Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Dublin Mid-Leinster Quality and Patient Safety Service

Strictly Private and Confidential

Final Report Incident Review QPS 50069

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1.0 Executive Summary:

This is the report of an investigation conducted into the circumstances surrounding the care, management and treatment delivered to Mrs. Molloy and her infant son at the Midland Regional Hospital at Portlaoise during the period of her delivery on the 24th January 2012.

Mrs. Molloy was admitted to the Midland Regional Hospital at Portlaoise at 05.05 hours on the 24th January. She was transferred to the Labour Ward following an initial assessment of her labour. On arrival on the Labour Ward, continuous foetal heart monitoring (CTG) was commenced. It was established during the investigation that the CTG was nonreassuring between 06.33 and 07.15 hours. Between 07.15 and 07.47 hours approximately the Midwifes involved in Mrs. Molloy's care contacted the Obstetrician Gynaecology Registrar on call as it was observed that Mrs. Molloy's labour was failing to progress.

Following assessments of Mrs. Molloy, the Obstetrician Gynaecology Registrar on call made the decision to transfer Mrs. Molloy to Theatre for delivery of her baby. The Obstetrician Gynaecology Registrar on call contacted the Consultant Obstetrician Gynaecologist on call at 08.30 hours to inform her of his concerns about Mrs. Molloy's condition.

The Consultant Obstetrician Gynaecologist on call arrived on the Labour Ward at 08.39 hours when she carried out an assessment of Mrs. Molloy. Following Consultant Obstetrician Gynaecologist on call's assessment of Mrs Molloy a decision was made at 08.45 hours to transfer Mrs. Molloy to Theatre for delivery of her baby.

Mrs. Molloy's baby son was delivered at 09.31 hours. His condition on delivery was flat and unresponsive and he was immediately transferred to the Resuscitaire where efforts were made to resuscitate him. Mr. and Mrs. Molloy's baby son was pronounced dead at 22 minutes of age.

Following the death of their baby; Mrs. Molloy and her husband raised concerns related to the care and management that both Mrs. Molloy and her baby had received prior to the couple's baby's delivery. Based on these concerns the Midland Regional Hospital Portlaoise initiated an investigation. This investigation was not completed and in March 2012 the H.S.E. Dublin Mid-Leinster (DML) Quality and Patient Safety Service assumed responsibility for the investigation.

The DML Quality and Patient Safety Service Review Team who undertook the investigation were;

- Mr. Kevin O'Malley, Healthcare Risk Manager, DML Quality and Patient Safety Service
- Ms. Annette Macken, HSE DML Regional Quality and Patient Safety Manager.

The following representatives from the HSE Midland Hospital Group and the Midlands Regional Hospital Portlaoise were asked for their comments on the report's recommendations.

- The Assistant National Director of Midland Hospital Group,
- The Complaints Officer of the Midland Regional Hospital Portlaoise,
- The Hospital Manager of the Midland Regional Hospital at Portlaoise,
- The Clinical Director of the Midland Regional Hospital at Portlaoise,
- The Director of Nursing of the Midland Regional Hospital at Portlaoise,
- The Divisional Nurse Manager, Obstetrics and Gynaecology, Midland Regional Hospital at Portlaoise.

The above individuals were previously described as the "Wider Review Team" in the Terms of Reference for the investigation completed in March 2012. For the avoidance of doubt, they were not members of the review team and the description of them as the "Wider Review Team" was inaccurate.

Consultant Obstetrician Gynaecologist A was initially identified as one of the Wider Review Team from whom the Review Team would seek comments on the recommendations.

During the investigation one member of staff expressed concerns to the Review Team related to Consultant Obstetrician Gynaecologist A's inclusion on the 'Wider Review Team' and that Consultant Obstetrician Gynaecologist A would have greater input to the investigation than other staff members who were involved in Mrs. Molloy's care.

When the concern related to Consultant Obstetrician Gynaecologist A's membership of the 'Wider Review Team' was highlighted to the Review Team a decision was made to remove Consultant Obstetrician Gynaecologist A from the 'Wider Review Team' and this change was reflected in the Terms of Reference for the investigation developed in January 2013.

The Review Team wishes to confirm that Consultant Obstetrician Gynaecologist A was not present for any of the interviews carried out with other staff/parties as part of the investigation; that she did not have input into the preparation of the investigation's report except in as far as she was interviewed and provided her account of events described in this report and has had no input whatsoever in relation to the conclusions drawn.

In addition in December 2012 Mr. and Mrs. Molloy requested that independent experts be appointed to examine additional aspects of the care provided to Mrs. Molloy and Baby Mark i.e. the anaesthetic care provided to Mrs. Molloy and the resuscitation efforts made in respect of Baby Mark and that these expert reports should be included in the overall investigation report. The Review Team considered this request and made a decision to seek the additional expert input. This amendment required that the Terms of Reference be updated which was done in January 2013.

Copies of both Terms of Reference for the investigation - March 2012 and January 2013 - can be found in Appendix I of this report.

As part of this investigation; independent expert opinion was sought by the Review Team from (a) Professor John Morrison, Consultant Obstetrician Gynaecologist; (b) Ms. Sheila Sugrue, Lead Midwife Health Services Executive; (c) Dr John Murphy, Consultant Neonatologist; and (d) Dr. Miriam Harnett, Consultant Anaesthetist.

The Review Team worked in collaboration with the clinical experts named above in relation to the specific clinical aspects of the care delivered to Mrs. Molloy and her baby son and issues highlighted by the overall systems analysis investigation process.

A copy of the reports prepared by the external clinical experts can be found in Appendix II of this report.

The investigation identified two Care Delivery Issues related to the care and management delivered to Mrs. Molloy and the couple's infant son. The Care Delivery Issues identified were;

- **Failure to recognise and act on the signs of foetal distress.**

- **Failure to fully assess all sections of the CTG resulting in a) the inappropriate prescribing and administration of Syntocinon and b) a delay in the decision to transfer Mrs. Molloy to the Theatre Department for an assisted delivery.**

Key findings of the investigation:

Two Care Delivery Issues were identified during the investigation.

In respect of Care Delivery Issue I; the investigation identified that there was evidence that Baby Mark Molloy was showing signs of foetal distress from 06.30 hours and that at that time assistance should have been sought from the obstetric gynaecology clinical team on duty; but that the signs of foetal distress were not identified and acted upon.

In respect of Care Delivery Issue II; the investigation found that when Mrs. Molloy was assessed by the Obstetric Gynaecology Registrar at 07.55 hours that all sections of the CTG trace were not inspected and assessed at that time and that therefore the earlier decelerations i.e. that had occurred between 06.33 hours and 07.15 hours and at 07.45 hours were not identified which led to the decision to inappropriately prescribe and administer Syntocinon.

The investigation aimed to identify the factors that contributed to the development of these two Care Delivery Issues and the recommendations required to prevent or to reduce the risk of recurrence of the Care Delivery Issues.

This investigation identified the following recommendations:

Recommendations relating to Care Delivery Issue 1: Failure to recognise and act on the signs of foetal distress.

1. That the HSE Obstetric and Gynaecology Clinical Care Programme considers developing a guideline on intrapartum care: management and care of a woman in labour which includes all aspects of a woman and her foetus's care throughout labour.

2. That as a matter of priority the HSE Obstetric and Gynaecology Clinical Care Programme consider including specific advice on a) when medical assistance should be sought and b) when immediate management is required in the event of an abnormal CTG trace; in the clinical guidelines on intrapartum care: management and care of a woman in labour.

3. That the facilities required to carry out foetal blood sampling should be provided at the Midland Regional Hospital at Portlaoise as a matter of priority.

4. That a formal process is introduced in the Maternity Department immediately that ensures that the functionality of all Avalon Fetal Monitors in use are checked prior to every episode of use. Furthermore that the guideline on intrapartum foetal surveillance and the care of women during labour includes specific reference to the process that must be followed for checking the Foetal Monitors when a expectant mother is admitted to the Labour Ward. The process should follow the basic operation of the Avalon Fetal Monitors as outlined in the Instructions for Use manual.

5. That the CTG training outlined in Section 6.1.4 of this report includes regular update training on the FM30 Avalon Fetal Monitor User Manual.

6. That in conjunction with the equipment supplier a 'user guide' is developed for the FM30 Avalon Fetal Monitors that staff can refer to during an episode of care.

7. That guidance is developed on the role of the 'second midwife' which includes reference to the requirement for communication of information between the primary and secondary midwives providing care to a woman in labour using a tool such as SBAR. Furthermore, it is recommended that any assessments undertaken jointly by the primary and secondary midwife are fully documented in the healthcare record including reference to all information reviewed.

8. Development and implementation of a standardised and agreed communication tool for the handover of information related to the condition of women in labour and that of their unborn infant e.g. SBAR (Situation, Background, Assessment, Recommendation).

9. It should be a mandatory requirement that all midwifery staff allocated to the Maternity Department at the Midland Regional Hospital Portlaoise must be rostered to day duty for a defined period of time so that they can avail of clinical assessment and supervision of their practice. It was recommended by the Director of Nursing of the Midland Regional Hospital at Portlaoise during the investigation that all midwifery staff on the Maternity Department should work a minimum of three months of day duty per year.

10. That all staff working in the Maternity Department must be provided with up to date and valid user names and passwords so that they can access the K2 training module. Any difficulties experienced by staff related to accessing the training module must be reported immediately and resolved as soon as is reasonably practicable.

11. That a policy is developed, implemented, monitored and reviewed related to implementation of the K2 training module for staff. The policy must include specific reference to (1) the frequency that staff must access the training (2) the process for checking that all staff have completed the training and (3) the process for the management of those staff who fail to complete the training programme as is required.

12. That attendance at CTG workshops becomes part of the mandatory training schedule for all medical and midwife staff on the Maternity Department; the frequency of attendance should be based on a training needs analysis but attendance at the workshop must be a minimum of three times a year.

13. That records are maintained related to each CTG workshop so that staff who do not attend the workshop can learn from the CTG tracings that were discussed at the workshop and so that managers are aware of which staff have attended the workshops. The records should include (1) details of staff who have attended the workshop (2) the CTG discussed and (3) CTG findings.

14. That an anonymised copy of Baby Mark's CTG should be included as a learning tool in the CTG workshops that take place within the Maternity Department.

15. That the HSE DML review and re-submit the application made related to the post of Midwifery Clinical Skills Facilitator at the Midland Regional Hospital Portlaoise with a view to securing approval for the post.

16. That the HSE DML Policy for the Provision of Statutory and Mandatory Training (January 2013) is implemented in Midland Regional Hospital at Portlaoise as a matter of priority and that a Training Needs Analysis is carried out on all staff of the hospital.

17. That the HSE process for Performance Management is expedited to ensure that all staff are supported to maintain and enhance their competence and capabilities.

18. That a specific risk assessment is carried out related to the unavailability of Shift Leaders to cover the Labour Ward on certain shifts i.e. night duty so that midwives can be adequately supervised and supported in caring for a woman in labour.

19. That any consideration given to the implementation of independent staffing for the Labour Ward should be predicated on best practice advice i.e. the recommendation contained in the document Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour and guidance from the HSE Clinical Care Programme.

20. That the midwifery staffing levels available to provide care to expectant mothers and their babies at the Midland Regional Hospital Portlaoise are reviewed as a matter of priority.

21. That a review and/or audit is carried out in six months related to the functioning of the Obstetrics and Gynaecology Quality and Safety Committee to ensure that the

Committee is working to its Terms of Reference and to ensure that any support required to assist the Committee to carry out its functions is provided.

22. That in line with standard governance arrangements that all Governance Committees operating in the hospital should submit annual assurance reports to the Senior Management Team/Hospital Clinical Governance Committee.

23. That a system is implemented that facilitates the Senior Management Team/Hospital Clinical Governance Committee to monitor individual departmental Quality and Safety Action Plans to ensure that recommendations are being implemented in a reasonable timeframe.

24. That the Maternity Department have an annual agreed audit plan which must be agreed by the Department's Clinical Governance Committee.

25. That the Maternity Department's audit plan must incorporate (1) participation in national audits (2) schedule of prioritised local audits and (3) targeted audits conducted in line with service requirements and priorities.

26. That the Midland Regional Hospital Portlaoise ensure that the I.T system developed to monitor the hospital's Quality and Safety Action Plans is in use and that it is actively monitored by the appropriate level governance committee; and that a named individual is identified to oversee and manage the system at local level.

27. That there are regular meetings between the Clinical Director and the Consultant Obstetrician Gynaecologists so that any issue relating to the maternity service provided by Midland Regional Hospital Portlaoise can be discussed and resolved. The meetings should be minuted with identified actions, responsible persons and a due date for implementing the actions identified in the minutes of the meeting.

28. That the Maternity Department at the Midland Regional Hospital Portlaoise develops and implements a strict policy that ensures that except in exceptional circumstances that all sections of the CTG are reviewed and assessed when assessing the wellbeing of a foetus and the expectant mother during labour.

Recommendations relating to Care Delivery Issue 2: Failure to fully assess all sections of the CTG resulting in a) the inappropriate prescribing and administration of Syntocinon and b) a delay in the decision to transfer Mrs. Molloy to the Theatre Department for an assisted delivery.

29. That the Syntocinon Infusion Guideline for Induction and Augmentation of Labour is audited within three months of development and that the guideline is audited at least twice a year thereafter as part of the routine audit schedule of the Maternity Department.

Recommendations on other issues identified during the investigation:

30. That the HSE provide guidance on the classification of babies who are born with minimal signs of life requiring resuscitation and who are not successfully resuscitated as outlined in the Australian New Zealand Clinical Practice Guideline for Perinatal Mortality.

31. That the Maternity Department of the Midland Regional Hospital Portlaoise develop, implement and audit a guideline related to the provision of mementos to bereaved parents which sets out the process to be followed when taking a lock of a baby's hair and their hand and foot prints following the baby's death. The guideline must state that the consent of the parents must be sought before taking mementos.

32. That all Maternity Hospitals should give information to parents of babies who have died soon after birth about the two Stillborn and Neonatal Death Organisations; A Little Life Time Foundation and Feileacain (Stillbirth and Neonatal Death Association of Ireland).

33. That the guideline on the management of an expectant mother's pain and pain relief during labour is updated to include extension of the scope of the guideline to the multidisciplinary team involved in the management of pain during labour.

34. That the Maternity Department at the Midland Regional Hospital Portlaoise review and update the guideline on the management of an expectant mother's pain and pain relief during labour to include the following elements; (1) the scope of the guideline is extended to include the multidisciplinary team involved in the management of pain during labour; (2) that the guideline refers to the decision making process that should be followed during the antenatal period in relation to the development of an expectant mother's plan of care for the relief of labour pain and (3) to ensure alignment of the guideline and the Epidural Observation Chart in relation to the frequency of recording vital signs.

35. That the guideline on the management of an expectant mother's pain and pain relief during labour is included in the routine audit schedule developed for the Maternity Department and that such audits must include the review of documentation of vital signs before and after commencement of epidural analgesia.

36. That it becomes standard practice that all midwives document the method used to assess the extent and level of epidural block.

37. That the Midland Regional Hospital Portlaoise review the National Healthcare Charter in respect of affording privacy and dignity to patients with a view of ensuring that all staff are aware of the requirements of the Charter.

38. That the Health Service Executive and the Institute of Obstetricians and Gynaecologists (Royal College of Physicians of Ireland) Clinical Practice Guidelines (2011) Investigation and Management of late fetal intrauterine death and stillbirth is reviewed with a view to full implementation by the Maternity Department of the Midland Regional Hospital Portlaoise.

39. That the Midland Regional Hospital Portlaoise 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.

40. Ensure that all relevant staff are aware of and adhere to the HSE Standard and Recommended Practice for Healthcare Records Management. It is further recommended that the hospital should organise in-service training/education sessions on the importance of appropriate clinical documentation (these training/education sessions should include best practice in correcting original entries to the healthcare record). Attendance at such sessions should be mandatory for all clinical staff.

41. The hospital should undertake an audit of compliance with the HSE Standard and Recommended Practice for Healthcare Records Management.

42. That a risk assessment should be carried out on the potential risk of injury to expectant mothers and their babies due to a lack of a dedicated operating theatre in or adjacent to the Maternity Department.

43. That the draft protocol for reporting, managing and escalation of incidents in the Midland Regional Hospital at Portlaoise is finalised and signed off by the Hospital Governance Committee as soon as possible and that the protocol is audited at least once a year thereafter.

3.0 Apology:

The Midland Regional Hospital Portlaoise and the Health Service Executive would like to sincerely apologise to Mr. and Mrs. Molloy and their family for the events that occurred on the 24th January 2012 related to Mrs. Molloy's labour and delivery and for the death of their infant son Mark.

The Midlands Regional Hospital Portlaoise and the HSE acknowledges that Mr. and Mrs. Molloy's experience on the 24th January was devastating for them and that it has had a profound and lasting effect on their family.

Many of the staff interviewed as part of this investigation expressed their sympathy for what had occurred related to the events of Baby Mark's delivery and death.

The willingness of Mr. and Mrs. Molloy to share their experience was invaluable in allowing this investigation to learn from their experience and in helping to make recommendations to improve the systems and processes in place at the Midland Regional Hospital Portlaoise related to the delivery of Maternity Services.

The HSE and the hospital have confirmed that it is committed to ensuring that the recommendations identified by this investigation report are implemented as a matter of urgency.

2.0 Methodology:

This is the report of a review conducted into the circumstances of the delivery of Mr. and Mrs. Molloy's infant son Mark and his subsequent death at 22 minutes of age.

The investigation was undertaken using the methodology for Incident Reviews outlined in the HSE Toolkit of Documentation to Support Incident Management (2008) which is based on the London Protocol (2006) for systems analysis[1] an internationally recognised methodology for investigating adverse incidents in healthcare.

The original draft Terms of Reference for the investigation was agreed with representatives from the HSE Midland Hospital Group and the Midland Regional Hospital Portlaoise on the 26th March 2012. The draft Terms of Reference were sent by email to Mr. and Mrs. Molloy for their consideration on the 28th March 2012. The Review Team did not receive any feedback from Mr. and Mrs. Molloy on the draft Terms of Reference at that time.

It was the Review Team's understanding that as Mr. and Mrs. Molloy did not submit feedback on the draft Terms of Reference that they had no comment and that they had agreed the Terms of Reference.

Mr. and Mrs. Molloy subsequently indicated that the Terms of Reference for the investigation were not agreed at this time and that further discussions took place regarding the shortfalls in the scope of the draft Terms of Reference. Mr. and Mrs. Molloy indicated in their feedback to the Review Team that they only received the final Terms of Reference for the investigation in January 2013.

In December 2012 Mr. and Mrs. Molloy requested that independent experts be appointed to examine additional aspects of the care provided to Mrs Molloy and Baby Mark i.e. the anaesthetic care provided to Mrs. Molloy and the resuscitation efforts made in respect of Baby Mark and that these expert reports should be included in the overall investigation report. Following consideration of this request by the Review Team the additional input was sought.

The updated Terms of Reference dated 10 January 2013 were communicated to the representatives of the HSE Midland Hospital Group and the representatives of the Midland Regional Hospital Portlaoise outlined in page 3 of this report.

The aim of this review as outlined in the Terms of Reference was to:

"Establish precisely what happened so that the Health Service Executive – Dublin Mid-Leinster and the Midland Regional Hospital at Portlaoise can identify all lessons that can be learned from the experience such that the likelihood of a recurrence is removed or reduced; and so that Mr. and Mrs. Molloy can have access to an explanation of the events leading up to the death of their baby son, the systems causes, and the actions identified to prevent a recurrence of these issues".

In addition Mr. and Mrs. Molloy raised the following specific issues that they required to be addressed as part of the investigation:

I. Should the Consultant Paediatrician have been present when the baby was delivered 'considering (my) records state that baby's heart rate was non-reassuring and also the

[1] 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.

Consultant Obstetrician's statement that they knew they would be delivering a very sick baby''?

II. Should a nurse from the Special Care Baby Unit have been present at the time of delivery?

III. Should Mrs. Molloy have been induced earlier given her due date (15th January) the 'size of the baby, the fact that he was face-up and her past history?'

IV. Did the delay in sectioning the patient compromise the patient's safety and health; Mrs. Molloy received an injury during the C-section; how and why was this injury sustained?

Prior to commencement of the review consent was sought and gained from Mrs. Molloy to allow the Review Team to access her healthcare record in order to complete a systems analysis review.

In addition permission was sought from Mr. and Mrs. Molloy in order to provide anonymised copies of Mrs. Molloy's healthcare record to the external clinical experts so that they could prepare their reports.

For the purposes of this investigation the Review Team examined the following documentation:

- Mrs. Molloy's maternity healthcare record,
- Relevant policies, procedures and guidelines.
- Document submitted by Mr. and Mrs. Molloy titled '***Schedule of Major Events'***.
- Document submitted by Mr. and Mrs. Molloy titled '**Account *of Events* during Roisin's labour at Midland Regional Hospital at Portlaoise on 24th January 2012'**[2].
- Documents submitted by Mr. and Mrs. Molloy titled ***Complaints and Concerns and Labour Complaints and Concerns Since Receipt of Clinical File (Currently being investigated by Risk Assessment as noted in cover letter')***.
- Three copies of Incident Near Miss Report Forms dated the 24th and 29th January and the 2nd March 2012

In addition interviews were undertaken with staff members involved in Mrs. Molloy's care and management at the hospital during the period covered by the scope of the Terms of Reference for the investigation.

A total of 19 people (apart from Mr. and Mrs. Molloy) were interviewed as part of the investigation.

Clinical Staff:

The following clinical staff were interviewed as part of the investigation[3]:

- Midwife B was interviewed on the 3rd May 2012 and on the 1st November 2012[4],
- Midwife C was interviewed on the 2nd August 2012,
- Midwife D was interviewed on the 3rd May 2012 and the 1st November 2012,
- Midwife E was interviewed on the 24th April 2012,
- Shift Leader A was interviewed on the 24th April 2012,

[2] Mrs. Molloy and her husband indicated that they documented their recollection of events on the 27th January 2012 following a discussion with Consultant Obstetrician Gynaecologist A who recommended that they should prepare this document.

[3] Midwife A referred to in this report was not interviewed as she was an agency staff member and her involvement in the care provided to Mrs Molloy only extended to Mrs. Molloy's initial assessment. However Midwife A was sent sections of the draft report for observation related to her involvement.

[4] The second meeting with Midwife B on the 1st November was terminated on the basis of concerns raised by Midwife B with a view to being rescheduled when Midwife B had an opportunity to review the relevant documentation. This rescheduled meeting did not take place.

- Consultant Obstetrician Gynaecologist A was interviewed on the 24th April 2012 and on the 22nd October 2012,
- Obstetrician Gynaecology Registrar A was interviewed on the 24th April 2012 and on the 22nd October 2012,
- Anaesthetic Registrar A was interviewed on the 24th April 2012,
- Consultant Anaesthetist A was interviewed on the 24th April 2012,
- Consultant Paediatrician A was interviewed on the 1st November 2012,
- Paediatric Registrar A was interviewed on the 1st November 2012.

Management Staff:

The following management staff from the Midland Regional Hospital Portlaoise were also interviewed as part of the investigation;

- Clinical Director A was interviewed on the 3rd December 2012,
- Hospital Manager A was interviewed on the 3rd May 2012,
- Director of Nursing A was interviewed on the 4th December 2012,
- Divisional Nurse Manager 1 was interviewed on the 24th April 2012 and on the 1st November 2012,
- Clinical Midwifery Manager II A was interviewed on the 22nd October 2012,

Others:

In addition the following staff were interviewed as part of the investigation;

- The Clinical Engineer attached to the Midland Regional Hospital Portlaoise was interviewed on the 30th November 2012,
- The Chief Clinical Engineer Technician, Health Service Executive Dublin Mid Leinster was interviewed on the 30th November 2012.
- Consultant Pathologist 1 was interviewed in February 2013.

The Review Team met with and interviewed Mr. and Mrs. Molloy on two occasions, as part of the investigation, on the 3rd April 2012 and on the 10th May 2012.

During the investigation it was identified that there was a variance in opinion between some clinical staff regarding the decisions made related to care provided to Mrs. Molloy and her baby on the 24th January.

An independent clinical review of Mrs. Molloy's healthcare record and the CTG tracings recorded during Mrs. Molloy's delivery was carried out by Professor John Morrison, Consultant Obstetrician Gynaecologist and by Ms. Sheila Sugrue, Lead Midwife Health Services Executive.

In addition requests were made to Dr. Miriam Harnett, Consultant Anaesthetist and Dr. John Murphy, Consultant Neonatologist so that they might review the relevant sections of Mrs. Molloy's healthcare record and those that related to the couple's infant son in order to answer the specific questions that Mr. and Mrs. Molloy had regarding the care provided during Mrs. Molloy's delivery.

The Review 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 external clinical experts was sought by making requests to the HSE National Incident Management Team (NIMT) who then sought the relevant nominations through the Office of the National Director Nursing and Midwifery Planning Unit (HSE), the Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland through the Forum of Irish Postgraduate Medical Training Bodies, the Faculty of Anaesthetists, Royal College of Surgeons of Ireland through the Forum of Irish Postgraduate Medical Training Bodies and the Institute of Neonatologists, Royal College of Surgeons through the Forum of Irish Postgraduate Medical Training Bodies.

Appointment of an independent expert in Midwifery
As a result of the requests from the NIMT to the Office of the National of Director Nursing and Midwifery Planning Unit (HSE) for the nomination of an expert Ms. Sheila Sugrue was assigned to undertake the review of Mrs. Molloy's healthcare record.

In May 2012 Ms. Sugrue was provided with an anonymised copy of Mrs. Molloy's healthcare record from the time Mrs. Molloy was admitted to the Maternity Department to the time it was decided to transfer Mrs. Molloy to Theatre. Included in the documentation sent to Ms. Sugrue was a copy of three sections of the CTG and a copy of Mrs. Molloy's antenatal care.

Ms. Sugrue was not sent a copy of the section of Mrs. Molloy's healthcare record relating to Mrs. Molloy's care following the decision to transfer her to Theatre in order to limit the effects of hindsight bias i.e. that Ms. Sugrue would not be aware of the eventual adverse outcome to Baby Mark.

Ms. Sugrue's anonymised report was received by the Review Team in September 2012. A copy of the report can be found in Appendix II of this report.

Appointment of an independent expert in Obstetrician Gynaecology
As a result of the request from the NIMT to the Institute of Obstetricians and Gynaecologists Royal College of Physicians through the Forum of Irish Postgraduate Medical Training Bodies for a nomination of an external obstetrical expert Professor John Morrison was assigned to undertake the review of Mrs. Molloy's healthcare record.

In July 2012 Professor Morrison was provided with an anonymised copy of Mrs. Molloy's healthcare record including a copy of the record relating to Mrs. Molloy's antenatal outpatient attendances, all sections of the CTG and the records relating to her admission to the Maternity Department up to the time she was discharged from hospital.

Professor Morrison was also provided with the relevant section of the healthcare record relating to the care Mrs. Molloy received following her surgery as Mr. and Mrs. Molloy requested that Professor Morrison provide in the report his opinion on a number of issues that related to the care Mrs. Molloy received following her surgery that they had highlighted. These issues are discussed in Section 6.3 of this report.

At the request of Mr. and Mrs. Molloy, Professor Morrison and Ms. Sugrue were also provided with a copy of the validated chronology of events prepared as part of this investigation.

Professor Morrison's anonymised report was received by the Review Team on the 2nd October 2012.

In December 2012 Mr. and Mrs. Molloy requested a meeting with Professor Morrison so that they could provide an account of their recollections of the events leading up to Mrs. Molloy's delivery and Baby Mark's death. Professor Morrison agreed to this request and Mr. and Mrs. Molloy met with Professor Morrison on the 25th January 2013. The Lead Reviewer Mr. Kevin O'Malley also attended this meeting and recorded the notes of the meeting.

In order to ensure that the principles of natural justice and fair procedures were applied those staff directly referred to in Professor Morrison's report were also offered the opportunity to meet with Professor Morrison so that they could communicate any feedback they had related to the section of the report that related to the actions and/or decisions taken or made by the individual staff members.

Midwife B and Consultant Obstetrician Gynaecologist A accompanied by representatives from their respective representative bodies availed of the opportunity to meet with Professor Morrison on the 25th January.

Obstetrician Gynaecology Registrar A declined the offer of a meeting.

Following the meetings that took place on the 25th January 2013 Professor Morrison submitted an updated version of his expert report to the Review Team which was received on the 31st January 2013. A copy of both versions of Professor Morrison's report can be found in Appendix II of this report.

Appointment of an independent expert in Neonatology:
Following a request from Mr. and Mrs. Molloy that an external opinion of the neonatal care delivered to their baby son be conducted; Dr. John Murphy, Consultant Neonatologist was nominated following a request from the Review Team to the NIMT.

Dr. Murphy was provided with an anonymised copy of the relevant section of Mrs. Molloy's healthcare record that related to the resuscitation of Baby Mark to include details of APGAR Scores, Blood Ph values, the Prescription Kardex. He was also provided with a copy of the Post Mortem report prepared in respect of Baby Mark dated the 27th February 2012.

Dr. Murphy's report was received by the Review Team on the 14th January 2013 and a copy of his report is included in Appendix II of this report.

Appointment of an independent expert in Anaesthetics:
Mr. and Mrs. Molloy also requested that a Consultant Anaesthetist review Mrs. Molloy's healthcare record with reference to the pain relief administered to Mrs. Molloy particularly the care provided to Mrs. Molloy related to the siting of an epidural and the administration of epidural medication. Dr. Miriam Harnett, Consultant Anaesthetist was nominated to provide this opinion following a request by the Review Team to the NIMT.

Dr. Harnett was provided with an anonymised copy of the relevant section of Mrs. Molloy's healthcare record that related to the administration of pain relief including Mrs. Molloy's Epidural Record and Epidural Observation Chart, Anaesthetic Record, Peri-Operative Patient Record and the Patient Continuation Notes recorded from the time Mrs. Molloy was admitted to the Midland Regional Hospital at Portlaoise up to the time Mrs. Molloy was transferred to the Recovery Room following her surgery.

In addition Dr. Harnett was also provided with a copy of the CTG tracings recorded in respect of Baby Mark. At Mr. and Mrs. Molloy's request Dr. Harnett was also provided with a copy of the document prepared by Mr. and Mrs. Molloy themselves i.e. 'Account of Event(s) during Roisin's labour at Midland Regional Hospital at Portlaoise on 24th January 2012'.

Dr Harnett's report was received by the Review Team on the 21st January 2013 and a copy of her report is included in Appendix II of this report.

As stated previously, as part of the investigation, a number of interviews were conducted. The interviews were conducted by the Review Team. 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 and in accordance with natural justice and fair procedure.

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

On completion of the interviews and documentation/literature review process a Draft Report was prepared. The Draft Report or extracts from same was shared with all of those individuals who were interviewed as part of the investigation to ensure that the report was factually and clinically accurate and to comply with fair procedure.

In order to assist in the preparation of her responses, Midwife B sought and obtained her own expert report related to Mrs. Molloy's delivery. Midwife B referenced the findings of that expert report in her response. The Review Team were not provided with a copy of this expert report.

Additionally the Draft Reports were made available to all of the external clinical experts who had input into the investigation to ensure that their expert opinion was correctly and appropriately referenced in the report.

Mr. and Mrs. Molloy were provided with a copy of the Draft Chronology Section of the report and a copy of the Final Draft Report for their comments.

Comments from all parties were considered by the Review Team and amendments were made to the Draft Reports where considered appropriate by the Review Team.

The Draft Report made recommendations to address those issues which were identified as contributing to the events described in this report and feedback was sought on the recommendations made.

4.0 Background to the Incident:

In 2011 Mrs. Molloy was a 37 year old woman who had undergone six previous pregnancies. She and her husband had four sons and Mrs. Molloy had experienced two previous miscarriages.

Mrs. Molloy's antenatal care during all of her previous pregnancies had been delivered at the Midland Regional Hospital at Portlaoise.

Mrs. Molloy's children had all been vaginal deliveries. Mrs. Molloy and her husband informed the investigation that Mrs. Molloy's treating Consultant Obstetrician Gynaecologist's presence was required at three of Mrs. Molloy's four previous deliveries due to a failure to progress in the second stage of labour and that the foetuses were in the occiput posterior position[5] prior to delivery and as a result Mrs. Molloy required assistance with the birth of the children[6].

On 22nd August 2011 Mrs. Molloy attended Consultant Obstetrician Gynaecologist A's[7] ante-natal outpatient clinic[8] for her first antenatal appointment; the expected date of delivery was estimated as the 15th January 2012. Mrs. Molloy and her husband indicated during the investigation that Mrs. Molloy's expected date of delivery was the 13th January 2012 as her last menstrual period was on the 8th April 2011.

The following information was documented by Consultant Obstetrician Gynaecologist A in Mrs. Molloy's antenatal record following her assessment at the clinic under the following headings;

Previous Medical History;

- Laparotomy for ovarian cystectomy[9],
- Rubella; immune
- Blood Group: O Positive
- Transfusions (i.e. blood transfusions): no

Family History;

- Father had died of a heart attack at the age of 52,
- Mother was alive and well,
- Brother has Downs Syndrome and heart problems.

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[5] 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 (reference: http://www.birthingnaturally.net/birth/challenges/posterior.html).

[6] An assisted birth (sometimes called an instrumental or operative vaginal birth) uses instruments (either forceps or ventouse) that are attached to your baby's head so that s/he can be pulled out (reference: http://www.babycentre.co.uk/pregnancy/labourandbirth/labourcomplications/assisteddelivery/).

[7] Mrs. Molloy had attended Consultant Obstetrician Gynaecologist B for the birth of her first three children and Consultant Obstetrician Gynaecologist A for the birth of her fourth child. Mrs. Molloy indicated during the investigation that while she was a private patient of Consultant Obstetrician Gynaecologist B for the birth of her first three children and a private patient of Consultant Obstetrician Gynaecologist A for the birth of her fourth child that she decided to attend Consultant Obstetrician Gynaecologist A as a public patient for the birth of this child, her fifth child having weighed up the benefits of a private versus a public room.

[8] Mrs. Molloy maintained regular antenatal attendances during her pregnancy. Her care was managed using 'Combined Care' i.e. her care was jointly managed by her General Practitioner and the Antenatal clinic at Midland Regional Hospital at Portlaoise.

[9] Cystectomy is the surgical removal of a cyst (reference: http://www.thefreedictionary.com/cystectomy).

Previous Obstetrical History;

- 17th August 2002, Term[10], vacuum delivery at Midland Regional Hospital at Portlaoise, 8 lbs 14 oz, Male.
- 22nd April 2004, Term, vacuum delivery at Midland Regional Hospital at Portlaoise, 8 lbs 5 oz, Male.
- June 2006, miscarriage at 4 weeks, ERPC[11], removal of ovarian cyst.
- 2nd May 2007, Term, vacuum delivery at Midland Regional Hospital at Portlaoise, 8 lbs 7 oz, Male,
- 11th September 2009, Term, vaginal delivery at Midland Regional Hospital at Portlaoise, 8 lbs 14 oz,
- March 2011, miscarriage at seven weeks, no ERCP.

The records state that;

- Mrs. Molloy's LMP (i.e. last menstrual period) was on the 8th April 2011,
- EDD (estimated date of delivery) was the 15th January 2012. As previously stated Mrs. Molloy has indicated that her last menstrual period was on the 8th April 2011 and that the estimated date of delivery was the 13th of January 2012. Consultant Obstetrician Gynaecologist A indicated during the investigation that the Naegele's rule is the method used for calculating the estimated date of confinement and that applying this rule to Mrs. Molloy's case, where the last menstrual period was the 8th April 2011, her estimated date of confinement was the 15th January 2012.
- Cycle; regular,
- Cigarette; nil,
- Alcohol; no alcohol,
- Height; 5 feet 2 inches,
- Teeth; no (i.e. no false teeth),
- Parent craft; no,
- Feeding; breastfeeding.

Consultant Obstetrician Gynaecologist A signed and dated the entry in the record.

The following information was also documented by Consultant Obstetrician Gynaecologist A in Mrs. Molloy's healthcare record;

- Para[12] 4^{+2} (i.e. 6 pregnancies with 4 live births),
- EDD - 15th January 2012,
- Weight - 60.6 kilograms,
- Urinalysis - NAD i.e. no abnormalities seen,
- Blood pressure - 112/70 millimetres of mercury,
- Last menstrual period (L.M.P.) was 19 weeks ago,
- Fundal height[13] was equal to dates,
- Foetal heart was heard,
- Foetal movement was felt,
- That Mrs. Molloy had the following routine blood tests carried out by her General Practitioner:
    - Antibodies[14],

[10] 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

[11] ERPC is an evacuation of retained products of conception (reference: http://www.nhs.uk/Conditions/Miscarriage/Pages/Treatment.aspx).

[12] 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).

[13]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).

- Haemoglobin,
- Wr (Wessermann Reaction)[15],
- Blood Group card,
- H.A.I. (haemagglutination inhibition)[16],
- HIV (human immunodeficiency virus),
- Hepatitis B and C.

Mrs. Molloy and her husband indicated during the investigation that at the time she had the cystectomy her right ovary and fallopian tube were removed.

The Antenatal Discussion Checklist[17] was completed and a hand written note on the checklist states "breast fed all 4 children".

Mrs. Molloy had a routine ultrasound scan carried out and the result of the scan was documented as follows:

- Single foetus,
- Foetal heart and movement present,
- Biometry = dates[18],
- Too late for nuchal translucency scan[19],

It was also documented (entry was not dated) that Mrs. Molloy had undergone a Smear Test[20] which was NAD, that she had two scans in the Early Pregnancy Unit and that she was advised about taking iron supplements[21].

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[14] 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).

[15] Wessermann Reaction is diagnostic test for syphilis involving the fixation or inactivation of a complement by an antibody in a blood serum sample (reference: http://www.thefreedictionary.com/Wassermann+reactions). Consultant Obstetrician Gynaecologist A indicated during the investigation that it was her understanding that the Laboratory Department in Midland Regional Hospital at Portlaoise does not carry out the Wessermann Reaction test. Midland Regional Hospital at Portlaoise's Laboratory Department was contacted in response to this information and they indicated that the Bioelisa Syphilis 3.0 kit is carried out instead of the Wessermann Reaction test which is a third generation Immunoenzymatic assay for determination of IgG and IgM Antibodies to T. pallidum in serum.

[16] Haemagglutination inhibition test is a serologic technique useful in testing for certain unknown soluble antigens. The unknown antigen is mixed with a known agglutinin. If a reaction occurs, the agglutinin can no longer adhere to the cells or particles that carry its corresponding antigen, and the unknown antigen is thus identified (reference: http://medical-dictionary.thefreedictionary.com/agglutination-inhibition+test).

[17] The following is documented on the antenatal Discussion Checklist "that all pregnant women and their partners should receive information and opportunity for one-to-one discussion before 32 weeks of pregnancy on the following; breastfeeding, skin to skin contact at birth, breastfeeding in the first hour after birth, good position, attachment and suckling, feeding on demand or baby lead feeding, giving formula or water supplements, support labour and birth practices, keeping baby near, the midwives on the post natal ward, Public Health Nurse, information on antenatal classes".

[18] Fetal biometric parameters are various antenatal ultrasound measurements that are used to indirectly assess the growth and well being of the fetus and in assessing dates - gestational age (reference: http://radiopaedia.org/articles/fetal-biometric-parameters).

[19] Nuchal Translucency is the collection of fluid under the skin at the back of the baby's neck. The nuchal is measured using ultrasound when the foetus is between 11 weeks and 13 weeks plus six days gestation. All foetuses will have some fluid; those with Down's Syndrome have an increased amount (reference: http://www.bmihealthcare.co.uk/treatment/treatmentsdetail?p_name=1%20-%20Nuchal%20translucency%20scan%20(11-13%20weeks)&p_treatment_id=415.

[20] A smear test is a screening test for precancerous and cancerous cells on the cervix. This simple test is done during a routine pelvic exam and involves scraping cells from the cervix (reference: http://medical-dictionary.thefreedictionary.com/smear+test).

On the 9th November 2011 Mrs. Molloy attended her second antenatal outpatient appointment.

At the clinic it was documented that Mrs. Molloy's;

- Urinalysis - NAD,
- Blood pressure - 101/66 millimetres of mercury,
- LMP was 30 weeks ago,
- Fundal height was equal to dates,
- Foetal presentation was cephalic[22],
- Foetal heart was heard.

It was also documented that Mrs. Molloy complained of a body itch for 10 weeks; that Mrs. Molloy had blood tests carried out by her General Practitioner and that Mrs. Molloy indicated that she would bring the results of the blood tests to the next antenatal clinic.

It was documented that Mrs. Molloy indicated that her General Practitioner had spoken to Consultant Obstetrician Gynaecologist A about the results of the blood tests.

A separate note in Mrs. Molloy's healthcare record states:

> *"Spoke to G.P. sec (secretary); only Rubella taken. No other booking bloods: bloods repeated today".*

It was documented that a specimen of Mrs. Molloy's blood was sent to the Laboratory for the following tests;

- Full Blood Count[23],
- Wessermann Reaction,
- Rubella,
- Hepatitis B and C,
- HIV,
- LFTs[24],
- Blood Group and antibodies.

A consent form was signed by Mrs. Molloy to have the blood tests carried out which was witnessed by a Midwife; the form is not dated.

It was documented that a repeat ultrasound scan was carried out on Mrs. Molloy which showed the following;

- Scan = dates,
- Liquor[25] volume normal,

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[21] Routine iron supplementation is a common practice for preventing iron deficiency (ID) and iron deficiency anemia (IDA) in pregnancy, because the dietary iron intake of pregnant women often does not meet the recommended dietary intake (reference: http://www.ajcn.org/content/83/5/1112.full.pdf).

[22] 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).

[23] 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).

[24] 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).

[25] 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).

It was also documented that Mrs. Molloy's LFTs were normal and that they would be repeated by her General Practitioner and that Mrs. Molloy was given advice about taking iron supplements i.e. Galfer.

Mrs. Molloy attended for her third antenatal outpatient appointment on the 7th December 2011 when she was seen by Consultant Obstetrician Gynaecologist A.

It was documented in the healthcare record that Mrs. Molloy's;

- Urinalysis - NAD,
- Blood pressure - 95/72 millimetres of mercury,
- LMP - 34 weeks,
- Fundal height was equal to dates,
- Foetal presentation was breech[26],
- Foetal heart was heard,
- Foetal movements felt.

The following was also documented in the healthcare record;

- Liquor volume normal,
- Estimated weight 2.3 kilograms.

Consultant Obstetrician Gynaecologist A documented that she would consider an ECV (external cephalic version)[27] if the foetus was still in the breech at the next visit.

Mrs. Molloy had an ultrasound scan carried out and the documented result of the scan was as follows:

- Foetus in the breech position,
- Liquor volume normal,
- Placenta in the upper segment of uterus.

Mrs. Molloy's antenatal record was stamped indicating that she should "be seen next visit by Consultant".

It was documented that Mrs. Molloy would be seen in the Antenatal Clinic again in two weeks time.

Mrs. Molloy informed the Review Team during the investigation that Consultant Obstetrician Gynaecologist A had informed her at the Antenatal clinic on the 7th December 2011 that she (i.e. Consultant Obstetrician Gynaecologist A) would not let Mrs. Molloy go over the expected date of delivery.

There was a difference in the recollections of Mrs. Molloy and Consultant Obstetrician Gynaecologist A in relation to whether Consultant Obstetrician Gynaecologist A informed Mrs. Molloy that she would not let her go over the expected date of delivery at this visit. Consultant Obstetrician Gynaecologist A indicated during the investigation that she did not inform Mrs. Molloy that she would not let her go over the expected date of delivery, Consultant Obstetrician Gynaecologist A indicated that if such a plan had been communicated that she would have documented the plan in Mrs. Molloy's healthcare record.

[26] Breech means that the baby is lying bottom first or feet first in the womb (uterus) instead of in the usual head first position. In early pregnancy, breech is very common. As pregnancy continues, a baby usually turns naturally into the head first position. Between 37 and 42 weeks (term), most babies are lying head first ready to be born. Three in every 100 (3%) babies are breech at the end of pregnancy (reference: http://www.rcog.org.uk/womens-health/clinical-guidance/breech-baby-end-pregnancy).

[27] External Cephalic Version is when pressure is put on the tummy to try to turn the baby into a head-down (cephalic) position (reference: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/breech-birth.aspx#close).

There is no reference in Mrs. Molloy's healthcare record to any conversation that took place between Mrs. Molloy and Consultant Obstetrician Gynaecologist A regarding a plan not to let Mrs Molloy go over her expected date of delivery.

Mrs. Molloy attended as scheduled for her fourth antenatal outpatient appointment on the 29th December 2011 at which time she was seen by Consultant Obstetrician Gynaecologist A who documented the following;

- Weight - 70.3 kilograms,
- Urinalysis - NAD,
- Blood pressure 123/78 millimetres of mercury,
- LMP 37 weeks ago,
- Fundal height was equal to dates,
- Foetal presentation was cephalic,
- Foetal heart was heard,
- Foetal movements felt.

It was also documented that Mrs. Molloy had requested a sweep[28] at her next appointment.

Mrs. Molloy had an ultrasound scan carried out; the result of the scan was documented as follows:

- Foetus in the cephalic position,
- Liquor volume normal,

Mrs. Molloy attended her fifth antenatal outpatient appointment on the 11th January 2012.

The documentation completed by Consultant Obstetrician Gynaecologist A indicates that Mrs. Molloy's;

- Weight was 70.4 kilograms,
- Urinalysis - NAD,
- Blood pressure 110/67 millimetres of mercury,
- Pulse rate was 94 beats per minute,
- LMP; Term minus 4 days,
- Fundal height was term,
- Foetal presentation was cephalic
- 3-4 fifths (of head) palpable[29],
- Foetal heart was heard,

[28] 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).

[29] The amount of descent and engagement of the head is assessed by feeling how many fifths of the head are palpable above the brim of the pelvis:
1. 5/5 of the head palpable mean that the whole head is above the brim of the pelvis.
2. 4/5 of the head palpable means that a small part of the head is below the brim of the pelvis and can be lifted out of the pelvis with the deep pelvic grip.
3. 3/5 of the head palpable means that the head cannot be lifted out of the pelvis. On doing the deep pelvic grip, your fingers will move outwards from the neck of the fetus, then inwards before reaching the pelvic brim.
4. 2/5 of the head palpable means that most of the head is below the pelvic brim, and on doing the deep pelvic grip, your fingers only splay outwards from the fetal neck to the pelvic brim.
5. 1/5 of the head palpable means that only the tip of the fetal head can be felt above the pelvic brim.
It is very important to be able to distinguish between 3/5 and 2/5 head palpable above the pelvic brim. If only 2/5 of the head is palpable, then engagement has taken place and the possibility of disproportion at the pelvic inlet can be ruled out (reference: http://www.gfmer.ch/PEP/pdf-MCM-2006/MCM_SW-8-1-2006.pdf.

- Foetal movements felt.

It was documented that;

- V/E cervix post,
- 2+ centimetres long,
- Admits 1 finger, S-3,
- Sweep.

It was documented that Mrs. Molloy's ultrasound scan carried out on the 11th January 2012 showed the following:

- Growth on centiles,
- Liquor volume normal,

It was also documented that Mrs. Molloy requested epidural analgesia[30] and there is a tick (√) beside FM (foetal movement) and iron.

Mrs. Molloy and her husband indicated during the investigation that Mrs. Molloy was anxious that she would receive epidural analgesia as she had not received epidural analgesia during her last three previous deliveries and that she had received epidural analgesia for the birth of her first child.

Mrs. Molloy and her husband indicated that Consultant Obstetrician Gynaecologist A had documented that Mrs. Molloy had requested epidural analgesia following a conversation that Mrs. Molloy had with Consultant Obstetrician Gynaecologist A when Mrs. Molloy had expressed her anxiety that she would not receive epidural analgesia in sufficient time to relieve her pain before the baby was delivered.

Mrs. Molloy attended for her sixth antenatal outpatient appointment on the 18th January 2012.

The documentation completed by Consultant Obstetrician Gynaecologist A at the clinic indicates that Mrs. Molloy's;

- Weight was 70.4 kilograms,
- Urinalysis - NAD,
- Blood pressure 107/61 millimetres of mercury,
- LMP; Term plus 3 days[31],
- Fundal height was term,
- Foetal presentation was cephalic,
- 2-3 fifths (of head) palpable,
- Foetal heart was heard,
- Foetal movements felt.

The following information was also documented;

- V/E cervix post,
- 1-2 centimetres long,
- Admits two fingers of S -3 sweep,

An ultrasound scan was carried out on Mrs. Molloy at the clinic; the result of scan was as follows;

[30] 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).

[31] Mrs. Molloy and her husband indicated that Mrs. Molloy's last menstrual period was on the 8th April 2011 and that she was term plus 5 days at this time.

- EFW (estimated foetal weight) 3.9 kilograms,
- AC on 90th centile,
- LV (liquor volume) normal.

It was documented that Mrs. Molloy would be admitted on the 24th January 2012 for induction of labour (IOL)[32].

[32]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).

The chronology of events has been established as follows:

Details provided in this report have been obtained from review of the relevant Documentation as listed on page 6 and on the basis of interviews with the relevant staff and Mrs. Molloy and her husband.

24th January 2012

04.10 hours:

Mrs. Molloy indicated that she had a 'show'[33] and started feeling labour pains while at home.

04.30 hours:

The report provided by Mrs. Molloy and her husband states that they left their home to travel to Midland Regional Hospital at Portlaoise as a result of the 'show' and onset of labour pains.

04.50 hours:

Mrs. Molloy and her husband recall that they arrived at Midland Regional Hospital at Portlaoise.

05.05 hours approximately:

It was documented in the sequence of events prepared by Mrs. Molloy and her husband and in Mrs. Molloy's healthcare record that Mr. and Mrs. Molloy presented to Reception of the Maternity Department where they were met by Midwife A.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy immediately requested epidural analgesia.

Mrs. Molloy and her husband recall that they were brought to Examination Room 3 by Midwife A where Mrs. Molloy was placed on the cardiotocography monitor (CTG)[34] and assessed; Mrs. Molloy's husband left the room while his wife was being examined. Mrs. Molloy and her husband also indicated that Midwife A left the room for a short period at this time.

The result of the assessment carried out by Midwife A was documented in Mrs. Molloy's maternity healthcare record[35] under the following headings;

History and Examination on Admission;

- Temperature 36 degrees centigrade,
- Blood pressure 141/86 millimetres of mercury,
- Pulse rate 87 beats per minute (normal adult heart rate 60-100 beats per minute),
- Foetal heart rate 134 beats per minute (normal foetal heart rate 110-160 beats per minute),

[33] 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).

[34] 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).

[35] Mrs. Molloy's maternity healthcare record was available on the Maternity Department when she arrived as she was scheduled to attend the Department for induction of labour that morning.

- Foetal movements felt,

Reason for Admission;

- Contractions 1:4 (i.e. one contraction every four minutes) at 04.20 hours with a show and slight backache,
- Fundus was equal to dates,
- Lie long,
- Cephalic presentation engaged.

Midwife A's documentation indicated that a vaginal examination was performed with consent; which showed the following;

- Foetal heart rate prior to examination 130 beats per minute,
- External genitalia: [there was no documentation on this part of the examination],
- Vagina: [there was no documentation on this part of the examination],
- Cervix: Thin
- Effacement[36]: effacing
- Consistency: medium
- Application: loose
- Dilation: 3cms
- Presentation: cephalic
- Relationship to ischial spines[37]: - 2
- Position[38] i.e. position of the head: [there was no documentation on this part of the examination],
- Membrane: intact
- Liquor: [there was no documentation on this part of the examination],
- Foetal heart rate post examination: 130 beats per minute.

The entry was signed by Midwife A.

It was documented in the healthcare record that Mrs. Molloy's vaginal examination took place at 04.15 hours however it was established during the investigation that this was an error and the examination took place at 05.10 hours.

05.10 hours:

The following information was documented in the 'Progress Notes' section of the healthcare record under the heading 'Mother's Notes':

- Admission, Contraction 1:4 @ 04.20 hours,
- + [i.e. positive] show with slight backache,
- T [i.e. temperature] 36 degrees centigrade,

[36] Effacement relates to the softening and shortening of the cervical canal from about 3cm long to less than 0.5cm long. (Reference: National Collaborating Centre for Women's and Children's Health 2008 ClinicalGuideline; Induction of Labour RCOG Press London).

[37] Ischial spines are two relatively sharp posterior bony projections into the pelvic outlet from the ischial bones that form the lower border of the pelvis (reference http://medical-dictionary.thefreedictionary.com/ischial+spines). The spines are the narrowest part of the pelvis and they are natural measuring point for the delivery progress. If the presenting part of the baby (the head, shoulder, buttocks or feet) lies above the Ischial spines, the foetal position is reported as a negative number from -1 to -5 (each number is a centimetre). If the presenting part lies below the Ischial spines, the station is reported as a positive number from +1 to +5. The baby is said to be 'engaged' in the pelvis when it is even with the Ischial spines at 0 station (reference: http://www.umm.edu/ency/article/002060.htm).

[38] Over 95 percent of fetuses are in cephalic presentation at term. The position of the fetal occiput (back of head or skull) can be anterior, transverse or posterior. Fifteen to 20 percent of term fetuses are in occiput posterior (OP) position before labour. Most of these fetuses rotate intrapartum: the incidence at vaginal birth is approximately 5 percent. Persistence of the OP position is important because it can be associated with labor abnormalities and maternal and neonatal complications (reference: http://www.uptodate.com/contents/management-of-the-fetus-in-occiput-posterior-position table 1).

- Pulse rate 87 beats per minute,
- Blood pressure 141/86 millimetres of mercury,
- FHR [foetal heart rate] 134 beats per minute,
- Fundus equal terms, lie long,
- Vaginal examination carried out with consent,
- Cervix 3cm dilated,
- Vestibular of head - 2 centimetres,
- Bulging membranes,
- FH 130 beats per minute,
- CTG commenced,
- Requesting epidural,
- To LW [Labour Ward] for same.

The entry was signed by Midwife A.

05.20 hours:

It was documented by Midwife A that Mrs. Molloy requested epidural analgesia and that a CTG was in progress; the result of the CTG was documented as follows; under the heading 'CTG Interpretation';

CTG Interpretation;

- Base line foetal heart rate[39]: 130 beats per min (i.e. minutes),

- Baseline variable: = 5 beats per min (i.e. minute),
- Accelerations x 2 in 20 mins (i.e. minutes): No
- Decelerations: No
- Uterine contractions:
  - Frequency: 3 in 10 mins (i.e. minutes) approx (i.e. approximately)

[39] **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. ***V*ariable deceleration** is defined as an apparent abrupt decrease in FHR below the baseline, with the time from the onset of the deceleration to the nadir of the deceleration as less than 30 seconds. The decrease is measured from the most recently determined portion of the baseline. Variable decelerations may or may not be associated with uterine contractions. The decrease from baseline is 15 beats per minute or higher and lasts less than 2 minutes from onset to return to baseline. When variable decelerations occur in conjunction with uterine contractions, their onset, depth, and duration may vary with each successive uterine contraction (reference: Robinson B. (2008) A Review of NICHD Standardized Nomenclature for Cardiotocograph: The Importance of Speaking a Common Language When Describing Electronic Fetal Monitoring. Rev Obstet Gynecol. 2008 Spring; 1(2): 56-60 (Available from: http://medical-dictionary.thefreedictionary.com/premature+labor).
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505172/).

- The duration of the contractions is not recorded.

The CTG interpretation was signed by Midwife A.

At interview Mrs. Molloy indicated that she informed Midwife A that Consultant Obstetrician Gynaecologist A had stated that she (i.e. Mrs. Molloy) could have an epidural when she was 3 centimetres dilated, Mrs. Molloy and her husband indicated that it was their recollection that Midwife A responded by stating "see how you go" and that Midwife A indicated that Mrs. Molloy was in luck as Consultant Obstetrician Gynaecologist A was on call[40].

Mrs. Molloy also indicated that it was her recollection that Midwife A suggested that she should spend an extended period of time on the CTG which Mrs. Molloy declined as she was anxious to be transferred to the Labour Ward.

Mrs. Molloy indicated at interview that judging from her previous experience and particularly the speed of her last labour, that she did not want to be too late to receive epidural analgesia.

05.27 hours:

Midwife A stated that she discontinued the CTG as Mrs. Molloy appeared nervous and she transferred her to the Labour Ward.

05.30 hours approximately:

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that they left the Assessment Unit to go to the Labour Ward accompanied by Midwife A.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that while walking to the Labour Ward that Mrs. Molloy had two labour contractions[41].

Mrs. Molloy and her husband recall that Midwife A was walking 9 metres ahead of them when Mrs. Molloy experienced these contractions and it was their recollection that Midwife A did not come back up the corridor to stand beside Mrs. Molloy to provide support during the contractions and that Midwife A stated "I'll wait for you here".

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that during her previous pregnancies that a midwife had stood beside her and had provided hands on support during contractions that she had experienced while walking to the Labour Ward.

Midwife A indicated during the investigation that she left Mrs. Molloy and her husband on two occasions while Mrs. Molloy was walking from the Assessment Unit to the Labour Ward. Midwife A indicated that on the first occasion she left Mrs. Molloy to go to the Nurses Station to identify which bed would be allocated to Mrs. Molloy following her delivery. Midwife A indicated that she left Mrs. Molloy on the second occasion so that she could show Mr. Molloy the bed in the ward that would be allocated to Mrs. Molloy following her delivery and to leave Mrs. Molloy's luggage on the bed.

05.40 hours approximately:

Mrs. Molloy indicated at interview that her husband and Midwife A accompanied her to the Labour Ward where she was allocated a room.
It was documented in the sequence of events prepared by Mrs. Molloy and her husband that when Mrs. Molloy arrived on the Labour Ward that she again requested epidural

[40]When a patient is admitted on any given day they automatically go under the care of whatever Consultant Obstetrician Gynaecologist is on call on that day regardless of whose clinic they are attending antenatally.
[41] It is 54 metres from Examination Room 3 to the Delivery Suite allocated to Mrs. Molloy on the 24th January 2012.

analgesia and that Midwife A stated that "it is not my job to call an Anaesthetist" and that she needed to hand over Mrs. Molloy's midwifery care to Midwife B.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Midwife B arrived on the Labour Ward soon after their arrival.

Midwife B indicated during the investigation that when Mrs. Molloy arrived on the Labour Ward that Midwife A showed her the initial CTG that was recorded in the Assessment Unit; and that Midwife A had informed her that the tracing was non-reassuring[42].

05.50 hours:

It was documented in the healthcare record by Midwife B that Mrs. Molloy requested epidural analgesia on arrival to the Labour Ward and that she appeared anxious and fearful that she would not get the analgesia[43].

Midwife B documented that she administered Entenox[44] to Mrs. Molloy as pain relief; and that she asked Mrs. Molloy if she was sure she wanted epidural analgesia as Mrs. Molloy was experiencing labour contractions and that she (i.e. Midwife B) was of the view that she expected the delivery to progress quickly.

It was documented by Midwife B that the on call Anaesthetic Registrar was contacted in relation to Mrs. Molloy's epidural analgesia.

Mrs. Molloy and her husband told the investigation that they were not informed that the on call Anaesthetic Registrar had been contacted at this time and that, if they had known, it would have reduced the "extreme anxiety" Mrs. Molloy had about receiving epidural analgesia.

Midwife B documented that Mrs. Molloy had an intravenous cannula in place, that intravenous fluids were in progress and that the plan was to hydrate Mrs. Molloy. Midwife B indicated during the investigation that expectant mothers often become dehydrated during labour which can have an adverse effect on the CTG i.e. that the CTG can be nonreassuring when the expectant mother is dehydrated. Midwife B indicated that the plan was to rehydrate Mrs. Molloy which would result in a reassuring CTG.

Mrs. Molloy and her husband indicated during the investigation that Mrs. Molloy continued to drink water while she was on the Labour Ward which was given to her by her husband.

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

[43] It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy had experienced delays in the commencement of epidural analgesia when she was admitted for her three previous pregnancies and that she had experienced severe pain as a result of these delays. Mrs. Molloy indicated that as a result of these delays that she frequently requested an epidural during her admission on the 24th January. Mrs. Molloy also indicated that she had discussed this issue with Consultant Obstetrician Gynaecologist A at an antenatal outpatient appointment and that Consultant Obstetrician Gynaecologist A had reassured her that she could choose her own pain relief and that she had a right to receive an epidural if she requested it. Consultant Obstetrician Gynaecologist A documented that Mrs. Molloy requested epidural analgesia at the Antenatal clinic on the 11th January 2012.

[44] Entenox is used as an analgesia and can be self administered using a demand valve which is popular in obstetric practice (Reference: British National Formulary 2009)

It was documented by Midwife B that the CTG that was recommenced on Mrs. Molloy when she arrived on the Labour Ward was reassuring i.e. all four features of the CTG were normal.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that while in the Labour Ward that Mrs. Molloy's husband remained on her left side holding her hand.

06.05 hours approximately:

Midwife B indicated at interview that Midwife C contacted the on call Anaesthetic Registrar again as Mrs. Molloy and her husband remained anxious and they continued to request epidural analgesia for Mrs. Molloy.

It was documented that the on call Anaesthetic Registrar responded to the bleep and that he informed Midwife C that he was on his way to the Labour Ward.

It was documented by Midwife B that the foetal heart rate was between 130-150 beats per minute at this time.

06.15 hours:

Midwife B documented that the foetal heart rate was 134 beats per minute, that the on call Anaesthetic Registrar was with Mrs. Molloy and that Mrs. Molloy was sitting at the side of the bed in readiness for insertion of the epidural cannula.

Mrs. Molloy indicated that she was assisted to the side of the bed by her husband and Midwife B.

Midwife B documented in Mrs. Molloy's healthcare record and confirmed at interview that she commenced intermittent auscultation[45] of the foetal heart rate while the epidural cannula was being inserted.

There is a difference in what is documented in the healthcare record and Mrs. Molloy and her husband's recollection in relation to whether the foetal heart rate was monitored during insertion of the epidural cannula. Mrs. Molloy and her husband stated that it was their recollection that the foetal heart rate was not intermittently monitored while the epidural cannula was being inserted into Mrs. Molloy's spine.

The on call Anaesthetic Registrar documented that he explained the risks of epidural analgesia to Mrs. Molloy. It was documented that the risks explained were as follows; headache, nerve injury, infection, haematoma, backache[46].

Mrs. Molloy signed the Consent Form for insertion of the epidural cannula.

06.20 hours:

Midwife B documented that the foetal heart rate was 144 beats per minute

06.25 hours:

Midwife B documented that the foetal heart rate was 136 beats per minute.

[45] Intermittent auscultation employs listening to foetal heart sounds at periodic intervals to assess the foetal heart rate (FHR) using either a Pinard stethoscope or a hand held (Doppler) devise (reference: Regional Maternity Department MRH Mullingar and MRH Portlaoise Foetal Heart Monitoring in the Maternity Department. Approval date: April 2011).

[46] Consultant Obstetrician Gynaecologist A indicated during the investigation that there is a leaflet on epidural analgesia which patients should read before insertion of the epidural cannula.

06:27 hours:

There is a difference in what is documented in the maternity healthcare record and the recollection of Midwife B and that of Mrs. Molloy and her husband related to whether Mrs. Molloy was turned onto her left side and whether the extent and level of sensory block of the epidural analgesia was checked.

It was documented on the Epidural Observation Chart by Midwife B that:

- Mrs. Molloy was lying on her left side,
- Left side T10 (thoracic 10) to L3 (lumbar 3)[47], right side T10, L3,
- Blood pressure was 114/66 millimetres of mercury,
- Pulse rate was 72 beats per minute,
- Respiration rate was 18 breaths per minute,
- Temperature was 36.2 degrees centigrade.

Mrs. Molloy and her husband informed the investigation that it was their recollection that at no time was Mrs. Molloy turned onto the left side.

Mrs. Molloy and her husband also indicated that they had no recollection of Midwife B carrying out assessments of the extent and level of the sensory block of the epidural analgesia[48].

It was documented that the foetal heart rate was 140 beats per minute.

It was documented by Midwife B that the epidural cannula was sited and that the CTG was recommenced.

Mrs. Molloy's vital signs were documented as follows;

- Blood pressure was 114/66 millimetres of mercury,
- Pulse rate was 72 beats per minute,
- Temperature was 36.4 degrees centigrade.

Midwife B also documented that the epidural analgesia was infusing at 10 millilitres per hour.

06.30 hours:

It was documented by the on call Anaesthetic Registrar that he administered a test dose of the epidural analgesia to Mrs. Molloy and that he observed Mrs. Molloy for 10 minutes to ensure that she did not have an adverse reaction to the drug.

The on call Anaesthetic Registrar indicated that he prescribed an infusion rate of 10 – 15 millilitres per hour of epidural analgesia which consisted of a premixed solution of Chirocaine 0.1% and Fentanyl 2 micrograms per millilitre when there was no evidence that Mrs. Molloy was experiencing any adverse reaction.

[47] The spine is divided into five regions: cervical (neck bones); thoracic (in the chest); lumbar (low back); sacral (attached to the pelvis); and, coccygeal (the tail bone). Each region has a number of vertebral bones. There are usually seven cervical vertebral bones, twelve thoracic bones, and five lumbar vertebral bones. The sacrum is a single, large, fused bone. The coccyx is made of one or two small bones (reference: http://www.neurosurgical.com/neuro_medical_info/spinal_anatomy.htm). T10 to L3 indicated that the epidural was effective from the level of T10 to L3.

[48] Midland Regional Hospital at Portlaoise's Guideline on the Management of an expectant mother's pain and pain relief during labour states that "half hourly assessment of the extent and level of the sensory block should be undertaken using ice-cubes or ethyl chloride spray".

06.35 hours:

Midwife B documented that Mrs. Molloy was pushing and that she was advised not to push as she was not fully dilated.

There is a difference in what is documented in the healthcare record and Mrs. Molloy and her husband's recollection in relation to the advice that was given to Mrs. Molloy on whether to push or not to push.

It was Mrs. Molloy and her husband's recollection that Mrs. Molloy was pushing and that Mrs. Molloy's husband informed Midwife B of this. Mrs. Molloy and her husband recall that Midwife B responded "if she wants to push she can push"[49].

06.40 hours:

The epidural infusion was commenced on Mrs. Molloy.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that following commencement of the epidural analgesia that Mrs. Molloy informed the on call Anaesthetic Registrar that she felt that the edge had gone off the contraction pains but that she could still feel pain. Mrs. Molloy and her husband indicated that Mrs. Molloy continued to use Entenox during her time on the Labour Ward until the time she was administered a bolus dose of epidural analgesia just before her surgery at 09.10 hours.

Midwife B documented that Mrs. Molloy had a strong urge to push and that she carried out a vaginal examination on her. The documented findings of the examination were as follows;

- Cervix dilated to 8 centimetres,
- Vertex minus[50] - 2,
- ARM (artificial rupture of membrane) preformed[51],
- Good volume of Grade I meconium[52] present,
- ~~Position~~*(*there is a line through the word position in the healthcare record),
- Contraction's strong and pushing,
- Late deceleration present → Left lateral position with quick recovery,
- Second litre (of) Hartmann's Solution[53] in progress.

Midwife B indicated at interview that it was her opinion at the time the CGT was recorded that the nonreassuring CTG was as a result of the ARM and descent of the baby's head into the pelvis. Midwife B indicated that as a result of the nonreassuring CTG she requested Mrs. Molloy to change position in the bed[54] i.e. to the left lateral position and that following the change in position the CTG was reassuring.

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[49] 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_).

[50] Please refer to Footnote 21 for explanation of Vertex minus.

[51] An artificial rupture of the foetal membranes, usually performed to stimulate or accelerate the onset of labour (reference: http://medical-dictionary.thefreedictionary.com/amniotomy).

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

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

[54] Variable decelerations on CTG could be associated with umbilical cord compression and may be relieved by changing the mother's position (reference: http://medical-dictionary.thefreedictionary.com/fetal).

Mrs. Molloy and her husband indicated during the investigation that it was their recollection that the CTG machine did not alarm at any stage during their time on the Labour Ward.

Midwife B indicated at interview that she then asked Mrs. Molloy to push but when there was no sign of the 2nd stage of labour progressing she requested that Mrs. Molloy stop pushing and requested her to turn onto her left side to facilitate the progression of labour.

There is a difference in Midwife B's recollection and those of Mrs. Molloy and her husband in relation to whether Mrs. Molloy was requested to stop pushing and to turn onto her left side. Mrs. Molloy and her husband informed the investigation that they were 'adamant' that at no stage was Mrs. Molloy requested to stop pushing by Midwife B or to turn onto her left side. Mrs. Molloy and her husband indicated during the investigation that the only person who requested that Mrs. Molloy stop pushing was the on call Obstetrician Gynaecologist Registrar when a urinary catheter was being inserted.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy was placed in the lithotomy position[55] at this time. Mrs. Molloy indicated that she was unable to reach the left or right hand grips to support herself in the lithotomy position and that while her husband directed her hand to the left hand grip she soon let this go as she was unable to reach the right hand grip.

Mrs. Molloy and her husband indicated during the investigation that Mrs. Molloy remained in the supine or lithotomy position throughout her time on the Labour Ward and that the only time she was in the sitting position was when the epidural cannula was being inserted into her spine.

There is a difference in the recollections of Mrs. Molloy and her husband and those of Midwife B in relation to whether Mrs. Molloy was placed in the lithotomy position. Midwife B indicated during the investigation that it was her recollection that Mrs. Molloy was not put in the lithotomy position at this time but that her feet were put in foot-paddles which afford counter traction for patients and supports their effort in pushing.

It was also documented in the sequence of events prepared by Mrs. Molloy and her husband that at this time Mrs. Molloy's husband noticed that the mouth piece used to deliver the drug Entenox was clogged with a mucus plug and that he brought the mouth piece into an adjacent room where he cleaned it.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Midwife C entered the room at this time and that she sat on a stool at the foot of the bed.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Midwife B informed Midwife C that there was a presence of meconium in Mrs. Molloy's liquor and that Midwife B queried if she should inform someone of this fact. Mrs. Molloy indicated that Midwife C then asked her i.e. Mrs. Molloy 'how far she was gone in her pregnancy' and that she (Mrs. Molloy) responded by informing Midwife C that she was term plus 9 days.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that following a conversation between Midwife B and Midwife C that a decision was made not to contact the on call Obstetrician Gynaecologist Registrar as meconium stained liquor was not unusual in women who are nine days overdue.

There is a difference in the recollections of Mr. and Mrs. Molloy and those of Midwife B and Midwife C in relation to whether a discussion took place to contact the on call Obstetrician Gynaecology Registrar at this time.

Midwife B and Midwife C indicated during separate interviews that when Mrs. Molloy asked whether it was normal for Grade 1 meconium stained liquor to be present following the

[55]Lithotomy position in which the patient is on their back with the hips and knees flexed and the thighs apart. The position is often used for vaginal examinations and childbirth (reference: http://www.medterms.com/script/main/art.asp?articlekey=25628)

artificial rupture of membrane that Mrs. Molloy was asked 'how far she was gone in her pregnancy' and that she (Mrs. Molloy) responded by informing them that she was term plus 9 days and that Mrs. Molloy was informed that it can be normal for women who are overdue in their labour to have Grade 1 meconium stained liquor present in their labour.

There is no documentation in the healthcare record in relation to the conversation that took place with Mrs. Molloy in relation to the Grade 1 meconium staining.

Midwife B and Midwife C indicated during separate interviews that they did not have any discussion on whether to contact the on call Obstetrician Gynaecologist Registrar in relation to the Grade 1 meconium stained liquor following the rupture of Mrs. Molloy's membranes.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Midwife C left the room following this conversation and that Mrs. Molloy commenced pushing directly after the artificial rupture of membranes.

There is no documentation in Mrs. Molloy's maternity healthcare record in relation to the conversation that took place between Midwife B and Midwife C about the meconium staining and/or related to any decision to contact the on call Obstetrician Gynaecologist Registrar at this time.

06.55 hours approximately:

It is documented in the sequence of events prepared by Mrs. Molloy and her husband that Midwife B informed Mrs. Molloy that she could have her baby by 07.00 hours and that she could see that her baby had fair hair.

07.00 hours:

It was documented by Midwife B that Mrs. Molloy had a strong urge to push and that she was advised not to push.

There was a difference in the recollections of Midwife B and those of Mrs. Molloy and her husband in relation to whether Mrs. Molloy was advised not to push at this time. It was Mrs. Molloy and her husband's recollection that at no stage during the time Mrs. Molloy was on the Labour Ward was she advised not to push except when the on call Obstetrician Gynaecology Registrar was inserting a urinary catheter.

It was documented that the foetal heart rate was 150 beats per minute at this time.

07.15 hours:

It was documented by Midwife B that the CTG showed a foetal heart rate of 130-150 beats per minute with early decelerations, that Mrs. Molloy was moved on to her left side[56] and that the CTG was reassuring following this.

There is a difference between what is documented by Midwife B and the recollections of Mrs. Molloy and her husband in relation to whether Mrs. Molloy was requested to move onto her side at this time. It was Mrs. Molloy and her husband's recollections that she remained on her back throughout the time that her care was managed on the Labour Ward and that she was not requested to move onto her side at any time on the 24th January. Mrs. Molloy indicated that she would have remembered if she had been asked to turn onto her left side as she had found turning on her left side very difficult and uncomfortable during her previous deliveries.

It was also documented by Midwife B that Mrs. Molloy had a small amount of blood stained liquor draining and that "Pt (i.e. patient) using ~~encouraged~~ Entenox but remains v (i.e. very) anxious".

[56] Variable deceleration could be associated with umbilical cord compression and may be relieved by changing the mother's position (reference: http://medical-dictionary.thefreedictionary.com/fetal).

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that on two occasions Midwife B called Midwife C to assist her 'in the birth of the baby' but that Midwife C left after a short period of time on both occasions as there was no progress in the delivery. Mrs. Molloy and her husband recall that Midwife B informed them that Mrs. Molloy's cervix was 8 centimetres dilated and that a lip of the cervix was over the baby's head which was preventing a full dilation of the cervix.

Mrs. Molloy indicated that it was her view that she received little verbal encouragement and support from Midwife B during her time on the Labour Ward and that it was her husband who provided most of the encouragement and support. Midwife B informed the Review Team that she was attentive and supportive to Mrs. Molloy while she was responsible for her midwifery care on the Labour Ward.

07.20 hours:

There was a difference in the recollections of Mrs. Molloy, her husband, Midwife C and Midwife B; and those of Obstetrician Gynaecology Registrar A related to the time Midwife C first contacted Obstetrician Gynaecology Registrar A to review Mrs. Molloy.

It was documented in Mrs. Molloy and her husband's sequence of events that while they could not be sure of the exact time Obstetrician Gynaecology Registrar A was contacted and what time he arrived on the Labour Ward because they were not taking notes at the time that it was their recollection that a decision was taken to contact Obstetrician Gynaecology Registrar A between 07.15 hours and 07.30 hours and that he arrived on the Labour Ward between 07.20 hours and 07.35 hours.

Midwife C and Midwife B indicated during the investigation that it was their recollection that Midwife C contacted Obstetrician Gynaecology Registrar A between 07.15 and 07.20 hours.

On the other hand Obstetrician Gynaecology Registrar A indicated during the investigation that it was his recollection that he was first contacted in relation to Mrs. Molloy's condition at 07.47 hours and that he arrived on the Maternity Department at 07.55 hours.

In an effort to reconcile the differences in the recollections of Mrs. Molloy, her husband, Midwife C and Midwife B; and those of Obstetrician Gynaecology Registrar A in relation to the time Obstetrician Gynaecology Registrar A was first contacted on the morning of the 24th January 2012 the Review Team requested a copy of the phone records including a copy of the record of staff who were bleeped on the morning of the 24th January 2012. The Review Team was informed that the record of staff bleeped on the 24th January 2012 had not been retained.

There was no documentation in Mrs. Molloy's healthcare record in relation to Midwife C's contact with Obstetrician Gynaecology Registrar A at this time i.e. between 07.15 hours and 07.45 hours.

Midwife C indicated during interview that she contacted Obstetrician Gynaecology Registrar A and informed him that Mrs. Molloy was involuntarily pushing, that Mrs. Molloy was fully dilated but that her labour was not progressing. Midwife C indicated that she requested Obstetrician Gynaecology Registrar A to review Mrs. Molloy and that Obstetrician Gynaecology Registrar A agreed to this request.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that following a discussion between Midwife B and Midwife C that a decision was made to contact a member of the Obstetric Gynaecology on call team to inform them that Mrs. Molloy's labour was not progressing. Mrs. Molloy recalls that a discussion then took place between Midwife B and Midwife C in relation to which member of the on call Obstetric Gynaecology team to contact; and that following this discussion a decision was made to contact Obstetrician Gynaecologist Registrar A.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy was surprised with this decision as Midwife A had informed her that Consultant Obstetrician Gynaecologist A was on call.

There was a difference in the recollections of Mrs. Molloy and her husband and those of Midwife B and C in relation to whether a discussion took place on which member of the on call Obstetrician Gynaecology team to call. Midwife B and C indicated during the investigation that it was their recollections that no discussion took place in relation to which member of the on call Obstetrician Gynaecology team to contact at this time as it is the policy within the Maternity Department that the on call Obstetrician Gynaecology Registrar is the first member of the on call team to be contacted to review public patients

07.30 hours:

It was documented by Midwife B that Mrs. Molloy's vital signs were as follows;

- Pulse rate was 91 beats per minute,
- Temperature was 36.8 degrees centigrade,
- Blood pressure was 101/52 millimetres of mercury.

Midwife B carried out a vaginal examination on Mrs. Molloy and documented the following findings;

- Foetal heart rate before examination 140 beats per minute,
- External genetalia: NAD,
- Vagina: Blood stained liquor,
- Cervix: Thin,
- Effacement: Fully,
- Consistency: soft,
- Application: Close,
- Dilation: 9+ centimetres,
- Relationship to the ischial spines: - 2, - 1,
- Position: i.e. position of the head: [there was no documentation on this part of the examination],
- Membrane: ruptured,
- Liquor: blood stained,
- Foetal Heart Rate Post Examination: 150 beats per minute,

Midwife B documented that Mrs. Molloy was "Pushing ~~well~~ continually encouraged not to". Midwife B documented that the CTG's baseline was 125 beats per minute with variables present which recovered to baseline quickly.

There is a difference in what is documented in Mrs. Molloy's maternity healthcare record and Mrs. Molloy and her husband's recollection related to whether Mrs. Molloy was requested not to push. Mrs. Molloy and her husband informed the investigation that they were 'adamant' that at no stage was Mrs. Molloy requested not to push except when the on call Obstetrician Gynaecology Registrar made the request when he was inserting a urinary catheter.

It was documented by Midwife B that Mrs. Molloy had a urethral catheter inserted and that no urine was passed through the catheter.

It was documented in the Epidural Observation Chart that Mrs. Molloy's vital signs were as follows;

- Blood pressure was 101/52 millimetres of mercury,
- Pulse rate was 76 beats per minute,
- Respiration rate was 18 breaths per minute,
- Temperature was 36.4 degrees centigrade,
- Foetal heart rate was 144 beats per minute,
- Right side; thoracic 10 to lumbar 3,
- Left side; thoracic 10 to lumbar 3.

07.35 hours:

Midwife B documented that Mrs. Molloy had an urge to push and that she (Midwife B) carried out a vaginal examination which showed that the cervix was fully dilated, vertex

minus - 2, - 1 and that as a result of the cervix being fully dilated that Mrs. Molloy began to actively push.
The foetal heart rate was documented as 110-120 beats per minute.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy was pushing for 55 minutes at this stage.

07.40 hours:

It was documented by Midwife B that the foetal heart rate was 90-110 beats per minute, that Mrs. Molloy was pushing but that there was no descent i.e. of the foetus.

Midwife B indicated during the investigation that she requested Midwife C to contact the Obstetrician Gynaecology Registrar on call. Midwife C indicated at interview that she rang Obstetrician Gynaecology Registrar A by speed dial and informed him that there was a pattern of variables emerging on the CTG and that there was a failure to progress. Midwife B indicated at interview that Obstetrician Gynaecology Registrar A responded to the bleep immediately and informed Midwife B that he was in the building and that he would review Mrs. Molloy[57].

07.45 hours:

It was documented by Midwife B that the foetal heart rate was 90-110 beats per minute and that there were early decelerations and variables on the CTG.

Midwife B documented that Mrs. Molloy had a strong urge to push with good maternal effort but that there was no descent of the foetus into the cervix and that as a result she (Midwife B) requested Mrs. Molloy not to push.

There is a difference in what is documented in Mrs. Molloy's maternity healthcare record and Mrs. Molloy and her husband's recollection in relation to whether Mrs. Molloy was requested not to push. Mrs. Molloy and her husband informed the investigation that it was their recollection that at no stage was Mrs. Molloy requested not to push except when the on call Obstetrician Gynaecology Registrar made the request when he was inserting a urinary catheter.

Midwife B documented that she thought that Mrs. Molloy's baby might be bigger than she (Midwife B) had previously thought and for that reason the baby was not descending.

Midwife B indicated during interview that she informed Mrs. Molloy that the baby was getting tired and that she was going to call the doctor. There was a difference in the recollections of Midwife B and those of Mrs. Molloy and her husband in relation to whether they were informed that their baby was getting tired. It was Mrs. Molloy and her husband's recollection that they were not informed that their baby was getting tired and indicated that if they had been informed of this fact that they would have definitely remembered it.

07.47 hours:

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that when Obstetrician Gynaecology Registrar A arrived on the Labour Ward that he introduced himself to them. Mrs. Molloy indicated that Obstetrician Gynaecology Registrar A then proceeded to wash his hands.

Mrs. Molloy and her husband informed the investigation that Obstetrician Gynaecology Registrar A gesticulated with his elbow that one of the stirrups was set up back to front and that in response Midwife B turned the stirrup through 180 degrees.

Mrs. Molloy and her husband informed the investigation that they requested Obstetrician Gynaecology Registrar A to review Mrs. Molloy's maternity healthcare record as the records showed that, similar to this pregnancy, Mrs. Molloy had failed to progress during the

[57] As previously stated Obstetrician Gynaecology Registrar A indicated during the investigation that he was contacted in relation to Mrs. Molloy at 07.47 hours.

delivery of her second child and that suction[58] was used in three of Mrs. Molloy's previous deliveries as in all cases the babies were in the occiput posterior position.

Mrs. Molloy and her husband indicated that they requested staff on the Labour Ward to review Mrs. Molloy's healthcare record on several occasions due to the similarities between this labour and her previous episodes of labour.

In a retrospective record recorded later that day Obstetrician Gynaecology Registrar A documented that he was called to assess Mrs. Molloy; that she was para 4 plus 2 and that she was in the second stage of labour[59].

07.50 hours:

It was documented by Midwife B that;

- Mrs. Molloy was in the lithotomy position,
- That the epidural analgesia was infusing at a rate of 10 millilitres per hour,
- That a second litre of fluids was infusing,
- That Mrs. Molloy's temperature was 36.4 degrees centigrade,
- That Mrs. Molloy's pulse rate was 80 beats per minute.

Midwife B documented that she encouraged Mrs. Molloy not to push as there was no progress in the delivery of the foetus.

Mrs. Molloy and her husband informed the investigation that it was their recollection that at no stage was Mrs. Molloy requested not to push except when the on call Obstetrician Gynaecology Registrar made the request for her not to push when he was inserting a urinary catheter.

07.55 hours:

It is Obstetrician Gynaecology Registrar A's recollection that he arrived on the Labour Ward to review Mrs. Molloy[60].

Obstetrician Gynaecology Registrar A indicated during the investigation that it was his recollection that he arrived on the Labour Ward at 07.55 hours and not at 07.47 hours as recalled by Mr. and Mrs. Molloy.

Entries made in Mrs. Molloy's maternity healthcare record that relate to the time period between 07.47 hours and 08.25 hours indicate that Obstetrician Gynaecology Registrar A assessed Mrs. Molloy on five occasions; at 07.47 hours, 07.55 hours, 08.10 hours, 08.20 hours and 08.25 hours. Entries made in Mrs. Molloy's healthcare record indicate that Obstetrician Gynaecology Registrar A documented the results of his assessments retrospectively at 11.30 hours that day.

Mrs. Molloy and her husband informed the investigation that it was their recollection that Obstetrician Gynaecology Registrar A documented his retrospective note in the Recovery Room following Mrs. Molloy's surgery and that she was present in the room with her baby lying in the bed beside her.

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[58] A ventouse (vacuum extractor) is an instrument that uses suction to pull the baby out. A soft or hard plastic or metal cup is attached by a tube to a suction device. The cup fits firmly onto your baby's head and, with a contraction and your pushing, the obstetrician or midwife gently pulls to help deliver your baby (reference: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/ventouse-forceps-delivery.aspx).

[59] 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).

[60] Refer to Note 66

In his retrospective record made at 11.30 hours on the 24th January Obstetrician Gynaecology Registrar A documented that at this time i.e. 07.55 hours that the CTG was satisfactory[61] and that Mrs. Molloy was pushing for the last 30 minutes (since 07.25 hours).

Obstetrician Gynaecology Registrar A indicated during the investigation that when he arrived on the Labour Ward he introduced himself to Mrs. Molloy and her husband and that he obtained consent from Mrs. Molloy to examine her.

Obstetrician Gynaecology Registrar A indicated during the investigation that his assessment of Mrs. Molloy showed that she was in the 2nd stage of labour since 07.25 hours and that she was using Entenox to augment epidural analgesia. Obstetrician Gynaecology Registrar A indicated that at the time of his review of Mrs. Molloy that he noted that the CTG was non-reassuring with a few variable decelerations.

Obstetrician Gynaecology Registrar A documented that on examination Mrs. Molloy appeared distressed with labour, that she had a urinary catheter inserted by Obstetrician Gynaecology Registrar A and that Mrs. Molloy's cervix was fully dilated with a vertex at queried minus one (-1) and that the lie of the foetus head was ? LOA (i.e. queried left occipital anterior).

The plan of care documented by Obstetrician Gynaecology Registrar A was to drain Mrs. Molloy's bladder and to reassess her again in 15 minutes.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Obstetrician Gynaecology Registrar A informed Mrs. Molloy that the lip of the cervix was over her baby's head and that in response to this Mrs. Molloy informed Obstetrician Gynaecology Registrar A that this was similar to one of her previous deliveries and that Obstetrician Gynaecology Registrar A responded by stating "what did the doctor do then".

Obstetrician Gynaecology Registrar A informed the reviewers that while he cannot remember his exact response to Mrs. Molloy at this time he did not state "what did the doctor do then" and that it was his recollection that he was courteous and professional to Mr. and Mrs. Molloy at all times.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that it was at this stage that Mrs. Molloy lost complete faith in the team that was delivering her baby and that she began to cry.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Obstetrician Gynaecology Registrar A told Mrs. Molloy not to push for a while and that she should breathe through the contractions. Mrs. Molloy indicated that she slid forward in the bed to try and reach the bed grips which would help in supporting her to remain in the lithotomy position.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that a number of attempts were made to empty Mrs. Molloy's bladder by the insertion of a urinary catheter and that she was encouraged to push when her bladder was empty.

Midwife D (day duty) entered the Labour Ward and she indicated that she observed Midwife B encouraging Mrs. Molloy to push. Midwife E also (day duty) entered the Labour Ward.

Mrs. Molloy and her husband informed the reviewers that they found the number of staff entering and leaving the room during this period distressing as Mrs. Molloy was in a vulnerable and exposed position i.e. lithotomy position.

[61] It was established during the investigation that Obstetrician Gynaecologist Registrar A had initially documented that the "CTG noted to be satisfactory" and that this entry was subsequently changed to "CTG noted to be unsatisfactory (Non-reassuring)".

08.00 hours:

Midwife D documented that she received care of Mrs. Molloy, that she noted Mrs. Molloy's past medical history and that the foetal heart rate was 100 beats per minute.

It was established during the investigation that Midwife D and Midwife E initially documented the care they provided to Mrs. Molloy on a blank sheet of paper as Midwife B was writing in Mrs. Molloy's healthcare record between 08.00 hours and 08.20 hours[62].

Midwife B informed the Review Team that she did not get an opportunity to document the care she provided to Mrs. Molloy between 07.45 and 08.00 hours as she was busy caring for Mrs. Molloy and that when Midwife D took over Mrs. Molloy's care she took the opportunity to document this care.

08.05 hours:

Midwife D documented that at this time that the baby's foetal heart rate was 120 beats per minute with late decelerations noted on the CTG, that Obstetrician Gynaecology Registrar A was present and that Mrs. Molloy was pushing.

In a retrospective record documented by Midwife D (timed at 16.00 hours) that relates to this time period it was noted that late decelerations were noted with a foetal heart rate down to 90 beats per minute.

In the same retrospective record Midwife D noted that Obstetrician Gynaecology Registrar A was present, that he was informed of the late decelerations and that he requested that Syntocinon[63] should be commenced at 30 millilitres per hour to aid delivery.

Midwife D noted that Shift Leader A was present and that Obstetrician Gynaecology Registrar A was advised to contact Consultant Obstetrician Gynaecologist A to inform her of Mrs. Molloy's condition.

There is a difference in what was documented in the healthcare record and the recollection of Obstetrician Gynaecology Registrar A in relation to the CTG at this time. It was Obstetrician Gynaecology Registrar A's recollection that he was not informed that there were late decelerations on the CTG at this time, that while the CTG was initially nonreassuring when he first assessed Mrs. Molloy that it was reassuring when he ordered the Syntocinon and that it remained reassuring up to the time Consultant Obstetrician Gynaecologist A arrived on the Labour Ward.

Shift Leader A[64] indicated during the investigation that she arrived on the Maternity Department at approximately 08.05 hours. Shift Leader A indicated that when she entered the Labour Ward that Midwife B, Midwife D and Midwife E were present.

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[62] Midwife D documented during the investigation that as she and Midwife E did not have access to Mrs. Molloy's healthcare record as Midwife B was writing in the records at this time that they documented the care provided to Mrs. Molloy on a piece of paper with a view to transcribing this care into Mrs. Molloy's healthcare record. Midwife D indicated that when she went back to the Delivery Suite following Mrs. Molloy's surgery the piece of paper that had been used to document Mrs Molloy care had been discarded by domestic staff when they were cleaning the room. Midwife D indicated that she could not gain access to Mrs. Molloy's healthcare record until 16.00 hours to document some of care that she provided to Mrs. Molloy as Mrs. Molloy's healthcare record had been transferred from Theatre to the Coronary Care Unit following her surgery and that she documented the care that she provided to Mrs. Molloy as soon as she got access to Mrs. Molloy healthcare record.

[63] Syntocinon is administered to induce or augment labour, usually in conjunction with amniotomy (surgical rupture of the foetal membrane to induce labour) (reference British National Formulary 2008).

[64] Shift Leader A indicated during the investigation that she was not scheduled to be on duty on the morning of the 24th January 2012, that she had misread the off duty roster and mistakenly came on duty on the 24th.
Shift Leader A indicated that once she had discovered that she should not have been on duty she went to discuss the issue with Clinical Midwifery Manager II A who informed her that a midwife was on

Shift Leader A indicated that when she entered she observed that Midwife B was writing in Mrs. Molloy's healthcare record. Shift Leader A indicated that she received a short report from Midwife B in relation to Mrs. Molloy's condition. Shift Leader A indicated that Midwife B did not inform her of the late decelerations that were present on the CTG.

Shift Leader A indicated that when she entered the ward she observed Obstetrician Gynaecology Registrar A carrying out a vaginal examination of Mrs. Molloy and that Mrs. Molloy had a urinary catheter in place which was not draining any urine.

Shift Leader A indicated that she was not present for a conversation between Midwife D and Obstetrician Gynaecologist Registrar A in relation to the presence of late decelerations on the CTG.

08.07 hours:

Obstetrician Gynaecology Registrar A indicated during the investigation that when he examined Mrs. Molloy he found that she was having abdominal contractions lasting between 30 and 40 seconds and that a vaginal examination showed that Mrs. Molloy's cervix was fully dilated with a vortex minus of - 1 ? (i.e. queried -1) and that the position of the foetus's head was queried in the left occipital anterior position.

Obstetrician Gynaecology Registrar A indicated during the investigation that he informed Mrs. Molloy of his finding; that the baby was not descending and that Mrs. Molloy might require an instrumental delivery.

08.10 hours approximately:

Mrs. Molloy was assessed by Obstetrician Gynaecology Registrar A; Obstetrician Gynaecology Registrar A documented that a semi-rigid urethral catheter was inserted into Mrs. Molloy's bladder which drained 60 millilitres of urine.

Shift Leader A indicated during the investigation that Obstetrician Gynaecology Registrar A removed Mrs. Molloy's urinary catheter as it was not draining any urine and that he decided to insert a semi-rigid urinary catheter which drained 60 millilitres. Shift Leader A indicated that when Mrs. Molloy's semi-rigid catheter stopped draining that Obstetrician Gynaecology Registrar A tried to reinsert the flexible urinary catheter.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that, as Mrs. Molloy's husband was at Mrs. Molloy's side, he noticed that Mrs. Molloy was vomiting before the team of midwives noticed, that he immediately requested a container and that he held the container under Mrs. Molloy's mouth while she was vomiting.

08.15 hours:

Midwife D documented that Mrs. Molloy was commenced on Syntocinon five international units in one litre of Normal Saline[65] at a rate of 30 millilitres per hour; that 60 millilitres was emptied from Mrs. Molloy's bladder by insertion of a urethral catheter and that the foetal heart rate was 99 beats per minute.

Obstetrician Gynaecology Registrar A indicated during the investigation that he assessed the CTG which had improved and as a result he requested that Syntocinon should be commenced to augment labour.

It was documented that the Syntocinon infusion was prepared and commenced by Midwife D and Shift Leader A; both staff members signed the Drug Prescription Kardex.

Shift Leader A indicated during the investigation that at this time, along with Midwife E, she tried to make Mrs. Molloy comfortable in the bed while leaving her in the lithotomy

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sick leave on the morning of the 24th January and as a result there was reduction in the number of midwives on duty and it was decided that Shift Leader A would remain on duty.

[65] Sodium Chloride contains sodium chloride 0.9% (reference: British National Formulary 2009).

position to await the arrival of Consultant Obstetrician Gynaecologist A, that Mrs. Molloy was offered a drink and that Vaseline was applied to Mrs. Molloy's lips.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband[66] that Mrs. Molloy was informed by Obstetrician Gynaecology Registrar A that in the event that her labour did not progress over the next 10 minutes that he would contact Consultant Obstetrician Gynaecologist A and that he also stated "your baby is not in distress". Mrs. Molloy and her husband also indicated that they were given no information on Syntocinon when Mrs. Molloy was commenced on the drug.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that Mrs. Molloy continued to push and that her husband felt that his wife was getting weaker as her hand grip was weaker. Mrs. Molloy and her husband also indicated that Mrs. Molloy intermittently held the foetal heart monitor electrode on her abdomen from 08.00 hours until the time she was transferred to theatre as she felt it would fall off at any time[67].

08.20 hours approximately:

It was documented by Midwife D that the foetal heart rate was 127 beats per minute.

Mrs. Molloy was assessed by Obstetrician Gynaecology Registrar A; Obstetrician Gynaecology Registrar A documented the following information;

- Cx; full,
- Vx; remained same,
- Poor descent in second stage.

Obstetrician Gynaecology Registrar A's documented plan of care for Mrs. Molloy was that Mrs. Molloy was for a possible trial of instrumental delivery in the Theatre Department and a possible emergency Caesarean Section and that he had informed and counselled Mrs. Molloy of this plan.

There is a difference in what is documented by Obstetrician Gynaecology Registrar A and Mrs. Molloy and her husband's recollections of whether Mrs. Molloy was informed that she might require an assisted birth. It was Mrs. Molloy and her husband's recollection that they were not informed that Mrs. Molloy might be transferred to Theatre for a possible trial of instrumental delivery and a possible emergency Caesarean Section.

In a retrospective record which was documented at 11.30 hours Obstetrician Gynaecology Registrar A indicated that he would inform Consultant Obstetrician Gynaecologist A of the plan of care developed for Mrs. Molloy.

Obstetric Gynaecology Registrar A indicated during the investigation that he remained in the Delivery Suite allocated to Mrs Molloy from the time of his arrival on the Labour Ward at 07.55 hours up to the time Mrs. Molloy was transferred to the Theatre Department at 09.05 hours.

08.25 hours:

Shift Leader A indicated that she left the Delivery Suite that had been allocated to Mrs. Molloy as she had been requested to take over the care of another woman who was thought to be in premature labour.

[66] Mrs. Molloy indicated that her husband was certain of the time this conversation took place with Obstetrician Gynaecologist Registrar A as he had looked at the clock above the head of the bed.

[67] An examination of the CTG from 08.00 hours to 09.00 hours i.e. when Mrs. Molloy was transferred to theatre indicated that the electrode was in contact with her abdomen during this time as there is a good CTG trace.

08.30 hours approximately:[68]

Obstetrician Gynaecology Registrar A contacted Consultant Obstetrician Gynaecologist A by phone. In a retrospective record Obstetrician Gynaecology Registrar A documented that he discussed Mrs. Molloy's condition with Consultant Obstetrician Gynaecologist A as there was a failure to progress in the 2nd stage of labour; that as a result Mrs. Molloy might require an instrumental delivery in Theatre and queried whether Mrs. Molloy would require a Lower Segment Caesarean Section[69].

There is a difference between Obstetrician Gynaecology Register A and Consultant Obstetrician Gynaecology A in relation to the detail that Obstetrician Gynaecology Registrar A gave to Consultant Obstetrician Gynaecology A in relation to Mrs. Molloy's condition during the phone call that took place at this time. It is Consultant Obstetrician Gynaecologist A's recollection that she was informed by Obstetrician Gynaecology Registrar A during that phone call that Mrs. Molloy had been pushing for an hour without progress and that he had concerns about the fetal heart rate.

Midwife D documented that the foetal heart rate was 119 beats per minute and that the Syntocinon infusion was increased to a rate of 60 millilitres per hour as requested by Obstetrician Gynaecology Registrar A.

08.31hours:

Midwife E documented that the foetal heart rate was 101 beats per minute and that the Syntocinon was infusing at a rate of 90 millilitres per hour.

08.34 hours:

Midwife E documented that the foetal heart rate was 118 beats per minute. Mrs. Molloy and her husband informed the investigation that Mrs. Molloy was given huge support and encouragement to push during her time on the Labour Ward by Midwife E.

08.36 hours:

Midwife E documented that the foetal heart rate was 133 beats per minute.

08.39 hours:

Consultant Obstetrician Gynaecologist A arrived on the Labour Ward.

Midwife E documented that the foetal heart rate was 118 beats per minute and that Consultant Obstetrician Gynaecologist A was on the Labour Ward.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that when Consultant Obstetrician Gynaecologist A arrived on the Labour Ward that she requested Mrs. Molloy to "get her bum back up on the bed" and that Mrs. Molloy remained in the lithotomy position at this time however she was further up in the bed.

08.45 hours:

Midwife E documented that Mrs. Molloy's Syntocinon infusion was discontinued.

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[68] While it was documented in Mrs. Molloy's healthcare record that Obstetrician Gynaecology Registrar A contacted Consultant Obstetrician Gynaecologist A by phone at 08.25 hours Consultant Obstetrician Gynaecologist A documented that her phone records indicate that Obstetrician Gynaecologist Registrar A rang her at 08.30 hours.

[69] 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).

Mr. and Mrs. Molloy indicated during the investigation that the decision to transfer Mrs. Molloy to Theatre i.e. the Theatre Department was made at this time.

08.50 hours:

Consultant Obstetrician Gynaecologist A indicated at interview that she left Mrs. Molloy's room to ring the hospital's Theatre Department to inform the nurses in the department that a lady might require a Caesarean Section and requested that a Theatre be prepared for the surgery.

Shift Leader A indicated during the investigation that at this time she was informed that Mrs. Molloy was being transferred to Theatre and that it was decided following a discussion with Clinical Midwifery Manager II A that Shift Leader A would go to Theatre with Mrs. Molloy while Clinical Midwifery Manager II A would take over the care of the woman who was in premature labour.

09.00 hours:

Mrs. Molloy was assessed by Consultant Obstetrician Gynaecologist A; Consultant Obstetrician Gynaecologist A documented the following information:

- Phone call at 08.39 hours,
- Re poor progress - second stage (i.e. second stage of labour),
- In LW (i.e. Labour Ward) @ 08.50hrs,
- CTG satisfactory,
- Some lates earlier (i.e. some late decelerations seen earlier),
- Not seen at present (i.e. late decelerations not seen),

There was a retrospective note made in Mrs. Molloy's healthcare record documented on the 30th January 2012. The note states "Clarification phone call at 08.30 hours. In D/S (i.e. Delivery Suit) at 08.39 hours''. Consultant Obstetrician Gynaecologist A signed the note.

- On examination:
  - Fundus = dates (full term),
  - Cep (i.e. Cephalic) 0/5 i.e. engaged,
  - Impression: fully dilated,
  - Deflexed Occiput posterior,
  - 5^0 -1,
- Plan:
  - Transfer to OT (i.e. Operating Theatre),
  - E.I.T. (examination in theatre),
  - +/- LSCS (i.e. that Mrs. Molloy might or might not require Lower Segment Caesarean Section)
  - Consent √ i.e. consent to surgery,
  - Zantac√
  - O.T. (i.e. Operating Theatre) √
  - Bloods,

It was documented on the consent form relating to Mrs. Molloy's surgery that the following complications of surgery were discussed with Mrs. Molloy;

- Complications relating to the anaesthetic,
- Risk of bleeding and the possibility that Mrs. Molloy might require a blood transfusion if she bled,
- Risk of infection,
- VTE (i.e. venous thromboembolism),
- Trauma,
- Transferred to OT (i.e. Operating Theatre) at 09.05 hour.

The consent form was signed by Mrs. Molloy and Consultant Obstetrician Gynaecologist A.

It was documented by Midwife D that Mrs. Molloy was assessed by Consultant Obstetrician Gynaecologist A and that the plan developed was that Mrs. Molloy was to be transferred to

Theatre for an instrumental delivery and queried whether Mrs. Molloy would require a Lower Segment Caesarean Section (LSCS).

It was documented that the foetal heart rate was 100 beats per minute.

09.05 hours:

Mrs. Molloy was transferred to the Theatre Department and the CTG was discontinued while Mrs. Molloy was en route to the department[70]. Shift Leader A indicated during the investigation that Midwife D and Midwife E accompanied Mrs. Molloy while she was being transferred to the Theatre Department.

It was documented in the sequence of events prepared by Mrs. Molloy and her husband that when Mrs. Molloy arrived in the Theatre Department that Mrs. Molloy's husband was requested to wait in the Reception Area. Mrs. Molloy's husband indicated that he remained in the Reception Area for approximately 15-20 minutes. Mrs. Molloy indicated that while Mr. Molloy was waiting in the corridor she was asking when he would be allowed to come into the Theatre.

Mrs. Molloy and her husband indicated that when Mrs. Molloy arrived in Theatre that Consultant Obstetrician Gynaecologist A spoke to her briefly and then left. Consultant Obstetrician Gynaecologist A explained that she left so that she could prepare for Mrs. Molloy's surgery.

09.07 hours:

It was documented by Midwife D that Mrs. Molloy was in Theatre, that she was transferred from the trolley to the theatre bed and that Mrs. Molloy was positioned in the lithotomy position on the theatre trolley.

There was a difference in the recollection of Mrs. Molloy and those of Consultant Obstetrician Gynaecologist A in relation to whether Consultant Obstetrician Gynaecologist A carried out a vaginal examination on Mrs. Molloy at this time. It was Mrs. Molloy's recollection that while Consultant Obstetrician Gynaecologist A had a discussion with her at this time that she did not carry out a vaginal examination.

Consultant Obstetrician Gynaecologist A indicated during the investigation that it was her recollection that she carried out a vaginal examination on Mrs. Molloy at this time. This examination is documented in Mrs. Molloy's Operation Sheet as follows;

- Non-reassuring CTG
  - Defluxed OP (occiput posterior position),
  - Fully dilated.
  - In O.T. (operating theatre) – PP (presenting part) S^{-1}
  - -> LSCS

- Foetal heart rate difficult to hear prior to the procedure.

09.10 hours:

Midwife D documented that Mrs. Molloy was for review by Consultant Obstetrician Gynaecologist A, that the CTG was recommenced, that it was very difficult to auscultate the foetal heart rate and that the foetal heart rate which was recorded was at ? (i.e. query) 115 beats per minute.

Midwife D documented that she requested Shift Leader A to review the foetal heart rate.

[70] The CTG was discontinued during Mrs. Molloy's transfer to the Theatre Department as Midland Regional Hospital at Portlaoise does not have a portable CTG machine.

Shift Leader A indicated during the investigation that, when she arrived in the Theatre Department, Mrs. Molloy was in the lithotomy position and that she requested Midwife D to recommence the CTG while she went to prepare the resuscitaire[71] for Mrs. Molloy's baby.

Shift Leader A indicated during the investigation that when she tried to auscultate the foetal heart rate following the request from Midwife D she also found it difficult to hear the heart beat and that she thought that the heart rate was 115 beats per minute.

Shift Leader A indicated that because of the difficulty in auscultating the foetal heart beat that she used a hand held ultrasound transducer i.e. a Sonicaid[72]. Shift Leader A indicated during the investigation that the foetal heart beat was difficult to locate using the Sonicaid and that she queried that the foetal heart rate was 90 beats per minute.

Shift Leader A indicated during the investigation that Midwife D was requested to take over the care of another woman who was undergoing a planned Caesarean Section in another theatre and that she i.e. Shift Leader A took over Mrs. Molloy's midwifery care.

The Clinical Nurse Manager of the Theatre Department documented in the healthcare record that Mrs. Molloy arrived in the department at this time, that she was brought straight to Theatre 2, that Consultant Obstetrician Gynaecologist A spoke with Mrs. Molloy in Theatre 2 before going into the scrub area, that Mrs. Molloy was positioned on the theatre table and that the monitor to record vital signs was attached to her.

Mrs. Molloy was assessed by Consultant Anaesthetist A; Consultant Anaesthetist A documented that he was called at 08.50 hours and that a top up of the epidural analgesia was administered by the on call Anaesthetic Registrar to Mrs. Molloy at 09.00 hours.

Mrs. Molloy and her husband informed the investigation that it was only after the administration of the top up of the epidural analgesia that Mrs. Molloy could not feel pain.

Consultant Anaesthetist A also documented the following information in the **Anaesthetic Record;**

- **Allergies**; N.K.D.A. (i.e. no known drug allergies),
- **Medication**; nil,

General Examination;
- CVS (Cardiovascular System) S1 and S2 (i.e. heart sounds 1 and 2) present with no additional heart sounds,

- **Airways** MP 1[73],
- **ASA** 1[74].

History / Assessment / Risk;
- Fasting since last night,

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[71] 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/).

[72] Sonicaid fetal monitors are indicated for use during labour and delivery and to monitor fetal and maternal vital signs during the antepartum period. Sonicaid monitors the fetal heart rate with an ultrasound transducer. (http://www.frankshospitalworkshop.com/equipment/documents/ultrasonographs/user_manuals/Sonicaid%20Team%20CTG%20-%20Operators%20manual.pdf).

[73] This classification was designed to predict difficult intubating conditions in obese patients, derived from the proportion between the mouth soft tissues and the oral cavity. Grade I is the normal configuration and grade IV corresponds to a reduced oral cavity, most of it occupied with soft tissues. Grade III and IV can be used as a predictor of difficult intubation (reference http://understanding-anesthesia.com/articles/mallampati_score.pdf).

[74] The ASA physical status classification system is a system for assessing the fitness of patients before surgery. The American Society of Anesthesiologists (ASA) adopted the five-category physical status classification system. ASA 1 indicates that a patient is healthy.

- Epidural in situ – Block T10 T10 (i.e. epidural effective from the level of the 10th thoracic vertebrae on the left and right side),
- Epidural analgesia top up given and procedure explained to patient.

Pre-operative Instructions;
- Ranitidine (Zantac) 50 milligrams intravenously[75],
- Sodium Citrate 30 millilitres[76] orally preoperatively,

09.15 hours approximately:

A retrospective note was recorded by Shift Leader A in Mrs. Molloy's healthcare record as follows;

- "Difficult to auscultate foetal heart,
- Consultant Obstetrician Gynaecologist A informed - out on corridor".

09.16 hours approximately:

Midwife D documented that Consultant Obstetrician Gynaecologist A was present, that she had palpated and listened to the foetal heart rate using the Sonicaid, that the foetal heart rate was ? (i.e. query) 90 beats per minute and that the decision was made to carry out a Lower Segment Caesarean Section on Mrs. Molloy.

09.20 hours:

The Clinical Nurse Manager of the Theatre Department documented that Consultant Obstetrician Gynaecologist A returned to Theatre 2, that Consultant Obstetrician Gynaecologist A examined Mrs. Molloy and that following the examination Consultant Obstetrician Gynaecologist A informed the theatre staff that she was proceeding to a Lower Section Caesarean Section.

The Clinical Nurse Manager of the Theatre Department indicated during the investigation that while she recalls seeing Consultant Obstetrician Gynaecologist A carrying out an examination of Mrs. Molloy's abdomen that she could not recall if the examination included a vaginal examination as there was a lot of activity in Theatre 2 while Consultant Obstetrician Gynaecologist A was examining Mrs. Molloy and that she i.e. the Clinical Nurse Manager of the Theatre Department was assisting the Scrub Nurse to prepare for Mrs. Molloy's surgery.

The Clinical Nurse Manager of the Theatre Department documented that Mrs. Molloy was placed in the supine position for the surgery and that she was secured on the theatre table.

09.25 hours:

The Clinical Nurse Manager of the Theatre Department documented that Mrs Molloy's surgery commenced at this time.

It was documented by Consultant Anaesthetist A in the Anaesthetic Record that an incision was made in Mrs. Molloy's abdomen and that the baby was delivered at 09.29 hours[77].

Mrs. Molloy and her husband documented that they had no idea that their infant son was in trouble prior to his birth and that as he was delivered they were expecting a healthy baby.

[75] Ranitidine used for the prophylaxis of stress ulcers (reference; British National Formulary 2008).
[76] Sodium citrate is licensed for use as a prophylaxis of acid aspiration (reference; British National Formulary 2008).
[77] The Paediatric Registrar documented in neonatal notes that Baby Mark's time of birth was 09.31 hours.

Mrs. Molloy and her husband documented in their feedback to the Review Team that when their infant son was born that Mr. Molloy told Mrs. Molloy "it's a boy" and that they were both thrilled and they laughed as it was their fifth son. Mrs. Molloy documented that she had a very clear "image" at this time of Baby Mark running after his older brothers wearing a pair of red wellington boots.

09.31 hours:

The Paediatric Registrar on call documented the following in the baby's neonatal record;

- Date of Birth: 24/1/12
- Time of Birth: 09.31 hours
- Birth Weight (kg): 3.890
- Alive/Still Birth: there is no entry opposite this heading[78]
- If Stillbirth: Fresh√[79] Macerate
- Maturity by dates: T (term) +9
- Apgar 0 at 1 minute[80] and 0 at 5 minutes[81]
- Resuscitation: Method used, including oxygen and drugs:

    - Baby came out,
    - No respiratory effort,
    - Cynosed,
    - ~~Poor muscle~~* (*there was a line through the words poor muscle in the healthcare record),
    - No muscle tone,
    - No reflex during cord examination,
    - No meconium below cord,
    - Neopuff 20/5 inhalatory breath given at 100% oxygen,
    - Heart sound checked by Anaesthetist, very faint heart rate, very slow, CPR (cardiopulmonary resuscitation)[82] started at a rate of 1 breath for every 3 heart compressions after 1 minute,
    - Heart rate checked again; no heart rate, no respiratory effort, no change in colour, no movement,
    - Trial of intubation[83] which was unsuccessful,

[78] Mrs. Molloy and her husband's baby boy was initially classified as a still birth however this was subsequently changed to a alive birth as Consultant Anaesthetist A confirmed that the baby might have had a heart beat when he was born.

[79] A macerated stillbirth is defined as having degenerative skin changes as recorded by the delivering clinician and is presumed to have occurred 12 hours or more before delivery. A recent (fresh) stillbirth is defined as having no such skin changes and is presumed to have occurred within 12 hours of delivery, usually in labour (reference: http://journals.lww.com/greenjournal/Fulltext/2011/05000/Determinants_of_Stillbirth_in_Zambia.18.aspx)

[80] There was a number documented in the Neo-natal Record under the heading APGAR opposite heart rate and directly under 1 minute (0, 1 or 2) with a line through the number. The Paediatric Registrar on call confirmed during the investigation that the number documented was an error and that there was no heart beat at 1 minute of age.

[81] 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).

[82] 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.

[83] 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

- CPR continued,
- Another trial of intubation by anaesthetist, tried to intubate for a second time which was successful after four minutes 30 seconds then continued CPR,
- Consultant Paediatrician arrived at 5 minutes of age,
- Two doses of adrenaline[84] given to baby through his endotracheal tube and CPR continued,
- No heart rate, no change in colour, no respiratory effort,
- UVC (Umbilical vein catheter) access obtained and bolus of 20 millilitres of Normal Saline administered followed by adrenaline and then 40 millilitres of Normal Saline.

The on call Paediatric Registrar documented that the on call Consultant Paediatrician requested that the CPR should be stopped at 22 minutes and that the on call Consultant Paediatrician pronounced the baby dead.

The Consultant Anaesthetist on call documented the following information in the baby's neonatal record;

- Patient intubated with size 3.5 endotracheal tube,
- CPR 3:1 throughout (i.e. three heart compressions to one breath),
- No FH (foetal heart) audible throughout ?? (i.e. query) significant brady (i.e. bradycardia[85]) initially.

Mrs. Molloy and her husband documented that at this time Mrs. Molloy could see the team resuscitating Baby Mark; that they were pressing on his chest but that she was completely unaware that baby Mark "was in trouble". Mr and Mrs. Molloy documented that the first time that they were aware that Baby Mark was ill was approximately 10 minutes after his birth when Consultant Obstetrician Gynaecologist A indicated to them that 'things behind me do not sound good'.

Mrs. Molloy documented that she had no memory from the time Baby Mark was approximately 12 minutes old up to the time that she was informed that he had died. Mrs. Molloy indicated that she did not pray for Baby Mark or hope that he would survive as she did not know that he was ill.

Mrs. Molloy documented that when the resuscitation team stopped resuscitating Baby Mark that Mr. Molloy stated "Oh God, we're not getting him". Mrs. Molloy documented that when she heard this that she turned away and took a deep breath; that she then turned back and said "give him to me" as she needed to see him, smell him and feel him. Mr. Molloy indicated that he took a picture of Baby Mark using his mobile phone.

09.37 hours:

A sample of blood was taken from baby's umbilical cord and the ph of the blood was 6.716 (normal range 7.350-7.450)[86].

09.41 hours approximately:

Shift Leader A documented the following information in Mrs. Molloy's healthcare record;

- Paediatric Registrar present,
- Male infant delivered (later christened Mark) and was brought to resuscitation,

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into the airway; the tube goes through the nose or mouth (reference : http://medical-dictionary.thefreedictionary.com/intubation) .

[84] Adrenaline is administered following a cardiac arrest associated with ventricular fibrillation, pulseless ventricular tachycardia, asystole and electromechanical dissociation (Reference: British National Formulary 2009)

[85] 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)

[86] 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).

- Baby flat,
- Immediate resuscitation began,
- No cord (i.e. umbilical cord) pulsation felt,
- Emergency bell activated,
- Emergency bell reactivated because of poor response.

Shift Leader A also documented that the Consultant Anaesthetist was present and that he assisted the Paediatric Registrar with the resuscitation of the baby.
Shift Leader A documented that after 25 minutes of resuscitation the baby still had no heart rate.

Shift Leader A documented that the on call Consultant Paediatrician talked to Mrs. Molloy's husband and that the baby was given to Mrs. Molloy and her husband to hold. Shift Leader A also documented that Mr. and Mrs. Molloy's new born baby son was baptised and that his name was Mark.

Consultant Obstetrician Gynaecologist A documented the following information in Mrs. Molloy's Operation Sheet;

- Epidural,
- Painted and draped,
- Foleys catheter (i.e. a type of urinary catheter inserted).

L.S.C.S. (i.e. Lower Segment Caesarean Section):

- Foetal heart rate difficult to hear prior to the procedure.

Transverse suprapubic incision;

- Cephalic presentation 0/5,
- Clinically OP (occiput posterior),
- Thin lower segment,
- Blood stained peritoneal fluid before opening uterus,

Procedure;

- Lower Segment opened transversely,
- Relatively easy delivery of a flat male infant who was resuscitated immediately,
- Infant died,
- Cord Ph <,
- Third stage of labour complete,
- There was a deep extension of uterine incision on the right hand side,
- The apex of the tear was identified and closed,
- There was persistent bleeding from RHS (i.e. right hand side),
- Side wall of uterus was sutured from above down with good effect,
- The right uterine vein was identified and tied off,

Consultant Obstetrician Gynaecologist A also documented that Consultant Obstetrician Gynaecologist C was asked to scrub in for a second opinion in relation to Mrs. Molloy's bleeding and it was identified that the bleeding was well controlled and a decision was taken to suture Mrs. Molloy's abdomen.

Consultant Obstetrician Gynaecologist A documented in Mrs. Molloy's Operation Sheet that a Redivac drain[87] was inserted intra-peritoneal, that Cytotec[88] 600 milligrams was administered to Mrs. Molloy and that Mrs. Molloy's abdomen was sutured and closed.

[87] This is a closed drainage system in which a vacuumed container is attached to the end of the plastic tubing which will draw fluid from the wound (reference: http://www.royalfree.nhs.uk/documents/Equality/1050_Wound%20%20drain%20final%202010.pdf).
[88] Cytotec makes the uterus contract and expel the pregnancy tissue (reference: http://www.whcoso.com/index.cfm/fuseaction/site.content/type/index.cfm/fuseaction/site.content/mode/dtl/type/45105/post/61678.cfm)

The post operative instructions documented by Consultant Obstetrician Gynaecologist A for Mrs. Molloy were as follows:

- Transfer to the Intensive Care Unit or Coronary Care Unit,
- Intravenous Syntocinon infusion charted,
- Send a specimen of Mrs. Molloy's blood to the laboratory for PTT[89] and if fibrinogen[90] is low administer Octoplas[91] and Fibrinogen,
- Blood transfusion which the Anaesthetists would arrange,
- Observe urinary output hourly,
- Administer analgesia as required,
- Administer further Cyto (i.e Cytotec) as required,
- Hold Innohep[92] at present,
- Given Augment and Flagyl[93].

Mrs. Molloy's Blood Loss Sheet indicated that she lost 3235 millilitres of blood during the surgery.

10.00 hours:

The on call Consultant Paediatrician documented the following information in the baby's neonatal record;

- Called to theatre for emergency LSCS -> baby being resuscitated, arrived at 09.36 hours,
- Baby was already intubated and being resuscitated,
- HR (i.e. heart rate) zero, no respiratory effort, 2 adrenaline administered via ETT (endotracheal tube) given,
- Umbilical venous catheter (UVC) inserted at 10 minutes of age,
- Adrenaline x 1 administered via UVC then NaCl (i.e. Sodium Chloride) 60 millilitres (20 millilitres per kilogram),
- No heart rate or respiratory effort,
- At 22 minutes of age pupils fixed -> pronounced dead -> R.I.P.
- Talked to father,
- For post mortem.

[89] 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).

[90] Fibrinogen helps to evaluate your body's ability to form and break down blood clots (reference: http://www.labtestsonline.org.uk/understanding/analytes/fibrinogen/tab/test).

[91] Octoplas is a preparation of solvent/detergent treated human plasma (frozen) (Reference: British National Formulary 2008).

[92] Innohep is used a prophylaxis of deep-vein thrombosis (Reference: British National Formulary 2008).

[93] Augmentin is a broad-spectrum penicillin and Flagyl is an antimicrobial drug with high activity against anaerobic bacteria and protozoa (Reference British National Formulary 2009).

Aftermath of Mrs. Molloy's delivery and baby Mark's death:

24th January 2012:

Following her surgery Mrs. Molloy was transferred to the Recovery area in the Theatre Department and she remained in the Recovery area for four hours.

Mr. and Mrs. Molloy documented that while Mrs. Molloy was in the Recovery area that she was given a memory booklet containing a lock of Baby Mark's hair and a card that contained his hand and foot prints. Mr. and Mrs. Molloy documented that they were given these document by a Midwife. Mr. and Mrs. Molloy indicated that in addition to the lock of hair and hand and foot prints the memory booklet also contained information on breast feeding.

Mrs. Molloy indicated that she could not recall which Midwife had given her the memory booklet as she was recovering from surgery at the time and as a result she was in shock and confused. Mrs. Molloy documented that when handing her the memory booklet the Midwife stated that '*this is something nice for you when you go home*'.

Mrs. Molloy indicated that when she was given the booklet Mrs. Molloy's sister was also in the Recovery area holding Baby Mark in her arms and that Mr. Molloy had returned home to inform their four sons that Baby Mark had died.

A Theatre Nurse completed a HSE Dublin Mid-Leinster 'Incident Near Miss Report Form'[94] in relation to Mrs Molloy's surgery. The Theatre Nurse documented the following on the form;

'Baby boy delivered @ 09.30 (hours) – stillbirth'.

An additional entry on the Incident Near Miss Report Form states the following;

"Baby was Still Born".

Consultant Obstetrician Gynaecologist A indicated during the investigation that she also completed an Incident Near Miss Report Form in relation to Mrs. Molloy's surgery and Baby's Mark's death[95].

Mr. and Mrs. Molloy indicated that while they were in the Recovery area Consultant Obstetrician Gynaecologist A discussed with them the requirement to carry out a post mortem examination on Baby Mark. Mr. Molloy indicated that following the discussion with Consultant Obstetrician Gynaecologist A that he signed the consent form for the post mortem.

Mr. and Mrs. Molloy indicated that they were surprised and upset to hear that Baby Mark was to be transported to the Midland Regional Hospital at Tullamore by public taxi for his post mortem. Mr. Molloy indicated that he requested that he would transport Baby Mark himself with a family member driving or alternatively he would accompany Baby Mark in the taxi.

Mrs. Molloy was transferred from the Recovery area in the Theatre Department to the Coronary Care Unit where she remained until her discharge on the 31st January 2013.

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[94] It is the policy of the HSE that all incidents shall be identified, reported, communicated and investigated (reference: http://hsenet.hse.ie/mZHmaJRc9WUn4sNFdV9p7w%3d%3d/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/incident.pdf?ImportedResourceId=mZHmaJRc9WUn4sNFdV9p7w%3d%3d). The form in place for reporting incidents and near misses in the HSE Dublin Mid-Leinster region is titled 'Incident Near Miss Report Form'.

[95] The reviewers did not receive a copy of this Form and were informed that it could not be located.

Clinical Midwifery Manager II A indicated that the room that had been allocated to Mrs. Molloy on the Maternity Department was kept free for use by Mr. Molloy and their extended family.

Mrs. Molloy's haemoglobin was low due to her intraoperative blood loss and as a result she had the following transfusions;

- Six units of red cell concentrate,
- 400 millilitres of Octoplas,
- 100 millilitres of Fibrogen.

Mr. and Mrs. Molloy documented that on the evening of the 24th January Consultant Obstetrician Gynaecologist A informed Mr. Molloy while he was in the corridor outside the Coronary Care Unit that she had serious concerns about the management of Mrs. Molloy's labour prior to her arrival on the Labour Ward.

25th January 2012:

Mr. and Mrs. Molloy documented that on the morning of the 25th January that it was confirmed to them that Baby Mark was to be transferred to the Midland Regional Hospital Tullamore for his post mortem by public taxi and that Mr. Molloy could accompany him in the taxi.

Mr. Molloy indicated that he held Baby Mark in the back of the taxi en route to Tullamore and that he handed him over to the hospital's Mortician.

Mr. Molloy indicated that he received a phone call four hours later to inform him that the post mortem had been completed and that he could collect Baby Mark. Mr. Molloy indicated that when he returned to the Midland Regional Hospital Tullamore he met with the Consultant Pathologist who had completed the post mortem on Baby Mark who informed Mr Molloy that, while he did not have all results, it seemed that Baby Mark was a healthy baby who died as a result of hypoxia.

The official Pathologist's report (dated the 7th February 2012) of the post mortem carried out on Baby Mark contained in Mrs. Molloy's healthcare record states as follows;

- Weight in delivery room: 3890 grams,
- Weight at post-mortem: 3870 grams,
- Gestation at delivery: Term+9,
- Weight of placenta without cord and membrane: 358 grams,
- Crown-heel length: 55.0 centimetres,
- Crown-rump length: 35 centimetres,
- Head circumference: 35 centimetres,
- Chest circumference: upper: 31.0 centimetres, lower: 35.0 centimetres,
- Abdominal circumference: 30.0 centimetres,
- Foot length: right: 8.6 centimetres. Left: 8.7 centimetres,

Provisional Anatomical Diagnosis/summary of Findings;

- TA 15 12,
- Fresh Male Stillborn infant,
- Normal weight and size for Term gestation,
- Bone age on X-ray = Term,
- Anoxic[96] congestion and anoxic congestive haemorrhage of Meninges[97] and Thoracic and Abdominal organs,
- Bilateral large anoxic congestive haemorrhage of adrenal medulla[98],

[96] Anoxic - relating to or marked by a severe deficiency of oxygen in tissues or organs (reference: http://www.thefreedictionary.com/anoxic).

[97] Meninges are the three membranes that enclose the vertebrate brain and spinal cord: the pia mater, arachnoid, and dura mater (reference: http://www.thefreedictionary.com/Meninges).

- Antepartum[99] meconium passage and aspiration,
- Aerated lungs due to resuscitation,
- No congenital abnormalities,
- Small size of placenta and very congested appearance of section,
- Major organs sampled for histological examination. No organ retained.

Following the post mortem Baby Mark was transferred back to the Midland Regional Hospital at Portlaoise accompanied by Mr. Molloy.

Mr. and Mrs. Molloy indicated that during a conversation between Mr. Molloy and Clinical Midwifery Manager II A which took place in the corridor outside the Coronary Care Unit Clinical Midwifery Manager II A stated that *'Roisin presented like so many other women'* and that '*she would have done nothing differently herself had she been there'*. Mr. Molloy documented that Mrs. Molloy's sister was present beside Clinical Midwifery Manager II A in the corridor when this conversation took place.

There was a difference in the recollections of Mr. Molloy and those of Clinical Midwifery Manager II A in relation to what Clinical Midwifery Manager II A said to Mr. Molloy and Mrs. Molloy's sister on the corridor outside the Coronary Care Unit on the 25th January.

Clinical Midwifery Manager A confirms that she did have a conversation with Mr. Molloy and Mrs. Molloy's sister outside of the Coronary Care Unit when she was entering the unit to visit Mrs. Molloy. Clinical Midwifery Manager II A indicated during the investigation that it was her recollection that she did not say that '*Roisin presented like so many other women'* and that '*she would have done nothing differently herself had she been there*' as she had reviewed Mrs. Molloy's healthcare record and the CTG on the 24th January following the death of Baby Mark and that on the basis of her review of the healthcare record she, i.e. Clinical Midwifery Manager II A, had concerns related to the CTG tracings carried out as part of the care delivered to Mrs. Molloy. Clinical Midwifery Manager II A indicated during the investigation that she did not inform Mr. Molloy of her concerns relating to the CTG tracing at this time.

Clinical Midwifery Manager II A told the Review Team that she made daily visits to the Coronary Care Unit to talk to Mrs. Molloy while Mrs. Molloy was an inpatient in the Unit. She indicated that during the visits Mrs. Molloy would frequently ask her to comment on the circumstances surrounding aspects of her intrapartum care and Baby Mark's death.

Clinical Midwifery Manager II A informed the Review Team that while she did not discuss any aspects of the care delivered to Mrs. Molloy on the 24th January she did discuss the general issues relating to the care of expectant mothers who have had multiple pregnancies, the risk of complications associated with multiple pregnancies and the expected outcome.

Clinical Midwifery Manager II A also indicated that she informed Mr. and Mrs. Molloy that an investigation of Mrs Molloy's care and management would take place with the support of the healthcare risk management service and that all relevant staff would have input to this process which would ensure a full disclosure of the circumstances surrounding Mrs. Molloy's delivery and Baby Mark's death.

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[98] Adrenal medulla; The adrenal gland is located above each kidney. The medulla is the inner, reddish-brown portion of the adrenal glands that synthesizes, stores, and releases epinephrine and norepinephrine (reference: http://www.thefreedictionary.com/Adrenal+medulla).

[99] Antepartum - occurring or existing before birth; "the prenatal period"; "antenatal care" (reference: http://www.thefreedictionary.com/Antepartum).

26th to the 31st January 2012:

The Divisional Nurse Manager of the Maternity Department indicated during the investigation that following a discussion with Mr. and Mrs. Molloy a decision was taken that the hospital would purchase a coffin for Baby Mark.

Mr. and Mrs. Molloy documented that during a conversation with Clinical Midwifery Manager II A that Mr. Molloy stated that he would be starting to plan Baby Mark's funeral arrangements and that Clinical Midwifery Manager II A informed him that the hospital had baby coffins and that Clinical Midwifery Manager II A showed him one of the coffins which was in her office at the time.

Mr. and Mrs. Molloy documented that Mr. Molloy and Mrs. Molloy's sister returned later to the office to view the coffin and that Mr. Molloy indicated to Clinical Midwifery Manager II A that he was concerned that Mrs. Molloy would not like the coffin and that he would speak directly to the undertaker in relation to a coffin for Baby Mark.

Mr. Molloy documented that he spoke to the undertaker about a coffin for Baby Mark and that the undertaker informed him that he, the undertaker, supplied coffins to the Maternity Department free of charge. Mr. Molloy indicated that the undertaker agreed to deliver a second coffin which was different to the initial coffin that he had seen. Mr. Molloy indicated that when he saw the second coffin he decided that the initial coffin he had viewed in Clinical Midwifery Manager II A's office would be used for Baby Mark's funeral.

Mr. and Mrs. Molloy documented that when this coffin was delivered it was left in the room in the hospital which had been allocated for Mr. Molloy's use while his wife was a patient in the hospital and that the coffin remained in the room for three days during which time the inside of the coffin was upholstered by Mrs. Molloy's mother and sister using the baby blankets which had been purchased for Baby Mark's cot.

Baby Mark was brought to the Coronary Care Unit every day until the 29th January. Mr. and Mrs. Molloy held a 'Flight of the Angel' funeral service for Baby Mark in the Oratory of the hospital and following the service Baby Mark's coffin was closed.

Mr. and Mrs. Molloy documented that Clinical Midwifery Manager II A visited Mrs. Molloy regularly on the Coronary Care Unit.

Mr. and Mrs. Molloy documented that Mrs. Molloy requested a meeting with Consultant Obstetrician Gynaecologist A and Clinical Midwifery Manager II A before she was discharged from hospital and that this meeting took place on the 31st January 2012. Clinical Midwifery Nurse Manager II A confirms that Mr. and Mrs. Molloy requested a meeting and that she could not give them an exact time for the meeting as the Maternity Department was busy and that she informed them that she would call down to the Coronary Care Unit before Mrs. Molloy was discharged.

Mr. and Mrs. Molloy documented that at the meeting with Consultant Obstetrician Gynaecologist A and Clinical Midwifery Manager II A that they made a detailed verbal complaint about the care Mrs. Molloy and Baby Mark had received on the Labour Ward on the 24th January.

Mr. and Mrs. Molloy documented that at the meeting Mr. Molloy referred to Clinical Midwifery Manager II A's earlier statement that *'Roisin had presented like so many other women'* and that *'she would not have done anything differently herself had she been there'*. Mr. Molloy indicated that he stated that it was his belief that this type of complacency i.e. where Roisin was not treated as an individual was a major factor in Baby Mark's death.

Mr. and Mrs. Molloy documented in their record of events that they stated at the meeting that their intention was to "*pursue every possible means to find out what happened to Baby Mark*" and that they would "*leave no stone unturned*" in relation to finding out how and why their baby son died.

Mr. and Mrs. Molloy also indicated that they were not given any information when Mrs. Molloy was discharged as to how the Midland Regional Hospital at Portlaoise intended to address/investigate the concerns that they had highlighted in relation to Mrs. Molloy's care and the management of her labour.

There was a difference in the recollection's of Mr. and Mrs. Molloy and those of Clinical Midwifery Manager II A in relation to who attended that meeting and what was said at the meeting on the 31st January.

Clinical Midwifery Manager II A indicated during the investigation that an opportunity arose on the 31st January to visit Mrs. Molloy at 10.00 hours as the Maternity Department was quiet at this time and that when she arrived on the Coronary Care Unit Consultant Obstetrician Gynaecologist A was assessing Mrs. Molloy. Clinical Midwifery Manager II A indicated that following her assessment of Mrs Molloy Consultant Obstetrician Gynaecologist left the Coronary Care Unit.

Clinical Midwifery Manager II A indicated during the investigation, and it is documented in Mrs. Molloy's healthcare record that Mr. and Mrs. Molloy indicated at the meeting with her that they were "*unhappy with aspects of the standard of care*" provided to Mrs. Molloy on the 24th January and that Clinical Midwifery Manager II A had informed them that a local investigation would be carried out into the care provided to Mrs. Molloy.

Clinical Midwifery Manager II A documented in the healthcare record that Mr. Molloy stated that he would be writing to the Hospital Manager to highlight their concerns at a later stage.

Clinical Midwifery Manager II A documented that she informed Mr. and Mrs. Molloy of the availability of counselling services provided to parents who had lost a baby and that they indicated that they would reflect on this and inform Consultant Obstetrician Gynaecologist A if they required access to these services.

Clinical Midwifery Manager II A indicated that during the meeting with Mr. and Mrs. Molloy she expressed her personal sympathies and regret related to the negative experience of Mrs. Molloy's care.

Consultant Obstetrician Gynaecologist A indicated that she has no recollection of participating in a meeting with Mr. and Mrs. Molloy and Clinical Midwifery Manager II A on the 31st January 2013.

Mrs. Molloy was discharged from hospital on the 31st January and when she returned home Mr. and Mrs. Molloy held a funeral service for Baby Mark.

29th February 2012:

An 'Incident Near Miss Report Form' was completed by Clinical Midwifery Manager II A in relation to Mrs. Molloy's labour. Clinical Midwifery Manager II A documented the following on the Incident Near Miss Report Form;

'male infant delivered @ 09.31 (hours) – APGAR 0/1 min & 0/5 min – active resuscitation by Paed Team (Paediatric Team) – no response to resuscitation -> stopped at 22 min of age at inst (instructions) of Consultant Paediatrician A -> Parents informed of death of baby (Mark)'.

2nd March 2012:

An Incident Near Miss Report Form[100] was completed by Consultant Obstetrician Gynaecologist A in relation to Mrs. Molloy's delivery and Baby Mark's death as the original form that she had completed on the 24th January 2012 could not be located.

The Incident Near Miss Report Form that Consultant Obstetrician Gynaecologist A completed stated the following;

"Failure to progress 2 stage
But CTG abnormal earlier
➔ theatre for delivery
Stillbirth

- ****- (*unable to decipher writing)***
- ***Coroner -> done following surgery***
- ***Incident Report -> this done out at time of incident cannot be found"***

25th May 2012:

The Consultant Pathologist who undertook the post mortem examination on Baby Mark, Consultant Pathologist 1 indicated during the investigation that he received an email from Mr. Molloy. Consultant Pathologist 1 indicated that in the email Mr. Molloy informed him that the Midland Regional Hospital at Portlaoise had changed the classification of Baby Mark's death from a 'stillbirth' to a 'neonatal death' and that he wished to inform Consultant Pathologist 1 of this fact.

Consultant Pathologist 1 indicated during the investigation that when he received the email from Mr. Molloy he contacted Consultant Obstetrician Gynaecologist A in relation to the classification of Baby Mark's death and that she confirmed to him that the classification of Baby Mark's death had been changed to a neonatal death.

22nd September 2012:

An updated post mortem report relating to Baby Mark was sent to the Midland Regional Hospital at Portlaoise. The report was signed by Consultant Pathologist 1 and classifies Baby Mark's death as an 'Early Neonatal Death'.

The post mortem report also states the following:

"Further clinical history indicated a faint heart beat was detected during resuscitation and even though there was no further signs of life guidelines state that the baby is a live birth".

[100] The Review Team was provided with a copy of the Incident Near Miss Report Form completed by Consultant Obstetrician Gynaecologist A in March 2012 in relation to Mrs. Molloy's surgery and Baby Mark's death in March 2013.

6.0 Findings and 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 management delivered to Mrs. Molloy and her baby son.

Using a systems analysis methodology in line with the HSE policy; the Review Team used Professor Morrison's findings to identify the Care Delivery Issues related to the care and management delivered to Mrs. Molloy and her baby son during Mrs. Molloy's labour and delivery at the Midland Regional Hospital Portlaoise on the 24th January 2012.

Care Delivery Issues are problems that arise in the process of care, usually actions or omissions by members of staff. They have two essential features:

- Care deviated beyond safe limits of practice,
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient, member of staff or general public.

These Care Delivery Issues result from systemic contributory factors which must be identified and appropriately managed in order to prevent recurrence or where this is not possible to reduce the risk of recurrence as far as is reasonably practicable.

An examination of the care of Mrs. Molloy from the time of her admission to the Midland Regional Hospital at Portlaoise on the morning of the 24th January 2012 up to 09.53 hours i.e. the time Baby Mark was pronounced dead identified two Care Delivery Issues; these were as follows;

- **Failure to recognise and act on the signs of foetal distress.**

- **Failure to fully assess all sections of the CTG resulting in a) the inappropriate prescribing and administration of Syntocinon and b) a delay in the decision to transfer Mrs. Molloy to the Theatre Department for an assisted delivery.**

The investigation notes that Professor Morrison states that in his opinion decisions made by the clinical staff managing Mrs. Molloy's labour i.e. the decision made to commence Syntocinon and the failure to identify signs of foetal distress were causally linked to the foetal hypoxia damage that occurred to Mr. and Mrs. Molloy's baby son and ultimately to the death of Mr. and Mrs. Molloy's baby son.

This review endeavoured to specify the factors that contributed to the occurrence of these Care Delivery Issues utilising the framework of influencing / contributory factors outlined in the HSE Toolkit of Documentation to Support Incident Management (2009) and the Healthcare Risk Management Guideline HSEMARM006 (Complaints and Incident Management and Investigation).

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 each of the Care Delivery Issues is included under Appendix IV 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 of 'Additional areas for system improvement identified by the investigation'.

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

This investigation identified a variance of opinion related to the decisions that were made regarding aspects of Mrs. Molloy's care during her delivery.

Midwife B expressed the view that the CTG recorded was generally reassuring during the period that she was caring for Mrs. Molloy i.e. between 05.40 hours and 08.00 hours and that when the CTG was noted to be non-reassuring for short periods of time she took the required actions which resulted in the resumption of a reassuring CTG trace. Midwife B indicated that when she identified that Mrs. Molloy's labour was not progressing adequately that she immediately rang Obstetrician Gynaecologist Registrar A to assess Mrs. Molloy.

Consultant Obstetrician Gynaecologist A who did not attend with Mrs. Molloy until 08.39 hours stated at interview that in her view based on the medical records that Mrs. Molloy should have been reviewed by the on call Obstetrician Gynaecologist Registrar at 06.40 hours as there were signs of foetal distress at that time in that the CTG was non-reassuring and there was Grade 1 meconium staining of amniotic fluid following artificial rupture of membranes.

Arising from the different views expressed in relation to aspects of the care provided to Mrs. Molloy on 24th January 2012 the Review Team sought (as noted earlier in this Report) input initially from the following experts: Professor John Morrison, Consultant Obstetrician Gynaecologist and Ms. Sheila Sugrue, Lead Midwife, Health Services Executive and thereafter, Dr. Miriam Harnett Consultant Anaesthetist and Dr. John Murphy, Consultant Neonatologist.

The purpose of the independent clinical reviews undertaken by Professor Morrison and Ms. Sugrue was to provide the investigation with expert opinions related to the clinical care provided to Mrs. Molloy and her baby including the interpretation of the CTG tracings recorded during the period of Mrs. Molloy's delivery on the 24th January 2012.

It has been established that Mrs. Molloy was admitted to the Maternity Department at 04.50 hours on the 24th January 2012 following a 'show' and the onset of labour pains. Following her arrival on the Maternity Department Mrs. Molloy was assessed by Midwife A and the assessment showed that;

- Mrs. Molloy was in labour,
- her cervix was 3 centimetres dilated,
- there was a cephalic presentation of the foetus,
- the station of the head was at -2 i.e. two centimetres above the ischial spines,
- the CTG was nonreassuring.

Mrs. Molloy's blood pressure on admission was 141/83 millimetres of mercury and her pulse rate was 87 beats per minute and she was requesting epidural analgesia.

Mrs. Molloy was transferred to the Labour Ward at 05.30 hours. On arrival on the Labour Ward the CTG was recommenced and Mrs. Molloy was commenced on intravenous fluids; the CTG was documented as reassuring at this time.

At 06.15 hours an epidural cannula was inserted and epidural analgesia commenced.

Mrs. Molloy's blood pressure was 114/66 millimetres of mercury and her pulse rate was recorded as 72 beats per minute at 06.27 hours.

Professor Morrison states in his report that Mrs. Molloy received good care in the antenatal period and that features described in the labour up to the time of 06.30 hours on the 24th January were unremarkable.

Ms. Sugrue did not address in her Report the care delivered to Mrs. Molloy up until this time.

It has been established that at 06.40 hours Mrs. Molloy's cervix was eight centimetres dilated, the fetal head was at station -2 and she had an artificial rupture of her membranes carried out with Grade 1 meconium present in the amniotic fluid. It was documented that Mrs. Molloy had a strong urge to push and that a late deceleration was noted on the CTG.

Mrs. Molloy's blood pressure was 101/52 millimetres of mercury at 06.50 hours.

When commenting on Mrs. Molloy's care for the period after 06.30 hours Professor Morrison indicated that the CTG trace was abnormal from 06.33 hours, that there was meconium staining of the amniotic fluid and that Mrs. Molloy's cervix was eight centimetres dilated. Professor Morrison stated that;

> ***"in my view that at some period of time shortly after 06.30 hours, and certainly by 06.50 hour, that the midwife should have requested that the Obstetric Registrar review the trace and the overall clinical situation".***

Ms. Sugrue stated when commenting on the CTG and Grade 1 meconium that:

> ***"although the CTG tracing was reported as being assuring throughout the labour, it is my opinion that foetal distress was worsening from around 06.30 hours of the Jan 24th 2012. Another sign of fetal distress was the presence of Grade 1 meconium at ARM (artificial rupture of membrane) (06.35 hours) with no further recording of meconium after that time".***

At 07.15 hours it was documented that the CTG was non-reassuring with a foetal heart rate of 130-150 beats per minute with early decelerations, that Mrs. Molloy was moved onto her left side[101] and that the CTG was reassuring following this.

Between 07.15 hours and 07.47 hours Obstetrician Gynaecologist Registrar A was contacted and informed of Mrs. Molloy's condition. There were differences in the recollections of those present as to the exact time of this contact. It was Midwife B's and Midwife C's recollections that Obstetric Gynaecologist Registrar A was first contacted to assess Mrs. Molloy at 07.15 hours while it was Obstetrician Gynaecologist Registrar A's recollection that he was first contacted to assess Mrs. Molloy at 07.47 hours.

At 07.30 hours it was documented that Mrs. Molloy's cervix was 9 centimetres dilated and that the station of the head was between -2 and -1. The maternal blood pressure was recorded at 101/52 millimetres of mercury and Mrs. Molloy's pulse rate was 91 beats per minutes.

At 07.35 hours it was documented that Mrs. Molloy's cervix was fully dilated and that the foetal heart rate was 110-120 beats per minute.

Between 07.40 and 07.45 hours it was documented that the foetal heart rate was 90-110 beats per minute with early decelerations and that while Mrs. Molloy had a strong urge to push there was no descent of the foetus into the cervix.

Obstetrician Gynaecologist Registrar A assessed Mrs. Molloy at 07.55 hours and the result of the assessment showed that the CTG was satisfactory[102] and that the station of the head was -1 with the lie of the foetus's head in the left occipital anterior position.

At 08.00 hours it was documented that the foetal heart rate was 120 beats per minute with late decelerations.

Mrs. Molloy was commenced on Syntocinon to augment her labour at 08.15 hours by Obstetrician Gynaecologist Registrar A.

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[101] As indicated previously Mr. and Mrs. Molloy indicated that Mrs. Molloy was not requested to turn onto her left side at this time.

[102] As previously stated it was established during the investigation that Obstetrician Gynaecologist Registrar A had initially documented that the "CTG noted to be satisfactory" and that this entry was subsequently changed to "CTG noted to be unsatisfactory (Non-reassuring)".

At 08.30 hours Obstetrician Gynaecologist Registrar A made the decision that Mrs. Molloy might require assistance with the delivery of her baby as her labour was not progressing and he contacted Consultant Obstetrician Gynaecologist A to inform her of Mrs. Molloy's condition.

Consultant Obstetrician Gynaecologist A arrived on the Labour Ward at 08.39 hours when she assessed Mrs. Molloy. The result of Consultant Obstetrician Gynaecologist A's assessment of Mrs. Molloy found that the cervix was fully dilated, that the station of the head was -1 and that the CTG was satisfactory but that late decelerations had been seen earlier. Consultant Obstetrician Gynaecologist A requested that the Syntocinon infusion that was being administered to Mrs. Molloy should be stopped.

Based on her assessment Consultant Obstetrician Gynaecologist A decided to transfer Mrs. Molloy to Theatre and that she would examine Mrs. Molloy again in Theatre with a view to proceeding to an assisted delivery. Following a second vaginal examination in the Theatre Consultant Obstetrician Gynaecologist A decided that a Lower Segment Caesarean Section (LSCS) should be carried out on Mrs. Molloy.

In their feedback to the Review Team Mr. and Mrs. Molloy stated when referring to the vaginal examinations of Mrs. Molloy carried out by Consultant Obstetrician Gynaecologist A and the time period from the decision to proceed to an emergency Caesarean Section to commencement of surgery that it was their view that a vaginal examination was not carried out in respect of Mrs. Molloy at 09.07 hours. Mrs Molloy indicated that Consultant Obstetrician Gynaecologist A had a discussion with her at this time but that a vaginal examination was not carried out.

Consultant Obstetrician Gynaecologist A has stated that she did carry out two separate examinations of Mrs. Molloy. Consultant Obstetrician Gynaecologist A said that no decision had been made as to the mode of delivery until after Mrs Molloy had been transferred to the operating theatre and a second examination carried out. The second vaginal examination established that there had been no further descent of the presenting parts so as to enable a vaginal delivery. Therefore, it was necessary to carry out a Caesarean Section and to facilitate this she attempted to disimpact the head from the pelvis.

Professor Morrison has also commented on this and he stated that in the healthcare record that relates to the Caesarean Section operation the findings of a vaginal examination are documented and that the findings are documented in a way that indicates that this examination was done in the actual Theatre - that 'OT' (i.e. Operating Theatre) is stated on the Operation Sheet.

At 09.31 hours Mrs. Molloy had a baby boy, later christened Mark, delivered by Lower Segment Caesarean Section. Baby Mark's Apgar score at 1 minute was 0 requiring immediate resuscitation which was continued for 22 minutes without success and Baby Mark was pronounced dead at 09.51 hours.

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.1 Task and Technology Factor I (Availability and Use of Policies, Procedures, and Guidelines) and recommendations to address these:

The University of Edinburgh (2008) indicates that a measure of the degree of foetal distress is an alteration in the foetal heart rate and that the CTG should be considered with reference to the overall clinical situation and other indicators of foetal compromise such as gestation for the pregnancy, foetal growth, foetal movements, bleeding, high blood pressure, diabetes, progress in labour and the presenting part of the foetus[103].

The University of Edinburgh also indicates that another feature of foetal distress is when the foetus moves its bowels i.e. meconium staining of liquor.

Midwife B indicated that it was her view that there was no sign of foetal distress during the period of time that she was providing care to Mrs. Molloy in that the CTG was generally reassuring and that when the CTG was non-reassuring she took the necessary actions which resulted in a reassuring CTG i.e. administered intravenous fluid and turned Mrs. Molloy onto her side.

Midwife B indicated that when she identified that Mrs. Molloy's labour was not progressing in the second stage of labour she immediately contacted Obstetrician Gynaecology Registrar A between 07.11 and 07.47 hours and requested that he assess Mrs. Molloy.

However Professor Morrison has stated in his report that:

> ***'Starting at the time of 06.33 hours there were decelerations evident on the CTG. Between 06.33 hours and 07.15 hours there were numerous decelerations, some early in nature, some late and some variable. These decelerations occurred down to a rate of 70 – 80 beats per minute.'***

As indicated (see Page 54) the external experts have indicated that the CTG tracing was nonreassuring from 06.30 hours. It was also identified that there was Grade 1 meconium stained liquor following the artificial rupture of membrane at 06.40 hours; these are two factors that indicated that the foetus was distressed.

Ms. Sugrue indicated that progress in labour is measured by an increase in the length, strength and frequency of contractions accompanied by a dilatation of the cervix and appropriate descent of the head or presenting part.

Ms. Sugrue indicates that from her assessment of these parameters as they relate to Mrs. Molloy's labour there were a number of delays in diagnosing a failure to progress in the first stage of Mrs. Molloy's labour and that these delays in identifying the failure to progress led to consequent delay in seeking medical assistance.

Ms. Sugrue indicates that one of these parameters i.e. the position of the head was not recorded on any of the vaginal examinations undertaken on Mrs. Molloy although there is a space set aside for it to be recorded in the healthcare record[104]. Ms. Sugrue indicated that

[103] Year 4 Obstetrics and Gynaecology; Labour Ward Handbook Version 2 (2008) the University of Edinburgh available from http://www.rds.mvm.ed.ac.uk/Labour%20Suite%20Handbook/PDF/Labour%20Ward%20Handbook.pdf

[104] There is a sticker placed in the healthcare record. The finding of the vaginal examination is recorded on the sticker i.e. cervical position, consistency, length, dilation and effacement, the station, position and identity of the presenting part, membranes should be assessed to determine if they are intact, ruptured or bulging. The colour, clarity and odour of any amniotic fluid should be assessed (reference:

the identification of the position of the head might have been difficult to determine and that this should have raised concerns so that a medical review should have taken place earlier then 07.47 hours.

Ms. Sugrue states that when Mrs. Molloy was reviewed by Consultant Obstetrician Gynaecologist A that she identified that the head of the foetus was in the deflex occipito-posterior position[105].

In their feedback to the Review Team Mr. and Mrs. Molloy indicated that there should have been further examinations carried out of Mrs. Molloy by midwifery staff other than those recorded in the healthcare record. Ms. Sugrue was requested to comment on this view and she confirmed that she had no changes to make to her report which is referred to above.

Professor Morrison states that in his opinion there was a failure to recognise the abnormalities demonstrated on the CTG tracing by the staff managing Mrs. Molloy's labour and that there was a consequent failure by the midwifery staff to request the Obstetric Registrar to review the CTG in a timely fashion.

Midwife B stated in her reply that based on independent expert advice available to her for this period of time, the effect that a review of Mrs. Molloy by an Obstetric Registrar i.e. Obstetrician Gynaecology Registrar A, carried out in or about 07.10 – 07.15 hours that morning, when the CTG had recovered to a normal pattern with variability, could reasonably have resulted in a decision to continue with the labour (if a foetal blood sample was not taken) subject to the proviso that the Obstetric Registrar be called if there were any further concerns on the CTG.

Midwife B indicated in her response that in accordance with this expert opinion she had contacted Obstetrician Gynaecology Registrar A to assess Mrs. Molloy at 07.20 hours when she had identified that the CTG was nonreassuring and that he was contacted for a second time at 07.40 hours.

It was noted during the investigation that while there is a HSE (as part of the Obstetric and Gynaecology Clinical Care Programme) and a Midland Regional Hospital at Portlaoise guideline on monitoring i.e. intrapartum foetal heart rate monitoring; that these guidelines focus solely on foetal heart monitoring and that the guidelines do not refer to the other parameters/indicators that would assist staff in conducting an overall assessment of the condition of the foetus and the mother.

The Review Team note that in 2007 the National Institute for Health and Clinical Excellence (NICE)[106] replaced their clinical guideline on electronic foetal monitoring: the use and interpretation of cardiotocography in intrapartum foetal surveillance with the clinical guideline on intrapartum care: management and care of a woman in labour. The former guidance focussed solely on one parameter of foetal well-being i.e. electronic foetal monitor while the later guideline includes all relevant parameters to assist clinical staff to better consider the entire clinical picture when making an assessment of foetal well-being; the following parameters are included in the 2007 NICE guideline:

Midland Regional hospital at Mullingar and Portlaoise: Admission of an expectant mother to the Maternity Department. Version 1, Approved April 211).

[105] The Royal College of Midwives (2012) indicated that between 15-32% of women experience a baby in an occipital-posterior or occipito-lateral position at the onset of labour.

[106]The National Institute for Health and Clinical Excellence (NICE) was set up in 1999 to reduce variation in the availability and quality of NHS treatments and care - the so called 'postcode lottery'. Our evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures and devices represent the best quality care and which offer the best value for money for the NHS. We also produce public health guidance recommending best ways to encourage healthy living, promote wellbeing and prevent disease. Our public health guidance is for local authorities, the NHS and all those with a remit for improving people's health in the public, private, community and voluntary sectors (Reference: http://www.nice.org.uk/aboutnice/whoweare/who_we_are.jsp).

- Care of the woman throughout labour,
- Pain relief,
- Normal labour: first, second and third stage of labour,
- Normal labour: care of the baby and woman immediately after birth,
- Meconium-stained liquor,
- Complicated labour: monitoring babies in labour,
- Complicated labour: first, second and third stage,
- Complicated labour: immediate care of newborn.

Recommendation:

- **That the HSE Obstetric and Gynaecology Clinical Care Programme considers developing a guideline on intrapartum care: management and care of a woman in labour which includes all aspects of a woman and her foetus's care throughout labour.**

As indicated above it was identified during the investigation that there are HSE and Midland Regional Hospital at Portlaoise guidelines on intrapartum foetal heart rate monitoring.

These guidelines contain guidance on the features of a normal CTG i.e. baseline heart rate, baseline variability, accelerations and the criteria for identifying a normal, suspicious (i.e. one feature is abnormal) and pathological (i.e. two or more features are abnormal) CTG.

However the guidelines do not specifically identify when medical assistance should be sought i.e. in the presence of a suspicious or pathological CTG. Therefore, while the guidelines outline the features of normal, suspicious and pathological tracings, they do not indicate in which situations additional clinical input and/or immediate management is required.

In contrast the Royal Australian and New Zealand College of Obstetricians and Gynaecologists Clinical Guidelines Intrapartum Fetal Surveillance – Second Edition December (2009) gives advice on the features of an abnormal CTG and further advises that an abnormal CTG requires further evaluation taking into account the full clinical picture.

The guideline specifically identifies features of the CTG that;

- Are unlikely to be associated with significant compromise when occurring in isolation,
- May be associated with significant foetal compromise and require further action,
- Are very likely to be associated with significant foetal compromise and require immediate management; which may include urgent delivery.

It is the view of this investigation that clear and unambiguous guidance should be included in clinical guidelines related to foetal heart monitoring. This guidance should outline the requirement to seek additional clinical input and/or initiate immediate management related to the assessment of CTG tracings.

Recommendation:

- **That as a matter of priority the HSE Obstetric and Gynaecology Clinical Care Programme consider including specific advice on a) when medical assistance should be sought and b) when immediate management is required in the event of an abnormal CTG trace in the clinical guidelines on intrapartum care: management and care of a woman in labour.**

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.1.1 Task and Technology Factor II (Decision Making Aids) and recommendation to address these:

Professor Morrison indicated in his report that as part of Obstetric Gynaecology Registrar A's review of Mrs. Molloy that he had identified that Mrs. Molloy's cervix was 8 centimetres dilated and that there were significant decelerations evident on the CTG and that it would have been appropriate for Obstetric Gynaecology Registrar A to carry out foetal blood sampling at that time to assess the foetal blood pH and base excess values in order to determine if the foetus was acidotic.

Sufficient degree and duration of acidemia, increased acidity of the blood, can cause brain damage with resultant neurological sequelae in surviving children, organ damage, or intrapartum or neonatal death[107].

It was identified during the investigation that Midland Regional Hospital Portlaoise does not have facilities for foetal blood sampling.

The Royal College of Obstetricians and Gynaecologists et al (2007) document on Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour[108] indicates that the ability to assess fetal blood gases by modern, easily used equipment should be available in any unit undertaking continuous foetal heart rate monitoring and that the two elements should not be separated.

A previous investigation carried out that related to the Maternity Department at the Midland Regional Hospital Portlaoise recommended that a risk assessment be carried out on the risk of injury to a foetus due to the failure to provide foetal blood sampling on the Maternity Department of the hospital.

The Review Team was informed during this investigation when they requested an update on the implementation of the recommendations of the previous investigation that the Maternity Department had identified this deficit as a risk and that consequently Consultant Obstetrician Gynaecologist A had highlighted the issue of access to foetal blood sampling facilities to the HSE Clinical Lead for the Obstetric and Gynaecology Clinical Care Programme with a view to obtaining the resources necessary for the facilities to carry out foetal blood sampling in the Midland Regional Hospital Portlaoise. The Review Team was informed by Clinical Midwifery Manager II A and Divisional Nurse Manager of the Maternity Department that it was their understanding that in 2012 the resources required to put in place the facilities for foetal blood sampling were not available from within the hospital's allocated budget.

Recommendation:

- **That the facilities required to carry out foetal blood sampling should be provided at the Midland Regional Hospital at Portlaoise as a matter of priority.**

[107] Reference: Liston R., Crane J. (2002) Fetal Health Surveillance in Labour. SOGC Clinical Practice Guidelines. JOGC No. 112, March 2002.

[108] Royal College of Obstetrician and Gynaecologist, Royal College of Midwives, Royal College of Anaesthetist and the Royal College of Paediatrics and Child Health (2007). Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour. {available from http://www.rcog.org.uk/files/rcog-corp/uploaded-files/WPRSaferChildbirthReport2007.pdf}.

6.1. Care Delivery Issue I: Failure to recognise and act on the sign of foetal distress

6.1.1.2 Task and Technology Factor III (Decision Making Aids) and recommendations to address these:

A CTG machine is a technical means of recording the foetal heart beat and the uterine contractions during pregnancy, typically in the third trimester[109]. One of the features of the CTG machine is that the machine will alert staff to an abnormal CTG tracing.

Mr. and Mrs. Molloy informed the Review Team that they do not recollect hearing the CTG audible alarm while they were in the Labour Ward. Midwife B has also confirmed that she does not recollect hearing the CTG alarm while she was caring for Mrs. Molloy.

As part of this investigation the Review Team contacted and spoke to the Chief Clinical Engineering Technician, Estates Department, HSE Dublin Mid-Leinster and the Clinical Engineer based at the Midland Regional Hospital at Portlaoise.

The Chief Clinical Engineering Technician informed the Review Team that the type of CTG machine in use in the Maternity Department is the Philips Avalon Fetal Monitor FM30; one machine was purchased in 2006 and four in 2007.

The Chief Clinical Engineering Technician stated that the company who supplied the machines stated that the Avalon Fetal Monitor should be serviced yearly; it was established that the five monitors in use are serviced every six months. The Clinical Engineer informed the Review Team that all of the Avalon Fetal Monitors on the Maternity Department had been serviced by the Service Agent in September 2011 (i.e. last service prior to January 2012), that the service carried out was in line with the manufacturer's instructions and that no service issues were identified with the monitors during that service.

The Chief Clinical Engineering Technician informed the Review Team that he had received occasional reports of faults related to the functioning of the CTG machines since they had been purchased; however he confirmed that the faults reported related to the probes i.e. the oxygen probe attached to the machine and not the machine itself and that the probes were replaced as required.

It was also confirmed that the foetal monitor that had been attached to Mrs. Molloy on the 24th January 2012 was serviced on the 1st March 2012 and that the Engineer's Report of this service stated that

"Checked and tested this device. This device is fully functional. Unable to confirm consumer problem".
(A copy of the report can be found in Appendix IV of this report).

In their feedback to the Review Team Mr. and Mrs. Molloy stated that the records show that the fetal monitor in the Theatre was broken, as the time and dates on the Theatre element of the CTG do not match the actual time and date of the 24th January and of 9.00 - 9.31 hours.

The Midland Regional Hospital Portlaoise guideline on Fetal Heart Rate Monitoring during labour in the Maternity Department[110] states that when commencing continuous electronic fetal monitoring that the operator should "Ensure that the time and date on the CTG monitor are accurate".

[109] 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

[110] Regional Maternity Departments, Midland Regional Hospital Mullingar and Midland Regional Hospital Portlaoise Guideline Fetal heart rate monitoring during labour in the Maternity Department. Document reference number: RGOU017. Revision number 1. Approval date: April 2011.

It was established that the time and date recorded at the beginning of the CTG trace recorded in the Theatre Department was "**00.00. 04.04.44**."

Midwife D indicated during the investigation that she checked the time and date on the CTG machine before attaching it to Mrs. Molloy in the Theatre Department, that she was aware at the time that the time and date on the CTG trace was incorrect and that as a result she documented the following at the beginning of the CTG trace: the time the trace commenced i.e. 09.10 hours, Mrs. Molloy's name, her date of birth and her hospital number.

The Review Team contacted the Clinical Engineering Department in the Midland Regional Hospital Portlaoise who informed the Review Team that the CTG machine that was attached to Mrs. Molloy in the Theatre Department was serviced on the 9th March 2012 and that the Engineer's Report of this service states that:

"*Carried out a full PM on this device. Unit has passed*".
(A copy of the report can be found in Appendix IV of this report).

The Review Team note that at the time Midwife D was attaching the CTG to Mrs. Molloy in the Theatre Department that;

- the CTG had been nonreassuring before leaving the Delivery Suite,
- Mrs. Molloy was for an assisted delivery and queried an emergency Caesarean Section,
- the foetal heart rate was difficult to auscultate in the Theatre Department,

The Review Team was of the view for the reasons outlined above that it was reasonable in this instance for Midwife D not to follow the guideline on Fetal Heart Rate Monitoring during labour in the Maternity Department in relation to ensuring that the time and date on the CTG monitor was accurate as to do so would have resulted in a delay in commencement of monitoring of the foetal heart rate. The Review Team noted that Midwife D documented the correct time and date on the CTG trace, which was reasonable in this circumstance.

The Clinical Midwifery Manager of the Maternity Department confirmed to the Review Team that training on the Avalon Fetal Monitor was provided to all midwives before the monitors were commissioned for use in the Maternity Department in 2006.

The Avalon Fetal Monitor FM30 Instructions for Use Manual[111] indicates that the FM30 carries the IP label indicating that it is capable of intrapartum monitoring.

The User Manual states that the Avalon Fetal Monitor:

> **"should be used by trained health care professionals whenever there is a need for monitoring of the following physiological parameters 1) uterine activity, 2) heart rate, 3) oxygen saturation, 4) non-invasive blood pressure, 5) pulse rate of pregnant women and 6) the fetal heart rates of single foetuses, twins, and triplets in labour and delivery rooms and in antepartum testing areas".**

All of the physiological parameters are displayed on the CTG machine's screen which is a touch screen[112].

The User Manual indicates that the foetal monitor has three alarm levels: red, yellow and INOP; red and yellow alarms are patient alarms while INOPs are technical alarms. The User Manual states that a red alarm indicates a high priority situation, such as a potentially life threatening situation i.e. oxygen saturation below the desaturation alarm limits; and that a yellow alarm indicates a lower priority alarm i.e. a fetal heart rate alarm limit violation.

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[111] Relevant sections of the Avalon Fetal Monitor Instruction for Use manual relation the alarms can be found in Appendix 4 of this report.
[112] A monitor screen that can detect and respond to something, such as a finger or stylus, pressing on it (Reference: http://www.thefreedictionary.com/touch+screen).

The User Manual also indicates that the CTG machines have both visual and audible alarms; the vital sign that activated the alarm will flash on the monitor's screen and an audible alarm will be heard.

The User Manual indicates that the monitor's visual and audible alarms automatically activate when the maternal heart rate, oxygen saturation or the foetal heart rate falls outside the preset higher and lower parameters for a specific time period; the Chief Clinical Engineering Technician attached to the HSE Midland Area confirmed during the investigation that CTG monitors in use in the Midland Regional Hospital at Portlaoise are configured to activate after a time delay of 30 seconds i.e. the parameter that activated the alarm must be outside the preset parameters for a period in excess of 30 seconds before the alarm will activate.

The purpose of the alarm is to inform the clinical staff that the relevant vital sign is abnormal. The User Manual indicates that the audible alarm will continue to activate until it is acknowledged by switching it off (this action can only be performed by accessing the monitor's set up menu) or by pausing it, or until the alarm condition ceases i.e. the vital sign that activated the alarm returns to within the preset higher and lower parameters.

In relation to audible alarm notifications the User Manual indicates that the alarm volume symbol is at the right corner of the monitor screen giving the operator an indication of the current volume of the alarm. The User Manual indicates that the alarm volume can be adjusted on a scale of zero (off) to 10 and that if the alarm volume is off the operator will not get any audible indication of alarm conditions.

However the Chief Clinical Engineering Technician attached to the HSE Midland Area indicated during the investigation that the CTG machines in use in the Midland Regional Hospital at Portlaoise are configured so that volume cannot be set lower than 4 i.e. the minimum volume level is 4.

The Chief Clinical Engineering Technician attached to the HSE Midland Area also indicated during the investigation that while the CTG audible alarm can be reduced to a minimum volume level of 4 by the operator the vital signs visual alarm will continue to flash on the monitor's screen.

The User Manual indicates that the foetal monitors audible alarm can be manually paused i.e. "Alarm Pause" mode or permanently turned off i.e. "Alarm off" mode however the Review Team was informed that the fetal monitors in use in the Maternity Department are configured to pause the alarm for three minutes i.e. the audible alarm will re-start after three minutes following depression of the "Alarm Pause" button and that none of the monitors were configured in an alarm off mode.

It was noted that the User Manual indicates that while the alarms are paused or off, the monitor displays the message "Alarm Paused" or "Alarm Off" together with the alarm symbol and the remaining pause time in minutes and seconds or an alarm off symbol.

It was established during the investigation that when the CTG machine is in the "Alarms Off" mode the event is annotated on the CTG graph paper by removal of the alarms parameters on the graph paper; but that the "Pause Alarm" is not annotated.

A review of the CTG graph paper relating to Mrs. Molloy's care undertaken as part of this investigation indicated that the foetal heart rate, a symbol of a bell and alarm parameters i.e.  [113] were printed on the CTG graph paper on 20 separate occasions between 05.40 hours i.e. the time Mrs. Molloy was commenced on the CTG tracing paper up to 08.50 hours approximately i.e. the time Mrs. Molloy was transferred to Theatre.

As part of the investigation, the Review Team contacted the company that services the foetal monitors at the Midland Regional Hospital Portlaoise. The Engineer that the Review Team spoke with informed the Review Team that the printing of the foetal heart rate, a

[113] An enlarged copy of this picture is available in Appendix VI of this report.

symbol of a bell and alarm parameters on the CTG graph paper is an automatic function indicating that the foetal heart rate is being monitored within the present parameters i.e. 110-160 beats per minutes by the CTG machine. The display of the symbols does not indicate that the alarm had activated as a result of the foetal heart rate being outside the preset upper and lower limits.

The Engineer that the Review Team spoke with indicated that if a monitor is in the 'Alarms Off' mode the alarm parameters do not print on the CTG graph paper. However as indicated previously, the foetal heart rate parameters are printed on the CTG graph paper related to Baby Mark's CTG indicating that the monitor was monitoring the foetal heart rate during this time period.

Midwifery staff involved in Mrs. Molloy's care between 05.40 hours and 08.00 hours on the 24th January 2012 confirmed to the Review Team that they did not in any way alter the foetal heart monitor's alarm settings while they were caring for Mrs. Molloy and there is no evidence that this was the case.

The Review Team was unable to establish why the audible alarm function of the Avalon Fetal Monitor could not be heard by Mr. and Mrs. Molloy nor Midwife B.

While the Review Team was cognisant of the fact that the CTG alarm is not designed to replace a visual review of the CTG trace by experienced and competent clinical personnel, the visual and audible alarms do serve as an added device to notify clinical personnel that one or more of the vital signs being monitored by the machine have dropped below or exceeded the pre-set parameters programmed into the machine. Had Midwife B heard the alarm when the CTG was nonreassuring between 06.33 hours and 07.15 hours and at 07.45 hours it might have assisted her in identifying the signs of foetal distress at an earlier point in Mrs. Molloy's labour.

Section 3 Basic Operations of the Avalon Fetal Monitor Instructions for Use manual indicates that the following process should be followed when attaching the monitor to an expectant mother;

- Power on the CTG machine. The device will run a self-test and generate a test sound to confirm a functioning speaker,
- Adjust the display to ensure it can be viewed clearly,
- Confirm that there is sufficient paper in the device,
- If prompted, select a new patient or discharge the previous patient. This will apply the default settings on the device,
- Verify fetal position and apply the transducers accordingly,
- Connect the transducers to the device,
- Verify that each desired parameter is displayed on the screen and that the alarm limits are set to appropriate values,
- Start the recorder.

The investigation noted that while it is documented in the Maternity Department's guideline on foetal heart rate monitoring during labour that the CTG paper should be set at a rate of 1 centimetre per minute and the tocometer set at 20 when the abdomen is soft that there was no process/policy in place for ensuring that the process outlined in Section 3 Basic Operations of the Avalon Fetal Monitor Instructions for Use manual was followed.

Recommendation:

- **That a formal process is introduced in the Maternity Department immediately that ensures that the functionality of all Avalon Fetal Monitors in use are checked prior to every episode of use. Furthermore that the guideline on intrapartum foetal surveillance and the care of women during labour includes specific reference to the process that must be followed for checking the Foetal Monitors when an expectant mother is admitted to the Labour Ward. The process should follow the basic operation of the Avalon Fetal Monitors as outlined in the Instructions for Use manual.**

It was established during the investigation that the Avalon Fetal Monitor can store basic patient demographic information used to identify patients. The User Manual indicates that it is important that this facility is used in order to properly identify a patient on records. The User Manual indicates that a patient can be admitted and discharged by using the Patient Demographics window and its associated pop-up keys.

A review of Mrs. Molloy's CTG trace identified that Mrs. Molloy's name was not printed on the vertical header on the CTG graph paper indicating that her demographics were not entered onto the machine. However there was a laser label containing Mrs. Molloy's demographic details attached to the CTG graph paper and her name was also hand written on the CTG graph paper.

The Chief Clinical Engineering Technician attached to the Midland Regional Hospital Portlaoise indicated during the investigation (confirmed by the Service Company) that the Avalon Fetal Monitors in use in the Maternity Department cannot store data on their hard drives, that the monitor's hard drive is a buffer storage only to facilitate the changing of the graph paper and that therefore the data relating to Mrs. Molloy's episode of care could not be retrieved from the machine's hard drive.

CTG monitors are complex machines requiring regular machine operator interaction. While training on the monitors had been provided to staff in the Maternity Department when they were first purchased in 2006/7, there was no evidence that staff had received any update training on the monitors since that time.

It was also the view of the Review Team that while the FM30 Avalon Fetal Monitor User Manual is a comprehensive document which includes detailed technical information and operator instructions i.e. the manual is over 220 pages, that the manual was not developed as a user guide which an operator can refer to easily and readily during an episode of care.

Recommendation:

- **That the CTG training outlined in Section 6.1.4 of this report includes regular update training on the FM30 Avalon Fetal Monitor User Manual.**

- **That in conjunction with the equipment supplier a 'user guide' is developed for the FM30 Avalon Fetal Monitors that staff can refer to during an episode of care.**

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.2 Individual factors (Skills and Knowledge):

6.1.2.1 Midwife B's skill and knowledge:

Midwife B informed the Review Team that she was a practicing midwife for the last 25 years, that she has a degree in Midwifery from Trinity College, Dublin, that she was a trainer in neonatal resuscitation and that she was also qualified in general and psychiatric nursing.

It was also established during the investigation that Midwife B had attended study days on the Fundamentals of Fetal Monitoring Training in 2011. In addition the Review Team was also informed that Midwife B attended the following study days between 2010 and 2011;

- Professional and legal issues,
- Management of high risk pregnancy,
- Obstetric Emergencies.

Midwife B indicated that she is currently undertaking a Masters in Leadership and Management in the Royal College of Surgeons in Ireland.

Midwife B informed the Review Team that she made every effort to ensure that she maintained her knowledge and competence related to best practice in nursing and midwifery practice.

Midwife B when referring to her professional development indicated that she had registered to attend a Fundamentals of Foetal Monitoring Study day in October 2012 but that she was unable to attend due to a late change to the duty roster. When she was informed of the change to the duty roster she contacted Clinical Midwifery Manager II A who informed her that participation in the study day was recommended but not mandatory. Midwife B indicated that she highlighted her concerns to Clinical Midwifery Manager II A at this time that she had not attended a study day organised by the hospital since 2011.

Midwife B also informed the Review Team that following the conversation with Clinical Midwifery Manager II A that she sent an email to the Director of Nursing to highlight her concerns that she had not attended a study day since 2011 and that she received no response to the email. Midwife B indicated that she also contacted the company who provided the Fundamentals of Foetal Monitoring study day requesting that they notify her when the next study day was being organised.

Midwife B indicated during the investigation that she is committed to her own professional development as reflected in her attendance at the Masters in Leadership and Management but that the difficulty she experienced in attending study days organised by the Maternity Department highlighted an institutional problem in the roster of midwifery staff to attend study days.

In feedback to the Review Team Clinical Midwifery Manager II A indicated that midwifery staff self roster and that in October 2012 Midwife B had self rostered to work on night duty which had prevented her attendance at the Fundamentals of Foetal Monitoring study day.

Clinical Midwifery Manager II A also informed the Review Team that following a request from Midwife B, the duty roster was changed so that Midwife B could attend the study day. Clinical Midwifery Manager II A indicated that subsequent to this change unscheduled leave had reduced the staffing levels/skill mix available to the department and as a result the study day was cancelled and that this had been communicated to Midwife B; that during that conversation with Midwife B that Clinical Midwifery Manager II A informed her that it was not mandatory to attend two yearly CTG training in Ireland but that it was recommended and that Clinical Midwifery Manager II A strongly supported this recommendation.

Clinical Midwifery Manager II A indicated during the investigation that she informed Midwife B during the phone call that the latest research findings pertaining to CTG training strongly advised that all midwives should participate in the online K2 fetal monitoring and fetal surveillance education programme which was now available in the Maternity Department. She also informed Midwife B during the telephone conversation of the weekly CTG workshops which were held in the department and that she expressed her regret that the study day had to be cancelled.

In feedback to the Review Team the Director of Nursing indicated that she encourages and assists all nursing and midwifery staff in the hospital to actively engage in continuous professional development and that all nursing and midwifery staff have a professional responsibility to continue their own professional development.

The Director of Nursing also informed the Review Team that she did receive an email from Midwife B and that she responded to the email to inform Midwife B that travel to attend the course would be approved but that she must submit the Study Day Request Form. The Director of Nursing indicated that she subsequently received an email from Midwife B on the 3rd October to inform her that due to an imbalance in skill mix on the night of the 3rd October that Midwife B had been requested to work an extra night on duty and as a result she would be unable to attend the study day on the 4th October.

Midwife B also informed the Review Team that in 2010 she attended an interview to appoint midwifery shift leaders[114] to the Maternity Department and that she had come first on the panel established following the interview process, Midwife B indicated that she was not appointed as a shift leader at the time.

It was established during the investigation that the positions of midwifery shift leader were advertised as full time positions and that a number of midwives on the panel established following the interview process could not increase their hours of working to full time to meet the requirements of the advertised positions and as a result these midwives were not appointed as shift leaders.

The midwifery and senior nursing managers of the Maternity Department and hospital i.e. the Midwifery Manager and Divisional Nurse Manager, and the Director of Nursing of the Midland Regional Hospital at Portlaoise confirmed to the Review Team that Midwife B was an extremely experienced and knowledgeable midwife. Additionally they all confirmed that they had no concerns related to any aspects of Midwife B's practice previously and that no issues had arisen related to her practice before this incident.

6.1.2.2 Obstetrician Gynaecology Registrar A's skill and knowledge:

Obstetrician Gynaecology Registrar A informed the Review Team that he has been working in the area of obstetrics and gynaecology since 2005 and that he commenced training as a Specialist Registrar in Ireland in 2010. This training is overseen by the Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland.

Obstetrician Gynaecologist Registrar A stated that he had worked in a number of Maternity Departments in other hospitals in Ireland prior to taking up his position at the Midland Regional Hospital Portlaoise and that he had extensive experience in the management of women in labour. Obstetrician Gynaecologist Registrar A also informed the Review Team that he had completed the K2 training module[115].

Obstetrician Gynaecologist Registrar A stated that, in all of his previous experience and placements, he had not made an error in his assessment of a patient as had occurred in his assessment of Mrs. Molloy on the 24th January.

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[114] A shift leader provides support, direction and assistance to Midwives when the Midwifery Manager is not on duty.

[115] 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).

Obstetrician Gynaecology Registrar A informed the Review Team at interview that when he first assessed Mrs. Molloy at 07.47 hours that he did not take time to assess all of the CTG i.e. he indicated that he only assessed the most recent section of the CTG that had been recorded and not the previous segments of the tracing.

Obstetrician Gynaecology Registrar A indicated that had he assessed all sections of the CTG he would have identified that it was non-reassuring.

Obstetrician Gynaecology Registrar A informed the Review Team that he very much regretted this error and that he has learned from the events that occurred on the 24th January and that in future it would be his consistent practice to review all sections of the CTG when assessing a woman in labour.

Obstetrician Gynaecology Registrar A also indicated that he frequently recalls the events of the 24th January and he offered his sincere apologies to Mr and Mrs. Molloy.

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.3 Team Factors (Verbal Communication) and recommendation to address these:

Midwife B was the primary midwife responsible for Mrs. Molloy's midwifery care from the time Mrs. Molloy was transferred to the Labour Ward up to the time Midwife B went off duty. At that time the responsibility for Mrs. Molloy's midwifery care was handed over to Midwife D.

Midwife C was also allocated to the Labour Ward on the night of the 24th January and she indicated that she was in and out of the room allocated to Mrs. Molloy and that she assisted Midwife B in caring for Mrs. Molloy when requested.

Midwife C indicated that she was Mrs. Molloy's "second midwife"; Midwife C informed the Review Team at interview that the role of the second midwife was to assist the primary midwife to care for the expectant mother in the second stage of labour.

It has been established during the investigation that Mrs Molloy had Grade 1 meconium stained liquor following artificial rupture of membranes and that when Mrs. Molloy queried if it was normal for meconium to be present following artificial rupture of membranes that it was her and her husband's recollection that she was informed that meconium stained liquor could sometimes be present following rupture of membranes in women who were overdue in their labour.

Midwife C informed the Review team that at the time Mrs Molloy was advised that meconium stained liquor could sometimes be present following artificial rupture of membrane in women who were overdue in their labour that she had not seen the CTG and therefore she was not aware that the CTG was nonreassuring.

Midwife C indicated that as she was Mrs. Molloy's second midwife it was her view that it was not her role nor would she be expected to have referred to the CTG when she was informed of the Grade 1 meconium stained liquor. Midwife C also indicated that Midwife B did not ask for her opinion on the progress of Mrs. Molloy's labour or on Mrs. Molloy's midwifery care at any time on the 24th January 2012.

Notwithstanding the role of the "second midwife" in the care of an expectant mother as outlined by Midwife C it was the view of this investigation that an opportunity was lost at this time i.e. at the time of the discussion related to the Grade 1 meconium stained liquor which was followed by a nonreassuring CTG that might have allowed the midwifery staff present to carry out a full re-appraisal of Mrs. Molloy's and her baby's condition.

Recommendation:

- **That guidance is developed on the role of the 'second midwife' which includes reference to the requirement for communication of information between the primary and secondary midwives providing care to a woman in labour using a tool such as SBAR. Furthermore, it is recommended that any assessments undertaken jointly by the primary and secondary midwife are fully documented in the healthcare record including reference to all information reviewed.**

As indicated above it was the view of this investigation that an opportunity was lost to fully assess Mrs. Molloy's and her baby's condition at 06.40 hours when there was Grade 1 meconium stained liquor followed by a nonreassuring CTG and that had such a discussion taken place that it might have allowed for a full re-appraisal of Mrs. Molloy's and her baby's condition.

The UK document on Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour[116] highlights the importance of effective communication in the safe delivery of care. Failure to communicate information clearly and to ensure that it has been received and understood has been highlighted as a cause of unsafe care[117]. The Kings Fund recommends that a structured communication tool such as Situation, Background, Assessment, Recommendation (SBAR) should be used to improve communication at handover.

It was also noted during the investigation that the National Clinical Effectiveness Committee of the Department of Health has adopted the ISBAR (Identify, Situation, Background, Assessment, Recommendation) technique to enhance effective verbal communication of the deteriorating patient among clinical staff[118].

Recommendation:

- **Development and implementation of a standardised and agreed communication tool for the handover of information related to the condition of women in labour and that of their unborn infant e.g. SBAR (Situation, Background, Assessment, Recommendation).**

[116] Royal College of Obstetrician and Gynaecologist, Royal College of Midwives, Royal College of Anaesthetist and the Royal College of Paediatrics and Child Health (2007). Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour. {available from http://www.rcog.org.uk/files/rcog-corp/uploaded-files/WPRSaferChildbirthReport2007.pdf}.
[117] The Kings Fund (2012). Communication. Available from: http://www.kingsfund.org.uk/sites/files/kf/field/field_related_document/Improving-safety-in-maternity-services-communication1.pdf {accessed 28th February 2013}. The Kings Fund is an independent charity working to improve health and health care in England.
[118] Clinical Effectiveness Committee (Department of Health February 2013) National Early Warning Score. National Guideline No 1. Available from http://www.hse.ie/eng/about/Who/clinical/natclinprog/EWSguide.pdf (accessed 28th February 2013.

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.4. Work Environment Factor I (Education and Training) and recommendations to address these:

Clinical Midwifery Manager II A indicated during the investigation that the current configuration of the midwifery team does pose a number of challenges related to the supervision of some midwifery staff. Clinical Midwifery Manager II A stated that:

- as some members of the midwifery team work continually on night duty i.e. they did not rotate from day duty to night duty as is the practice for most midwifery staff on the Maternity Department that opportunities for ongoing supervision and assessment were limited.
- in order to assess the practice of midwifery staff on the Maternity Department she would directly supervise midwives while they are delivering care and she would regularly review healthcare records following the discharge of a woman from the Labour Ward and that on the basis of the documentation recorded in the healthcare record that she would make an assessment of the care provided by midwifery staff in these cases.
- directly supervising midwives and reviewing the healthcare record following discharge is used as an opportunity to provide clinical supervision to midwives in the Department.
- she was unable to directly supervise the cohort of midwives who work continuously on night duty as Clinical Midwifery Manager II A works day duty shifts only. Clinical Midwifery Manager II A indicated that the use of healthcare records as a sole means of supervising midwives has limitations as the records do not give the full context of care provided which can be achieved when directly supervising the midwife.

The Director of Nursing of the Midland Regional Hospital at Portlaoise informed the Review Team that the practice of some midwifery staff working continuous night duty was an issue that had been identified by senior nursing and midwifery management as needing to be addressed. Consequently she had planned to meet with the midwives and their staff representation group(s) in order to progress the rotation of midwives from day to night duty but that to date no meeting had taken place with the staff representation groups(s) in relation to this issue.

To ensure that clinical managers can assess and provide clinical supervision to all staff under their direction and on the basis that the absence of an agreed system for the rotation of midwives from night to day duty impacts on patient safety as it restricts the supervision of midwives and the number of CTG workshops/training days that the midwifery staff permanently rostered to night duty can attend. This investigation recommends that all midwifery staff should be rostered on day duty for a defined period of time.

Recommendation:

It should be a mandatory requirement that all midwifery staff allocated to the Maternity Department at the Midland Regional Hospital Portlaoise must be rostered to day duty for a defined period of time so that they can avail of clinical assessment and supervision of their practice. It was recommended by the Director of Nursing of the Midland Regional Hospital at Portlaoise during the investigation that all midwifery staff on the Maternity Department should work a minimum of three months of day duty per year.

The New Zealand College of Midwives recommend that midwives and doctors should receive annual joint education on foetal surveillance and CTG interpretation as a core competency standard for all staff involved in intrapartum care. The College also recommend that formal learning should be complimented by annual completion of computerised learning packages such as K2 fetal monitoring and fetal surveillance

education programmes and weekly review of CTG strips presentation in the Labour Ward[119].

In February 2012 the Midland Regional Hospital Portlaoise introduced K2 CTG training for all medical and midwifery staff.

The Review Team was informed that Obstetric Gynaecology Registrar A, Midwifes C and D had completed the K2 training on one occasion since February 2012. Midwife B had not been able to access the training module due to difficulties relating to her user name and password.

Recommendation:

- **That all staff working in the Maternity Department must be provided with up to date and valid user names and passwords so that they can access the K2 training module. Any difficulties experienced by staff related to accessing the training module must be reported immediately and resolved as soon as is reasonably practicable.**

The Midwifery Manager of the Maternity Department indicated that while there is a Notice displayed on the Maternity Department stating that all midwifery staff are required to access the K2 training that there is no policy in place outlining how frequently the training should be accessed by staff or a process to be implemented/followed if or when a member of staff does not access the training.

Recommendation:

- **That a policy is developed, implemented, monitored and reviewed related to implementation of the K2 training module for staff. The policy must include specific reference to (1) the frequency that staff must access the training (2) the process for checking that all staff have completed the training and (3) the process for the management of those staff who fail to complete the training programme as is required.**

It was established during the investigation that the Maternity Department in the Midland Regional Hospital Portlaoise has also provided a series of study days for midwives over the last five years in addition to K2 training and weekly CTG workshops.

The study days provided for the midwives in the Midland Regional Hospital Portlaoise by the Centre of Nurse Education at the Midland Regional Hospital at Tullamore covered the following subjects;

- Obstetric emergency,
- Fundamentals of fetal monitoring,
- Importance of comprehensive documentation,
- Neonatal resuscitation,
- Epidural analgesia

These study days were provided by the Centre following a request from the Director of Nursing of Midland Regional Hospital Portlaoise.

In relation to ongoing education for midwifery staff the Review Team was informed;

- that staff from the Maternity Department have access to Athens[120] which they can access from home, on the Maternity Department and at the hospital's Library,

[119] Intrapartum fetal heart rate monitoring: using audit methodology to identify areas for research and practice improvement. New Zealand College of Midwives Journal (April 2009)**.**

[120] Athens is an Access Management System developed by Eduserv that simplifies access to the electronic resources i.e. professional journal your organisation has subscribed to. Eduserv is a not-for-profit, professional IT services group (Referencehttps://www.evidence.nhs.uk/nhs-evidence-content/journals-and-databases/about-nhs-athens).

- that two midwifery journals are delivered to the hospital and that these journals are available to staff on the Department or in the hospital's Library.
- that weekly CTG workshops are held on the Maternity Department. These workshops were commenced in 2010. The purpose of the workshops is that they provide a forum for learning and improving competence on the interpretation of CTG tracings. The workshops are open to both medical and midwifery staff.
- that there is a process in place whereby midwives can request that a patient's CTG be discussed at the workshop.

It was established during the investigation that while there was good attendance by medical staff members at the CTG workshops that the sessions are less well attended by midwifery staff. The midwifery managers of the Maternity Department informed the Review Team that the CTG workshops are held on Thursday morning at 08.00 hours and that it was difficult to release midwifery staff to attend the workshops as the Department is often busy at that time. The Review Team was informed that midwifery staff can attend the sessions during their off-duty periods but that this was difficult for many staff due to family and personal commitments. Additionally due to the complement of midwifery staff available to roster to the Department that in the event that midwifery staff do attend the sessions during their off-duty periods that it was difficult for the Department managers to allocate these staff the hours due to them in lieu of their attendance.

It was also established that currently no minutes are maintained related to the cases discussed at the workshops nor of the staff who attended. Therefore midwives and medical staff who do not attend the workshops are unable to review the minutes so that they can learn from the CTG tracings that had been discussed at the workshops and managers are unable to determine if all staff are availing of the opportunity to review CTG tracings.

Recommendations:

- **That attendance at CTG workshops becomes part of the mandatory training schedule for all medical and midwife staff on the Maternity Department; the frequency of attendance should be based on a training needs analysis but attendance at the workshop must be a minimum of three times a year.**

- **That records are maintained related to each CTG workshop so that staff who do not attend the workshop can learn from the CTG tracings that were discussed at the workshop and so that managers are aware of which staff have attended the workshops. The records should include (1) details of staff who have attended the workshop (2) the CTG discussed and (3) CTG findings.**

- **That an anonymised copy of Baby Mark's CTG should be included as a learning tool in the CTG workshops that take place within the Maternity Department.**

The Director of Nursing of the Midland Regional Hospital Portlaoise informed the Review Team that she had planned to appoint a Midwifery Clinical Skills Facilitator. The Director of Nursing indicated that the role and function of the Midwifery Clinical Skills Facilitator would be to support and teach midwives. The literature suggests that the presence of a Clinical Skills Facilitator can result in increased levels of staff morale, effective change management, improved quality of patient care, an empowered midwifery profession and a positive impact upon recruitment and retention[121].

The Director of Nursing stated that she had identified a post within her complement of staff that could be suppressed so that the Midwifery Clinical Skills Facilitator post could be appointed and that she had made the relevant applications to seek support for the approval of the post but that she position was not sanctioned.

[121] Whitehead W. (2009) An investigation into the Effects of Clinical Facilitator Nurses on Medical Wards. {available from http://etheses.nottingham.ac.uk/1264/1/11_thesis_20100401_revised_following_viva_as_BOUND.pdf) . Accessed 20th December 2012}

Action taken since the 24th January 2012:

It was confirmed by the Director of Nursing that the request for approval of the post of Midwifery Clinical Skills Facilitator had been submitted on three occasions to the Area Employment Monitoring Group in the HSE Dublin Mid Leinster during 2012. Due to the moratorium on staff recruitment it is a requirement that all requests to hire staff are formally submitted and approved by the Monitoring Group. It was additionally confirmed that senior management within the HSE DML have continued to submit the required information/documentation in order to seek approval to recruit this post.

Recommendation:

- **That the HSE DML review and re-submit the application made related to the post of Midwifery Clinical Skills Facilitator at the Midland Regional Hospital Portlaoise with a view of securing approval for the post.**

Despite the evidence of training and learning opportunities that the Maternity Department has in place it was established that there is currently no formal system in place for performance management or training needs analysis in many services within the HSE including the Midland Regional Hospital Portlaoise.

In March 2012 the HSE published its guidance document on Performance Management in the HSE. The document was introduced as part of the HSE's fulfilment of the terms of the Public Service Agreement (2010-2014)[122] and the guidance relates to all grades of staff and professional disciplines.

The HSE Performance Management guideline states that it is the policy of the HSE;

> ***"to implement, maintain and monitor a Performance Management System that develops the capacity and capability of its employees, improves the performance of the organisation and addresses underperformance in a timely and constructive manner".***

The document indicates the intention to introduce the guideline on a phased basis commencing at National Director level to Grade VIII and equivalent level including comparable clinical grades in 2012.

The investigation is also aware that the HSE DML has recently approved for implementation a policy related to the provision of mandatory and statutory training of staff. The policy states that:

> ***'—it is critical that training requirements for staff within the HSE are established through an evidence based, systematic approach e.g. Training Needs Analysis so as to identify the essential training that is required to provide safe and high quality care to our service users, to ensure a safe workplace and safe systems of work for our staff and to ensure that the required competencies and skills are in place. The HSE adopts an approach to the identification of staff training and education requirements that is based on the assessment of risks for each activity within each service. The identified risks will dictate the appropriate mandatory training to be undertaken by staff.'***

Recommendations:

- **That the HSEDML Policy for the Provision of Statutory and Mandatory Training (January 2013) is implemented in Midland Regional Hospital at Portlaoise as a matter of priority and a Training Needs Analysis is carried out on all staff of the hospital.**

[122] Public Service Agreement available from http://per.gov.ie/wp-content/uploads/Public_Service_Agreement_2010_-_20141.pdf

- **That the HSE process for Performance Management is expedited to ensure that all staff are supported to maintain and enhance their competence and capabilities.**

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.4 Work environment factors (Staffing Levels and Skills Mix) and recommendations to address these:

The Maternity Department in Portlaoise is a 30 bedded ward which includes antenatal and postnatal care. In addition there are three individual labour/delivery rooms and a three bedded maternity assessment unit which is used to assess women when they arrive on the Maternity Department. The Review Team was informed that the three bedded maternity assessment unit is also used to accommodate the overflow of patients when a situation arises where there are more than three women in labour.

The Review Team was informed during the investigation that the approved midwifery staffing complement for the Maternity Department is 31.12 whole time equivalents (wte) to cover the basic roster i.e. day and night duty, seven days a week with additional wte's necessary to cover leave e.g. annual, maternity, parental and sick leave resulting in a total wte of 37.34.

The Review Team was informed that two Clinical Midwifery Manager posts have been approved for the Maternity Department but that one of these posts has not been filled due the moratorium on recruitment.

The Review Team was also informed that five Midwifery Shift Leader posts were approved and that currently there were two Midwifery Shift Leaders working on the Maternity Department.

It was established during the investigation that there had been plans to appoint five Midwifery Shift Leaders to the Maternity Department so that a Shift Leader could be assigned to most of the shifts on the Maternity Department i.e. day and night duty. The Review Team was informed that seven Shift Leaders are required to cover all shifts on the Maternity Department and that initially three positions were filled in 2008 following an interview process.

Clinical Midwifery Manager II A indicated that one of the three Shift Leaders appointed had retired in 2011 and had not been replaced due the moratorium on recruitment. Clinical Midwifery Manager II A indicated that as a result of the lack of Shift Leaders available she cannot roster a Shift Leader to supervise all shifts on the Maternity Department.

Clinical Midwifery Manager II A indicated during the investigation that she had carried out a risk assessment on the risk of injury to patients due to inadequate midwifery staffing levels on the labour ward, assessment unit and main ward to ensure a safe standard of care in line with best practice and that she had included reference to the lack of Shift Leaders in the risk assessment. The Review Team noted that the date of the risk assessment was 8th March 2010.

Clinical Midwifery Manager II A informed the Review Team that seven midwives and a Clinical Midwifery Manager are allocated to the Maternity Department on day duty Monday to Friday and seven midwives on Saturdays and Sundays and that six midwives are allocated to the department on night duty. Clinical Midwifery Manager II A indicated that three midwives are allocated to the antenatal/postnatal ward, three are allocated to the Labour Ward and one midwife is allocated to the Assessment Area on day duty; and that the eighth midwife on duty is the midwife in charge of the Maternity Ward i.e. Clinical Midwifery Manager II A.

Clinical Midwifery Manager II A indicated that in line with the risk assessment that she had carried out that she had identified and implemented control measures in order to limit the risk of injury to women in labour due to the unavailability of a Shift Leader on night duty. Clinical Midwifery Manager II A stated that it is her practice to ensure that of the five midwifes rostered to work the night duty shift in the Maternity Department that this always includes a senior experienced midwife and that additionally the senior experienced midwife is allocated to work on the Labour Ward.

The Review Team was informed by the Director of Nursing for Midland Regional Hospital at Portlaoise that this risk assessment was escalated for inclusion on the Midland Regional Hospital Portlaoise Risk Register and that it was then escalated to the Assistant National Director for the Midland Hospital Group for inclusion on the Area level Risk Register.

The Director of Nursing indicated that the control measures identified to manage the risk included continued use of agency staff, use of overtime and additional hours. The Director of Nursing also confirmed that she had submitted a Business Case in order to ensure a safe standard of care in line with best practice.

Recommendation:

- **That a specific risk assessment is carried out related to the unavailability of Shift Leaders to cover the Labour Ward on certain shifts i.e. night duty so that midwives can be adequately supervised and supported in caring for a woman in labour.**

The Review Team was informed by the Director of Nursing during the investigation that in 2005 it was the practice in all 19 Maternity Departments in Ireland that Labour Wards were staffed separately and independently to the main department. The Director of Nursing indicated that the Maternity Department had carried out a study on midwifery staffing levels with a view to implementing this practice in the Midland Regional Hospital Portlaoise. The Review Team was informed that the study found it would take 17 additional midwives to separately staff the Labour Ward in Portlaoise.

The Review Team undertook a literature review of the practice of separately staffing Labour Wards but could find no research to support the practice.

The UK document on Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour indicates that the need for continuous care means that Labour Ward staffing requirements cannot be considered in isolation or separate from the total establishment of the maternity service.

In addition it should also be considered that the practice of separate staffing of the Labour Ward might adversely impact on the general skills of midwives i.e. related to the delivery of antenatal, labour and postnatal care in that the midwives might be limiting their scope of practice related to the delivery of all aspects of care to women in pregnancy.

Recommendation:

- **That any consideration given to the implementation of independent staffing for the Labour Ward should be predicated on best practice advice i.e. the recommendation contained in the document Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour and guidance from the HSE Clinical Care Programme**.

The Review Team should highlight the fact that the Labour Ward was not busy during the early morning of the 24th January and that Mrs. Molloy was the only patient on the ward at that time; and that additional midwifery assistance was available to the primary midwife caring for Mrs. Molloy.

The Review Team was informed that there is a high turnover of midwives on the Maternity Department at the hospital; that seven midwifery staff had been appointed in July and August 2012 and that two of these seven staff had left at the time of investigation i.e. three to four months later.

The Director of Nursing for Midland Regional Hospital Portlaoise informed the Review Team that the reason given by the midwives for leaving the service included leaving to take up another position elsewhere for domestic and/or personal reasons, further education, and migration.

It was established during the investigation that the Maternity Department had 2,060 deliveries in 2012 (including twin deliveries) and that the midwife to woman ratio for that

period was 1:81. The Director of Nursing of Midland Regional Hospital at Portlaoise indicated during the investigation that the midwife to woman ratio in the tertiary hospitals in Ireland i.e. Holles Street, the Rotunda and Coombe Hospitals, Dublin was approximately 1:35.

The Royal College of Obstetricians and Gynaecologists, Royal College of Midwives, Royal College of Anaesthetists and the Royal College of Paediatrics and Child Health (2007) recommend that the minimum midwife to woman ratio for direct maternity care is 1:28 and that the ratio may rise to 1:25 depending on the complexity and model of care provided.

Notwithstanding this the investigation notes that the document Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour (2007) indicates that it is known that inadequate staffing levels in Maternity Departments have an adverse impact on the quality of care and risk management and that inadequate staffing levels can result in;

- Difficulties in allocating midwives to attend mandatory training and continuous professional development,
- Forcing midwives to spend a greater proportion of their time on clerical duties at the cost of direct care to mother and babies,
- Prejudicing any contingency plans for unexpected surges in the birth rate,
- Compromising the level of clinical support and leadership available for less experienced staff and students,
- Increasing stress levels for midwives,
- Negatively impacting on recruitment and retention.

It was highlighted to the Review Team during the investigation that the Maternity Department at the hospital is known to be of very high activity and that this does cause increased levels of stress to staff allocated to the Unit at times.

Recommendation:

That the midwifery staffing levels available to provide care to expectant mothers and their babies at the Midland Regional Hospital Portlaoise are reviewed as a matter of priority.

6.1. Care Delivery Issue I: Failure to recognise and act on the signs of foetal distress

6.1.5 Management and organisational factors and recommendations to address these:

Mr. and Mrs. Molloy informed the Review Team during the investigation that they had serious concerns about the standard of care that Mrs. Molloy received on the Maternity Department on the 24th January.

The HSE document on Achieving Excellence in Clinical Governance: towards a culture of accountability (2010)[123] states that:

> ***"healthcare organisations are responsible and accountable for delivering safe, high quality, cost effective care that achieves the best possible health outcomes for people in Ireland".***

To this end as part of the HSE's stated aim of enhancing quality and safety in the services that it provides, the HSE has embraced the concept of 'clinical governance'. Clinical governance is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver[124]. Clinical governance facilitates an organisation to improve patient outcomes by ensuring that;

- each individual as part of a team knows the purpose and function of leadership and accountability for good clinical care;
- each individual as part of a team knows their responsibility, who they are accountable to and their level of authority;
- each individual as part of a team understands how the principles of clinical governance can be applied in their diverse practice;
- a culture of trust, openness, respect and caring is evident among managers, clinicians staff and patients;
- each individual as part of a team consistently demonstrates a commitment to the principles of clinical governance in decision making; and
- clinical governance will be embedded within the overall governance arrangements for the HSEs statutory and voluntary health and social services in realising improved outcomes for patients.

The Director of Nursing of Midland Regional Hospital at Portlaoise indicated during the investigation that the Maternity Department established a Clinical Governance Committee in 2010 and that the Committee had Terms of Reference which included the following:

- Review the status of the department's risk register, clinical audit projects, quality improvement plans and key performance indicators,
- Identify training needs and draw up an annual training plan,
- Review the status of the Site Specific Safety Statement,
- Provide a forum so that learning from complaints/incident reviews/clinical audits conducted in other areas/sites can be disseminated.

A review of the documentation submitted to the investigation relating to the Maternity Department Clinical Governance Committee indicated that the Committee met on two occasions in 2010 and that no further meetings have taken place since that time.

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[123] Achieving excellence in clinical governance: towards a culture of accountability (reference: http://hsenet.hse.ie/FQTAqjnHd7ygNFru0QoUag%3d%3d/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/CLINGOV.pdf?ImportedResourceId=FQTAqjnHd7ygNFru0QoUag%3d%3d)

[124] Achieving excellence in clinical governance: towards a culture of accountability (reference: http://hsenet.hse.ie/FQTAqjnHd7ygNFru0QoUag%3d%3d/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/CLINGOV.pdf?ImportedResourceId=FQTAqjnHd7ygNFru0QoUag%3d%3d)

It was established during the investigation that in 2011 the managers of the Maternity Department i.e. the Midwifery Manager, the Divisional Nurse Manager and the Consultant Obstetrician Gynaecologists met once per month to discuss issues that arose related to the general operation and functioning of the Department.

The Review Team was informed that these meetings are not formal Maternity Department Clinical Governance meetings and that the meetings did not have a Terms of Reference and functionality in line with the recommendations contained in the HSE document 'Achieving Excellence in Clinical Governance: towards a culture of accountability.'

Action taken since the 24th January 2012:
In July 2012 the Midland Regional Hospital Portlaoise became the HSE Dublin Mid Leinster pilot site for a HSE initiative to support the implementation of clinical governance within hospitals. The initiative is being overseen by a National Working and Steering Group and an International Reference panel[125].

The Review Team was informed by the Director of Nursing of the Midland Regional Hospital at Portlaoise that the hospital has established a Clinical Governance Development Project Group as part of the pilot to oversee the development of clinical governance structures in the hospital.

The Director of Nursing informed the Review Team that as part of the hospital's Clinical Governance Development Project that a Clinical Speciality Lead and Deputy Lead in Obstetrics and Gynaecology were appointed in January 2013 and that one of the roles of the Clinical Speciality Lead is to chair the Obstetrics/Gynaecology Quality, Patient Safety and Risk Committee meetings i.e. Governance Committee. The Review Team was informed that the Obstetrics/Gynaecology Quality Patient Safety and Risk Committee has met on four occasions since it was established in July 2013 and that the Terms of Reference for the committee included the following;

- Review of risks on the Maternity Department's Risk Register,
- Review the trending of incidents that occur in the Department,
- Review of incidents, complaints and claims,
- Develop a yearly audit plan and oversee the audits,
- Oversee the implementation of recommendations from incident investigation, audits etc,
- Review of equipment requirements,
- Review of local guidelines to ensure they are in line with national and international best practice.

Additional Recommendations:

- **That a review and/or audit is carried out in six months related to the functioning of the Obstetrics and Gynaecology Quality and Safety Committee to ensure that the committee is working to its Terms of Reference and to ensure that any support required to assist the Committee to carry out its functions is provided.**

- **That in line with standard governance arrangements that all Governance Committees operating in the hospital should submit annual assurance reports to the Senior Management Team/Hospital Clinical Governance Committee.**

Clinical governance requires that healthcare organisations, amongst other things, have in place clear and documented accountability arrangements for healthcare services.

Accountability for the governance of the Maternity Department is through the Midwifery Manager and the Divisional Nurse Manager of the Maternity Department and the Consultant Obstetrician Gynaecologists who in turn report to the hospital's Senior

[125] Reference: http://hsenet.hse.ie/cVae8Ctt2NSp3%2b9GtI7K%2bg%3d%3d/eng/about/Who/qualityandpatientsafety/Clinicalgovernance/qpsleaflet.pdf?ImportedResourceId=cVae8Ctt2NSp3%2b9GtI7K%2bg%3d%3d).

Management Team i.e. the Director of Nursing, the Clinical Director and the Hospital Manager of the Midland Regional Hospital Portlaoise. In turn the Senior Management Team report to the Assistant National Director of the Midland Hospital Group (i.e. the Midland Regional Hospital at Mullingar, Portlaoise and Tullamore).

As part of the governance structure at the Midland Regional Hospital at Portlaoise and in line with the HSE guidance on clinical governance, the Senior Management Team established a Hospital Clinical Governance Committee in January 2010.

One of the key responsibilities of a governance committee is to agree and recommend a strategic approach to clinical governance whilst ensuring that high quality systems and safe services are in place for the benefit of service users, staff and visitors[126].

As part of the governance process and in line with HSE policy the Review Team was informed that the Maternity Department and the Midland Regional Hospital at Portlaoise have a Departmental and Hospital Risk Register and that risks/control measures are escalated to the Hospital's Risk Register when they cannot be controlled and/or implemented at departmental level.

It was identified during the investigation that the Senior Management Team and the hospital's Clinical Governance Committee receive trending reports on incidents reported by staff in the hospital, including trending reports related to incidents that have occurred in the Maternity Department.

The Review Team was informed that the Senior Management Team of the Midland Regional Hospital Portlaoise has a system in place for monitoring the implementation of recommendations of the investigations of incidents that occurred in the hospital including recommendations of investigations that relate to the Maternity Department. This monitoring is undertaken by the maintenance of a Quality and Safety Action Plan i.e. a documented repository of all recommendations that facilitates the tracking of implementation of recommendations of incident investigations.

The results of clinical audits that have been carried out in the hospital are also discussed at the hospital's Clinical Governance Committee. However the status of the implementation of recommendations of clinical audits is not currently discussed at the Hospital Clinical Governance meetings.

The Senior Management Team indicated that four quarterly meetings i.e. one meeting every three months are held to review the hospital's Quality and Safety Action Plan.

However it was established during the investigation that the Senior Management Team had been unable to organise a meeting during 2012 to review the Quality and Safety Action Plan due to an increase in their workload and the resultant unavailability of staff.

It was also identified that the hospital Clinical Governance Committee does not currently receive regular assurance reports from all hospital Departments including the Maternity Department.

Action taken since the 24th January 2012:

As previously stated the Midland Regional Hospital at Portlaoise has established a Clinical Governance Development Project Group to oversee the development of clinical governance structures in the hospital. The Review Team was informed during the investigation that the Project Group has completed an assessment of the structures and process for clinical governance in the hospital using the 36 statements contained in the HSE Quality and

[126] Achieving excellence in clinical governance: towards a culture of accountability (reference: http://hsenet.hse.ie/FQTAqjnHd7ygNFru0QoUag%3d%3d/eng/about/Who/qualityandpatientsafety/Quality_and_Patient_Safety_Documents/CLINGOV.pdf?ImportedResourceId=FQTAqjnHd7ygNFru0QoUag%3d%3d)

Patient Safety Clinical Governance Development Assurance Check for Health Service Providers (2012)[127] resulting in the identification of the following work streams;

- Development of accountability structure in the hospital,
- Identification of 5 (of 6) Clinical Specialty Leads,
- Development of a Guidance Document for Clinical Specialty Leads,
- Initiation of an Open Disclosure Process,
- Establishment of a Patient Partnership Forum,
- Preparation of a Quality & Safety Annual Report 2012,
- Provision of educational sessions for staff on aspects of quality, patient safety and risk,
- Distribution of a Quality, Patient Safety and Risk monthly newsletter for staff has commenced,
- A structured agenda for all Quality, Patient Safety and Risk Committee meetings has been developed based on the HIQA standards.

Additional Recommendation:

- **That a system is implemented that facilitates the Senior Management Team / Hospital Clinical Governance Committee to monitor individual departmental Quality and Safety Action Plans to ensure that recommendations are being implemented in a reasonable timeframe.**

One of the key elements of clinical governance is that all healthcare organisations should have a suite of key performance indicators/quality indicators that assists and provides assurance on the quality and safety of the service provided by the organisation; it is a key requirement that the performance/quality indicators developed should be monitored at regular intervals.

It was established during the investigation that the Maternity Department have a range of activity and outcome key performance/quality indicators which are collected, monitored and reviewed.

For example the Review Team was informed that the Maternity Department reports data to the Health Research and Information Division of the Economic and Social Research Institute (ERSI)[128] through the Hospital In-Patient Enquiry Scheme (HIPE) and the National Perinatal Reporting System (NPRS).

The ERSI publish yearly reports on Maternity Discharges which includes statistics on the following;

- Time trends and international comparisons including;
    - Perinatal mortality,
    - Birth rates,
    - Fertility,

[127] The HSE Quality and Patient Safety Directorate developed the Quality and Patient Safety Clinical Governance Development Assurance Check for Health Service Provider as a support for health service providers. The document is intended as a guide for clinical governance development across the continuum of care (statutory or voluntary hospital/network, mental health service, primary care services, area management etc). It is based on the relevant national standards and legislation (Health Information and Quality Authority, Mental Health Commission, Health and Safety Authority, etc). (Reference: http://hsenet.hse.ie/J8gW%2f54EMCifCMOlfvXFWQ%3d%3d/eng/about/Who/qualityandpatientsafety/Patient_Safety/Clinicalgovernance/assurancecheck.pdf?ImportedResourceId=J8gW%2f54EMCifCMOlfvXFWQ%3d%3d

[128] The Health Research and Information Division has responsibility for support, management and development of two national data bases on behalf of the Health Service Executive. HIPE is the principal source of national data on discharges from acute hospitals in Ireland. NPRS provides national statistics on perinatal events, in particular data on pregnancy outcomes, perinatal mortality and important aspects of perinatal care. For both data systems, the core objective of the work of the Division is ensuring that accurate data are available to users on a timely basis (Reference: http://www.esri.ie/health_information/).

  - Singleton and multiple births,
  - Method of delivery for primiparous and multiparous women.
- General characteristics including;
  - Maternal age,
  - Mother's marital status,
  - Mother's and father's occupation
  - Mother's and father's nationality,
  - Maternal parity,
  - Number of previous stillbirths,
  - Interval since last birth,
  - Birthweight,
  - Gestational age,
  - Month of birth.
- Perinatal Care
  - Type of perinatal care
  - Duration of pregnancy at first antenatal visit,
  - Advance hospital bookings,
  - Mother's antenatal length of stay,
  - Mother's postnatal length of stay,
  - Rubella: Immune status of mother,
  - Method of delivery,
  - Distribution of births by size of maternity unit,
  - Inter-hospital transfer of infant,
  - Infant's length of stay,
  - Infant's type of feeding.
- Perinatal outcomes
  - Mortality by birthweight and parity,
  - Cause of death by birthweight,
  - Mortality by gestational age,
  - Cause of death,
  - Post-mortem examination.

The Review Team was informed that the Maternity Department at the Midland Regional Hospital Portlaoise has consistently been included as one of the top three maternity services with the lowest number of perinatal deaths in the country; and that in 2010 the Department reported the lowest number of perinatal deaths nationally. A comparison of the Midland Regional Hospital Portlaoise perinatal mortality statistics against the national statistics for the three year period 2009 - 2011 [129] are outlined in the Table below:

[129] HIPE and NPRS reports are published on the Economic and Social Research Institute website and links to the report can be found on the webpage:
http://www.esri.ie/health_information/latest_hipe_nprs_reports/

Perinatal mortality statistics for 2009

- **National; 6.90 per 1,000 live and still births**
- **Maternity Department in Portlaoise; 7.49 per 1,000 live and still births**

Perinatal mortality statistics for 2010

- **National; 6.80 per 1,000 live and still births**
- **Maternity Department in Portlaoise; 4.28 per 1,000 live and still births**

Perinatal mortality statistics for 2011

- **National; 6.10 per 1,000 live and still births**
- **Maternity Department in Portlaoise; 5.75 per 1,000 live and still births**

Source: The perinatal mortality statistics for the Maternity Department in Midland Regional Hospital Portlaoise were provided to the Reviewers by Hospital Manager. The national perinatal mortality statistics can be found on the Economic Social Research Institute website on the following webpage: http://www.esri.ie/health_information/latest_hipe_nprs_reports/

The review also established that the Maternity Department at the Midland Regional Hospital Portlaoise also reports data to the National Perinatal Epidemiological Centre[130] which began collecting data on perinatal mortality i.e. the rate of stillbirths and neonatal deaths in 2003 and has been collecting data on severe maternal morbidity over the last two years.

The 2011 Annual Report published by the National Epidemiology Centre[131] confirmed that neither the stillbirth nor the neonatal death rate from any of the 19 Irish Maternity Units in the country significantly deviated from the overall national perinatal mortality rate during 2010 i.e. the period covered in the most recent report published by the Centre.

At a local level the Review Team was informed that Consultant Obstetrician Gynaecologist A presents the Maternity Department's activity and outcome data to the Department's multidisciplinary team every month. This presentation includes a review of the monthly statistics on delivery discharges, perinatal mortality and severe maternal mortality.

The Clinical Director and Director of Nursing for the Midland Regional Hospital Portlaoise attend some of these meetings when possible.

Clinical Midwifery Manager II A indicated that the Maternity Department at the hospital are active participants in the HSE's Obstetric and Gynaecology Clinical Care Programme[132] which is at an early stage of development and that she is a member of the national committee that is responsible for developing and monitoring the overall effectiveness of the programme.

[130] The National Perinatal Epidemiology Centre is based in the University College Cork And Research Centre in Cork University Maternity Hospital. The overall objective of the Centre is to collaborate with Irish maternity hospitals to translate clinical audit data and epidemiological evidence into improved maternity services for families in Ireland.

[131] The National Epidemiology Centre's Annual Report 2011 can be found on the following website; http://www.ucc.ie/en/npec/publications/reports/NPECAnnualReport2011.pdf

[132] Clinical Strategy and Programmes has been established to improve and standardise patient care throughout the organisation by bringing together clinical disciplines and enabling them to share innovative solutions to deliver greater benefits to every user of HSE services. The directorate has established a number of National Clinical Programmes. The Programmes are based on three main objectives; to improve the quality of care we deliver to all users of HSE services, to improve access to all services, and to improve cost effectiveness (reference: http://hsenet.hse.ie/clinicalstrategyandprogrammes/).

While the Review Team found that the Maternity Department have a range of key performance/quality indicators based on national requirements to collect and submit data that assist to monitor the activity and outcomes of the Maternity Department i.e. as outlined above there was little evidence found that the Department has in place a schedule of routine and locally targeted audits for monitoring their systems and processes of work to ensure that they are in line with the best available evidence and to ensure continuous quality improvement.

Despite this the Review Team was informed that 18 audits have been completed by the Department since 2008[133]. The Review Team was informed that 90% of the recommendations for the 18 audits have been implemented and that the remaining 10% are in the process of being implemented.

The Review Team was informed that while the managers and clinical staff in the Maternity Department are committed to implementing the recommendations of audits and investigations it was difficult to monitor and track the implementation of recommendations in the absence of an efficient and user-friendly system.

It was established during the investigation that the Maternity Department do not currently have a user friendly and efficient system in place for monitoring the implementation of recommendations of audits and incident investigations. Systems in place rely on Excel data bases which are time-consuming to populate and are not easily interrogated.

Standard 2.8 of the National Standards for Safer Better Healthcare June (2012)[134] states that healthcare organisations should have an agreed annual plan for audit, which incorporates participation in national audit programmes, and local, targeted audits conducted in line with service requirements and priorities.

In October 2012 the Dublin Mid-Leinster Clinical Audit Team developed a Clinical Audit Strategy for the development and implementation of routine and non routine audit plans in the Maternity Department. This strategy was communicated to the managers of the Maternity Department in October 2012 with information outlining the background and the context of the audit strategy. The strategy identified key performance areas within the Maternity Services and proposed a number of audits for consideration by the Maternity Department management structure for local implementation on an ongoing basis. The Clinical Audit Team requested that an action plan be agreed by the Maternity Department for the implementation of these audits.

One of the key areas identified for routine auditing is foetal heart monitoring. This routine audit will ensure that periodic measurement of performance against national and international standards is undertaken. In general, the implementation of the routine audits would greatly assist the service in monitoring the implementation of their policies, procedures and guidelines and in the early identification and quantification of risks and areas where improvement is required.

The Clinical Audit Strategy recommends that the results of the routine and non-routine audits should be incorporated into the agenda of the Maternity Department Clinical Governance Committee where issues arising from the audits may be discussed and addressed.

Action taken since the 24th January 2012:

In early 2012, in collaboration with front-line services, the HSE Dublin Mid-Leinster Quality and Patient Safety Service initiated development of an I.T. system to assist individual departments/services across the region to monitor the implementation of recommendations contained on their Quality and Safety Action Plans. The Quality and Patient Safety Action Plan will contain all of the recommendations emanating from audits

[133] A list of audits carried out in the Maternity Department can be found in Appendix V of this report.
[134] A copy of the National Standards for Safer Better Healthcare can be found on the following website; http://www.hiqa.ie/standards/health/safer-better-healthcare

and incident/complaint investigations i.e. recommendations of investigations undertaken by the hospital, recommendations of investigations carried out by the Health Information and Quality Authority or HSE national investigations that are relevant to the individual departments/services etc. The implementation of the system will facilitate easier tracking, monitoring and audit of quality and safety improvements.

Additional Recommendation:

- **That the Maternity Department have an annual agreed audit plan which must be agreed by the Department's Clinical Governance Committee.**

- **That the Maternity Department's audit plan must incorporate (1) participation in national audits (2) schedule of prioritised local audits and (3) targeted audits conducted in line with service requirements and priorities.**

- **That the Midland Regional Hospital Portlaoise ensure that the I.T system developed to monitor the hospital's Quality and Safety Action Plans is in use and that it is actively monitored by the appropriate level governance committee; and that a named individual is identified to oversee and manage the system at local level.**

The Review Team was informed that the Maternity Department at the Midland Regional Hospital Portlaoise introduced the National Maternity Healthcare Record (NMHCR: 2011) apart from the discharge element of the record in June 2012. The Department is among the first Maternity Services to have implemented the record nationally.

The NMHCR is a unified healthcare record that supports continuity of care and facilitates communication between all members of the multidisciplinary team.

The HSE indicates that the introduction of a standardised chart is a significant factor in improving maternity care nationally[135]. It is stated that the NMHCR will help to improve the quality of care delivered as staff move between hospitals. It will also assist in the collection of standardised data in maternity hospitals/units and facilitate future research into maternal and foetal health.

An additional issue highlighted by the Clinical Director of the Midland Regional Hospital at Portlaoise during the investigation was that a Senior Consultant Obstetrician Gynaecologist within the Maternity Department at the Midland Regional Hospital Portlaoise had retired from the service in November 2011 and that a newly appointed Consultant Obstetrician Gynaecologist had recently taken up a post within the Department. In the intervening period Consultant cover had been provided on a locum basis.

The Clinical Director indicated that the Consultant who had retired had provided a high level of clinical leadership and direction to the Department and that he had been instrumental in bringing a sense of cohesiveness to the clinical teams operating within the department.

The Clinical Director indicated that in order to overcome this situation that he plans to commence regular team meetings with the two remaining Consultant Obstetrician Gynaecologists so that any issues that might affect the safe functioning of the maternity service can be identified at an early stage and the necessary action taken.

Recommendation:

- **That there are regular meetings between the Clinical Director and the Consultant Obstetrician Gynaecologists so that any issue relating to the maternity service provided by Midland Regional Hospital Portlaoise can be**

[135] Reference: http://hsenet.hse.ie/Intranet/qualitypatientsafety/?importUrl=http://localhost:82/eng/about/Who/qualityandpatientsafety/New_QPS/QPS_health_information/Healthcare_Records_Management.html).

discussed and resolved. The meetings should be minuted with identified actions, responsible persons and a due date for implementing the actions identified in the minutes of the meeting.

6.2. Care Delivery Issue II: Failure to fully assess all sections of the CTG resulting in the inappropriate prescribing and administration of Syntocinon and a delay in the decision to transfer Mrs. Molloy to the Theatre Department for an assisted delivery.

6.2.1 Task factors and technology factors and recommendations to address these:

6.2.1.1 Assessments of CTG tracing

The Review Team was informed during the investigation that it was the practice that all women in labour admitted to the Maternity Department are commenced on continuous electronic foetal monitoring (CTG) and in line with this practice continuous electronic foetal monitoring was commenced on Mrs. Molloy.

It was documented that the CTG on admission was nonreassuring. However as Mrs. Molloy appeared anxious and was requesting an epidural it was decided to transfer her to the Labour Ward. Professor Morrison noted in his report that the CTG was nonreassuring but that the care provided to Mrs. Molloy at this time was appropriate and in line with acceptable practice.

On arrival on the Labour Ward the CTG was recommenced and at this time it was documented that the tracing was reassuring.

However Professor Morrison indicated in his report that the CTG was abnormal at 06.33 hours and that the CTG remained abnormal throughout the period of time from 07.00 hours to 08.00 hours.

Between 07.15 and 07.47 hours a decision was made to contact Obstetrician Gynaecology Registrar A as Mrs. Molloy's labour was not progressing. There were differences in the recollections of those present as to the exact time of this contact. It was Midwife B's and Midwife C's recollections that Obstetric Gynaecologist Registrar A was first contacted to assess Mrs. Molloy at 07.15 hours while it was Obstetric Gynaecologist Registrar A's recollection that he was first contacted to assess Mrs. Molloy at 07.47 hours.

Between 07.55 and 08.39 hours on the 24th January 2012 Mrs. Molloy was assessed on four occasions by Obstetrician Gynaecology Registrar A and on one occasion by Consultant Obstetrician Gynaecologist A.

Obstetrician Gynaecology Registrar A's initial assessment of Mrs. Molloy took place at 07.55 hours and in a retrospective note related to this assessment which Obstetrician Gynaecology Registrar A documented at 11.30 hours, Obstetrician Gynaecology Registrar A recorded that he was asked to review Mrs. Molloy due to poor descent of the baby's head in the second stage of labour.

Obstetrician Gynaecology Registrar A also documented that the CTG trace at that time was satisfactory[136]. Obstetrician Gynaecology Registrar A informed the Review Team that when he reviewed the CTG at 07.55 hours he identified that the CTG was nonreassuring with a few variable decelerations and that he mistakenly documented that the CTG was satisfactory because he was tired as a result of being on call and that he was in a rush as he was scheduled to travel to England for a course the next morning.

Obstetrician Gynaecology Registrar A indicated during the investigation that when he reviewed the CTG at 07.55 hours he only reviewed the recent section of the CTG; and that he did not review all previous sections of the CTG at this time. Therefore, Obstetrician Gynaecology Registrar A did not review the sections of the CTG recorded from the time Mrs. Molloy was admitted to the Maternity Department up until his review at 07.55 hours;

[136] It was established during the investigation that Obstetrician Gynaecologist Registrar A had initially documented that the "CTG noted to be satisfactory" and that this entry was subsequently changed to "CTG noted to be unsatisfactory (Non-reassuring)".

and on that basis he was not aware that the CTG had demonstrated a nonreassuring trace from 06.33 hours until 07.15 hours and that it was nonreassuring again at 07.45 hours.

Obstetrician Gynaecology Registrar A indicated at interview that if he had reviewed all sections of the CTG he would in all probability have recognised that the CTG had been nonreassuring from 06.33 hours until 07.15 hours and that it was nonreassuring again at 07.45 hours and that he would have identified that Mrs. Molloy's baby was in distress and as a result he would have made an earlier decision to transfer Mrs. Molloy to Theatre for an assisted delivery.

Obstetrician Gynaecology Registrar A's second assessment of Mrs. Molloy took place at 08.07 hours approximately and following that assessment he made a decision to insert a urinary catheter into Mrs. Molloy's bladder as a full bladder can obstruct the descent of the baby's head.

There is no reference recorded in the healthcare record regarding an assessment of the CTG during this time by Obstetrician Gynaecology Registrar A although it was noted that Midwife D had documented that there were late decelerations present on the CTG at 08.05 hours.

Obstetrician Gynaecology Registrar A's third assessment of Mrs. Molloy took place at 08.15 hours and that assessment found that the CTG had improved and that it was now reassuring and as a result he prescribed Syntocinon to augment Mrs. Molloy's contractions. The Syntocinon infusion was commenced by Midwife D and Shift Leader A at 08.15 hours.

Obstetrician Gynaecology Registrar A's fourth assessment of Mrs. Molloy took place at 08.20 hours and during this assessment it was identified that there was poor descent of the baby's head and as a result Obstetrician Gynaecology Registrar A made the decision to proceed to a trial of instrumental delivery with the possibility of proceeding to a Caesarean Section. Obstetrician Gynaecology Registrar A documented that he contacted Consultant Obstetrician Gynaecologist A and informed her of this plan of care for Mrs. Molloy.

There were differences in the recollections of Obstetrician Gynaecology Register A and Consultant Obstetrician Gynaecologist A in relation to whether Obstetrician Gynaecology Registrar A informed Consultant Obstetrician Gynaecologist A about the plan for Mrs. Molloy to proceed to a trial of instrumental delivery with the possibility of proceeding to a Caesarean Section at this time. It was Consultant Obstetrician Gynaecologist A's recollection that she did receive a phone call from Obstetrician Gynaecology Registrar A at 08.30 hours and that during the phone call Obstetrician Gynaecology Registrar A informed her that Mrs. Molloy had been pushing for an hour without progress and that he had concerns about the fetal heart rate.

Consultant Obstetrician Gynaecologist A attended the Labour Ward to review Mrs. Molloy and her baby's condition. Consultant Obstetrician Gynaecologist A assessed Mrs. Molloy at 08.39 hours and following her assessment Consultant Obstetrician Gynaecologist A documented that Mrs. Molloy was fully dilated, that the baby's head was in the deflexed occiput posterior position and that the station of the head was -1.

Consultant Obstetrician Gynaecologist A also documented that the CTG was satisfactory at this time; that late decelerations had been seen earlier but that the decelerations were not present on the recent section of the CTG. Consultant Obstetrician Gynaecologist A indicated that based on the evidence of the late decelerations seen on the section of the CTG trace that she reviewed that she formed a plan to:

- Transfer Mrs Molloy to Theatre,
- Examine Mrs. Molloy again in the Theatre Department (documented in the healthcare record as "EIT" i.e. examination in Theatre) and that following the examination that she would make a decision on whether to proceed to a Lower Section Caesarean Section.

Consultant Obstetrician Gynaecologist A indicated that she did not review earlier sections of the CTG i.e. the section of the CTG from the time of admission up to 08.05 hours approximately as there were late decelerations on the section of the CTG she had reviewed

i.e. the section of the CTG between 08.05 and 08.39 hours. Consultant Obstetrician Gynaecologist A indicated that in conducting her assessment of Mrs. Molloy that she considered not only the CTG trace but also the findings of the vaginal examination she carried out, Mrs Molloy's prior obstetric history and the duration of the second stage of labour.

Consultant Obstetrician Gynaecologist A informed the Review Team that had she reviewed all sections of the CTG at the time of her assessment of Mrs. Molloy and her baby's condition at 08.39 hours including the section of the CTG from the time of admission up to 08.05 hours that her decision on the plan of care for Mrs. Molloy and her baby would have remained unchanged i.e. to bring Mrs. Molloy to Theatre and to reassess her there to decide on whether to proceed to a Caesarean Section. On this basis Consultant Obstetrician Gynaecologist A indicated that it was not necessary to review the entire CTG trace.

Following Consultant Obstetrician Gynaecologist A's review of Mrs. Molloy and her baby's condition, Consultant Obstetrician Gynaecologist A requested that the Syntocinon that had been prescribed for Mrs. Molloy be discontinued.

Shift Leader A indicated during the investigation that she was not informed when she came on duty that the CTG tracing recorded in respect of Mrs. Molloy had demonstrated a nonreassuring trace and that she did not review the CTG before commencing the administration of Syntocinon. Shift Leader A indicated that had she been aware that the CTG was nonreassuring she would not have commenced the Syntocinon infusion.

Mr. and Mrs. Molloy indicated in their feedback to the Review Team that Shift Leader A indicated that had she been aware of the presence of late decelerations that she would not have commenced Syntocinon infusion. Mr. and Mrs. Molloy referred to the retrospective note made by Shift Leader A at 16.00 hours.

Shift Leader A has stated in her response to Mr. and Mrs. Molloy's comments as outlined above that when she entered the Labour Ward shortly after 08.05 hours there were three midwives already in the labour room i.e. Midwife D, Midwife E and Midwife B, that Midwife B was writing in Mrs. Molloy's healthcare record and that she was not informed of the presence of any late decelerations on the CTG.

The Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009) states that medical practitioners "must ensure as far as possible that any treatment, medication or therapy prescribed for a patient is safe, evidence-based and in the patient's best interests".

An Bord Altranis Guidance to Nurses and Midwives on Medication Management (2007) indicates that Midwives should have an awareness of and observation for medication allergies, possible side effects, adverse reactions, toxicity, interactions and contraindications of medicinal products administered".

Macones G et al (2008)[137] indicates that the fetal heart rate response is a dynamic process, and one that evolves over time, the categories of fetal heart rate patterns are dynamic and transient, requiring reassessment. The authors state that in order to assess the status of the foetus wellbeing over time all sections of the CTG should be reviewed.

Recommendation:

- **That the Maternity Department at the Midland Regional Hospital Portlaoise develops and implements a strict policy that ensures that except in exceptional circumstances that all sections of the CTG are reviewed and assessed when assessing the wellbeing of a foetus and the expectant mother during labour.**

[137] 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, Interpreation, and Research Guidelines. 2008 AWHONN, the Association of Women's Health, Obstetric and Neonatal Nurses

6.2.1.2 Prescribing and administration of Syntocinon

As indicated previously Obstetrician Gynaecology Registrar A prescribed Syntocinon for Mrs. Molloy.

Obstetrician Gynaecology Registrar A informed the Review Team that while the CTG trace was nonreassuring at 07.55 hours when he first assessed Mrs. Molloy, when he reviewed the CTG trace at 08.15 hours the trace was reassuring. On this basis and on the basis that there was no progress in the second stage of labour he made the decision to prescribe Syntocinon for Mrs. Molloy in order to augment her labour.

Following her review of Mrs. Molloy and her baby's condition at 08.39 hours Consultant Obstetrician Gynaecologist A made a decision that the Syntocinon infusion should be stopped and the infusion was subsequently stopped at 08.45 hours. Consultant Obstetrician Gynaecologist A indicated that in her opinion a Syntocinon infusion should not have been commenced for Mrs. Molloy as Syntocinon is contraindicated in the presence of a nonreassuring CTG tracing.

Professor Morrison stated in his expert report that the "*decision to commence Syntocinon was wrong*" and that the decision to start Syntocinon should not have been made because;

- Mrs. Molloy had progressed quickly to full dilatation hence there was no need or clinical indication to augment labour,
- The contractions on the tocogram were regular and satisfactory,
- The CTG was markedly abnormal.

It was documented in Mrs. Molloy's healthcare record that the Syntocinon infusion was commenced at 08.15 hours at a rate of 30 millilitres per hour, that the infusion was increased at 08.25 hours to 60 millilitres per hours and that it was increased again to 90 millilitres per hour. The Syntocinon was discontinued at 08.45 hours.

It was established during the investigation that Syntocinon was being administered to Mrs. Molloy for a period of 30 minutes and that approximately 45 millilitres would have infused during that period of time. Consultant Obstetrician Gynaecologist A indicated that in her opinion approximately 45 millilitres i.e. 0.225 international units was a low dose of Syntocinon and that it was unlikely in this case to have a significant effect. Notwithstanding this the investigation notes that the decision to commence a Syntocinon infusion for Mrs. Molloy was incorrect.

It was established during the investigation that following the investigation of an incident that occurred in 2008 involving the inappropriate prescribing of Syntocinon in the presence of efficient uterine contraction and a nonreassuring CTG it was recommended that a guideline on the use of Syntocinon should be developed, implemented, monitored and reviewed in the Maternity Department at the Midland Regional Hospital at Portlaoise.

As a means of addressing this recommendation the two Consultant Obstetrician Gynaecologists at the hospital signed an "Important Notice" which was dated the 22nd November 2011; the title of the Notice was "Administration of Syntocinon" and the Notice was pinned to a notice board in the Maternity Department.

The Notice states that: "Syntocinon must not be commenced in the presence of late decelerations. If there are any concerns the Consultant on call should be contacted".

It was confirmed to the Review Team that all relevant staff on the Maternity Department were informed of this Notice; however it was not made clear to the Review Team how this communication was made.

It was also noted during the investigation that the advice contained in the Notice was not in the form of a policy, Standard Operating Procedure (SOP) or Guideline as advised in the HSE Policy Procedure Protocol Guideline (PPPG) template.

Action taken since the death of Baby Mark:

In October 2012 the Maternity Department developed a formal Syntocinon Infusion Guideline for Induction and Augmentation of Labour in the first and second stages of labour in the HSE Policy Procedure Protocol Guideline (PPPG) template. The Guideline was developed by Clinical Midwifery Manager II A, the Divisional Nurse Manager of the Maternity Department and the two Consultant Obstetrician Gynaecologists and is due for review in 2014.

Recommendation:

- **That the Syntocinon Infusion Guideline for Induction and Augmentation of Labour is audited within three months of development and that the guideline is audited at least twice a year thereafter as part of the routine audit schedule of the Maternity Department.**

6.3 Additional areas for system improvement identified by the investigation:

A number of other issues/findings made during the investigation serve to highlight areas for system improvement and these will be discussed in this section of the report.

These issues will be grouped under the following headings:

1. **Issues identified by Mr. and Mrs. Molloy that were included in Professor Morrison's expert report at their request,**
2. **Other issues highlighted by Mr. and Mrs. Molloy during the investigation,**
3. **Incidental findings.**

6.3.1 Issues identified by Mr. and Mrs. Molloy that were included in Professor Morrison's expert report at their request:

Mr. and Mrs. Molloy requested that Professor Morrison provide his expert opinion on a number of specific issues. On that basis the specific issues referred to below were included in the request for external clinical review made to the Institute of Obstetricians and Gynaecologists when seeking an appropriate nomination.

Professor Morrison's responses to the specific issues highlighted are outlined below. They are also included in Professor Morrison's report in Appendix II of this report.

1. **Should the Consultant Paediatrician have been present when the baby was delivered 'considering (my) records state that baby's heart rate was non-reassuring and also the Consultant Obstetrician's statement that they knew they would be delivering a very sick baby''?**

2. **Should a nurse from the Special Care Baby Unit have been present at the time of delivery?**

3. **Should the patient have been induced earlier given her due date (15th January) the 'size of the baby, the fact that he was face-up and her past history.'**

4. **Did the delay in sectioning the patient compromise the patient's safety and health; Mrs. Molloy received an injury during the C-section; how and why was this injury sustained?**

6.3.1.1 Should the Consultant Paediatrician have been present when the baby was delivered 'considering (my) records state that baby's heart rate was non-reassuring and also the Consultant Obstetrician's statement that they knew they would be delivering a very sick baby''?

During the investigation Mr. and Mrs. Molloy queried whether a Consultant Paediatrician should have been present when Baby Mark was delivered as there were signs of foetal distress immediately before he was delivered.

Professor Morrison stated in his expert report that:

> ***"It is my view that it was not necessary for the Consultant Paediatrician to have been present when the baby was delivered. It is standard practice for a Registrar to be present in the circumstances described here. When it became evident that the baby was in worse condition than expected a Consultant was summoned, and duly attended rapidly. This represents standard practice".***

During the investigation the Consultant Paediatrician who was on call on the 24th January indicated that he was in the hospital reviewing patients on a ward when he received the emergency bleep to attend Baby Mark's resuscitation. The Consultant Paediatrician indicated that when he received the bleep he immediately went to the Theatre Department.

In a comment submitted by Mr. and Mrs. Molloy to the Review Team they indicated that the information given to Dr Murphy relating to the question of Mark's resuscitation was incomplete. The question asked was should the Consultant Paediatrician have been present when Mark was born given that Consultant Obstetrician Gynaecologist A stated that she knew that she was going to deliver a very sick baby but she did not think that he would die? Mr. and Mrs. Molloy asked why the team with this knowledge waited until after Mark was born to call the Consultant Paediatrician, rather than calling him prior to his birth, meaning a critical five minutes were lost?

Dr Murphy stated that it would be unusual for a Consultant Paediatrician to be present at an emergency term Caesarean Section. He stated that these are very common events in a maternity hospital. They are situations that are attended by the Senior House Officers and Registrars. The reason being is that these staff are in house and are readily available for such emergencies. In addition he stated that hospitals have arrangements in place so that these doctors have been fully trained in methods of resuscitation. He confirmed that in his own hospital that the arrangements would be very similar to this case in that the emergency Caesarean Section would be attended by the resident hospital doctors and a Consultant will arrive if the baby has not responded to the routine resuscitation measures.

He also confirmed that the relevant international guidelines and best practice standards were followed when trying to resuscitate Baby Mark and that the resuscitation efforts were only discontinued when it became obvious that Baby Mark could not be resuscitated.

Dr. Murphy, Consultant Neonatologist, indicated in his expert report when referring to the resuscitation of Baby Mark that in his opinion:

> ***"the resuscitation of the infant was performed in a satisfactory manner. The ABCD (Airway, Breathing, Circulation, Drugs) components of neonatal resuscitation were applied in a timely manner."***

6.3.1.2 Should a nurse from the Special Care Baby Unit have been present at the time of delivery?

Professor Morrison stated in his expert report that:

"It would not be standard practice to have a Nurse from the Special Care Baby Unit present in theatre at a delivery of a term infant in these circumstances. In my view this was not necessary at the outset".

6.3.1.3 Should the patient have been induced earlier given her due date (15th January) the 'size of the baby, the fact that he was face-up and her past history.'

Professor Morrison stated in his expert report that:

> ***"It is my opinion that induction of labour earlier was not clinically indicated, nor can one say it would have altered the circumstances that transpired during the labour".***

6.3.1.4 Did the delay in sectioning the patient compromise the patient's safety and health; Mrs. Molloy received an injury during the C-section; how and why was this injury sustained?

Professor Morrison's stated in his expert report that:

> ***"It is not clear which patient is being referred to in this question, or if it is both mother and baby. As stated in this report, it is my view that fetal blood sampling should have been performed from 06.50 onwards, and failure to do so, and procure a normal result, meant that caesarean section was indicated earlier than when it was performed. Failure in this regard was linked to the fetal hypoxia that occurred. The timing of the caesarean section, which finally occurred at full dilatation, is associated with a greater risk of a surgical tear and haemorrhage than caesarean section performed in the 1st stage of labour.***

Mr. and Mrs. Molloy in their feedback to the Review Team stated that at a follow up meeting with Consultant Obstetrician Gynaecologist A following Mrs. Molloy's discharge from hospital that Consultant Obstetrician Gynaecologist A stated "hands up, my fault" when referring to the uterine tear that Mrs. Molloy sustained. Mr. and Mrs. Molloy also commented that they did not know why the uterine tear occurred i.e. if a scalpel slipped, if it was an insufficient incision, or something Baby Mark did, or any other reason. They also indicated that in the event that Mrs. Molloy became pregnant again that they would not know what to be aware of or to report to her medical team.

Consultant Obstetrician Gynaecologist A in her response stated that she had no recollection of ever saying "hands up, my fault" nor does she believe she would have made such a comment.

How and why the injury occurred:
Consultant Obstetrician Gynaecologist A stated that the uterine tear did not occur as a result of the scalpel slipping. The tear on the right side of Mrs. Molloy's uterus occurred as an extension of the surgical incision on the lower segment of the uterus. She also stated that a uterine tear can occur during a Caesarean Section and is more likely to do so when the Caesarean Section is performed during the second stage of labour.

Professor Morrison highlighted in his report that the timing of the Caesarean Section, which finally occurred at full dilatation, is associated with a greater risk of a surgical tear and haemorrhage than Caesarean Section performed in the 1st stage of labour.

From the literature, the Review Team note that Selo-Ojeme D, Sathiyathasan S, et al (2008)[138] indicated that Caesarean Section in the second stage of labour is associated with higher risk of maternal morbidity; that compared with caesarean delivery in the first stage of labour, women undergoing Caesarean delivery at full cervical dilatation were 4.6 times more likely to have composite intraoperative complications. Spencer C. and Murphy D. (2006)[139] stated that the "maternal risks of second stage Caesarean Section include major haemorrhage, longer hospital stay, greater risk of bladder trauma, and extension tears of the uterine angle leading to broad ligament haematoma".

Upon a request from the Review Team in September 2013 Professor Morrison was asked to consider the point again and he did not make any additions to his report and findings.

[138] Selo-Ojeme D, Sathiyathasan S, Fayyaz M. (2008). Caesarean delivery at full cervical dilatation versus caesarean delivery in the first stage of labour: comparison of maternal and perinatal morbidity. Archives of Gynaecology and Obstetrics. September 2008, Volume 278, Issue 3, pp 245-249.
[139] Spencer C, Murphy D, Bewley S. (2006). Caesarean delivery in the second stage of labour; Better training in instrumental delivery may reduce rates. BMJ. September 23: 333(7569): 613-614.

6.3.2 Other concerns highlighted by Mr. and Mrs. Molloy during the investigation:

Mr. and Mrs. Molloy highlighted the following concerns to the Review Team and requested that these issues be addressed as part of the investigation report.

I. **Resuscitation of Baby Mark,**

II. **Classification of Baby Mark as a stillbirth,**

III. **The cutting of a lock of Baby Mark's hair and taking of his hand and foot prints,**

IV. **Access to epidural analgesia during labour and the recording of vital signs when epidural analgesia has commenced,**

V. **Number of staff present in the Labour Ward leading up to the time Mrs. Molloy was transferred to Theatre,**

VI. **Scheduling of six week Outpatient appointment and the provision of information on discharge following the postpartum death of a baby,**

In addition the following issue was subsequently highlighted in Mr. and Mrs. Molloy's feedback:

VII. **Use of the Naegale's Rule.**

6.3.2.1 Resuscitation of Baby Mark

During the investigation Mr. and Mrs. Molloy highlighted concerns that they had in relation to the resuscitation of Baby Mark and on the basis of their concerns it was agreed that an independent Consultant Neonatologist would be requested to examine this aspect of the care delivered. Consequently an independent clinical review of Baby Mark's neonatal record was carried out by Dr. John Murphy, Consultant Neonatologist.

The purpose of the independent clinical review undertaken by Dr. Murphy was to provide the investigation with an expert opinion related to Baby Mark's resuscitation on the 24th January 2012. Dr. Murphy's report was submitted to the investigation team on the 15th January 2013; a copy of Dr. Murphy's report can be found in Appendix II of this report.
It was established during the investigation that Baby Mark was born at 09.31 hours on the 24th January, that he had a very slow faint heart beat when he was born and that he had no respiratory effort, muscle tone or reflux during cord examination.

Baby Mark's APGAR score at 1 and 5 minutes was 0; there was no heart rate, no respiratory effort, no muscle tone, no reflex response to suctioning and he was cyanosed. The Paediatric Registrar and Consultant Anaesthetist on call were present at Baby Mark's birth and the Consultant Paediatrician arrived five minutes after Baby Mark's birth.

The neonatal record indicates that neopuff with 100% oxygen was administered to Baby Mark immediately after birth and that chest compressions were commenced at a rate of one breath to every three chest compressions.

Baby Mark was intubated at 4 minutes and 30 seconds and two doses of Adrenaline were administered through the endotracheal tube. The neonatal record indicates that an umbilical venous line was inserted at 10 minutes of age and 60 millilitres of Normal Saline in two divided doses and a third dose of adrenaline was administered via the umbilical line. The neonatal record indicates that there was no response to the resuscitation efforts carried out and Baby Mark was pronounced dead at 22 minutes.

In his report Dr. Murphy states that:

"The management of the infant was satisfactory. Full cardio-pulmonary resuscitation was administered in a timely manner.

In the case of Baby X, the extent and severity of the hypoxia at birth indicates that it was of a profound nature and that is the reason why he did not respond to cardiopulmonary resuscitation administered after birth".

6.3.2.2 Classification of Baby Mark as a still birth

Mr. and Mrs. Molloy indicated in their sequence of events that they were informed that Baby Mark was a stillbirth.

Mr. and Mrs. Molloy indicated that they were not aware that Baby Mark had a heart beat when he was born and therefore that he was alive at that time and that on that basis he should not have been classified as a stillbirth but as a neonatal death[140].

In addition Mr. and Mrs. Molloy indicated that they would have arranged a funeral for Baby Mark if they had known that he was alive at the time of his birth.

The HSE Clinical Practice Guidelines on the Investigation and Management of Late Fetal Intrauterine Death and Stillbirth[141] defines a live birth as "delivery of an infant which, after complete separation from its mother, shows sign of life.

The guidelines state that evidence of life includes "breathing movements, presence of a heartbeat, pulsation of the cord or definite movement of voluntary muscles".

The HSE guideline defines a stillbirth as "a baby delivered without signs of life after 23+6 weeks of pregnancy".

The Consultant Anaesthetist involved in the resuscitation of Baby Mark
It was documented by Consultant Anaesthetist A i.e. the Consultant Anaesthetist who attended Theatre on the morning of the 24th January 2012 to provide anaesthetic care to Mrs. Molloy in Baby Mark's neonatal notes when referring to Baby Mark's resuscitation that there was no foetal heart audible throughout i.e. from the time of Baby Mark's delivery until the time that Baby Mark was pronounced dead. However, in brackets, Consultant Anaesthetist A documented the following; ***"(significant brady initially)".***

Consultant Anaesthetist A informed the Review Team at interview that he was present when Baby Mark was delivered and that when he initially listened to Baby Mark's heart with a stethoscope that he had thought that there was a faint heart beat present but that at the time of the events that he could not be sure of this fact.

Consultant Anaesthetist A indicated that, following completion of the resuscitation efforts made to revive Baby Mark, he considered that, in retrospect and on the balance of probabilities, he had not heard a heart-beat when he had initially listened to Baby Mark's chest.

Consultant Anaesthetist A indicated that during the resuscitation of Baby Mark there was a lot of activity and noise in the resuscitation area of the Theatre. This activity included the Paediatric Registrar trying to intubate Baby Mark, staff drawing up medications while other staff were trying to gain umbilical venous access. In addition Mrs. Molloy's care was being attended to in another area of the Theatre.

Consultant Anaesthetist A stated that when he realised that the issue of the classification of Baby Mark as a live birth was of such significance to the family and on the basis that he could not with one hundred per cent certainty state that he did or did not hear an initial heartbeat, he made the decision to alter his initial finding that there had been no heart-

[140] Mr and Mrs. Molloy did receive a Birth Certificate for their son Mark in May 2012
[141] HSE and Institute of Obstetricians and Gynaecologists (2011) Clinical Practice Guidelines on Investigation and Management of Late fetal Intrauterine Death and StillBirth.

beat at birth to a finding that there might have been an audible heart-beat in order to ensure the family were able to obtain a Birth Certificate for Baby Mark.

In their feedback to the Review Team Mr. and Mrs. Molloy requested clarification as to the time that the retrospective notes recorded by Consultant Anaesthetist A were made.

Consultant Anaesthetist A has stated to the Review Team that it is his routine practice to always document his resuscitation notes with his Medical/Paediatric colleagues' notes to facilitate good record keeping, hence their position on the one page. Consultant Anaesthetist A also stated that his note of Baby Mark's resuscitation was written in good faith and that it was a fair and accurate reflection of his involvement in the resuscitation. Consultant Anaesthetist A stated that the note was completed in its entirety contemporaneously after the notes made by the Paediatricians and before the completion of Mrs. Molloy's Caesarean Section and that it was not added to or subtracted from at any later stage.

The Consultant Paediatrician present during Baby Mark's resuscitation

The Consultant Paediatrician who was present during Baby Mark's resuscitation, Consultant Paediatrician A, indicated during the investigation that he was aware when Baby Mark was classified as a stillbirth that Consultant Anaesthetist A had queried if Baby Mark had a heart beat when he was born.

Consultant Paediatrician A indicated that it was his clinical experience that newly born babies who require resuscitation as a result of a slow faint heart rate usually respond to first line resuscitation medication i.e. Adrenaline by increasing the rate and strength of the heart beat even if this response was for a short period of time.

Consultant Paediatrician A indicated during the investigation that as Baby Mark's heart did not respond to the administration of Adrenaline on the 24th January i.e. Baby Mark's APGAR score at one minute was 0 indicating no signs of life that he took the decision that Baby Mark did not have a heart beat when he was born and as a result Baby Mark was classified as a fresh stillbirth.

Consultant Paediatrician A indicated during the investigation that he was aware of the HSE definition for a stillbirth and live birth and that if it had been his view that Baby Mark had signs of life when he was born including the presence of a heart beat that he would have classified him as a neonatal death.

Professor Morrison's comment on the classification of Baby Mark

Professor Morrison indicated in his expert report that in his opinion Baby Mark was not alive at the time of delivery but that he had just recently died.

Professor Morrison indicated that this is known as a 'fresh stillbirth' and that in such cases there can occasionally be a period of time when intermittent beating of the heart can be heard at a very low rate in the minutes following a fresh stillbirth.

Mr. and Mrs. Molloy in their feedback to the Review Team stated that it is known that Baby Mark had a heartbeat when he was delivered, albeit for a very short period. They stated that he was also cyanosed which implies circulation, another sign of life. It was their view that it had already been established that Baby Mark was alive at birth. Therefore Mr. and Mrs. Molloy indicated that they had serious concerns related to Professor Morrison's opinion and they expressed the view that it was not consistent with other definitions or classifications that they had identified.

Professor Morrison was given an opportunity to comment on this and he stated that his expert report was based on the anonymised copy of Mrs. Molloy's healthcare record that was sent to him when he was nominated as the external obstetrical expert and the objective evidence documented in the record.

He also stated that in the section of the healthcare record titled 'Neo-Natal Record' it is documented that Baby Marks Apgar score was 0 at one minute and 0 at five minutes and in the section of the healthcare record relating to the 'Labour Summary' and the delivery of Baby Mark the term 'SB' (i.e. stillbirth) is documented. He stated that it was for these

reasons that he stated that the consensus was that Baby Mark was a stillbirth. He also stated that it was his view that it was a matter for the hospital how they classified Baby Mark's death.

The Consultant Pathologist who carried out the post mortem on Baby Mark

The Consultant Pathologist who carried out the post mortem on Baby Mark, Consultant Pathologist 1 indicated that the classification of resuscitated stillbirths had been discussed at meetings between The International Stillbirth Alliance, The Stillbirth and Neonatal Death Society and members of the British and Irish Paediatric Pathology Association and that the consensus opinion was that babies born with minimal signs of life who are not successfully resuscitated should be classified as a neonatal death. Consultant Pathologist 1 indicated that this consensus opinion is contained as a recommendation in the Australian New Zealand Clinical Practice Guideline for Perinatal Mortality (2009).

Consultant Pathologist 1 indicated during the investigation that when he was first contacted about Baby Mark's death in January 2012 he was informed that Baby Mark was a fresh stillbirth. Consultant Pathologist 1 indicated that he subsequently received an email from Mr. Molloy on the 25th May to inform him that the Midland Regional Hospital at Portlaoise had reclassified Baby Mark's death as a neonatal death. Consultant Pathologist 1 indicated that following Mr. Molloy's email he contacted Consultant Obstetrician Gynaecologist A and that she confirmed to him that Baby Mark's death had been reclassified as a neonatal death.

Consultant Pathologist 1 indicated during the investigation that it was not possible for him to identify if Baby Mark was a fresh stillbirth or a neonatal death during the post mortem.

Consultant Pathologist 1 informed the Review Team that, based on the information that he had received from Consultant Obstetrician Gynaecologist A that Baby Mark's death had been reclassified as a neonatal death, he issued an updated official report of Baby Mark's post mortem and that the updated report stated that Baby Mark's death was an early neonatal death.

Consultant Pathologist 1 indicated during the investigation that the issue of the classification of resuscitated stillbirths[142] has often confounded Obstetricians and Paediatricians in the past.

Dr. Murphy's comments on the classification of Baby Mark:

Mr. and Mrs. Molloy indicated in their feedback to the Review Team that Dr Murphy's expert report stated that when Baby Mark was born "the only sign of life at birth was a very faint slow heartbeat" and that despite this knowledge that Dr Murphy did not question the classification of Baby Mark as a stillborn.

Dr Murphy stated that he appreciates the issue of whether Mark was classified as a stillbirth rather than a neonatal death is a sensitive issue for Mr. and Mrs. Molloy. It is a matter that is frequently raised in relation to babies who are born with no visible external signs of life but are thought perhaps to have a slow faint heart rate. In Mark's case the APGAR score which was filled in at one minute and five minutes of age, the readings were zero. Thus there appeared to be certainty that he had no heart rate at the age of one minute. The doubt does arise whether there was a very faint heart rate, very slow between birth and one minute. This apparently was documented by the anaesthetist. Given the noisy environment of resuscitation it can be difficult to be certain whether or not a faint heart rate had been heard. If a doctor is certain that there has been a heart rate, there is a case for classifying the infant as a live-born birth. He also noted that he had not been sent a copy of the death certificate.

[142] Resuscitated Stillbirth is where an infant is stillborn and, following active resuscitation, a heart beat is detected, the birth is required to be registered as a livebirth. If the infant subsequently dies up to 28 days of age registration as a neonatal death is necessary (Reference: Perinatal Society of Australian New Zealand (Perinatal Mortality Group) (2009) Clinical Practice Guidelines for Perinatal Mortality. Available from http://www.stillbirthalliance.org.au/doc/Section_1_Version_2.2_April_2009.pdf [accessed 8th March 2013].

A copy of the Baby Mark's death certificate was not sent to Dr. Murphy as the Review Team was informed that Baby Mark's death had not been registered with the Civil Registration Service.

Incident Near Miss Report Forms completed in relation to Mrs. Molloy's delivery and Baby Mark's death

It was established during the investigation that an Incident Near Miss Report Form was completed by a Theatre Nurse on the 24th January in relation to Mrs. Molloy's delivery and Baby Mark's death. The Theatre Nurse documented on the Incident Near Miss Report Form that Baby Mark was a stillbirth.

The Theatre Nurse who completed the Incident Near Miss Report Form indicated during the investigation that she was the Circulating Nurse[143] for Mrs. Molloy's surgery on the 24th January, that she was present when Baby Mark was born and to her knowledge that Baby Mark was "flat" when he was born i.e. that Baby Mark had no signs of life when he was born and for that reason she documented on the Incident Near Miss Report Form that Baby Mark was a stillbirth.

The Theatre Nurse also indicated that while she was present during the resuscitation of Baby Mark that she was not involved in his resuscitation as she was involved in Mrs. Molloy's surgery.

An additional entry on the Incident Near Miss Report Form completed by the Theatre Nurse on the 24th January 2012 states the following; "Baby was still born". It was established during the investigation that this entry was made by the Clinical Nurse Manager III of the Theatre Department, Clinical Nurse Manager III B. Clinical Nurse Manager III B indicated during the investigation that she was present during the resuscitation of Baby Mark and that it was her recollection that Baby Mark showed no signs of life while he was being resuscitated and that she consequently documented that "Baby was still born" when she reviewed the Incident Near Miss Report Form as part of her standard process of reviewing all Incident Near Miss Report Forms completed by staff in the Theatre Department.

Recommendation:

- **That the HSE provide guidance on the classification of babies who are born with minimal signs of life requiring resuscitation and who are not successfully resuscitated as outlined in the Australian New Zealand Clinical Practice Guideline for Perinatal Mortality.**

6.3.2.3 The cutting of a lock of Baby Mark's hair and taking of his hand and foot prints

Mr. and Mrs. Molloy indicated during the investigation that they were given a memory booklet containing a lock of Baby Mark's hair and his hand and foot prints by a Midwife a few hours after Baby Mark's death. Mr. and Mrs. Molloy indicated that Mrs. Molloy found the gesture of the memory booklet very distressing and that her initial concern was that Baby Mark would have dirty hands and feet as the prints were taken using black ink. Mr. and Mrs. Molloy indicated that when they were given the memory booklet the Midwife stated "something nice for when you go home". Mr. and Mrs. Molloy indicated during the investigation that this statement was inappropriate and insensitive considering that Mrs. Molloy was in complete shock as Baby Mark had just died and was lying beside her at the time.

Mr. and Mrs. Molloy indicated during the investigation that it is their view that the parent's permission should be sought before mementos are obtained following the death of a baby.

[143] A Circulating nurse is a nurse who has not scrubbed in with the surgical team, but nonetheless participates in a surgical procedure by coordinating, planning and implementing all the nurse-related activities during an operation (Reference: http://medical-dictionary.thefreedictionary.com/circulating+nurse).

For example Mrs Molloy indicated that it was her preference that her sister who was a hairdresser should have cut Baby Mark's hair.

The HSE and the Institute of Obstetricians and Gynaecologists (Royal College of Physicians of Ireland) Clinical Practice Guidelines Post-natal Care and the Investigation and Management of Late Fetal Intrauterine Death and Stillbirth (2011)[144] indicates that a foetus's footprints, handprints and a lock of their hair (if available) can be taken for memory booklets with the parents consent.

In line with this guideline Mr. and Mrs. Molloy's consent should have been sought before taking Baby Mark's footprint, handprints and a lock of his hair.

Mr. and Mrs. Molloy also indicated that the final report should include a recommendation that all Maternity Hospitals should give information to parents of babies who have died soon after birth about the two Stillborn and Neonatal Death Organisations; A Little Lifetime Foundation and Feileacain (Stillbirth and Neonatal Death Association of Ireland). This recommendation is also contained in the Clinical Practice Guidelines Post-natal Care and the Investigation and Management of Late Fetal Intrauterine Death and Stillbirth.

Recommendation:

- **That the Maternity Department of the Midland Regional Hospital Portlaoise develop, implement and audit a guideline related to the provision of mementos to bereaved parents which sets out the process to be followed when taking a lock of a baby's hair and their hand and foot prints following the baby's death. The guideline must state that the consent of the parents must be sought before taking mementos.**

- **That all Maternity Hospitals should give information to parents of babies who have died soon after birth about the two Stillborn and Neonatal Death Organisations; A Little Life Time Foundation and Feileacain (Stillbirth and Neonatal Death Association of Ireland).**

6.3.2.4 Access to epidural analgesia during labour and the recording of vital signs when epidural analgesia had commenced.

Mr. and Mrs. Molloy indicated during the investigation that Mrs. Molloy had experienced delays in receiving epidural analgesia during labour for her three previous deliveries and that in order to prevent any delays during this pregnancy Mrs. Molloy discussed the issue of pain relief during labour with Consultant Obstetrician Gynaecologist A at an antenatal outpatient appointment.

Mrs. Molloy stated that Consultant Obstetrician Gynaecologist A had assured her at the Antenatal Clinic that she could "choose her own pain relief and that she had a right to receive an epidural if she requested it".

Mrs. Molloy's healthcare record indicated that Mrs. Molloy started to feel labour pains at 04.10 hours, that she was admitted to the Maternity Department at 05.05 hours, that the on call Anaesthetist was contacted at 05.50 hours to insert the epidural cannula and that the epidural analgesic was commenced at 06.27 hours i.e. 82 minutes following admission to the Maternity Department and 37 minutes after the on call Anaesthetist was contacted.

[144] The purpose of this guideline is to assist all healthcare professionals in the diagnosis, investigation and management of late intrauterine death and stillbirth (reference: http://hsenet.hse.ie/uRfi2iW7dw3SbjVfgZSVnA%3d%3d/eng/about/Who/clinical/natclinprog/guide4.pdf?ImportedResourceId=uRfi2iW7dw3SbjVfgZSVnA%3d%3d

Mrs. Molloy also indicated that while the epidural analgesia did take the edge off her pain she continued to experience some pain[145] up to the time she received the bolus of epidural analgesia prior to her surgery.

The Cochrane Collaboration (2012)[146] indicates that pain relief is an important issue for women in labour and the level of pain experienced and the effectiveness of pain relief may influence a woman's satisfaction with delivery.

The Midland Regional Hospital Portlaoise's guideline on the management of an expectant mother's pain and pain relief during labour indicates that the method of pain relief used should be discussed jointly between the woman, her Midwife and the Consultant Obstetrician Gynaecologist and that if pain relief or epidural problems are anticipated the woman should be seen antenatally by a member of the anaesthetic team.

It was identified during the investigation that while Mrs. Molloy did discuss her choice of pain relief with Consultant Obstetrician Gynaecologist A at an antenatal outpatient appointment that there was no evidence found that a similar discussion took place with a member of the midwifery team.

There was also no evidence found during the investigation that Mrs. Molloy was referred to an anaesthetist or that her case was discussed with the anaesthetic service so that the anaesthetic service was aware of her anxieties in relation to epidural analgesia.

It was also noted during the investigation that the purpose of the guideline on the management of an expectant mother's pain and pain relief during labour was to "guide midwives in the provision of appropriate, effective and timely pain relief during labour and birth". However, the investigation notes that the guideline is not designed for use by the multidisciplinary team although the provision of pain relief to expectant mothers during labour can involve midwifes, the anaesthetic service and the Consultant Obstetrician Gynaecologist.

Recommendation:

- **That the guideline on the management of an expectant mother's pain and pain relief during labour is updated to include extension of the scope of the guideline to the multidisciplinary team involved in the management of pain during labour.**

Mr. and Mrs. Molloy raised other issues related to the administration of epidural analgesia that they requested should be addressed in the investigation; these were whether the administration of the epidural and the resulting lowering of Mrs. Molloy's blood pressure impacted on the well-fare of their baby and, secondly, to comment on the overall standard of pain relief administered.

It was noted during the investigation that Mrs. Molloy's blood pressure fell following commencement of the epidural analgesia; the causal relationship between acute maternal hypotension and acute fetal distress is well recognised.[147]

Mrs. Molloy's epidural analgesia was commenced at 06.30 hours. It is recorded that her blood pressure was 114/66 millimetres of mercury[148] and her pulse rate was 72 beats per

[145] There is no internationally validated standard scale available to measure labour pain (reference: http://www.biomedcentral.com/content/pdf/1472-6963-10-268.pdf).
[146] The Cochrane Collaboration (2012) Pain management for women in labour: an overview of systemic reviews (Review) (Available from; http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009234.pub2/pdf). The Cochrane Collaboration is an international, independent, not-for-profit organisation of over 28,000 contributors from more than 100 countries, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide (reference: http://www.cochrane.org/).
[147] Warland, J. Low Blood Pressure; Oral Presentation. BMC Pregnancy and Childbirth 2012, 12(Suppl 1):A. {available from http://www.biomedcentral.com/content/pdf/1471-2393-12-S1-A9.pdf}

minute at 06.27 hours. Her blood pressure was recorded as 101/52 millimetres of mercury at 07.30 hours. Mrs. Molloy's pulse rate was not recorded at this time.

The epidural analgesia commenced was levobupivacine and fentanyl, one of the side effects of levobupivacine is hypotension[149].

In relation to this aspect of care Dr. Harnett states in her expert report that;

> ***"The placement of the epidural was uneventful and the blood pressure was maintained within normal limits after epidural placement and during subsequent caesarean section".***

Dr. Harnett also indicated in her report that the epidural analgesia prescribed and administered would be considered a very standard regime for establishing epidural analgesia.

In their feedback to the Review Team Mr. and Mrs. Molloy stated that it was their view that the following issues were not adequately addressed in Dr Harnett's report;

a) if the anaesthesia was in fact working given that Mrs. Molloy was distressed and only received momentary relief from the labour pains,

b) whether the administration of anaesthesia could have had any effect on Mark given that both significant effects on his heart rate coincided with the administration of epidural.

The Review Team asked Dr Harnett for her further comments. Dr Harnett in reply stated that the initial request for her opinion did not cover point a) but having reviewed the healthcare record again Dr Harnett commented that though there is documentation by the midwife of the patient having the "the urge to push", there is no documentation made by midwifery staff that Mrs. Molloy had any discomfort or pain.

Dr Harnett also noted that the Anaesthetist was not asked to review Mrs. Molloy following the commencement of epidural analgesia and that no further epidural medication was administered while she was in the labour ward.

Dr Harnett did indicate that Mrs. Molloy's epidural was topped-up in preparation for the Caesarean Section procedure and that the epidural was effective at that point.

In relation to point b) Dr Harnett stated that she had not reviewed any antenatal notes prior to Mrs. Molloy's admission to the Labour Ward and that therefore she could not comment on Mrs. Molloy's normal blood pressure in the antenatal period based on one single blood pressure reading at the time of her admission.

In relation to point b) Dr Harnett stated that based on one single blood pressure reading taken on admission when Mrs. Molloy was in labour and two other blood pressure readings peri-epidural placement that she was of the opinion that there is insufficient evidence to suggest that the blood pressure had significant effects on the CTG.

Mr. and Mrs. Molloy's stated that it is their recollection that following insertion and commencement of the epidural analgesia the extent and level of the sensory block was not checked by midwifery staff and they also highlighted that Mrs. Molloy's Epidural Observation Chart was not fully completed.

The Midland Regional Hospital Portlaoise's guideline on the management of an expectant mother's pain and pain relief during labour states that "half hourly assessment of the

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[148] Normal blood pressure is below 140/90 mm Hg (reference: http://www.patient.co.uk/health/Pregnancy-and-High-Blood-Pressure.htm).

[149] Reference: British National Formulary 2009

extent and level of the sensory block should be undertaken using ice and ethyl chloride spray". The guideline also states that;

> ***"During establishing of regional anaesthesia or after administration of a bolus, blood pressure and pulse should be measured every 5 minutes for 15 minutes and if satisfactory, thereafter every 30 minutes".***

As indicated above Mrs. Molloy's epidural infusion was commenced at 06.27 hours. Mrs. Molloy's Epidural Observation Chart indicated that the following was documented at 06.27 hours, at 07.00 hours and at 07.30 hours;

- That Mrs. Molloy was in the left lateral position on each occasion,
- That the extent and level of sensory block on the left and right side were from the 10th thoracic vertebrae to the third lumbar vertebrae. There was no documentation on how the extent and level of sensory block was established.
- That Mrs. Molloy's pulse rate, blood pressure, respiratory rate, temperature and the foetal heart rate were documented at 06.27 hours and 07.30 hours; these vital signs were not recorded at 07.00 hours although the foetal heart rate was recorded on Mrs. Molloy's Continuation Notes at 07.00 hours.

It was noted during the investigation that Mrs. Molloy's blood pressure was lowered (101/52 millimetres of mercury) at 07.30 hours and that there was no further documentation that her blood pressure was recorded until Mrs. Molloy was transferred to the Theatre Department at 09.05 hours when the blood pressure was recorded by the Consultant Anaesthetist.

Mrs. Molloy's blood pressure was recorded in Theatre as 100/75 millimetres of mercury at 09.00 hours. Mrs. Molloy's blood pressure was documented every 10 minutes during her surgery.

There was no evidence found during the investigation that Mrs. Molloy's blood pressure was documented every five minutes for the first 15 minutes following establishment of the regional block as outlined in the Maternity Department guideline on the management of an expectant mother's pain and pain relief during labour.

During the review of documents submitted to the Review Team as part of this investigation it was noted that there is an inconsistency related to the requirements for documentation outlined in the guideline on the management of an expectant mother's pain and pain relief during labour and documentation required in the Epidural Observation Chart.

The guideline on the management of an expectant mother's pain and pain relief during labour indicates that a patient's blood pressure and pulse rate should be recorded every five minutes for 15 minutes on establishing a regional block while the Epidural Observation Chart states that "observations to be recorded every ½ hour for the first 2 hours after epidural placement and one hourly until delivery".

As indicated above it was also noted that Mrs. Molloy's blood pressure fell following commencement of the epidural infusion i.e. her blood pressure fell from a systolic blood pressure[150] of 114 millimetres of mercury and a diastolic blood pressure of 66 millimetres of mercury to a systolic blood pressure of 101 millimetres of mercury and a diastolic blood pressure of 52 millimetres of mercury.

It is the stated policy in the Maternity Department and is also documented on the Epidural Observation Chart that an Anaesthetist should be advised if the systolic blood pressure falls below 90 millimetres of mercury. The investigation notes that this did not occur in this instance.

[150] 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).

Recommendations:

- **That the Maternity Department at the Midland Regional Hospital Portlaoise review and update the guideline on the management of an expectant mother's pain and pain relief during labour to include the following elements; (1) the scope of the guideline is extended to include the multidisciplinary team involved in the management of pain during labour; (2) that the guideline refers to the decision making process that should be followed during the antenatal period in relation to the development of an expectant mother's plan of care for the relief of labour pain and (3) to ensure alignment of the guideline and the Epidural Observation Chart in relation to the frequency of recording vital signs.**

- **That the guideline on the management of an expectant mother's pain and pain relief during labour is included in the routine audit schedule developed for the Maternity Department; and that such audits must include the review of documentation of vital signs before and after commencement of epidural analgesia.**

- **That it becomes standard practice that all midwives document the method used to assess the extent and level of epidural block.**

6.3.2.5 Number of staff present in the Labour Ward leading up to the time Mrs. Molloy was transferred to Theatre.

Mr. and Mrs. Molloy documented that a large number of staff who were not involved in Mrs. Molloy's care were in the delivery room from 08.00 hours. Mr. and Mrs. Molloy indicated that the staff did not remain in the room for a prolonged period of time. Mr. and Mrs. Molloy indicated that the number of staff in the Delivery Suite was highly embarrassing for Mrs. Molloy as she was placed in the lithotomy position at this time.

It was established during the investigation that when Consultant Obstetrician Gynaecologist A arrived to assess Mrs. Molloy at 08.39 hours the following staff were present in the delivery room; Consultant Obstetrician Gynaecologist A, Obstetrician Gynaecologist Registrar A and Obstetrician Gynaecologist Registrar B (Obstetrician Gynaecologist Registrar B had accompanied Consultant Obstetrician Gynaecologist A to the Delivery Room), Midwife D and Midwife E.

Therefore there were a total of six healthcare staff present in the area in addition to Mrs. Molloy and Mrs. Molloy's husband. The dimensions of the delivery room allocated to Mrs. Molloy on the 24th January were 3.4 metres by 4.8 metres.

It is acknowledged that although the staff present were in attendance in order to assist in the provision of care to Mrs. Molloy at the time, it would be preferable if numbers were limited to essential staff.

The Health Service Executive and the Department of Health National Healthcare Charter You and Your Health Service[151] (2012) states that the Health Service Executive ***"will do our best to ensure that you have adequate personal space and privacy when you use our health services".***

The Charter also states that patients, their family and carers will be treated with "dignity, respect and compassion".

[151] The Charter is a statement of commitment by the HSE on healthcare expectations and responsibilities. The charter outlines what service users can and should expect every time that they use health services (reference: Health Service Executive and Department of Health National Healthcare Charter You and Your Health Service (National Healthcare Charter, National Advocacy Unit, Quality and Patient Safety Directorate HSE 2012).

Recommendation:

That the Midland Regional Hospital Portlaoise review the National Healthcare Charter in respect of affording privacy and dignity to patients with a view of ensuring that all staff are aware of the requirements of the Charter.

6.3.2.6 Scheduling of six week Outpatient appointment and the provision of information on discharge following the postpartum death of a baby

The HSE and the Institute of Obstetricians and Gynaecologists (Royal College of Physicians of Ireland) Clinical Practice Guidelines (2011) Post-natal Care and the investigation and management of late fetal intrauterine death and stillbirth indicate that parents should be given the following information postnatally following intrauterine death and stillbirth;

- Lactation,
- Thromboprophylaxis i.e. the measures taken to prevent the development of a thrombus,
- Birth registration,
- Burial and cremation,
- Support care i.e. bereavement counselling.

Mrs. Molloy informed the Review Team during the investigation that the memory booklet that was given to her following Baby Mark's death contained a statement on breastfeeding which she indicated was inappropriate and inconsiderate in the circumstance of Baby Mark's death. Mr. and Mrs. Molloy subsequently indicated that the memory booklet also had Baby Mark's hospital card taped to it which contained his name, date of birth, weight when he was born and the following statement "smoking can seriously harm your baby".

Mr. and Mrs. Molloy stated during that they are faced with both of these statements i.e. the statements on breastfeeding and smoking every time they wish to look at the memory booklet.

It was established during the investigation that Mr. and Mrs. Molloy were given the contact number of a bereavement councillor however there was no evidence found during the investigation that Mrs. Molloy was given information on thromboprophylaxis, birth registration or burial/cremation.

Mr. and Mrs. Molloy indicated that Mrs. Molloy rang Consultant Obstetrician Gynaecologist A's secretary on the 17th February to make a follow up outpatient appointment and that she received no answer to her call.

Mrs. Molloy indicated that she then rang Consultant Obstetrician Gynaecologist A's office on the 20th February and that an outpatient appointment was consequently arranged for the 27th February.

Mr. and Mrs. Molloy attended Consultant Obstetrician Gynaecologist A's private clinic on the 27th February where she was examined and a discussion took place in relation to the document titled "Roisin & Mark's Molloy's Account of Events during Roisin's labour at Midland Regional Hospital Portlaoise on 24th January 2012".

Mrs. Molloy also indicated that she discussed with Consultant Obstetrician Gynaecologist A the location of the six week follow up appointment. Mrs. Molloy indicated that she informed Consultant Obstetrician Gynaecologist A that it was her preference to attend an outpatient appointment at a location where she would not meet other women who would be discussing the progress of their newly born babies and where she might be asked questions about Baby Mark.

Mrs. Molloy indicated that on the 29th February that she received an appointment to attend for an outpatients appointment at Consultant Obstetrician Gynaecologist A's public clinic on the 8th March.

Mrs. Molloy indicated that she subsequently called Consultant Obstetrician Gynaecologist A's public secretary on the 5th March to rearrange the location of the appointment as had been discussed with Consultant Obstetrician Gynaecologist A on the 27th February and indicated that as the secretary was unaware of the circumstances surrounding the appointment that she decided to call Consultant Obstetrician Gynaecologist A's private secretary.

Mrs. Molloy indicated that she subsequently called Consultant Obstetrician Gynaecologist A's private secretary to discuss the appointment and that Consultant Obstetrician Gynaecologist A's private secretary informed her that Consultant Obstetrician Gynaecologist A would call her back in relation to the appointment but that she (Mrs. Molloy) did not receive a call from Consultant Obstetrician Gynaecologist A or her secretary.

On the 6th March Mrs. Molloy called Consultant Obstetrician Gynaecologist A's private secretary and she was informed that Consultant Obstetrician Gynaecologist A had been informed that she had called the previous day.

On the 7th March Mrs. Molloy indicated that as she had not received a return phone call from Consultant Obstetrician Gynaecologist A that she rang Consultant Obstetrician Gynaecologist A public secretary in relation to the location for the outpatient appointment scheduled for the 8th March. Mrs. Molloy indicated that Consultant Obstetrician Gynaecologist A's public secretary informed her that Consultant Obstetrician Gynaecologist A would meet Mrs Molloy at her private clinic but that she had no available dates for the appointment at the time but that Consultant Obstetrician Gynaecologist A could meet her at the public outpatient clinic as scheduled on the 8th March.

Mrs. Molloy indicated during the investigation that she initially agreed to these arrangements but that she later called back to cancel the appointment as she did not want to meet other women who she had met during her antenatal appointments. Mrs. Molloy indicated that no further outpatient appointment was offered to her at this time.

Mrs. Molloy's healthcare record indicated that Mrs. Molloy attended Consultant Obstetrician Gynaecologist A's public outpatient clinic on two occasions following her discharge from hospital; the first appointment was on the 9th February 2012 i.e. 16 days following her surgery and the second was on the 4th April 2012.

Consultant Obstetrician Gynaecologist A indicated during the investigation that she met with Mrs. Molloy in Consultant Obstetrician Gynaecologist A's private clinic on the 9th and on the 27th February 2012 because it provided a quiet and undisturbed location. Consultant Obstetrician Gynaecologist A also indicated that at that time she gave Mrs. Molloy her mobile number to enable Mrs. Molloy to contact her directly.

Consultant Obstetrician Gynaecologist A indicated during the investigation that she recalls that she received a number of phone calls from Mrs. Molloy following this and that at the times the phone calls were received it was not possible to answer the calls.

Consultant Obstetrician Gynaecologist A indicated that at the time of receiving these calls her mobile phone indicated that the calls came from a landline number and that the missed calls were returned at the earliest opportunity and voice messages left.

Section 6.5 of the Clinical Practice Guidelines (2011) related to Post-natal Care and the Investigation and Management of Late Fetal Intrauterine Death and Stillbirth developed by the Health Service Executive and the Institute of Obstetricians and Gynaecologists (Royal College of Physicians of Ireland) when referring to the provision of follow up appointments to women who have experienced intrauterine and/or stillbirth states that ***"subsequent clinic appointments should take place in a quiet and undisturbed location within the hospital, for example at the end of a gynaecology clinic''.***

The review notes that the two outpatient appointments facilitated by Consultant Obstetrician Gynaecologist A with Mrs. Molloy were conducted in a quiet and undisturbed location i.e. Consultant Obstetrician Gynaecologist A's private clinic.

It is a recommendation of this review that all such appointments should be conducted in this manner.

Recommendation:

- **That the Health Service Executive and the Institute of Obstetricians and Gynaecologists (Royal College of Physicians of Ireland) Clinical Practice Guidelines (2011) Investigation and Management of late fetal intrauterine death and stillbirth is reviewed with a view to full implementation by the Maternity Department of the Midland Regional Hospital Portlaoise.**

6.3.2.7 Use of the Naegale's Rule

In their feedback to the Review Team Mr. and Mrs. Molloy stated that the report makes reference to the use of the Naegale's Rule for establishing a due date. Mr. and Mrs. Molloy noted that the Naegale's Rule employs two different calculations, 1) add 12 months to the date of LMP, subtract 3 months and add 7 days or, 2) add 280 days to the date of LMP.

Mr. and Mrs. Molloy stated that the former is a less accurate calculation which is only reliable where February falls within the gestational period. Where February is not one of the months of pregnancy, as in Baby Mark's case, this calculation is out by two days.

Mr. and Mrs. Molloy stated that it was their view that the former and more accurate method gave a due date of 13th January for Baby Mark i.e. by adding 280 days to the 8th April 2011. Mr. and Mrs. Molloy expressed the view that there is an important difference, given that Midland Regional Hospital Portlaoise has a maximum 10 day overdue allowance before induction of labour as by the 24th January 2012, Baby Mark was 11 days overdue.

Consultant Obstetrician Gynaecologist A and Professor Morrison were asked to comment on this. Consultant Obstetrician Gynaecologist A confirmed her comments as set out on page 17 of this report and she noted that Professor Morrison also addressed this issue. Professor Morrison confirmed that his comments were as set out in his expert report.

6.3.3 Incidental findings:

I. **Disclosure of information relating to Baby Mark Molloy and issues related to the investigation of adverse incidents,**
II. **Documentation Issues,**
III. **Transfer of Mrs. Molloy to Theatre,**
IV. **Incident Near Miss Report Forms completed in relation to Mrs. Molloy's delivery and the death of Baby Mark.**

6.3.3.1 Disclosure of information relating to Baby Mark.

Mr. and Mrs. Molloy informed the Review Team that the first they were aware that Baby Mark was distressed was when he was delivered and when he was brought straight to the resuscitation area of the Theatre.

Midwife B
Midwife B informed the Review Team that she contacted Obstetrician Gynaecologist Registrar A at 07.20 hours as Mrs. Molloy's labour was not progressing and that she had no concerns for the wellbeing of Baby Mark at the time that she made this contact.

Obstetrician Gynaecologist Registrar A
Obstetrician Gynaecologist Registrar A documented at 07.55 hours that the CTG was "satisfactory"[152] however there was no documentation found that Mr. and Mrs. Molloy were informed of this fact. Mr. and Mrs. Molloy documented in their sequence of events that Obstetrician Gynaecologist Registrar A informed them at 08.15 hours that Baby Mark was not in any distress.

Consultant Obstetrician Gynaecologist A
Consultant Obstetrician Gynaecologist A documented an entry in the healthcare record following her assessment of Mrs. Molloy at 08.39 hours that she had assessed Mrs. Molloy due to poor progress in the second stage of labour, that the CTG was satisfactory but that there was some late decelerations earlier.

Following her reassessment of Mrs. Molloy in Theatre, Consultant Obstetrician Gynaecologist documented that the CTG trace was non-reassuring and that the foetal heart rate was difficult to hear prior to Mrs. Molloy's surgery.

There was no evidence found in Mrs. Molloy's healthcare record that Consultant Obstetrician Gynaecologist A informed Mr. and Mrs. Molloy that the foetus was distressed at this time.

Consultant Obstetrician Gynaecologist A indicated during the investigation that she does not recall what specific information she communicated to Mr. and Mrs. Molloy about the condition of Baby Mark while in the Theatre Department.

Consultant Obstetrician Gynaecologist A indicated that she recalls explaining to Mr. and Mrs. Molloy the need to expedite the delivery of Baby Mark prior to Mrs. Molloy's transfer to Theatre and that this explanation was given as part of the consent process for the assisted delivery and emergency Caesarean Section. Consultant Obstetrician Gynaecologist A indicated during the investigation that as part of the consent process for both procedures she explained to Mrs. Molloy the risks to the foetus and the mother including the risk of trauma.

The National Patient Charter indicates that there should be open and appropriate communication throughout a patient's care about what is wrong and what the treatment or care aims to do concerning the results of any proposed treatment and medication.

[152] As previously stated it was established during the investigation that Obstetrician Gynaecologist Registrar A had initially documented that the "CTG noted to be satisfactory" and that this entry was subsequently changed to "CTG noted to be unsatisfactory (Non-reassuring)".

The Charter indicates that communication will also include the possible risks and alternatives regarding the type of continuing healthcare the patient may need, including medication, continuing care in hospital, timely and appropriate referrals, convalescence or rehabilitation and that communication will also take place regarding what discharge arrangements are in place and, when appropriate, what end-of-life care the patient will receive and especially when plans change or if something goes wrong.

Recommendation:

That the Midland Regional Hospital Portlaoise 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.

6.3.3.2 Documentation issues and recommendations to address these:

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

During this investigation it was identified that on occasions the quality of record keeping was very poor and that the standard of record keeping fell well below the acceptable standards.

This included;

- Alterations made to the healthcare record i.e. satisfactory altered to unsatisfactory,
- Entries not timed or dated
- The use of abbreviations which were not in accordance with the HSE Standard and Recommended Practice for Healthcare Records Management Abbreviations
- Entries not signed
- The use of tippex in the healthcare record.

It was identified during the investigation that although a Syntocinon infusion was commenced for Mrs. Molloy there was no reference included to the commencement of Syntocinon in Obstetrician Gynaecologist Registrar A's documentation in Mrs. Molloy's healthcare record.

Professor Morrison indicates in his report that the prospective documentation pertaining to Obstetrician Gynaecologist Registrar A's decision to commence Syntocinon was entirely lacking.

As stated above it was also identified that Obstetrician Gynaecologist Registrar A made changes to the retrospective note that he documented at 11.30 hours; the documentation initially stated that the "CTG noted to be satisfactory" and this was later changed to "CTG noted to be unsatisfactory (nonreassuring)".

Obstetrician Gynaecology Registrar A informed the Review Team that when he reviewed the CTG at 07.55 hours he identified that the CTG was non-reassuring with a few variable decelerations and that he mistakenly documented that the CTG was satisfactory because he was tired as a result of being on call and that he was in a rush as he was scheduled to travel to England for a course the next morning.

Mr. and Mrs. Molloy stated that Shift Leader A had made no entry in the healthcare record despite her significant role in Mrs. Molloy's care between the hours of 8.00am and 9.00am.

Shift Leader A in her reply to the Review Team stated that she was not Mrs. Molloy's primary midwife while Mrs. Molloy was in the Delivery Suite between 08.00 and 09.00 hours but that she was supporting Mrs Molloy's primary midwife, Midwife D, to care for Mrs. Molloy between 08.05 hours and 08.25 hours.

Shift Leader A indicated that she was requested to care for another women in labour at 08.25 hours and that she remained with this women until she was requested to go to the Theatre Department to assist with Mrs. Molloy's and Baby Mark's care at 09.00 hours. Mrs. Molloy's healthcare record indicates that Shift Leader A was involved in Baby Mark's resuscitation and she has documented her involvement in this process in the healthcare record.

The Review Team are satisfied that Shift Leader A's documentation in respect of Mrs. Molloy's and Baby Mark's care is in line with recommended best practice as outlined in the HSE Standards and Recommended Practice for Healthcare Records Management.

In their feedback to the Review Team Mr. and Mrs. Molloy stated that they had reviewed Mrs. Molloy's healthcare record in April 2013 that they noted the use of underlining of words with different coloured pens and the use of tippex. Mr. and Mrs. Molloy indicated that it was their understanding that this is against HSE healthcare records management policy and queried why the Final Draft Report made no reference to same.

When Mr. and Mrs. Molloy submitted their comment on the use of tippex the Review Team reviewed Mrs. Molloy's original healthcare record.

During the review it was noted that there was two instances related to the use of tippex. Tippex was used on two words; "food" and "oratory". The two incidences related to the use of tippex occurred in the section of the healthcare record which was outside the scope in time for the investigation as outlined in the investigation's Terms of Reference and related to the period when Mrs. Molloy was in the Coronary Care Unit following her surgery. The Review Team did not receive a copy of this section of the healthcare record as part of their investigation.

Notwithstanding that the comments received from Mr. and Mrs. Molloy do not relate to the Review Team's investigation; the Review Team confirm that best practice provides that tippex must not be used to correct an entry in the healthcare record and any correction to an entry should be signed, dated with a line through the original entry; and the corrections that were made in Mrs. Molloy's healthcare record were not appropriate or in line with accepted practice.

In relation to Mr. and Mrs. Molloy's comment on the underlining of words with different colour pens; it was noted during the review of Mrs Molloy's healthcare record undertaken by the Review Team that certain words were underlined in Mrs Molloy's healthcare record. The words underlined related to the entry that was made in the healthcare record at 06.40 hours. The words underlined were; 06.40, ARM (Artificial Rupture of Membrane), 8 cms dilated, Vx -2, ARM. The Review Team could not establish when the words were underlined.

Recommendations:

- **Ensure that all relevant staff are aware of and adhere to the HSE Standard and Recommended Practice for Healthcare Records Management. It is further recommended that the hospital should organise in-service training/education sessions on the importance of appropriate clinical documentation (these training/education sessions should include best practice in correcting original entries to the healthcare record). Attendance at such sessions should be mandatory for all clinical staff.**

- **The hospital should undertake an audit of compliance with the HSE Standard and Recommended Practice for Healthcare Records Management.**

6.3.3.4 Transfer of Mrs. Molloy to Theatre

Professor Morrison indicated in his expert report that while it was not possible to discern the exact timing of transfer of Mrs. Molloy from the labour ward to the Operating Theatre it was his view that the period of time from the initial assessment of Mrs. Molloy's condition

undertaken in the Labour Ward by Consultant Obstetrician Gynaecologist A at 08.39 hours until the time of Baby Mark's delivery at 09.31 hours i.e. in the order of 52 minutes was rather long in this situation.

Professor Morrison indicated that from the time the decision was taken to take Mrs. Molloy to Theatre for delivery of her baby at 09.00 hours to the time of delivery was 30 minutes which was broadly in line with relevant clinical guidelines.

In their feedback to the Review Team Mr. and Mrs. Molloy stated that it was their view that a decision was taken to proceed to a Caesarean Section for the delivery of Baby Mark at 08.45 hours and that Baby Mark was delivered at 09.31 hours; a period of 46 minutes.

Professor Morrison, upon a request from the Review Team, considered the issue again and stated that he had alluded to the timing issues related to the decision to take Mrs. Molloy to Theatre and the delivery of Baby Mark in his expert report. Professor Morrison also stated that he had simply stated in the report the times written in Mrs. Molloy's healthcare record and that he had not made a judgement on what times were actually correct.

Consultant Obstetrician Gynaecologist A indicated during the investigation that she arrived on the Labour Ward at 08.39 hours and spent approximately 10 minutes assessing Mrs. Molloy. Following the assessment Consultant Obstetrician Gynaecologist A indicated that she made the decision to bring Mrs. Molloy to Theatre and to reassess her there so that a definitive decision could be made on whether to proceed to an instrumental delivery or a Caesarean Section.

Consultant Obstetrician Gynaecologist A indicated that in the intervening time that she informed Mrs. Molloy of her plan of care, outlined the risks and benefits of the plan and that Mrs. Molloy signed a consent form in order to allow Consultant Obstetrician Gynaecologist A to proceed to an instrumental delivery or Caesarean Section.

Consultant Obstetrician Gynaecologist A indicated that following her assessment of Mrs. Molloy she went directly to a phone in order to contact the nursing staff in the Theatre Department to inform them of the plan of care for Mrs. Molloy so that they could prepare an Operating Theatre for an instrumental delivery or Caesarean Section.

Consultant Obstetrician Gynaecologist A indicated that Mrs. Molloy arrived in the Theatre Department at 09.05 hours at which time Consultant Obstetrician Gynaecologist A re-examined Mrs. Molloy. Following the examination Consultant Obstetrician Gynaecologist A made the decision to proceed to a Caesarean Section.

Baby Mark was delivered at 09.31 hours i.e. 26 minutes following the decision to proceed to a Caesarean Section which was in line with recommended best practice.

Consultant Obstetrician Gynaecologist A, Obstetrician Gynaecology Registrar A and Midwife D indicated during the investigation that it was their recollections that there were no delays in transferring Mrs. Molloy to Theatre or in delivering Baby Mark.

It was highlighted during the investigation that the Maternity Department in Portlaoise does not have a dedicated Operating Theatre in or adjoined to the Maternity Department and that consequently the department uses the Operating Theatres in the hospital's Theatre Department which is located on the first floor of the hospital. The Maternity Department is located on the second floor of the hospital.

The Royal College of Obstetricians and Gynaecologists document outlining their report on Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour states that an Operating Theatre dedicated for obstetrics should be close to the birth unit or preferably within it and that one Theatre should be provided for the birth of up to 4,000 babies a year.

Another issue that was highlighted during the investigation and which has the potential to impact on the quality and safety of care delivered to expectant mothers and their unborn babies in the Maternity Department related to the lack of dedicated theatre facilities for the Maternity Department, is that Midland Regional Hospital Portlaoise does not have the

facilities to monitor the foetus while the mother is being transferred to the hospital's Theatre Department on the floor below i.e. a portable CTG machine to be used during the transfer.

In light of the issues highlighted above it is a recommendation of this report that a risk assessment be carried out on the potential risk of injury to expectant mothers and their babies due to a lack of a dedicated Operating Theatre in or adjacent to the Maternity Department.

Recommendation:

- **That a risk assessment should be carried out on the potential risk of injury to expectant mothers and their babies due to a lack of a dedicated operating theatre in or adjacent to the Maternity Department.**

6.3.3.5 Incident Near Miss Report Forms completed in relation to Mrs. Molloy's delivery and the death of Baby Mark.

It is the policy of the HSE that all incidents shall be identified, reported, communicated and investigated[153]. Incidents that occur in HSE Dublin Mid-Leinster Midland Area which includes the Midland Regional Hospital at Portlaoise are reported on an Incident Near Miss Report Form.

The Review Team was informed that all Incident Near Miss Report Forms completed by the midwifery and nursing staff in the hospital are sent to the office of the Director of Nursing where they are entered onto a database of incidents reported by the midwifery and nursing staff. The Director of Nursing indicated that she maintains this database so that she can monitor/manage incidents that relate to midwifery and nursing staff in the hospital.

It was established during the investigation that four (4) Incident Near Miss Report Forms were completed by staff in the Midland Regional Hospital at Portlaoise in relation to Mrs. Molloy's delivery and Baby Mark's death.

Form No. 1
The first Incident Near Miss Report Form that was completed in relation to Mrs. Molloy's delivery and Baby Mark's death was completed by a Theatre nurse and this form was forwarded to the office of the Director of Nursing of the Midland Regional Hospital at Portlaoise where it was received on the 31st January.

The form was forwarded by the office of the Director of Nursing to the Dublin Mid-Leinster Quality and Patient Safety Service where it was received on the 8th February 2012. The Review Team was informed that the Dublin Mid-Leinster Quality and Patient Safety Service inputted all relevant information relating to Mrs. Molloy's delivery and Baby Mark's death onto the national Clinical Incident Reporting System maintained by the Clinical Indemnity Scheme[154] on the 10th February 2012. There is a legislative requirement that all incidents that occur in the HSE must be reported to the Clinical Indemnity Scheme[155].

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[153] HSE OQR006 Incident Management Policy and Procedure (Version 12; September 2008).
[154] 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).
[155] State Claims Agency (2009). The State Claims Agency Clinical Indemnity Scheme Incident Notification Requirements. Available form http://www.stateclaims.ie/ClinicalIndemnityScheme/publications/2009/SCACISIncidentNotificationReqs.pdf [accessed 7th March 2013].

Form No. 2
The second form that was completed in relation to Mrs. Molloy's delivery and Baby Mark's death was completed by Clinical Midwifery Manager II A on the 29th February 2012. This form was also sent to the office of the Director of Nursing. It was received by the office on 29th February 2012 and the form was forwarded to the Dublin Mid-Leinster Quality and Patient Safety Service. It was received by the Service on the 13th March 2012.

Forms No. 3 / 4
The Review Team was informed during the investigation that Consultant Obstetrician Gynaecologist A completed two Incident Near Miss Report Forms in relation to Mrs. Molloy's delivery and Baby Mark's death. The first form was completed by Consultant Obstetrician Gynaecologist A on the 24th January 2012 and the second form was completed on the 2nd March 2012.

The second Incident Near Miss Report Form completed by Consultant Obstetrician Gynaecologist A i.e. 2nd March 2011 indicates that the form was completed because the original form that she completed on the 24th January 2012 could not be located. It was also established during the investigation that while the Review Team obtained a copy of the second Incident Near Miss Report Form completed by Consultant Obstetrician Gynaecologist A on the 2nd March 2012 the Review Team were informed that the original form completed by Consultant Obstetrician Gynaecologist A could not be located.

The DML Quality and Patient Safety Service informed the Review Team that Incident Near Miss Report Forms completed by Clinical Midwifery Manager II A and Obstetrician Gynaecologist A were not reported on the national Clinical Incident Reporting System as Mrs. Molloy's delivery and Baby Mark's death had previously been reported to the system on the 10th February 2012; this is in line with standard practice i.e. that an event is only reported on one occasion onto the system.

While there is a HSE Dublin Mid-Leinster guideline in place related to incident reporting it was established during the investigation that the Midland Regional Hospital at Portlaoise do not have a local documented protocol in place for reporting, managing and escalating incidents that occur in the hospital. The Review Team was informed that a draft protocol on reporting, managing and escalating of incidents in the Midland Regional Hospital at Portlaoise has been completed as part of the hospital's Clinical Governance Development Project but that this protocol has not yet been finalised and signed off by the Hospital Governance Committee.

The Review Team notes that despite the absence of a local incident management protocol that staff did take appropriate steps to ensure that all relevant parties were notified of the events that had taken place.

Recommendation:

- **That the draft protocol for reporting, managing and escalation of incidents in the Midland Regional Hospital at Portlaoise is finalised and signed off by the Hospital Governance Committee as soon as possible and that the protocol is audited at least once a year thereafter.**

In their feedback to the Review Team Mr. and Mrs. Molloy asked why an Incident Near Miss Report Form had not been completed in relation to the tear to Mrs Molloy's uterus which occurred during her surgery.

The HSE define an incident as "an event or circumstance which could have, or did lead to unintended and/or unnecessary harm"[156].

[156] HSE (2009) HSE Quality and Risk Taxonomy as quoted in the HSE Guideline for System Analysis Investigation of Incident and Complaints (QPSD-GL-52-1.1 November 2012). Available from: http://hsenet.hse.ie/2nR39zw9qZ8xyZ%2fJ6AYiow%3d%3d/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/QPSDGL5211.pdf?ImportedResourceId=2nR39zw9qZ8xyZ%2fJ6AYiow%3d%3d {accessed 11th July 2013}

The tear that occurred to Mrs Molloy's uterus during her surgery was a known complication of her surgery and there was an increased risk of a uterine tear occurring due to the timing of Mrs. Molloy's surgery i.e. in the second stage of labour. Professor Morrison stated in his expert report that "The timing of the caesarean section, which finally occurred at full dilatation, is associated with a greater risk of a surgical tear and haemorrhage than caesarean section performed in the 1st stage of labour". In the literature Kreckler et al (2009)[157] indicates that surgical complications are unlikely to be reported as they are regarded as inevitable consequence of a high risk activity.

The Review Team formed the view that it was reasonable in this circumstance for the staff not to have completed a separate Incident Near Miss Report Form related to the uterine tear sustained by Mrs. Molloy and that in the context of Mrs. Molloy's care and management on the 24th January that the appropriate Incident Near Miss Report Forms were completed.

[157] Kreckler S., Catchpole K., McCulloch P., Handa A. (2009) Factors influencing incident reporting in surgical care. Quality Saf Health Care 2009; 18:116-120

7.0 Conclusion:

During the course of this review the care provided to Mrs. Molloy and her baby son on the 24th January 2012 was examined and two Care Delivery Issues were identified and these were;

- **Failure to recognise and act on the signs of foetal distress.**

- **Failure to fully assess all sections of the CTG resulting in a) the inappropriate prescribing and administration of Syntocinon and b) a delay in the decision to transfer Mrs. Molloy to the Theatre Department for an assisted delivery.**

As part of the analysis of Mrs. Molloy's and her baby son's care, the factors that contributed to the development of the Care Delivery Issues identified were examined and consequently a number of recommendations have been identified with the aim of eliminating or where this is not possible reducing the degree of harm associated with the factors that contributed to the Care Delivery Issues as far as is reasonably practicable.

In addition, questions highlighted by Mr. and Mrs. Molloy during the investigation up the time of completion of the report were also examined as part of the investigation. These questions were put to the relevant clinical experts and their responses have been included in this report.

As part of the investigation additional issues were highlighted that have the potential to impact on the quality and safety of care provided to expectant mothers and their babies. These issues have also been addressed in this report.

7.1 Urgent Follow up Post Review Required:

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

In order to ensure that the recommendations contained in this report are implemented as expediently as is reasonably practicable it is of the utmost importance that the relevant managers in the Midland Regional Hospital Portlaoise are convened at the earliest opportunity to agree a schedule of prioritisation of the recommendations and to further agree the named person who will take responsibility for advancing specific recommendations.

Appendix I

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Terms of Reference I (March 2012)

Strictly Private and Confidential

Complaint Review QPS 50069

Introduction

The purpose of this complaint review is to establish if any failures occurred in relation to the care, management and treatment delivered to Mrs Roisin Molloy and her infant son Mark at the Midland Regional Hospital Portlaoise during the period of her delivery on the 24th January 2012.

If failures are identified, a further purpose of the review is to identify the systems causes of these failures and the actions necessary to remedy these so as to prevent, or if prevention is impossible to reduce the likelihood of a recurrence of such failures as far as is reasonably practicable.

(For Mrs Molloy and her husband, this means that they have access to an explanation of the events leading up to the complaint/incident reported, the systems causes, and the actions identified to prevent a recurrence of these issues. For staff involved in the delivery of the services implicated in the complaint/incident reported, and for the HSE, this means that all possible learning is derived from the complaint/incident so that the risk of recurrence is eliminated or reduced and quality and safety is enhanced.)

This review will be undertaken in a spirit of openness and in keeping with the HSE's commitment to the development of a positive and supportive environment where learning is derived from all reported complaints/incidents.

1. Purpose of the Review

The purpose of the review into the circumstances surrounding Mrs Molloy's delivery on the 24th January 2012 and the death of Mr and Mrs Molloy's infant son Mark is to establish precisely what happened so that:

- A full and proper explanation of the events leading up to the complaint/incident can be given to Mr and Mrs Molloy.
- The Midland Regional Hospital Portlaoise and the Health Service Executive (HSE) can identify all lessons that can be learned from the experience such that the likelihood of a recurrence of the complaint/incident is removed or if this is not possible, is reduced as far as is reasonably practicable.

2. Scope (In time) of the Review

The scope in time of the review will be of a sufficient period to ensure that the purpose of the review as outlined in Section 1 above will be achieved. A finite time frame will be stipulated and adhered to unless good and valid reasons for extending this time frame become apparent during the review process.

For this review the scope in time will cover the period from the time of Mrs Molloy's admission to the Midland Regional Hospital Portlaoise on January 24th 2012 until the time that her infant son Mark was delivered at 09.31 hours and the confirmation of his death.

3. Review Team

The reviewers undertaking this review will be;

- Mr Kevin O'Malley, Risk Manager, DML Quality and Patient Safety Team
- Ms Annette Macken, HSE DML Regional Quality and Patient Safety Manager

The reviewers will work in close collaboration with the following representatives as required i.e. the Wider Review Team, who will give input to the formulation and implementation of recommendations precipitated by the review:

- Mr James Conway, Assistant National Director, Midland Hospital Group
- Ms Ann Delaney, Complaints Officer, Midland Regional Hospital Portlaoise
- Ms Jacqueline Mc Nulty, Hospital Manager, Midland Regional Hospital Portlaoise
- Dr John Connaughton, Clinical Director, Midland Regional Hospital Portlaoise
- Ms Maureen Nolan, Director of Nursing, Midland Regional Hospital Portlaoise
- Dr Miriam Doyle, Consultant Obstetrician/Gynaecologist, Midland Regional Hospital Portlaoise
- Ms Dolores Booth, Divisional Nurse Manager, Obstetrics and Gynaecology, Midland Regional Hospital Portlaoise

4. Review Method

The review method will follow the process set out in the HSE Incident Management Policy and Procedure (2008) and the Healthcare Risk Management Guidelines for Complaints and Incident Investigation (2011).

It will involve a review of all relevant documentation and interviews with all relevant personnel.

Hence, the review team will require copies of any documentation deemed appropriate to the completion of the review process and will also require facilitation in the conduction of interviews with relevant personnel.

The review will be conducted in a manner that is impartial and effective at achieving its purpose.

5. Review Report

Following completion of the review, an anonymised report will be prepared by the reviewers outlining the findings and identifying any actions required to remove or reduce as far as is reasonably practicable the risks identified by the review.

All who participated in the process will have the opportunity to give input into a final draft report in the interest of natural justice, and for the purpose of ensuring that the report is accurate and correct. Mr and Mrs Molloy will be provided with a draft copy of the Chronology section of the report to ensure that it is factually accurate from their perspective.

The Final Report when complete will be copied to the Wider Review Team i.e. those individuals outlined in Section 3 of this document. The Wider Review Team are also responsible for ensuring that the required actions identified in the report are valid and appropriate based on their area of competence/expertise.

It is the responsibility of those individuals who are in receipt of such copies to make them available on a read only basis to all staff in their area of responsibility who participated in the review process.

The Final Report will be shared with Mr and Mrs Molloy.

6. Implementation of the Recommendations of the Review:
The complaint/incident review report will include an action plan for the implementation of recommendations identified. It will be the responsibility of the Hospital Management Team and the wider Review Team identified in Section 3 of this document to ensure that recommendations contained in the review report pertaining to local management structures and issues are implemented appropriately and in a timely manner.

It will be the responsibility of the Assistant National Director, Midland Hospital Group to ensure that the recommendations that pertain to regional management structures and issues are implemented.

7. Communications Strategy for the Review.
A link person will be identified for the purpose of communicating information pertaining to the review to the person affected/complainant/family involved in the complaint/incident.

Ms Annette Macken, Regional Manager HSE DML, Quality and Patient Safety will be the link person with Mr and Mrs Molloy for the purpose of this review.

Bibliography:

- Healthcare Risk Management Guidelines HSEMARM006 (2009): *Complaints and Incident Management and Investigation Guidelines*
- HSE Incident Management Policy and Procedure ORR006 (2008)
- HSE Toolkit of Documentation to Support Incident Investigation (2009)

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Terms of Reference II (10 January 2013)

Strictly Private and Confidential

NIMT50069

Introduction

The purpose of this complaint review is to establish if any failures occurred in relation to the care, management and treatment delivered to Mrs Roisin Molloy and her infant son Mark at the Midland Regional Hospital at Portlaoise on the 24th January 2012.

If failures are identified, a further purpose of the review is to identify the systems causes of these failures and the actions necessary to remedy these so as to prevent, or if prevention is impossible to reduce the likelihood of a recurrence of such failures as far as is reasonably practicable.

For Mrs. Molloy and her husband, this means that they have access to an explanation of the events leading up to Mrs. Molloy's delivery and Baby Mark's death, the system causes, and the actions identified to prevent a recurrence of these issues. For staff involved in the delivery of services to Mrs. Molloy and Baby Mark, and for the Health Service Executive (HSE), this means that all possible learning is derived from the death of Baby Mark so that the risk of recurrence is eliminated or reduced and quality and safety is enhanced.

This review will be undertaken in a spirit of openness and in keeping with the HSE's commitment to the development of a positive and supportive environment where learning is derived from all reported complaints/incidents.

1. Purpose of the Review

The purpose of the review into the circumstances surrounding Mrs. Molloy's delivery and the death of her infant son Mark on the 24th January 2012 is to establish precisely what happened so that:

- A full and proper explanation of the events leading up to Baby Mark's death can be given to Mr and Mrs. Molloy.
- The Midland Regional Hospital Portlaoise and the HSE can identify all lessons that can be learned from the experience such that the likelihood of a recurrence of the complaint is removed or if this is not possible, is reduced as far as is reasonably practicable.

2. Scope (In time) of the Review

The scope in time of the review will be of a sufficient period to ensure that the purpose of the review as outlined in Section 1 above will be achieved. A finite time frame will be stipulated and adhered to unless good and valid reasons for extending this time frame become apparent during the review process.

For this review the scope in time will cover the period from the time of Mrs. Molloy's admission to the Midland Regional Hospital Portlaoise on January 24th 2012 until the time that her infant son Mark was delivered and the confirmation of his death at 09.53 hours.

The investigation report will also make reference to a meeting that took place between Mr and Mrs. Molloy and the Midwifery Manager of the Maternity Department at the Midland Regional Hospital at Portlaoise on the 31st January 2012 when Mr and Mrs. Molloy highlighted a number of concerns that they had in relation to Mrs. Molloy's and Baby Mark's care and management.

Mr and Mrs. Molloy also requested that the investigation report would cover a number of specific issues that related to Mrs. Molloy and her infant son's care and management, these issues are outlined below:

1 Should the Consultant Paediatrician have been present when the baby was delivered 'considering (my) records state that baby's heart rate was non-reassuring and also the Consultant Obstetrician's statement that they knew they would be delivering a very sick baby''?
2 Should a nurse from the Special Care Baby Unit have been present at the time of delivery?
3 Should the patient have been induced earlier given her due date (15th January) the 'size of the baby, the fact that he was face-up and her past history.
4 Did the delay in sectioning the patient compromise the patient's safety and health; Mrs. Molloy received an injury during the C-section; how and why was this injury sustained?

The investigation report will cover these issues.

3. Review Team
The reviewers undertaking this review will be;

- Mr Kevin O'Malley, Risk Manager, DML Quality and Patient Safety Team
- Ms Annette Macken, HSE DML Regional Quality and Patient Safety Manager

The reviewers will work in close collaboration with the following representatives as required i.e. the Wider Review Team, who will give input to the formulation and implementation of recommendations precipitated by the review:

- Mr. James Conway, Assistant National Director, Midland Hospital Group
- Ms. Ann Delaney, Complaints Officer, Midland Regional Hospital Portlaoise
- Ms. Jacqueline Mc Nulty, Hospital Manager, Midland Regional Hospital Portlaoise
- Dr. John Connaughton, Clinical Director, Midland Regional Hospital Portlaoise
- Ms. Maureen Nolan, Director of Nursing, Midland Regional Hospital Portlaoise
- Ms. Dolores Booth, Divisional Nurse Manager, Obstetrics and Gynaecology, Midland Regional Hospital Portlaoise

The following external clinical advisors will give input to the clinical aspects of the review:
- Professor John Morrison, Head of Department of Obstetrics and Gynaecology National University of Ireland, Galway/Consultant Obstetrician Gynaecologist, Galway University Hospital
- Ms. Sheila Sugrue, National Lead Midwife HSE/Adjunct Senior Lecturer, School of Nursing, Midwifery and Health Services UCD.
- Dr.. John Murphy, Consultant Neonatologist, National Maternity Hospital, Holles Street, Dublin.
- Dr. Miriam Harnett, Consultant Anaesthetist, Cork University Hospital, Wilton, Cork.

4. Review Method
The review method will follow the process set out in the HSE Incident Management Policy and Procedure (2008) and the Healthcare Risk Management Guidelines for Complaints and Incident Investigation (2011).

It will involve a review of all relevant documentation and interviews with all relevant personnel.

Hence, the review team will require copies of any documentation deemed appropriate to the completion of the review process and will also require facilitation in the conduction of interviews with relevant personnel.

The review will be conducted in a manner that is impartial and effective at achieving its purpose.

5. Review Report
Following completion of the review, an anonymised report will be prepared by the reviewers outlining the findings and identifying any actions required to remove or reduce as far as is reasonably practicable the risks identified by the review.

All who participated in the process will have the opportunity to give input into a final draft report in the interest of natural justice, and for the purpose of ensuring that the report is accurate and correct. Mr and Mrs. Molloy will be provided with a draft copy of the Chronology section of the report to ensure that it is factually accurate from their perspective.

The Final Report when complete will be copied to the Wider Review Team i.e. those individuals outlined in Section 3 of this document. The Wider Review Team are also responsible for ensuring that the required actions identified in the report are valid and appropriate based on their area of competence/expertise.

It is the responsibility of those individuals who are in receipt of such copies to make them available on a read only basis to all staff in their area of responsibility who participated in the review process.

The Final Report will be shared with Mr and Mrs. Molloy.

6. Implementation of the Recommendations of the Review:
The complaint/incident review report will include an action plan for the implementation of recommendations identified. It will be the responsibility of the Hospital Management Team and the wider Review Team identified in Section 3 of this document to ensure that recommendations contained in the review report pertaining to local management structures and issues are implemented appropriately and in a timely manner.

It will be the responsibility of the Assistant National Director, Midland Hospital Group to ensure that the recommendations that pertain to regional management structures and issues are implemented.

7. Communications Strategy for the Review.
A link person will be identified for the purpose of communicating information pertaining to the review to the person affected/complainant/family involved in the complaint/incident.

Ms Annette Macken, Regional Manager HSE DML, Quality and Patient Safety will be the link person with Mr and Mrs. Molloy for the purpose of this review.

Bibliography:

- Healthcare Risk Management Guidelines HSEMARM006 (2009): *Complaints and Incident Management and Investigation Guidelines*
- HSE Incident Management Policy and Procedure ORR006 (2008)
- HSE Toolkit of Documentation to Support Incident Investigation (2009)

Appendix II: External Expert Reports

External report 1: Report from Ms Sheila Sugrue, National Lead Midwife, HSE Nursing and Midwifery Planning and Development Unit

Report of Findings following a Review of Clinical Records
NIMT 50069

Introduction

A request for an external independent midwife to be nominated via the NIMT to contribute to an investigation was forwarded to Dr. Michael Shannon, Director of Nursing and Midwifery Services on May 15th 2012. I was nominated as HSE Midwifery Lead, to this case and I agreed to provide the external review.

Purpose of the Review: The purpose of the review into Mrs X's labour on January 24th from the time of her admission to the hospital to the time of her transfer to the Operating Theatre, is to establish precisely what happened from a midwifery perspective during the care and management of this woman and her baby.

Review Method: I was provided with an anonymised copy of the clinical notes and a number of segments of CTG tracings from that labour (sent on June 5th 2012) and this report is based on those documents. In the notes I examined the Obstetric history, the pregnancy and the account of the woman's labour from admission to the hospital on the 24th January 2012 until her transfer to the operating theatre. As this case is known to have had an adverse outcome, hindsight bias could be applied to my findings which are presented within the report.

Relevant History: This woman, a 37 year old Para 4+2 has four boys ranging in age from 2 to 12 years of age. All the children weighed between 8lbs 5oz and 8lbs 14 oz at birth. The first 3 babies were all delivered by Vacuum extraction. No reason was provided but it may be significant as regards management of current labour and birth. However last birth was a spontaneous vaginal birth which may have reassured the clinicans as to the adequacy of the pelvis. This woman is 5ft 2 in stature and her BMI was not recorded.

Pregnancy

This woman complained of body itch during pregnancy and Liver Function Tests were found to be normal. Ultrasound x 3 indicate a very good sized baby with abdominal circumference plotted on the upper centile of the U/S graph indicating that the size of the baby is at least as big as her previous infants.

Labour: Chronology of events

The following is the chronology of events as they occurred from admission to the hospital until transfer to the Operating Theatre on the **24.01.12**.

04:15: Vaginal examination performed – in labour and cervix dilating with a high head – not unusual in a multigravida. B/P on admission 141/86 (baseline B/P)

05.05: Admitted to Labour Ward at Term +9. Had been booked for induction on the 24th, but she went into spontaneous labour. An epidural was requested. Notes recorded CTG trace commenced and it was noted to be reassuring

06.27 Epidural sited. B/P after procedure completed 104/66 at 06.27 and 101/52 at 07.30

06.35 Urge to push noted. Vaginal examination (VE) performed, Cervix 8 cms dilated. Not in 2nd stage, therefore discouraged from pushing. Artificial Rupture of membranes performed and found to have a good volume of Grade 1 Meconium stained liquor. Late decelerations noted and treatment to correct same commenced. It would have been expected that a fetal scalp electrode was applied at this VE so the CTG tracing is of good quality (better contact). If this was done it was not recorded

07.00 urge to push still strong – discouraged. No record of a VE done at this stage

07.15: Notes state CTG was reassuring

07.30 VE now performed and cervix found to be dilated 9+ cms. No meconium

noted at this point, but recorded as slight blood stained liquor recorded. This alongside a poor CTG might indicate Gr 3 or "thick meconium" ie. worsening fetal distress requiring urgent attention. Urinary Catheter inserted with no urinary output. Also B/P at this time much lower than baseline 101/52 – may have adverse effect on fetal heart. I/V fluids given which was appropriate. No further B/P recordings noted for the rest of the time.

07.35: Allowed to commence active pushing
07:45: Recorded in the notes for the first time "a big baby"
07.47: Called Assistance
07: 55: Assistance arrived – seems from notes to be Registrar.
Now a Doctors Case. CTG noted as unsatisfactory, poor descent of the head and not sure of position of baby. Plan review 15 mins
08:15 Commenced Syntocinon infusion
08:20 For trial of Instrument or C/S in theatre
08:25 informed Consultant – to review
0900 Reviewed by Consultant –deflexed occipito posterior position, for immediate transfer for C/S
09:16 ??? Time of Birth. Possibly delivered 1 hour and 41 mins after commencing active pushing and 1 hr 21 mins after first review by a doctor. Operation Sheet not included to note length of time from decision to scalpel and then to birth of baby.
Condition at birth provided. Difficulty or ease of delivery of head at C/S not noted.
It was noted that there was poor response to first emergency call. Emergency bell activated a second time. Response time not noted in the records

CTG
There are 4 strips of CTG and each tracing is reported on in order as follows

1. **24 Jan 2012: 05:10.28- 05:27** when transferred to Labour Ward, requesting Epidural. In my opinion there is poor variability, baseline 130 b.p.m. with no decelerations

2**. 24 Jan 2012: 05:39.17 - 06:00** + stopped not documented why on trace. It could be concluded that this was the time of insertion of Epidural. There would appear to be a 20 minute gap between tracings and intermittent auscultation of the fetal heart was used and documented. Continuous fetal monitoring of the fetal heart could be maintained if a fetal scalp electrode was attached to the baby's scalp and attached to the monitor. It would have provided better quality tracing. This was not done.
CTG recommenced 06:26 until 06:50-06:55.
At 06:31 FH decelerations noted. Placed on left lateral position and quick fetal heart recovery noted.

3. **24 Jan 2012 recommenced at 06: 58.49 until 08:40**.
07.15: Early decelerations noted in the chart, woman in left lateral position and CTG recorded as reassuring, though woman is noted to 'remain very anxious'
08:08 : Commenced Syntocinon infusion (usually used to accelerate labour) @30 mls per hour increasing to 60 and to 90. Tracing continues to show ever increasing decelerations. There is no record of who ordered Syntocinon. It was however commenced shortly after the doctor came to assess the woman.
08:40 Syntocinon discontinued when Consultant came to review
09.00 Transferred to OT (Operating Theatre)

4. **09:10 – end time not documented.** There appears to be loss of contact therefore unable to comment on status of fetal heart at that time or indeed if it was present.

CTG Findings:
I have reviewed all four segments of CTG tracing and note that in the presence of meconium stained liquor I would not find three (1-3) tracings reassuring. I am unable to comment on the fourth segment.

It is recommended in the Practice Guideline for Midwives (2010) that the midwife practises in accordance with the scope of midwifery practice and develops and maintains ongoing competence. Regular updates in core areas of midwifery practice include fetal-monitoring, both intermittent auscultation and CTG trace interpretation. The Centres of Nursing and

Midwifery Education provide ongoing education for all midwives in this area. In some units midwives are expected to update their skills every 2 years

Findings
There are a number of issues apparent that in hindsight could have been done differently. I believe a number of key signs were missed

1. Relevant History: This woman's obstetric history along with her stature of 5ft 2 inches should have prompted a care pathway to be put in place in the event of need for similar methods of delivery so that earlier action might have been taken.

2. Pregnancy
Serial ultrasounds show a big baby whose abdominal circumference was plotted on the upper centile. A large baby should have been expected and together with her previous obstetric history a difficult 2nd stage might have been anticipated

3. Fetal Heart Recordings:
Although the CTG tracing was reported as being reassuring throughout the labour, it is my opinion that fetal distress was worsening from around 06:30hrs of Jan 24th 2012. Another sign of fetal distress was the presence of Grade 1. meconium at ARM (06:35) with no further recording of meconium after that time. This may be indicative of "thick meconium" or Grade 3 requiring urgent attention. An experienced midwife would have anticipated this and called for assistance possibly at an earlier point in time. I suggest that an Obstetrician should also review the CTG traces.

4. Progress in the 1st and 2nd stage of labour
Progress in labour is measured by an increase in length, strength and frequency of contractions accompanied by dilatation of the cervix and appropriate descent of the head or presenting part. Position of the head was not recorded on any of the vaginal examination recordings although there is a space set aside for it. Position was obviously difficult to determine but that should have raised the alarm so that a doctor might be asked to review earlier. The Doctor however did note that the presentation was high at this examination and the head was recorded as being in a deflexed op (occipito-posterior) position at 09.00 hrs. This would indicate obstructed labour and account for the lack of progress in the 2nd stage and the accompanying fetal distress.

The second stage commenced at 07.35 but as the time of birth was not available (in the notes reviewed), the length of 2nd stage is not completely known but it is known that the woman was in Theatre at 09.16. This indicates that length of 2nd stage was at least 1 hour and 56 mins. Second stage in a multigravida lasts on average 30 minutes. One would expect the head to descend within 30-40 minutes of active pushing, with regular strong contractions unless there was an obstruction of labour, which turned out to be the case. Active pushing began at 07.35 hrs. The midwives sought assistance within 12 min when there was no progress noted and that is to be commended.

However there is no doubt that earlier recognition of obstructed labour would have led to the midwife calling for assistance earlier. It is difficult to determine if the outcome would have been any more positive with the undoubted delays following the arrival of assistance.

5. Record Keeping:
- CTG paper requires commentary if and when the tracing is stopped and transferred to intermittent auscultation and a rational should be provided. When an intervention such as insertion of epidural or commencement of syntocinon is conducted it should be recorded so that any fetal reaction is noted.
- Vaginal Examination recordings incomplete
- Partogram – descent of the head not recorded
- Notes written around the time of delivery require timelines and as it was a retrospective note none seemed to be available. Such gaps in the records leave a number of questions around delay in resuscitation as it was apparent that response to an emergency call out had to be activated twice. However we do not know how long the response took, or indeed if it would have changed the outcome. The weight of this baby is not provided but should be considered.

Recommendations

A number of recommendations could be inferred from examining this case.

- A care plan for a woman's labour should have been designed and discussed during pregnancy especially if there are complications noted in the history at the booking visit.
- The Midwife has a responsibility to develop and maintain ongoing competence to provide safe an effective midwifery care (An Bord Altranais July 2010). All midwives should undergo regular mandatory CTG Interpretation training. There should be at least one experienced midwife on each shift with up to date knowledge and skills.
- Effective record keeping is an integral part of midwifery practice and midwives are accountable for the quality of their record keeping (An Bord Altranais July 2010). Record keeping in this instance requires improvement. All aspects of a vaginal examination should be completed after each examination. The tool used should be commended but not all sections were completed and the partogram should be used appropriately.
- The provision of continuous professional education for midwives is paramount in the provision safe evidenced based care to women and their babies.

Conclusion

It is my view that there were a number of delays in diagnosing obstructed labour in the first stage of labour. This led to delay in seeking medical assistance. Once the obstruction was recognised in the second stage of labour assistance was immediately sought by the midwife. However the baby was not delivered for almost 2 hours after 2nd stage was confirmed. Records are also poorly utilised and a number of omissions were noted throughout the labour. A number of tools existed to assist with maintaining accurate records but they were not fully utilised or completed.

References

An Bord Altranais. July 2010, *Practice Standards for Midwives* An Bord Altranais

Abbreviations

Abbreviations/ Terms	**Definition**
Cervix	Neck of the Womb
CTG	Cardiotocograph.
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
Intermittent Auscultation	Listening to the fetal heart intermittently (15 min intervals) with a hand held Pinnards (listening device) or sonicaid (machine)
Labour 1st stage **Labour 2nd stage**	From the onset of strong regular contractions until the cervix is fully dilated From full dilatation to birth of the baby
Meconium	Description of the liquor or water around the baby. They are green in colour and indicate fetal distress. They are classified in different grades, grade 1 being the least severe
Multigravid	A woman who has 2 or more pregnancies.
Partogram	As per page 39 of the Clinical Notes. It provides an instant picture of the labour and its progress
Registered Midwife:	***"****A registered midwife is a person who, having been regularly admitted to a midwifery educational programme …has acquired the requisite qualifications to be registered and/or legally licensed to practise midwifery…"* (Adopted by ICM, July 2005) and is considered competent to provide care in pregnancy, childbirth and the postnatal period.
Syntocinon	An oxytocic drug added to an i/v infusion to induce or augment labour
U/S	Ultrasound or Scan
Vacuum Extraction	Instrumental delivery often performed instead of a Forceps delivery

External report 2 (a): Report from Professor John Morrison, Consultant Obstetrician Gynaecologist submitted to the Reviewers on the 2nd October 2012.

Medical Investigative Report

Report Re: **HSE Reference 50069 / Information related to Faculty Request**
For External Expert Clinical Input

Report Re: **Obstetric care provided to Patient X at Hospital 1.**

Report prepared by:
Professor John J. Morrison MD FRCOG FRCPI BSc BCH
Professor of Obstetrics & Gynaecology
Consultant Obstetrician & Gynaecologist / RCOG Sub-Specialist in Feto-Maternal Medicine
HSE and National University of Ireland, Galway.
Galway University Hospitals

Professor Morrison has been a Consultant Obstetrician Gynaecologist and a sub-specialist in Feto-Maternal Medicine at Galway University Hospital since 1997. His clinical commitment includes general obstetrics & gynaecology, but with a special emphasis on disorders of pregnancy, high risk obstetrics, disorders of labour, preterm labour, operative delivery, fetal abnormalities, and multiple pregnancy. In addition to Consultant accreditation in Obstetrics and Gynaecology, he has completed a 2 year sub-specialist training programme to be an accredited Royal College of Obstetricians and Gynaecologists Feto-Maternal Sub-Specialist. He has more than 250 publications in total including approximately 110 original peer review manuscripts listed on Pubmed / Medline between 1995 and 2012. These manuscripts have been published in international journals of high impact factor including the Lancet, British Journal of Obstetrics & Gynaecology, American Journal of Obstetrics & Gynaecology, Reproductive Sciences, Biology of Reproduction, Obstetrics & Gynecology, Journal of Perinatal Medicine, American Journal of Perinatalogy, Irish Medical Journal, European Journal of Obstetrics & Gynaecology & Reproductive Biology, and others. He is a member of, or has served on, numerous national and international committees pertaining to clinical practice, research, and education in Obstetrics & Gynaecology. He is a member of the Executive Committee, the Standing Committee and the Specialty Training Committee, of the Institute of Obstetrics & Gynaecology, Royal College of Physicians of Ireland. He has also served as External Examiner and assessor for Universities throughout the island of Ireland , the UK, Europe and Australia.

This report was prepared at the request of:

Mr Kevin O'Malley,
Health Care Risk Manager,
Quality and Patient Safety Service HSE DML
Unit 4
Central Business Park,
Clonminch,
Tullamore,
Co Offaly.

This report was prepared using the following documentation:

1. Copy of anonymised healthcare records of the patient referred to in the Terms of Reference for the investigation HSE 50069
2. Information in hindsight bias
3. List of specific questions that the patient and family have requested that would be addressed as part of the investigation.

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ANTENATAL HISTORY

Patient X was booked for antenatal care at Hospital 1 on 22nd August 2011 at 19 weeks gestation in this pregnancy. She had previously delivered four infants vaginally at term, in 2002, 2004, 2007 and 2009. These deliveries had all taken place in Hospital 1. All of her infants had weighed between 8 lbs and 9 lbs, and for three of these deliveries, the infant was delivered with the assistance of vacuum or ventouse. The estimated date of delivery was 15th January 2012. The clinical details documented in relation to the booking antenatal visit were normal or unremarkable. Patient X was subsequently seen at Hospital 1 for antenatal visits at 30 weeks gestation, and 34 weeks gestation, on 9th November 2011 and 7th December 2011 respectively. All was deemed to be progressing well in the pregnancy. It is evident from the ultrasound documents that scans were performed in the third trimester at 34^{+}, 37^{+} and 40^{+} weeks gestation, all of which revealed the fetus to be growing on a line above the 50th centile for gestation. On 29th December 2011, at 37 weeks gestation, the estimated fetal weight was deemed to be 3.1 kg and it is stated that Patient X wished to have a sweep performed. Subsequent visits to the antenatal clinic took place at 39^{+3} and 40^{+3} weeks gestation, and all was progressing normally. At the final antenatal visit, on 18th January 2012, induction of labour was arranged to take place on 24th January 2012, when Patient X would have been 40^{+9} or 41^{+2} weeks of gestation.

Commentary

The above outline describes a relatively normal antenatal history for Patient X in this pregnancy. Of note is the fact that she had four previous children, but also had two previous miscarriages. All of her previous infants weighed what appeared to be above the 50th centile for gestation, and in three previous pregnancies the delivery was assisted with ventouse or vacuum instrumental delivery. There is nothing remarkable about these features. The reasons why one might need delivery to be assisted with vacuum can vary significantly from one patient to the next. There was good clinical and ultrasound surveillance of the pregnancy in the antenatal period, and in compliance with standard practice, induction of labour was scheduled for 41^{+2} weeks gestation.

LABOUR

On January 24th 2012, sometime after 04.00 hours, it is apparent that Patient X had a show and started getting labour pains or contractions. The exact time Patient X presented to Hospital 1 is unclear, as the records from Patient X have stated that she left home sometime after 04.30 hours and arrived at approximately at 04.50 hours. However there is a vaginal examination in the hospital notes that was apparently performed at 04.15 hours. In any case, at some point in time at approximately between 04.15 and 05.00 hours on January 24th 2012 Patient X was admitted to Hospital 1 and assessed. It is apparent that at the time of admission Patient X was requesting epidural analgesia. It is clear from the assessment documented that she was in labour, with cervical dilatation of 3 cms, a cephalic presentation and the station of the head at – 2 (i.e. 2cm above the ischial spines.

Commentary
Patient X was in labour with the cervix 3 cm dilated and the head at – 2 station. These findings are typical of those commonly observed in a parous woman (i.e. a woman who has had children previously), admitted in labour.

The Cardiotocorgram (CTG) was commenced at 05.09 hours. The CTG tracing I have received is in four separate components albeit they may have been continuous on the original recording. The initial CTG recording extends from 05.09 house to 05.27 hours. The baseline rate was 130 beats per minute with reduced beat to beat variability and no episodes of reactivity.

Commentary
While there were some issues that required observation in this first segment of the CTG, it was for a relatively short period of time (18 minutes). A longer segment of recording is necessary to properly evaluate the situation. It was appropriate to continue with this recording and observe it throughout the labour.

The CTG recording was next initiated at 05.39 hours, and between that time and 06.30 hours, the baseline rate was 130 beats per minute with good beat to beat variability and episodes of reactivity present. It is also evident from the CTG that Patient X was having uterine contractions approximately every 4 – 5 minutes. At 06.05 hours the Anaesthetic Registrar was contacted. He duly arrived at 06.15 hours and at 06.27 hours an epidural was sited for analgesia.

Commentary
The outline above describes a normal sequence of events for a woman in early labour in these circumstances. She was contracting regularly. The CTG was overall satisfactory by the time of 06.30hours, despite the slight concerns relating to the first 18-minute segment of recording. By the time she was approximately 1½ hours in the hospital an epidural had been arranged and sited. All of these features constitute a standard level of care.

Starting at the time of 06.33 hours there were decelerations evident on the CTG. Between 06.33 hours and 07.15 hours there were numerous decelerations, some early in nature, some late and some variable. These decelerations occurred down to a rate of 70 – 80 beats per minute. It is also clear from the documentation that Patient X had an urge to push during this time period. She was reassessed at 06.40 hours and artificial rupture of the membranes was performed revealing grade 1 meconium stained liquor. The cervix was then 8cm dilated and the fetal head was at station of -2. It is stated that the contractions were strong. It is stated that at 07.15 Patient X was discouraged against pushing, albeit there is documentation in the chronology of events stating that this was not the perception that Patient X had of events. It appears from the chronology of events that on occasions when it is stated in the notes that Patient X was discouraged from pushing that her interpretation was that she was being encouraged to push.

Commentary

From 06.33 hours the CTG was abnormal. Some decelerations occurred with the contractions (early) and some occurred independent of the contractions (late) and others displayed a mixture of these two features. There was also meconium staining of the amniotic fluid. Patient X was 8 cm dilated. It is my view that at some period of time shortly after 06.33 hours, and certainly by 06.50 hours, that the midwife should have requested that the Obstetric Registrar review the trace and the overall clinical situation. Fetal blood sampling would have appropriate at this stage as she was 8cm dilated with significant decelerations evident on the CTG. I am unable to comment about the exact sequence of events that occurred in relation to pushing, but am of the view that this matter did not have a significant bearing on the final outcome.

Between 07.15 hours and 07.40 hours, the baseline CTG rate was 140 beats per minute and there was good beat to beat variability. There were four decelerations between 07.40 hours and 07.50 hours, down to a baseline rate of 80 – 90 beats per minute. At 07.35 hours, when Patient X had a strong urge to push, vaginal examination was performed by the midwife and she was deemed to be fully dilated with the station of the head at – 1 to -2. At 07.40 hours it is stated that Patient X was pushing well, and that there was no descent of the presenting part. At 07.45 hours the decelerations are described, and documented, in the written notes by the midwife. At what appears to be 07.47 hours, (albeit some controversy about this exact time) the Obstetric Registrar was contacted and requested to come and review the CTG trace.

Commentary

While the CTG trace was briefly better between 07.15 hours and 07.40 hours, it was clear by 07.45 hours that the trace had become abnormal once again, and on this occasion the Registrar was requested to review the trace.

At 07.55 hours the Obstetric Registrar was present. It is apparent that patient X was in lithotomy, presumably in stirrups, and was essentially in the second stage of labour and pushing. It is evident from the midwifery documentation, and the chronology of events, that the Registrar requested that a catheter be inserted in her bladder. At 07.55 hours Registrar A has documented, in a retrospective note (written at 11.30 that morning), that the CTG was 'unsatisfactory' and that the Patient was pushing for 30 minutes prior to that. In the communications I have received it is apparent that the initial entry by the Registar which described the CTG as 'satisfactory', was later altered to 'unsatisfactory (non-reassuring)'. The Registrar has documented that Patient X was fully dilated, and it is clear that the Registrar was unsure about the position of the fetal head, but questioned that it may have been left occipito-anterior. At 08.15 hours it is documented (by the midwife) that Syntocinon was to be commenced as per the instructions of the Obstetric Registrar. It was commenced at 08.15 hours at a rate of 30 mls per hour.

Commentary

The Registrar A has not made any prospective documentation in relation to their assessment and decision pertaining to the care of Patient X when they reviewed the case at 07.55hours. However it can be gleaned from the midwifery notes, and from the retrospective note (albeit this note is incomplete) that the Registrar examined Patient X, requested that a catheter be inserted to empty the bladder, and ultimately made a decision to commence a Syntocinon infusion. It is surprising that a catheter was not already in situ in the bladder considering that the epidural was inserted at 06.27hours. It can only be presumed that Registrar A felt that a full bladder might be hindering progress. In addition, this Registrar felt that it was appropriate to augment the contractions with Syntocinon in order, presumably, to achieve a vaginal delivery. It is my view that this decision to commence Syntocinon was wrong, and this decision should not have been made in these circumstances. In the first instance, Patient X had progressed quickly to full dilatation, and hence there was no need or clinical indication to augment the labour with Syntocinon. Secondly the contractions on the tocogram were regular and satisfactory. Thirdly, one has to be careful using Syntocinon in a parous woman in this situation. Fourthly, and most importantly, the CTG was markedly abnormal over the previous period of at least 1½ hours, and it was incorrect and inappropriate to commence a Syntocinon infusion in this situation. There is no reference to the Syntconin infusion in the retrospective note made by the Registrar, but the midwife has documented at 08.15hours that it was started 'as per' the instructions of the Registrar. As a separate matter, the failure of the Registrar to make prospective notes at the time of review of the patient, and the possibility that the retrospective note made by that doctor at 11.30am that day was later altered, are serious matters for clinical governance.

The rate of infusion of the Syntocinon drip was increased to 60 mls per hour at 08.25, and to 90 mls per hour at 08.31 hours. It appears that Patient X continued with pushing during this period of time. At approximately 08.25 - 08.30 hours, Patient X had been pushing for an hour in the second stage of labour. The written entry by the Registrar in the retrospective note (for 08.20 and 08.25 hours) is not easily consistent with the prospective notes made by the midwife. The midwife has outlined that the Syntocinon infusion was increased at the Registrar's instructions, while the Registrar does not refer to Syntocinon, but states a decision to go to theatre at 08.20 hours for trial of instrumental delivery or caesarean section. In any case, at some time between 08.30 hours and 08.39 hours (there is confusion about the exact time) the Consultant Obstetrician Gynaecologist A was contacted. It is likely that Consultant Obstetrician Gynaecologist A was present on the labour ward by 08.39 hours. The patient was assessed by Consultant Obstetrician Gynaecologist A and deemed to be fully dilated with the position of the fetal head occipito posterior (OP), and deflexed, and the station was described as being – 1. A plan was made to transfer patient X to the operating theatre to decide whether delivery would be possible with instrumental assistance (vacuum or forceps), or whether a caesarean section was necessary. The Syntocinon infusion was discontinued at 08.45 hours.

Commentary

The inconsistencies between the prospective notes made by the midwife, and the retrospective documentation entered by the Registrar, are a matter of concern. By the time the consultant was contacted the woman had an abnormal CTG and was more than one hour pushing in the second stage of labour. It is evident from the findings described that the baby was in an unfavourable position for vaginal delivery in terms of being OP and deflexed, with the station remaining at – 1, i.e. 1 cm above the ischial spines. It was appropriate to decide to bring the woman to theatre to expedite delivery by the safest means possible. It is also my view that this line of approach should have been embarked upon earlier than the time of 08.30 hours. Finally, while the exact timing of the decision to go to theatre is unclear, it is my view that this decision was very likely to have been made at 08.45 hours, i.e. when the Syntocinon was discontinued, or shortly thereafter.

The Consultant's written entry in the notes was made at 09.00 hours, but reading the other documentation attached it would appear that this decision to transfer Ms X to the operating theatre was made at approximately 08.45 hours, at which time the Syntocinon was discontinued, or shortly thereafter. It is documented that the Consultant was present at 08.39hours. During that period of time between 08.45 hours and 09.00hours the CTG showed a baseline rate of 110 beats per minute with decelerations and poor beat to beat variability.

Commentary

The timings are always critical in a case like this. It is not clear what level of urgency was presented in the telephone call contact to the Consultant. However the Consultant was contacted at 08.30 hours, and presented on the labour ward at 08.39 hours, which represents a timely attendance. It appears to have taken 21 minutes for the Consultant to review the case, and to transfer the patient to a trolley for transfer to the operating theatre.

At 09.07 hours it is documented that Patient X was in the operating theatre and transferred onto the operating table. The consultant Gynaecologist A was present and carried out a repeat vaginal examination in theatre and outlined similar findings to those documented. It was deemed that Patient X was not suitable for vaginal delivery and hence a decision made for caesarean section. Between 09.07 hours, and 09.15 hours, preparations were being made in the operating theatre to initiate the caesarean section. At 09.15 hours it is documented that it was difficult to auscultate the fetal heart. The CTG recording that is available from the operating theatre, which commenced at 09.10 hours, is very abnormal. The baseline rate is 80 beats per minute. There is a very intermittent recording up to approximately 09.17 hours. It is apparent that the midwife also listened using the Doppler sonicaid instrument at 09.16hours and questioned that the heart rate was approximately 90 beats per minute ('?90bpm'). In any case it is evident that in the operating theatre the fetal heart rate was low indicating significant fetal distress from the point of initiation of monitoring at 09.10hours. The infant was ultimately delivered at 09.31 hours.

Commentary

It is my view that the period of time from assessment in the labour ward by the Consultant (08.39 hours), to final delivery of the infant (09.31hours), which was in the order of 52 minutes, was rather long in this situation. However, having said that, the final decision for delivery is documented in the notes at 09.00hours, and the delivery took place at 09.31 hours. Clinical guidelines suggest that a time period of approximately 30 minutes, from decision to delivery, should be aimed for in Category 1 or urgent caesarean sections (Reference 1). In this situation, where the decision for delivery for Patient X was documented at 09.00 hours, this guideline was broadly speaking adhered to.

NEONATAL HISTORY

It is apparent that the infant was extremely flat at birth and there was no heart rate easily audible. The Paediatric Registrar was present at the time of the birth and immediate resuscitation began. The resuscitation was aided by the Consultant Anaesthetist. The Apgar score was zero at 1 minute and zero at 5 minutes. There was debate about whether or not a heart beat was heard at one point, which may have occurred, but the exact answer to this is unclear. Attempts were made to intubate the baby, and it was noted that there was no meconium below the vocal cords. The initial trial at intubation was unsuccessful but the infant was successfully intubated after four minutes and thirty seconds. The Consultant Paediatrician arrived at 5 minutes of age. Full resuscitation was applied including two doses of Adrenaline. No heart rate or respiratory effort were observed. An umbilical vein catheter was inserted infusing saline and adrenaline again. After 25 minutes of resuscitation the baby still had no heart rate and the resuscitation was abandoned. The Consultant Paediatrician discussed the matter with Patient X's husband.

Commentary

The consensus is that the baby was dead at delivery and obviously had just recently died. This is called a fresh stillbirth. There can occasionally be a period of time when intermittent beating of the heart can be heard at a very low rate in the minutes following a fresh stillbirth. Whether or not this was heard on this occasion is unknown. What is entirely clear is that the baby was essentially dead on delivery and it was not possible to resuscitate him to any successful degree. There are no umbilical cord vessel pH values documented in the notes as far as I could ascertain.

CAESAREAN SECTION AND POSTPARTUM HISTORY

It was apparent at the caesarean section that there was a tear to the lower uterine segment after delivery of the infant. The placenta was delivered but Patient X continued to bleed from the right hand side of the uterus. The apex of the tear was identified and the right uterine vein was identified and ligated. Consultant Obstetrician Gynaecologist A requested that Consultant Obstetrician Gynaecologist C would scrub in for a second opinion, and the procedure was gradually completed. Patient X was treated with intravenous Oxytocin, and transferred to a high dependency area (either intensive care

unit or coronary care unit) for follow-up. She was also treated with Cytotec to control the postpartum haemorrhage. It appears that over the course of 24th and 25th January 2012 Patient X received six units of Red cell concentrate as well as other blood products. She made a gradual recovery as an in-patient was discharged on 31st January 2012.

Commentary
It is apparent that Patient X had significant postpartum haemorrhage due to a surgical tear in the uterus which was duly repaired. She was also looked after in the standard way postpartum.

POSTMORTEM EXAMINATION
The summary of findings of provisional anatomical diagnosis from the post-mortem reveal that it was a normal infant with no congenital abnormalities. There were bilateral large anoxic congestive haemorrhage changes of the meninges, thoracic and abdominal organs, and the adrenal medulla. It was described as a fresh stillborn infant. It is stated that there was antepartum meconium passage and aspiration. Histology of the placenta revealed it to be small and congested.

Commentary
The post-mortem revealed the baby to have no congenital abnormality. There was evidence of anoxic change in the organs and it is stated that there was meconium passage and aspiration. In relation to this latter point I am unclear as to the evidence for this but presumably that was obtained at post-mortem. The placental histology was not contributory in relation to the findings.

OVERALL OPINION / COMMENTARY:

It is my view that Patient X received good care in the antenatal period while attending Hospital 1 in this pregnancy. The features described in the labour up to the time of 06.30 hours on 24th January 2012 are unremarkable. From the time of 06.33 hours the CTG trace was abnormal as described above. It is my view that within 15 minutes or so after this period of time (i.e. approximately 06.50hours), that a medical review of the CTG should have been ascertained. It is also my opinion that fetal blood sampling should have been performed at this time to assess the fetal pH and base excess values in order to determine if the fetus was acidotic. In the absence of availability of fetal blood sampling, the infant should have been delivered at this time on the basis of the CTG findings. The CTG remained abnormal throughout the period of time from 07.00 hours to 08.00 hours on that date, as well as the fact that the labour ultimately became obstructed. It is apparent finally that the position was that of deflexed OP and that Patient X was unable to spontaneously deliver the infant.

Patient X was reviewed because of a combination of these factors, failure of progression of the presenting part, and the abnormal CTG, at 07.55 hours on 24th January 2012. After being assessed by Registrar A a Syntocinon infusion was commenced. The prospective documentation pertaining to this decision is entirely lacking, and it is not correct for an

Obstetric Registrar to have made that decision without correctly documenting it prospectively at that time. The retrospective documentation made at 11.30 hours on 24th January 2012 is not complete, and apparently was later altered. In specific terms this retrospective entry does not refer to commencing the Syntocinon infusion. It is my view that commencing a Syntocinon infusion at 08.15 hours was an unsafe and incorrect decision. For the reasons outlined above, both maternal and fetal reasons, it was an inappropriate medical decision that could only serve to exacerbate the adverse outcome from the problems already present. In this situation a fetus who is already hypoxic can suffer further damage. In addition, a parous woman in obstructed labour is also at risk from inappropriate Syntocinon stimulation.

When the Consultant was called at 08.30 hours, and arrived at 08.39hours, an appropriate assessment and decision was made. However there should have been adequate medical Obstetric input, of a standard that one would reasonably expect, sooner than this time. The 21-minute period required for transfer of the patient to the operating theatre seems rather long, but in objective terms the time required from final decision for delivery, to actual delivery, was 31 minutes, which represents an acceptable standard by international guidelines (Reference 1).

In summary, there was failure of recognition of the CTG abnormalities by the midwifery staff, and failure on behalf of the midwifery staff to request the Obstetric Registrar to review the CTG in a timely fashion. When the Obstetric Registrar finally did attend at request, an erroneous and unsafe decision was made to start a Syntocinon infusion. The combination of these failures in the standard of care provided were causally linked to the fetal hypoxic damage that occurred, and ultimately the stillbirth, in my opinion.

Specific Questions Posed by the Family to be considered in the Report

1. It is my view that it was not necessary for the Consultant Paediatrician to have been present when the baby was delivered. It is standard practice for a Registrar to be present in the circumstances described here. When it became evident that the baby was in worse condition than expected a Consultant was summoned, and duly attended rapidly. This represents standard practice.

2. It would not be standard practice to have a Nurse from the Special Care Baby Unit present in theatre at a delivery of a term infant in these circumstances. In my view this was not necessary at the outset.

3. It is my opinion that induction of labour earlier was not clinically indicated, nor can one say it would have altered the circumstances that transpired during the labour.

4. It is not clear which patient is being referred to in this question, or if it is both mother and baby. As stated in this report, it is my view that fetal blood sampling should have been

performed from 06.50 onwards, and failure to do so, and procure a normal result, meant that caesarean section was indicated earlier than when it was performed. Failure in this regard was linked to the fetal hypoxia that occurred. The timing of the caesarean section, which finally occurred at full dilatation, is associated with a greater risk of a surgical tear and haemorrhage than caesarean section performed in the 1st stage of labour.

References

1. Caesarean Section. NICE Clinical Guideline 132. November 2011. National Institute for Health and Clinical Excellence.

Signed: _____ Date: _____

Professor John J. Morrison

External report 2 (b): Report from Professor John Morrison, Consultant Obstetrician Gynaecologist submitted to the Reviewers on the 31st January 2013.

Medical Investigative Report

Report Re: HSE Reference 50069 / Information related to Faculty Request For External Expert Clinical Input

Report Re: Obstetric care provided to Patient X at Hospital 1.

Report prepared by:
Professor John J. Morrison MD FRCOG FRCPI BSc BCH
Professor of Obstetrics & Gynaecology
Consultant Obstetrician & Gynaecologist / RCOG Sub-Specialist in Feto-Maternal Medicine
HSE and National University of Ireland, Galway.
Galway University Hospitals

Professor Morrison has been a Consultant Obstetrician Gynaecologist and a sub-specialist in Feto-Maternal Medicine at Galway University Hospital since 1997. His clinical commitment includes general obstetrics & gynaecology, but with a special emphasis on disorders of pregnancy, high risk obstetrics, disorders of labour, preterm labour, operative delivery, fetal abnormalities, and multiple pregnancy. In addition to Consultant accreditation in Obstetrics and Gynaecology, he has completed a 2 year sub-specialist training programme to be an accredited Royal College of Obstetricians and Gynaecologists Feto-Maternal Sub-Specialist. He has more than 250 publications in total including approximately 110 original peer review manuscripts listed on Pubmed / Medline between 1995 and 2012. These manuscripts have been published in international journals of high impact factor including the Lancet, British Journal of Obstetrics & Gynaecology, American Journal of Obstetrics & Gynaecology, Reproductive Sciences, Biology of Reproduction, Obstetrics & Gynecology, Journal of Perinatal Medicine, American Journal of Perinatalogy, Irish Medical Journal, European Journal of Obstetrics & Gynaecology & Reproductive Biology, and others. He is a member of, or has served on, numerous national and international committees pertaining to clinical practice, research, and education in Obstetrics & Gynaecology. He is a member of the Executive Committee, the Standing Committee and the Specialty Training Committee, of the Institute of Obstetrics & Gynaecology, Royal College of Physicians of Ireland. He has also served as External Examiner and assessor for Universities throughout the island of Ireland , the UK, Europe and Australia.

This report was prepared at the request of:
Mr Kevin O'Malley,
Health Care Risk Manager,
Quality and Patient Safety Service HSE DML
Unit 4
Central Business Park,
Clonminch,
Tullamore,
Co Offaly.

This report was prepared using the following documentation / sources of information:

4. **Copy of anonymised healthcare records of the patient referred to in the Terms of Reference for the investigation HSE 50069.**
5. **Information in hindsight bias.**
6. **List of specific questions that the patient and family have requested that would be addressed as part of the investigation.**
7. **Meetings that took place in Tullamore on Friday January 25th which included Professor Morrison, Mr Kevin O'Malley, Midwife A and representative, Consultant A and representative, and Patient X and her husband.**

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ANTENATAL HISTORY

Patient X was booked for antenatal care at Hospital 1 on 22nd August 2011 at 19 weeks gestation in this pregnancy. She had previously delivered four infants vaginally at term, in 2002, 2004, 2007 and 2009. These deliveries had all taken place in Hospital 1. All of her infants had weighed between 8 lbs and 9 lbs, and for three of these deliveries, the infant was delivered with the assistance of vacuum or ventouse. The estimated date of delivery was 15th January 2012. The clinical details documented in relation to the booking antenatal visit were normal or unremarkable. Patient X was subsequently seen at Hospital 1 for antenatal visits at 30 weeks gestation, and 34 weeks gestation, on 9th November 2011 and 7th December 2011 respectively. All was deemed to be progressing well in the pregnancy. It is evident from the ultrasound documents that scans were performed in the third trimester at 34^{+}, 37^{+} and 40^{+} weeks gestation, all of which revealed the fetus to be growing on a line above the 50th centile for gestation. On 29th December 2011, at 37 weeks gestation, the estimated fetal weight was deemed to be 3.1 kg and it is stated that Patient X wished to have a sweep performed. Subsequent visits to the antenatal clinic took place at 39^{+3} and 40^{+3} weeks gestation, and all was progressing normally. At the final antenatal visit, on 18th January 2012, induction of labour was arranged to take place on 24th January 2012, when Patient X would have been 40^{+9} or 41^{+2} weeks of gestation.

Commentary

The above outline describes a relatively normal antenatal history for Patient X in this pregnancy. Of note is the fact that she had four previous children, but also had two previous miscarriages. All of her previous infants weighed what appeared to be above the 50th centile for gestation, and in three previous pregnancies the delivery was assisted with ventouse or vacuum instrumental delivery. There is nothing remarkable about these features. The reasons why one might need delivery to be assisted with vacuum can vary significantly from one patient to the next. There was good clinical and ultrasound surveillance of the pregnancy in the antenatal period, and in compliance with standard practice, induction of labour was scheduled for 41^{+2} weeks gestation.

LABOUR

On January 24th 2012, sometime after 04.00 hours, it is apparent that Patient X had a show and started getting labour pains or contractions. The exact time Patient X presented to Hospital 1 is unclear, as the records from Patient X have stated that she left home sometime after 04.30 hours and arrived at approximately at 04.50 hours. However there is a vaginal examination in the hospital notes that was apparently performed at 04.15 hours. In any case, at some point in time at approximately between 04.15 and 05.00 hours on January 24th 2012 Patient X was admitted to Hospital 1 and assessed. It is apparent that at the time of admission Patient X was requesting epidural analgesia. It is clear from the assessment documented that she was in labour, with cervical dilatation of 3 cms, a cephalic presentation and the station of the head at – 2 (i.e. 2cm above the ischial spines.

Commentary
Patient X was in labour with the cervix 3 cm dilated and the head at – 2 station. These findings are typical of those commonly observed in a parous woman (i.e. a woman who has had children previously), admitted in labour.

The Cardiotocorgram (CTG) was commenced at 05.09 hours. The CTG tracing I have received is in four separate components albeit they may have been continuous on the original recording. The initial CTG recording extends from 05.09 house to 05.27 hours. The baseline rate was 130 beats per minute with reduced beat to beat variability and no episodes of reactivity.

Commentary
While there were some issues that required observation in this first segment of the CTG, it was for a relatively short period of time (18 minutes). A longer segment of recording is necessary to properly evaluate the situation. It was appropriate to continue with this recording and observe it throughout the labour.

The CTG recording was next initiated at 05.39 hours, and between that time and 06.30 hours, the baseline rate was 130 beats per minute with good beat to beat variability and episodes of reactivity present. It is also evident from the CTG that Patient X was having uterine contractions approximately every 4 – 5 minutes. At 06.05 hours the Anaesthetic Registrar was contacted. He duly arrived at 06.15 hours and at 06.27 hours an epidural was sited for analgesia.

Commentary
The outline above describes a normal sequence of events for a woman in early labour in these circumstances. She was contracting regularly. The CTG was overall satisfactory by the time of 06.30hours, despite the slight concerns relating to the first 18-minute segment of recording. By the time she was approximately 1½ hours in the hospital an epidural had been arranged and sited. All of these features constitute a standard level of care.

Starting at the time of 06.33 hours there were decelerations evident on the CTG. Between 06.33 hours and 07.15 hours there were numerous decelerations, some early in nature, some late and some variable. These decelerations occurred down to a rate of 70 – 80 beats per minute. It is also clear from the documentation that Patient X had an urge to push during this time period. She was reassessed at 06.40 hours and artificial rupture of the membranes was performed revealing grade 1 meconium stained liquor. The cervix was then 8cm dilated and the fetal head was at station of -2. It is stated that the contractions were strong. It is stated that at 07.15 Patient X was discouraged against pushing, albeit there is documentation in the chronology of events stating that this was not the perception that Patient X had of events. It appears from the chronology of events that on occasions when it is stated in the notes that Patient X was discouraged from pushing that her interpretation was that she was being encouraged to push.

Commentary
From 06.33 hours the CTG was abnormal. Some decelerations occurred with the contractions (early) and some occurred independent of the contractions (late) and others displayed a mixture of these two features. There was also meconium staining of the amniotic fluid. Patient X was 8 cm dilated. It is my view that at some period of time shortly after 06.33 hours, and certainly by 06.50 hours, that the midwife should have requested that the Obstetric Registrar review the trace and the overall clinical situation. Fetal blood sampling would have appropriate at this stage as she was 8cm dilated with significant decelerations evident on the CTG. I am unable to comment about the exact sequence of events that occurred in relation to pushing, but am of the view that this matter did not have a significant bearing on the final outcome.

Between 07.15 hours and 07.40 hours, the baseline CTG rate was 140 beats per minute and there was good beat to beat variability. There were four decelerations between 07.40 hours and 07.50 hours, down to a baseline rate of 80 – 90 beats per minute. At 07.35 hours, when Patient X had a strong urge to push, vaginal examination was performed by the midwife and she was deemed to be fully dilated with the station of the head at – 1 to -2. At 07.40 hours it is stated that Patient X was pushing well, and that there was no descent of the presenting part. At 07.45 hours the decelerations are described, and documented, in the written notes by the midwife. At what appears to be 07.47 hours, (albeit some controversy about this exact time) the Obstetric Registrar was contacted and requested to come and review the CTG trace.

Commentary
While the CTG trace was briefly better between 07.15 hours and 07.40 hours, it was clear by 07.45 hours that the trace had become abnormal once again, and on this occasion the Registrar was requested to review the trace.

At 07.55 hours the Obstetric Registrar was present. It is apparent that patient X was in lithotomy, presumably in stirrups, and was essentially in the second stage of labour and pushing. It is evident from the midwifery documentation, and the chronology of events, that the Registrar requested that a catheter be inserted in her bladder. At 07.55 hours Registrar A has documented, in a retrospective note (written at 11.30 that morning), that the CTG was 'unsatisfactory' and that the Patient was pushing for 30 minutes prior to that. In the communications I have received it is apparent that the initial entry by the Registar which described the CTG as 'satisfactory', was later altered to 'unsatisfactory (non-reassuring)'. The Registrar has documented that Patient X was fully dilated, and it is clear that the Registrar was unsure about the position of the fetal head, but questioned that it may have been left occipito-anterior. At 08.15 hours it is documented (by the midwife) that Syntocinon was to be commenced as per the instructions of the Obstetric Registrar. It was commenced at 08.15 hours at a rate of 30 mls per hour.

Commentary

The Registrar A has not made any prospective documentation in relation to their assessment and decision pertaining to the care of Patient X when they reviewed the case at 07.55hours. However it can be gleaned from the midwifery notes, and from the retrospective note (albeit this note is incomplete) that the Registrar examined Patient X, requested that a catheter be inserted to empty the bladder, and ultimately made a decision to commence a Syntocinon infusion. It is surprising that a catheter was not already in situ in the bladder considering that the epidural was inserted at 06.27hours. It can only be presumed that Registrar A felt that a full bladder might be hindering progress. In addition, this Registrar felt that it was appropriate to augment the contractions with Syntocinon in order, presumably, to achieve a vaginal delivery. It is my view that this decision to commence Syntocinon was wrong, and this decision should not have been made in these circumstances. In the first instance, Patient X had progressed quickly to full dilatation, and hence there was no need or clinical indication to augment the labour with Syntocinon. Secondly the contractions on the tocogram were regular and satisfactory. Thirdly, one has to be careful using Syntocinon in a parous woman in this situation. Fourthly, and most importantly, the CTG was markedly abnormal over the previous period of at least 1½ hours, and it was incorrect and inappropriate to commence a Syntocinon infusion in this situation. There is no reference to the Syntconin infusion in the retrospective note made by the Registrar, but the midwife has documented at 08.15hours that it was started 'as per' the instructions of the Registrar. As a separate matter, the failure of the Registrar to make prospective notes at the time of review of the patient, and the possibility that the retrospective note made by that doctor at 11.30am that day was later altered, are serious matters for clinical governance.

The rate of infusion of the Syntocinon drip was increased to 60 mls per hour at 08.25, and to 90 mls per hour at 08.31 hours. It appears that Patient X continued with pushing during this period of time. At approximately 08.25 - 08.30 hours, Patient X had been pushing for an hour in the second stage of labour. The written entry by the Registrar in the retrospective note (for 08.20 and 08.25 hours) is not easily consistent with the prospective notes made by the midwife. The midwife has outlined that the Syntocinon infusion was increased at the Registrar's instructions, while the Registrar does not refer to Syntocinon, but states a decision to go to theatre at 08.20 hours for trial of instrumental delivery or caesarean section. In any case, at some time between 08.30 hours and 08.39 hours (there is confusion about the exact time) the Consultant Obstetrician Gynaecologist A was contacted. It is likely that Consultant Obstetrician Gynaecologist A was present on the labour ward by 08.39 hours. The patient was assessed by Consultant Obstetrician Gynaecologist A and deemed to be fully dilated with the position of the fetal head occipito posterior (OP), and deflexed, and the station was described as being – 1. A plan was made to transfer patient X to the operating theatre to decide whether delivery would be possible with instrumental assistance (vacuum or forceps), or whether a caesarean section was necessary. The Syntocinon infusion was discontinued at 08.45 hours.

Commentary

The inconsistencies between the prospective notes made by the midwife, and the retrospective documentation entered by the Registrar, are a matter of concern. By the time the consultant was contacted the woman had an abnormal CTG and was more than one hour pushing in the second stage of labour. It is evident from the findings described that the baby was in an unfavourable position for vaginal delivery in terms of being OP and deflexed, with the station remaining at – 1, i.e. 1 cm above the ischial spines. It was appropriate to decide to bring the woman to theatre to expedite delivery by the safest means possible. It is also my view that this line of approach should have been embarked upon earlier than the time of 08.30 hours. Finally, while the exact timing of the decision to go to theatre is unclear, it is my view that this decision was very likely to have been made at 08.45 hours, i.e. when the Syntocinon was discontinued, or shortly thereafter.

The Consultant's written entry in the notes was made at 09.00 hours, but reading the other documentation attached it would appear that this decision to transfer Ms X to the operating theatre was made at approximately 08.45 hours, at which time the Syntocinon was discontinued, or shortly thereafter. It is documented that the Consultant was present at 08.39hours. During that period of time between 08.45 hours and 09.00hours the CTG showed a baseline rate of 110 beats per minute with decelerations and poor beat to beat variability. It is not possible to discern the exact timing of transfer of Patient X from the labour ward to the operating theatre.

Commentary

The timings are always critical in a case like this. It is not clear what level of urgency was presented in the telephone call contact to the Consultant. However the Consultant was contacted at 08.30 hours, and presented on the labour ward at 08.39 hours, which represents a timely attendance. It appears to have taken 21 minutes for the Consultant to review the case, and to transfer the patient to a trolley for transfer to the operating theatre.

At 09.07 hours it is documented that Patient X was in the operating theatre and transferred onto the operating table. The consultant Gynaecologist A was present and carried out a repeat vaginal examination in theatre and outlined similar findings to those documented. It was deemed that Patient X was not suitable for vaginal delivery and hence a decision made for caesarean section. Between 09.07 hours, and 09.15 hours, preparations were being made in the operating theatre to initiate the caesarean section. At 09.15 hours it is documented that it was difficult to auscultate the fetal heart. The CTG recording that is available from the operating theatre, which commenced at 09.10 hours, is very abnormal. The baseline rate is 80 beats per minute. There is a very intermittent recording up to approximately 09.17 hours. It is apparent that the midwife also listened using the Doppler sonicaid instrument at 09.16hours and questioned that the heart rate was approximately 90 beats per minute ('?90bpm'). In any case it is evident that in the operating theatre the fetal heart rate was low indicating significant fetal distress from the

point of initiation of monitoring at 09.10hours. The infant was ultimately delivered at 09.31 hours.

Commentary

It is my view that the period of time from assessment in the labour ward by the Consultant (08.39 hours), to final delivery of the infant (09.31hours), which was in the order of 52 minutes, was rather long in this situation. However, having said that, the final decision for delivery is documented in the notes at 09.00hours, and the delivery took place at 09.31 hours. Clinical guidelines suggest that a time period of approximately 30 minutes, from decision to delivery, should be aimed for in Category 1 or urgent caesarean sections (Reference 1). In this situation, where the decision for delivery for Patient X was documented at 09.00 hours, this guideline was broadly speaking adhered to.

NEONATAL HISTORY

It is apparent that the infant was extremely flat at birth and there was no heart rate easily audible. The umbilical cord vessel pH and base excess values were as follows: artery, pH 6.716, base excess -24.9; vein pH 6.941, base excess -17.8. The Paediatric Registrar was present at the time of the birth and immediate resuscitation began. The resuscitation was aided by the Consultant Anaesthetist. The Apgar score was zero at 1 minute and zero at 5 minutes. There was debate about whether or not a heart beat was heard at one point, which may have occurred, but the exact answer to this is unclear. Attempts were made to intubate the baby, and it was noted that there was no meconium below the vocal cords. The initial trial at intubation was unsuccessful but the infant was successfully intubated after four minutes and thirty seconds. The Consultant Paediatrician arrived at 5 minutes of age. Full resuscitation was applied including two doses of Adrenaline. No heart rate or respiratory effort were observed. An umbilical vein catheter was inserted infusing saline and adrenaline again. After 25 minutes of resuscitation the baby still had no heart rate and the resuscitation was abandoned. The Consultant Paediatrician discussed the matter with Patient X's husband.

Commentary

The consensus is that the baby was dead at delivery and obviously had just recently died. This is called a fresh stillbirth. There can occasionally be a period of time when intermittent beating of the heart can be heard at a very low rate in the minutes following a fresh stillbirth. Whether or not this was heard on this occasion is unknown. What is entirely clear is that the baby was essentially dead on delivery and it was not possible to resuscitate him to any successful degree. There are no umbilical cord vessel pH values documented in the notes as far as I could ascertain.

CAESAREAN SECTION AND POSTPARTUM HISTORY

It was apparent at the caesarean section that there was a tear to the lower uterine segment after delivery of the infant. The placenta was delivered but Patient X continued to bleed from the right hand side of the uterus. The apex of the tear was identified and the right uterine vein was identified and ligated. Consultant Obstetrician Gynaecologist A requested that Consultant Obstetrician Gynaecologist C would scrub in for a second

opinion, and the procedure was gradually completed. Patient X was treated with intravenous Oxytocin, and transferred to a high dependency area (either intensive care unit or coronary care unit) for follow-up. She was also treated with Cytotec to control the postpartum haemorrhage. It appears that over the course of 24th and 25th January 2012 Patient X received six units of Red cell concentrate as well as other blood products. She made a gradual recovery as an in-patient was discharged on 31st January 2012.

Commentary
It is apparent that Patient X had significant postpartum haemorrhage due to a surgical tear in the uterus which was duly repaired. Such tears, and the consequent postpartum haemorrhage, are more common when caesarean section is performed in the second stage of labour. She was also looked after in the standard way postpartum.

POSTMORTEM EXAMINATION
The summary of findings of provisional anatomical diagnosis from the post-mortem reveal that it was a normal infant with no congenital abnormalities. There were bilateral large anoxic congestive haemorrhage changes of the meninges, thoracic and abdominal organs, and the adrenal medulla. It was described as a fresh stillborn infant. It is stated that there was antepartum meconium passage and aspiration. Histology of the placenta revealed it to be small and congested.

Commentary
The post-mortem revealed the baby to have no congenital abnormality. There was evidence of anoxic change in the organs and it is stated that there was meconium passage and aspiration. In relation to this latter point I am unclear as to the evidence for this but presumably that was obtained at post-mortem. The placental histology was not contributory in relation to the findings.

OVERALL OPINION / COMMENTARY:

It is my view that Patient X received good care in the antenatal period while attending Hospital 1 in this pregnancy. The features described in the labour up to the time of 06.30 hours on 24th January 2012 are unremarkable. From the time of 06.33 hours the CTG trace was abnormal as described above. It is my view that within 15 minutes or so after this period of time (i.e. approximately 06.50hours), that a medical review of the CTG should have been ascertained. It is also my opinion that fetal blood sampling should have been performed at this time to assess the fetal pH and base excess values in order to determine if the fetus was acidotic. In the absence of availability of fetal blood sampling, the infant should have been delivered at this time on the basis of the CTG findings. The CTG remained abnormal throughout the period of time from 07.00 hours to 08.00 hours on that date, as well as the fact that the labour ultimately became obstructed. It is apparent finally that the position was that of deflexed OP and that Patient X was unable to spontaneously deliver the infant.

Patient X was reviewed because of a combination of these factors, failure of progression of the presenting part, and the abnormal CTG, at 07.55 hours on 24th January 2012. After being assessed by Registrar A a Syntocinon infusion was commenced. The prospective documentation pertaining to this decision is entirely lacking, and it is not correct for an Obstetric Registrar to have made that decision without correctly documenting it prospectively at that time. The retrospective documentation made at 11.30 hours on 24th January 2012 is not complete, and apparently was later altered. In specific terms this retrospective entry does not refer to commencing the Syntocinon infusion. It is my view that commencing a Syntocinon infusion at 08.15 hours was an unsafe and incorrect decision. For the reasons outlined above, both maternal and fetal reasons, it was an inappropriate medical decision that could only serve to exacerbate the adverse outcome from the problems already present. In this situation a fetus who is already hypoxic can suffer further damage. In addition, a parous woman in obstructed labour is also at risk from inappropriate Syntocinon stimulation.

When the Consultant was called at 08.30 hours, and arrived at 08.39hours, an appropriate assessment and decision was made. However there should have been adequate medical Obstetric input, of a standard that one would reasonably expect, sooner than this time. The 21-minute period required for transfer of the patient to the operating theatre seems rather long, but in objective terms the time required from final decision for delivery, to actual delivery, was 31 minutes, which represents an acceptable standard by international guidelines (Reference 1).

In summary, there was failure of recognition of the CTG abnormalities by the midwifery staff, and failure on behalf of the midwifery staff to request the Obstetric Registrar to review the CTG in a timely fashion. When the Obstetric Registrar finally did attend at request, an erroneous and unsafe decision was made to start a Syntocinon infusion. The combination of these failures in the standard of care provided were causally linked to the fetal hypoxic damage that occurred, and ultimately the stillbirth, in my opinion.

Specific Questions Posed by the Family to be considered in the Report

1. It is my view that it was not necessary for the Consultant Paediatrician to have been present when the baby was delivered. It is standard practice for a Registrar to be present in the circumstances described here. When it became evident that the baby was in worse condition than expected a Consultant was summoned, and duly attended rapidly. This represents standard practice.

2. It would not be standard practice to have a Nurse from the Special Care Baby Unit present in theatre at a delivery of a term infant in these circumstances. In my view this was not necessary at the outset.

3. It is my opinion that induction of labour earlier was not clinically indicated, nor can one say it would have altered the circumstances that transpired during the labour.

4. It is not clear which patient is being referred to in this question, or if it is both mother and baby. As stated in this report, it is my view that fetal blood sampling should have been performed from 06.50 onwards, and failure to do so, and procure a normal result, meant that caesarean section was indicated earlier than when it was performed. Failure in this regard was linked to the fetal hypoxia that occurred. The timing of the caesarean section, which finally occurred at full dilatation, is associated with a greater risk of a surgical tear and haemorrhage than caesarean section performed in the 1st stage of labour.

References

2. Caesarean Section. NICE Clinical Guideline 132. November 2011. National Institute for Health and Clinical Excellence.

Signed: _____ Date: _____

Professor John J. Morrison

External report 3: Report from Dr John Murphy, Consultant Neonatologist

Report on Baby X

Anaesthetist. The infant was intubated with a 3.5mm endotracheal tube at 4 mins 30 secs of age. The infant was administered 2 doses of Adrenaline through the endotracheal tube. An umbilical venous line was inserted at 10 mins of age and the infant was administered 20 mls Saline, I.V. Adrenaline, followed by 40 mls Saline. There was no response. The heart rate remained zero and there was no respiratory effort. The cardio-respiratory resuscitation was continued until the infant was 22 mins old. At that time resuscitation was discontinued and the infant was pronounced dead.

The biochemistry results show that the venous cord blood gas was pH 6.94, Pco2 10.87, Po2 4.67, base excess -17.8, HCO3 17.2

An arterial blood gas performed on the infant at 9:37 (at 6 mins old) was pH 6.71, PCO2 15.69, PO2 3.28, Base Excess -24.69, HCO3 14.8.

The outline findings of the post-mortem were:

1. Fresh male stillborn infant
2. Antenatal meconium passage and aspiration
3. Anoxic congestion of the meninges. thoracic and abdominal organs.
4. No congenital abnormality
5. Small placenta with very congested appearance.

Interpretation of the Case: Baby X was born with no visible signs of life apart from a very slow faint heart rate which had ceased by age 1 minute. The cord blood gases demonstrated a severe degree of acidosis. In the light of these poor clinical circumstances it is understandable that baby X would not respond to resuscitation.

In my opinion the resuscitation of the infant was performed in a satisfactory manner. The ABCD (Airway, Breathing, Circulation, Drugs) components of neonatal resuscitation were applied in a timely manner. The Paediatric Registrar was present at the birth. Senior help was summoned and the consultant Paediatrician was present by 5 minutes after the birth. Ventilatory support was commenced with 100% Oxygen delivered by face mask and a Neopuff Infant T-Piece Resuscitator. In view of the slow, faint heart rate less than 100/min cardiac compressions were commenced. Due

Report on Baby X

to the absence of any response by the infant the team proceeded to intubate the infant. The infant was intubated by 4:30 mins which is similar to the time it takes in our Unit at Holles Street. The infant was administered adrenaline through the endotracheal tube on 2 occasions. There was no response by the infant. The team sited an umbilical venous catheter and administered intravenous Adrenaline and two boluses of saline. The infant remained completely unresponsive to these measures. The resuscitation was discontinued at 22 minutes and the infant was pronounced dead.

The post-mortem findings are indicative hypoxia as the underlying cause of the infant's death. There was the presence of antenatal meconium passage and aspiration. There were anoxic haemorrhages of the internal organs. The placenta was small and congested.

Conclusion: Baby X was born in an extremely poor condition. The only sign of life at birth was a very faint slow heart rate which had disappeared when checked again at age 1 minute. Thereafter no signs of life were detected. The cord blood gas sample taken at the time of birth (pH 6.94) showed a marked level of acidosis indicative of severe hypoxia. A further blood gas taken from the infant at 6 minutes old showed a pH (6.71) which is incompatible with life.

The management of the infant was satisfactory. Full cardio-pulmonary resuscitation was administered in a timely manner.

In the case of Baby X, the extent and severity of the hypoxia at birth indicates that it was of a profound nature and that is the reason why he did not respond to cardio-respiratory resuscitation administered after birth.

Report on Baby X

Separate Question- Should an independent Consultant Anaesthetist be appointed to give an expert opinion on the anaesthetic input into the resuscitation?

Given the clinical circumstances of this case I don't think that it is necessary to seek a further additional Anaesthetic opinion. The cause of the infant's death was the hypoxic event that took place before birth. The resuscitation of the infant was undertaken in a timely and orderly manner. There is nothing further that could have been done in relation to the resuscitation after the birth that would have altered the outcome for the infant.

I trust that this Report is helpful.

Yours Sincerely

Dr. John F. Murphy

Consultant Neonatologist

The National Maternity Hospital

Holles Street

Dublin 2

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External report 4: Report from Dr Miriam Harnett, Consultant Anaesthetist

NIMT 50069

I have reviewed the anaesthesia records and the midwifery notes from the time this patient requested an epidural for labour analgesia to the time of delivery of the baby and I am aware of the sad outcome of the case. In addition I have read the account of events supplied by the patient.

The anaesthetic registrar was present to place an epidural at 06.15. At that time the anaesthesia registrar documented assessing the patient and obtaining informed consent prior to epidural placement. The epidural was sited at 06.27 and after a test dose of 4 cc levobupivacine 0.25% a further dose of 6cc levobupivavine 0.25% was administered in conjunction with 100mic of fentanyl through the epidural catheter. This would be considered a very standard regime for establishing epidural analgesia. A sensory level of T10 bilaterally is documented and an epidural infusion of 0.1% with fentanyl 2mic/cc was commenced. The blood pressure is documented as within normal limits at 114/66 after epidural placement. The blood pressure is documented at 101/52 by midwife at 07.30.

The anaesthesia registrar was contacted again at 08.50. The epidural was "topped up" at 09.00 with 9 cc of 0.5% levobupivacine and 9cc of 2 % lignocaine to establish an epidural level for an interventional delivery. Again this would be considered standard epidural management. In the operating theatre between 09.10 and 09.30 the blood pressure was maintained within normal levels.

In summary - the patient requested and received an epidural for labour analgesia. The placement of the epidural was uneventful and the blood pressure was maintained within normal limits after epidural placement and during subsequent cesarean delivery.

Appendix III

Chapters 5 and 6 of the Avalon Fetal Monitor Instructions for Use Manual:

Alarms

The alarm information here applies to all measurements. Measurement-specific alarm information is contained in the sections on individual measurements.

The fetal monitor has three alarm levels: red, yellow, and INOP.

Red and yellow alarms are patient alarms. A red alarm indicates high priority, such as a potentially life threatening situation (for example, SpO_2 below the desaturation alarm limit). A yellow alarm indicates a lower priority alarm (for example, a fetal heart rate alarm limit violation).

INOPs are technical alarms. They indicate that the monitor cannot measure and therefore not detect critical conditions reliably. If an INOP interrupts monitoring and alarm detection (for example, **MECG LEADS OFF**), the monitor places a question mark in place of the measurement numeric and sounds an audible tone. INOPs without this tone indicate that there may be a problem with the reliability of the data, but that monitoring is not interrupted.

Alarms are indicated after the specified alarm delay time. This is made up of the system delay time plus the trigger delay time for the individual measurement. See the Specifications section for details.

If more than one alarm is active, the alarm messages are shown in the alarm status area in succession. An arrow symbol next to the alarm message informs you that more than one message is active.

The monitor sounds an audible indicator for the highest priority alarm. If more than one alarm condition is active in the same measurement, the monitor announces the most severe.

WARNING

Alarm systems of the monitor and those of the connected OB system are independent and not synchronized.

Alarm Mode

You can configure the alarm mode for your fetal monitor. There are two possible modes:

- **All**: alarms and INOPs are enabled, with all audible and visual indicators active.
- **INOP Only** only INOPs are enabled, with audible and visual indication active. This is the default alarm mode.

WARNING

In **INOP Only** mode, no fetal/maternal patient alarms are enabled or indicated.

The alarm status area for yellow and red alarms shows the **INOP only** indication in conjunction with the "Alarms Off" symbol. No alarm limits or alarm off icons are displayed. No fetal/maternal patient alarm settings are available in the setup menus.

Visual Alarm Indicators

Alarm message: An alarm message appears in the alarm status area on the second line at the top of the screen indicating the source of the alarm. If more than one measurement is in an alarm condition, the message changes every two seconds, and has an arrow at the side. The background color of the alarm message matches the alarm priority: red for red alarms, yellow for yellow alarms, and light blue for INOPs. The asterisk symbols (*) beside the alarm message match the alarm priority: *** for red alarms, ** for yellow alarms. INOPs are displayed without asterisks.

Depending on how your monitor is configured, it may display alarm limit violation messages:

- in text form, for example **** FHR1 LOW** or
- in numeric form, for example ****FHR1 94<110**, where the second number shows the currently set alarm limit, and the first number shows the value at which that alarm limit was violated by the widest margin.

Flashing numeric: The numeric of the measurement in alarm flashes.

Bright alarm limits: If the alarm was triggered by an alarm limit violation, the corresponding alarm limit on the monitor screen is shown more brightly.

Audible Alarm Indicators

The audible alarm indicators configured for your fetal monitor depend on which alarm standard applies in your hospital. Audible alarm indicator patterns are repeated until you acknowledge the alarm by switching it off or pausing it, or until the alarm condition ceases (if audible alarm indication is set to non-latching).

WARNING

Do not rely exclusively on the audible alarm system for fetal monitoring. Adjustment of alarm volume to a low level or off during monitoring may result in a dangerous situation. Remember that the most reliable method of fetal monitoring combines close personal surveillance with correct operation of monitoring equipment.

Alarm Tone Configuration

The audible alarm indicators of your monitor are configurable. In the monitor's Configuration Mode, you can change the alarm sound to suit the different alarm standards valid in different countries.

Standard Philips Alarms

- Red alarms: A high pitched sound is repeated once a second.

- Yellow alarms: A lower pitched sound is repeated every two seconds.
- INOPs: an INOP tone is repeated every two seconds.

ISO/IEC Standard 9703-2 Audible Alarms

- Red alarms: A high pitched tone is repeated five times, followed by a pause.
- Yellow alarms: A lower pitched tone is repeated three times, followed by a pause.
- INOPs: a lower pitched tone is repeated twice, followed by a pause.

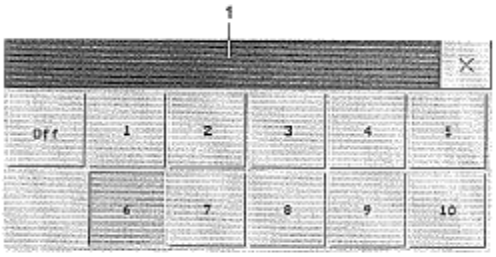
Changing the Alarm Tone Volume

The alarm volume symbol at the top right of the monitor screen gives you an indication of the current volume. To change the volume:

1 Select the volume symbol  The volume scale pops up.

2 Select the required volume from the volume scale.

1 Alarm Volume



When the alarm volume is set to zero (**Off**), the alarm volume symbol shows this. If you switch the alarm volume off, you will not get any audible indication of alarm conditions.

Power Loss Tone

FM40/50 and FM20/30 with Battery Option

When power is lost - no power is available from the AC power source or from the battery - before the monitor is put into Standby, a beeper will sound. The tone can be silenced by pressing the On/Standby switch.

Acknowledging Alarms

To acknowledge all active alarms and INOPs, select the **Silence** key  . This switches off the audible alarm indicators.

A check mark beside the alarm message indicates that the alarm has been acknowledged.

If the condition that triggered the alarm is still present after the alarm has been acknowledged, the alarm message stays on the screen with a check mark symbol beside it.

If the alarm condition is no longer present, all alarm indicators stop and the alarm is reset.

Switching off the alarms for the measurement in alarm, or switching off the measurement itself, also stops alarm indication.

Acknowledging Disconnect INOPs

Acknowledging an INOP that results from a disconnected transducer switches off the associated measurement.

Pausing or Switching Off Alarms

If you want to temporarily prevent alarms from sounding, for example while you are moving a patient, you can pause alarms. Depending on your fetal monitor configuration, alarms are paused for one, two, or three minutes, or infinitely.

To view the alarm pause setting chosen for your unit:

1 Select **Main Setup** -> **Alarms** -> **Alarm Settings.**

2 Check the **Alarms Off** setting.

This setting can be changed in Configuration Mode.

To Pause All Alarms

If you have configured alarms to be paused for one, two or three minutes, the SmartKey is labeled **Pause Alarms**.

Select the **Pause Alarms** SmartKey to pause all alarms.

Or

1 Select **Main Setup**.

2 Select**Alarms**.

3 Select **Pause Alarms**.

To Switch All Alarms Off

You can switch alarms off permanently if your monitor is configured to allow infinite alarms pause and the SmartKey is labeled **Alarms Off**.

Select the **Alarms Off** SmartKey.

Or

1 Select **Main Setup.**

2 Select **Alarms**.

3 Select **Alarms Off**.

To Switch Individual Measurement Alarms On or Off

This applies to alarm mode **All**.

1 Select the measurement numeric to enter its setup menu.

2 Select **Alarms** to toggle between **On** and **Off**.

The alarms off symbol is shown beside the measurement numeric.

While Alarms are Paused or Off

- In the alarm field, the monitor displays the message **Alarms Paused** or **Alarms Off**, together with the alarms paused symbol  and the remaining pause time in minutes and seconds, or alarms off symbol  .
- No alarms are sounded and no alarm messages are shown.
- INOP messages are shown but no INOP tones are sounded.

The following INOPs are the only exceptions:

NBP CUFF OVERPRESS, Batt EMPTY and **Batt MALFUNCTION** (these INOPs are issued even if alarms are paused or off).

If a disconnect INOP is present and alarms are paused or switched off, the measurement in question is switched off.

Restarting Paused Alarms

To manually switch on alarm indication again after a pause, select the SmartKey **Pause Alarms** (or **Alarms Off**) again.

Alarm indication starts again automatically after the pause period expires. If the monitor is configured to stay paused infinitely, you must select **Alarms Off** again to restart alarm indication.

Alarm Limits

The alarm limits you set determine the conditions that trigger yellow and red limit alarms.

WARNING

Be aware that the monitors in your care area may each have different alarm settings, to suit different scenarios. Always check that the alarm settings are appropriate before you start monitoring.

Viewing Individual Alarm Limits (Alarm Mode "All" Only)

1 Alarm Limits
2 Audio source symbol

You can usually see the alarm limits set for each measurement next to the measurement numeric on the main screen.

If your monitor is not configured to show the alarm limits next to the numeric, you can see them in the appropriate measurement setup menu. Select the measurement numeric to enter the menu and check the limits.

Changing Alarm Limits

To change individual measurement alarm limits using the measurement's Setup Menu:

1 In the measurement's Setup Menu, select the alarm limit you want to change. This calls up a list of available values for the alarm limit.

2 Select a value from the list to adjust the alarm limit.

Reviewing Alarms

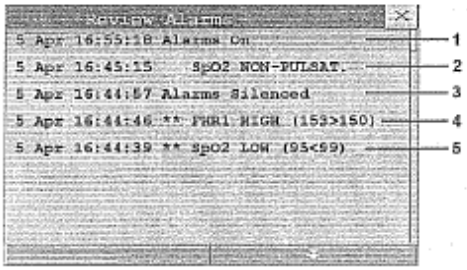
To review the currently active alarms and INOPs, select any of the alarm status areas on the fetal monitor screen. The **Alarm Messages** window pops up . All alarms and INOPs are erased from the monitor's alarm history when you discharge a patient, or if you enter Demonstration Mode.

Alarm Messages Window

The **Alarm Messages** window shows all the currently active alarms and INOPs in chronological order, beginning at the top with the most recent. INOPs are shown on the left hand side and alarms are shown on the right hand side. Any active red alarms are shown first, followed by yellow alarms. Acknowledged alarms or INOPs are shown with the check mark symbol.

The **Alarm Messages** window pop-up keys appear when the window is opened. Selecting the **Review Alarms** pop-up key opens the **Review Alarms** window.

Review Alarms Window



Alarms On
SpO_2 NON-PULSAT.
Alarms Silenced
** FHR1 HIGH
** SpO_2 LOW

The **Review Alarms** window contains a list of up to 300 of the most recent alarms and INOPs with date and time information. If configured to do so, each alarm is shown with the alarm limit active when the alarm was triggered and the maximum value measured beyond this limit. The **Review Alarms** window also shows any changes made to the Alarms On/Off or Silence status. Note that only main alarms On/Off transitions are logged in the alarm history, and On/Off alarm transitions for individual measurements are not logged.

The information in the **Review Alarms** window is deleted when a patient is discharged.

The **Review Alarms** window pop-up keys appear when the window is opened. Selecting the **Active Alarms** pop-up key opens the **Alarm Messages** window.

Latching Alarms

The alarm latching setting for your monitor defines how the alarm indicators behave when you do not acknowledge them. When alarms are set to non-latching, their indicators end when the alarm condition ends. Switching alarm latching on means that visual and/or audible alarm indications are still displayed or announced by the monitor after the alarm condition ends. The indication lasts until you acknowledge the alarm.

Viewing the Alarm Latching Settings

To see the alarm latching setting for your monitor:

1 In the monitor's **Main Setup** menu, select **Alarms**.

2 Select **Alarm Settings**, and see the **Visual Latching** and **Audible Latching** settings.

This setting can be changed in Configuration Mode. You should be aware of the settings chosen for your unit. There are three possible choices each for visual and audible latching: Red, Red and Yellow, and Off. The audible latching configuration can never be configured to a higher level than that configured for the visual latching. In other words, the audible latching setting is always the same level, or lower, than the visual latching setting. For example, if visual latching is configured to **Red Only**,

then audible latching can only be set to **Red** or **Off**. The following table shows the possible combinations for latching settings:

Possible Combinations for Alarm Latching Settings	
Visual Latching Setting	**Audible Latching Setting**
Red and Yellow	Red and Yellow
Red and Yellow	Red
Red and Yellow	Off
Red	Red
Red	Off
Off	Off

Alarm Latching Behavior

Alarm Condition		Red and Yellow Measurement Alarms		
Acknowledgment	**Presence**	**Non-latching alarms**	**Visual and audible latching**	**Visual latching, audible non-latching**
Alarm has not been acknowledged.	Alarm condition still present.	Alarm tone on. Alarm message.	Alarm tone on. Alarm message. Flashing numerics.	Alarm tone on. Alarm message. Flashing numerics.
	Alarm condition no longer present.	All audible and visual alarm indicators automatically stop.	Alarm tone on. Alarm message. Flashing numerics.	Alarm message. Flashing numerics. Audible alarm indicators automatically stop.
Alarm has been acknowledged.	Alarm condition still present.	Alarm tone off. Alarm message.	Alarm tone off. Alarm message. Flashing numerics.	Alarm tone off. Alarm message. Flashing numerics.
	Alarm condition no longer present.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.

All INOPs except the "unplugged" INOPs are non-latching.

Testing Alarms

In general, to test the functioning of visible and audible alarms, do the following:

1 Enable the alarm.

2 Set the alarm limits.

3 Measure or simulate the parameter that is out of range, or signal loss.

4 Verify that the visible and audible alarms are working.

As an example, to test the FHR alarms:

1 Connect the US transducer to a fetal sensor socket.

2 Enable the FHR alerting (see "Turning Alarms On or Off" on page 127).

3 Set the high alert limit and delay to 150 bpm and 60 seconds respectively, and the low alert limit and delay to 110 bpm and 60 seconds respectively (see "Changing Alarm Limits" on page 127).

4 Generate a fetal heart rate of approximately 180 bpm (3 beats per second) for more that one minute.

5 Verify the functioning of the visible and audible alarm.

Alarm Behavior at Power On

Selecting **AlarmsOffAtStart** will cause alarms to be initially suspended or off the next time the monitor is switched on (depending on the setting for Alarms Off). The Alarms Off as Infinite behaves in the same manner as when Alarm Mode equals INOP Only.

In order for alarms to be suspended or switched off initially, the monitor must be switched off for more than one minute, the last main alarm state was set to off or suspended.

The exception to this condition is when the alarms off state has been set to Infinite, and the new active setting is set to Infinite.

Admitting and Discharging

The fetal monitor can store basic patient demographic information used to identify patients.

Admit/Discharge on the Monitor

This section describes how you admit and discharge patients when using the monitor as a stand-alone device (that is, when not used with a obstetrical information and surveillance system such as OB TraceVue).

Admitting a Patient

The fetal monitor displays physiological data as soon as a patient is connected. This lets you monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings.

Use the **Patient Demographics** window and its associated pop-up keys to admit and discharge patients.

To admit a patient,

1 Select the patient name field or select the **Admit/ Dischrge** SmartKey to open the **Patient Demographics** window.

2 Clear any previous patient data by selecting **Dischrge Patient** and then **Confirm**.
If you do not discharge the previous patient, you will not be able to distinguish data from the previous and current patients, for example, on the recording.

3 Select **Admit Patient**.

4 Enter the patient information: select each field and use the on-screen keyboard.
If a conventional keyboard is connected to the monitor you can use this to enter patient information:
   - **Last Name**: Enter the patient's last name (family name), for example **Doe**.
   - **First Name**: Enter the patient's first name, for example **Jane**.
   - **MRN**: Enter the patient's medical record number (MRN), for example **12345678**.

5 Select **Confirm**. The patient status changes to admitted. If the recorder is running, the recorder stops and immediately restarts to annotate the new patient data.

Editing Patient Information

To edit the patient information after a patient has been admitted, select the patient name field on the main screen of the fetal monitor to open the **Patient Demographics** window, and make the required changes.

Discharging a Patient

You should always perform a discharge even if your previous patient was not admitted. A discharge:

- clears the information in the **Patient Demographics** window.
- resets all monitor settings to the settings defined in the User Default.
- advances the paper automatically if the recorder is running.
- stops the fetal recorder.

When a patient is discharged from the monitor, all patient demographic data is deleted (trace data is not affected).

To discharge a patient,

1 Select the patient name field to display the **Patient Demographics** window and associated pop-up keys.

2 Select the pop-up key for **Dischrge Patient**.

3 Select **Confirm** to discharge the patient.

CAUTION

In order to ensure that the settings are reset to user defaults for a new patient, always discharge the previous patient from the fetal monitor.

NOTE

In order to ensure a continuous record, it is recommended to discharge the patient before performing a new patient admission in OB TraceVue.

New Patient Check

The fetal monitor can be configured to ask you in certain situations:

- after a specified power-off period
- after a specified standby period

whether a new patient is now being monitored. The pop-up window is entitled **Is This A New Patient?** The monitor offers a **Yes** key to discharge the previous patient and begin monitoring a new patient and a **No** key to continue monitoring with the current patient data and settings.

The time periods for the two conditions can be configured independently.

Appendix IV

Service Dockets:

- Service Documents Docket No. 49847 relates to the service check of the CTG monitor used to monitor Mrs. Molloy performed. The service was performed on the 6th September 2011.

- Service Docket No. 59652 relates to the service check performed on the 1st February 2012.

- Service Docket No. 59658 relates to the service check performed on the 1st March 2012.

ENGINEER'S REPORT

Cardiac services
Sisk Group

Dublin	**Telephone: (01) 830 7499** **support@cardiac-services.com**	**Fax: (01) 830 7662**
Belfast	**Telephone: 028 9066 9000** **support@cardiac-services.com**	**Fax: 028 9068 7100**
Manchester	**Telephone: 01625 878999** **support@cardiac-services.com**	**Fax: 01625 878880**

15588
49847

Customer Order No: Contract Job Number: Arrival Date/Time: 06-09-11

Customer Details: Midland Regional Portlaoise Maternity	Invoice Details:

Equipment Serviced:	Model No:	Asset No:	Serial No:
Fan 20	M2703A	P0301	DE53106364

Reported Problem: PM Visit

Normal Call out ☐ Emergency Call out ☐ Service Visit ☑ Workshop Work ☐ Training ☐ Installation ☐ Supply ☐

Solution: Carried out a full PM on this device. Unit has passed.

Safety Test: CL 2

Follow up:

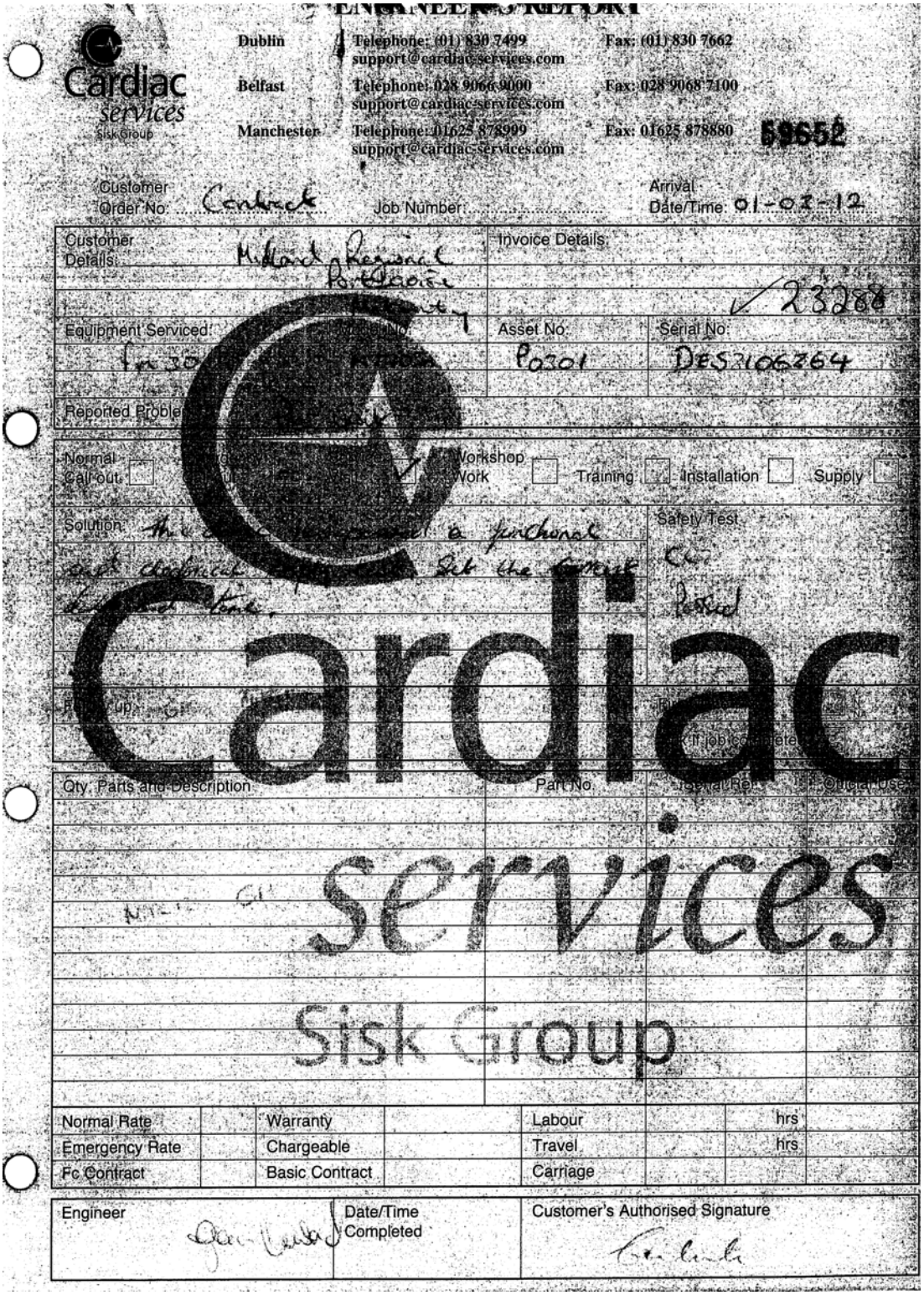
First Time Fix ☐ Y ☐ N ☐ NA

Tick if job completed ☐

Qty.	Parts and Description	Part No.	Serial Ref.	Official Use

Normal Rate		Warranty		Labour		hrs	
Emergency Rate		Chargeable		Travel		hrs	
Fc Contract		Basic Contract		Carriage			

Engineer	Date/Time Completed	Customer's Authorised Signature



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Manchester Telephone: 01625 878999 Fax: 01625 878880
support@cardiac-services.com

59652

Customer Order No: Contract Job Number: Arrival Date/Time: 01-02-12

Customer Details: Midland Regional Hospital Portlaoise

Invoice Details: 23288

Equipment Serviced: Fan 30 Asset No: P0301 Serial No: DES1106264

Reported Problem:

Normal Call-out ☐ Workshop Work ☐ Training ☑ Installation ☐ Supply ☐

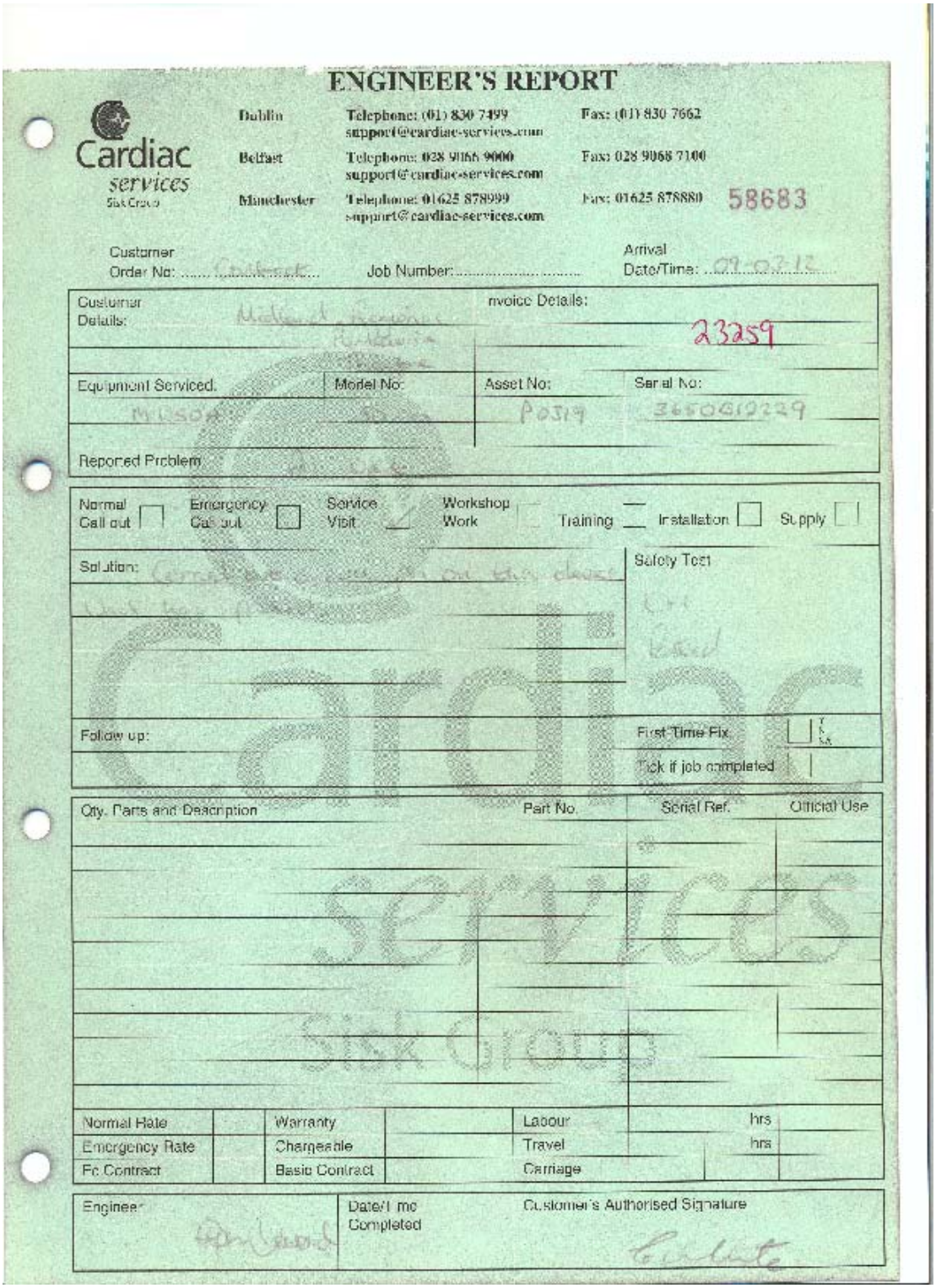
Solution: Safety Test Ok Passed

Follow up: If job complete

Qty. Parts and Description | Part No. | Serial No. | Office Use

Normal Rate | Warranty | Labour | hrs
Emergency Rate | Chargeable | Travel | hrs
Fc Contract | Basic Contract | Carriage

Engineer | Date/Time Completed | Customer's Authorised Signature



ENGINEER'S REPORT

Cardiac services

Dublin	Telephone: (01) 830 7499 support@cardiac-services.com	Fax: (01) 830 7662
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Manchester	Telephone: 01625 878999 support@cardiac-services.com	Fax: 01625 878880

58683

Customer Order No: ..... Job Number: ..... Arrival Date/Time: 09.03.12

Customer Details: Medical Services Foundation

Invoice Details: 23259

Equipment Serviced: MUSOM | Model No: | Asset No: P0319 | Serial No: 3650619229

Reported Problem:

Normal Call out ☐ Emergency Call out ☐ Service Visit ✓ Workshop Work ☐ Training ☐ Installation ☐ Supply ☐

Solution: Completed service on the above

Safety Test: OK

Follow up: | First Time Fix: ☐ Y ☐ N

Tick if job completed: ☐

Qty. Parts and Description	Part No.	Serial Ref.	Official Use

Normal Rate		Warranty		Labour	hrs
Emergency Rate		Chargeable		Travel	hrs
Fc Contract		Basic Contract		Carriage	

Engineer: [signature] | Date/Time Completed | Customer's Authorised Signature: [signature]

Appendix IV:

List of contributory factors outlined in the Contributory Factors Framework:

Factor type	Influencing contributory factors
Patient factors (For clinical incidents)	Conditions (Complexity and seriousness) Language and communication Personality and social factors.
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Individual Factors	Skills and knowledge Competence Physical and mental stressors
Team Factors	Knowledge and skills Competence Physical and mental health
Work environment factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership etc)
Organisational and management factors	Financial resources and constraints Organisational structure Policy standards and goals Safety culture and priorities
Institutional Context	Economic and regulatory context Department of Health and Children

Appendix V:

List of audits carried out in the Maternity Department since 2008:

Audit Title
Clinical Re-Audit of Baby Temperatures on admission to SCBU
Quality Improvement Project - Blood Gas Analysis, SCBU
Clinical Audit of Breastfeeding Supplementation
Evaluation of the Revised Midwifery Documentation on the Maternity Ward
Skin to Skin Audit 2009 (3 small audits Feb, Mar & April)
Breastfeeding supplementation audit July 2009
Audit of Foetal heart rate monitoring during labour in the Maternity Ward
Management of Expectant Mother's pain and pain relief during labour
Re-Audit of Admission temperatures to SCBU
Audit of Glucometer test results in the SCBU
Audit on Management of Pre Labour Rupture of Membranes
Supplementation Audit
Rooming-in
Skin to Skin Audit
Audit of Information Disseminated at Antenatal Clinics March 2011 at MRHP
Rooming-in (October 2011)
Skin to Skin Audit (October 2011)
Audit of Breastfeeding Supplementation (October 2011)

Appendix VI

Enlarged copy of the CTG trace with foetal heart alarm parameters: