obstetrician and Gynaecologist A claims to have handed over care to Consultant Obstetrician and Gynaecologist B, and why did he not state for Consultant Obstetrician and Gynaecologist B that I was a high risk patient, was in pain, and was having contractions with no sign of delivery since 11.30 that morning.

This is a totally unacceptable communication method, and how would the other consultant read the note on the white board if she was in clinic.

Consultant Obstetrician and Gynaecologist A was in the hospital and was aware of my situation, he induced me and knew I was a high risk and still walked out and abandoned me and my unborn child.

Consultant Obstetrician and Gynaecologist A knew he was going to a funeral prior to inducing me, so why did he not tell me'.

14:00 Hours

At interview Midwife M2 stated that;

'Mrs Conroy was very stressed, her cervix started to dilate, vertex coming down, she was 1 cm dilated at 2pm. The Fetal Heart Beat was 162 and Consultant Obstetrician and Gynaecologist A was called and suggested an epidural. This was refused by the patient'.

There is a variance in opinion in relation to how far Mrs Conroy was dilated by 14:00 hours. Mrs Conroy outlined during the feedback process that Midwife M1 informed Mrs Conroy at approximately 14:00 hours that she was 4cm dilated on examination, however Midwife M1 documented that Mrs Conroy was only 1cm dilated in the healthcare record.

Dr Gardeil is of the opinion that Mrs Conroy was most likely 4 cm dilated at this time and was progressing rapidly.

According to Dr. Gardeil and the Investigation Team this was another missed opportunity for Consultant Obstetrician and Gynaecologist A to communicate with Consultant Obstetrician and Gynaecologist B to inform her of the Mrs Conroy's current status.

Midwife M1 during the interview process and feedback process was unable to account for this variance.

The investigation notes that Baby Róisín's head was still mid cavity when Mrs Conroy's cervix was noted to be 1 cm dilated so one would expect that there would be liquor draining if it was there to drain unless it was blocked with thick meconium which was not draining.

According to Dr. Gardeil and Ms Hughes the fact that there was no liquor would be a sign to be wary of, clear liquor is a reassuring sign whereas meconium stained liquor may be an incidental finding in a well-baby or may be a sign that the baby is unwell and needs to be delivered.

In either case, meconium stained liquor or no liquor may give rise to the need for further tests in the event of suspected or actual fetal distress.

Where there is no liquor, you do not have the reassurance of clear liquor and one must be extra vigilant to the wellbeing of the baby in utero.

14:00 Hours - Recording of Contractions on the Operation Sheet

The contractions are shaded in block fashion and as there is no key code to determine what this shading means, it is not possible to decipher information from this.

14:14 hours

The CTG machine was attached to Mrs Conroy five hours post prostin gel insertion.

Note: CTG (cardiotocograph) is a technical means of externally recording a baby's heartbeat (cardio) and uterine contractions (toco) during pregnancy and labour.

The equipment used to monitor the baby's heart is placed on the tummy (abdomen) of the mother.

- An elastic belt is placed around the mother's abdomen.
- It has two round plates about the size of a tennis ball which make contact with the skin.
- One of these plates measures the baby's heart rate.
- The other assesses the pressure on the tummy.
- In this way it is able to show when each contraction happens and an estimate of how strong it is.
- The midwife may put some jelly on the skin to help get a strong signal.
- The CTG belt is connected to a machine which interprets the signal coming from the plates.
- The baby's heart rate can be heard as a beating or pulsing sound which the machine produces.
- The CTG machine also provides a printout which shows the baby's heart rate over a certain length of time.
- It also shows how the heart rate changes with contractions.

When Mrs Conroy was attached to the CTG machine the contraction belt was not applied therefore there was no electronic monitoring of contractions.

For that reason the CTG trace from 14:14 hours until 16:32 hours cannot be considered a complete CTG trace however it is a continuous fetal heart rate trace.

Even in the absence of a policy, it was/is common practice that a baby in-utero would be monitored with a CTG for a minimum of 20 minutes to assess fetal wellbeing at this point as Mrs Conroy;

- had been induced for post maturity,
- had diminished liquor as recorded at 09.00 hrs,
- had had 2 doses of Cyclimorph,
- there were no membranes felt and
- there was no liquor draining and

- she had made what would have been considered to be rapid progress in the first stage of labour for a woman in her first pregnancy.

Figure 1 - Sample of a complete CTG Trace: Top line shows the intrapartum fetal heart rate: Bottom line shows contractions.

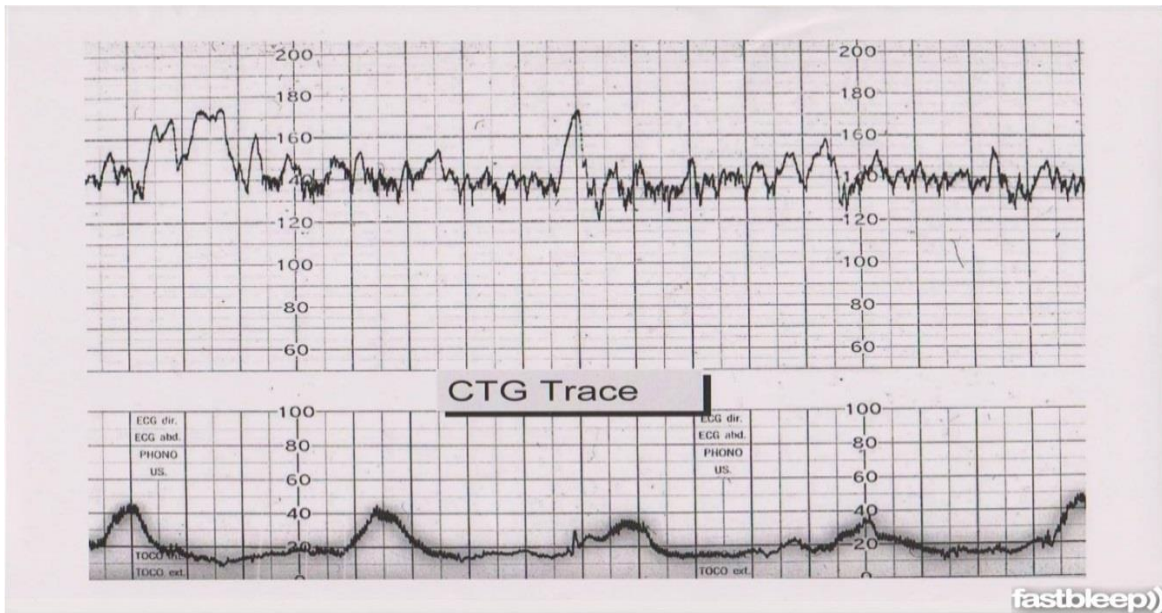
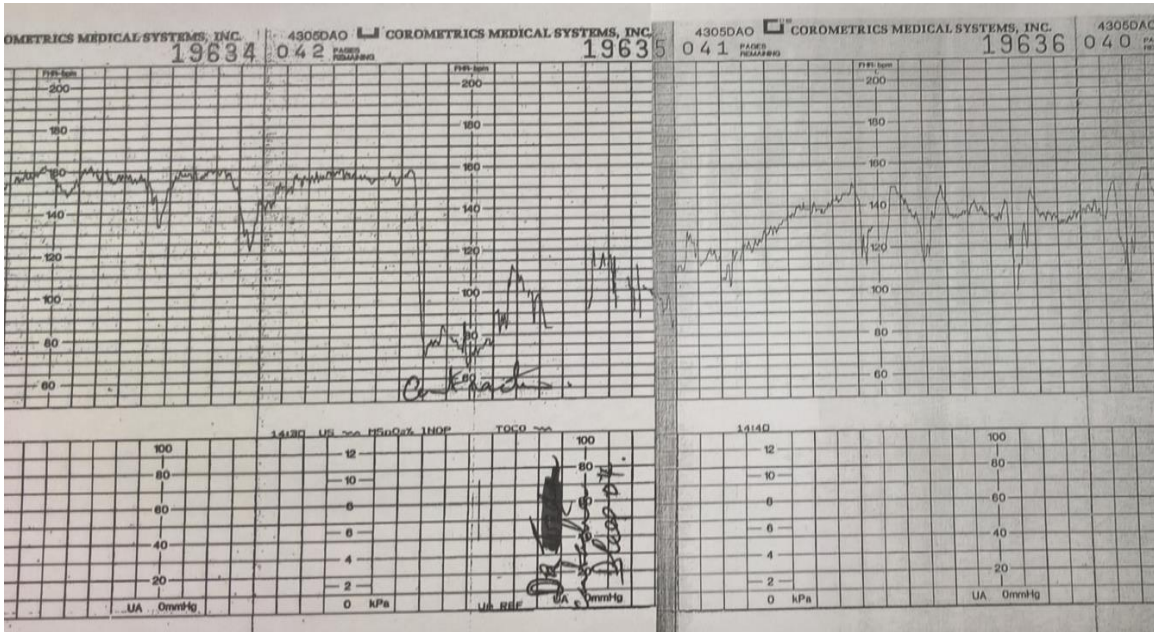


Figure 2 - Mrs Conroy's CTG Trace: Top line shows the intrapartum fetal heart rate: The bottom line as the tocograph was not attached to record contractions.



Dr. Francois Gardiel stated in his report that the absence of a tocograph on Mrs Conroy's CTG trace makes the interpretation of the fetal heart tracing more challenging.

According to the entries made by Midwife M1 in the healthcare record and the time on the intrapartum cardiac trace, intra-partum continuous fetal heart monitoring commenced at approximately 14:14 hours.

At interview Midwives M2, M8, M3 confirmed that in 2001 that when a mother was connected to the CTG⁶⁵ machine both the cardiac tracing and tocograph was commenced.

At interview when Midwife M1 was asked why she didn't use the tocograph, Midwife M1 stated that she didn't use the tocograph as it was problematic in general.

During the feedback process Consultant Obstetrician and Gynaecologist Consultant A and B stated that there were '*difficulties*' experienced with the use of the tocograph so that its application was frequently '*abandoned*'.

The Investigation Team consider that it is not appropriate to abandon the appropriate use of any medical equipment where staff would disconnect them to reduce the effects caused by the overload of noise on the team or the patient as a result of poor positioning or for other reasons.

Furthermore, alarms and/or tracings are a critical issue in the context of deviating from appropriate use, especially when they are disconnected and a complication is undetected. Any deviation to recommended practice only places mother and baby in a position of unnecessary risk.

The Investigation Team considers that while the deviation from the user manual was intentional, staff did not appear to do so with the intention to cause harm.

14:20 hours – Midwife M1 Entry in Healthcare Record Continuation Notes

Midwife M1 documented in the healthcare record that cyclimorph 10mgs was given at 14:20 hours to Mrs Conroy.

No Time

Mrs Conroy recalled at interview that she was given entonox for pain which she considered to be beneficial.

14:30 Hours – Midwife M1 Special Instruction Sheet contained in the Healthcare Record

It is documented by Midwife M1 that Mrs Conroy was 6cm at 14:30 hours.

This entry suggests that Mrs Conroy went from 1cm to 6cm in less than 30 minutes.

Dr. Gardeil stated for the investigation that Mrs Conroy was in established labour prior to 14:00 hours prior to Consultant Obstetrician and Gynaecologist A leaving Hospital S1.

14:32 Hours

The Investigation Team note at 14.32 hours the intrapartum cardiac trace became grossly pathological; there was a prolonged bradycardia of 70 beats per minute lasting 7 minutes which is deeply concerning and warranted review by a Doctor.

⁶⁵ The CTG (cardiotocograph) is a technical means of recording a baby's heartbeat (cardio) and uterine contractions (toco) during pregnancy and labour. The contractions were not electronically monitored during Mrs Conroy's labour therefore making it difficult to interpret the CTG in the context of considering decelerations and contractions simultaneously.

14:35 Hours approximately–Note on the CTG trace by Midwife M1

Documented on the CTG trace under the time 14:35 hours is a note stating Consultant Obstetrician and Gynaecologist B was contacted on 'Bleep 04'.

Midwife M1 confirmed at interview that this was her handwriting and she did recall writing this note on Baby Róisín's intrapartum cardiac trace.

Midwife M1 did not record this attempt to contact Consultant Obstetrician and Gynaecologist B in the healthcare record or the nature of her concerns.

At interview Midwife M1 stated that looking back now she should have documented her concerns.

Midwife M1 stated that she acknowledged at the time the intrapartum cardiac trace was 'very poor', and was less concerned about the documentation and more concerned about 'looking after' mum and Baby Róisín.

With the benefit of hindsight Midwife M1 stated that if she was faced with the same situation again she would respond differently and make further attempts to contact a Doctor.

Midwife M1 outlined at interview that there was no policy with regard to carrying out a CTG prior to the administration of prostin gel.

Family outlined that at no point do they recall anyone writing on the intrapartum trace printout which was at the time printing off continuously from the CTG machine directly beside Mrs Conroy and her husband.

The Investigation Team note that there is no entry in the healthcare record referring to;

- an abnormal CTG at this time, or
- Midwife M1's concerns regarding the CTG, or that;
- Consultant Obstetrician and Gynaecologist B was informed of Midwife M1's concerns.

Midwife M1 recalled while reviewing the healthcare records during the interview that, at 14:35 hours she left the labour ward to bleep Consultant Obstetrician and Gynaecologist B who was covering for Consultant Obstetrician and Gynaecologist A. Midwife M1 stated at interview that this is how she contacted Consultant Obstetrician and Gynaecologist B.

Midwife M1 stated that Consultant Obstetrician and Gynaecologist A was 'gone away' and Consultant Obstetrician and Gynaecologist B was 'doing duty'.

In addition Midwife M1 recalled that she was also not happy with the absence of liquor during labour.

During the interview process Midwife M1 stated she could remember Consultant Obstetrician and Gynaecologist B coming to the labour ward shortly after being contacted.

Midwife M1 outlined at interview that;

'I know that Consultant Obstetrician and Gynaecologist B came and I can see her standing at the window in the delivery room and she didn't do anything.'

Consultant Obstetrician and Gynaecologist B is a very relaxed type of person and does not get excited as I might.

She definitely came in and I was waiting for a long time for her, I was concerned'.

Midwife M1 also stated at interview that;

'I can read this and the documentation is very poor, at the time you were more concerned with the woman and baby than with documentation. There were many occasions where there was a poor trace and the baby was still ok. I thought Baby Róisín would be ok. It would have been better for me if I had documented what happened.'

Mrs Conroy and her husband outlined that Consultant Obstetrician and Gynaecologist B did not attend until after Baby Róisín was born and that was just to suture Mrs Conroy.

During the feedback process Consultant Obstetrician and Gynaecologist Consultant B stated that;

'Midwife M1's mental image of Consultant Obstetrician and Gynaecologist Consultant B 'standing next to the window in the labour ward and she didn't do anything', Midwife M1 would undoubtedly have seen me many nights standing by the window waiting watchfully (rather than "doing nothing").

But perhaps Midwife M1 did not see me on this occasion as Mrs Conroy and her husband's commentary outlined that Consultant Obstetrician and Gynaecologist Consultant B did not attend until after Baby Róisín was born and that was just to suture'.

During the interview process Mrs and Mr Conroy stated that Consultant Obstetrician and Gynaecologist Consultant A was due to be present for the delivery of Baby Róisín and not Consultant Obstetrician and Gynaecologist B.

Mrs and Mr Conroy stated at interview that Consultant Obstetrician and Gynaecologist B did not review Mrs Conroy prior to the delivery of Baby Róisín, nor were they aware that a Doctor had been called at 14:32 hours approximately due to concerns.

Consultant Obstetrician and Gynaecologist B did not recall the events relating to the 14th November 2001 and outlined at interview that it was her practice to have gone to the labour ward when requested to do so by a senior midwife and to make a note in the chart when she reviewed a woman in labour;

Consultant Obstetrician and Gynaecologist B outlined at interview;

'It was my practice to write in the chart whenever I met a patient'.

Consultant Obstetrician and Gynaecologist B also outlined that if she did not respond to a bleep she would have expected to be contacted again.

At interview Consultant Obstetrician and Gynaecologist A when reviewing the CTG trace agreed that the continuous fetal heart rate recorded was not reassuring and at 2 cm and Mrs Conroy should have had a c-section⁶⁶. Dr. Gardeil stated that had Consultant Obstetrician and Gynaecologist A reviewed Mrs Conroy prior to his departure the decision to carry out a c-section may have been made at that point.

It is the opinion of Dr. Gardeil that Mrs Conroy should have had a c-section at or before 15:30 hours.

Consultant Obstetrician and Gynaecologist B stated at interview that there was no formal process for handover and she did not recall whether Consultant Obstetrician and Gynaecologist A handed over the care of Mrs Conroy or not.

⁶⁶Caesarean section: an operation by which a fetus is taken from the uterus by cutting through the walls of the abdomen and uterus. (Reference: <http://www.thefreedictionary.com/C-section>). The Investigation Team were informed that there was no written policy at the time for fetal distress.

There is no documented evidence to suggest that Consultant Obstetrician and Gynaecologist A handed over care to Consultant Obstetrician and Gynaecologist B.

At interview Midwives M2, M3, M4, M5, M6, M7, M8 all outlined that Consultant Obstetrician and Gynaecologist B would always come to the labour ward if contacted by a midwife.

Dr Gardeil considers that the fetal heart trace showed significant decelerations throughout from approximately 14:20 hours onwards showing clear signs of fetal compromise.

The Investigation Team were informed that there was no written policy at the time for fetal distress.

During the feedback process Consultant Obstetrician and Gynaecologist A stated that unfortunately the tracing showing abnormal signs was not detected and acted upon with the subsequent result that Baby Róisín was delivered in poor condition. Consultant Obstetrician and Gynaecologist A specified that;

'in the chart and nursing notes there is nothing written either by myself or the nurses with regard to conversations and meetings I had with the parents'.

From a midwifery perspective Ms Hughes stated in her report that from the commencement of the cardio only recording at about 14:14 hours and even in the absence of the tocograph recording, the trace showed worrying features. The fetal heart rate appeared to recover from a level of about 90 bpm and accelerated to about 130 bpm.

Within one minute, it dropped again over 30 seconds in a V shape to about 95 bpm recovering over a 60 second period to about 130 bpm. So, there were aspects of bradycardia with delayed recovery whether they coincided with contractions or not. The fetal heart rate continued to escalate over the next two minutes to a level of about 160 bpm.

The fetal heart rate then fell sharply again to about 115 bpm over a period of about 30 seconds. It rose again gradually over three minutes to a baseline of about 155 bpm but continued to decelerate in a V shape every 2-3 minutes by about 20 to 25 bpm from the baseline.

About 18-19 minutes after the commencement of this CTG, there appears to be a very sudden (within a 15 second interval) drop in the fetal heart rate from a baseline of 155 to about 70 bpm. It remains below 100 for at least 2 minutes. There is a handwritten entry stating "contraction" which appears to coincide with this bradycardia.

At interview Consultant Obstetrician and Gynaecologist A reviewed the CTG trace again and outlined that the CTG was not reassuring and there was reduced liquor.

During the feedback process Mr and Mrs Conroy stated the following day on the morning of the 15th November 2001 Consultant Obstetrician and Gynaecologist A informed them that the CTG was 'perfect'.

14:40 Hours

Mrs Conroy recalled at interview that she thought everything '*was plain sailing now*'. Mrs Conroy stated that she was offered an epidural on two occasions however she declined because she wanted to be able to push properly.

14:45 Hours

An assessment at 14:45 hours by Midwife M1 noted strong contractions and the cervix was 6cms dilated. Labour was progressing rapidly.

Dr. Gardeil stated that this CTG was characterised by a baseline rate of approximately 130/140 with slightly reduced variability and decelerations characterised by 'shouldering'⁶⁷.

This C.T.G. was not reassuring.

14: 45 hours – Midwife M1 Entry in Healthcare record

- Contractions 1:2 strong
- Vaginal Examination Cervix 6cm dilated.
- Vertex presentation mid cavity
- No membranes felt or liquor seen.

The Investigation Team consider that the frequency of contractions which was recorded at this point as being 1:2 and strong suggests that Mrs Conroy was in well-established labour.

The investigation notes that there is no reference to the fetal heart rate after this vaginal examination.

14:45 hours until 16:32 hours

The Investigation Team note that there is no contemporaneous entries in the healthcare records from 14:45 hours until after the delivery which occurred by spontaneous vertex delivery at 16:32 hours.

There is also no evidence from the healthcare records and through the interview process to suggest that Mrs Conroy was seen by a Consultant Obstetrician after Consultant Obstetrician and Gynaecologist A inserted the Prostin Gel at 9:15 hours until Baby Róisín was delivered at 16:32 hours.

15:00 to 16:00 Hours - Recording of Contractions on the Sheet titled 'Operation Notes' contained within the Healthcare record

The contractions are shaded in block fashion and as there is no key code to determine what this shading means, it is not possible to decipher information from this.

It would appear that Mrs Conroy was having 4 contractions every 10 minutes but this cannot be confirmed and this block shading is identical to the 14:00 hours recording of Mrs Conroy's contractions.

One would expect the frequency to escalate as labour progressed from 14:00 hours not remain the same.

15:10 Hours - Midwife Entry in Special Instruction Sheet

It is recorded on the summary page that the second stage of labour began at 15:10 hours; it is not clear who made this entry.

15:10 Hours Approximately– Midwife M1 Special Instruction Sheet contained in the Healthcare Record

It is documented by Midwife M1 that Mrs Conroy was 6cm at 15:10 hours.

It is also documented by Midwife M1 that Mrs Conroy was fully dilated by 15:10 hours.

⁶⁷ An acceleration before and after the deceleration called "shouldering" denotes a healthy fetus. Progression to tachycardia, reduced variability, loss or exaggerated "shouldering", late recovery, biphasic deceleration denotes pathological changes.

16:00 Hours

The Investigation Team note that the baseline fetal heart rate was approximately 150 and there were associated decelerations on the background of slightly reduced variability. The CTG during the course of the labour was abnormal from the beginning suggesting fetal compromise.

Based on Midwives M1, M8 and M10 entries in the healthcare records there appears to be excessive uterine action which was not recorded using the tocograph.

Dr. Gardeil considers that this is an occasional side effect seen in the administration of Prostaglandin, as it was only following the initial administration of prostin gel that there was an onset of uterine contractions and diagnosis of labour it is clear that Baby Róisín was showing signs of compromise.

There is no record of Mrs Conroy being asked to push⁶⁸ prior to the delivery of Baby Róisín.

Ms Hughes states in her report that the partogram is blank for maternal BP, pulse and temperature for the two and a half hours duration of labour that it appears to have been used for and there is no record of any urinary output.

Standard Midwifery practice would have involved a minimum of quarterly Fetal heart rate recordings during labour, one hourly maternal pulse in early labour moving to half hourly maternal pulse during active labour, initial 2-4-hour BP recordings unless there was concern requiring more frequent monitoring and then moving to hourly BP recordings in active labour. Fluid intake and urinary output was expected to be recorded throughout labour.

Without commentary relating to the actual reality of the cardio recording, or any of the related care including the psychosocial aspects of care, the partogram gives an incomplete and ambiguous picture of how either Mrs Conroy or her baby in utero was coping with labour.

In addition cervical dilatation is plotted on three occasions at 14:00 hours, 14:30 hours and 15:10 hours. There is no narrative to explain how the 15:10 hours finding was established, i.e., whether by external signs and urge to push with a visible vertex or whether by a further vaginal examination.

"No Liquor" is noted to be written in a horizontal fashion across the duration of time from 14.00-16.00 hours which suggests a retrospective entry rather than a contemporaneous record.

Approximately 16:30 Hours

At interview Midwife M2 stated that she recalled Mrs Conroy progressing very quickly and stated that she recalled Midwife M1 rang the call bell when Mrs Conroy was pushing. Midwife M2 stated she was on the corridor at the time and responded and was there to take Baby Róisín.

Midwife M2 stated at interview that Consultant Obstetrician and Gynaecologist B was present when Baby Róisín was delivered, this was normal practice, and stated that the doctors normally responded when called to the labour ward.

Midwife M2 recalled at interview that the call bell for Mrs Conroy's bed in the labour ward was pressed and she responded and attended the delivery of baby Róisín.

⁶⁸ The pushing stage of labour occurs after the cervix is completely dilated and no longer in front of the baby's head (Reference: http://www.babies.sutterhealth.org/laboranddelivery/labor/ld_push.html).

Midwife M2 recalled Consultant Obstetrician and Gynaecologist B attending the delivery of Baby Róisín and suturing Mrs Conroy's episiotomy post-delivery.

16:32 Hours - Midwife Entry in Special Instruction Sheet

It is recorded on the summary page that the third stage of labour began at 16:32 hours and that it was complete by 16:45 hours. It is not clear who made this entry.

As outlined in Mrs Conroy's healthcare record it is calculated that Labour was of a 7 ½ hour duration if one is to take the onset of labour as 09:15 hours.

It is a concern that the midwife documented that Mrs Conroy was in established labour from 09:15 hours. This is not a correct entry. It is not clear whether that was a prospective or retrospective judgement.

In either case the care recorded as being provided and the quality of record keeping is seriously below the standard of care and record-keeping required for a woman in the first, second, and third stages of labour as previously outlined.

Approximately 16:32 Hours – Midwife Entry in the sheet titled 'Operation Notes' for Second Stage (Normal delivery)

- Position and presentation at time of delivery
- Cord around neck: ticked yes and tightly x 2
- No liquor seen until after crowning of baby's head, same appeared old brown meconium.

Mrs Conroy recalled at interview that Consultant Obstetrician and Gynaecologist B was present when Baby Róisín *'was crowning and pulled out'*.

Mrs Conroy recalled Midwife M1 stating *'you have a little black beauty'*.

Midwife M2 recalled at interview that it was routine for a Consultant Obstetrician and Gynaecologist to be called for a delivery of a private patient.

At interview Midwife M2 stated that;

'it was a fast delivery , the cord was tightly around the baby's neck. No liquor seen until after the delivery with old stained meconium, Baby Róisín was born flat, apgar score⁶⁹ 1, Consultant Obstetrician and Gynaecologist B called the other Doctors (Medical Team for Resuscitation) or asked Midwife M1 to call the team, I cannot remember clearly. I can't recall how long Consultant Obstetrician and Gynaecologist B was there but she was present for the delivery when I arrived'.

16:32 Hours

The Investigation Team noted that there is no Reference in the healthcare records or evidence through the interview process that Mrs Conroy had her membranes ruptured artificially⁷⁰. Based on the available evidence it appears to be a very dry labour with meconium⁷¹.

⁶⁹ APGAR is a quick test performed on a baby at 1 and 5 minutes after birth. The 1 minute score determines how well the baby tolerated the birthing process. The 5-minute score tells the doctor how well the baby is doing outside the mother's womb. The APGAR test will examine the baby's: breathing effort, heart rate, muscle tone, reflexes, skin colour

(Reference: <http://www.nlm.nih.gov/medlineplus/ency/article/003402.htm>).

⁷⁰ An artificial rupture of the fetal membranes, usually performed to stimulate or accelerate the onset of labour (Reference: <http://medical-dictionary.thefreedictionary.com/amniotomy>).

⁷¹ 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

16:32 Hours

Mrs Conroy and her husband recalled at interview that they did not see a doctor until after Baby Róisín was delivered. At which point Mr Conroy recalled at interview that Consultant Obstetrician and Gynaecologist B walked in to stitch Mrs Conroy's episiotomy.

Mr Conroy recalled Baby Róisín was blue and not crying. Mrs Conroy asked her husband to go and check on her. Mr Conroy stated that he asked Consultant Obstetrician and Gynaecologist B how the Baby was and she told Mr Conroy;

'I'm here to look after mother'.

Mr Conroy recalled at interview that he went out to the resusitaire to check on Baby Róisín.

Baby Róisín weighted 3.55kgs and had Apgar scores of 1 at 1 minute, 4 at 5 minutes, and 8 at 10 minutes.

It would appear from the labour summary note that Consultant Obstetrician and Gynaecologist B was present at delivery although there is no note by Consultant Obstetrician and Gynaecologist B apart from a note regarding perinaeal repair of an episiotomy.

At interview Midwife M2 stated that she recalled;

'I carried the Baby to the resusitaire⁷², which was not in the labour ward at the time, it was across the corridor. The medical team took over to try and resuscitate the Baby.

I can remember clearly it was very distressing for everybody, I knew the mother from antenatal classes. Staff were very concerned for baby Róisín, the parents were very upset'.

Labour Summary Sheet in Healthcare Records

Contained within the healthcare records was a Labour Summary Sheet containing the following information:

Third Stage – This Section was completed by Midwife M1

Under Method of Delivery of Placenta it is documented that:

- **Controlled cord traction** is ticked as yes
- **Blood Loss estimated** is documented as being 200mls
- **Total Loss 0-500mls** is ticked as being the approximate amount.
- **Placenta membranes** it is documented in this section that they *'appear complete'*.

Remarks included by the midwife stated that; *'Placenta and cord were meconium stained'*.

The Investigation Team consider that such staining is usually indicative of the presence of meconium over a longer period.

Drugs Used – Syntometrine⁷³ I.M. (the actual dose/volume is not recorded)

presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so (Reference: <http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf>).

⁷² A resusitaire 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/).

Stage Given Ant. Shoulder

Blood taken – No is ticked

Perineal Repair

Type: Episiotomy ticked'

Suture material used: it is documented that Vicryl Rapide (Suture material)

Number for removal: 'None'

Under Inserted by:

This section was signed by Consultant Obstetrician and Gynaecologist B

Table 1: Duration of labour Summary

Stages of labour ⁷⁴	Time	Date	Duration of labour	
			Hours	Minutes
First stage began	14:00	14 th Nov. 2001	2	32
Second stage began	15:10	14 th Nov. 2001	1	22
Third stage began	16:32	14 th Nov. 2001		13
Third stage ended	16:45	14 th Nov. 2001	7	30

The Investigation Team note that the above times in relation to the stages of labour are inaccurate and misleading. It appears that the entire labour was calculated as 7 hours 30 minutes. This has serious implications in that Mrs Conroy was not monitored during this time.

It is documented in the healthcare record by Midwife M1 that Baby Róisín was delivered by Midwife M1. It is also documented on the Labour Summary Sheet by Midwife M1 that:

Present at the Time

- Midwife M2
- Consultant Obstetrician and Gynaecologist B
- Student Nurse AB

The blood pressure recorded by Midwife M1 is documented as BP 120/78

During the feedback process Consultant Obstetrician and Gynaecologist Consultant B stated that;

'it was usual practice to append the name of the doctor who sutured with the names of those present at the moment of birth'.

A Stamp on Labour Summary Sheet contains the following details

- Sex: Girl circled
- Weight 3.55kgs
- Apgar score 1 at 1minute 4 at 5 minutes 8 at 10 minutes
- Remarks query Meconium Aspiration

⁷³ Syntometrine is indicated in the active management of the third stage of labour (as a means to promote separation of the placenta and to reduce blood loss) or, routinely, following the birth of the placenta, to prevent or treat postpartum haemorrhage in those patients who have not recently received a pressor agent.

⁷⁴ 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: <http://www.umm.edu/pregnancy/000126.htm#ixzz1x0x7XMI5>).

Special Instructions Section of Antenatal record

- Blood Group Rh Positive

Fetal Heart Rate (HR) contained in the Labour Summary Form (Completed by a Midwife)

- **At 14:00 hours – 140** (If this recording is based on the CTG trace this is not correct. The CTG was not commenced until 14:14 hours and there is no evidence that the heart rate was checked manually.)
- **At 14:30 hours – 125** (The investigation cannot confirm where this reading came from as it does not accurately reflect the HR on the CTG at 14:30 hours)
- **At 15:00 Hours – 119** (It is extremely difficult to establish whether this HR is accurate as the CTG became increasingly more difficult to read after 14:32 hours)
- **At 15:30 Hours – 130** (It is extremely difficult to establish whether this HR is accurate as the CTG became increasingly more difficult to read after 14:32 hours)
- **At 16:00 Hours – 138** (It is extremely difficult to establish whether this HR is accurate as the CTG became increasingly more difficult to read after 14:32 hours)
- **At 16:30 Hours – 145** (It is uncertain how this HR was captured as the CTG does not capture this HR)

Following an examination of the CTG tracing the Investigation Team note that the documented fetal heart rate above in the summary form does not reflect the episodes where Baby Róisín's heart rate dropped significantly during labour which is of significant concern.

Nor does the author of the summary sheet take into consideration the fact that a doctor was apparently contacted as a result of a prolonged deceleration.

Again these entries are grossly misleading.

The Investigation Team consider that if there was concern why these bradycardia events not recorded on the fetal heart rate chart along with the above.

Dr. Gardeil considers that it is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed.

Fetal heart rate became pathological at 14:32 hours with a prolonged bradycardia⁷⁵ down to a heart rate of 70 beats per minute that lasted for 7 minutes.

After this episode, and until delivery of Baby Róisín at 16:32 hours the fetal heart rate showed persistent abnormalities.

There were recurrent decelerations, probably of the variable type but the absence of recording of the uterine contractions makes analysis very difficult.

Dr. Gardeil considers that this should have been documented under the above **Fetal Heart Rate** contained in the Healthcare record in order to correctly highlight the abnormalities evident during Mrs Conroy's labour and set out what actions were taken and why.

During the feedback process Mrs Conroy and her husband outlined that the fetal heart rates documented above were very selective.

Mrs Conroy and her husband outlined their concern in relation to the poor quality of documentation in the healthcare record which does not highlight the very obvious distress that Baby Róisín was experiencing during labour.

⁷⁵ 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>)

The Investigation Team have no reason to dispute the family's recollections.

It is also documented in the Labour Summary Form

Liquor – no liquor

Fully Dilated 15:10 hours

Spontaneous Vaginal Delivery 16:32 hours

Drugs (Including Epidural) and Maternal Posture

- Entonox⁷⁶ 14.20 hours
- Cyclimorph⁷⁷ 10mg

Labour Summary Sheet - continued contains the following details:

Third Stage labour Summary

Under **Method of Delivery of Placenta** was by controlled cord traction

Under **Blood loss** the estimated volume was documented as 200mls

Under **Total loss** 0-500 ml is ticked as the appropriate amount.

Under **Placenta** it is documented that the placenta appeared complete

In the **Remarks** section it is documented that Placenta and cord were meconium stained.

Drugs used

- Syntometrine no dose provided however Intramuscular (IM) as a route is ticked
- Stage given anterior shoulder
- Blood taken No ticked
- Perineal Repair

Type: Episiotomy ticked

Table 2: Summary of Medication

Date	Time	Drug	Given By
14 th Nov. 2001	12.45 Hours	Cyclimorph 10mgs	Midwife
14 th Nov. 2001	14:20 Hours	Entonox	Midwife
14 th Nov. 2001	14:20 Hours	Cyclimorph 10mgs	Midwife

⁷⁶ Entonox is a medicinal gas mixture supplied in cylinders filled to a high pressure. Entonox is used to relieve pain during: • labour in childbirth • wound cleaning, stitching or dressing • acute trauma such as broken bones • other medical conditions or surgical and investigative treatments where pain relief is required.

(Reference: http://www.hpra.ie/img/uploaded/swedocuments/2148290.PA0208_005_001.25f18867-8ce1-4da8-8ec0-6049eaa4c1e7.000001entonox%20PIL.150327.pdf)

⁷⁷ Cyclimorph 10 mg Solution for Injection or Cyclimorph 15 mg Solution for Injection (called Cyclimorph Injection in this leaflet). It contains morphine tartrate which belongs to a group of drugs called opioids. Cyclimorph Injection also contains cyclizine tartrate which is an anti-histamine with activity against feeling sick (nausea) and being sick (vomiting). Cyclimorph Injection is used in adults and children for the relief of moderate to severe pain in which reduction of nausea and vomiting associated with morphine is required.

(Reference: https://www.hpra.ie/img/uploaded/swedocuments/2158231.PA1142_003_001.8a7fdaaf-9934-4f52-af68-e8d06d8c1bb4.000001Product%20Leaflet%20Approved.150325.pdf)

There is no note in the healthcare record from 14:45 hours until after the delivery which occurred by spontaneous vertex delivery at 16:32 hours.

Table 3: Labour Progression

Date	Time	Cervix Dilatation in cm
14 th Nov. 2001	14:00 Hours	1cm
14 th Nov. 2001	14:45 Hours	6cm
14 th Nov. 2001	15:10 Hours	10cm

It is stated in the healthcare record that Mrs Conroy progressed to SVD of live female infant at 16:32 hours. 3rd Stage appeared complete.

Sutured with Vicryl BP 120/78 on ward NPU (Not Passed Urine)

16:32 Hours

Mrs Conroy recalled at interview that Baby Róisín was not crying after she was delivered and that Baby Róisín being taken immediately to a room across the corridor.

Mrs Conroy stated at interview that she asked about Baby Róisín and Consultant Obstetrician and Gynaecologist B responded abruptly by stating;

'I'm looking after you, the nurse is looking after Baby'.

Mrs Conroy recalled at interview that;

'I saw a very slight glimpse of Baby Róisín, she was blue in colour, I asked if she will be brain damaged'.

During the feedback process Consultant Obstetrician and Gynaecologist Consultant B stated;

'I regret that Mrs Conroy recalls that I responded abruptly. Naturally Mrs and Mr Conroy would expect that an older doctor would have some information, however, in this instance, Mrs and Mr Conroy were more aware of the situation than I was'.

Mr Conroy recalled going across the corridor to see Baby Róisín and saw a doctor bagging⁷⁸ Baby Róisín. He recalled 4 staff standing around Baby Róisín resuscitating her.

Baby Róisín's clinical treatment was captured in the Neo-Natal Records from 16:32 Hours

The information below was documented by a Midwife on the **NEO-NATAL RECORD SHEET** of Baby Róisín's healthcare record.

Under the section **Summary of Labour** it is documented by a Midwife:

- Induction of labour: Prostaglandin
- Delivery: Nil ticked
- Liquor: Nil ticked
- Estimated Date of Delivery: 4.11.01
- Type of Feed: Breast Feed
- Mothers Age: 32 years

⁷⁸ Extubation refers to removal of the endotracheal tube (ETT) which was placed in Baby Róisín's airway during resuscitation.

- Parity: 0+0
- Blood Group: A Positive
- Family History: Nil included

The following information is contained in the **NEO-NATAL RECORD SHEET** of Baby Róisín's healthcare record.

Table 4: Baby Róisín Birth Details

NEO-NATAL RECORD SHEET				
Details	BABY 1			
Date of birth	14.11.01			
Time of Birth	16.32hrs			
Sex (Boy/Girl)	GIRL			
Birth Weight (Kg.)	3.55kgs			
Alive/Stillborn	Alive			
If Stillborn				
Maturity by dates	T + 10 days			
Meconium staining of vernix or skin	Not ticked to indicate yes or no			
BLOODS	Coombs Not ticked to indicate yes or no			
APGAR	1 min	2 mins	5 mins	10 mins
1. Heart rate	1	2	2	2
2. Respiratory effort	0	0	1	2
3. Muscle tone	0	0	0	1
4. Reflex irritability	0	0	0	1
5. Colour	0	1	1	2
Total	1	3	4	8
Onset of regular respiration (min)	Not completed			

Table 5: Baby Róisín Birth Details continued

⁷⁹ The information below was documented by NCHD AB on the **NEO-NATAL RECORD SHEET** of Baby Róisín's healthcare record.

NEO-NATAL RECORD SHEET	
Resuscitation ⁸⁰ : Method used, including oxygen and drugs:	<ul style="list-style-type: none"> • Naloxone 400mcg stat @ 3 mins I.M. • Naloxone 400mcg stat @ 10 mins I.M. • CPR soon after birth • Compressions until H.Róisín. increased • Bag and mask until intubated⁸¹ at approx 5 mins (signed by NCHD) • Vitamin K 2mgs I.M. given

⁷⁹ The Neo-natal record sheet contained within Baby Róisín's healthcare record was completed by a Midwife whom the review team were unable to identify as the entries on this sheet were unsigned and by NCHD AB who signed her entry.

⁸⁰ Cardiopulmonary resuscitation involves physical interventions to create artificial circulation through rhythmic pressing on the patient's chest to manually pump blood through the heart, called chest compressions, and usually also involves the rescuer exhaling into the patient (or using a device to simulate this i.e. an ambu bag and oxygen mask) to ventilate the lungs and pass oxygen in to the blood, called artificial respiration.

⁸¹ Endotracheal intubation is the insertion of a tube into the trachea for purposes of anesthesia, airway maintenance, aspiration of secretions, lung ventilation, or prevention of entrance of foreign material into the airway; the tube goes through the nose or mouth (Reference : <http://medicaldictionary.thefreedictionary.com/intubation>) .

16:32 Hours

As indicated in Baby Róisín's⁸² healthcare records, Baby Róisín was severely compromised at birth with a slow heart rate, absent respirations, severe hypotonia, absent reflex response, and poor colour. Based on the available evidence it would appear that Midwife M1 did not expect Baby Róisín to be born in such poor condition, particularly as the paediatric team were not called until after baby Róisín was born.

During the feedback process paediatric NCHD AB outlined that;

At the time I cared for Baby Róisín in November 2001, I had been a paediatric senior house officer since July 2001 at the Hospital S1. This was my first paediatric post. My report is based solely on the clinical records of Baby Róisín made available to me. Given the passage of time I cannot accurately recall the order of events or at what stage post-delivery I arrived apart from the note stating that naloxone was administered by me at 3 minutes. On 14 November 2001 I attended the neonate Baby Róisín.

Baby Róisín was term plus 10 days. Her mother had been induced with prostaglandin and weighed 3.55 kg. She was delivered by normal vaginal delivery.

On the neonatal record I have written a brief note regarding the resuscitation of Baby Róisín. My note states that I administered naloxone 400mcg at 3 minutes and a further naloxone 400mcg at 10 minutes.

Naloxone is a drug administered to the neonate to reverse the respiratory depression which may be caused by the administration of opioid painkillers to the mother during labour.

My note states that compressions were performed on Baby Róisín until heart rate increased and it states that bag and mask was used until Baby Róisín was intubated at approximately 5 minutes. The Apgar scores are recorded but it is not my handwriting. The Baby Róisín's Apgar score at 1 minute is recorded as 1 for heart rate and 0 for all others.

This would indicate that the baby had a heart rate less than 100 requiring cardiac compressions. The score of 0 in the other 4 parameters indicate that Baby Róisín was either blue or pale in colour, there was no response to reflex irritability, there was no respiratory effort and that the baby was limp.

There is a comprehensive note timed at 5.45pm made by the paediatric registrar who intubated Baby Róisín. His note states that he was called after delivery and arrived at approximately 5 minutes of age.

16:37 Hours (approximately)

Baby Róisín intubated after 5 minutes

17:00 Hours

There is an entry by NCHD AB in Baby Róisín's healthcare record regarding resuscitation indicated cardiac compressions and bag and mask for 2 minutes. Then intubated with a size 3.5 ETT. Spontaneous respiration @ 15 mins old. Naloxone 400mcg IM @ 3 mins and again at 17:00 hours.

- Treatment with Phenobarbitone 35.5mgs x 3 does
- IV Dextrose 10% infusion.

⁸² All new born infants are provided with a unique identification number and healthcare record separate to the mothers.

- Chest X-Ray
- Drugs administered today included
- Naloxone 400mg IM x 2 doses, Penobarbitone 35.5 mg x 3 doses.
- IV penicillin and netillin x 1 dose

17:07 Hours (approximately)

Baby Róisín extubated⁸³ after 35 minutes

For the purposes of completeness the Investigation Team requested a review of Baby Róisín's resuscitation in the event that there were any issues that required attention. Dr. John Murphy neonatologist outlined that:

'The resuscitation and management of Baby Róisín after her birth was satisfactory and of good standard. Her care in the SCBU was appropriate. The decision to transfer her to the Hospital S2 was correct'.

17:45 Hours - Paediatric Registrar Healthcare record entry

A medical entry made by the Paediatric Registrar in the healthcare records states:

- 41 +3 delivered by Standard Vaginal Delivery, Weight 3.55kgs
- Problem: low Apgar score
- Meconium Stained liquor with possible Meconium Aspiration
- Mother: 32 years old
- PO +o 9 (No previous pregnancies)
- Blood Group A Rhesus positive
- Received cyclimorph 10mgs x 2 doses @ 12.50 hours and 14.20 hours
- Rubella-immune, HIV (Human immunodeficiency virus - Negative, VDRL – Negative
- Delivery: Standard Vaginal Delivery, Slow, heart beats at birth but CPR (Cardiopulmonary
- Resuscitation) started. Meconium Grade 3 at birth.
- Called after delivery. I arrived at approximately 5 minutes of age.
- Heart Rate less than 100
- Respiration effort very poor
- Intubated size 3.5 Endotracheal Tube (ETT)
- No meconium could be aspirated from ETT.
- Air entry bilateral equal
- Injection of Naloxone 400 mcg given at 3 minutes and 10 minutes of age
- Improved well
- O2 saturation 100% in Room Air
- Extubation at 35 minutes of age
- *Apgar⁸⁴ 1 (1), 3 (2), 4 (5), 8 (10)
- On Examination it is documented that Baby Róisín was
- Generally Stable
- SpO2 100% on Room air
- Respiration Rate 64
- Heart rate 174
- Chest Bilaterally Clear
- CVS (Cardiovascular System) S1 and S2 (i.e. heart sounds heard) and identified as

⁸³ Extubation refers to removal of the endotracheal tube (ETT) which was introduced into Baby Róisín's airway when she was undergoing resuscitation.

⁸⁴ APGAR is a quick test performed on a baby at 1 and 5 minutes after birth. The 1 minute score determines how well the baby tolerated the birthing process. The 5-minute score tells the doctor how well the baby is doing outside the mother's womb. The APGAR test will examine the baby's: breathing effort, heart rate, muscle tone, reflexes, skin colour
(Reference: <http://www.nlm.nih.gov/medlineplus/ency/article/003402.htm>).

- normal
- Abdomen soft and no distension
- Impression: Fetus with poor Apgar score

Plan:

- Full Blood Count, Urea and Electrolytes, Sodium Carbonate, CPK (Creatine phosphokinase), LDH (lactate dehydrogenase)⁸⁵
- Blood for culture and sensitivity, VBG (Venous Blood Gases). Baby's cord blood
- Penicillin + Netillium
- Injection of Sodab carbonate.
- Injection of Phenobarbitone 10mg/Kg I.V. loading dose repeat if seizure develops.
- I.V. fluids: Dextrose 10% 50 ml/kg/d
- Chest X-Ray- no meconium in lung fluids
- Inform Consultant Paediatrician on call
- Discuss with Parents

18:45 Hours - Doctors Entry Neo-natal Healthcare record

- Improving
- In Room Air
- Received Sodab carbonate
- Vital signs normal
- Plan: Repeat Arterial Blood Gases

No Time - Paediatric NCHD Entry Neo-natal Healthcare record

Blood Results - taken at 17:30 hours approximately

- White Blood Cells $26.6 \times 10^9/L$ - Normal range (10.0 – 26.0)
- Neutrophils 11.0 44% - Normal range (3.0 – 14.5)
- Lymphocytes 12.1 45% - Normal range (2.0 – 11.0)
- Haemoglobin 18.0 g/dL - Normal range (16.8 – 21.2)
- Haematocrit 56.2
- PH 7.39
- Sodium 140 mmol/L - Normal range (133-142)
- Potassium 7.43 mmol/L - Normal range (3.4 – 5.3)
- Urea 4.0 mmol/L- Normal range (0 – 5.0)
- Calcium 2.72 mmol/L- Normal range (1.80 – 2.7)
- Creatine phosphokinase (CPK) 281 U/L- Normal range (22 to 198)
- LDH (lactate dehydrogenase) 1281 U/L- Normal range (140 - 280)

Full Blood Count:

- Haemoglobin 18.0
- White Cell Count $26.6 \times 10^9/L$ - Normal range (150 – 400)

22:15 Paediatric NCHD AB Entry Neo-natal Healthcare record

It is documented by the NCHD AB that Baby Róisín was:

⁸⁵ LDH is most often measured to check for tissue damage. LDH is in many body tissues, especially the heart, liver, kidney, muscles, brain, blood cells, and lungs.

'Smacking of lips, Extensor movts (movements) of both upper limbs. Episodes individually of 10 sec duration but come in runs 4-5 together. 2nd dose phenobarbitone given.

D/W (discussed with) Registrar for 2.5mg/kg BD (twice a day) phenobarbitone @ 12 hrs post 1st dose if prolonged seizure or too frequent of episodes consider phenytoin 10mg/kg Diazepam 0.3mg/kg also may be used. If O2 Sats < 95% for head box⁸⁶ O2'.

No Time

During the feedback process the NCHD AB stated;

'I have written in blood results of Baby Róisín a later stage in the notes. There is no time on this entry.

The bloods recorded were a full blood count and electrolytes. I have marked the potassium as elevated. As it is some time since I worked with neonates I cannot recall the normal Reference ranges in this area and cannot comment on the significance.

I was asked by the nursing staff to review Baby Róisín on 14th November 2001 note timed at 10.15 pm.

My note states that there was smacking of the lips and extensor movements of both upper limbs. The episodes were lasting 10 seconds and occurring in 4-5 runs together. Blood glucose is recorded at 4.9.

As this presentation was suggestive of seizures I proceeded to prescribe the second and third dose of phenobarbitone, an antiepileptic drug. Baby Róisín had previously been prescribed a first loading dose of phenobarbitone post resuscitation.

My note states that I discussed with the paediatric registrar and I have documented instructions re administration of phenobarbitone 2.5 mg per kilogram twice daily 12 hours after the loading doses.

I have written that if there was a prolonged seizure or too frequent episodes that phenytoin 10mg per kg or diazepam 0.3mg per kg could also be used.

I have written that if oxygen saturations dropped under 95% that Baby Róisín was to receive head box oxygen.

The prescription sheet for Baby Róisín documents the medications prescribed for Baby Róisín'.

22:15 Hours - Midwife M9 Entry

An entry in the Healthcare record by a Midwife stated that Mrs Conroy was;

'Visiting baby in SCBU (special baby unit) – anxious. Advised to try sleep. Stilnoct 10mgs PO given'.

22:25 Hours – Midwife M9 Entry Neo-natal Healthcare record

It is documented by Midwife M9 that baby Róisín was seen by NCHD AB and that baby Róisín was for repeat phenobarbitone.

⁸⁶ An oxygen hood is used for babies who can breathe on their own but still need extra oxygen. A hood is a plastic dome or box with warm, moist oxygen inside. The hood is placed over the baby's head.

NCHD AB spoke with the Paediatric Registrar regarding Baby Róisín's lip smacking, extensor movements and twitching of upper limbs, episodes of 10 seconds by 4 -5 then rest. If Oxygen saturation drops below 95% baby Róisín is for head box oxygen of around 35%.

Table 6: Summary of Baby Róisín's Cord Blood Gas Test Results

Cord Blood (16.32Hr) Approx.	Baby's VBG (18.10 Hr)	CBG (10.39 Hr)
pH ⁸⁷ 7.08	pH 7.09	pH 7.37
pCO2 7.7 kPa	pCO2 5.45 kPa	pCO2 3.56 kPa
pO2 3.73 kPa	pO2 9.34 kPa	pO2 7.12 kPa
HCO3 16.8 mmol/L	HCO3 12.2 mmol/L	HCO3 15.3 mmol/L
BE – 136 mmol/L	BE 17.0 mmol/L	BE 8.1 mmol/L

23:20 Hours

During the feedback process the NCHD AB stated;

'The nursing notes timed at 23.20 documents on-going limb tremor and they asked the Paediatric Registrar to review'.

23:20 Hours - Midwife M9 Entry Neo-natal Healthcare record

It is documented by Midwife M9 that Baby Róisín continues to have upper limb tremor when she moves her legs. The Paediatric Registrar was informed and was to review Baby Róisín.

23:45 Hours

During the feedback process the NCHD AB stated;

'Baby Róisín was reviewed (note timed at 11.45pm) by the Paediatric Registrar in view of the recurrent seizures'.

23:45 Hours - Paediatric Registrar Entry in Healthcare Record

- Recurrent seizures +
- Vitals – Normal
- Chest – Both sides clear
- CVS (Cardiovascular System) – S1 S2 Normal
- Passed small amount of urine, RBC ++, Proteins p

Plan:

- Discuss with Consultant on call
- Injection Phenobarbitone 10mg/kg
- 3rd dose (total 30mg/kg)
- Transfer to Large Maternity Unit in Dublin Hospital S2
- Cord Blood Gases

⁸⁷ 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>).

23:50 Hours - Midwife M9 Entry Neo-natal Healthcare record

Midwife M9 spoke with the Paediatric NCHD AB and Baby Róisín is to be transferred to a Hospital S2 in Dublin for additional care and treatment. Mr Conroy and the priest were both contacted and a photograph of Baby Róisín taken. Mrs Conroy was asleep and staff were awaiting Mr Conroy's arrival at Hospital S1.

23:50 Hours

Mr Conroy recalled at 23:50 hours he received a call informing him Baby Róisín had a seizure and advised it was best to transfer her to Hospital S2 in Dublin.

No Time

Consultant Obstetrician and Gynaecologist A stated at interview that he returned to hospital S1 later that evening to deliver a primigravida (a woman who is pregnant for the first time);

'When I came back in the evening the baby was in the special care unit. The cord was around the baby's neck, I wanted the placenta to be reviewed in case there was anything else going on'.

The investigation was unable to establish what time Consultant Obstetrician and Gynaecologist A returned to Hospital S1 to deliver another baby as the records show that he was not present for any delivery that evening or night⁸⁸.

Consultant Obstetrician and Gynaecologist A stated at interview that he reviewed the clinical records for Mrs Conroy and found the nursing notes to be poor, and in addition outlined that there was an absence of policies in the department, poor staffing levels, no proper training on CTG's.

The Investigation Team wish to highlight poor staffing levels is not a contributory factor in this case.

No time

During the feedback process Mrs Conroy and her husband stated that Consultant Obstetrician and Gynaecologist A did not visit Mrs Conroy or Baby Róisín.

The family outlined their concern that the above comment from Consultant Obstetrician and Gynaecologist A implies that he met with Mrs Conroy when he returned to hospital S1 later that evening.

If Consultant Obstetrician and Gynaecologist A did review Baby Róisín there is no entry in healthcare record for the evening of the 14th November 2001.

Mr Conroy indicated during the feedback process that following the delivery of Baby Róisín, a family member or relative was present in the SCBU with Baby Róisín continuously and at no point did Consultant Obstetrician and Gynaecologist A come to review Baby Róisín.

During the feedback process Consultant Obstetrician and Gynaecologist A stated that in the evening when he returned he was made aware of how ill Baby Róisín was and the possible need to transfer at that stage.

⁸⁸ The Investigation Team were informed that the Birth Registration Log on the maternity Unit in Hospital S1 for 14th November 2001 contained two Primigravida admissions. The first at 01:36hours and two midwives recorded as being present at this birth, no other person attended. The second Primigravida relates to this investigation and Mrs Conroy who delivered Baby Róisín at 16:32hours (Baby Róisín) and two midwives and student midwife were in attendance. There were no other births recorded that evening, the next birth was recorded @ 00:35hrs on 15/11/2001 with and two midwives were in attendance.

Section 3: Aftermath of Incident

15th November 2001

Baby Róisín developed abnormal neurological signs over the next few hours following delivery. Baby Róisín experienced seizure activity with lip smacking, extensor limb movements, and hand fisting.

The seizures were treated with 3 successive doses of Phenobarbitone (30mgs/Kg).

Baby Róisín's urine contained both Red Blood Cells and protein suggestive of trauma.

At 7 hours old the Paediatricians decided to transfer Baby Róisín to Hospital S2 for further management and investigation.

00:20 Hours – Midwife M9 Entry Neo-natal Healthcare record

It is documented by Midwife M9 on duty that there was a bed available in the Neonatal Intensive Care for Baby Róisín in Hospital S2 located in Dublin. Ambulance transport was contacted and available to leave Hospital S1 at 02:00 hours. Mrs Conroy and her husband spoke with the paediatric Registrar regarding the reasons for transfer.

The Investigation Team note that Baby Róisín required admission to the NICU at Hospital S2 as a result of the on-going seizures.

01:00 Hours - Midwife Entry M9 Neo-natal Healthcare record

It is documented by Midwife M9 on duty that Baby Róisín's vital signs were recorded as follows:

- Temperature 36 Degrees Celsius
- Pulse 105 beats per minute
- Respiration rate 50 breaths per minute
- SpO2 97% on room air

In addition it was documented that Baby Róisín's hands were held like fists and she had upper limb tremors⁸⁹.

01:15 Hours Approximately

During the feedback process Mrs Conroy and her husband outlined that the Priest arrived and Baby Róisín was '*Baptised and given the Last Rites*'.

Transfer Letter by Paediatric Registrar in Hospital S1 to Hospital S2

It is documented by the paediatric Registrar in a transfer letter to Hospital S2 that:

⁸⁹ The Investigation Team consider that this was indicative of Hypoxic Ischemic Encephalopathy (HIE) that is most often the result of a birth injury. Due to lack of oxygen to the brain, it creates a neurological disorder and can be mild to severe. The condition causes children to be unable to always control their muscular actions, and while some cases involve only mild spasms, there are also many that cause the infant to have stiffened muscles. Unfortunately Brain Cooling was unavailable at this time, Cooling the baby's brain or body to reverse brain hypoxia caused by high temperatures.

Baby Róisín was delivered at 16:32 Hours on 14.11.01 by standard vaginal delivery with an Apgar score 1 at 1 min, 4 at 5 minutes 8 at 10mins and Birth weight = 3.55kg. She was meconium stained grade III at birth. Initially resuscitated with bag and mask ventilation, intubated at 5mins of age and extubated at 30 minutes.

Naloxone 400mcg I.M. given twice at 3 minutes and 10 mins of age. Mother is 32 year old, Blood Group A positive, Rubella immune, VDRL Negative and HIV negative. She was given an Injection of Cyclimorph 10 mg at 12.50 Hours and 14.20 Hours (2 Hrs before delivery).

Baby is in room air since 30 minutes of age and breathing spontaneously. Generalized tonic seizures started at 5½ hour of age. Injection of Phenobarbitone 10mg/kg was given at 1 Hour of age and repeated twice more total 30mg/kg). Seizures still persisting. Baby also received Injection Penicillin 50 mg/kg and Injection Netillim 3mg/kg, Injection Sodabarbonate (4.2%) 10ml I.V. and I.V fluids Dextrose 10% at 50ml/kg/day.

Baby Róisín's tests are documented as follows in the Transfer letter from Hospital S1 to S2:

Full Blood Count:

- Haemoglobin 18.0 g/dL - Normal range (16.8 – 21.2)
- White Cell Count $26.6 \times 10^9/L$ - Normal range (10.0 – 26.0)
- Platelets $239 \times 10^9/L$ - Normal range (150 – 400)

Blood results taken at 17.30 approximately

- Serum Sodium 140 mmol/L - Normal range (133-142)
- Serum potassium 7.43mmol/L - Normal range (3.4 – 5.3)
- Urea 4.0 mmol/L- Normal range (0 – 5.0)
- Calcium 2.72mmol/L- Normal range (1.80 – 2.7)
- CPK 281 U/L- Normal range (22 to 198)
- LDH 1281 U/L- Normal range (140 - 280)

Urine Sample Test

- Red Blood cells +++
- Protein 3+

Chest X Ray showed no signs of meconium aspiration.

02:00 Hours – Approximately

During the feedback process the NCHD AB stated;

'Transferred to Hospital S2 in Dublin at 2.00am 15th November 2001'.

02:10 Hours - Midwife Entry Neo-natal Healthcare record

It is documented by a Midwife on duty that Baby Róisín was transferred to Hospital S2 in Dublin.

02:15 Hours – Cord Blood Gases Results Neo-natal Healthcare record Hospital S1

The following information in relation to Baby Róisín's cord blood gases are contained within the healthcare record.

- PH 7.41
- pCO2 4.9 kPa
- pO2 3.9 kPa

- HCO₃ 23.2 mmol/L
- Base Excess - 1.0 mmol/L

02:30 Hours – Midwife Entry in Mrs Conroy's Healthcare Records

It is documented by a Midwife that Mrs Conroy was sleeping.

03:18 Hours - Hospital S2 Inpatient Admission Form

It is electronically recorded on the inpatient admission form that Baby Róisín was admitted to Neonatal Intensive Care Unit (NICU) at hospital S2 at 03:18 hours.

04:30 Hours – Neo-natal NCHD Review at Hospital S2

It is documented by a Neo-natal NCHD in the healthcare records that Baby Róisín was transferred from Hospital S1 with HIE grade 1-2.

It is documented by a Neo-natal NCHD:

Under Background it is documented that;

- Mum is 32 years old
- Para 0+0
- Blood Group A Rhesus positive
- Uncomplicated pregnancy
- Induced post-dates with reduced liquor
- Given cyclimorph 10mgs at 12:50 hours and 14:20 Hours

Baby Róisín had meconium Grade 3 at delivery, cord around neck twice.

On examination Baby Róisín was pink in colour and active. In addition it is documented that Baby Róisín was;

- Hyper alert and irritable
- Increased tone and fisting of upper limbs
- Head extension
- Complete head lag
- Suck ok
- Pupils medium sized reactive
- Good respirations no apnoea

Imp: HIE Sarnat 2
Low apgar and Low cord pH

Plan

- Repeat Urea and electrolytes and Calcium
- Watch Calcium, oxygenation
- Measure urine output
- Urinalysis
- Liver Function Tests, Full Blood Count in the am
- Cerebral Ultrasound Scan am.

06:00 Hours Hospital S1

At interview Mr Conroy outlined that he returned from Dublin and called into hospital S1 at approximately 06:00 hours to check on Mrs Conroy and left some photos which he had taken of Baby Róisín on Mrs Conroy's bed.

09:30 Hours Approximately

At interview Mr Conroy stated that he went to see Mrs Conroy in hospital S1.

During the feedback process Mrs Conroy and her husband outlined that Consultant Obstetrician and Gynaecologist A met with Mrs Conroy on a ward round at approximately 09:30 hours. Mr Conroy recalled walking into Mrs Conroy's room and Consultant Obstetrician and Gynaecologist A was already there talking to Mrs Conroy.

Mrs Conroy and her husband stated at interview that Consultant Obstetrician and Gynaecologist A stood at the end of the bed and had Mrs Conroy's healthcare record in his hand when he talked about Baby Róisín.

During the feedback process on the final draft report the family are of the opinion that Consultant Obstetrician and Gynaecologist A reviewed the CTG before and during the ward round and 'still' told them that the CTG was 'perfect' which they stated was 'untrue'.

Mrs Conroy and her husband recalled Consultant Obstetrician and Gynaecologist A said in a flippant way that he was very surprised to hear that something had happened to Baby Róisín.

At interview Mr Conroy stated that Consultant Obstetrician and Gynaecologist A;

'started the conversation that morning with half a laugh and stated "yeah I was very surprised to hear there had been a problem". His attitude really vexed me and I said from across the room 'surprised' isn't the word I would use. He went on and opened the notes again to explain that the trace was 'perfect'⁹⁰ only a dip at the end when baby was leaving the canal, which you would expect'.

Mrs Conroy and her husband stated Consultant Obstetrician and Gynaecologist A proceeded to go through the birth and said 'nothing could have been done about the outcome'.

It is the opinion of Dr. Gardeil that once the CTG became pathological Mrs Conroy should have had a c-section to minimise and potential harm Baby Róisín.

Dr. Gardeil reiterated for the investigation that it would take an obstetrician approximately 2-3 minutes to establish that this CTG was pathological. Dr. Gardeil also outlined that the CTG which was commenced at 14:14 hours became pathological within minutes; this was immediately evident when Dr. Gardeil reviewed the CTG.

Mrs Conroy and her husband stated that they are 'extremely annoyed and angry' that Consultant Obstetrician and Gynaecologist A at this time stated that; the trace was 'perfect', the cord was wrapped around Baby Róisín's neck twice, there is no way of detecting this, Consultant Obstetrician and Gynaecologist A stated he had to go away the day of the delivery, something came up, and even if he had been there, nothing that could have been done.

Consultant Obstetrician and Gynaecologist A then stated to Mrs Conroy and her husband that 'let's hope it's not too bad'.

During the feedback process Mrs Conroy and her husband outlined that Consultant Obstetrician and Gynaecologist A went on to say that the placenta could be the problem.

⁹⁰ Consultant Obstetrician and Gynaecologist A outlined at interview; *although I met with the parents the following morning I have no recollection of what exact information I gave them at the time. I would not have had the opportunity to do a detailed review of the labour or the tracing and probably relied on the fact that the hypoxia was caused by a tight cord around the neck. I asked the family to bring the placenta to hospital S2 in Dublin.*

Consultant Obstetrician and Gynaecologist A outlined at interview that;

'Although I met the parents the following morning I have no recollection of what exact information I gave them at the time. I would not have had the opportunity to do a detailed review of the labour or the tracings and probably relied on the fact that the anoxia was caused by a tight cord around the neck'. I asked the family to bring the placenta with them to Hospital S2 in Dublin.'

According to Dr. Gardeil, it would take an obstetrician only a few minutes to review a CTG trace and establish whether there was a problem during labour. It was misleading to inform the family that the trace was 'perfect'.

Approximately 09:30 Hours - No Time Hospital S1- Ward round Consultant Obstetrician and Gynaecologist A - Unsigned Entry

The following information was documented by Consultant Obstetrician and Gynaecologist A in Mrs Conroy's healthcare record;

'Hospital S2, Baby has arching + Haematuria, No fits, In room air, Breathing on own, Mother well – going to Hospital S2 to visit baby. Placenta to Hospital S2....'

No Time

Mr Conroy outlined that they received a bill that morning for Consultant Obstetrician and Gynaecologist B attending the delivery.

During the feedback process Consultant Obstetrician and Gynaecologist B stated that this bill was not from her.

Mrs Conroy stated at interview that she felt everyone was avoiding her. Mr Conroy was given the placenta in a bucket to bring to Hospital S2:

'I felt isolated no explanation was given to me, they gave me sleeping pills and I asked them to do their best for Baby Róisín'.

At interview Consultant Obstetrician and Gynaecologist A was asked if he told the family the CTG was normal;

'I don't think so, I don't remember'.

The family stated 'categorically' that Consultant Obstetrician and Gynaecologist A informed them the following day that the CTG was 'perfect'.

No Time

At interview Midwife M3 stated that;

'the following day after Baby Róisín's delivery Consultant Obstetrician and Gynaecologist A came into the midwives office and that the 2 midwives present pleaded with Consultant Obstetrician and Gynaecologist A to tell the family that Baby Róisín was really very sick, was born not breathing, no reflexes, meconium grade 3, very distressed and please be up front with the family.'

I cannot recall Consultant Obstetrician and Gynaecologist A's response. There was no brain cooling at the time. During the feedback process Mrs and Mr Conroy outlined that no one told them anything about their concerns'.

No time

During the feedback process Mrs Conroy and her husband outlined that;

'Midwife M1 came in after the ward-round and said; "well what did the Doctor say" and we told her what Consultant Obstetrician and Gynaecologist A said to us, and she responded by saying "well he is very experienced".

21:00 Hours - Midwife Entry

It is documented by a Midwife in the healthcare record that Mrs Conroy;

'Returned from Hospital S2 very upset regarding baby's status. Night sedative. Slept on and requests to explain what happened to Baby Róisín after breakfast'.

- *2nd Day. Fundus involuting locha normal. Perineum bruised but healing.*
- *Upset ++ re baby. Patient's husband requests Mrs Conroy's discharge.*
- *13:15 Hours Midwife entry*
- *Seen By Consultant Obstetrician and Gynaecologist A who spoke with Mrs Conroy and her Husband. Discharged home'.*

During the feedback process Mrs Conroy and her husband outlined that nothing was explained to them following requests for information.

16th November 2001

11:30 Hours

It is documented in the healthcare record that Baby Róisín had MRI of brain in Hospital S2

A detailed Radiological Report of an MRI Brain carried out on the 16 November 2001 states;

'Sedation was achieved without difficulty with oral Chloral Hydrate. Axial T1 and T2 and sagittal T2 weighted images of the brain were obtained. Diffusion weighted sequence was also obtained.

The ventricles are normal in size and configuration. The brain parenchyma has a normal configuration, without evidence of malformation. The signal intensity throughout the brain, on the standard sequences, is normal. In particular no abnormal signal is seen in the basal ganglia or thalami. There is no evidence of brain swelling or of ischaemia or infarction.

Very discrete areas of very abnormal signal are, however, seen in the lateral aspect of both thalami on the diffusion weighted sequence. Minimal increase in signal in the high parietal peri-Rolandic area is also suspected.

CONCLUSION: Abnormal signal in the diffusion weighted imaging in the thalami is consistent with ischaemia of these areas.

The appearance of these areas and the remainder of the brain is normal on the standard sequences.'

No Time – Ward round Hospital S1 Consultant Obstetrician and Gynaecologist A - Signed Entry

The following information was documented by Consultant Obstetrician and Gynaecologist A in Mrs Conroy's healthcare record;

'Baby in ICU in Hospital S2, Fisting etc. No convulsions on room air. Awaiting MRI + U/S, Parents will go to Hospital S2 today.'

13:15 Hours – Midwife M6 Entry Hospital S1

The following information was documented by Midwife M6;

'Seen By Consultant Obstetrician and Gynaecologist A, who spoke to Mrs Conroy and her husband. Discharged.'

During the feedback process Mrs and Mr Conroy outlined that Consultant Obstetrician and Gynaecologist A told them to do their best for their daughter.

No Time - Entry by a member of the Medical Staff in Baby Róisín's Healthcare record in Hospital S1

- Baby in ICU in Hospital S2
- No convulsions
- On room air and awaiting MRI and Ultrasound scan
- Parents will go to Hospital S2 today.

02: 01 Hours - Entry by a member of the Medical Staff in Baby Róisín's Healthcare record in Hospital S2 regarding a Cranial Ultrasound

An entry in the healthcare record by a staff member at Hospital S2 states;

'Echogenicity thalamus and to a lesser extent lentiform nuclei both sides. Ventricles small – otherwise normal'.

17th November 2001

11:30 Hours – Hospital S2 Doctors Entry

The following information was documented by a Doctor in Baby Róisín's healthcare record;

'Discussed outcome with parents, 50% poor outcome possible motor control'.

18th November 2001

15:55 Hours - Doctors Entry in Healthcare Record Hospital S2

The following information was documented by a Doctor in Baby Róisín's healthcare record that Baby Róisín has on-going abnormal neurology.

21st November 2001

Consultant Obstetrician and Gynaecologist A's letter to Mrs Conroy's GP of 21st November 2001 indicates Baby Róisín developed cerebral ischaemic hypoxia, had a convulsion, and was transferred to Hospital S2 for further care and treatment on the 15th November 2001.

26th November 2001

Baby Róisín was transferred back from Hospital S2 on 26th November 2001. The healthcare records indicate that Baby Róisín remained neurologically abnormal. Her feeding was poor, there were abnormal movements, and head lag.

Her brain MRI was abnormal showing increased echogenicity of the thalami.

No Time

It is documented in Baby Róisín's healthcare record in Hospital S2 by a member of the medical team that this was day 12 of baby Róisín's admission to Hospital S2;

- Baby Róisín was going back to Hospital S1 today.
- HIE Grade II
- Low Apgars following delivery
- Meconium Grade III
- Currently on no medications
- Taking ½ of feeds by teat
- Feeds 160ml/kg
- Heart rate - 140 beats per minute
- Respirations – 40 per minute
- Temperature normal
- CVS (Cardiovascular System) Heart Sounds S1 and S2 normal
- Pulses Normal
- Respirations – Equal air entry into both lungs
- Soft abdomen
- Neurologically there is evidence of increased peripheral tone with fisting of hands and reduced axial tone with head lag
- Abnormal gaze doesn't fix
- Impression: can travel back to Hospital S1
- Plan: to be seen by Consultant Paediatrician in 4 weeks' time and Consultant Paediatric Neurologist when Baby Róisín is 4 years old.

No Time

Baby Róisín returned to Hospital S1. It is documented by a member of the medical team that Baby Róisín continues to have abnormal movements, fisting and some axial hypotonia.

The MRI scan of brain carried out in Hospital S2 showed increased echogenicity of the thalamus and confirmed on cranial ultrasound.

Mrs and Mr Conroy outlined at interview that there was no follow-up or contact with them or no offer of counselling.

'I got an appointment to see Consultant Obstetrician and Gynaecologist A three months later and he asked how was Baby Róisín, he said the trace was perfect from the beginning to end, fluid was low but there was enough, the result on the placenta was inconclusive, PH of the Cord was abnormal. In fact the placenta was perfect. If the truth

had been told at the start we would be in a much better position now, we could have put all the correct supports in place for Baby Róisín. If you have your baby, and mistakes are made, own up, they said there was a problem with the placenta, I felt the blame was put on me. There was a cost to Baby Róisín by not having the supports in place. Nobody seemed to have learned after Baby Róisín'.

Mrs Conroy and her husband outlined during the feedback process;

'that the lack of disclosure of the events surrounding Baby Róisín's delivery further compounded the fact that Baby Róisín did not receive the appropriate care, treatment and therapies in the subsequent years to come. They told us there was nothing that could be done and left us to manage Baby Róisín on our own. Consultant Obstetrician and Gynaecologist A said to us to just "do your best for your daughter and get on with it now".

Tuesday 27th November 2001

It is documented by a member of the medical team that Baby Róisín continues to have evidence of head lag and is taking a mix of oral and tube feeds due to a poor suck.

Saturday 1st December 2001

It is documented by a member of the medical team in Baby Róisín's healthcare records that Baby Róisín's feeding has improved and is on all bottle feeds now. Baby Róisín continues to have jerky movements.

Wednesday 5th December 2001

It is documented by a member of the medical team in Baby Róisín's healthcare records that Baby Róisín is bottle feeding well. Baby Róisín's tone is improving and may go home tomorrow.

Thursday 6th December 2001

Feeding improved over the past few days and Baby Róisín was discharged on 6th December 2001. It is documented by a member of the medical team in Baby Róisín's healthcare records that Baby Róisín was reviewed by the consultant paediatrician and can go home today as planned.

Chronology included for the purposes of completeness and at the request of the Family

2009

During the interview process Mr Conroy stated that he recalled his brother had heard a solicitor speak about medical errors on the radio, and suggested that Mr Conroy contact the solicitor to find out what happened to Róisín during her delivery on the 14th November 2001.

Mr Conroy stated at interview;

'we contacted the solicitor who said he would look into this for us. We sent Róisín's records to him and my wife's. It took 9 months to get Róisín's records. The solicitor said there was an issue with the care Róisín received. The statute of limitations did not apply as we had only found out and we could now commence legal proceedings.'

2010

Mr Conroy stated at interview that they commenced legal proceedings in 2010.

8th May 2012

According to the records held by the Medical Council Consultant Obstetrician and Gynaecologist A removed his name from the Medical Council Register.

26th November 2013

The family outlined *'that legal proceedings were completed on the 26th November 2013, where the HSE and Consultant Obstetrician and Gynaecologist A admitted full liability for the failings identified on the 14th November 2001'*.

January 2014

In 2014, following a Prime Time Report into maternity service, Mrs Conroy and her husband contacted the national HSE helpline (set up as a result of the Prime Time report) to raise concerns relating to the care and management Mrs Conroy received prior to and during Baby Róisín's delivery along with the lack of disclosure following the events on the 14th November 2001.

A clinical review team was established to review the cases of all those who have come forward with concerns, following the prime time investigation report. The family consented to their case being included in the review being carried out by the clinical review team. This clinical review team was chaired by an external independent Consultant Obstetrician and Gynaecologist, Dr Peter Boylan, who was nominated to chair this group by the Forum of Post Graduate Training Bodies (FPGTB).

This clinical review process included another six Consultant Obstetrician Gynaecologists also nominated by the FPGTB. NIMT 50554 is a group of cases where concerns were raised by

families in relation to care delivered at the Maternity Service at Hospital S1 following the Primetime Investigates Documentary broadcast on the 30th of January 2014.

Following this process it was deemed that this incident should be subject to a systems analysis review. The event was also reported on a Clinical Incident Form for notification to the Clinical Indemnity Scheme and was also entered on the HSE Incident Information Management system.

11th March 2014

Mr Conroy stated at interview that they wrote to the medical council to make a complaint against Consultant Obstetrician and Gynaecologist A on the 11th March 2014.

14th March 2014

Mr Conroy stated the following at interview;

'We received a response to our complaint from the Medical Council but were informed that this could not be progressed as Consultant Obstetrician and Gynaecologist A had removed his name from the register'. (Appendix F – Medical Council Correspondence).

15th June 2015

The letter contained in Baby Róisín's Healthcare record summarises Baby Róisín's medical problems as follows:

- Cerebral Palsy---Dystonic type
- Strabismus (squint)
- Right subluxating hip
- Nutritional and feeding difficulties
- Cough aspiration with thick puree

Section 4: Key Causal Factors, Contributory Factors, Incidental Factors and Linked Recommendations

In line with current thinking and best practice for the development of safety management systems in healthcare settings this investigation used a systems analysis approach in undertaking the overall review of the care and treatment Mrs Conroy received while under the care of hospital S1.

The aim of this investigation as outlined in the terms of Reference was to establish whether there were any failures in relation to the care and management received by Mrs Conroy during her admission on the 14th November 2001.

Key Causal Factors

Key causal factors are defined by the HSE Guideline for the Systems Analysis Investigation of Incidents (Revision 2, 2015) as issues that arise during the process of delivering and managing health services that are considered by the investigation team to have had an effect on the eventual adverse outcome.

Following an analysis of the chronology, this investigation identified the following two Key Causal Factors.

Key Causal Factor 1: Failure to perform competently during a high risk labour regarding the;
c) assessment and monitoring of Baby Róisín and;
d) recognition of fetal distress
placed Mrs Conroy and Baby Róisín in a position of unnecessary risk.

Key Causal Factor 2: Failure to demonstrate proper dedication, thoroughness, professional duty and responsibility as set out in professional regulatory guidelines resulted in;
c) A serious absence of the required level of professional communication expected during a high risk labour and;
d) Baby Róisín being catastrophically injured at birth.

This review endeavoured to specify the factors that contributed to the occurrence of these Key Causal factors utilising the framework of influencing / contributory factors outlined in the HSE Guideline for Systems Analysis Investigation of Incidents (Revision 2, 2015).

Contributory factors are defined as “the causes of harm in the incident being investigated”.

They are also considered to be hazards and potential causes of harm, if not mitigated through the implementation of appropriate recommendations.

The list of contributory factors outlined within the Contributory Factor Framework used to analyse the key causal factor is included under Appendix H of this report.

During the course of this investigation other issues were identified that serve to highlight areas for system improvement and these will be discussed in the report under the heading ‘Incidental Findings’.

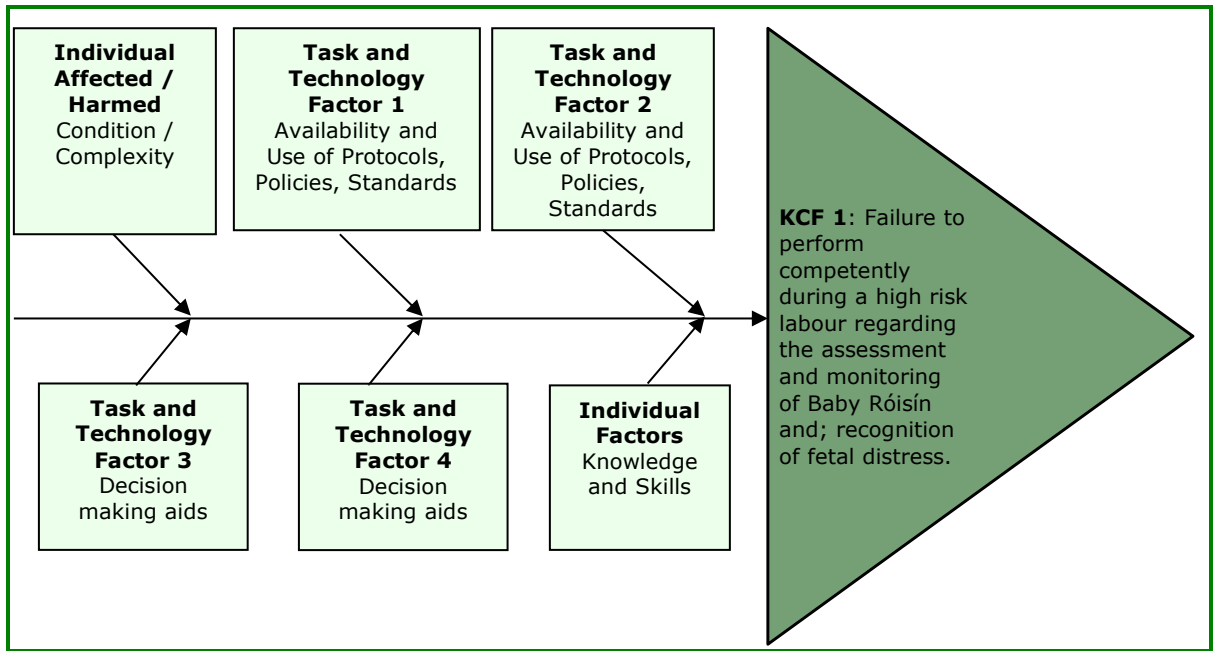
The Key Causal Factors were analysed by the Investigation Team in order to identify the Contributory Factors.

Key Causal Factor 1:

Key Causal Factor 1: Failure to perform competently during a high risk labour regarding the;
e) assessment and monitoring of Baby Róisín and;
f) recognition of fetal distress
 placed Mrs Conroy and Baby Róisín in a position of unnecessary risk.

Factors that contributed to Key Causal Factor 1:

Figure 1: Key Causal Factor 1 (KCF 1) and associated Contributory Factors



Contributory Factors and recommendations to address these:

Individual Affected / Harmed: Condition / Complexity

Mrs Conroy and her husband outlined at interview that they were so looking forward to the birth of their first baby. Even with the pain from the rapid onset of contractions following induction, the experience for Mrs Conroy and her husband should have been one of tremendous joy. However, the Investigation Team consider that the problems that occurred during labour have taken away from what was meant to be a joyous occasion and left Baby Róisín suffering with severe lifelong disabilities.

The only available evidence to the Investigation Team indicating Baby Róisín's condition was deteriorating during labour was a continuous fetal heart rate trace commenced at 14:14 hours on the 14th November 2001, 5 hours after intravaginal administration of Prostaglandin gel.

Non-reassuring features were evident on Baby Róisín's fetal heart tracing from the beginning of the recording with decelerations and reduced variability.

When commenting on Mrs Conroy's care, Dr Francois Gardeil Consultant Obstetrician and Gynaecologist for the period after 14:14 hours, Dr Francois Gardeil indicated that it is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed.

Baby Róisín's fetal heart rate became pathological at approximately 14:32 hours with a prolonged bradycardia down to a heart rate of 70 beats per minute that lasted for 7 minutes. After this episode, and until delivery of Baby Róisín at 16:32 hours, Baby Róisín's fetal heart rate showed persistent abnormalities.

Dr Francois Gardeil, stated that;

Non-reassuring features were evident on the fetal heart rate tracing from the beginning of the recording with decelerations⁹¹ and reduced variability⁹². It is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed. Fetal heart rate became pathological at 14.32 hour with a prolonged bradycardia⁹³ down to a heart rate of 70 beats per min that lasted for 7 minutes. After this episode, and until delivery of Baby Róisín at 16.32 hour the fetal heart rate showed persistent abnormalities. There were recurrent decelerations, probably of the variable type but the absence of recording of the uterine contractions makes analysis very difficult'.

It is the opinion of the Investigation Team that Baby Róisín suffered from oxygen deprivation brought about by the uterine contractions. Fetal distress was probably precipitated by uterine hyperstimulation⁹⁴. Labour was extremely fast for a first time mother.

It is recorded by Midwife M1 that Mrs Conroy went from 1 cm at 14:00 hours to full dilatation at 15.10 hour, i.e. 70 minutes. Hyperstimulation can explain the adverse outcome; when the uterus contracts, the flow of blood and oxygen in or out of the placenta slows or stops. Between contractions the placenta is able to recharge with a fresh supply of blood.

The Investigation Team was informed by Mrs Conroy that Midwife M1 informed her at 14:00 hours following an examination that she was 4 cm dilated not 1cm as previously stated in the chronology. The Investigation Team believes that it is most likely that Mrs Conroy was in fact 4 cm dilated based on her symptom history.

Dr Francois Gardeil, stated that;

Hyperstimulation reduces the ability of the placenta to replenish its oxygen supply and can, therefore, lead to fetal distress. Hyperstimulation is most common with the use of Oxytocin but it can also occur with Prostaglandin E2 (Prostin). In addition to excessive

⁹¹ Early deceleration is defined as an apparent gradual decrease and return to the baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer. Variable deceleration is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline. When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (Reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol, 2008 Spring; 1(2): 56-60 (Available from: <http://medical-dictionary.thefreedictionary.com/premature+labor> and <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/>).

⁹² Baseline FHR variability is based on visual assessment and excludes sinusoidal patterns. Variability is defined as fluctuations in the FHR baseline of 2 cycles per minute or greater, with irregular amplitude and inconstant frequency. These fluctuations are visually quantitated as the amplitude of the peak to trough in beats per minute. By visual assessment, acceleration is defined as an apparent abrupt increase in FHR above baseline, with the time from the onset of the acceleration to the acme of less than 30 seconds. Late deceleration is defined as an apparent gradual decrease and return to baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer.

⁹³ 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>)

⁹⁴ Hyperstimulation reduces the ability of the placenta to replenish its oxygen supply and can, therefore, lead to fetal distress.

uterine activity, the cord was noted to be tight around Baby Róisín's neck at the time of delivery. This fact probably contributed to impaired delivery of oxygen to Baby Róisín during labour and delivery.

It is probable that signs of fetal distress would have been apparent before 14.14 hour if the fetal heart had been monitored from 11.00 hour approximately when Mrs Conroy started to have strong contractions. Given that appropriate monitoring of the fetal wellbeing only started at 14:14 hours in this case, I contend that a decision to proceed to an emergency caesarean section should have been made at approximately 14:35 hours when the CTG was grossly abnormal, with the aim of delivering Baby Róisín within 30 minutes'.

According to Dr. John Murphy, Consultant Neonatologist and Clinical Expert to the Investigation Team, Baby Róisín was severely compromised at birth with a slow heart rate, absent respirations, severe hypotonia, absent reflex response, and poor colour.

It would also appear that staff did not expect Baby Róisín to be born in such poor condition despite the pathological cardiac trace requiring a consultant obstetric review and paediatric team to be present at delivery.

During the interview process Midwife M1 outlined that she expected Baby Róisín to be 'ok'.

Baby Róisín is a case of perinatal asphyxia leading to severe neonatal encephalopathy. She has had an abnormal neurological outcome with severe motor and intellectual disability.

Baby Róisín was diagnosed with HIE⁹⁵ Grade 2 and returned to Hospital S1 on the 26th November 2001.

When Baby Róisín suffered a catastrophic injury at birth, Baby Róisín and her entire family has been affected for life.

⁹⁵ The clinical characteristics of HIE (Hypoxic-Ischemic Encephalopathy) can be described as mild, moderate, or severe. The most common grading or staging system is by the Sarnat scale developed by Sarnat and Sarnat in 1976.

Mild HIE – Sarnat Stage I

- Hyper-alert
- Eyes wide open
- Does not sleep
- Irritable
- No seizures
- Usually lasts < 24 hours

Moderate HIE – Sarnat Stage II

- Lethargy (difficult to rouse)
- Reduced tone of the extremities and/or trunk
- Diminished brainstem reflexes (pupil/gag/suck)
- Possible clinical seizures

Severe HIE – Sarnat Stage III

- Coma (cannot be roused)
- Weak or absent respiratory drive
- No response to stimuli (may have spinal reflex to painful stimuli)
- Flaccid tone of the extremities and trunk (floppy)
- Diminished or absent brain stem reflexes (pupil/gag/suck)
- Diminished tendon reflexes
- EEG severely abnormal (suppressed or flat EEG with or without seizures)

Contributory Factors and recommendations to address these:

Task and Technology Factor 1: Availability and Use of Protocols, Policies, Standards: Continuous Fetal Monitoring

The Investigation Team consider that the induction of labour for Mrs Conroy was a high-risk situation. Continuous fetal heart rate monitoring in labour, together with monitoring of the frequency and duration of contractions (the cardiotocograph⁹⁶) was indicated in this high-risk labour.

As outlined in the chronology on the 13th of November 2001 Mrs Conroy was 9 days overdue and Consultant Obstetrician and Gynaecologist A performed a scan in his consulting rooms that showed a decreased amount of amniotic fluid.

This was a concerning finding and Consultant Obstetrician and Gynaecologist A made the correct decision to induce labour the following day, Wednesday 14th of November 2001. Dr Gardeil outlined to the investigation that an induction of labour is associated with increased risk compared to labour that starts spontaneously. The decreased amniotic fluid volume noted on scan in this case was an additional risk factor.

During the investigation process the Investigation Team note in Mrs Conroy's case, on 14th November 2001 continuous fetal heart rate monitoring was not commenced until 14.14 hours, although Mrs Conroy had been having severe labour pains since 11.00 hours, 2 hours after intravaginal administration of Prostaglandin gel.

Non-reassuring features were evident on the fetal heart rate tracing from the beginning of the recording with decelerations and reduced variability. It is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed. Fetal heart rate became pathological at 14.32 hours with a prolonged bradycardia down to a heart rate of 70 beats per min that lasted for 7 minutes.

After this episode, and until delivery of Baby Róisín at 16.32 hours the fetal heart rate showed persistent abnormalities. There were recurrent decelerations, probably of the variable type but the absence of recording of the uterine contractions makes analysis very difficult.

Midwife M1 stated at interview that she did inform Consultant Obstetrician and Gynaecologist A at 14:00 hours when she contacted him about her concerns relating to the absence of liquor. Consultant Obstetrician and Gynaecologist A does not recall this conversation.

Based on a handwritten note on the CTG trace, it appears that Midwife M1 made an attempt to contact Consultant Obstetrician and Gynaecologist B at approximately 14:35 hours. The reason for contacting Consultant Obstetrician and Gynaecologist B is not documented in the healthcare records. Midwife M1 stated during interview that she recognised the intrapartum cardiac trace was non-reassuring and there was also no liquor which she stated meant '*danger*'.

Ms Hughes states in her report that there is evidence of fetal distress on this tracing however there is no evidence in the records to suggest that it was brought to the attention of an obstetrician apart from a handwritten entry on the CTG timed at about 14.35 hours stating Consultant Obstetrician and Gynaecologist B had been bleeped.

This entry on the CTG record coincides with a portion of a prolonged bradycardia. However, there are no entries in the records for this period from any Consultant Obstetrician.

⁹⁶ CTG is the continuous recording of the fetal heart rate obtained via an ultrasound transducer placed on the mother's abdomen.

It is not clear whether the obstetrician attended or not. If not, there is also no record of any attempt by the midwife to re-establish contact with a Consultant Obstetrician.

There is no maternal pulse recorded by hand on the CTG. This falls short of the standards of care/ recordkeeping; "It is essential to record the maternal pulse once at the beginning of the trace and document it on the trace" (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

At interview Midwife M1 outlined that on reflection she was more concerned about Mrs Conroy and delivering Baby Róisín safely, that she did not make a second attempt to contact Consultant Obstetrician and Gynaecologist B. Midwife M1 also stated that she did not expect Mrs Conroy to deliver Baby Róisín so quickly and believed that Baby Róisín would be ok.

Midwife M1 also outlined at interview that at the time of this incident;

'if you showed a CTG to a consultant obstetrician they didn't pay much attention, credence wasn't given to the midwife's opinion'.

In addition Midwife M1 stated at interview that having reviewed the case she would have done things differently now, and she would have made additional attempts to call a doctor and would not have waited.

The Investigation Team believe that there is a requirement to highlight the procedural deficiencies in relation to local policy relating to the management of the expectant mother and labour at the time of Baby Róisín's delivery on the 14th November 2001.

The investigation identified that there were no guidelines in place at Hospital S1 at the time of the incident in November 2001 with regard to the monitoring of the fetal heart rate and contractions and, parameters/indicators that can assist staff in conducting an overall assessment of the condition of the baby during labour.

Guidelines are designed to reduce variations in practice, support the decision-making in delivery safe patient care and have the potential to improve both the process of care and patient outcomes.

International and National guidelines can be used as the basis for local guideline development taking into account local service provision needs. Ideally, local development should take place in a multidisciplinary group setting. This practice did not occur in Hospital S1.

Dr. Gardeil outlined that the basic principle of having a guideline to support intrapartum monitoring is to detect developing fetal hypoxia with the aim of preventing subsequent acidemia and cell damage.

The Investigation Team wish to highlight that 'The Use of Electronic Fetal Monitoring: The use and interpretation of cardiotocography in intrapartum fetal surveillance RCOG (The Royal College of Obstetricians and Gynaecologists (UK)) May 2001⁹⁷ was available at the time of this incident to support local guideline development.

In 2001 the RCOG recommended that Continuous EFM (Electronic fetal monitoring) should be offered and recommended for high-risk pregnancies where there is an increased risk of

⁹⁷ The Use of Electronic Fetal Monitoring The use and interpretation of cardiotocography in intrapartum fetal surveillance Evidence-based Clinical Guideline Number 8 Clinical Effectiveness Support Unit, Royal College of Obstetricians and Gynaecologists May 2001. These guidelines highlight recommended practice that allows some discretion in interpretation, implementation or use. The Royal College of Obstetricians and Gynaecologists (UK) produces guidelines as an aid to good clinical practice. The guidelines present recognised methods and techniques for clinical practice, based on published evidence, for consideration by obstetricians / gynaecologists and other relevant health professionals.

perinatal death, cerebral palsy or neonatal encephalopathy and should be used where oxytocin is being used for induction or augmentation of labour.

Consultant Obstetrician and Gynaecologist A outlined at interview that there was no designated individual to coordinate the work of policy and guideline development. In addition Consultant Obstetrician and Gynaecologist A indicated that there was no Midwifery Manager for the labour ward that could have fulfilled this role.

Consultant Obstetrician and Gynaecologist A stated at interview that the lack of policy and guidance was indicative of *'how things were done then'*.

Ms Hughes states in her report to the Investigation Team that it was and is usual practice to assess the fetal heart rate prior to the administration of Prostin by either carrying out a CTG (depending upon the circumstances of the fetus) or to listen in to the fetal heart rate for one minute beforehand. There is no evidence of either action being taken in this case according to examination of the records.

In relation to monitoring of the fetal heart rate in Hospital S1 during and before 2001, Consultant Obstetrician and Gynaecologist A stated that he did not interfere with midwifery practice and outlined that he was happy with practice of the midwives' and he had no cause for concern at the time.

During the feedback process Mrs Conroy and her husband outlined that Consultant Obstetrician and Gynaecologist A should have had cause for concern if he had reviewed Mrs Conroy when he was asked to prescribe pain relief for strong contractions at 12:30 hours and before leaving hospital S1.

At interview Consultant Obstetrician and Gynaecologist A outlined that the practice at the time was not to carry out continuous fetal monitoring and Midwives used a Doppler to listen to the fetal heart rate every half hour. This monitoring did not occur during Mrs Conroy's labour.

Notwithstanding this, Dr. Gardiel outlined for the investigation that Consultant Obstetrician and Gynaecologist A had it within his authority to challenge the practice of any colleague and employ fetal monitoring to safe guard the wellbeing of both mother and baby.

In relation to the monitoring of contractions Consultant Obstetrician and Gynaecologist A stated at interview that the use of the tocograph was not consistent with staff and was often considered problematic and therefore abandoned, due to connectivity issues.

It is the opinion of the Investigation Team that Baby Róisín suffered from oxygen deprivation brought about by the uterine contractions. Fetal distress was probably precipitated by uterine hyperstimulation⁹⁸. Labour was extremely fast for a first time mother. Based on the family's recollections the investigation believes Mrs Conroy most likely went from 4 cm at 14:00 hours to full dilatation at 15:10 hours, i.e. 70 minutes.

Dr Gardeil stated for the investigation that hyperstimulation can explain the adverse outcome; when the uterus contracts, the flow of blood and oxygen in or out of the placenta slows or stops, therefore between contractions the placenta is able to recharge with a fresh supply of blood.

⁹⁸ Uterine hyperstimulation or hypertonic uterine dysfunction is a potential complication of labor induction. It is defined as either a series of single contractions lasting 2 minutes or more or a contraction frequency of five or more in 10 minutes. Uterine hyperstimulation may result in fetal heart rate abnormalities, uterine rupture, or placental abruption. It is usually treated by administering terbutaline. Reference: American College of Obstetricians and Gynecologists (December 1999). "Induction of labor". ACOG practice Bulletin. Washington, DC. 10.

Dr. Gardeil stated for the investigation that Mrs Conroy should have been reviewed.

Hyperstimulation reduces the ability of the placenta to replenish its oxygen supply and can, therefore, lead to fetal distress. Hyperstimulation is most common with the use of Oxytocin but it can also occur with Prostaglandin E2 (Prostin).

Together with the excessive uterine activity, the cord was noted to be tight around Baby Róisín's neck at the time of delivery. This fact probably contributed to impaired delivery of oxygen to Baby Róisín during labour and delivery.

It is probable that signs of fetal distress would have been apparent before 14:14 hours if the fetal heart had been monitored from 11.00 hours approximately when Mrs Conroy started to have strong contractions.

Given that appropriate continuous monitoring of the fetal wellbeing only started at 14:14 hours in this case, Dr. Gardeil believes that a decision to proceed to an emergency caesarean section should have been made at approximately 14:35 hours when the CTG was grossly abnormal, with the aim of delivering Baby Róisín within 30 minutes.

According to Dr Francois Gardeil, although it is impossible to know what the outcome would have been, on the balance of probabilities it is likely that Baby Róisín's condition at birth would not have been as serious as it was if the pathological changes identified at 14:35 hours where acted on appropriately.

Recommendations linked to this contributory factor⁹⁹:

Recommendation 1 (*Hierarchy of Hazard Controls - Administrative Procedure*):

Hospital S1 must develop a local policy adapted from national guidelines with regard to intrapartum fetal heart rate monitoring and ensure appropriate compliance (RCPI/HSE intrapartum fetal heart rate monitoring guideline) and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be action on and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Action taken since the events described in this report

Response provided from Hospital S1: *The guideline PHOG011 was developed and approved in May 2016 "Fetal heart rate monitoring in labour in the maternity department". The guideline has been fully implemented in the maternity department. This guideline co-exists with the Guideline on Intrapartum care PHOG002 which has also been fully implemented in the department. An audit of PHOG011 was completed in November last and no issues were identified from same.*

Recommendation 2 (*Hierarchy of Hazard Controls - Administrative Procedure*):

All Hospital Groups have in place guidelines/protocols adapted from national guidelines with regard to intrapartum fetal heart rate monitoring and ensure appropriate compliance (RCPI/HSE intrapartum fetal heart rate monitoring guideline) and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be action on and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

⁹⁹ The Investigation Team acknowledge that the above recommendations may have been implemented already given the historical nature of this investigation.

Task and Technology Factor 2: Availability and Use of Protocols, Policies, Standards: Induction of labour Guidelines

The Investigation Team was informed that at the time of this incident there were no guidelines in place for the induction of labour (IOL) in Hospital S1.

While induction of labour is a common intervention in pregnancy, it is undertaken when it is thought that the outcome of the pregnancy will be better for the mother and/or her baby if the baby is born. Common reasons include prolonged pregnancy, prelabour rupture of the membranes, concerns about the health of the mother such as pre-eclampsia or the baby such as poor growth.

Prostaglandins i.e Prostin Gel has been used for induction of labour since the 1960s. Prostaglandins are hormones, produced throughout the body and can be used to start (induce) labour.

In relation to Mrs Conroy, she had Prostin Gel applied by Consultant Obstetrician and Gynaecologist A at 09:00 hours alongside the cervix (neck of the womb).

The dose, number of doses, and time between doses was decided by the Consultant Obstetrician and Gynaecologist A responsible for the care of Mrs Conroy.

According to Dr Francois Gardeil vaginal prostaglandins increase the likelihood of vaginal birth within 24 hours, but they can also stimulate the uterus to contract too much and this may cause the Baby's heart to slow.

Table 7 : Summary of Mrs Conroy's Rapid Labour Progression

Date	Time	Dilated (cm)
14 th Nov. 2001	14:00 Hours	1cm
14 th Nov. 2001	14:45 Hours	6cm
14 th Nov. 2001	15:10 Hours	10cm

Following the insertion of the Prostin Gel to induce labour at 09:00 hours there is no available evidence documented in the healthcare record or available through the interview process that indicates Mrs Conroy's IOL was managed in line with best practice and that she was monitored in a safe environment.

Ms Hughes states in her report that in the absence of sound evidence based guidelines for practice, practice varied in relation to CTG monitoring post Prostin. Some hospitals used to, and some still do, a CTG immediately after administration of Prostin. Others would listen into the fetal heart and if it was normal would await the onset of contractions or one-hour post Prostin (whichever came first) to commence a CTG.

In all cases thereafter, and in the absence of contractions, practice would usually involve listening into the fetal heart for a minimum of one minute at least 4 hourly.

Women who are having their labours induced have had an intervention of Prostin on top of a reason to induce thus requiring at least 4-hourly surveillance. The level of surveillance could be higher as recommended by the obstetrician and as determined by the clinical circumstances and may include repeat or less commonly, continuous CTG monitoring throughout the induction process whilst awaiting the establishment of labour.

The staff interviewed outlined that there was an absence of guidelines in Hospital S1. Notwithstanding this commentary the investigation notes that the Nurse/Midwife Scope of Practice Decision-Making Framework 2000 (NMBI) (Appendix G) indicates that Midwives have

a responsibility to ensure that the appropriate guidance is in place to ensure the safe execution of their roles and responsibilities.

Guidance was available for local use in *Induction of Labour*, an RCOG/NICE evidence-based national clinical practice guideline, June 2001. In addition best practice suggested that if induction or augmentation of labour is undertaken there is a significant risk of hypercontractility and electronic fetal monitoring (EFM) should be used.¹⁰⁰

Recommendations linked to this contributory factor:

Recommendation 3 (*Hierarchy of Hazard Controls - Administrative Procedure*):

The Maternity Unit located in Hospital S1 should develop a local policy adapted from national guidelines with regard to Induction of Labour and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings. Non-compliance should be managed via the risk register in line with Risk Management Policy.

Action taken since the events described in this report

Response provided from Hospital S1: *The Guideline "Management of Antenatal Women admitted for induction of Labour" PHOG022 was developed in 2015 and has been fully implemented in the maternity department. This guideline has been audited since its development and will be re-audited in 2018.*

Task and Technology Factor 3: Decision Making Aids: CTG Machine Use and Maintenance

A CTG machine is a technical means of recording the fetal heart beat and the uterine contractions during pregnancy, typically in the third trimester¹⁰¹. One of the features of the CTG machine is that the machine will alert staff to an abnormal CTG tracing.

There are four features of the CTG (baseline fetal heart rate, baseline fetal heart rate¹⁰² variability, presence or absence of decelerations and the presence or absence of accelerations)

¹⁰⁰ American College of Obstetricians and Gynaecologists. *Induction of Labour*. Washington DC; 1999.

¹⁰¹ 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

¹⁰² **Baseline fetal heart rate** is the average fetal heart rate (FHR) rounded to increments of 5 beats per minute during a 10-minute segment, excluding periodic or episodic changes, periods of marked variability, or baseline segments that differ by more than 25 beats per minute. In any given 10-minute window, the minimum baseline duration must be at least 2 minutes, or else the baseline is considered indeterminate. In cases where the baseline is indeterminate, the previous 10-minute window should be reviewed and utilized in order to determine the baseline.

A normal FHR baseline rate ranges from 110 to 160 beats per minute. If the baseline FHR is less than 110 beats per minute, it is termed **bradycardia**. If the baseline FHR is more than 160 beats per minute, it is termed *tachycardia*.

Baseline FHR variability is based on visual assessment and excludes sinusoidal patterns. **Variability** is defined as fluctuations in the FHR baseline of 2 cycles per minute or greater, with irregular amplitude and inconstant frequency. These fluctuations are visually quantitated as the amplitude of the peak to trough in beats per minute. By visual assessment, **acceleration** is defined as an apparent abrupt increase in FHR above baseline, with the time from the onset of the acceleration to the acme of less than 30 seconds.

Late deceleration is defined as an apparent gradual decrease and return to baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer.

Early deceleration is defined as an apparent gradual decrease and return to the baseline FHR in association with a uterine contraction, with the time from onset of the deceleration to its nadir as 30 seconds or longer.

Variable deceleration is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is

which when examined are classified as either Reassuring, Non-reassuring or Abnormal based on the criteria in the table below:

Table 8: CTG Classification/Decision Tool

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

The CTG is then classified as follows:

- **Normal:** A Fetal Heart Rate (FHR) in which all four features are classified as reassuring
- **Suspicious:** A FHR trace with one feature classified as non-reassuring and the remaining features classified as reassuring.
- **Pathological:** A FHR trace with two or more features classified as non-reassuring or one or more classified as abnormal.

measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline. When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (Reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol. 2008 Spring; 1(2): 56-60.

The intra-partum cardiac trace which commenced at approximately 14:14 hours on the 14th November 2001 highlights that Baby Róisín's fetal heart rate was recorded and uterine contractions were not measured by a tocodynamometer.

The main purpose for using the cardiotocography (C.T.G) is that it allows the clinical team to monitor and record the fetal heartbeat and the uterine contractions during pregnancy and labour. Both pieces of equipment are held in place using abdominal belts. Two recordings are combined on a single CTG continuous paper print out.

There is no output printed on the CTG trace from the tocograph monitor, which suggests that it was either not put on or it was defective. In either case, there is no explanation documented by the Midwife in relation to this absence of contraction monitoring on the 14th November 2001.

At interview the explanation provided by Midwife M1 in relation to the absence of the tocograph recording was that connectivity was a problem in general and as a result its use was frequently abandoned.

The Investigation Team consider that in a situation such as Mrs Conroy's labour the incorrect application of the CTG machine and the absence of the tocograph makes the interpretation of the intrapartum cardiac trace a challenge. Notwithstanding this, there is clear evidence of fetal compromise from 14:14 hours until delivery.

During the investigation process the Investigation Team requested information regarding the type of CTG machine used in Hospital S1 along with any maintenance records from the Medical Engineer at Hospital S1.

It was established that there was no evidence available to clarify the make and model of CTG machine used at the time in Hospital S1 or any records relating to the maintenance of CTG machines.

The investigation team therefore considered it essential to seek the opinion of Mr Ger Flynn Clinical Head of Devices and Liam Hackett, National Medical Equipment Advisor Community Services to provide guidance on what should have been in place regarding medical equipment maintenance and recording keeping.

Mr Ger Flynn provided the following guidance;

'The service that is required to be carried out on the medical equipment (in this case the CTG machine) should be in accordance with the instructions set out in the service and maintenance manual for the model machine by the manufacturer. This information and these check lists are located in the service manual. In addition an IEC electrical safety test should also be carried out in accordance with the 'Type' and 'class' of the medical equipment.

With regard to the type of maintenance records that should be retained by the clinical engineering/ biomedical engineering department or hospital ward/department manager, either of the following three formats are acceptable;

- 1. A hard copy paper record (with the service engineers signature and date the work was carried out) should be filed plus a copy of the result of the IEC electrical safety test*
- 2. if possible an electronic scanned copy (with the service engineers signature and date the work was carried out) plus a copy of the result of the IEC electrical safety test*
- 3. electronic record (with the service engineers signature and date the work was carried out) plus a copy of the result of the IEC electrical safety test*

Liam Hackett, National Medical Equipment Advisor Community Services, outlined for the investigation that in Hospital S1 in 2001,

'All maintenance records would be paper based as there was no electronic Asset/Maintenance Management System in place. As the details such as equipment type, manufacturer, model or serial number of the equipment involved in the incident were not recorded, it is impossible to obtain the relevant maintenance records of the equipment.

In 2001 in Hospital S1, there was no in-house Clinical Engineering services, so therefore all maintenance was carried out on a contract basis. In 2004, a Clinical Engineering Technician was employed to provide in-house support of Medical Devices within the Hospital. The initial task for this person was to identify and asset tag all Medical Devices that were in use in the Hospital and enter details of these devices on the ECRI HECS Asset Management System.

This process included acceptance testing, asset tagging of equipment, entering on the HECS Database and setting up Preventative Maintenance schedules as per local SOP CED032P. A procedure was also implemented for management of medical devices that were involved in a patient related incident.

This procedure includes identification of the device, details of incident and the removal of the device from service as per local SOP CED010P. Full Technical Assessment is carried out on the device and report completed prior to device being placed back in clinical use.

The next generation of ECRI HECS Asset Tracking and Maintenance Management System (ECRI AIMS- Asset Information Management System) was implemented and this system has since been moved onto the National ECRI AIMS system.

The ECRI AIMS System maintains a full history of all medical devices in use in the Hospital including asset acceptance, commissioning, preventative maintenance records and corrective maintenance records, including a full history of the device up to and including de-commissioning. Following de-commissioning of device, the complete record is retained on the ECRI System.

Recommendations linked to this contributory factor:

Recommendation 4 (Hierarchy of Hazard Controls - Engineering controls)

Hospital S1 should ensure the correct application of the CTG machine in all situations where continuous monitoring is required. Managing risks from using equipment is essential for all services, with a focus on factors that intervene with safety, such as the inappropriate use of medical equipment. Issues relating to deviation must be managed and addressed.

Action taken since the events described in this report

Response provided from Hospital S1: *All midwives are trained and competent in the application of CTG monitoring equipment in the department. There is a daily check of CTG equipment function undertaken and a log of these checks is maintained. The maintenance of all CTG machines in the department is scheduled annually. Where faults and maintenance issues are identified, they are communicated to and addressed promptly by the Clinical Engineering team.*

Recommendation 5 (Hierarchy of Hazard Controls - Engineering controls)

Hospital S1 should ensure that all equipment is appropriately maintained and recorded. The recording of this practice must be audited and findings acted on.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department completes a daily check of equipment including the function of CTG monitors as per guideline PHOG013 "Avalon Fetal Monitors". The record of these checks is retained. The inventory of equipment and maintenance programme is retained by the Clinical Engineering department.*

Contributory Factors and recommendations to address these:

Task and Technology Factor 4: Decision Making Aids: Fetal Blood Sampling

The Consultant Obstetrician / Gynaecologist C indicated at interview that:

'The only real opportunity to deliver Mrs Conroy would have been soon after the onset of labour, sometime after 14:00 hours onwards. At this stage the C.T.G. was showing significant abnormality, certainly in comparison with the previous C.T.G. carried out between 9.15 - 09:40 hours.

The choices were either to perform a fetal scalp sample to assess the condition of the baby by way of pH measurement and base excess values in order to determine if the foetus was acidotic, or to deliver by caesarean section.'

Consultant Obstetrician / Gynaecologist C outlined following a review of the healthcare record that;

'the fetus depends on the mother for placental exchange of oxygen and carbon dioxide. This in turn relies on adequate uterine blood supply, placental transfer and fetal gas transport. Disruption of any of these can cause fetal hypoxia, may lead to acidosis. When acute (lasting hours), hypoxia and therefore acidosis, are associated with significant morbidity and mortality with potential long term neurological sequelae in surviving children¹⁰³.'

The Investigation Team were informed that Hospital S1 did not have the facilities for fetal blood sampling in 2001.

The Institute of Obstetricians and Gynaecologists Royal College of Physicians Ireland document on Intrapartum Fetal Heart Rate Monitoring Guideline No. 6 April 2014¹⁰⁴ provides guidance in relation to the use of fetal sampling.

A previous investigation carried out in 2013 that related to the Maternity Department at Hospital S1 recommended that a risk assessment be carried out on the risk of injury to a fetus due to the failure to provide foetal blood sampling on the Maternity Department of the hospital.

Recommendations linked to this contributory factor:

Recommendation 6 (Hierarchy of Hazard Controls - Engineering controls)

The Maternity Unit located in Hospital S1 should ensure the facilities required to carry out fetal blood sampling should be provided at Hospital S1 as a matter of priority.

¹⁰³ Reference: Liston Róisín., Crane J. (2002) Fetal Health Surveillance in Labour. SOGC Clinical Practice Guidelines. JOGC No. 112, March 2002.

¹⁰⁴ Reference: <https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2016/05/6.-Intrapartum-Fetal-Heart-Rate-Monitoring.pdf>

Action taken since the events described in this report

Response provided from Hospital S1: *There are two fetal blood sampling machines in operation in the labour ward of the maternity department. The machines were installed in October and December 2013. The maternity department provides regular training to midwifery and medical staff on the functionality of the FBS machines and fetal blood sampling kits.*

Contributory Factors and recommendations to address these:

Individual Factor 1: Skills and Knowledge: CTG Interpretation

Dr Francois Gardeil indicated in his report that labour was extremely fast for a first time mother. While it is documented that Mrs Conroy went from 1 cm at 14:00 hours to full dilatation at 15:10 hours i.e. 70 minutes; Mrs Conroy outlined during interview and the feedback process that she was informed by Midwife M1 that she was in fact 4 cm at 14:00 hours and not 1 cm as documented in the healthcare record. Nevertheless labour was progressing rapidly for a first time mother.

From 11:00 hours when Mrs Conroy started to experience very strong contractions, there was an clear opportunity to commence fetal monitoring and establish how Mrs Conroy's labour was progressing. Consultant Obstetrician and Gynaecologist A at the point of prescribing pain relief had it within his ability to review Mrs Conroy and request continuous fetal monitoring at 12:30 hours.

Non-reassuring features were evident on the fetal heart rate tracing from the beginning of the recording at 14:14 hours with decelerations and reduced variability.

Dr Gardeil stated for the investigation that it is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed. Fetal heart rate became pathological at 14:32 hours with a prolonged bradycardia down to a heart rate of 70 beats per min that lasted for 7 minutes. After this episode, and until delivery of Baby Róisín at 16:32 hours the fetal heart rate showed persistent abnormalities.

There were recurrent decelerations, probably of the variable type but the absence of recording of the uterine contractions makes analysis very difficult.

Mrs Conroy and her husband outlined during the feedback process that Mrs Conroy went to the labour ward of her own accord at 14:00 hours as she felt she was about to deliver Baby Róisín. Mrs Conroy stated that there was no one monitoring or checking up on her or Baby Róisín.

As indicated by Dr Gardeil the CTG is used in an attempt to identify babies at risk of hypoxia (lack of oxygen) during labour. Fetal heart rate monitoring is only of value when abnormalities are recognised and acted upon.

The Investigation Team became aware during the interview process that there was no local coherent programme of continuing professional development to help address the development needs of the local midwives.

Midwife M1 at interview stated that she recognised that the intrapartum cardiac trace was 'very poor' but failed to document her concerns. Midwife M1 outlined that she had not received any training in relation to the use or interpretation of CTG's.

There is a disparity in some staff recollections regarding the availability of CTG training.

Midwife M1 outlined that there was never any training available to staff on the use and interpretation of CTG's.

At interview Midwife M2 stated that there was training available;

'We had CTG training previously for half a day and about 400 people attended in a hotel'.

Consultant Obstetrician and Gynaecologist A informed the Investigation Team at interview that the training available to staff at the time was provided by the company that supplied the CTG machines. Maternity services were notified of training via a memo from the company outlining the venue (usually a hotel in Dublin), date and time.

Junior midwifery staff outlined at interview that it was generally the more senior midwives who were afforded the opportunity to attend these training sessions. Attendance varied, in some cases the staff attended or if the ward was busy they were unable to attend and remained in the unit. There was no monitoring of attendance at this time.

During the feedback process Nursing Management at Hospital S1 stated that there are no records available in relation to CTG training from 2000/2001.

In the context of a Midwives 'Knowledge and Skills' the Investigation Team reviewed The 'Scope of Nursing and Midwifery Practice Framework / An Bord Altranais 2000 which states that a registered Midwife should be able to recognise the warning signs of abnormality in the mother or infant which necessitate referral to a doctor.

The principles underpinning the Scope of Nursing and Midwifery Practice 2000¹⁰⁵ include the promotion and maintenance of high standards of care, protection of the uniqueness and dignity of the patient/client, trust, advocacy and empowerment.

The framework takes cognisance of the best interests of the patient/client, legislation, local and national guidelines/policies and the concepts of accountability and competency.

The purpose of The Code of Professional Conduct for each Nurse and Midwife April 2000 was to provide a framework to assist the nurse to make professional decisions, to carry out his/her responsibilities and to promote high standards of professional conduct.

The nursing and midwifery profession demands a high standard of professional behaviour from its members and each registered nurse is accountable for his or her practice. The aim of the nursing profession is to give the highest standard of care possible to patients.

Therefore circumstances which could place patients in jeopardy or which militate against safe standards of practice should be made known to appropriate persons or authorities.

The Investigation Team consider that the nurse or midwife must take appropriate measures to gain competence in the particular area. There is a precarious lack of evidence following the interview process that staff challenged the lack of training to support them in the delivery of their duties or indeed the lack of policy and guidance.

The recommendations emerging from this investigation include: an imperative that the quality of competence-based training should be monitored and controlled; that course content and delivery should meet both service requirements and the realities of service provision; that the methods of delivery should be based on needs; and that training should be adapted to meet these needs.

Clinical staff interviewed outlined there was very limited training offered to staff regarding interpretation of CTG findings. The lack of knowledge and experience contributed to a 'wait and see' approach.

¹⁰⁵ Available at: <http://www.lenus.ie/hse/handle/10147/91150>

According to Dr. Gardeil a consequence of this action was a further deterioration in Baby Róisín's condition.

Notwithstanding the opinion of the staff interviewed, Electronic Fetal Monitoring is not a new practice and has been available since the late 1960's. For monitoring to be effective it must be performed correctly, its results interpreted satisfactorily and this interpretation must provoke an appropriate response (Grant, 1989) and could not be considered a relatively new technique even in 2001.

The Investigation Team accepts based on the literature that there are inconsistencies in the interpretation of CTG recordings.

There is also an acceptance that training in the interpretation of CTG must be maintained to minimise these inconsistencies and prevent harm.

The 7th annual Confidential Enquiry into Stillbirths and Deaths in Infancy Report (CESDI) report in the UK recommended that interactive computer based training should be made available to staff involved in the management of labour.

Action taken since the time of the events described in this report:

Since July 2013 an electronic Perinatal Training Programme has been mandatory in Hospital S1. The training requirement is to complete all modules within a twelve month period, as a rolling programme.

On the 18th July 2013 a Senior Nursing and Midwifery Manager wrote to Midwives identifying that the electronic Perinatal Training Programme (CTG Training) was mandatory from that point onward and in addition to this there was also a mandatory requirement for Midwives to:

- Take part in annual CTG training
- Take part in Obstetric emergency drills
- Attend CTG review meetings (3 per year minimum)
- Complete the required electronic Perinatal Training Programme
- Read all current policies, procedures and guidelines

Following the introduction of the mandatory electronic Perinatal Training Programme compliance reports relating to attendance are retained and monitored.

Monitoring covers both Midwives and NCHDs (Non-Consultant Hospital Doctors) and once the report is produced it is the responsibility of the Clinical Lead for Obstetrics and Gynaecology to follow-up non-compliance with Medical staff and the Senior Midwifery Manager to address non-compliance with Midwifery Staff.

A guideline titled: Mandatory K2 Fetal Monitoring Training (PHOG019) was provided to the investigation team. This guideline was issued in November 2013.

In addition to the above, since January 2016, on each Monday morning in Hospital S1, the Caesarean sections from the previous week are reviewed. All of the CTGs relating to the sections done from the labour ward are discussed. At this meeting, there is also the opportunity to discuss CTGs in cases that were not delivered by caesarean section.

Recommendations linked to this contributory factor:

Recommendation 7 (*Hierarchy of Hazard Controls - Administrative Procedure*)

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

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department ensures that all midwives and obstetricians' have completed K2 fetal monitoring training on an annual basis. A twice yearly report is provided by K2 medical systems to validate this. In addition midwives at the maternity unit must undertake a CTG workshop every 2 years as mandatory training.*

Recommendation 8 *(Hierarchy of Hazard Controls - Administrative Procedure)*

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

Action taken since the events described in this report

Response provided from Hospital S1: *All midwifery and medical staff are required to complete mandatory annual K2 CTG training online and training records are maintained. This training is complimented with a study day provided every two years at the centre of midwifery education CWIUH for midwives. The record of compliance is overseen by the Director of Midwifery (DoM) and the Clinical lead for obstetrics.*

Recommendation 9 *(Hierarchy of Hazard Controls - Administrative Procedure)*

That systems and processes are established, up to and including the disciplinary process, within each National Division to ensure compliance with mandatory training. This recommendation is to be implemented within three months of acceptance of this report by the reports Commissioner.

Key Causal Factor 2:

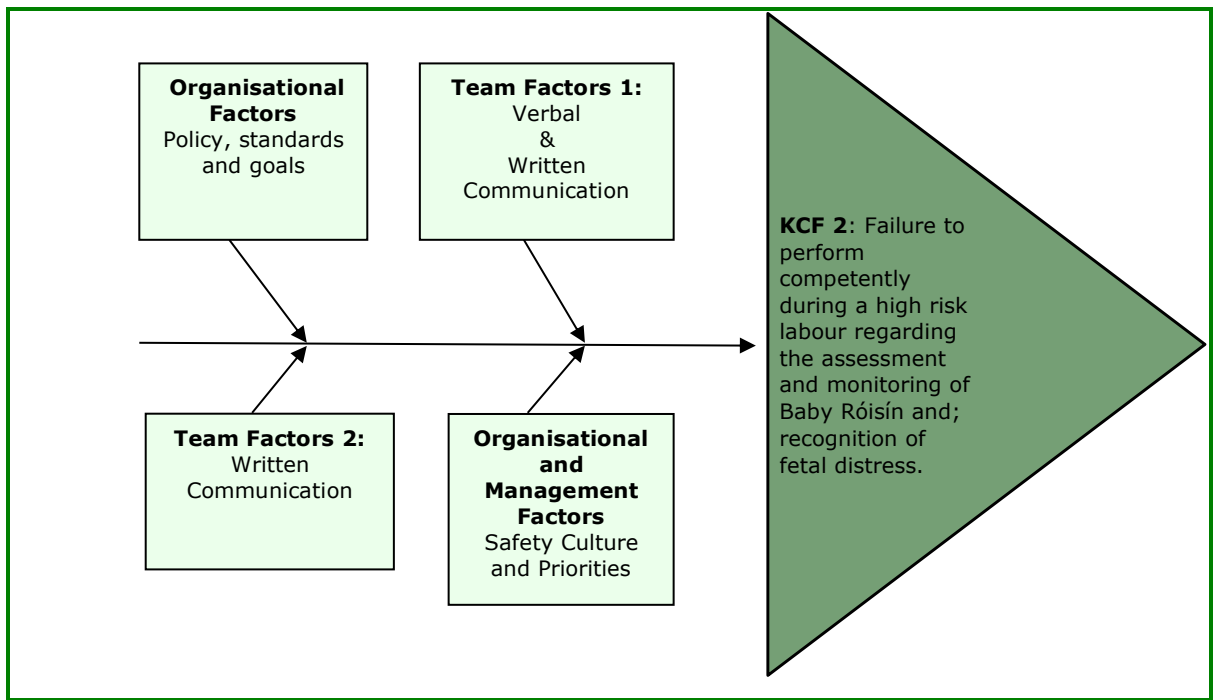
Key Causal Factor 2: Failure to demonstrate proper dedication, thoroughness, professional duty and responsibility as set out in professional regulatory guidelines resulted in;

e) A serious absence of the required level of professional communication expected during a high risk labour and;

f) Baby Róisín being catastrophically injured at birth.

Factors that contributed to Key Causal Factor 2:

Figure 1: Key Causal Factor 2 (KCF 2) and associated Contributory Factors



Contributory Factors and recommendations to address these:

Organisational Factor: Policy, Standards and Goals: Ethical Guidelines

The expectations of Mrs Conroy and her husband were two-fold following admission on 14th November 2001; the doctors and midwives were expected to provide care and treatment with all the knowledge and skill at their command and secondly that they would not do anything to harm Mrs Conroy or Baby Róisín in any manner.

The Medical Council and Nursing & Midwifery Board of Ireland expect medical staff, midwives and nurses to remain focused on delivering high quality safe patient centred care.

The Medical Council is the regulator of the medical profession in Ireland. It maintains the register of medical practitioners licensed to practice. The objective of the Medical Council is to protect the public by promoting and better ensuring high standards of professional conduct and professional education, training and competence among registered medical practitioners.

In addition to establishing and maintaining the register of all medical practitioners in the Republic of Ireland the medical council also has a principle objective which involves specifying standards of practice for registered medical practitioners, including providing guidance on all matters related to professional conduct and ethics.

In 1998 the medical council published Professional-Conduct-Ethics, Ethical Guide, 5th edition¹⁰⁶. This document outlines the importance of communication along with doctor's professional responsibilities.

On 14th November 2001, Consultant Obstetrician and Gynaecologist A left Hospital S1 before 14:00 hours to attend a funeral and outlined that he handed over care to Consultant Obstetrician and Gynaecologist B, by documenting the handover on a white board in the 'labour ward and nurses' station'.

The family stated during the feedback process that Consultant Obstetrician and Gynaecologist A;

'placed his personal wishes above his professional obligations and simply abandoned Mrs Conroy'.

There is no available evidence that any handover took place in relation to this high risk labour between Consultant Obstetrician and Gynaecologist A and Consultant Obstetrician and Gynaecologist B. Consultant Obstetrician and Gynaecologist B did not recall any handover occurring.

Consultant Obstetrician and Gynaecologist A stated at interview that he would have handed over care to Consultant Obstetrician and Gynaecologist B and outlined that he would have documented his absence and the handover of care on a whiteboard and this was the practice in place for 20 years and was consider sufficient.

No handover is documented in Mrs Conroy's healthcare record. As outlined in the chronology of events Consultant Obstetrician and Gynaecologist B has no re-collection of a handover taking place.

The Investigation Team considers the absence of a transfer of responsibility to another consultant of a high risk patient to fall seriously short of what would be expected in the context of patient handover and is not in line with the Ethical Guidelines set out by the medical Council.

Dr. Gardeil stated for the investigation that the priority must always be given to providing safe care, even when this involves the handover of care to another consultant.

Consultant Obstetrician and Gynaecologist A did not review Mrs Conroy's progress and clinical condition prior to his departure. The Investigation Team consider that Consultant Obstetrician and Gynaecologist A left Hospital S1 without making a determination on the safety of both mother and baby to inform a clinical handover to Consultant Obstetrician and Gynaecologist B and potentially prevent any avoidable harm to Baby Róisín.

Consultant Obstetrician and Gynaecologist A must have known when he made the decision, on the 13th of November 2001, to induce labour the following day that he wouldn't be available at all times as he had planned to go to a funeral on the 14th November 2001.

Mrs Conroy and her husband are unyielding that Consultant Obstetrician and Gynaecologist A did not inform them of his unavailability on that day and did not inform them of same on the morning of the induction when he administered the Prostaglandin gel to start the process of labour. They were not informed that Consultant Obstetrician and Gynaecologist B would take over care.

Dr. Gardeil considers that Mrs Conroy was induced, her labour was elective, not an unplanned situation. Although consultants can never guarantee they will be available when their private

¹⁰⁶ <https://www.medicalcouncil.ie/News-and-Publications/Publications/Professional-Conduct-Ethics/Ethical-Guide-5th-ed-1998-.pdf>

patients require obstetrical attention, Consultant Obstetrician and Gynaecologist A was aware that Mrs Conroy was experiencing strong contractions, and prescribed pain relief at 12:30 hours.

It is the opinion of Dr. Gardeil that Consultant Obstetrician and Gynaecologist A elected to leave Hospital S1 for personal reasons without reviewing Mrs Conroy and the wellbeing of Baby Rosin or handing over care to another obstetrician.

Dr. Gardeil views this as a serious missed opportunity to safe guard mother and baby.

Based on the chronology of events Consultant Obstetrician and Gynaecologist A had a number of opportunities to inform the family.

Furthermore, there is no plan of care documented in the healthcare record by Consultant Obstetrician and Gynaecologist A or Midwifery Staff.

Dr. Gardeil also states that Consultant Obstetrician and Gynaecologist A did not communicate clearly, openly and honestly with Mrs Conroy and her husband following Baby Róisín's delivery. This was not in accordance with applicable professional and ethical guidelines.

Following delivery, there were many missed opportunities to meet with the family to discuss Baby Róisín's condition. Mrs Conroy and her husband were never informed of any problems during or indeed after delivery.

Mrs Conroy and her husband strongly believe that, had they known the truth, they could have obtained the help and resources required to initiate a programme of intensive early intervention that could have allowed their child to achieve greater autonomy and a better quality of life.

Mrs Conroy informed the investigation that on the 15th November 2001 Consultant Obstetrician and Gynaecologist A informed them that there was no issue with the fetal heart trace during labour and that nothing could have been done differently, subsequently Consultant Obstetrician and Gynaecologist A has now stated that the fetal heart trace was abnormal and required urgent intervention which is deeply upsetting for the family.

Dr. Gardeil contents that Consultant Obstetrician and Gynaecologist A did not adhere to guidelines from the Irish Medical Council regarding professional conduct and ethics for registered medical practitioners.

Regulatory Considerations Medical

Irish Medical Council, A Guide to Ethical Conduct and Behaviour: Fifth Edition 1998 outlines;

Under Section B: Responsibility to patients (3.6 procedures): patients undergoing procedures or treatment of any sort have the right to be informed as to which doctors or doctors are to be involved.

Under Section C Professional Responsibilities: It is in the interest of both doctors and patients that accurate records are always kept.

Under Section 12 Deputising and locum arrangements (12.1) Absence: Practitioners must ensure that patients receive adequate care when alternative arrangements have been made during absence and ensure a high standard of continuing medical care is provided for their patients. Patients should be informed of this change.

In relation to deputising and locum arrangements the 1998 'A Guide to Ethical Conduct and Behaviour' outlines that practitioners must ensure that patients;

- receive adequate care when alternative arrangements have been made during absence and must satisfy themselves that a high standard of continuing medical care is provided for their patients
- are well informed in advance that in certain circumstances they will be seen by a doctor acting as their deputy for their own doctor.
- An efficient communications link is provided by the Doctor and locum at all times, and sufficient information is available for the locum to do his/her work adequately.
- The registered medical practitioner who agrees to undertake the antenatal and delivery care of a woman should clearly inform her at the time of the booking about the arrangements for delivery.
- Patients undergoing procedures or treatment of any sort have the right to be informed as to which doctors or doctors are to be involved.

Dr Gardeil outlined that it is evident from the chronology of events that the arrangements put in place during Consultant Obstetrician and Gynaecologist A's absence fall seriously short of what was required.

Ethical guidance places a strong emphasis on putting adequate alternative arrangements in place during absence. Consultant Obstetrician and Gynaecologist B was covering for another Consultant Obstetrician and Gynaecologist D in Hospital S1 for planned annual leave on the 14th November 2001.

It was also identified from outpatient records that Consultant Obstetrician and Gynaecologist B reviewed patients in Consultant Obstetrician and Gynaecologist A's Gynaecology clinic that afternoon. The burden of clinical duties for Consultant Obstetrician and Gynaecologist B on the 14th November 2001 was considered by Dr Gardeil to be substantial.

Regulatory Considerations Midwifery

The Nursing and Midwifery Board of Ireland provides for the registration, control and education of nurses and midwives. It holds a register of nurses and midwives, who having undergone the appropriate education, may practice as such. It can also remove nurses and midwives from the register if they are proven to be unfit to practice. The NMBI also provide guidance on practice for Nurses and Midwives.

In September 2001 the NMBI published the 3rd edition Guidelines for Midwives, which sets out a midwife's¹⁰⁷ professional responsibilities.

Ms Hughes in her report states that the standard of record keeping in relation to the history of Mrs Conroy's labour i.e. contractions does not meet the standard of recordkeeping for a midwife.

This aspect of assessment and documentation and communication comprise a vital part in the care and surveillance of a pregnant and /or labouring woman and are necessary for the safe and on-going planning of care relevant to the factors of pregnancy which are individual to the pregnant woman.

Ms Hughes also states that it is reasonable to expect that a Midwife would and should have been able to assess the parameters of labour which include the presence, frequency, strength / duration and regularity of contractions using hand palpation plus or minus the use of a CTG monitor.

Collectively, the recordkeeping and therefore the care provided, in respect of care from about 11.00 hours, but with increasing levels of serious omission of care with time, until the delivery

¹⁰⁷ The Definition of a Midwife (ABA 2001) states that "she must be able to give the necessary supervision, care and advice to women during pregnancy, labour and the postpartum period.....".

of the baby is grossly deficient and does not meet the required standards (An Bord Altranais (NMBI), Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

Overall the midwifery care as recorded and the quality of record keeping was in breach of the Scope of Midwifery Practice as set out in the Guidelines to Midwives 3rd Edn Sept 2001) and specifically, the EEC Directive of 1980 (80/155/EEC) points as follows:

5. "to care for and assist the mother during labour and to monitor the condition of the fetus in utero by the appropriate clinical and technical means"
7. "to recognise the warning signs of abnormality in the mother or infant which necessitate referral to a doctor and to assist the latter where appropriate..."

Dr Gardeil stated for the investigation that healthcare staff must work to the highest standards to deliver safe high quality care for our patients and their families. To do this staff must be supported by their organisation.

Hospital leaders and staff must demonstrate a constant commitment to quality and safety, raise concerns and challenge poor practice.

All staff must be reminded of their professional values on a regular basis. Delivering high quality, safe patient and family focused care does not rely solely on technical and clinical skills, but also involves teamwork, communication, leadership and a culture where health professionals can discuss any issues openly with all those involved in the patient's care, including the patient's and their families.

All patients and their families who access our services expect and require the support of professionals who can empathise and display humanity. These are core principles to good medical, nursing and midwifery practice.

Recommendations linked to this contributory factor:

Recommendation 10 (*Hierarchy of Hazard Controls - Administrative Procedure*):

The Hospital S1 must remind registrants of their professional values in order to ensure compliance with national regulatory guidelines circulated by the Professional Regulatory Bodies.

Action taken since the events described in this report

Response provided from Hospital S1: *The verification of Annual registration of Midwifery and Nursing staff is overseen by the Assistant Director of Midwifery and Director of Midwifery. The hospital ensures that all staff comply with the requirements of the relevant regulatory bodies to assure individual maintenance of codes of conduct and practice. The Hospital ensures all Medical staff are registered with the Medical Council in the relevant discipline prior to and during employment. The introduction of initiatives such as CBAS-I, What matters to me and Values in action programmes enhance communication and staff engagement.*

Recommendation 11 (*Hierarchy of Hazard Controls - Administrative Procedure*):

Hospital S1 must review the National Healthcare Charter in respect of communicating with patients with a view to ensuring that all staff are aware of the requirements of the Charter.

Action taken since the events described in this report

Response provided from Hospital S1: *The national healthcare charter has been adopted by the hospital. The eight principles of access, dignity and respect, safe and effective services, communication and information, participation, privacy, improving health and accountability are being implemented hospital wide to improve patient experience. This includes open disclosure, patient advocacy services, access and information on the hospital complaints procedure and prompt response to complaints. The hospital has provided training for all staff*

in relation to customer care programmes and implementing initiatives such as the CBAS I programme to improve our patient experience. These initiatives have been fully implemented in the maternity services.

Contributory Factors and recommendations to address these:

Team Factors: Verbal Communication

Communication failures are an extremely common cause of unintentional patient harm. Effective and timely communication along with good teamwork is essential to support the delivery of high quality, safe patient care (Leonard M et al, 2004).

Therefore communication between staff should convey the clinical context and use consistent terminology to describe the features of the CTG, the level of concern and the urgency of the situation. CTGs can be classified as normal, suspicious or pathological.

This Investigation identified a number of communication failures, not only between staff but between staff and the family affected.

Consultant Obstetrician and Gynaecologist A must have known when he made the decision, on the 13th of November 2001, to induce labour the following day that he wouldn't be available for the delivery as he had planned to go to a funeral on that day.

It is the opinion of Dr. Gardeil that Consultant Obstetrician and Gynaecologist A failed in his obligations to communicate, monitor and manage Mrs Conroy who was considered to be high risk.

Mrs Conroy and her husband are unyielding that Consultant Obstetrician and Gynaecologist A did not inform them of his unavailability on that day and did not inform them on the morning of the induction when he administered the Prostaglandin gel to start the process of labour.

Mrs Conroy was induced. Her labour was elective, not an unplanned situation. Although consultants can never guarantee they will be available when their private patients require obstetrical attention, Consultant Obstetrician and Gynaecologist A was available but chose to leave the hospital for personal reasons.

It appears Midwife M1 only became aware that Consultant Obstetrician and Gynaecologist A would not be available after 14.00 hours on the day of delivery after she attempted to contact him at 14:00 hours to inform him of Mrs Conroy's labour progression. Midwife M1 stated that she contacted Consultant Obstetrician and Gynaecologist A at 14:00 hours at which point he had left hospital S1 to go to a funeral and instructed Midwife M1 to contact Consultant Obstetrician and Gynaecologist B.

Consultant Obstetrician and Gynaecologist A did not make contact with Consultant Obstetrician and Gynaecologist B following this call from Midwife M1.

At interview, Consultant Obstetrician and Gynaecologist A and Consultant Obstetrician and Gynaecologist B both stated they had no recollection of any handover or communication between them; by phone or otherwise.

There is no documented handover between consultants for this a high risk labour. Consultant Obstetrician and Gynaecologist A outlined that he wrote on a white board that Consultant Obstetrician and Gynaecologist B was covering his clinical practice in his absence from approximately 14:00 hours on the 14th November 2001.

During the feedback process Mrs Conroy and her husband stated that;

'there were so many opportunities to review Mrs Conroy; at 12:30 hours and before Consultant Obstetrician and Gynaecologist A left hospital S1. There was no plan of care

documented in Consultant Obstetrician and Gynaecologist A's absence to ensure the safety of both mother and baby, despite being informed of strong contractions as early as 12:30 hours. He had hoped he would be back in time to deliver Baby Róisín, but how could he know this without the relevant clinical information which can only be achieved from a proper clinical and physical examination before leaving'.

It appears, from an entry made on the CTG paper during Mrs Conroy's labour that Midwife M1 attempted to contact Consultant Obstetrician and Gynaecologist B through the bleep system at approximately 14.34 hours. The entry on the CTG record coincides with a portion of a prolonged bradycardia.

Midwife M1 did not document the nature of her concerns in the healthcare record. It appears this was a single attempt to contact an obstetrician.

Following this attempt to contact, there is no entry in the healthcare records from Consultant Obstetrician and Gynaecologist A or B regarding attendance during labour. There is no entry from Midwife M1 documenting Consultant Obstetrician and Gynaecologist B's response, or lack of response, to bleep or possible instructions given over the phone.

There is also no record of any attempt by the midwife to re-establish contact with Consultant Obstetrician and Gynaecologist A or B.

The Investigation Team have been unable to establish whether Consultant Obstetrician and Gynaecologist B was informed of Midwife M1's concerns.

The family outlined that Mrs Conroy was not reviewed by a Doctor during her labour.

In addition Consultant Obstetrician and Gynaecologist B stated that if she was successfully contacted she would attend the labour ward and would document her review of Mrs Conroy.

All Midwives interviewed stated that Consultant Obstetrician and Gynaecologist B always came promptly to the ward when contacted.

There is no entry from Consultant Obstetrician and Gynaecologist B until after delivery (i.e. a short entry regarding repair of an episiotomy) suggesting that Consultant Obstetrician and Gynaecologist B did not see Mrs Conroy until after 16:32 hours.

Consultant Obstetrician and Gynaecologist A stated at interview that he recalled that Consultant Obstetrician and Gynaecologist B was doing a gynaecology clinic at the time, in hospital S1 and was therefore on the grounds of Hospital S1 making her easily accessible.

At interview Midwife M1 recognised that she should have made additional attempts to contact a Doctor, however she stated she was more concerned about delivering Baby Róisín safely and believed Baby Róisín would actually be 'ok'.

The family outlined during the feedback process that there was no evidence suggesting that Midwife M1 made any attempt to safeguard Baby Róisín.

At interview Midwife M2 stated that in general;

'you always called a Doctor for a type 2 dip, a type 2 dip stays down even after the contraction has passed, a contraction can last between 60-90 seconds, and a Midwife may call a doctor for a type 1 dip, if the doctor did not respond to a call from a Midwife another Doctor would come'.

It is evident from Mrs Conroy's healthcare record that Midwives contacted Consultant Obstetrician and Gynaecologist A on 2 occasions successfully at 12:30 hours and again at 14:00 hours for advice regarding pain relief. It is not clear from the healthcare record whether

Consultant Obstetrician and Gynaecologist A was informed of any concerns Midwife M1 had regarding the absence of liquor at 14:00 hours.

The Investigation Team consider that Midwives are the principal carers for women during labour.

Midwives are trained to recognise abnormalities that may arise during the course of labour and seek the opinion of an obstetrician when this is the case.

It is the opinion of the Investigation Team that, if Midwife M1 recognised fetal heart rate abnormalities, communication of her concerns to an obstetrician failed. If the bleep system was faulty other means of contacting Consultant Obstetrician and Gynaecologist B or, indeed, another consultant or an obstetric registrar would have been available.

The Investigation Team consider that it is not clear from the records whether a Doctor was called because;

- 1) Mrs Conroy was a private patient, therefore one would routinely expect to have a consultant present for delivery;
- 2) Suspected fetal distress or
- 3) A combination of 1) and 2).

Based on the chronology it is evident that staff failed to appreciate and communication the severity of the fetal heart rate abnormalities in the context of a high-risk labour and respond appropriately.

A formal exchange via a recognised communication tool e.g. ISBAR¹⁰⁸ was not available at the time of this incident to be used.

In addition, there was no documented evidence of any communication with paediatricians prior to delivery of Baby Róisín despite abnormalities of the fetal heart rate and the noted absence of liquor seen during labour, which constitutes an ominous feature. Paediatricians were only called after delivery. A senior house officer arrived approximately 3 minutes after birth of Baby Róisín and a Paediatric Registrar 2 minutes later.

Ms Hughes states in her report that it is not clear from the records whether the condition of Baby Róisín was anticipated or not prior to the birth of Baby Róisín by the Midwifery staff caring for Mrs Conroy.

It is not clear from the midwifery records whether the paediatric team were requested to be present for the birth or were called to attend after the birth of Baby Róisín. Such information should have been recorded.

The Investigation Team content that it is good practice to communicate with and have a paediatrician present at the time of delivery for all caesarean sections, all instrumental deliveries, and all normal deliveries where there have been fetal heart rate abnormalities or other abnormalities such as presence of thick meconium or absence of liquor during labour.

¹⁰⁸ A situation communication tool to standardise communications: **I**dentify (Identify yourself, who you are talking to and who you are talking about), **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation.

ISBAR correlates to:

o **IDENTIFY**: Identify yourself, who you are talking to and who you are talking about

o **SITUATION**: What is the current situation, concerns, observation and EWS.

o **BACKGROUND**: What is the relevant background? This helps set the scene to interpret the situation above accurately.

o **ASSESSMENT**: What do you think the problem is? This requires the interpretation of the situation and background information to make an educated conclusion about what is going on.

o **RECOMMENDATION**: What do you need them to do? What do you recommend should be done to correct the current situation?

A review of the Healthcare records indicates that Baby Róisín was not expected to be delivered in poor condition.

The Investigation Team identified an number of opportunities for staff both during and following Mrs Conroy's labour to communicate alternative arrangements during Consultant Obstetricians and Gynaecologist A's absence.

The Investigation Team consider that the tragic outcome for Baby Róisín (oxygen deprivation during labour and its long-term consequences) was caused by a failure to recognise the severity of fetal distress during labour and a failure of effective communication between health professionals.

Action taken since the events described in this report:

The investigation team identified that in July 2013, a Guideline entitled: Guideline for Midwives on when to refer to the Consultant Obstetrician and or On Call Consultant Obstetrician (PHOG005) was published. This guideline made specific Reference to the ISBAR tool and includes the following:

7.1 All midwives must work within their scope of practice and if they require Medical Assistance from the Consultant Obstetrician **THEY MUST NOT HESITATE TO CALL THE ON CALL CONSULTANT OBSTETRICIAN.**

7.3 Any suspicious non reassuring **CTG** or pathological features must be reported to the Registrar using the ISBAR tool as a means of effective communication.

7.4 If the midwife is not satisfied with the recommendation and or decision from the Registrar s/he may contact the Consultant on Call

This guideline also identifies the immediate treatment to be provided by a Midwife in the event of any suspicious non-reassuring CTG. This guideline was due for review in July 2015.

The investigation team identified that a Guideline entitled: Communication among Health Care Professional at Hospital S1 was introduced in May 2015 (Reference PHOG035) which identifies the ISBAR communication tool (Identification, Situation, Background, Assessment and Recommendation) as the mechanism by which information about a deteriorating and/or critically ill patient is to be communicated.

This document identifies the line of communication with the Obstetrician in the event of reporting IMEWS (Irish Maternity Early Warning System) triggers and it states that the staff Midwife caring for the patient is responsible for contacting the relevant Obstetrician whilst the shift leader must contact the senior Obstetrician. This document set out lines of communication which indicate that the line of communication between a Midwife and the Consultant Obstetrician should be via the Shift Leader.

A Guideline entitled Guideline for Midwives on Seeking Advice/Second Opinion from a Midwifery Colleague (PHOG004), published in July 2013, was provided to the investigation team. This guideline sets out both the roles of the Midwife seeking a second opinion and the Midwife providing a second opinion; it includes the use of the ISABR communication tool and the requirement to document the interaction. The guideline states "*Clear documentation of all discussions and information provides evidence of decision-making and is therefore a vitally important aspect of midwifery care*". This Guideline was due for review in July 2015.

In May 2013 the then Minister for Health launched three new guidance documents that had been prepared by the HSE's National Quality and Patient Safety Directorate. One of these documents was entitled "*The Safety Pause*". The purpose of the information sheet was to heighten safety awareness and to assist teams in being proactive about the challenges they face in providing high-quality care for patients. It focused on one question which was "*What*

patient safety issues do we need to be aware of today". The safety pause, if enacted, may in future assist in bringing a safety concern to the attention of the multidisciplinary team.

The investigation team did note in the re-audit of Continuous electronic Fetal Monitoring during Labour, in 2014 it was found that half of the mothers whose case notes were audited had a deviation from the normal CTG during labour. The audit found that an Obstetric Registrar/Consultant was informed about all mothers who had a CTG trace that deviated from the normal during labour.

Recommendations linked to this contributory factor:

Recommendation 12: *(Hierarchy of Hazard Controls - Administrative Procedure):*

That each Hospital Group and Community Healthcare Organisations have a documented escalation process for the escalation of clinical concerns, with clear lines of accountability, operational within their area of responsibility. To be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Recommendation 13: *(Hierarchy of Hazard Controls - Administrative Procedure):*

The ISBAR communication tool should be used when communicating information in relation to deteriorating and/or critically ill patients. Where a situation is deemed to be critical, this must be clearly stated at the outset of the conversation.

Action taken since the events described in this report

Response provided from Hospital S1: *The ISBAR communication tool has been fully implemented in the maternity department. PHOG035 Guideline on communication between healthcare professionals at MRHP maternity department supports the training which has been facilitated by the practice development department reflecting national policies. A clinical handover audit was completed earlier this month.*

Recommendation 14: *(Hierarchy of Hazard Controls - Administrative Procedure):*

That the Guideline on Communication among Health Care Professionals at Hospital S1 introduced in May 2015 (Reference PHOG035) is audited. Non-compliance to be addressed within 3 months of the audit report being finalised. To be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *A guideline on communication has been fully implemented and will be audited within 3 months.*

Recommendation 15: *(Hierarchy of Hazard Controls - Administrative Procedure):*

That all Hospital Groups and Community Healthcare Organisations circulate information on the Safety Pause process for implementation in all Wards/Departments. To be implemented within 3 months of the acceptance of this report by the report's Commissioner.

Action taken since the events described in this report

Response provided from Hospital S1: *Clinical handover has been fully implemented. A safety pause is also now being piloted in the maternity department. A time out policy has been fully implemented in the operating theatre.*

Recommendation 16: *(Hierarchy of Hazard Controls - Administrative Procedure):*

Hospital S1 should implement processes to ensure that the consultant obstetrician and gynaecologist on-call is aware of activity levels, potential high-risk situations and staff concerns.

Action taken since the events described in this report

Response provided from Hospital S1: *The maternity department have fully implemented a daily multidisciplinary handover at nine a.m. The clinical handover policy is used at this meeting using the ISBAR tool. The escalation of care to the Consultant on call, (PHOG005) Guideline for midwives on 'when to refer to the Consultant Obstetrician and/or on call Consultant Obstetrician' has been fully implemented. A clinical activity handover occurs each evening.*

Contributory Factors and recommendations to address these:

Team Factors: Written Communication

Prior to 2001 the importance of good record keeping, and the consequences of poor record keeping, have been highlighted repeatedly by such reports as the Confidential Enquiry into Maternal Deaths (Department of Health et al, 1997), the Annual Report of the Ombudsman (1997), the Confidential Enquiry into Stillbirths and Deaths in Infancy (Maternal and Child Health Research Consortium, 2001) and the Report of the Inspector of Mental Hospitals (Department of Health and Children, 2001).

At the time of this incident there was no HSE healthcare records management policy in place to provide guidance on the level of input, however there was clear guidance available from regulatory bodies. The GUIDELINES TO MIDWIVES 3rd Edition, Nursing and Midwifery Board of Ireland (formerly known as An Bord Altranais) September 2001 suggests the following for Midwifery staff:

Record keeping is an integral part of midwifery practice and a reflection of the standard of an individual midwife's professional practice and is essential for the following reasons:

- a) To document the condition and care of women and babies.
- b) To facilitate communication between the woman and all members of the healthcare team.

At the time of this incident The GUIDELINES TO MIDWIVES 3rd Edition, Nursing and Midwifery Board of Ireland (formerly known as An Bord Altranais) September 2001 suggests the following recommendations for good quality record keeping and which were clearly absent in this case:

- 10.3.1 - All entries should be written in legible handwriting. Midwives who have handwriting that is difficult to read should print their entries.
- 10.3.2 - Entries should be dated and timed using the 24-hour clock. The timing of entries is particularly important in the labour/delivery record and if complications occur.
- 10.3.3 - Entries should be in chronological order.
- 10.3.4 - All signatures should be legible and the surname should be written in full. The use of initials is not acceptable except on charts where there is a designated place to write a full signature and initials and thereafter, in that chart, initials are used e.g. a drug administration record.
- 10.3.5 - If all members of the healthcare team write in the same areas of the chart, the status of each individual making an entry in the chart should be clearly identifiable.
- 10.3.6 - If a midwife consults with or makes a referral to another member of the healthcare team, then that person should be clearly identified by name in the chart. 'Seen by doctor' or 'doctor informed' is not acceptable.
- 10.3.7 - All decisions to take no immediate action but review the situation later ('wait and see') should be clearly documented.
- 10.3.7 - It is best practice to document in the notes as soon as possible after providing midwifery care. However, this may at times prove to be difficult especially in an emergency situation.

There was a series of deficits in the documentation as outlined in this report ranging from minor to serious and grossly deficient.

The deficits in care recorded as provided and the quality of recordkeeping is not consistent with:

- The Definition of a Midwife as endorsed by An Bord Altranais (2001) and previously been amended and adopted by the International Confederation of Midwives (1990),
- the International Federation of Gynaecologists and Obstetricians (1991)
- and the World Health Organisation (1992).

There is an increasing rate of absence of midwifery record-keeping in relation to the monitoring of the condition of the mother and baby in utero in this case from about 11:00 hours but particularly from about 14:20 hours until the time of the birth at 16:32 hours. According to the records which appear in the summary of care, as opposed to being included in the narrative record, Mrs Conroy's cervix reached full dilatation at 15:10 hours however it is unclear as to how this was determined, i.e. whether it was on the evidence of external signs or by a vaginal examination as there are no records detailing either.

There are a number of inaccuracies within the healthcare as outlined in the chronology particularly the absence of any reference to the pathological CTG.

The Investigation Team consider at the time of this incident in 2001 nursing and midwifery care should have been communicated and recorded comprehensively as part of Mrs Conroy's care and treatment.

Recommendations linked to this contributory factor:

Recommendation 17: (*Hierarchy of Hazard Controls - Administrative Procedure*) Implement the HSE Standards and Recommended Practices for Healthcare Records Management V3.0 (May 2011) and make arrangements for an audit of compliance with this standard (and any subsequent standard) within a six-month timeframe and yearly thereafter.

Action taken since the events described in this report

Response provided from Hospital S1: *The Healthcare records committee meets quarterly. The national guideline has been adopted and is implemented at the hospital. A Healthcare records audit was completed earlier this year.*

Organisational and Management Factors: Safety Culture and Priorities

Throughout Mrs Conroy's entire labour and following Baby Róisín's delivery the family stated at interview that they felt isolated and unsupported while at Hospital S1.

The family stated that Consultant Obstetrician and Gynaecologist A must have known when he made the decision, on the 13th November 2001, to induce labour the following day that he wouldn't be available at all times as he had planned to go to a funeral on that day.

Mrs Conroy and her husband are unyielding that Consultant Obstetrician and Gynaecologist A did not inform them of;

- His unavailability on the morning of the induction when he administered the Prostaglandin gel to start the process of labour.

Mrs Conroy's labour was elective and not an unplanned situation; Consultant Obstetrician and Gynaecologist chose to leave the hospital following induction for personal reasons and did not meet Mrs Conroy again for 24 hours after inducing her.

The Investigation Team consider that an effective and safe handover did not take place between Consultant Obstetrician and Gynaecologist A and B in the context of transferring responsibly of a high-risk labouring woman for one Doctor to another.

Based on the records there is no evidence of any handover of care. Consultant Obstetrician and Gynaecologist A outlined that this was the way things were done.

In addition the family stated following a review of the Final Draft Report that;

'If Consultant Obstetrician and Gynaecologist A did in fact handover care to another Consultant Obstetrician and Gynaecologist why was there no evidence of any subsequent meeting between Consultant Obstetrician and Gynaecologist A & B to examine what went wrong.'

'There is no incident form yet staff knew that there was an adverse event. We were always led to believe nothing could have been done differently and I (Mrs Conroy) blamed myself for 9 years thinking this was my fault. There was nothing wrong with my placenta when we got the results back.'

Consultant Obstetrician and Gynaecologist A spoke with Mrs Conroy and her husband on days 1 and 2 after the birth of Baby Róisín. He also reviewed Mrs Conroy on the 22nd January 2002, approximately 10 weeks after delivery.

Consultant Obstetrician and Gynaecologist A did not document what he told Mrs Conroy and her husband with regard to possible explanations for the poor outcome and stated at interview that he had no recollection of what he had said to them.

Based on the feedback from the family Consultant Obstetrician and Gynaecologist A did not inform them of the adverse event and had an number of opportunities to do so. During the feedback on the Final Draft Report the family stated;

'We cannot understand why staff would not tell us that something went wrong during labour that led to Baby Róisín being so seriously injured, why would staff deny her the opportunity to get the proper care and treatment. We didn't find out for 9 years that something had gone wrong and we had to do this ourselves. We know now that information was withheld by staff we placed our trust in. Even staff that were not involved in the labour knew that something happened.'

Mrs Conroy stated at interview that the following morning after Baby Róisín's delivery Consultant Obstetrician and Gynaecologist A said in an unprofessional way that Baby Róisín was delivered unexpectedly flat and unresponsive and that the CTG was 'perfect'. During the process Consultant Obstetrician and Gynaecologist A outlined that he briefly looked at the CTG the following morning.

The family stated Consultant Obstetrician and Gynaecologist A told them that the problem could not have been anticipated and that the oxygen deprivation could not have been prevented as there were no warning signs of fetal distress on review of the fetal heart rate tracing.

Notwithstanding this, Dr. Francois Gardeil stated for the report that it would have taken as little as 2-3 minutes for a Consultant Obstetrician to identify the pathological findings evident on Baby Róisín's CTG.

The intrapartum trace exhibited very concerning pathological findings strongly suggestive of fetal distress which should have been acted upon.

There is no evidence throughout the interview process that any review of the events or debrief to establish what happened on the 14th November 2001.

Baby Róisín's parents consistently stated at interviews and during the feedback process that Consultant Obstetrician and Gynaecologist A told them the poor outcome was due to the cord being around the baby's neck.

During the feedback process Mrs Conroy and her husband outlined their concern regarding these comments from Consultant Obstetrician and Gynaecologist A.

Mr and Mrs Conroy believe they were not treated with dignity and respect at the time. The family believed *'we were not listened to'*.

Mrs Conroy was given the task of bringing the placenta in a bucket to Hospital S2 for further investigation as they were led to believe there was a problem with the placenta; this was deemed by the family to be insensitive and misleading.

Mrs Conroy outlined during the feedback process that she recalled;

'sitting in the front seat of the car holding the placenta in a bucket when my husband was driving me to Hospital S2, I was so upset'.

Mrs Conroy outlined at interview that it was her understanding that there was a problem with the placenta (Mrs Conroy was informed by Consultant Obstetrician and Gynaecologist A that the result placental examination was inconclusive) which led to Baby Róisín's hypoxia.

Mrs Conroy found this to be deeply distressing at the time and stated that she blamed herself for what happened to Baby Róisín for 9 years as the family were never told the truth regarding the adverse event.

Mrs Conroy and her husband later established that the placenta was in fact normal and was not the reason for Róisín being born in very poor condition.

Following the events of 14th November 2001 Mrs Conroy elected to have a c-sectioned for her subsequent two pregnancies for fear of a re-occurrence of another poor outcome during delivery.

The Investigation Team were informed that the results from the placenta examination were later to be reported as inconclusive.

The family outlined throughout the course of the investigation that information had been withheld that resulted in Baby Róisín not receiving timely interventions, they received inaccurate, untruthful and misleading information.

The family stated during the feedback process on the final draft report;

'our experience over the past 16 years, leads us to believe that there was an inherent culture of 'covering up and self-preservation' within this maternity unit at the time of this incident. It was concerning for us that the same staff involved in Róisín's delivery and adverse event continued to work in Hospital S1 for 11 years after the events of the 14th November 2001'. This was for a further 11 years after Róisín's catastrophic injuries'.

In addition the family outlined their *'disbelief'* when staff even after being informed of the deficits in basic intrapartum policy and guidelines, continued to function for years after Baby Róisín's delivery with no acknowledgement that there was a requirement for such guidelines to increase safety.

The family were concerned that there was no evidence of accountability for the failures in delivering appropriate timely care to Mrs Conroy during labour and in the subsequent months and years after Baby Róisín's delivery.

In conclusion the investigation found it to be completely unacceptable to have such an adhoc and hazardous approach to communication, delivery of safe care, along with critical training for CTG use and interpretation.

Mr and Mrs Conroy strongly believe that, had they known the truth, they could have obtained the help and resources required to initiate a programme of intensive early intervention that could have allowed their child to achieve greater autonomy and a better quality of life.

Recommendations linked to this contributory factor:

Recommendation 18: *(Hierarchy of Hazard Controls - Administrative Procedure)*

Maternity unit S1 needs to ensure the implementation and compliance with all national communication policies, procedures and guidelines and an audit of compliance must be carried out within 6 months of implementation and yearly thereafter. In addition the outcome(s) of the audit must be actioned and any emerging trends must be considered at local governance committee meetings.

Action taken since the events described in this report

Response provided from Hospital S1: *The NEWS, IMEWS, PEWS early warning scores have been fully implemented in the hospital. IMEWS and NEWS have been fully implemented in the maternity department and have been audited.*

Incidental Findings

During the course of the investigation, however, the Investigation Team have identified issues that did not impact on the outcome but should be appropriately addressed. The Investigation Team contend that these issues had a significant bearing on the poor experience had by Mrs Conroy and her husband.

- I. Disclosure of information relating to Baby Róisín's condition and issues related to the investigation of adverse incident.
- II. Absence of an Incident Report Form completed in relation to Mrs Conroy's delivery and subsequent injury to Baby Róisín.

Incidental Finding 1: Disclosure of information relating to Baby Róisín's condition and the investigation of this adverse incident.

Mrs Conroy and her husband informed the Investigation Team that the first time they became aware that Baby Róisín was distressed was at delivery when Baby Róisín was brought straight to the resuscitation area of the Labour ward.

Midwife M2 informed the Investigation Team that she was on the corridor of the labour ward at the time Baby Róisín was about to be delivered and responded to the delivery room call bell to assist with Baby Róisín's delivery at approximately 16:30 hours. Midwife M2 stated that there appeared to be some surprise that Baby Róisín was in such poor condition.

There was no evidence found in Mrs Conroy's healthcare record that Midwife M1 or Consultant Obstetrician Gynaecologist B informed Mr and Mrs Conroy that Baby Róisín had been in distress.

Consultant Obstetrician Gynaecologist B was unable to recall specific events relating to Baby Róisín's delivery and appeared to be unaware that there were issues regarding the CTG or indeed that there had been an attempt to contact her earlier.

Consultant Obstetrician Gynaecologist A indicated during the investigation that he could not recall what specific information he communicated to Mr and Mrs Conroy about the condition of Baby Róisín the following day during the ward round which occurred shortly after 09:00 hours on the 15th November 2001.

As previously stated by the family, Consultant Obstetrician Gynaecologist A informed them the morning after Baby Róisín's delivery that the CTG trace from the labour was '*perfect*' and nothing else could have been done, he also suggested that there may have been an issue with the placenta.

During the feedback process the family wished to reiterate that Mrs Conroy blamed herself for Baby Róisín's catastrophic injury at birth as they were led to believe that the placenta may be the problem.

After being informed by Consultant Obstetrician and Gynaecologist A that there was a problem with the placenta Mrs Conroy informed the investigation that she blamed herself for the nine years after Baby Róisín's delivery, believing that she;

'had done something wrong during the pregnancy that led to the placenta failing resulting in Baby Róisín's cerebral palsy....for subsequent pregnancies I requested a caesarean section because of the fear of something happening again. This took away from what should have been joyous occasions for us as a family'.

Dr. Gardeil stated for the investigation that based on the available evidence that Consultant Obstetrician and Gynaecologist A did not communicate clearly, openly and honestly with Baby Róisín's parents, open disclosure did not take place.

It is the opinion of this Investigation Team that Consultant Obstetrician Gynaecologist A did not communicate with the family regarding the possible risks and alternatives regarding the type of continuing healthcare that Baby Róisín may need, including medication, continuing care in hospital, timely and appropriate referrals, long term supports, despite the Midwives concerns the following morning.

It is the opinion of the family that Consultant Obstetrician and Gynaecologist A with-held information that he was obliged to provide the family to ensure the best possible outcome for Róisín. According to the family, Consultant Obstetrician and Gynaecologist A failed in his professional obligations to ensure that Róisín received all appropriate care and treatment delivery, particularly as staff were aware of an adverse event occurring and discussed this with Consultant Obstetrician and Gynaecologist A. The family outlined that this withholding of vital information has had a serious impact on Róisín quality of life and recovery. There were a number of opportunities following delivery to address this issue of non-disclosure on the part of Consultant Obstetrician and Gynaecologist A.

Furthermore conflicting and incorrect medical/clinical information was provided by professional staff to the family the following morning creating unnecessary concern and anxiety for the family.

The family had every right to dispute the information provided to them following Baby Róisín's delivery particularly once it became clear that the information previously provided to them was incorrect.

Dr Gardeil outlined that there was a lack of a governance framework within Hospital S1 resulting in a lack of;

'accountability for continuously improving the quality of services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish,' (DH 2009).

Mr and Mrs Conroy strongly believe that, had they known the truth, they could have obtained the help and resources required to initiate a programme of intensive early intervention that could have allowed their child to achieve greater autonomy and a better quality of life.

In conclusion, Dr. Gardeil outlined that it is clear that many complaints invariably relate to communication or lack of, or indeed discourtesy on the part of a member of staff. Where differences do arise between staff and patients or relatives there is much to be gained and rarely anything to be lost by an expression of regret by the staff member.

Recommendation linked to Incidental Finding 1: (*Hierarchy of Hazard Controls - Administrative Procedure*) Hospital S1 must review the National Healthcare Charter in respect of communicating with patients with a view to ensuring that all staff are aware of the requirements of the Charter.

Action taken since the events described in this report

Response provided from Hospital S1: *The open disclosure policy has been fully implemented in the maternity department. Any issues arising from open disclosure are addressed promptly.*

Incidental Finding 2: Absence of an Incident Report Form completed in relation to Mrs Conroy's delivery and subsequent injury to Baby Róisín.

In terms of an adverse event occurring on 14th November 2001, no incident report form was completed.

The Investigation Team were informed by Midwife M3 (senior midwifery manager) that was no formal incident reporting process in place in relation to capturing maternity incidents.

Incident reporting systems in place in 2001 were based on local arrangements. Incidents were recorded locally and sent in the most part to the Irish Public Bodies Insurance.

From a national perspective the State Claims Agency only came in 2002 in an effort to centralise and take account of the number of incidents occurring for the purposes of claims management initially. This has since evolved into a comprehensive reporting system. It is a legislative requirement for all public services to report adverse events.

In 2001 when an adverse event was identified, the first responsibility was and is to ensure the safety, health and welfare of the person affected. Any care that was required should have been provided without delay and circumstances reported. The incident form should have been completed.

The investigation considers that there was an ethical obligation (as set out in the professional regulatory guidance) to inform the family that an adverse event occurred. Not acknowledging that an incident occurred resulted in no review of events, no debrief of the incident and no learning to prevent further harm to other mothers and babies.

During the interview process Midwife M1 and Midwife M3 stated that they had a discussion with Consultant Obstetrician and Gynaecologist A on the morning of the 15th November 2001 and requested that he tell the family that '*this baby is very sick*'.

Mrs and Mr Conroy outlined their concerns regarding the inadequacy of the local response to this incident which resulted in no sharing of learning from the events. Mrs and Mr Conroy outlined that if incidents are managed appropriately and families are communicated with, there is an opportunity to take early remedial action before more babies are harmed.

The Investigation Team consider that following any adverse incident, the local hospital management team must as part of their governance and assurance role, ensure that incidents are;

- reported in line with policy
- reviews take place in a timely manner, that these are of an acceptable quality, that they result in action plans which ensure that services are safe, fit for purpose and meet identified quality standards and current best practice guidance, and
- they have an identified role to play in the implementation and monitoring of the action plan.

Recommendation linked to Incidental Finding 2: (*Hierarchy of Hazard Controls - Administrative Procedure*) There must be prompt notification by all hospitals when an adverse event is identified whether the actual event occurred in that hospital or another, this must be in line with the HSE Safety Incident Management Policy, 2017.

There must be prompt investigation of safety incidents within the acute hospital services in line with HSE Safety Incident Management Guidelines 2015. The service must implement and carry out Audits of Compliance with Safety Incident Management and Systems Analysis Investigation Guidelines (HSE 2017, HSE 2016 respectively).

Key staff must be trained in Safety Incident Management and Systems Analysis Investigation Methodology i.e. Senior Management Teams must be trained in Incident Management and staff assigned to carrying out investigations must receive systems analysis investigation training.

Action taken since the events described in this report

Response provided from Hospital S1: *A culture of incident reporting is supported by the Quality and Patient Safety department and Management in the hospital. Incident forms are completed and recorded on the National Incident Management System (NIMS). The Senior Incident Management Team is convened as required to review serious incidents.*

Summary of additional concerns that the Family wished to have explored and highlighted which fall outside the scope of this Investigation

- I. The requirement to expedite the provision of support for families affected by catastrophic injuries at birth to ensure the best possible outcome for babies.
- II. The inability to progress a complaint about a Doctor through the Irish Medical Council's Preliminary Proceedings Committee¹⁰⁹ ("the PPC") if a Doctor removes his/her name from the register prior to the complaint being made irrespective of legacy cases or if the Doctor was registered with the Medical Council at the time of the incident.

Requirement to expedite the provision of support for families affected by catastrophic injuries at birth to ensure the best possible outcome for babies.

Dr. Gardeil outlined for the investigation that birth injuries to a baby are very serious and have long term consequences for both the baby and their family.

During the feedback process Mrs Conroy and her husband outlined that consideration must be given to changes to the birth injury compensation process. Mrs Conroy and her husband stated that based on their experience there is a requirement to expedite the provision of support for families affected by catastrophic injuries at birth to ensure the best possible outcome for babies.

Mrs Conroy and her husband informed the Investigation Team that it was 9 years after Róisín's birth when they became aware that an incident occurred concerning Mrs Conroy's care during labour, and that there was a clear lack of accountability in Hospital S1.

The family hope any new birth injury compensation scheme would also have a focus on reducing the numbers of errors on maternity wards causing these life-long struggles for children and their families.

Mrs Conroy and her husband also stated that the priority should also be to ensure when errors occur, families have the support required to ensure both the family and the affected child can live as comfortable a life as possible. The requirement for aggressive intervention regardless of how the injury occurred is essential. Any new system applied here in Ireland should be benchmarked against countries such as Norway, Sweden and New Zealand.

Mrs Conroy and her husband simply wish to ensure children and families who have been affected by brain injuries at birth and who have been let down by the systems in place are fully supported for a long and challenging life ahead.

Action taken since the time of the events described in this report:

Mr Ciaran Breen, Director State Claims Agency informed the investigation for the national recent developments and that the early resolution of clinical negligence cases is now a reality as a result of the introduction of a pre-action protocol.

This was introduced as a result of the Legal Services Regulation Act 2015, which was signed into Law on the 30th December 2015. This Act amends the Civil Liability and Courts Act 2004 and the Minister for Justice intends to introduce the Regulations enabling the adoption of the pre-action protocol in clinical negligence cases by the end of 2017.

¹⁰⁹ The PPC is the committee of the Medical Council that looks into and gives initial consideration to complaints about doctors.

The new pre-action protocol provides for the following:

- The disclosure of medical and other records to persons enquiring into or alleging possible clinical negligence
- The giving of notifications of enquiries into, and allegations of, possible clinical negligence, the acknowledgement of notifications of enquiries and the giving of responses to notifications of allegations
- The time within which records must be disclosed and notifications given and acknowledged or responded to
- The form of requests for disclosure or notifications of enquiries and allegations and acknowledgments of and responses to such notifications
- The disclosure of material relevant to allegations and responses
- Agreements to submit issues for resolution otherwise than by a court

The purpose of the pre-action protocol is to remove the adversarial nature of current clinical negligence cases before the courts and to ensure that cases are settled much more quickly and compensation paid expeditiously.

The protocol sets out very tight time limits between the parties and cases cannot go before the courts until the protocol has been exhausted.

In addition, the SCA has offered families of brain-damaged children, as a result of a clinical negligence event, the choice of having their compensation paid on an annual basis to cover all the care and other expenses so that families do not have to worry about "lump sum" payments and the possibility that the lump sum might run out before the anticipated life expectancy.

Finally, the SCA is working with the HSE to explore the provision of care packages to families in infant brain injury cases even when the cause of the brain injury has not been established.

From the family's point of view while this is an improvement there is still no provision for accountability.

The inability to progress a complaint about a Doctor through the Irish Medical Council's Preliminary Proceedings Committee¹¹⁰ ("the PPC") if a Doctor removes his/her name from the register prior to the complaint being made irrespective of legacy cases or if the Doctor was registered with the Medical Council at the time of the incident¹¹¹.

As previously outlined in this report the family voiced their disappointment and upset to the Investigation Team as they were not made aware of the incident relating to Baby Róisín until 9 years after the events of the 14th November 2001. Following the discovery that an incident occurred, the family commenced legal proceedings in 2010.

On 11th March 2014, Mrs Conroy and her husband submitted a formal complaint to the Medical Council against Consultant Obstetrician and Gynaecologist A. Mrs Conroy and her husband outlined their concern when they were informed by the Medical Council that the complaint they made to the Council could not be progressed as Consultant Obstetrician and Gynaecologist A was not registered with the Medical Council at the time of the complaint. Having checked the Register, it was noted by the Council that Consultant Obstetrician and Gynaecologist A withdrew from the Register on 8 May 2012. The family stated that this was during their legal proceedings.

¹¹⁰ The PPC is the committee of the Medical Council that looks into and gives initial consideration to complaints about doctors.

¹¹¹ The Investigation Team wish to highlight that while this incidental finding falls outside of the scope of the investigation, the issue in question does relate to the events that occurred on the 14th November 2001. In addition the family during the investigation process requested that this finding be contained within this report as it caused them significant upset.

Mrs Conroy and her husband were informed that in order for the Medical Council to consider any complaint about a medical practitioner, the practitioner must be currently registered with the Medical Council however if it is the case that Consultant Obstetrician and Gynaecologist A's name is restored to the Register of Medical Practitioners, the Medical Council outlined the Medical Council will be in contact in relation to the complaint.

Feedback from the Medical Council (Appendix E) states that the Medical Council is a statutory body, governed by the Medical Practitioners Act 2007; Part 7 of the Medical Practitioners Act deals with complaints concerning registered medical practitioners. The legislation, under which the Medical Council operates, enables the Medical Council to consider and investigate complaints against medical practitioners registered with the council at the time of receiving a complaint.

Mr Kennedy, Director of Regulation and Professional Standards, at the Medical Council informed the investigation;

'it is simply not open to this office, under the law, to open a complaint against any practitioner who is not listed on our register at the time of receipt of complaint...matters regarding legal proceedings or civil claims against any practitioner are a separate matter to complaints considered by this office. Whether there are any legal proceedings in being against a practitioner, is a matter to which this office will have no knowledge, or regard, as such civil claims are a matter overseen by the civil courts, and not one which a regulator is involved in.'

In relation to international practice, the General Medical Council in the UK requests that all practitioners apply in writing to have their name withdrawn from the register to ensure that practitioners do not withdraw to avoid investigation, consideration is also given at this time to any pending legal proceedings and/or complaints made against a practitioner.

The documents required by the GMC for voluntary erasure include a declaration that the practitioner is unaware of any matter that might lead the GMC to investigate fitness to practise.

Mr Kennedy informed the investigation;

'In relation to voluntary withdrawals from the register I don't believe the Council's process is different or appreciably different from that of the GMC's.

'Like the GMC, the Council's procedure requires a practitioner to apply to voluntarily withdraw their name from the register under section 52 of the Medical Practitioners Act 2007. A practitioner cannot withdraw their name if there is a complaint in being at the time. If a practitioner wishes to be restored to the Register at any time, following a voluntary withdrawal, they can apply to do so but must complete the restoration process'.

While a HSE investigation has been conducted, using systems analysis methodology; this is not a peer review process; evidence of poor professional conduct must be communicated to the relevant regulatory body for further consideration.

At the request of Mrs Conroy and her husband, the following commentary from the family has been included;

'We believe we have been denied the opportunity to have Mrs Conroy's care and treatment investigated by the Medical Council as a result of the current legislative requirements which appears to fall short in terms of medical practitioners being held to account for their practice once they withdrawn from the register'.

Dr. Gardeil outlined that it is understandable why the inability to progress a complaint against Consultant Obstetrician and Gynaecologist A to the Medical Council is frustrating for the parents.

According to the Medical Practitioners Act 2007 the Medical Council cannot consider a complaint if the practitioner is not registered at the time the complaint is received. The family informed the investigation that the Consultant withdrew from the Register in 2012 during legal proceedings and as a result, he can't be held to account for possible Poor Professional Performance or Professional Misconduct.

Dr Gardeil suggests the UK legislation offers the opportunity to investigate legacy issues. This opportunity may be in the interest of the public.

This will take a ministerial order for the legislation may need to be amended. The family have outlined that they will seek a meeting with the Minister for Health to progress this recommendation.

Recommendation: *(Hierarchy of Hazard Controls - Administrative Procedure)*

Based on feedback from the family, it is the opinion of the Investigation Team and the family that a mechanism for reviewing poor professional performance must be considered in cases where there are a number of legacy cases against a practitioner who has withdrawn from the register.

Dr. Gardeil contends that the UK legislation offers the opportunity to investigate legacy issues. This opportunity may be in the interest of the public.

The Investigation Team cannot be prescriptive with respect to how this can be achieved however the adequacy and appropriateness of mechanisms currently in place under existing legislation to consider and/or investigate complaints against a practitioner not on the register does require reflection.

A change to the legislation will be required to address this concern. Through the Commissioner the family will request a meeting with the Minister for Health to explore this recommendation further.

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Appendix A: 51449 Terms of Reference

Terms of Reference 51449

Introduction

These are the terms of Reference for an investigation commissioned by the CEO, Dublin Midlands Hospital Group into a complaint by the parents of a baby regarding the circumstances of her birth at the Midlands Regional Hospital Portlaoise in 2001

Purpose

The purpose of this investigation is to:

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

Scope of the Investigation:

The time frame of this investigation will be from the 10/11/2001 until the 30/11/2001. The review will consider the care provided to the woman from her admission to the Midland Regional Hospital Portlaoise on the 14th November 2001 until her baby's birth on the 14/11/2001.

The Investigation Team members

Membership of the investigation team includes:

- Ms Deirdre O Keeffe, Lead Investigator
- Ms. Susan Temple, Group Quality and Safety Manager, Dublin Midlands Hospital Group
- Dr Francois Gardeil Independent Consultant Obstetrician and Gynaecologist

Through the Investigation Commissioner, the Investigation Team will:

- Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Lead Investigator will convey the details of these safety concerns to the Investigation Commissioner as soon as possible.

Investigation method

The investigation will follow a systems analysis methodology as per the HSE Guidelines for the Systems Analysis of Incidents (2015) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures.

The investigation will commence in April 2016 and will be expected to last for a period of 3 months approximately, provided unforeseen circumstances do not arise.

Following completion of the investigation, an anonymised draft report will be prepared by the investigation team outlining the chronology, findings and recommendations. All who participated in the investigation will have an opportunity to give input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Investigator will ensure that the Investigation Team apply a quality assurance process to ensure compliance of the investigation process with the systems analysis guidelines prior to delivery of the final report to the Investigation Commissioner. The Investigation Commissioner will seek assurance that the quality assurance process has been completed.

The anonymised report may be published. There is currently no specific legislation and common law dealing with the protection of individual data, confidential data, data disclosed on the basis of confidence etc and no guarantee can be given by the HSE that information received as part of an incident investigation will be protected from legal discovery or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Investigation Commissioner.

The Investigation Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred implement the recommendations of the investigation report. The Investigation Commissioner is responsible for communicating nationally applicable recommendations to the relevant National Director(s) for national implementation.

Communication Strategy for the Investigation

A communication strategy will be determined. Ms Loretta Jenkins, Quality and Patient Safety Risk Manager, will be appointed for the purpose of communicating information pertaining to the investigation and to the family affected by and involved in the complaint.

Dr Susan O' Reilly
CEO Dublin Midlands Hospital Group

Reference:

HSE Safety Incident Management Policy (2014, and any subsequent revisions) HSE Guideline for Systems Analysis Investigation of Incidents (2015)

Appendix B: Consultant Obstetrician and Gynaecologist Disclaimer

Consultant Obstetrician - Gynaecologist

CARE OF OBSTETRIC PATIENTS

1. Patients are accepted on referral from their Family Doctor.
2. While every effort will be made to be in attendance at the delivery, this may be physically impossible at the time. No Guarantee can be given to attend the delivery.
3. When I am unable to attend a delivery, a Consultant colleague will be available for the delivery.
4. Normal labour and delivery is conducted by the Midwife.
5. Booking Fee is payable at 25 weeks gestation.
6. As Private Medical Insurance only gives a Grant-in-Aid, you are responsible for the full fee.

Date of Agreement:

Signature:

Appendix C: Report Dr. Francois Gardeil, Consultant Obstetrician and Gynaecologist, Wexford General Hospital, Wexford

REVIEW. TRACKING NUMBER 51449

Key Points:

- The safety of both Mother and Baby is paramount and must be above all personal considerations.
- It is unacceptable to state that there is no requirement to intervene with a midwife's practice, practically in high risk cases. Staff must work as a team not as individuals to deliver the best possible outcome for all.
- There were too many missed opportunities to establish how labour was progressing. Mrs Conroy could have been reviewed at 12:30 hours following a pain relief prescription for strong contractions and prior to Consultant Obstetrician and Gynaecologist A leaving the Hospital.
- Consultant Obstetrician and Gynaecologist A believed he would be back in time for the delivery however he could not be certain of this as he never reviewed Mrs Conroy and therefore he did not have a complete clinical impression of Mrs Conroy's condition/progress prior to leaving Hospital S1. This was a serious misjudgement on Consultant Obstetrician and Gynaecologist A's behalf.
- Consultant Obstetrician and Gynaecologist A stated he handed over care. There is no evidence of this handover. Handover means that you must provide emergency services and any care that may be required by those for whom you hold clinical responsibility. When alternative medical care is in place, you should transfer the patient's medical records without delay. You should provide medical information, normally with the patient's knowledge and agreement, to another member of the profession when requested.
- It would appear that Consultant Obstetrician and Gynaecologist B was left to cover the wards, labour ward with a high risk patient, outpatient clinics and work on call. There is no evidence to suggest that Consultant Obstetrician and Gynaecologist A returned to hospital S1 that evening.
- No review of care in the immediate aftermath even though staff were aware that an incident occurred. This is particularly important if we are ever to find out what went wrong and learn from incidents
- Cons A chose to leave hospital S1 for personal reasons.

KEY CAUSAL FACTORS:

1 *Failure to recognise fetal distress in labour*

Mrs Conroy's pregnancy progressed normally up to the 13th of November 2001. On that date, Mrs Conroy was 9 days overdue and Cons A performed a scan in his consulting rooms that showed a decreased amount of amniotic fluid. This was a concerning finding and Cons A made the correct decision to induce labour the following day, Wednesday the 14th of November 2001.

Induction of labour is associated with increased risk compared to labour that starts spontaneously. The decreased amniotic fluid volume noted on scan in this case was an additional risk factor. Induction of labour for Mrs Conroy was a high-risk situation. Continuous fetal heart rate monitoring in labour, together with monitoring of the frequency and duration of contractions (the cardiotocograph) should always be performed in high-risk labours. In Mrs Conroy's case, continuous fetal heart rate monitoring was not commenced until 14.14 hr although Mrs Conroy had been having severe labour pains since 11.00 hr, 2 hours after intravaginal administration of Prostaglandin gel. The frequency of uterine contractions was not electronically recorded.

Non-reassuring features were evident on the fetal heart rate tracing from the beginning of the recording with decelerations (footnote 1) and reduced variability (footnote 2). It is probable that the tracing would have shown abnormalities earlier on if monitoring had been performed. Fetal heart rate

became pathological at 14.32 hr with a prolonged bradycardia (footnote 3) down to a heart rate of 70 beats per min that lasted for 7 minutes. After this episode, and until delivery of Baby Róisín at 16.32 hr the fetal heart rate showed persistent abnormalities. There were recurrent decelerations, probably of the variable type but the absence of recording of the uterine contractions makes analysis very difficult.

The CTG is used in an attempt to identify babies at risk of hypoxia (lack of oxygen) during labour. Fetal heart rate monitoring is only of value when abnormalities are recognised and acted upon. It appears, from an entry made on the CTG paper, that Mid M1 contacted Cons B through the bleep system at approximately 14.34 hr. She did not document the nature of her concerns in the notes. It appears this was a single attempt to contact an obstetrician. The Investigation Team have been unable to establish whether Cons B was actually informed of the concerns of the midwife and unable to establish whether Cons B attended the labour ward before delivery of Baby Róisín or soon afterwards. There is no entry in the notes from Cons B regarding attendance during labour. There is no entry from Mid M1 documenting Cons B's response, or lack of response, to bleep or possible instructions given over the phone. If Cons B attended soon after 14.34 hr and assessed the situation, it is the opinion of the Review Team that she failed to appreciate the severity of the fetal heart rate abnormalities in the context of a high-risk labour.

It is the opinion of the Investigation Team that Baby Róisín suffered from oxygen deprivation brought about by the uterine contractions. Fetal distress was probably precipitated by uterine hyperstimulation. Labour was extremely fast for a first time mother. As documented Mrs Conroy went from 1 cm at 14.00 hr (however based on feedback from Mrs Conroy, she was told by the midwife that she was 4cm at 14:00 hours which was most likely to be the case) to full dilatation at 15.10 hr, i.e. 70 minutes. Hyperstimulation can explain the adverse outcome; when the uterus contracts, the flow of blood and oxygen in or out of the placenta slows or stops. Between contractions the placenta is able to recharge with a fresh supply of blood. Hyperstimulation reduces the ability of the placenta to replenish its oxygen supply and can, therefore, lead to fetal distress. Hyperstimulation is most common with the use of Oxytocin but it can also occur with Prostaglandin E2 (Prostin). In addition to excessive uterine activity, the cord was noted to be tight around Baby Róisín's neck at the time of delivery. This fact probably contributed to impaired delivery of oxygen to Baby Róisín during labour and delivery.

It is probable that signs of fetal distress would have been apparent before 14.14 hr if the fetal heart had been monitored from 11.00 hr approximately when Mrs Conroy started to have strong contractions. Given that appropriate monitoring of the fetal wellbeing only started at 14.14 hr in this case, the Investigation Team contend that a decision to proceed to an emergency caesarean section should have been made at approximately 14.35 hr when the CTG was grossly abnormal, with the aim of delivering Baby Róisín within 30 minutes. Although it is impossible to know what the outcome would have been, on the balance of probabilities it is likely that Baby Róisín's condition at birth would not have been as serious as it was.

Contributory factors

- *Under "task and technology". There was no guideline at the time of the incident in 2001 with regard to fetal heart rate in labour and monitoring of contractions and parameters/indicators that can assist staff in conducting an overall assessment of the condition of the baby.*
- *Under "individual". There was very limited training offered to staff regarding interpretation of CTG findings.*

Recommendations to address contributory factors

- *Maternity unit S1 should develop local policy adapted from national guidelines with regard to intrapartum fetal heart rate monitoring and ensure appropriate compliance (RCPI/HSE intrapartum fetal heart rate monitoring guideline).*
- *The investigation Team recommend that Maternity unit S1 implement and monitor certified mandatory training and refresher training in CTG interpretation for all clinical staff.*

The investigation Team acknowledge that the above recommendations may have been implemented already given the historical nature of this investigation.

2 Failure of communication between care providers

Cons A had made the correct decision to induce labour and administered Prostaglandin vaginal gel himself at 09.00 hr on the 14th of November 2001. Midwives contacted him on 2 occasions afterwards, at 12.30 hr and 14.00 hr for advice regarding pain relief.

At 14.00 hr there was a missed opportunity for Cons A to phone Con B directly and request that she review Mrs Conroy and for Con B to take over care.

Midwives are the principal carers for women in labour. They are trained to recognise abnormalities that may arise during the course of labour and seek the opinion of an obstetrician when this is the case. Mid A must have known that Cons A was not available after 14.00 hr as she did not attempt to contact him at 14.34 hr. Instead, she bleeped Cons B, according to the note she made on the CTG paper. She did not document the nature of her concerns and did not document that Cons B attended. There is no entry from Cons B until after delivery (notes regarding repair of an episiotomy). Cons A stated at interview that he recalled that Cons B was doing a gynaecology clinic at the time, in hospital S1. She was on-site.

It is the opinion of the Review Team that, if Mid M1 recognised fetal heart rate abnormalities, communication of her concerns to an obstetrician failed. If the bleep system was faulty other means of contacting Cons B or, indeed, another consultant or an obstetric registrar would have been available. In addition, there was no documented evidence of communication with paediatricians prior to delivery of baby Róisín despite abnormalities of the fetal heart rate and the noted absence of liquor seen during labour, which constitutes an ominous feature. Paediatricians were only called after delivery. A senior house officer arrived approximately 3 min after birth of Baby Róisín and a paediatric registrar 2 minutes later.

It is good practice to have a paediatrician present at the time of delivery for all caesarean sections, all instrumental deliveries, and all normal deliveries where there have been fetal heart rate abnormalities or other abnormalities such as presence of thick meconium or absence of liquor during labour. It is impossible to know whether the outcome would have been better if there had been no delays in initiating medical resuscitation.

Contributory factors

- *Under "team". There were no guidelines for the escalation of concerns based on clinical "triggers".*

Recommendations to address contributory factors

- *Hospital S1 should develop an evidence-based guideline for the escalation of concerns based on clinical triggers. A guideline regarding communication between midwives/obstetricians and paediatricians should be developed.*
- *Hospital S1 should implement processes to ensure that the consultant obstetrician and gynaecologist on-call is aware of activity levels, potential high-risk situations and staff concerns.*

CARE DELIVERY ISSUES:

The tragic outcome for Baby Róisín (oxygen deprivation during labour and its long-term consequences) was caused by a failure to recognise the severity of fetal distress during labour and failure of effective communication between health professionals. In the course of the investigation, however, the Review Team have identified serious care delivery issues that did not impact on the outcome but should be appropriately addressed. The Review Team contend that these issues had a significant bearing on the poor service experienced by Baby Róisín, Mrs Conroy and her husband.

1 Failure by Cons A to communicate clearly with Baby Róisín's parents

Cons A saw Mrs Conroy and her husband on days 1 and 2 after the birth of Baby Róisín. He also reviewed Mrs Conroy on the 22nd of January 2002, approximately 10 weeks after delivery. Cons A did not document what he told Mrs Conroy and her husband with regard to possible explanations for the poor outcome and stated at interview that he had no recollection of what he had said to them.

Baby Róisín's parents consistently stated at interviews that Cons A told them the poor outcome was due to the cord being around the baby's neck. In addition, he told them that the problem could not have been anticipated and that the oxygen deprivation could not have been prevented as there were no warning signs of fetal distress on review of the fetal heart rate tracing.

Mrs and Mr Conroy strongly believe that, had they known the truth, they could have obtained the help and resources required to initiate a programme of intensive early intervention that could have allowed their child to achieve greater autonomy and a better quality of life.

The Review Team contend that Cons A did not communicate clearly, openly and honestly with Baby Róisín's parents. Open disclosure did not take place. Cons A did not adhere to guidelines from the Irish Medical Council regarding professional conduct and ethics for registered medical practitioners.

In addition, the Review Team identified a missed opportunity for communication with Baby Róisín's parents:

- Cons A must have known when he made the decision, on the 13th of November 2001, to induce labour the following day that he wouldn't be available at all times as he had planned to go to a funeral on that day. Mrs Conroy and her husband are adamant Cons A did not inform them of his unavailability on that day and did not inform them of same on the morning of the induction when he administered the Prostaglandin gel to start the process of labour. Mrs Conroy was induced. Her labour was elective, not an unplanned situation. Although consultants can never guarantee they will be available when their private patients require obstetrical attention, Cons A should have informed Mrs Conroy and her husband of his unavailability on the day of planned induction of labour. Cons A's priority at all times should have been his patients safety and that of her baby.

It appears Mid M1 knew Cons A would not be available after 14.00 hr on the day of delivery after she contacted him at 14.00 hr. It is probable he had told her. At interview, Cons A and Cons B both stated they had no recollection of communication between them.

Recommendations

- *Maternity unit S1 needs to ensure the implementation and compliance with all national communication policies, procedures and guidelines.*
- *Open Disclosure Policy (HSE 2013).*

2 Poor documentation

The very poor quality of documentation made the investigation particularly challenging. Recollections of staff members cannot be expected to be particularly accurate 15 years almost after the birth of Baby Róisín. As a result, some important facts that happened during the course of labour may never be discovered.

Recommendation: implementation of HSE policies regarding documentation in healthcare records

Appendix D: Report Dr. John F. Murphy, Dept. Of Neonatology, The National Maternity Hospital, Dublin

Thanks for asking me to provide a medical report on the above Baby Róisín, DOB 14/11/2001. My report is based on the copy of the case notes provided to me.

Antenatal History:

Mary Conroy aged 31 years (DOB 27/8/1969) booked for antenatal care on 3/5/01. She was 13 5/7 weeks since LMP. This coincided with the scan which dated the pregnancy at 14 3/7 weeks. There is a comment stating 'active fetus'. Mary was a Primigravida.

Between 17/7/01 and 13/11/01 she attended the hospital antenatal clinic 8 times. At the last visit on 13/11/01, she was Term + 9 days. The note at that time stated----scan, active fetus, diminished liquor, Induce.

Labour:

14/11/01 @9:00am. Term + 10 days. Admitted for induction, diminished liquor. Cephalic presentation, vertex engaged. Fetal heart 145/min.
Cervix unfavourable. Prostin Gel inserted.

9:15 – 9:40am: CTG recorded.

14/11/01 @ 11:30am: Strong contractions. Fetal heart 138/min. Cervix very posterior, unable to reach.

14/11/01 @ 12:30pm: Strong contractions. Cyclimorph 10mgs

14/11/01 @14:00pm: Distressed ++ Cervix very posterior, 1 cms dilated. No membranes felt. Fetal heart 142/min.

Consultant Obstetrician and Gynaecologist A phoned-----suggested epidural-----refused by patient

14/11/01 @14:45----contractions 1:2 strong----VE 6 cms dilated---no membranes felt or liquor seen

Second Stage:

Cord around neck tightly x2

No liquor seen until after crowning of baby's head

-----some old brown meconium.

Placenta and cord meconium stained

First Stage 5 hrs 55 mins

Second Stage 1hr 22 mins

Third Stage 13 mins

The Infant:

Time of Birth 16:32

The Infant's APGAR scores were:

1 @ 1 Min

4 @ 5 Mins

8 @ 10 Mins

At 1 Min----Heart Rate <100 min, Respiratory Effort 0, Tone 0, Reflex irritability 0, Colour 0

At 5 Mins-----Heart Rate >100, Respiratory effort 0, Tone 0, Reflex irritability 0, Colour 1

At 10 Mins----Heart Rate >100, Respiratory Effort regular, Muscle Tone moderate, Reflex Irritability moderate, Colour pink

The Resuscitation:

Cardiac Compressions until heart rate increased
Administered Naloxone 400 ug at 3 mins and at 10 mins
Bag and mask ventilation until intubated at approx. 5 mins
Improved. O2 saturation 100% in RA.
Extubated at 35 mins of age.

14/11/01 @ 18:10 Blood Gas:
pH 7.09
PO2 9.34
Pco2 5.45
HCO3 12.2
BE -17.0

14/11/01 @ 10:15pm----- Smacking of lips
Extensor moves of upper limbs
Episodes individually of 10 sec duration but come in runs 4-5 together
2nd dose Phenobarbitone given

14/11/01 @ 11:45----- Recurrent seizures +
Passed small amount of urine----RBC ++, Protein+
D/W Consultant on Call
3rd dose of Phenobarbitone (Total 30mgs/kg)
Transfer to Hospital S2
The transfer to Hospital S2 took place on 15/11/01 @ 2:00

26/11/01 Presentation:

There is a note referring to the transfer of baby Róisín back from Hospital S2 to Portlaoise.
There is a comment that 'continues to have abnormal movements, fisting + some axial hypotonia'
MRI scan in Hospital S2 showed increased echogenicity of the thalami.

27/11/01---- Hypotonia especially central----head lag +---poor suck--
29/11/01----Stable----taking bottle/ tube feeds
30/11/01----Try to feed with bottle only
1/12/01----Feeding improved----all bottle feeds-----had jerky movements of LUL yesterday
5/12/01-----Bottle feeding well-----tone improving
6/12/01----Stable----feeding well----home as planned

Summary of the Case:

Mrs Conroy was a 31 year old primigravida. She was Term + 10 days. She was admitted for induction because of reduced liquor. It was a prostin induction. By 2 hours she had developed strong contractions. The fetal heart rate was normal. There was no sentinel event. An epidural was considered for maternal distress but not subsequently administered.

The infant was unexpectedly flat at birth. The umbilical cord was wrapped around her neck. She did not breathe, her heart rate was slow, she was blue, she was limp, and there was no reflex response.

The Paediatricians were not present at the delivery. They were called after the birth. A full neonatal resuscitation was commenced. Baby Róisín received cardiac compressions, bag and mask ventilation, endotracheal intubation, naloxone injections (two). The infant responded to the resuscitation measures. The endotracheal tube was removed after 35 mins.

The infant developed abnormal neurological signs over the next few hours. There was seizure activity with lip smacking, extensor limb movements, and hand fisting. The seizures were treated with 3 successive doses of Phenobarbitone (30mgs/Kg).

The infant's urine contained both RBCs and protein.

At 7 hours old the Paediatricians decided to transfer Baby Róisín to Hospital S2 for further management.

I can't comment on the infant's progress in Hospital S2 as these notes weren't available to me. She was transferred back from Hospital S2 on 26/11/01. The notes indicate that remained neurologically abnormal. Her feeding was poor, there were abnormal normal movements, and head lag. Her brain MRI was abnormal showing increased echogenicity of the thalami. Feeding improved over the next few days and she was discharged on 6/12/01.

I've looked through the Portlaoise case notes in relation to Róisín's subsequent progress and outcome. There is a comprehensive letter written by Dr. J, Consultant Paediatrician on 15th June 2015. Róisín was thirteen and a half years old at that time. The letter summarises Róisín's medical problems as follows:

1. Cerebral Palsy---Dystonic type
2. Severe intellectual disability
3. Strabismus (squint)
4. Right subluxating hip
5. Nutritional and feeding difficulties
6. Cough aspiration with thick puree

Opinion:

Mrs Conroy was induced at Term + 10 days. There was reduced liquor. There were no other complications during the pregnancy.

The contractions were strong but there was no sentinel event during the labour. The infant was unexpectedly flat at birth with no respiratory effort and a slow heart rate. The infant was neurologically compromised at birth as manifested by hypotonia and absent reflex response.

The cord was wrapped twice around the infant's neck (nuchal cord). Most commentators are in agreement that a nuchal cord is usually an incidental finding rather the cause of asphyxia.

The infant was unexpectedly flat at birth. The Paediatricians were called after the birth. The resuscitation undertaken was satisfactory and correct. The infant was administered cardiac compressions because of the initial slow heart rate. She was administered bag and mask ventilation to improve her oxygenation. In view of her absent respiratory effort she was intubated and given respiratory support. She responded to these resuscitation measures and at age 35 mins she was sufficiently stable to be extubated.

Following admission to the SCBU her clinical and neurological status were monitored. Abnormal neurological behaviour including seizures was noted. She was treated with IV Phenobarbitone. In view of her persistent abnormal neurological behaviour the decision was made to transfer her to Hospital S2 for tertiary neonatal care. At Hospital S2 a brain MRI is reported as showing increased Thalamic echogenicity. This finding is in keeping with acute hypoxic-ischaemia. Baby Róisín's subsequent neurological disability is in keeping with this MRI finding in that she has dyskinetic cerebral palsy.

Baby Róisín's clinical condition is in keeping with Neonatal Encephalopathy. Her condition was poor at birth with low APGAR scores. Her blood gas taken at 1hr 38 mins showed acidosis. She developed neonatal seizures. Her urine contained both RBSs and Protein which is indicative of hypoxic kidney involvement. The brain MRI findings were in keeping with acute asphyxia.

She subsequently developed dyskinetic cerebral palsy with neurodevelopmental delay.

Summary:

Baby Róisín is a case of perinatal asphyxia leading to severe neonatal encephalopathy. She has had an abnormal neurological outcome with severe motor and intellectual disability.

The infant was severely compromised at birth with a slow heart rate, absent respirations, severe hypotonia, absent reflex response, and poor colour.

The Paediatric resuscitation was satisfactory and of good standard. The infant's slow heart rate was treated with cardiac compressions. The infant's poor respiratory effort was treated with bag and mask. When the poor respiratory effort persisted, the infant was intubated and commenced on positive ventilation. The measures worked and the infant was breathing spontaneously by 35 minutes.

On admission to the SCBU the infant was correctly monitored for abnormal neurological behaviour. The initial seizures were treated correctly with IV Phenobarbitone. In view of the significance of the infant's abnormal neurological behaviour a decision was made to transfer her to Hospital S2 for tertiary care.

Conclusion:

The resuscitation and management of Baby Róisín after her birth was satisfactory and of good standard. Her care in the SCBU was appropriate. The decision to transfer her to the Hospital S2 was correct.

Yours Sincerely

Dr. John F. Murphy
Consultant Neonatologist
The National Maternity Hospital
Holles Street
Dublin 2

Appendix E: Midwifery Report

Midwifery Report from Patricia Hughes

Date: 28th July 2017

Subject Matter: *"to review a clinical chart including CTGs (Incident No. 51449)".*

INTRODUCTION

1.0 As a Midwife, I have been requested *"to review a clinical chart including CTGs (Incident No. 51449)"*.

1.2 Summary of the Case

(as derived directly from a copy of the original healthcare records).

1.2.1 This case concerns a 31-year-old married woman, Mrs Conroy, in her first pregnancy who attended Consultant Obstetrician and Gynaecologist (Cons OandG) A as a private patient, and the maternity unit at Hospital S1 for care during pregnancy, labour /birth and the postnatal period.

1.2.2 Mrs Conroy worked as healthcare worker and gave up work midway through her pregnancy due to ongoing fatigue. After an otherwise relatively straightforward pregnancy, she presented to Hospital S1 on the 10th November with a history of irregular contractions and suspected rupture of membranes. The midwife recorded that there was *"no Liquor draining"*. Mrs Conroy had a CTG and she was reviewed by a Doctor and was discharged home. Mrs Conroy was reviewed in the antenatal clinic three days later and scheduled for induction the following day. Mrs Conroy had her pregnancy induced at term+10 for post maturity and reduced liquor volume. On the morning of her admission, Cons OandG A administered 2 mg of Prostin Gel. A CTG was performed shortly afterwards and after about 25 minutes, it was discontinued. Mrs Conroy was then cared for in the antenatal ward. Approximately two hours later, Mrs Conroy reported *"strong contractions"* as recorded by the Midwife. Mrs Conroy was *"advised to take a bath"* however it is recorded there was no hot water available. Pain relief was subsequently provided in the form of a Cyclimorph injection at 12.45 hours.

1.2.3 Mrs Conroy was re-examined at 14.00hrs and the cervix was found to be 1 cm dilated. At 14.20 hours, Mrs Conroy was administered a second dose of Cyclimorph. It is recorded that she had declined an epidural. It is noted on the partogram that Mrs Conroy also used Entonox for pain relief. She was then examined again by the same Midwife at 14.40 hours and by now the cervix was noted to be 6 cm dilated. It is recorded that no membranes were felt and no liquor seen.

1.2.4 There is an increasing rate of absence of midwifery record-keeping in relation to the monitoring of the condition of the mother and baby in utero in this case from about 11.00hrs but particularly from about 1420hrs until the time of the birth at 16.32 hrs. According to the records which appear in the summary of care, as opposed to being included in the narrative record, Mrs Conroy's cervix reached full dilatation at 15:10 hours however it is unclear as to how this was determined, i.e. whether it was on the evidence of external signs or by a vaginal examination as there are no records detailing either.

1.2.5 Using times that were visible on a segment of a CTG trace and then by working backwards on the segments, it seems that a CTG was commenced at about 14:14 hours (I did not receive a copy of this earlier part) however there is no output for the tocograph monitor on the CTG record. It is therefore not clear if it was attached as is required to undertake a CTG reading. The CTG reading contains the output from the cardio transducer only. Insofar as the fetal heart rate can be interpreted from this part of the CTG trace, there is evidence of fetal distress on this tracing however there is no evidence in the records to suggest that it was brought to the attention of an obstetrician apart from a handwritten entry on the CTG timed at about 14.33 hours stating a Dr (Not Cons OandG A) had been bleeped.

1.2.6 It is not clear from the records whether this Dr was called because; 1) Mrs Conroy was a private patient, therefore one would routinely expect to have a consultant present for delivery; 2) suspected fetal distress or 3) a combination of 1) and 2). This entry on the CTG record coincides with a portion

of a prolonged bradycardia. However, there are no entries in the records for this period from the Obstetrician. It is not clear whether the obstetrician attended or not. If not, there is also no record of any attempt by the midwife to re-establish contact with an obstetrician.

1.2.7 Mrs Conroy gave birth to a baby girl, Baby Róisín at 16:32 hours. According to the APGAR scores, the baby was born in poor condition with Apgar's 21, 45, 810 and required resuscitation. It is not clear from the records whether the condition of Baby Róisín was anticipated or not, prior to the birth, by the Midwifery staff caring for Mrs Conroy. It is not clear from the midwifery records whether the paediatric team were requested to be present for the birth or were called to attend after the birth of Baby Róisín. Such information should have been recorded.

1.2.8 According to the Neonatal Records, Baby Róisín was transferred to the Special Care Baby Unit (SCBU) at hospital S1 and was intubated later that evening. Seizure activity was noted and she was transferred to the Neonatal Intensive Care Unit (NICU) at hospital S2 in the early hours of the following day. She was diagnosed with hypoxic ischaemic encephalopathy (HIE 2) and was transferred back to hospital S1 at 12 days of age.

1.2.9 The day after the birth on the 15th November 2001, Mrs Conroy visited her baby in Hospital S2 and returned to Hospital S1 later that day.

1.2.10 Mrs Conroy was discharged home two days after the birth on 16th November 2001.

2.0 MY REVIEW OF THE CHRONOLOGY AND CONCLUSIONS

Antenatal Care

2.1 Mrs Conroy had originally attended her GP on 5th April 2001 and was referred to hospital S1 which she attended for her booking visit on the 3rd May 2001. Apart from a history of asthma, for which she was treated with Ventolin and Becotide inhalers, her medical and other history as recorded in Mrs Conroy's hospital chart, was unremarkable.

2.2 Although the 28th January 2001 is recorded (on page 3 of the copy of the Hospital records) as the first date of Mrs Conroy's last menstrual period (LMP), it was noted that that date was uncertain. That uncertainty was denoted using a question mark preceding the date. However, using that date, the expected date of delivery (EDD) was calculated and recorded to be the 4th November 2001.

2.3 The physical check on Mrs Conroy recorded on the 3rd May 2001 (see page 4 of the copy of the Hospital records) is unsigned for but states that a scan showed an "active fetus" at 14 weeks and 3 days gestation. It is not clear from the Hospital Chart who carried out the ultrasound examination. According to LMP dates, Mrs Conroy would have been 13 weeks and 5 days pregnant that day.

2.4 In practice and because there is an error range with most tests, a woman's dates would not normally be changed based on ultrasound dates unless there was a difference of at least a week or where the woman could not recollect the first date of her LMP. This would be a clinical decision usually made by a senior obstetrician. The accuracy of the scan was and is also determined by the level of training and experience of the person carrying out the scan and the quality of the equipment itself. These factors are unknown to me based on examination of the Hospital records.

2.5 Mrs Conroy was seen by Cons Obstetrician and Gynaecologist A on a further 7 occasions during her pregnancy as listed:

12th July 2001,
30th August 2001,
27th September 2001,
17th October 2001,
30th October 2001,
6th November 2001 and
13th November 2001 respectively.

This was and is in keeping with the normal pattern of antenatal care for a first-time mother without additional risks.

Antenatal Admission

2.6 On the 10th November 2001, Mrs Conroy presented to the hospital with a history suggestive of spontaneous rupture of membranes and irregular contractions. She was seen by a midwife initially, who

- 1) took her history,
- 2) carried out an abdominal examination
- 3) recorded that there was "no liquor draining".

Apart from the opening sentence in the admission notes, there is no further Reference by the Midwife to the presence and evaluation or absence of contractions after her admission and before her discharge home nor is it possible to deduce from the maternal chart how long Mrs Conroy spent in the hospital, whether it was a minimum of one hour, or up to 4 hours or more. In any case, it is not clear whether the irregular contractions were reported by the mother on admission or whether they continued after admission. This is a deficit in the standard of the midwifery recordkeeping. According to the records, the Midwife commenced a CTG, recorded Mrs Conroy's vital observations (temperature, maternal pulse and blood pressure - all of which were within normal limits) and performed a vaginal examination on her. The findings recorded do not indicate that Mrs Conroy was in labour at this time.

2.7 Although the Midwife does not comment further during this episode of care on the presence or absence of contractions, it would have been and is normal practice to consider the use of a sterile speculum examination prior to undertaking a vaginal examination where there is a suggestion of ruptured membranes in advance of labour / onset of contractions to outrule or confirm rupture of membranes. The reasons for this include the following;

- 1) it is easier to see liquor if it is present in the vagina using this assessment.
- 2) it can be used to carry out a test such as an Amnicator test which detects variances in the pH balance which can help indicate the presence or absence of amniotic fluid.
- 3) it is important to determine if a rupture of membranes has occurred in a non-labouring woman as once the membranes are ruptured, then the sterile field around the baby has been broken.
- 4) the risk of infection to the baby in the presence of ruptured membranes increases with time. Where liquor is found to be present and there are no contractions, one would consider avoiding the undertaking of a vaginal examination unless there was concern with the fetal heart rate. So, if the membranes are ruptured and the woman is not contracting then the midwife would alert the obstetrician who would most likely plan to induce labour after a given period.

There does not appear to have been a consideration of a sterile speculum examination and there may have been contractions but if so, there are no details of these recorded by the midwife.

This standard of record keeping in relation to the history of contractions does not meet the standard of recordkeeping for a midwife. This aspect of assessment and documentation and communication comprise a vital part in the care and surveillance of a pregnant and /or labouring woman and are necessary for the safe and ongoing planning of care relevant to the factors of pregnancy which are individual to the pregnant woman. It is reasonable to expect that a Midwife would and should have been able to assess the parameters of labour which include the presence, frequency, strength/duration and regularity of contractions using hand palpation plus or minus the use of a CTG monitor. The Definition of a Midwife (ABA 2001) states that "*she must be able to give the necessary supervision, care and advice to women during pregnancy, labour and the postpartum period.....*".

2.8 The Midwife recorded that she relayed her findings to a doctor however, it is not clear from the records at what grade this doctor was. It may have been the custom and practice in Hospital S1 to request Hospital doctors to make decisions on care of private patients but where a woman has "a

contract" with a consultant for private care, it would be the practice in some hospitals that the Consultant would be informed directly of a woman's admission and presenting signs and symptoms and findings. S/he may then choose to review the woman him/herself or may delegate the duty to the "on duty" doctor(s). The Midwife's records refer to the fact that Mrs Conroy was "anxious to go home" and that the Doctor who had been notified of this, requested that another Doctor be contacted to go and assess Mrs Conroy beforehand.

2.9 Mrs Conroy was then seen by that second Doctor who recorded a history of "*pains and ? Fluid PV loss*". An ultrasound examination was carried out. The examining Doctor made a Reference to "*good liquor*". It is also stated that "*CTG perfect*" and "*Amnicator negative*". Mrs Conroy was prescribed a cream for a rash on her thigh and she was discharged home with a plan to be seen in the antenatal clinic three days later the following Tuesday.

2.10 It should be noted that the Amnicator test is not a diagnostic test but is used to guide decision making in conjunction with maternal history and signs and symptoms as while it has a high sensitivity, it has a lower specificity. It involves placing a long swab or "cotton bud" like stick into the vagina. The cotton bud comes pre-prepared in a reagent which changes colour if the bud comes into contact with amniotic fluid in the vagina based on the pH properties of amniotic fluid.

2.11 Mrs Conroy attended her Consultant (Cons OandG A) 3 days later on the 13th November 2001. She would have been 9 days overdue as calculated by LMP and 14 days overdue by scan dates. Cons O and G A recorded that there was an active fetus, but with reduced liquor and so a decision was made to induce labour. The risk to a baby in-utero rises after 14 days following the expected date of delivery (EDD) and in practice most maternity hospitals in Ireland and elsewhere tend to offer induction of labour from about 10 days following the EDD as logistically, one cannot guarantee that an induction on day 14 will result in the birth on day 14 as the process can take 24- 48 hours.

3.0 Induction of Labour

3.1 It is recorded in the antenatal notes by the admitting midwife on the 14th November 2001 (no time recorded) that Mrs Conroy was admitted at T+10 for induction of labour. The inference here is that the midwife may have understood that Mrs Conroy was being induced for post maturity as there is no Reference to reduced liquor levels. It may not have been known to that midwife that there was also a concern regarding diminished liquor at that stage. This concern does not appear to have been recorded in Mrs Conroy's hospital records at that stage. Cons OandG A had used a separate record pack to document Mrs Conroy's antenatal history in the private rooms. It is not clear whether those records would have been available to that midwife when Mrs Conroy was admitted. The midwife's entry is not timed and therefore does not meet the standard of recordkeeping in that all entries should be dated, timed (24-hour clock) and signed (An Bord Altranais, Guidelines for Midwives 3rd edition, Sept 2001 section 10). In addition to entries made directly on the woman's chart, there are somewhat duplicate entries made on a separate midwifery Kardex. These are generally but not the same always. In the instance of Mrs Conroy's admission for her Induction of Labour, the handwriting in the Kardex includes a partial and unsigned entry as well as a signed entry which is similar but not the same as that made on the continuation sheet. The named midwife has recorded a set of vital observations which are recorded on the Kardex but not on the continuation sheet. Maternal pulse at this time was raised at 102 bpm (this may have been due to anxiety re the process of induction) but it appears to have gone without comment from the admitting Midwife). I view this duplication of effort in documentation as being a systems failure. It is an unnecessary and wasteful use of valuable time which should be afforded to direct care of woman and babies and is laden with risk as key factors may fail to be communicated (human error) to the entire team as generally only midwives would read the midwifery Kardex whereas all team members review the woman's chart.

3.2 It was and is usual practice to assess the fetal heart rate prior to the administration of Prostin by either carrying out a CTG (depending upon the circumstances of the fetus) or to listen in to the fetal heart rate for one minute beforehand. There is no evidence of either action being taken in this case according to examination of the records.

3.3 According to the Hospital Records, Mrs Conroy was reviewed by Cons OandG A at 09.00 hrs. S/he documented that Mrs Conroy was T+10, had diminished liquor, an unfavourable cervix, a high

presenting part (vertex at station -3) and s/he recorded that s/he administered Prostin Gel 2mg. This would have been inserted into the vagina. There is no Reference to presence or absence of membranes or to vaginal loss. There is no documented plan in respect of further reviews. However, the woman would have usually been asked to remain in bed for up to one-hour post Prostin to ensure its application and absorption by the cervix.

3.4 There is an unsigned record stating "CTG recorded" with a time span from 0915 hrs to 0940 hours noted. This does not meet the required standard of recordkeeping in that all entries should be dated, timed (24-hour clock) and signed (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). I examined that CTG. There does not appear to have been a Toco transducer in place at that time. This does not meet the required procedure for a CTG which is carried out to measure both the fetal heart rate and the presence of uterine activity, i.e. contractions and their relationship to each other. The Fetal Heart Rate on that tracing appears normal in all respects; baseline, variability, presence of accelerations and no decelerations.

3.5 In the absence of sound evidence based guidelines for practice, practice varied in relation to CTG monitoring post Prostin. Some hospitals used to, and some still do, a CTG immediately after administration of Prostin. Others would listen into the fetal heart and if it was normal would await the onset of contractions or one-hour post Prostin (whichever came first) to commence a CTG. In all cases thereafter, and in the absence of contractions, practice would usually involve listening into the fetal heart for a minimum of one minute at least 4 hourly. Women who are having their labours induced have had an intervention of Prostin on top of a reason to induce thus requiring at least 4-hourly surveillance. The level of surveillance could be higher as recommended by the obstetrician and as determined by the clinical circumstances and may include repeat or less commonly, continuous CTG monitoring throughout the induction process whilst awaiting the establishment of labour.

3.6 In this case, it seems that Mrs Conroy was cared for in the antenatal ward. Although the plan of care going forward from her first dose of Prostin is not documented by either the Consultant or the Midwife, practice at that time would have been to await labour to establish and to reassess the state of the cervix in 6 hours' time. If a woman needed another dose of Prostin, then it would be administered again and this would not be unusual in a first-time mother. A woman might have been given up to a total of 4 mg across a 24-hour period usually in 2, 1 and 1 mg doses and she would often remain on the antenatal ward for this period unless there were specific additional feto-maternal risks which would have called for a higher level of surveillance. This can be a very tiring period for women as they await events and women can experience discomfort with backache and /or irregular contractions in the lead up to the onset of regular contractions and the establishment of labour.

3.7 According to the records, Mrs Conroy had "strong contractions" as documented by the Midwife at 11.30 hrs on 14th November 2001. What s/he does not tell the reader is how frequent or regular those contractions are. This level of record keeping does not meet the required standard for midwives in that it is ambiguous and it does not give the full picture to the reader (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10.3.10). Even if s/he had not placed the woman on a CTG monitor, s/he would have been expected to have palpated those contractions by hand to adequately describe them in terms of frequency and regularity strength/ duration and the woman's response to them. It is not clear from the records whether the midwife had been called to the bedside by the woman or whether s/he had been doing her rounds. In either event, the documentation of his/her assessment is incomplete and therefore does not meet the standard of recordkeeping. S/He has documented her findings of a vaginal examination in which s/he indicates that the cervix was very posterior and s/he was unable to reach it. This finding and his/her decision to encourage the woman to have a bath would suggest that s/he deemed the woman not to have been in established labour at this point and so s/he may have been seeking to help make the woman comfortable during this period of waiting for labour to establish which is supportive midwifery care. S/he has documented the fetal heart rate as 138bpm and regular before s/he documented his/her findings of the vaginal examination. It is normal practice to also listen into the fetal heart rate after a vaginal examination to ensure that the baby in utero remains well after this intervention. The fetal heart rate is not documented and there is no Reference in the notes to vaginal loss. This does not meet the required standard of record keeping as it is incomplete leaving the reader with basic unanswered questions.

3.8 According to the records, a bath could not be taken because of a water problem on the day, and as recorded, a difficulty in contacting the maintenance services. It would not be unusual in such a case to then seek other forms of pain relief where required by the woman. There is an entry at 12.30hrs in the records stating, "*strong contractions, Cyclimorph 10 mg*". There are initials beside this record however I am unable to determine from that entry who prescribed the medication or what was meant by "*strong contractions*". According to the Midwifery Kardex, Mrs Conroy was "*S/B Cons OandG A*". There is an unsigned entry in the antenatal notes and in the midwifery Kardex stating that Cyclimorph 10 mg was administered at 12:45pm. This does not meet the required standard of recordkeeping in that all entries should be dated, timed (24-hour clock) and signed (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). Given that an hour had passed since the last vaginal examination and prior to administering an opioid for "strong contractions" albeit that it is not now known how frequent those contractions were, it would still have been prudent to carry out a further vaginal assessment in advance of administration.

This does not appear to have been done. A Reference such as "strong contractions" on its own is incomplete, ambiguous and unhelpful in assessing a woman's progress in labour.

3.9 There is no record of care provided in the period from 12.45 until 14.00 hrs. Following the administration of an opioid, a midwife was/is required to assess its effectiveness and this would or should have been done by 30 minutes after the administration. It is not now possible to know from the records if Mrs Conroy was considered at that time to be in labour during the period from 12.45 - 14.00 hrs.

3.10 At 14.00hrs another midwife has documented that Mrs Conroy is "distressed ++". S/He carried out a vaginal examination and noted that the cervix was very posterior, the os was 1 cm dilated, the vertex presentation was at mid cavity and that no membranes had been felt. The fetal heart rate is noted to have been heard at 144bpm and was regular on completion.

3.11 So there had been three areas of progress since the previous vaginal examination;

- 1) it appears that the presenting part had moved down the pelvis from being at station -3 at 0900 hrs to being at mid cavity now at 14.00 hrs.
- 2) the cervix was now reachable and the os was 1 cm dilated.
- 3) there were no membranes felt which indicated that at some point before this they had ruptured spontaneously.

There is no Reference in the notes at this stage to vaginal loss. This was a missed opportunity and falls short of the standard of recordkeeping in that one would want to know whether liquor was draining and especially in the event of not feeling the presence of membranes over the presenting part.

3.12 There can be several reasons for no liquor, as follows;

- 1) there is none to drain;
- 2) the head/ presenting part is well down and well applied to the cervix thus blocking drainage or
- 3) the presence of thick meconium may be blocking it.

The head was at station - 3 at 09.00hrs and was still mid cavity when the woman's cervix was noted to be 1 cm dilated so one would expect that there would be liquor draining if it was there to drain unless it was blocked with thick meconium which was not draining. The fact that there was no liquor would be a sign to be wary of as clear liquor is a reassuring sign whereas meconium stained liquor may be an incidental finding in a well baby or may be a sign that the baby is unwell and needs to be delivered. In either case, meconium stained liquor or no liquor may give rise to the need for further tests in the event of suspected or actual fetal distress. Where there is no liquor, you do not have the reassurance of clear liquor and so one must be extra vigilant to the wellbeing of the baby in utero.

3.13 The Midwife has stated that she relayed her 14.00hr findings to Cons O and G A who suggested an epidural. The woman declined the epidural. It is recorded that Cons O and G A stated that she could have a second dose of Cyclimorph 10mg and that this was administered at 14.20 hrs.

3.14 According to the healthcare records, the same midwife reassessed Mrs Conroy at 14.40 hrs. S/he does not indicate the rationale for a vaginal examination only 40 minutes following the last vaginal examination. Again, this is suboptimal recordkeeping and does not provide a reader of the records an understanding of what was happening to the woman (and especially to a caregiver who may take over care). A vaginal examination could/ would usually be carried out if there was a deterioration in the fetal heart rate or if there was a suspicion that a woman's cervix had reached full dilatation (especially considering a recent administration of Cyclimorph) possibly giving rise to a woman's urge to push. The frequency of contractions was recorded at this point as being 1:2 and strong. On its own, this would indicate to a midwife that a woman may be in well-established labour. The Midwife carried out a vaginal examination and recorded that the cervix was 6 cm dilated, the vertex was presenting at mid cavity. She documented that no membranes were felt and no liquor was seen. There is no Reference to the fetal heart rate after this vaginal examination.

Labour

4.0 The partogram (which would be commenced once labour is diagnosed) appears to have been commenced at 14.00 hrs. Even in the absence of a policy, it was/is common practice that such a baby as Baby Róisín in-utero would be monitored with a CTG for a minimum of 20 minutes to assess fetal wellbeing at this point as Mrs Conroy;

- had been induced for post maturity,
- had diminished liquor as recorded at 09.00 hrs,
- had had 2 doses of Cyclimorph,
- there were no membranes felt and
- there was no liquor draining and
- she had made what would have been considered to be rapid progress in the first stage of labour for a woman in her first pregnancy.

4.1 It is not clear from the records as to when Mrs Conroy was transferred to Delivery Suite or if in fact she ever was moved to the delivery suite. It is not clear which midwife was her case midwife. It is not clear who, if any midwife was providing 1:1 care for Mrs Conroy during this aspect of her labour. The fetal heart rate appears to have been recorded on the partogram at half hourly intervals (as opposed to the usual minimum of quarterly intervals in terms of the fetal heart rate during the first stage of labour and at 5-minute intervals or after each contraction (whichever is more frequent) as is required for the second stage of labour - Mayes Midwifery 12th edn p369 – p383). The contractions are shaded in block fashion and as there is no key code to determine what this shading means, it is not possible to decipher information from this. It appears that Mrs Conroy was connected to a CTG machine at about 14:14 hours but only the cardio recording is printed on the CTG tracing. This does not meet the required procedure for carrying out a CTG and renders accuracy of interpretation (especially in the presence of contractions during labour, 1:2 as previously stated in the woman's record's), impossible to achieve. The partogram is blank for maternal BP, pulse and temperature for the two and a half hours duration of labour that it appears to have been used for and there is no record of any urinary output. Standard Midwifery practice would have involved a minimum of quarterly Fetal heart rate recordings during labour, one hourly maternal pulse in early labour moving to half hourly maternal pulse during active labour, initial 2-4-hour BP recordings unless there was concern requiring more frequent monitoring and then moving to hourly BP recordings in active labour. Fluid intake and urinary output was expected to be recorded throughout labour. Without commentary relating to the actual reality of the cardio recording, or any of the related care including the psychosocial aspects of care, the partogram gives an incomplete and ambiguous picture of how either Mrs Conroy or her baby in utero was coping with labour.

4.2 Cervical dilatation is plotted on three occasions at 14.00hrs, 14.30 hours and 15.10 hours. There is no narrative to explain how the 15.10hrs finding was established, i.e., whether by external signs and urge to push with a visible vertex or whether by a further vaginal examination. "No Liquor" is noted to be written in a horizontal fashion across the duration of time from 14.00-16.00 hrs which suggests a retrospective entry rather than a contemporaneous record. There is a record of use of Entonox.

4.3 Collectively in my opinion, the recordkeeping and therefore the care provided, in respect of care from about 11.00hrs, but with increasing levels of serious omission of care with time, until the delivery of the baby is grossly deficient and does not meet the required standards (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

4.4 According to the records, Mrs Conroy gave birth to her daughter at 16.32 hours. There is no narrative of the second or third stages of labour, no commentary on an interpretation of how well Mrs Conroy was progressing during labour or how the baby in utero was coping; who was called for the birth, how, when or why. A summary sheet of the Labour has been completed and it has been noted that there was a cord tightly around the baby's neck twice. It is recorded that there was no liquor seen until after the crowning of the baby's head and that there was then some old brown meconium seen. It is recorded on the summary sheet that the placenta was delivered by controlled cord traction at 16:45 hours, and that the placenta and cord appeared complete and were meconium stained. Such staining is usually indicative of the presence of meconium over a longer period. It is recorded that there was a 200ml blood loss.

It is recorded that Syntometrine was administered intramuscularly with the delivery of the anterior shoulder but the actual dose/volume is not recorded. This is another deficit in recordkeeping. It is recorded on the summary page that the first stage of labour began at 09.15 hours; that the second stage of labour began at 15:10 hours; that the third stage of labour began at 16:32 hours and that it was complete by 16:45 hours. It is calculated that Labour was of a 7 ½ hour duration. It is a concern that the midwife documented that Mrs Conroy was in established labour from 09:15 hours. It is not clear whether that was a prospective or retrospective judgement. In either case the care recorded as being provided and the quality of record keeping is seriously below the standard of care and record-keeping required for a woman in the first, second, and third stages of labour as previously outlined.

5.0 CTG Details and Interpretation

5.1 In this paragraph, I will list the details of the 6 x A4 pages I received, containing copies of CTGs. I will also detail my interpretation of each where possible and collectively at the end. Please note, that I received a copy of a CTG which was not present in the original chart and there is a section of a CTG in the original chart which was not copied to me but which appeared to precede a section I did receive based on the sequencing of serial numbers.

Details:

Page 1:

This was numbered **21** by hand and had the **serial numbers 18020-18022** printed on the top margin of it. The CTG recording and the date and time which is usually pre-printed was not visible on the copy. The name of Mrs Conroy and her hospital Number was recorded on it. There is no maternal pulse recorded by hand on the CTG. This falls short of the standards of care/ recordkeeping; *"It is essential to record the maternal pulse once at the beginning of the trace and document it on the trace"* (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). There is an indecipherable signature on the CTG. I did not get to view the original record of this CTG.

Page 2

This was numbered **22** by hand and had **the serial numbers 19626-19628** printed on it. The trace is present but very faint on this copy. It is possible to note the date and time of 14th November 2001 09.15 hours on this trace. This indicates that this was the trace carried out after the Prostin administration. The name of Mrs Conroy and her hospital Number was recorded on it. There is no maternal pulse recorded by hand on the trace. There is no output printed on the CTG trace from the tocograph monitor, which suggests that it was either not put on or it was defective. In either case, there is no explanation from the Midwife in relation to this absence of monitoring. These deficits in care and recordkeeping fall short of the procedures and standards; *"It is essential to record the maternal pulse once at the beginning of the trace and document it on the trace"* (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). There is an indecipherable signature on the CTG. I examined the original record of this and was satisfied that the fetal heart rate and its characteristics were within the normal parameters.

Page 3

This was numbered **23** by hand and had **the serial numbers 19637-19639** printed on it. The trace is present but very faint on this copy. It is not possible to note the date and time on this trace. There are no identifying features on this trace. I examined the original record of this trace and it appeared to have been commenced at about 14.14 hours with the serial numbers 19633-19636 however I did not have these sections in my file copy. There is no output printed on the CTG trace from the tocograph monitor on this section, which suggests that it was either not put on or it was defective. In either case, there is no explanation from the Midwife in relation to this absence of monitoring. This falls short of the standards of care/ recordkeeping (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

Page 4

This had no handwritten number but **had the serial numbers 19640-19642** printed on it. The trace is present but very faint on this copy. It is not possible to note the date and time on this trace. There are no identifying features on this trace. There is no output printed on the CTG trace from the tocograph monitor on this section, which suggests that it was either not put on or it was defective. In either case, there is no explanation from the Midwife in relation to this absence of monitoring. This falls short of the standards of care/ recordkeeping (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). I examined the original record of this trace.

Page 5

This had no handwritten number but had **the serial numbers 19643-19645** printed on it. The trace is present but very faint on this copy. It is not possible to note the date and time on this trace. There are no identifying features on this trace. There is no output printed on the CTG trace from the tocograph monitor on this section, which suggests that it was either not put on or it was defective. In either case, there is no explanation from the Midwife in relation to this absence of monitoring. This falls short of the standards of care/ recordkeeping (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). I examined the original record of this trace.

Page 6

This had no handwritten number but had **the serial numbers 19646-19648** printed on it. The trace is present but very faint on this copy. It is not possible to note the date and time on this trace. There are no identifying features on this trace. There is no output printed on the CTG trace from the tocograph monitor on this section, which suggests that it was either not put on or it was defective. In either case, there is no explanation from the Midwife in relation to this absence of monitoring. This falls short of the standards of care/ recordkeeping (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10). I examined the original record of this trace which appears to end prior to the birth of Baby Róisín which is recorded elsewhere as at 16.32 hrs

5.2 Further comments on the notes in relation to copies on pages 3, 4, 5 and 6 as above:

5.2.1 I saw an original CTG marked **No. 23** (which was not included in the copy of notes provided to me) which was timed from about 14:14 hours It contained a cardio tracing only. It included serial numbers **19633-19636**. Based on the sequencing of the serial numbers of the parts of the tracings as described above under headings pages 3, 4, 5 and 6, it is most likely that these had all belonged to one continuous strip which belatedly came apart at various serrated sections. As Mrs Conroy was said to have been contracting at the rate of about 1: 2 minutes at this stage, it is not possible to interpret this CTG with accuracy in the absence of the tocograph apart from aspects which are of a distinct concern. The name of Mrs Conroy and her hospital number had been written onto the CTG by hand. There was no maternal pulse recorded by hand on the CTG. These deficits fall short of the standards of care/ recordkeeping; *"It is essential to record the maternal pulse once at the beginning of the trace and document it on the trace"* (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 10).

5.2.2 From the apparent commencement of the cardio only recording at about 14.14 hours and even in the absence of the tocograph recording, the trace showed worrying features. The fetal heart rate appeared to recover from a level of about 90 bpm and accelerated to about 130 bpm. Within one minute, it dropped again over 30 seconds in a V shape to about 95 bpm recovering over a 60 second period to about 130 bpm. So, there were aspects of bradycardia with delayed recovery whether they

coincided with contractions or not. The fetal heart rate continued to escalate over the next two minutes to a level of about 160 bpm. The fetal heart rate then fell sharply again to about 115 bpm over a period of about 30 seconds. It rose again gradually over three minutes to a baseline of about 155 bpm but continued to decelerate in a V shape every 2-3 minutes by about 20 to 25 bpm from the baseline. About 18-19 minutes after the commencement of this CTG, there appears to be a very sudden (within a 15 second interval) drop in the fetal heart rate from a baseline of 155 to about 70 bpm. It remains below 100 for at least 2 minutes. There is a handwritten entry stating "*contraction*" which appears to coincide with this bradycardia. And then there is an entry stating the name of a Dr who it is stated, was contacted on bleep 04 within a further 2-3 minutes at about 14.33 hrs.

5.2.3 There is no evidence in the records that such a doctor arrived and reviewed Mrs Conroy or that any other doctor was sought to review Mrs Conroy if the first named Doctor could not or did not arrive. About 10 minutes after it is recorded that a Dr was bleeped, the fetal heart rate appears to have recovered to a baseline of about 140 bpm however it continues to be abnormal in that there are continued decelerations and there is reduced variability.

5.2.4 Thereafter, the cardio recording becomes increasingly difficult to interpret in the absence of full information particularly its relationship to the presence and nature of contractions.

5.2.5 The recordkeeping in relation to; the monitoring of the mother and baby including the narrative; the inappropriate use of the CTG machine and the interpretation of the cardio-recording are grossly inadequate in this case.

5.2.6 The attempt to seek medical assistance was correct in that it was warranted at that stage. It should have been made earlier when the cardio recording was first commenced.

5.2.7 Failure to record the response to the attempt to seek medical assistance and / or to follow up on a failure to respond is in breach of the standards of midwifery care and record keeping (An Bord Altranais, Guidelines for Midwives, 3rd edition, Sept 2001 section 8.3 and section 10).

6.0 Summary of My Conclusions

6.1 Midwifery Care and Monitoring of the Condition of Mother and /or Baby in-utero

There was a series of deficits in the care and monitoring of the condition of the mother and of the baby in-utero as outlined in this report ranging from minor to serious and grossly deficient.

6.2 Documentation

There was a series of deficits in the documentation as outlined in this report ranging from minor to serious and grossly deficient. Overall the midwifery care as recorded and the quality of recordkeeping was in breach of the Scope of Midwifery Practice as set out in the Guidelines to Midwives 3rd Edn Sept 2001) and specifically, the EEC Directive of 1980 (80/155/EEC) points as follows:

5. *"to care for and assist the mother during labour and to monitor the condition of the fetus in utero by the appropriate clinical and technical means"*

7. *"to recognise the warning signs of abnormality in the mother or infant which necessitate referral to a doctor and to assist the latter where appropriate..."*

11. *"to maintain all necessary records".*

The deficits in care recorded as provided and the quality of recordkeeping is not consistent with the Definition of a Midwife as endorsed by An Bord Altranais (2001) and previously been amended and adopted by the International Confederation of Midwives (1990), the International Federation of Gynaecologists and Obstetricians (1991) and the World Health Organisation (1992).

Appendix F: Correspondence from the Medical Council



Comhairle na nDochtúirí Leighis
Medical Council

Strictly Private and Confidential
Addressee Only

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

BY EMAIL ONLY – [REDACTED]

13 March 2014

Dear Mr and Mrs [REDACTED]

Thank you for your correspondence dated 11 March 2014.

I am a Case Officer appointed and provided with a warrant by the Medical Council to assist the Preliminary Proceedings Committee (“the PPC”). The PPC is the committee of the Medical Council that looks into and gives initial consideration to complaints about doctors.

I have reviewed your correspondence dated 11 March 2014.

Having checked the Register, we note that Dr [REDACTED] does not currently hold registration with the Medical Council as he withdrew from the Register on 8 May 2012. As [REDACTED] is not currently registered with the Medical Council, the Medical Council cannot consider this complaint about him, as a medical practitioner must be currently registered with the Medical Council in order for the Medical Council to consider the complaint. Therefore we are unable to investigate your complaint about Dr [REDACTED]’s care and treatment of Mrs [REDACTED] and your daughter Roisin.

If it is the case that Dr [REDACTED]’s name is restored to the Register of Medical Practitioners, you will be contacted in relation to your complaint.

There are a number of patient support groups who may be able to advise you further. Please see attached for your information contact details for these patient support groups. You may also wish to consult www.healthcomplaints.ie. This is a website that provides information on how to make a complaint or give feedback about health and social care services in Ireland.

Medical Council
Kingram House
Kingram Place

t. +353 1 4983100
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www.medicalcouncil.ie



Comhairle na nDochtúirí Leighis Medical Council

I hope this is of assistance.

Yours sincerely,

[Redacted]

Case Officer

Professional Standards

Email: [Redacted]

Tel: [Redacted]

Sent by email only and accordingly bears no signature

Medical Council

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info@mcirl.ie



Comhairle na nDochtúirí Leighis Medical Council

Strictly Private & Confidential

Deirdre O'Keeffe
General Manager
Quality & Patient Safety
2nd Floor, HSE Offices
Model Business Park
Model Farm Road
Cork

By Post & Email: Deirdre.okeefe@hse.ie

17th October 2017

Re: HSE Investigation Process NIMLT Case 51449

Dear Ms O'Keeffe,

I write in response to your correspondence of the 11th October last, and note you are chairing a HSE Investigation relating to the birth of Baby R on 14th November 2001 in Portlaoise Hospital, who suffered a catastrophic injury at birth as a result of hypoxia. The circumstances appear to be wholly regrettable and tragic for the family and child.

I note that the family sought to make a complaint to the Medical Council in 2014, against Dr ~~John J. O'Connell~~ ~~Consultant~~, Consultant Obstetrician, having only become aware that an incident had occurred in relation to the birth of their baby girl some nine years later. As noted by you, this office confirmed that it was not possible to open a complaint against the said Dr ~~John J. O'Connell~~, as he was no longer on the Register of Medical Practitioners, as set out in correspondence issued by this office dated 13th March 2014. The doctor in question had withdrawn from the register in 2012, and accordingly, it was not open to this office to commence an investigation or complaint in those circumstances.

The Medical Council is a statutory body, governed by the Medical Practitioners Act 2007. Part 7 of the Medical Practitioners Act deals with complaints concerning registered medical practitioners. The legislation under which we operate, enables this office to consider and investigate complaints, against medical practitioners registered with this office, at the time of receipt of complaint. In summary, it is simply not open to this office, under the law, to open a complaint against any practitioner who is not listed on our register at the time of receipt of complaint.

In an effort to address the queries raised, matters regarding legal proceedings or civil claims against any practitioner are a separate matter to complaints considered by this office as regulatory body for medical practitioners. Varying standards and tests apply in civil claims, to those regulatory and disciplinary matters considered by this office. Accordingly, whether there are any legal proceedings in being against a practitioner, is a matter to which this office will have no knowledge, or regard, as such civil claims are a matter overseen by the civil courts, and not one which a regulator is involved in.

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Comhairle na nDochtúirí Leighis Medical Council

There is no statute of limitations on any complaint being made to this office as regulator, and this is in an effort to ensure doctors are unable to avoid being held to account for any Poor Professional Performance, being the failure to meet standards of competence (whether in knowledge and skill or the application of knowledge and skill or both) that can reasonably be expected of medical practitioners practising medicine, or Professional Misconduct. It is a requirement in law however, that the doctor be registered on the register of medical practitioners, at the time the complaint is open.

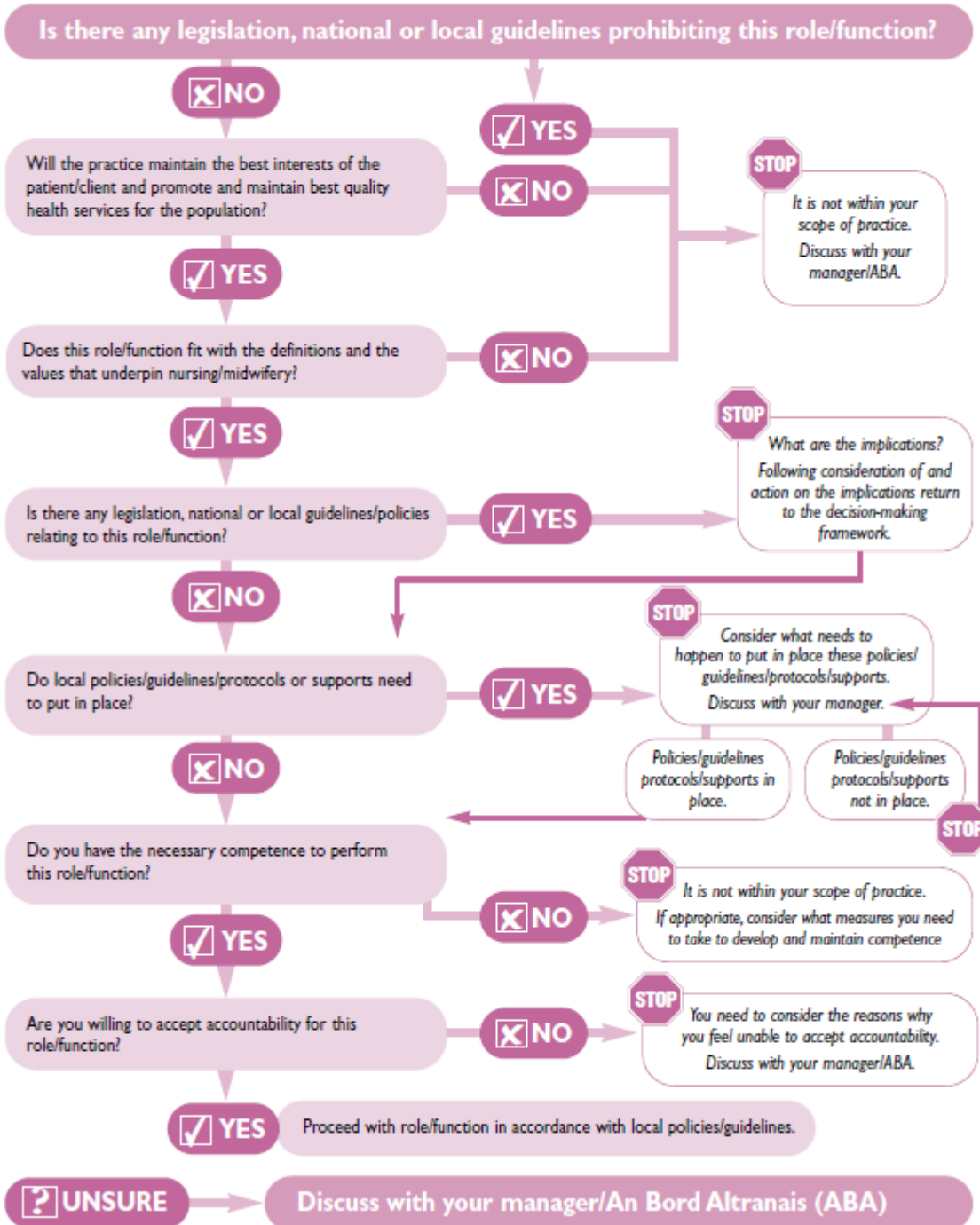
I trust this adequately addresses the queries posed by you in your correspondence, and this office remains available to assist you in any way possible, in conducting your investigation.

Yours sincerely,


William Kennedy
Director of Regulation
Professional Standards

Appendix G: Nurse/Midwife Scope of Practice Decision-Making Framework 2000 (NMBI)

CONSIDER THE NURSING/MIDWIFERY ROLE/FUNCTION



Appendix H: Framework of Contributory Factors

Table 1: Sub-Components Underpinning the Framework of Contributory Factors Influencing Practice

➤ Patient components

<u>Contributory factor</u>	Taxonomic components
Condition	<ul style="list-style-type: none"> – Complexity – Seriousness
Personal	<ul style="list-style-type: none"> – Personality – Language – External support – Social and family circumstances – Disability
Treatment History	<ul style="list-style-type: none"> – Know risks associated with treatment
	<ul style="list-style-type: none"> – Medical – Personal – Emotional
Staff-patient relationship	<ul style="list-style-type: none"> – Good working relationship

➤ Task components

<u>Contributory factor</u>	Taxonomic components
Availability and use of policies, procedures and guidelines	<ul style="list-style-type: none"> – Procedure for reviewing and updating protocols – Availability of protocols to staff – Use of protocols – Availability of specific types of policies, procedures and guidelines e.g. H&S... – Quality of information included in the policies, procedures and guidelines – Accident and incident investigation procedures
Availability and accuracy of test results	<ul style="list-style-type: none"> – Tests done? – Disagreements regarding the interpretation of the test results – Need to chase up test results
Decision making aids	<ul style="list-style-type: none"> – The availability, use and reliability of specific types of equipment e.g. CTG – The availability, use and reliability of specific types of tests (i.e. blood tests) – The availability and use of senior clinicians / managers
Task design	<ul style="list-style-type: none"> – Can a specific task be completed by a trained member of staff in adequate time and correctly

➤ **Individual (staff) components**

<u>Contributory factor</u>	<u>Taxonomic components</u>
Competence	<ul style="list-style-type: none"> – Verification of qualifications – Verifications of skills and knowledge
Skills and knowledge	<ul style="list-style-type: none"> – As Above
Physical and mental stressors	<ul style="list-style-type: none"> – Motivation – Mental stressors (e.g. the effects of workload, sickness, etc on the individual mental state) – Physical stressors (e.g. the effects of workload etc on the individuals physical health)

➤ **Team components**

<u>Contributory Factors</u>	<u>Taxonomic Components</u>
Verbal communication	<ul style="list-style-type: none"> – Communication between junior and senior staff – Communication between professions – Communication outside the ward / department, etc – Adequate hand over – Communication between staff and patient – Communication between specialities and departments – Communication between staff of the same grade – Voicing disagreements and concerns – Communication between staff and visitors / patients / relatives / carers
Written communication	<ul style="list-style-type: none"> – Incomplete absent information (i.e. test results) – Discrepancies in the notes – Inadequately flagged notes – Legibility and signatures of records – Adequate management plan – Availability of records – Quality of information in the notes
Supervision and seeking help	<ul style="list-style-type: none"> – Availability of senior staff – Responsiveness of senior staff – Willingness of junior staff to seek help – Responsiveness of junior staff – Availability of junior staff
Congruence / consistency	<ul style="list-style-type: none"> – Similar definition of tasks between professions – Similar definition of tasks between different grades of staff – Similar definition of tasks between same grade of staff
Leadership and responsibility	<ul style="list-style-type: none"> – Effective leadership – Clear definitions of responsibility
Staff colleagues response to incidents	<ul style="list-style-type: none"> – Support by peers after incident – Support by staff of comparable grades across professions e.g. senior nurse and junior Doctor.

➤ **Work environment components**

<u>Contributory factor</u>	Components
Administration	<ul style="list-style-type: none"> – Ease of running and review of general administration systems – Notes handling
Building and Design	<ul style="list-style-type: none"> – Maintenance management – Functionality (ergonomic assessment e.g. lighting, space, etc)
Environment	<ul style="list-style-type: none"> – Housekeeping – Control of physical environment – Movement of patients, staff, and visitors between wards or sites
Equipment / supplies	<ul style="list-style-type: none"> – Malfunction / failure / reliability – Unavailability – Maintenance management – Functionality (e.g. ergonomics design, fail-safe, standardisation)
Staffing	<ul style="list-style-type: none"> – (Un)availability
Education and training	<ul style="list-style-type: none"> – Induction – Management's influence on training – Process – Refresher training – Provision of training (in general)
Workload / hours or work	<ul style="list-style-type: none"> – Regular rest breaks – Optimal workload (neither too high or too low) – Involved in non job related duties
Time factors	<ul style="list-style-type: none"> – Delays

➤ **Organisational and management factors components**

<u>Contributory Factor</u>	Components
Organisational Structure	<ul style="list-style-type: none"> – Hierarchical arrangement of staff – Span of control – Levels of decision making
Policy, standards and goals	<ul style="list-style-type: none"> – Mission statement and objectives – Management arrangements (Functions) – Contract services – Human resources – Financial resources / constraints – Information services – Maintenance management – Task design – Education and training policy – Policies, procedures and guidelines – Facilities and equipment – Risk Management (e.g. incident reporting, investigation and analysis) – Health and safety management (Fire safety, waste management, infection control and occupational health) – Quality improvement
Risks imported / exported	
Safety culture	<p>Is invoked by other organisational processes and management factors:</p> <ul style="list-style-type: none"> – Attitude to work, safety and others in the workplace – Provision of support mechanisms by management for all staff
Financial Resources and constraints	

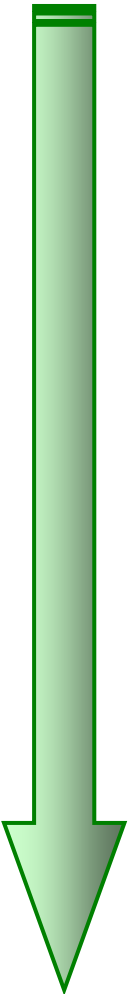
7. Institutional Context

Including:

- Economic and Regulatory Context
- Department of Health and Children
- Health and Information Quality Authority
- Health and Safety Authority
- Clinical Indemnity Scheme
- Links with external organisations

Appendix I: Hierarchy of Hazard Controls

Table 2: Hierarchy of Hazard Controls to support the development of recommendations

Strength of control	Category of control	Comments/Examples
<p>Strongest control</p>  <p>Weakest control</p>	Elimination	The work process or task is redesigned so as to remove the hazard/contributory factor. However, the alternative method should not lead to a less acceptable or less effective process e.g. stop providing service; discontinue a particular procedure; discontinue use of a particular product or service, e.g. stop using a particular type of equipment. <i>If hazard elimination is not successful or practical, the next control measure is Substitution.</i>
	Substitution	Replacing the material or process with a less harmful one. Re-engineer a process to reduce potential for 'human error'. <i>If no suitable practical replacement is available the next control measure is engineering controls.</i>
	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. <i>If no suitable engineering control is available the next control measure is administrative procedures.</i>
	Administrative procedures	Ensure that administrative policies, procedures and guidelines are in place. Ensure staff are appropriately trained in these. Monitor compliance with policies, procedures and guidance through audit. <i>If no administrative procedure is available the next control measure is work practice controls.</i>
	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 Controls should only be considered after all the previous measures have been considered and found to be impractical or unsuccessful.</i>