Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Strictly Private and Confidential

External Independent Clinical Review of the Maternity Services at Portiuncula Hospital, Ballinasloe (PUH) and of 18 perinatal events which occurred between March 2008 and November 2014.

External Independent Clinical Review Team Members:

- Professor James Walker (External Chairperson)
- Ms. Rachel Conaty (External Expert: Midwifery)
- Professor Sean Daly (External Expert: Obstetrics)
- Professor Eugene Dempsey (External Expert: Neonatology)
- Dr. Adrienne Foran (External Expert: Neonatology)
- Dr. Paul Hughes (External Expert: Obstetrics)
- Dr. Elaine Madden, MBE (External Expert: Midwifery)
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Report commissioned by: Chief Clinical Director, SAOLTA University Health Care Group.

Date of commissioning review: January 2015

Date review commenced: April 2015

Date report submitted to Commissioner: 11 April 2018

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Foreword

In 2014, six babies were referred from Portiuncula Hospital Ballinasloe ("PUH") for Therapeutic Hypothermia ("TH") which was considered higher than average at that time. The Preliminary Review of Adverse Perinatal Events at Portiuncula Hospital, Ballinasloe[1] ("the Preliminary Review") was a desktop review of these cases conducted by the SAOLTA Hospital Group ("SAOLTA"). The Preliminary Review was completed in December 2014 and due to issues identified, an external independent clinical review was commissioned by the Chief Clinical Director of SAOLTA in January 2015 under agreed Terms of Reference.

The scope of this commission initially involved a review of the 6 cases that were referred for TH in 2014 and were part of the Preliminary Review. An additional 12 cases involving 10 families relating to a range of different perinatal events at PUH dating from the seven year period 2008 to 2014 were later added. These self-reported cases were identified through a dedicated patient help line. Hence this review comprises 18 cases in total (16 families). It also includes a general review of maternity services at PUH between the years 2008-2014.

While the external independent Clinical Review Team ("CRT") analysed the aggregate findings of individual investigations of the 18 cases referred to above, for confidentiality reasons, this publication (the "Report") does not include the reports of these individual cases. These have been provided separately to the women and their families through the individual Systems Analysis Investigation ("SAI") of each of the 18 cases. The CRT have provided the families with short clinical summaries following its review of each SAI report.

The CRT notes that PUH and the Health Service Executive ("HSE") have indicated that they would like this Report to reflect their sincere apologies to the families referred to in this review, for the events documented in this Report. The hospital and the HSE acknowledge that the families' experiences were in some cases devastating and that these events have had a profound and lasting impact on all the families.

We recognise that this has been a long and difficult process for the families and staff due to the extensive time it has taken to complete. The reasons for this are discussed elsewhere in this Report. This has been a complex process and we have endeavoured to complete a rigorous review within the shortest possible timeframe. Never-the-less, we are conscious that these extended timelines can be very stressful for families and staff, especially to those who have waited many years for answers.

We would like to thank the families for their willingness to share their experiences with the CRT. We recognise that this may have been traumatic and time consuming for them. This contribution by families was invaluable in allowing the CRT, PUH, and the HSE to learn from every family's experiences. This facilitated the recommendations to improve the systems and processes, related to the delivery of maternity services in PUH.

We would also like to acknowledge the contribution of all the staff who participated in this review, often in difficult personal circumstances. Their participation and openness was invaluable in the process of sharing the learning from the events reflected in this Report. It is important to understand that this is a learning process not a blame exercise. The aim is to assist the hospital and the community to come through this and help the hospital become the best it can be. We believe that implementing the recommendations made within this Report will go a long way towards achieving these aims.

[1] Dr. Geraldine Gaffney, Ms. Dawn Johnston, Dr. Donough O'Donovan and Professor Declan Devane, Preliminary Review of Adverse Perinatal Events at Portiuncula Hospital, Ballinasloe, 21st December 2014

We understand that this process has been extremely difficult for all concerned and we recognise the impact that these events have had on individuals and the community. We would like to take this opportunity to express our fullest sympathies to all individuals affected by the events documented in this Report.

Professor J.J. Walker,

Chairperson,

External Independent Clinical Review Team ("CRT")

11 April 2018

Ms. Rachel Conaty (External Expert: Midwifery)

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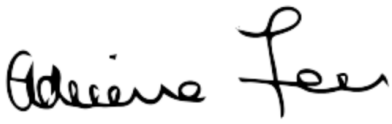

1. EXECUTIVE SUMMARY

1.1 Background

In 2014, six babies were born that required referral for Therapeutic Hypothermia ("TH")[2] out of a total of 1,983 births at PUH. This cluster of cases prompted an internal clinical review of these cases by the SAOLTA Hospital Group. The results of the Preliminary Review were reported to the Chief Clinical Director on the 21st December 2014.

Due to the concerns set out in more detail in the Preliminary Review, an external independent Clinical Review of Maternity Services at PUH was commissioned by the Chief Clinical Director in February 2015 under the Terms of Reference set out at Appendix 2.

After the commissioning of this review, a further 12 cases, involving 10 families, related to a range of different perinatal events at PUH, dating from the seven year period from 2008 to 2014, were included. These were self-reported cases identified through a dedicated patient help line. Hence the final review comprises of 18 cases in total (16 families).

The CRT met for the first time in April 2015 to discuss the Terms of Reference and the methodology of the review process and met, either in person or by teleconference, regularly since then. As well as reviewing the cases themselves, the CRT conducted a general review of maternity services at PUH and the structure and provision of maternity and new-born services.

The CRT has documented clinical errors that were made, the system errors that allowed them to happen, the environmental factors that influenced their occurrence and the failures in reporting, learning and communication that followed.

This review is not about blame, it is about finding cause and forming recommendations for change that will lead to improvements in the maternity and new-born services at PUH. However, this requires everyone, from the workplace to the national agencies to play their part in both taking responsibility for the incidents as well as the solutions. The incidents described in this Report have been highlighted in previous reports in other hospitals in Ireland and abroad and, without fundamental changes in process and training, will happen again.

1.2 Aims

The CRT carried out this review in two parts under the following headings in order to fulfil the Terms of Reference:

Part I

Review the maternity services at PUH as follows:

(a) Review the perinatal care provided by PUH maternity unit including the findings of the analysis of the perinatal care in the cases covered by this review;

(b) Review of the wider delivery of services at PUH maternity unit between 2008 and 2014;

(c) Examine the corrective measures put in place during the Preliminary Review;

[2] See Appendix 4 for the definition of Therapeutic Hypothermia ("TH")

(d) Examine the implementation of national HSE policies in relation to patient safety, risk management, incident management, reporting, investigation and open disclosure.

Part II

Review of the 18 individual cases including:

(a) A review of the 6 cases included in the Preliminary Review conducted by SAOLTA, which related to the referral of infants for TH in 2014.

(e) A review of 12 additional cases relating to a range of different perinatal events experienced by 10 families[3] at PUH over the seven year period from 2008 to 2014 and which were identified through a patient helpline.

1.3 External Independent Expert Clinical Review Team (CRT)

The review was conducted by:

- Professor James Walker (External Chairperson, University of Leeds)
- Ms. Rachel Conaty (Assistant Director of Nursing and Midwifery, National Maternity Hospital Dublin (Retired))
- Professor Sean Daly (Consultant Obstetrician, Coombe Women and Infants University Hospital Dublin)
- Professor Eugene Dempsey (Consultant Neonatologist, Cork University Hospital)
- Dr. Adrienne Foran (Consultant Neonatologist, Rotunda Hospital Dublin)
- Dr. Paul Hughes (Consultant Obstetrician, University Hospital Kerry)
- Dr. Elaine Madden (Head of Midwifery and Gynaecology, South Eastern Trust, Belfast (Retired))
- Ms. Breda Shiel (Service User Representative, AIMS Ireland[4])

1.4 Key Findings of the Overall Perinatal Care Provided in PUH Between 2008-2014

(a) General Findings

The CRT identified that staff at PUH maternity unit were caring professionals who were committed to the well-being of women and babies. Perinatal outcome statistics over the years at PUH were within national norms, and remain so, even with the inclusion of the cases reviewed within this Report. Therefore, overall the PUH maternity unit was, by comparison, as safe as other maternity unit in Ireland. [5]

Generally, just because statistics are good, does not mean that good practice is occurring all of the time and that best care is being provided to each individual woman (Berwick)[6]. All incidents need to be monitored, reported and investigated, recommendations made and

[3] Two of the families involved had two separate cases reviewed each.
[4] AIMS is the Association for Improvement in the Maternity Services.
[5] Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports 2008 and 2013. NPEC
[6] Berwick D.M. A promise to learn-a commitment to act. Improving the safety of patients in England. London: Department of Health, 2013

learning achieved if a unit is to maintain the highest standards of clinical practice and safety. The concerns about clinical care are not about routine care but the clinical response when things start to go wrong[7].

This review is historical and, in the course of the review, it became evident that many changes have already been put in place to overcome the issues identified by the Preliminary Review or that were presented by the SAI reports. We had several meetings with the senior staff in PUH and with the SAOLTA group management and discussed our concerns. We have tried to highlight the improvements made but it is inevitable that not all progress will have been captured in this Report. Thus the findings relate to the problems which occurred at the time and not necessarily to the current situation. The SAOLTA group will verify the changes that have been made and ensure the plans for further developments are followed.

(b) **Environment in PUH**

During the time frame considered by the CRT, it was the policy for PUH to care for all women with no clear risk categorisation. The CRT understands that PUH had in the past been a highly regarded unit. However, as was the case in every unit in Ireland at that time, PUH was faced with a changing population with increasing morbidity[8]. It became apparent to the CRT that during the period under review (2008-2014), a shortage in staff numbers, limited access to training and limited availability of resources impacted upon the ability of PUH to keep up to date with some of the latest developments in skills and techniques in clinical care[9].

The CRT was informed that there was a healthy mutual respect between midwives and doctors however, it is the opinion of the CRT that this was a very traditional model of the midwife/doctor relationship. In certain cases reviewed by the CRT, it appeared that problems during labour weren't identified or when identified, were not escalated, reflecting sub-optimal communications between professionals, resulting in poor multidisciplinary team-working.

The CRT noted from interviews with senior midwifery and obstetric staff, case record reviews, the 18 SAIs and PUH training records that the experience, level of ability and training of some obstetric Non Consultant Hospital Doctors (NCHDs[10]) was not at a level previously experienced, requiring greater senior support. However, the escalation of care to more senior colleagues did not always occur in a timely fashion due to lack of local escalation guidelines and shortage of consultant staff. It appeared from the records reviewed by the CRT that on occasions, during labour there was a significant delay between the first signs of concern and the decision to intervene. It similarly appeared from the records reviewed by the CRT that there was a general lack of consultant obstetrician input both routinely, and when problems arose, in maternity care. It was observed that there was a lack of staff numbers at both midwifery and consultant level, as evidenced by the significant locum consultant presence, meaning that there was difficulty in maintaining a safe cover of service when things went wrong. The CRT acknowledges that these staffing concerns had been escalated by staff in PUH over some time primarily through the Assistant

[7] Vincent, C., S. Burnett, and J. Carthey, Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. BMJ Qual Saf, 2014. 23(8): p. 670-7.
[8] Creating a Better Future Together. National Maternity Strategy 2016-2026
[9] The CRT received feedback from some clinicians who disagreed with this comment. The CRT would like to clarify that this observation was arrived at from the overall review of the maternity services in PUH, examples of which are set out in more detail in this Report.
[10] See Glossary for definition

Director of Nursing ("ADON"), both internally to the Director of Nursing ("DON") and General Manager and externally to SAOLTA as a whole.

There was no autonomous midwifery practice to take on low-risk care independently such as midwife led clinics and intrapartum care which might have helped in developing care pathways and allow the medical staff to concentrate on the cases of greatest need. On feedback, it was reported that the need for the development of midwifery led service was recognised by the ADON who made efforts through midwifery staffing application to develop this service but this was not supported at the time.

(c) **Geographical/Systems**

In 2008 PUH was a stand-alone HSE hospital operating under the HSE West. In 2012, PUH became part of the Galway Roscommon University Hospitals Group. Following the publication of the Higgins Report in February 2013[11], a national move towards re-organised hospital group structures, each with its own governance and management was recommended.

Further organisational changes occurred when three more hospitals joined the Galway Roscommon University Hospitals Group and it became the West/North West Hospitals Group. This subsequently became the SAOLTA group in 2014[12]. The appendices highlight how the management, reporting and governance structures during this time changed frequently, and, as will be highlighted later in this Report, the CRT were informed that these changes in structure led to confusion regarding the different roles and responsibilities.

It is known that hospital reconfiguration can be particularly problematic. [13] The multiple changes leading to the formation of the SAOLTA group, presented similar problems to those identified in relation to hospital group reconfiguration. This was compounded by various changes in personnel at management level.[14] Despite ongoing dialogue, planning and engagement at all levels within the SAOLTA group, the CRT were informed during interviews with PUH staff that they believed that there was no meaningful integration of PUH into the group management or governance processes. PUH staff also stated that there was no feeling of belonging to the bigger organisation.

The CRT was informed that during these reconfigurations, senior staff at PUH did not feel involved and believed that they no longer had ownership of their environment. It is the view of the CRT that this may have contributed to PUH being less able to respond to the problems that arose at a local level. At the time of the 2014 cases, incidents were reported onto Q-Pulse initially by PUH staff. Preliminary Assessment Reports ("PAR") were completed by PUH and forwarded to the Serious Incident Management Team "SIMT" meeting[15]. There was no further action after the escalation of the first two cases, until the third and fourth TH cases in 2014.

During the interviews with staff, the CRT was informed of media reports[16] in and around 2014 regarding the possibility of reconfiguration of hospitals in the West/NorthWest

[11] Higgins, Professor John R. The Establishment of Hospital Groups as a Transition to Independent Hospital Trusts. A Report to the Minister for Health, Dr. James Reilly T.D., Published February 2013
[12] Please see Appendix 6 for relevant organisational documentation
[13] Weil, T., Hospital mergers: a panacea? J Health Serv Res Policy, 2010. 15(4): p. 251-3.
[14] Reference Appendix 6 above
[15] The Serious Incident Management Team "SIMT" is a SAOLTA group-wide incident review and management team and was established in March 2014
[16] https://www.irishtimes.com/news/health/closure-of-up-to-four-west-northwest-obstetric-units-mooted-1.1793616

Hospitals Group which would result in the closure of maternity services at PUH. The CRT was informed that there had been a recommendation to close the PUH maternity unit and that this had created anxiety amongst PUH staff. Therefore, PUH staff felt that any criticisms of PUH could increase the likelihood of closure of the PUH consultant led maternity services.

During this review process, the CRT were informed by SAOLTA management that key members of the PUH staff were invited to join relevant committees (e.g. the Guidelines Committee) and as noted from the attendance records, the CRT accept that the PUH staff were invited to meetings, however attendances appeared to wane during the period under review. The CRT considered this to reflect what had been reported to them by PUH staff as a feeling of being marginalised at such meetings. The CRT is of the opinion that this perception impacted on the integration between the PUH maternity staff and the SAOLTA group.

As stated above, there had been no further action after the escalation of the first two TH cases in 2014, until the third and fourth TH cases occurred later that year. Although individual cases were identified and reported through the local governance mechanisms in PUH and recorded on Q-Pulse as part of the SAOLTA, SIMT governance process, it appeared to the CRT from its review of the records, that detailed investigations did not occur until after the third and fourth cases happened. Similar to findings in other reviews, this meant that potential opportunities to put preventive measures in place were missed[17]. The reviews of the 12 additional cases showed that some of the problems predated 2014. Of the 12 cases, only 3 had any form of in-depth review at the time, again highlighting further missed opportunities. Reviewing cases is not about apportioning blame but improving practice.

There needs to be standard triggers for a review process and a regular screening of all incidents to look for trends and decide which cases need a further review. These reviews should be robust and conducted by personnel with expertise in the area. This is being rolled out on a national basis starting with the Serious Reportable Events (SREs) - HSE Document in January 2015[18]. However, the culture of reviewing cases is not about apportioning blame but about learning and prevention. If the same mistake is repeated, part of the cause of that is the failure to review and learn from the one that happened before.

(d) **Findings Following An Examination of The Corrective Measures Put In Place During The Preliminary Review**

Following the cluster of cases referred for TH, The SAOLTA Preliminary Review in December 2014 highlighted certain problems and implemented corrective measures. A programme of planned audits in PUH in December 2014 appeared to show that the initial measures had led to an improvement of care. The findings from the Preliminary Review were all confirmed in both the SAIs and the overall clinical review by the CRT. The *Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16*, covers many of the recommendations from this Report including staffing, labour ward presence of senior midwifery management and obstetric consultant presence as well as training and governance issues.

(e) **Findings Following An Examination of the Implementation of National HSE Policies In Relation To Patient Safety, Risk Management, Incident Management, Reporting, Investigation and Open Disclosure.**

[17] Dr. Bill Kirkup, The Report of the Morecambe Bay Investigation, March 2015
[18] https://www.hse.ie/eng/services/publications/performancereports/srejan15.pdf

The CRT considered in detail, the HSE policies in relation to patient safety, risk management and incident management, reporting, investigation and open disclosure. However there were limitations in the CRT's ability to fully examine the implementation of these policies against each of the individual cases under this review within the period 2008-2014. Many of the relevant policies post-dated the cases under review and for that reason, it was not appropriate to review those policies in all of the individual cases. This is dealt with in detail in Section 11.

The CRT also considered the HSE policies at various points throughout this report, in the context of the 18 cases.

In addition the CRT also analysed the relevant prevailing policies in aggregate from its consideration of the themes which emerged from a review of the 18 SAIs in relation to patient safety, risk management and incident management. There have been various national reports and policy documents produced concerning improvements in maternity care in Ireland in recent years, but without government support and funding, such improvements cannot be realised. The Creating A Better Future Together, National Maternity Strategy 2016-2026[19] is an ambitious document that lacks detail but gives a good framework from which to start the change process. It highlights the importance of clinical networks being available to the smaller units. The need for clinical networks must be required throughout Ireland since half the hospitals deliver under 2000 babies a year[20]. National support is required to implement the changes proposed by the National Maternity Strategy. This also requires a significant increase in staffing, medical, midwifery and nursing. Geography restricts the options available, but the women living in the catchment area of PUH require the same level of service provision as that available to women living in other parts of the country. This can only be provided within a developed network of maternity services. Full change management is required to achieve this.

1.5 **Key Findings Following a Review of Care in the 18 individual cases**

(a) **Review of the 6 Cases in the Preliminary Review**

The CRT considered the SAI reports and healthcare records (HCR) in 6 cases that were referred for TH in 2014 and which were the subject of the Preliminary Review. Of the 6 cases, the SAIs found 4 cases in which there were Key Casual Factors. The CRT considered the SAI reports along with their review of the hospital case records and agreed with the findings made. In addition, CRT's felt that the quality of the care was a contributory factor in the requirement for Therapeutic Hypothermia in one additional case. Of the 6 cases, the outcome in 4 cases was good, which may have been the result of good paediatric care and timely referral for TH.

(b) **Review of the 12 Additional Cases**

In the additional 12 cases, the Systems Analysis Investigation and the CRT's analysis found none or only minor problems in patient care in 5 cases. In the remaining seven cases, the SAIs found 4 Key Causal Factors with which the CRT agreed. In addition, on consideration of the SAI reports and the patient medical notes, the CRT felt that there were a further 2 cases where the quality of care may have contributed to the outcomes. In a further 1 case there was moderate errors but these probably did not contribute to the outcome.

[19] Creating A Better Future Together, National Maternity Strategy 2016-2026
[20] NPEC Annual Figures

(c) **Summary of problems in Clinical Care found in review of all 18 cases**

A review of the SAI reports, the Health Care Records (HCRs), documentation made available by SAOLTA, interviews with members of staff and feedback from all stakeholders and taking into consideration best practice, the CRT identified the following key issues:

- A lack of risk assessment and forward clinical planning.
- A lack of skill and training surrounding the deteriorating clinical situations and escalation of maternity care.
- The standard of CTG interpretation and expected interventions was variable.
- Inappropriate use of oxytocin occurred at times.
- A number of occasions, particularly out of hours and at weekends, where there was a lack of, or a complete absence of Clinical Midwifery Manager or obstetric consultant input.
- Variations in skill at, and supervision of, instrumental delivery were noted.
- At other times, there were prolonged decision to delivery intervals .
- In certain cases, there was a delay in requesting early paediatric presence for resuscitation for the baby

Although cases were identified and reported within the local and SAOLTA group governance structures, the factors above, along with what appeared to be a failure to not always investigate cases fully, led to repeated missed opportunities to learn and thus to prevent the recurrence of incidents and thus improve patient safety. Similar to findings in other reviews, this meant that potential opportunities to put preventive measures in place were missed.[21]

(d) **Summary of Communication and Care Problems After Delivery**

The main difference between the first 6 and the additional 12 cases was how these incidents were managed after the event. This is largely because the additional 12 cases were self-selected as cases where the women or families believed that care or support that they had received was poor. The CRT measured three domains, communication, support and feedback.

- In only 20% of the incidents was the communication and provision of care assessed as satisfactory. In 44% it could have been better and in 35% it was poor and may have aggravated the stress and upset to the families.
- Women from the additional 12 cases described not being listened to or communicated with during the antenatal period and labour. They believed that they did not get full explanations of what tests and interventions were being performed, nor were they given the opportunity to consent to them. They felt their concerns were dismissed by staff.

[21] Dr. Bill Kirkup, The Report of the Morecambe Bay Investigation, March 2015

- There were challenges with access to translation services and sometimes partners had to be used as the best available alternative.

- Also in the additional 12 cases, some women reported that after the birth, they were not always informed as to what was going on, why things had turned out the way they had and how sick their baby was. There was often a failure to debrief the family in a timely manner.

- In the additional 12 cases, some families reported to the CRT that in their experience there was a lack of openness, with some reporting that they had received no feedback at all despite many staff believing that they had been open with and had provided feedback to the families.

- There was no bereavement midwife or a single contact for families. As a result, some families reported difficulties accessing their clinicians to get the information that they were looking for.

1.6 **Key Points Identified at PUH Maternity Unit**

Key Points Identified
Environment
(a) Although PUH is within the SAOLTA group, there was no effective integrated maternity clinical network or management structure to ensure that clinical care was at the highest level.
(b) There was a lack of a strong onsite midwifery framework and midwifery input at clinical governance meetings.
(c) For the majority of the period of time under review there was no local midwife above CMM3 in PUH, resulting in the lack of senior midwifery input in to the senior management structures, despite the supportive presence of the Assistant Director of Nursing. For the period of time under review, the two Directors of Nursing in place from 2008 to 2014 did not have a midwifery qualification. The Assistant Director of Nursing (ADON) in position from 2008 to August 2010 did have a midwifery qualification but the ADON in place from September 2010 did not.
(d) A Group Director of Midwifery was not appointed to the SAOLTA group until June 2014.
(e) The skills and training of some frontline staff appeared to the CRT to be insufficient in cases in which there was clinical deterioration and a need to escalate care
(f) There was ineffective team working in the maternity care provided in some of the cases.
(g) Poor obstetric clinical handover including processes for conveying clinical concerns and poor formal handover between on-call medical staff.
(h) Lack of the appropriate midwifery led care either in the clinics or the labour ward.
Clinical
(a) Failure in some cases to recognise an abnormal antenatal and intrapartum CTGs.
(b) Failure in some cases to use secondary monitoring such as ultrasound or fetal blood sampling.
(c) Failure in some cases to escalate abnormal intrapartum CTG findings.
(d) Failure in some cases to expedite delivery of the baby.
(e) Prolonged decision to delivery interval in some cases.
(f) Incorrect use of oxytocin infusion in the presence of an abnormal CTG in some cases.
(g) Failure to appropriately escalate care to the obstetric consultant in some of the cases reviewed
(h) In some cases poor system for contacting the paediatric staff on-call for resuscitation of the sick baby.

Staffing

(a) There was understaffing of both midwives and consultants resulting in a lack of support in the acute areas.

(b) There is a need to ensure that relevant and appropriate training and a hospital induction process is available for all new staff and that locum medical staff are provided with access to relevant clinical protocols.

(c) Lack of multidisciplinary training and maintenance of skills.

(d) Gaps in the appropriate staffing structures to ensure continuous CMM labour ward presence with the ability to escalate concerns, most notably out of hours and at weekends. During feedback the CRT was informed that this was normal staffing management in a mid-sized hospital during the time period under review and did not change until 2014.

(e) For the period of time under review, the two Directors of Nursing in place from 2008 to 2014 did not have a midwifery qualification. The Assistant Director of Nursing (ADON) in position from 2008 to August 2010 did have a midwifery qualification but the ADON in place from September 2010 did not.

Communication Issues

(a) In some of these cases, there was a lack of communication between staff groups, both in the clinical situation and in the governance process.

(b) Poor communication with some families during labour and after an event.

(c) In some cases, there was a lack of open disclosure of information to the family.

(d) In some cases, inappropriate/insensitive arrangements for follow-up appointments.

Clinical Governance Issues

(a) Audit activity within the unit and network needed improvement, in order to improve learning.

(b) Lack of perinatal structures to ensure appropriate midwifery, obstetrical and neonatal communication.

(c) Lack of implementation of common clinical maternity guidelines throughout the SAOLTA group.

(d) Difficulties in staff attending centralised training in Galway.

(e) Shortfalls in the initial management of the incidents and the implementation of the requirements for incident management prior to 2014.

(f) The HSE Safety Incident Management Policy May 2014 outlined the principles that should be followed when completing such investigations. These do not appear to have been fully implemented in the 2014 cases reviewed by the CRT to which this policy applies.

(g) Lack of a detailed investigation of incidents as they occurred by the appropriate professionals with appropriate knowledge and experience of intrauterine death or a serious clinical incident.

(h) The lack of a specific practice development midwife or risk midwife.

(i) No maternity dashboard or similar information feedback.

1.7 **Key Recommendations**

The CRT identified the following important issues that need to be addressed to enhance the safety of services for women and babies at PUH. Some are similar to the existing national strategy and others recommended by the Preliminary Review have been implemented.

Environment

(a) Need to establish a maternity network within SAOLTA allowing the sharing of expertise within the network to strengthen the operational resilience of the smaller units such as PUH and to enable such units to be supported so as to provide safe quality services.

(b) Need for the maternity services to be appropriately resourced, underpinned by strong and effective leadership, management and governance arrangements, and delivered by a skilled and competent workforce, in partnership with the women using the service.

(c) The maternity services must be in a position to respond to increasingly diverse and complex population needs in order to provide safe, evidence-based, accessible care to all women, babies and their families.

(d) Systems need to be developed to roll out new therapeutic techniques as quickly as possible throughout Ireland with the appropriate infrastructure, guideline development and training but with an emphasis on the local sites to ensure this process occurs in a timely fashion.

(e) Need to improve the governance structures to ensure the collection of robust data on outcomes, detect patterns and learn from serious incidents. There needs to be a structure with explicit lines of responsibility and accountability with the appropriate leadership.

(f) Improve the level of open disclosure occurring with the individuals involved in a serious incident

(g) There should be development of the appropriate risk assessment to allow autonomous midwifery working with an organised structure of care planning and escalation policies

Training

Development of training in:

(a) CTG training to include interpretation and appropriate intervention for all front-line staff.

(b) Multidisciplinary training in obstetric emergencies for all front-line staff.

(c) Drills on transfer to theatre in an emergency for all front-line staff.

(d) Fetal Blood Sampling and when to use it.

(e) Ultrasound including Doppler and when to use it.

(f) Instrumental delivery and assessment of chances of success.

(g) The appropriate use of an oxytocin infusion.

(h) Neonatal Resuscitation Training Program and Local Lead.

(i) Identifying babies suitable for TH.

(j) Incident recognition and reporting and incident management and review.

Clinical Care

(a) Need to introduce tools such as ISBAR to aid communication at handover or discussion of patient care between clinical staff.

(b) Need for one-to-one ratio of a midwife to each woman in labour.

(c) Need for the Obstetric and Midwifery leads to ensure that staff are aware of the current guidelines in PUH in relation to Trial of Labour (VBAC) and that it is implemented in practice.

(d) Need for a system for contacting the Paediatric Team to attend a high-risk delivery.

(e) Need for multi-disciplinary team training in newborn resuscitation scenarios such as 'mock codes.'

(f) Need to establish a lead paediatrician for newborn care.

Staffing

(a) Need for a review of staffing numbers to ensure midwifery leadership is enhanced and there is a dedicated midwifery manager on each shift who can work in a supervisory capacity overseeing the labour ward.

(b) Need for risk assessment regarding recruitment and employment of locum clinical staff particularly in those situations where locum staff are required on a short-term basis and where the post needs to be filled within a short timeframe.

(c) Need to ensure that local clinical staff receive appropriate training and hospital induction that clearly outlines their clinical roles and responsibilities for the period of their employment and that this information outlines the supervision structure in place for the locums.

Communication Issues

(a) Improve the communications between midwives and medical staff.

(b) Improve the communications with families during labour and after an event.

(c) Discuss options for birth and other interventions with the mother during pregnancy.

(d) Keeping the mother and her birth partner updated throughout labour on the progress of labour and/or the need for intervention(s).

(e) Need for the implementation of open disclosure.

(f) Each family should have an identified contact person within PUH that is responsible for follow-up contact with them following a serious incident

(g) Need for SAOLTA to ensure that the governance structures and processes within the group and individual hospitals regarding all aspects of incident management including investigation are fully aligned to the requirements as set out in the HSE Safety Incident Management Policy (2014).

(h) Need for SAOLTA to ensure that all relevant staff attend Incident Management Training (0.75 day) and SAI of Incidents (3 days) training and that these trainees are assigned investigations which are reviewed and quality assured to ensure that competency in investigations is achieved

(i) Need for the SAOLTA to ensure that all staff are aware of and comply with the HSE Open Disclosure Policy("Open Disclosure Policy") [22]; and that the related Open Disclosure Guidelines [23] are implemented in PUH

1.8 The Effects Of This Review On The Families And Staff

It is obvious to the CRT that this review process has taken a toll on both families and staff. It has taken a prolonged time of over three years and there are many reasons for that which are discussed within this Report. We always have to be careful that the process of review does not make the situation worse for the families or staff causing increased distress. Similarly, the review needs to help in staff learning and development. Staff are encouraged to participate in the review process and recognise that their valued participation will help in the long term improvement of the care which they provide. It is important to understand that this is learning process not a blame exercise. The aim is to help the hospital and the community to come through this and help the hospital become the best it can be. We believe that implementing the recommendations made within this Report will go a long way towards achieving these aims. However, inevitably, it may not appear that way at the time and consequently it is important that we acknowledge this and thank all the families and staff that took part and hope that they benefit from it.

[22] HSE Open Disclosure - National Policy, October 2013
[23] Open Disclosure: National Guidelines - Communicating with service users and their families following adverse events in healthcare

2. SAOLTA UNIVERSITY HEALTH CARE GROUP ("SAOLTA")

SAOLTA covers six counties, namely Galway, Mayo, Sligo, Leitrim, Donegal, and Roscommon. The population of the SAOLTA region (based on the 2011 census) stands at 703,684 (See Figure 1 below)

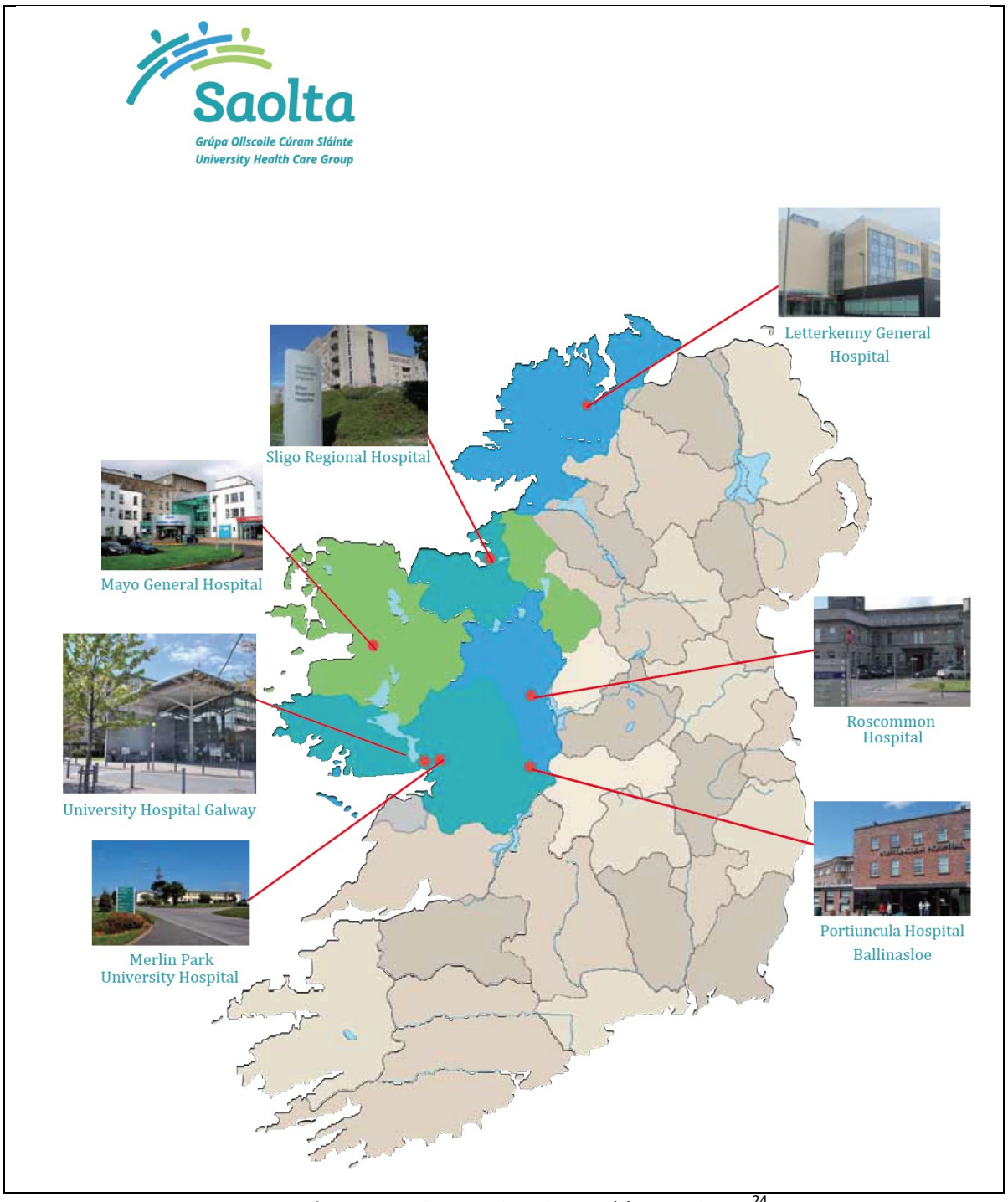

Figure 1: SAOLTA University Health Care Group[24]

2.1 SAOLTA comprises seven hospitals including Galway University Hospital, Roscommon University Hospital, Letterkenny University Hospital, Sligo University Hospital, Mayo University Hospital,

[24] SAOLTA website http://www.saolta.ie/

Merlin Park University Hospital, and PUH. Of these hospitals, all but Merlin Park and Roscommon University Hospital provide maternity services. SAOLTA was formed in 2014 from the previous West/North West Hospitals Group.

2.2 Maternity services at the five SAOLTA hospitals during the period under review were organised into the "Women and Children's Directorate" which was led by the Clinical Director for the Women's and Children's Directorate. An Associate Clinical Director was appointed to PUH for Women and Children's services, who then reported to the Group Clinical Director for Women and Children's services.[25] This was a relatively new development at the time and the overall clinical governance and working practice of the service were still being established.

2.3 As part of the feedback process the CRT were informed that the Women's and Children's Directorate was in place in GUH for many years. It's role was evolving to include the other sites including Portiuncula. Therefore, this was not the formation of a new unit but part of the evolution of the new group. The integration and governance reform is a major project and was still being progressed in 2014. There was a clear timeline and plan to have the directorate replaced by a Clinical Business Unit for Women and Children (with full executive authority and responsibility for maternity and children services across all hospital sites in the group - five sites with such services) by late 2018.

2.4 During the time period covered by this review, there was no integration strategy in the group and each hospital functioned independently. However, a plan for an integrated clinical strategy was in place to improve quality, safety and access for patients by developing an integrated structure across all hospitals in the SAOLTA group. This was part of a group-wide 5 year clinical strategy being developed[26] which planned to integrate with current strategies within hospital sites and directorates. At the time covered by the review, this integration was not fully in place and each hospital appeared to function relatively independently.

[25] Appendix 6 Organisational Structures
[26] Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/2016

3. PORTIUNCULA UNIVERSITY HOSPITAL BALLINASLOE (PUH)

Figure 2: Portiuncula University Hospital Ballinasloe (PUH)

3.1 Portiuncula University Hospital Ballinasloe (PUH)

PUH was originally founded by the Franciscan Missionaries of the Divine Motherhood in Ballinasloe and was officially opened in 1945. It is located 50km from Galway University Hospital (GUH) and 150 km from Dublin. The hospital transferred into the Western Health Board in 2001, and today operates as a constituent hospital within the SAOLTA University Health Care Group.

PUH is a 198 bedded Model 3 hospital providing 24/7 acute surgery, acute medicine and critical care along with emergency department and maternity services to adults and children in the catchment areas of East Galway, Westmeath, North Tipperary, Roscommon and Offaly.

PUH is a teaching hospital and has medical training schemes for Non Consultant Hospital Doctors (NCHDs), Interns, Senior House Officers (SHO's) and Specialist Registrars (SpRs), it has also developed academic links with the University of Limerick's post-graduate training scheme and an overseas medical student programme. In addition the hospital supports student nurse and midwifery training. A Joint Medical Academy opened in January 2013 in partnership with the National University of Ireland, Galway and the University of Limerick to facilitate and strengthen this training.

3.2 Maternity Services at PUH

PUH maternity unit is a 33 bedded unit providing 24 hour on-call teams in Obstetrics/Gynaecology, Anaesthetics and Paediatrics which has an onsite Special Care Baby Unit (SCBU). During the period under review (2008-2014), the hospital accepted all maternity cases in its catchment area. As with all the hospitals in the SAOLTA group, PUH worked relatively independently. The births in PUH have slowly declined in recent years, in keeping with national trends.[27]

Year	2013	2014	2015
Births	2052	1983	1853

Table 1 Number of deliveries in PUH, 2013-2015

[27] Central Statistics Office www.cso.ie

3.2.1 **Composition of PUH Maternity Unit:**

Maternity and Paediatric Services Provided in PUH
• 33 bedded unit providing antenatal, intrapartum and postnatal care
• Antenatal Education Classes in conjunction with a Multidisciplinary Team; Parent Craft Support
• 4 Labour suites with a 24 Hour Epidural Service; Theatre Suite in Main Theatre to support Caesarean Sections; a Special Care Baby Unit; Neonatal and Paediatric Services
• An Admission Room; an Early Pregnancy Assessment Unit; Antenatal Outpatient services including outreach clinics in Loughrea and Athlone; Gestational Diabetes Clinics; Post-natal Outpatient Service
• Crisis Pregnancy Service
• Breastfeeding support and education - Clinical Nurse Specialists in Lactation; Breastfeeding support Clinic (Drop in and Local Health Centre weekly)
• Pastoral Care and Bereavement Counselling
• Neonatal New-born Hearing Screening Programme

Table 2: Maternity and Paediatric Services Provided in PUH

3.2.2 **Bereavement Support at PUH**

PUH provided the CRT with information about the Pastoral Care Department and how, in conjunction with the Social Work department, it provides support and assistance to women, their partners and families in the provision of individualised care for women following miscarriage, still birth and neonatal death. This information indicated that the hospital facilitates an annual remembrance service for bereaved parents and that the Pastoral Care department supports families with funeral arrangements, blessings and naming ceremonies which may be held in the PUH Chapel.

However during the time of the cases for review, 2008-2014, although support was given through the Pastoral Care Department, there was no dedicated bereavement midwife. It is the view of the CRT that the lack of bereavement support and link midwife, was in part, responsible for the problems related to the 12 additional cases added to this Report, as it contributed to the deficiency in family support following the problems at birth.

PUH indicated that it works closely with Support Groups such as Féileacáin[28], that it had established a Perinatal Bereavement Group and that this group is working towards the implementation of the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death which were published in September 2016[29]. During this investigation, the hospital indicated that it is approved for a 0.5 Whole Time Equivalent (WTE) Perinatal Bereavement Midwife.

[28]Féileacáin is the stillbirth and neonatal death association of Ireland. It is a not for profit organisation that provides support to anyone affected by the death of a baby during or after pregnancy.
[29] HSE, National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death, August 2016

4. PUH AUDIT DATA 2008-2013[30]

4.1 Audit data from the Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports 2008 and 2013, NPEC (Figure 3 and Table 3) show that the number of Stillbirths occurring in PUH is comparable with the rest of Ireland[31]. The numbers are small which means the rate will fluctuate but overall there is a downward trend.

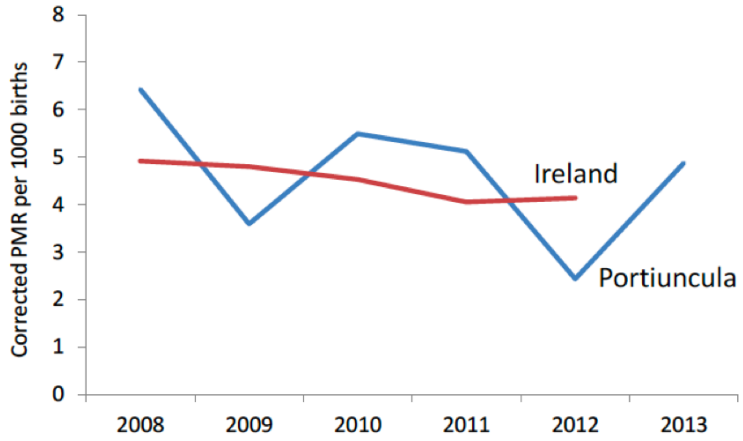

Figure 3: Perinatal mortality in PUH and nationally 2008-13[32]

Year	Births	Stillbirths	ENNDs	Perinatal deaths	Corrected perinatal deaths	Stillbirth rate per 1,000	ENND rate per 1,000	PMR per 1,000	Corrected PMR per 1,000
2008	2178	14	3	17	14	6.4	1.4	7.8	6.4
2009	2227	10	0	10	8	4.5	0.0	4.5	3.6
2010	2185	15	2	17	12	6.9	0.9	7.8	5.5
2011	2148	7	5	12	11	3.3	2.3	5.6	5.1
2012	2055	6	2	8	5	2.9	1.0	3.9	2.4
2013	2052	10	4	14	10	4.9	2.0	6.8	4.9

Note: Corrected perinatal deaths excludes perinatal deaths involving major congenital anomaly. PMR = perinatal mortality rate; ENND=early neonatal death.

Table 3 Trends in corrected perinatal mortality rate (PMR) for PUH, 2008-2013[33]

4.2 Similarly, the Severe Maternal Morbidity in Portiuncula Hospital Ballinasloe Annual Report 2012 and 2013, NPEC demonstrates that the outcomes in PUH are not out of line with the national average. (Figure 4)

[30] Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports, 2008 and 2013. NPEC
[31] Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports, 2008 and 2013. NPEC
[32] Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports, 2008 and 2013. NPEC
[33] Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports, 2008 and 2013. NPEC

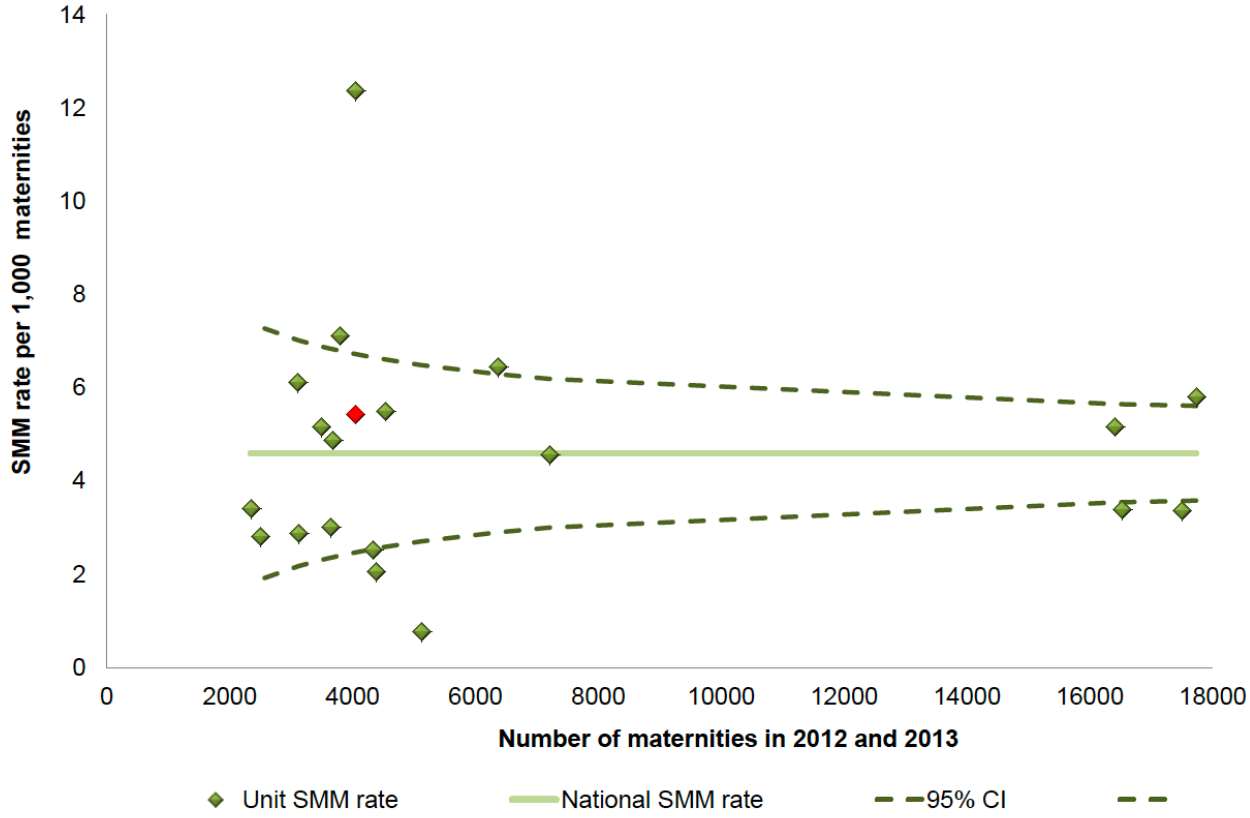

Figure 4 Funnel plot of the rate of severe maternal morbidity (SMM) by maternity Unit, 2012/2013

4.3 An internal clinical audit of instrumental delivery by the clinical teams within the hospital demonstrated no apparent problem with the incidence of failed attempts within what is expected and no change over the years.

Date	2010	2011	2012	2013	2014
Failed	23	20	23	22	21
Success	369	366	343	317	353
% failed	6.23	5.46	6.7	6.9	5.9

Table 4: Failed instrumental delivery in PUH

4.4 A Review of the numbers of babies that suffered from Hypoxic Ischaemic Encephalopathy (HIE) from 2010 to 2015 demonstrated that the cluster in 2014 appeared to be unexpected.

2010	2011	2012	2013	2014
1	4	3	3	6

Table 5: Number of babies with Hypoxic Ischaemic Encephalopathy (HIE), as reported by PUH Annual Reports

4.5 So at the end of 2013, PUH was not an outlier for baby deaths or morbidity or maternal morbidity and there were no apparent clinical concerns.

5. GENERAL REVIEW OF THE MATERNITY SERVICES AT PUH

5.1 The CRT Methodology

In order to complete a general review of the maternity services at PUH during the review period 2008-2014, the following steps were taken:

(a) The CRT interviewed relevant management and clinical staff members and met affected families who wished to meet the CRT;

(b) The CRT undertook a desktop review of all relevant documentation as provided to them including the hospital clinical records of all 18 cases;

(c) The CRT reviewed each of the 18 individual Systems Analysis Investigation (SAI) Reports

5.2 CRT Interviews With Clinical Staff

5.2.1 The CRT interviewed senior clinicians and managers between 9th June 2015 and 23rd May 2016 as follows (Two individuals were interviewed twice):

Date	Job Title of Staff Member Interviewed by CRT
9th June 2015	Chief Clinical Director, SAOLTA University Health Care Group
	Consultant Obstetrician & Gynaecologist and Associate Clinical Director, PUH, Women's and Children's Directorate
	General Manger, PUH
	Group Director of Midwifery, SAOLTA University Health Care Group
	Professor of Midwifery, NUI Galway and SAOLTA University Health Care Group
	Director of Nursing and Midwifery, PUH
	Assistant Director of Nursing, PUH
	Assistant Director of Nursing and Deputy of Care Directorate, PUH
	Midwife CMM3, PUH
	Midwife CMM2, PUH
1st February 2016	Teleconference with Chief Clinical Director, SAOLTA University Health Care Group
	Consultant Anaesthetists, PUH
	Consultant Paediatricians, PUH
	Consultant Obstetricians and Gynaecologists, PUH
	Director of Nursing and Midwifery, PUH
	Assistant Director of Nursing and Midwifery, SAOLTA University Health Care Group
	Chief Executive Officer, SAOLTA University Health Care Group
23rd May 2016	Chief Clinical Director, SAOLTA University Health Care Group
	Consultant Obstetrician and Gynaecologist, PUH (by telephone)

	Group Director of Midwifery, SAOLTA University Health Care Group
	Group Director of Nursing and Midwifery, SAOLTA University Health Care Group
	Group Clinical Director, Women's and Children's Directorate, SAOLTA 2012-2015

Table 6: Individuals interviewed as part of the CRT review process

5.2.2 This provided the broad information that was needed to address the issues raised in Part I of the Terms of Reference for this Report which related to a *General Review of Maternity Services at PUH.*

5.3 **Meetings with Families**

The CRT set a meeting in a neutral venue in October 2016 to meet and talk to the families involved in this review in an open forum setting. The meeting was open to all the families concerned. Eight families attended, who were involved in ten of the cases included within the 18 individual investigations that fell within this review. This was an open forum discussion involving the families and members of the CRT. This allowed the CRT to gain further insight into the general problems that the families experienced with the handling of their cases and the SAI reports.

A further series of private meetings with the individual families followed in April 2017. Nine of the families involved in the 18 cases affected took the opportunity to meet the CRT. Prior to these meetings, the families had received a copy of the SAI report(s) pertaining to their case(s). The purpose of the meetings was to afford the families the opportunity to discuss their case, receive feedback and have their questions answered by the CRT. Each family will be provided with written feedback in the form of a Mini Report from the CRT, in addition to the SAI, irrespective of whether they attended these meetings or not. For families who met with the CRT, those meetings were minuted and the families will receive a copy of the minutes. Both the Mini Reports and the meeting minutes (where applicable) will be provided to the families at the time of the publication of this Report.

5.4 **Documentation Reviewed by the CRT**

5.4.1 The CRT reviewed the following information related to maternity services at PUH:

- Annual Reports from PUH
- Morbidity and mortality reports from PUH
- Risk and incident information including incident reporting documentation for cases and statistics from PUH
- Internal audits of practice and maternity statistics
- The conclusions of the Preliminary Review of six cases[34] which was completed on the 23rd December, 2014
- Documentation in relation to the Organisational Structures in PUH and SAOLTA 2008-2014
- Documentation in relation to Midwifery Structures, Descriptions of Roles and Sample Midwifery

[34] Whilst the Preliminary Review concerned 7 babies born at PUH with severe perinatal outcomes in 2014, only 6 of those babies were referred for TH and are the subject matter of this review.

Job specifications

- Training Records
- Minutes of SIMT and other meetings such as the Minutes of PUH Maternity Risk Management Meetings (2014), Patient Safety Group Meeting Minutes (2014) and the Terms of Reference for the Patient Safety Group, Hospital Risk Register and Quality & Safety Governance Group Meeting Minutes (2014)
- Extracts from Q-Pulse (2014), Risk Assessment Forms and Serious Incident Logs
- Relevant exchanges between PUH clinicians and SAOLTA management regarding the Preliminary Review and the events which triggered the commissioning of this review
- Healthcare records related to the 18 cases that were individually investigated under this review.
- The SAI Reports for all 18 cases
- Health Service Executive National Consent Policy
- Health Service Executive Open Disclosure Policy, Document Reference Number: QPSD-D-062-1
- National Standards for Bereavement Care Following Pregnancy Loss & Perinatal Death (September 2016)
- Irish Multidisciplinary Obstetric Emergency Training (IMOET) 2014
- Irish Maternity Indicator System (IMIS) National Report 2015
- Creating A Better Future Together. National Maternity Strategy, 2016-2026
- Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16
- National Consultant Workforce Planning 2015 (Supplementary Report)
- Final Report of the HSE Midwifery Workforce Planning Project 2016
- Transport of Infants Referred for Cooling Treatment: NNTP Clinical Guideline Cooling on Transport. September 2011
- Perinatal Mortality at Portiuncula Hospital Ballinasloe Reports 2008 and 2013. NPEC
- Severe Maternal Morbidity in Portiuncula Hospital Ballinasloe Annual Report 2012 and 2013, NPEC

Table 7: Documents reviewed as part of the CRT review process

5.5 Fair Procedures

Prior to the finalisation of this Report the CRT conducted a fact-checking and fair procedures process. This involved engaging with persons affected by the contents of this Report, the Mini Reports and/or the Minutes of the meetings with the families to ensure that they are factually accurate and that fair procedures have been followed. (See Appendix 9 for full details)

6. SYSTEMS ANALYSIS INVESTIGATIONS (SAI) IN THE 18 INDIVIDUAL CASES

6.1 6 Original Cases

(a) Hypoxic Ischaemic Encephalopathy (HIE) and Therapeutic Hypothermia (TH)

TH is used to try and reduce the effect of a lack of oxygen and blood flow in the baby's brain at the time of delivery. Lack of oxygen in the brain around the time of birth affects 3-5 infants per 1000 live births in developed countries, with 0.5–1 infants per 1000 live births developing brain damage as a result of hypoxic ischaemic encephalopathy (HIE) (Ballot,2010; Levene et al,1986)[35].

Before the advent of TH, up to 60% of infants with HIE died and 25% of survivors were left with a significant disability (Vannucci,1999). Moderate cooling (to between 33 and 34 degrees Celsius) has been found to reduce secondary brain injury and death in new-born infants with moderate-to-severe HIE (Azzopardi et al)[36].

It might be expected that a hospital such as PUH (with approximately 2000 deliveries a year) would refer about 2-4 babies per year for TH, of which 1-2 would meet criteria for TH. So the number of 6 in 2014, was higher than would be expected. The reasons for this could be an increase in the babies at risk, due to problems with delivery or a lowering of the threshold for referral. The Preliminary Review has suggested that there were problems to address hence the commissioning of this Report.

(b) Patient selection for the Preliminary Review

This CRT review was commissioned because of the concerns over 6 babies that were referred for TH in 2014 and were part of the Preliminary Review that was conducted by SAOLTA.

6.2 12 Additional Cases

(a) After the announcement of this external independent clinical review, a dedicated helpline was set up and a further 10 families[37] (12 cases) asked for their cases to be added to the external review. These cases spanned the years 2008 to 2014 and had a variety of clinical presentations, not all relating to HIE. This was a significant challenge to the original review as it gave a different purpose to the review and greatly increased the workload and the length of time it took to complete the review. There is a significant difference in a review of a cluster of cases with the same outcomes and assessing the care provided to 18 cases with different outcomes, with many wanting personal feedback of their own cases. However, the additional 12 cases offered the CRT a wider review of the care provided over a longer period of time. It also gave insight into the after care, particularly the problems with communication and pastoral support provided to the families. For these reasons, the

[35] Levene, M.I., C. Sands, H. Grindulis, and J.R. Moore, Comparison of two methods of predicting outcome in perinatal asphyxia. Lancet, 1986. 1(8472): p. 67-9.
[36] Azzopardi, D., P. Brocklehurst, D. Edwards, H. Halliday, M. Levene, M. Thoresen, A. Whitelaw, and T.S. Group, The TOBY Study. Whole body hypothermia for the treatment of perinatal asphyxial encephalopathy: a randomised controlled trial. BMC Pediatr, 2008. 8: p. 17.
[37] Two of the families involved had two separate cases reviewed each.

CRT welcomed the opportunity to review these cases in addition to the 6 cases reviewed by the Preliminary Review.

(b) It is important to point out at this time, that this review assessed the practices at PUH at the time of the cases and is largely a historical review centred around these 18 cases and not an assessment of the care received by almost 15,000 women[38] who delivered in PUH between 2008 and 2014, the majority of whom, had a positive experience and a good outcome. These 18 cases contribute a small but important cohort of pregnancies that can be used to assess a system under stress.

The years in which these 18 cases occurred were:

2008	2009	2010	2011	2012	2013	2014
1 case	1 case	5 cases	0 cases	2 cases	1 case	8 cases

Table 8: The year of delivery of the cases reviewed

Therefore, most cases relate to births in either 2010 or 2014.

6.3 The SAI Methodology

The HSE SAI process is conducted in accordance with the HSE's Guideline for Systems Analysis Investigation of Incidents and Complaints[39] ("the SAI Guidelines"). The SAI Guidelines require the involvement of staff and families in the development of the chronology. Thereafter, the SAI investigation teams assess the care provided against the standards expected. This is a well-structured and detailed methodology. As part of this review, SAI reports were commissioned for all 18 cases to help the CRT assess the overall care provided.

The SAIs were carried out by HSE appointed investigators who were not employed by SAOLTA and who followed the SAI Guidelines.

The CRT were consulted by the SAI investigators only when there was a specific need for expert opinion or where medical input relating to data interpretation was required, such as the interpretation of CTG charts and clinical judgment. In addition, all SAI reports were submitted initially in draft form to the CRT for review before finalisation.

The individual investigation of each of the 18 cases was carried out by an Investigation Team named in each SAI report.

The same investigation teams were assigned to investigate both cases in the two families with two cases each, so that the families would not have to be interviewed by two different investigation teams. However, staff involved in more than one case were often interviewed on separate occasions by different investigators. The difficulty assigning investigators and the addition of 12 cases prolonged the overall review timelines.

[38] Estimated figure based on local audit
[39] HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints (2012 and updated 2016)

The SAI approach is an internationally recognised methodology for investigating adverse events in healthcare which involves the following 6 steps (HSE Investigation Guidelines):

The six steps used in the System Analysis Investigation	
Step 1:	Organise the investigation and gather the data (including conducting interviews)
Step 2:	Determine the incident chronology
Step 3:	Identify Key Causal Factors[40] and Incidental Findings[41]
Step 4:	Identify Contributory Factors[42]
Step 5:	Make recommendations
Step 6:	Write the investigation report and submit to the Investigation Commissioner.

6.4 SAI Data Collection And Review

For each individual SAI, the individual investigation teams collected and reviewed the following documentation as relevant:

- The patient's maternity healthcare record and the initial neonatal care
- Relevant policies, procedures, protocols and guidelines
- Relevant literature including Clinical Guidelines and peer reviewed articles
- Copies of Incident/Near Miss Report Forms

6.5 SAI Interviews With Families and Staff

For each of the 18 SAI reports, interviews were undertaken with women and their families, and with staff members involved in each patient's care.

The number of staff interviewed for each of the 18 individual investigations ranged from 4 to 17. Overall, a total of 201 staff interviews were conducted including interviews with midwifery staff; shift leaders; consultant obstetricians; consultant paediatricians and NCHDs. Due to the methodology of the SAI investigations, many of the staff were interviewed on different occasions for each case they were involved with instead of once for all the cases they were involved in. This caused added stress and disruption to the staff in the performance of their duties. Doctors and especially the midwives involved participated in these interviews whilst still delivering ongoing care to women and their families attending PUH.

[40] *Key Causal Factors* are defined as issues that arise in the process of delivering and managing health services which the Investigation Team considers had an effect on the eventual harm.
[41] *Incidental Findings* are defined as issues that arise in the process of delivering and managing health services identified during the course of an investigation which the Investigation Team consider did not impact on the outcomes but which serve to identify issues for system improvement
[42] *Contributory factors* are defined as circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

6.6 **Process for Assigning Investigators to Individual SAI Reports**

6.6.1 The conduct of the SAIs was a parallel process carried out by the National Incident Management and Learning Team (NIMLT). The CRT were not involved in the setting up or conduct of the SAIs. During March and April 2015, it was planned to carry out full SAIs of the 6 cases. An additional 12 cases for review were identified by April 2015.

6.6.2 It was agreed that two investigators from NIMLT would conduct the first 6 investigations. After the addition of the 12 further cases, (involving 10 families), two further NIMLT investigators were assigned to one of those 12 cases. By May 2015 the remaining 11 investigations still required investigators to be assigned. The Commissioner of this Report indicated that the additional investigators should not come from within SAOLTA. A further investigator was nominated by the Quality and Patient Safety Office within the Acute Hospital Division (AHD). Consequently, a request was made via the National Director for the Acute Hospital Division to the Chief Executive Officers of the remaining 6 Hospital Groups (HG) to nominate investigators.

6.6.3 Once nominated, investigation teams were assigned cases to investigate based on their current work load, and on their ability to undertake a number of investigations. Four of the additional 12 cases identified through the helpline related to two families i.e. two families had two cases for investigation. The difficulty assigning investigators and the addition of 12 further cases prolonged the overall time taken to complete the SAIs and hence, the overall review process.

6.7 **The SAI Workflow:**

- Process for assigning investigators to individual investigations
- Withdrawal of investigators from investigation teams in 4 cases due to individual difficulties
- Management of sensitive and confidential information
- Developing draft investigation reports
- Factual accuracy checking and fair procedures
- Quality checking
- Legal review
- Submission to the Clinical Review Team for inclusion in the review process

6.8 **Timing of submission of the SAIs to the Clinical Review Team**

6.8.1 As already stated, the addition of the 12 further cases to the Terms of Reference significantly extended the time taken to complete the SAI reports, for the CRT to review them in draft and for final submission to the CRT and the Commissioner for inclusion in the review process.

6.8.2 The first meeting of the CRT was in April 2015 to discuss the processes. See Appendix 8.

6.8.3 The timing of submission of the commencement, first draft and the final report in the 18 cases is set out in Table 9 below:

No	Date of Commencement of the Investigation	Date of Submission of Draft Report	Date of Final Submission to Commissioner and CRT
1	01/05/2015	17/08/2015	03/06/2016
2	01/05/2015	27/08/2015	27/06/2016
3	01/05/2015	09/09/2015	11/07/2016
4	01/05/2015	11/09/2015	31/05/2016
5	01/05/2015	24/09/2015	02/06/2016
6	01/05/2015	08/10/2015	19/05/2016
7	01/05/2015	13/10/2015	14/07/2016
8	26/05/2015	20/11/2015	04/08/2016
9	26/05/2015	29/11/2015	04/08/2016
10	26/05/2015	01/09/2016	23/02/2017
11	26/05/2015	28/02/2017	10/04/2017
12	02/06/2015	04/11/2015	30/01/2017
13	02/06/2015	04/12/2015	05/10/2016
14	13/07/2015	23/10/2015	30/03/2017
15	28/07/2015	25/10/2015	05/10/2016
16	28/07/2015	25/03/2016	25/10/2016
17	11/08/2015	08/04/2016	15/11/2016
18	13/08/2015	25/03/2016	22/11/2016

Table 9: The timing of submission of the commencement, first draft and the final report in the 18 cases

6.8.4 Once the draft report was submitted by the investigators, it was reviewed by the CRT who assessed them for clinical accuracy. They were also reviewed by the staff and families for factual accuracy and by the PUH legal team for compliance with fair procedures as required by the SAI Guidelines. When considering the draft SAI reports, the CRT made no alteration to the conclusions reached by the SAI investigation team. If there was a concern about the clinical accuracy of the SAI report then the report was returned to the SAI team for consideration.

6.8.5 The first SAIs were assigned on the 1st May 2015 and the last on 13th of August 2015, the first draft report was received on 17th August 2015 and the last on 28th February 2017. The first completed report was received on 19th of May 2016 and the last completed report was submitted on the 10th April 2017 (Table 9). The average length of time from assigning a SAI team and submission of the draft report was 29 weeks, and a further 39 weeks of reviewing and fact checking and completion until the final report was received. This meant an average time between the start and finish of the each SAI of 68 weeks. The CRT could not complete this Report until all the SAIs were submitted, to allow them all to be included in the analysis.

6.8.6 Although this timescale has been long, the process involved the review of 18 individual SAIs and a full review of the maternity service at PUH, which of themselves have been very complex. In addition the CRT was obliged to undertake a significantly complex fair procedures process as detailed in Appendix 9.

7. THE CRT CLINICAL REVIEW METHODOLOGY

As part of the Terms of Reference, the CRT reviewed the SAI reports. The CRT review was a parallel process to the SAI process. The processes complemented each other and informed the findings and recommendations of this Report.

The CRT reviewed the clinical cases along with the SAI reports and came to an assessment based on:

(a) Obstetric and midwifery clinical care and immediate paediatric clinical care;

(b) Patient Perceived Support (Including general communication, practical support, and feedback related to the incident).

7.1 CRT Clinical Review Steps

7.1.1 Prior to the commencement of each of the 18 individual SAI investigations, consent was sought and gained from each of the 16 families to allow the SAI investigators (as outlined in the Terms of Reference (See Appendix 2) to access their healthcare records.

7.1.2 The CRT looked at all the relevant Health Care Records ("HCRs") to assess the clinical care on an individual case by case basis. This assessed the care deficiencies that might not have been identified as Key Causal Factors but may have contributed towards the clinical outcome (see desktop separate scoring system below). The methodology used was modified from that used in the Morecambe Bay Investigation[43.] This was initially completed by August 2015 and was used as a method of comparing the results with the SAIs. The conclusions made by the CRT are included in the review but were also delivered to the families independently as secondary reports and personal interviews took place where requested.

7.1.3 There were some issues in relation to the chronology and factual accuracy of the SAIs where they were at odds with the families' memories. In all 18 cases the CRT largely agreed with the findings of the SAI reports with some differences found in the assessment of care and cause. However, in two cases, the CRT disagreed with the SAI report and considered the factors identified in the SAIs to have more substantially contributed to the outcome than was stated in the SAI. Generally, the CRT noted that the SAI reports were concordant with their desktop scoring system (see below). When there were areas of clinical difficulty, individual members of the CRT gave support to the individual investigation teams providing clinical expert knowledge but the conclusions of the individual SAIs were never altered by the CRT.

7.1.4 An aggregate analysis of the 18 individual investigations was conducted to identify themes which are important to achieve improved safety

7.1.5 Initially, the Terms of Reference for this Report stated that this part of the review would identify the current status of the babies who are alive and who had TH. Following discussion between the Commissioner and the Chairperson of the CRT, it was agreed that the focus of the review was to assess the maternity care provided and, in that regard, it was not within the scope of this review, to assess the longer term clinical care provided to the babies and for that reason it was agreed to

[43] Dr. Bill Kirkup, The Report of the Morecambe Bay Investigation, March 2015

remove this term (7) from the Terms of Reference. The women whose cases were included in this review were informed of this decision by the Commissioner.

7.2 **CRT Desktop Scoring System**

7.2.1 The scoring of the standard of care provided for each case used a modified grading system according to the categories developed by the University of Leicester and used in the MBRRACE[44] reports and the Morecambe Bay Investigation Report.

7.2.2 This validated methodology allowed the CRT to assess the standard of the clinical care and whether this related to the outcome. The standard applied by the CRT was based on the balance of probabilities that the care contributed to the outcome. The decision was also informed by the available guidelines and the clinical experience of the CRT panel. This methodology is validated for assessing clinical incidents and gaining learning from them. It is a real world practiced methodology based on case record review and interviews or statements from staff and input from the families which are integral to the review process. In addition, the overall review of clinical practice was informed from the assessment of the SAI but, also from the many staff and families that were interviewed by the CRT in addition to those carried out in the SAIs.

7.2.3 The SAI reports were used as a starting point and were added to by the case record review. This made it possible to assess whether the care given was sub-optimal even though it was not certain that it made a difference to the outcome, (and thus was not necessarily a Key Causal Factor). This gave the CRT a better assessment both of the unit itself and the care that was provided which was the original remit of the review.

7.2.4 The scoring chart for clinical care adapted by the CRT from that used in the Morecambe Bay Report:

Obstetric/Neo-natal Clinical Care Score		A	B	C
		No. of cases where different management would have made no difference to the outcome	No. of cases where different management *might* have made a difference to the outcome	No. of cases where different management would have reasonably been expected to have made a difference to the outcome
3	Major			
2	Moderate			
1	Minor			
0	Appropriate care			
	Total			

7.2.5 The CRT also assessed the support provided during and after the event, how open the hospital was and how the families viewed the care provided. The HSE Open Disclosure Policy was introduced in 2013, after some of these incidents occurred but this grading gave the CRT a measure of how open

[44] Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester, 2017.

the hospital was and how that was reflected in the outcome for the families. Obviously, this grading was more relevant to the second group of incidents, since the dissatisfaction expressed by the ten families with the care and support they received was the main reason they self-referred their cases for review.

7.2.6 **The scoring chart for family support**

Patient Perceived Support	No. of Cases Deemed Satisfactory	No. of Cases That Could have been better and might have alleviated problems	No. of Cases With Very poor and aggravated the problems
Communication (Verbal and written)			
Practical Support			
Feedback[45]			
Total			

[45] Feedback in this context referred to feedback in relation to the adverse event and/or concerns conveyed by the family.

8. THE CRT FINDINGS FOLLOWING A REVIEW OF MATERNITY SERVICES AT PUH

The Terms of Reference called for a review of the perinatal care provided by PUH maternity unit including the findings of the analysis of the perinatal care in the cases covered by this review.

The CRT carried out various interviews with members of staff within SAOLTA and PUH and received various written communications from others. The CRT identified that staff at the PUH maternity unit were caring professionals who were committed to the well-being of women and their babies. Perinatal outcome statistics over the years at PUH were within national norms and remained so even with the inclusion of the cases reflected within this Report. Therefore, PUH maternity unit appeared to be as safe as any other maternity unit in Ireland. As long as things went well, the level of care provided was at a satisfactory level. Therefore, the CRT was given the impression that at the beginning of 2014, that there did not appear to be any major clinical concerns.

8.1 Interviews with Staff

8.1.1 When interviewing staff, it was sometimes difficult to separate out what was happening in 2014 and what was happening now. Significant changes have been implemented and plans were in place to improve care provision in PUH, which is an acknowledgment that improvement was required. It is a matter for SAOLTA to implement those changes and to provide evidence of such improvement over time.

8.2 Management

8.2.1 With the changes in management structure and the formation of SAOLTA, group management was centred in Galway with local management support in the other hospitals. The SAOLTA CEO reports directly to the National Director of Acute Hospitals[46]. The SAOLTA board currently does not have statutory responsibility for the hospital group, but oversees the governance processes. The CRT were informed that there are executive walkabouts on a regular basis and regular feedback to board level.

8.2.2 There is a Chief Clinical Director in SAOLTA based in Galway and five Group Clinical Directors who report to him. One of those is a Clinical Director of Women's and Children's Services. The Women's and Children's Directorate was one of the first formed within the SAOLTA group, with an Associate Clinical Director for the Women's and Children's Directorate at PUH, who was part of the SAOLTA group directorate team. However, the CRT was told by senior PUH staff, both obstetric and midwifery, that the new management structure did not appear to function well over the time to which this review pertains (2008-2014). Although there were Directorate meetings then, which were open to representation from all hospitals, using both video and telephone links, the minutes of these meetings show that the input from PUH was not consistent. While there was evidence of an attempt to develop group KPIs across the Directorate, the minutes of these meetings from the summer of 2014 reflect poor engagement across the group. PUH appeared to work as an autonomous unit with some shared practices being developed across the group. The CRT formed the opinion that there appeared to be no group feeling within SAOLTA and they did not work as a common virtual unit. The CRT are aware that the integration and governance reform was a major project and was still being progressed in 2014. There was a clear timeline and plan to have the

[46] Appendix 6 Organisational Structures

directorate replaced by a Clinical Business Unit for Women and Children (with full executive authority and responsibility for maternity and children services across all hospital sites in the group - 5 sites with such services) by late 2018.

8.2.3 With the reconfiguration of the hospitals, the CRT was told by senior medical and midwifery staff that in practice, there appeared to be a blurring of roles and responsibilities. The CRT was told that staff in PUH did not feel that they were fully involved within the SAOLTA Group workings and some members of PUH felt that they had no local ownership of clinical governance, support or guidance from the SAOLTA group following its formation. There was a belief by some that they were being judged by management in Galway and were not being involved in the discussions of problems or solutions. The CRT were also told during staff interviews that there were some internal concerns expressed about the governance processes although they did feel that there had been some improvements. Although individual cases were identified and reported through the local governance mechanisms in PUH and recorded on Q-Pulse as part of the SAOLTA SIMT governance process, it appeared to the CRT that detailed investigations did not occur until after the third and fourth cases referred for TH had occurred in 2014 although the previous two cases that year had been escalated to the SIMT.

8.2.4 The SAOLTA board was first notified of the concerns raised by the SIMT over the number of babies referred for TH in December 2014. After the Preliminary Review, these cases and the progress of this review was discussed at all board meetings. There was a declaration from the board that a safe service was a priority and protective measures were put in place as soon as the problems were highlighted. The CEO was kept informed of the ongoing situation through regular meetings with the Chief Clinical Director.

8.2.5 In early December 2014, some initial improvements had already been implemented in PUH. A meeting took place attended by key SAOLTA and PUH clinical and management personnel on the 5th December 2014. The CRT were told that following the meeting, there was a perception by some clinicians in PUH that the SAOLTA group management were overreacting in implementing the recommended improvements. The CRT reviewed an exchange which reflected this perception. Some of the medical staff in PUH were not convinced that there was any problem. By December 2014, the six cases were logged as incidents and the Preliminary Review had taken place. Protective measures were put in place with a clear directive communicated by the SAOLTA Chief Clinical Director on the 23rd December 2014. The main issue that was highlighted was the way in which cases were managed rather than the outcomes of the newborns referred for therapeutic hypothermia. This was subsequently escalated to the National Director of Quality and Patient Safety in the HSE.

8.2.6 Since 2014, two new consultant obstetricians (one a replacement, one a new appointee) and additional midwifery managers have been appointed. However, PUH management, during interview, acknowledged to the CRT that there was poor team working. This, they believed, was due to a deferential approach with not enough challenging of the existing system. The CRT are aware that PUH is not unique in this practice. The CRT now believes that in PUH, there is an improved team approach in the maternity services.

8.2.7 The CRT were informed by senior management in SAOLTA that there were no plans to close the consultant-led maternity services in PUH and, in fact, new obstetric consultant appointments have since been made. SAOLTA management advised the CRT that they had highlighted the risk in managing the 5 small maternity units spread across a large geographical area in the SAOLTA group. SAOLTA management also informed the CRT that they were aware that the clinical governance systems had not been robust and that communication with the families had often been poor after adverse events occurred. The CRT was informed that changes have been instigated to improve these clinical governance systems and there does appear to be progression in this area, with a reduction in clinical incidents and improved supportive care following any incident occurring.

8.3 **Obstetricians**

8.3.1 In 2014, there were 5 Obstetric Consultants[47], 6 doctors at registrar level and 6 SHOs. There was 1 training Specialist Obstetric Registrar ("SpR") position approved but it had not been filled for at least the 2 years prior to 2015 but has now subsequently been filled. It was recognised that any unit needs 7 Obstetric consultants to provide full 8-5 labour ward obstetric consultant presence Monday to Friday[48].

Grade	2014	Since 2014
Consultant	3 (5 from September 2014)	5
Registrar	6 (1 SpR not filled)	6 (1 SpR not filled)
SHO	6	6

Table 10: Obstetric staffing

8.3.2 During interviews with the obstetric consultants, they expressed concern to the CRT that the level of training and experience of some of the NCHDs was not of a standard previously seen. This was compounded by the fact that there was an unfilled registrar training post in PUH. The junior grades were often filled by using agency (locum) doctors (NCHD) to cover registrar positions as is the case in many hospitals in Ireland of this size. This meant that these doctors came with different levels of knowledge and varied experience of the Irish maternity system. The CRT were informed that there were no formal clinical assessments of new appointees nor an increase in supervision by the consultants. This was largely due to there being only three consultants to run the service.

8.3.3 The obstetric consultant staff told the CRT that prior to the Preliminary Review in 2014, they did not share the same degree of concern about safety as expressed by management. PUH annual figures[49] appeared to show that the outcomes were the same as most hospitals in Ireland. The obstetric consultants did not feel it was necessary to increase their presence in labour ward to compensate for the perceived reduction in the experience of the NCHDs. This was partly due to the lack of obstetric consultant numbers but also they felt that their role was to consult and respond if requested by the midwife or NCHD. The CRT had concerns that not all the obstetricians appeared to be aware of the changes that had been instigated at the end of 2014 following the Preliminary Review and had not changed their practice, such as the need for a consultant obstetrician to be in attendance for caesarean section at full dilation, or the need to carry out consultant ward rounds regularly throughout the day. The CRT was told that it was common practice during the time period under review for an obstetric consultant to carry out a ward round at 9am and not return to the labour ward again that day, unless requested.

8.3.4 The CRT was concerned that during the course of the interviews, in some cases the consultant obstetricians did not appreciate that only referring to outcomes is not necessarily indicative of good overall care.

8.3.5 The CRT learned from interview and case record review that due to the lack of sufficient obstetric consultant numbers, the experienced NCHDs sometimes acted up as obstetric consultant locums which resulted in confusion about who was in charge, as the same individual would act as an obstetric consultant and registrar at different points of the patient's care. At obstetric registrar level, there were was an unfilled training post in PUH during the relevant period. The importance

[47] In 2014, there were three permanent consultant obstetricians in PUH and in September 2014 two more permanent consultant obstetricians were appointed.
[48] RCOG, Good Practice No.10. LABOUR WARD SOLUTIONS, January 2010.
[49] Perinatal Mortality in Ireland NPEC Annual Report 2012

of having training doctors in any hospital is that such doctors are part of a training and research programme overseen by a training college and can bring new ideas and enquiring minds into the practice.

8.3.6 From its review of the PUH training records, the CRT did not find any evidence of a formal induction training programme and little evidence of mandatory in-house training for NCHDs which meant that many of the clinical staff were not facilitated in ensuring that their skills were up-to-date, which is required in a modern maternity unit. PROMPT[50] training had been carried out in PUH for a number of years but the CRT was informed during the review process, that at the time of these events, this was not multidisciplinary (which is the whole point of PROMPT training).

8.3.7 As far as increased fetal assessment was concerned, Fetal Scalp Blood Sampling (FBS) was not carried out regularly but facilities had only been put in place in the labour ward of PUH since July 2014. The unit did not have enough ultra-sonographers to carry out Doppler ultrasound or regular fetal ultrasound assessments. The reporting of scans was not uniform with no plotting of measurements on a chart to screen for growth restriction or customised growth charts. Scanning was often done by doctors without specialised training rather than as part of an integrated care pathway which is a problem in a number of units in the country (National Maternity Strategy)[51]. The CRT has been informed that since then, efforts have been made to increase the sonographer numbers.

8.3.8 The CRT felt that not all the obstetric consultant body had embraced the changes that were instigated at the end of 2014 following the Preliminary Review. The CRT has been informed that new appointments have been made which do appear to have made significant improvement and this needs to be encouraged and supported. Furthermore, it should be noted that there appears to be an increase in clinical intervention following the review of the cases in 2014. The caesarean section (CS) rate has risen to 37% with only 35% of women experiencing a normal vaginal birth and 28% delivered by vaginal instrumental delivery (local audit figures). The contemporaneous national average for CS is around 30% nationally. This could be suggestive of a number of factors including defensive medical practice and a lack of targeted risk assessment. This increase in intervention brings new risks to the mother and baby and reduces the choice available for women to make. (During feedback the CRT were informed that the CS rate had reduced in 2017.)

8.4 **Midwives**

8.4.1 The CRT heard a lot of concerns from the midwifery staff who felt generally unsupported and felt that the midwifery management structure was fragmented. Between 2008 and 2010, the ADON in place had a midwifery qualification but from 2010 to 2014, the highest grade of midwife in PUH was a CMM3 who reported directly to an Assistant Director of Nursing in PUH (with no midwifery training)[52] and for whom midwifery was a part of a wide-ranging divisional responsibility. A Group Director of Midwifery was appointed in June 2014 but did not have a direct reporting role to SAOLTA and appeared to have more of an advisory role rather than a management role[53].

8.4.2 The midwifery lines of responsibility were very convoluted. At interview the CRT was informed that there was a plan to appoint a new Assistant Director of Midwifery who would report to a Group Director of Midwifery who in turn would directly report to CEO but this change had not yet been implemented.

[50] PRactical Obstetric Multi Professional Training www.promptmaternity.org
[51] Creating a Better Future Together- National Maternity Strategy 2016-2026 (Department of Health)
[52] Appendix 7 Midwifery Staffing
[53] Appendix 7 Midwifery Staffing

8.4.3 The CRT was informed that midwifery staff levels were deficient with a lack of consistent CMM cover in the labour ward. The national moratorium on new appointments[54] had made this situation worse. During the period under review, the CRT reviewed evidence of declining midwifery staff numbers[55]. Midwives had requested more staff as early as 2013. It is clear since the time of this review that the numbers of midwives has increased.[56]

8.4.4 As a result of these staffing deficits, with no continuous CMM presence on the labour ward, there was a lack of support for the more junior midwives. Consequently, the midwives reported to the CRT that if they were concerned with a registrar decision, they sometimes found it difficult to escalate to the obstetric consultant.

8.4.5 Of the cases under review, some of the midwives acknowledged to the CRT that they had not provided the level of care expected in some of the cases. These included a failure in detecting the deteriorating clinical situation and the interpretation of abnormal CTGs. The midwives reported to the CRT that there was a failure in some cases in communication with the registrars and a problem with escalation and a failure to involve the obstetric consultant when the midwives were unhappy with the medical care provided. Some of the midwives felt that the patient experience was not always to as high a standard as they would like. However, the CRT felt that it was important to acknowledge that much of the midwifery practice was exemplary. The midwives interviewed did realise that they needed to learn from this review and improve their emergency care provision.

8.4.6 Since the incidents in 2014, new training had been put into place especially around CTG assessment. They are also introducing Caring Behaviour Assurance System (CBAS) training which highlights patient and team needs. They have trained champions in PUH and this has been reflected by staff feeling that can now work more freely and feel more empowered. They have also implemented the "Productive Ward" – which puts patients care at the centre of practice. They were appointing a Patient Advice and Liaison Service (PALS) officer in PUH to help reinforce the patient experience.

8.4.7 With these changes and others that have occurred, it was felt that the escalation policy had improved with better obstetric consultant presence in the labour ward. The new obstetric consultant appointments have helped this as it has brought better support and team work.

8.4.8 At interview the CRT was notified that the 2014 cases referred for TH, were reported onto Q-Pulse by staff in PUH and local Preliminary Assessment Reviews (PAR) were carried out. These cases were promptly escalated to the SIMT, following its establishment in March 2014. The first of these two cases was referred to the SIMT meeting in May 2014 and the second referred to the SIMT meeting in June 2014. It was recorded in the SIMT minutes that the local PUH staff recommended that these cases undergo a full case review. The conclusion of these meetings was that both of these cases were to be discussed by the Group Clinical Director with the Clinical Director of the Women's and Children's Directorate who was provided with copies of the clinical notes relating to both cases for review.

8.4.9 At the end of September 2014, the third case was identified, put onto Q-Pulse by PUH staff. A PAR was undertaken and discussed at group SIMT in October 2014[57]

[54] HSE HR Circular 015/2009 Moratorium on Recruitment and Promotions in the Public Services – Revised Employment Control Framework for the Health Services 15th May 2009
[55] Appendix 7 Midwifery Staffing
[56] Appendix 7 Midwifery Staffing
[57] It was noted in feedback that the escalation of incidents was not solely the responsibility of midwives.

8.4.10 By November 2014, a fourth case had occurred. This cluster of four cases, had been reported to SIMT and to the Group Director of Midwifery. This prompted an internal review ("the Preliminary Review"), there was group midwifery presence on-site in PUH and a programme of planned audits on site in PUH during the month of December 2014 to address compliance with the agreed corrective measures of December 5th 2014.

8.4.11 This received a lot of criticism from staff in PUH who felt the initial investigation team were exaggerating issues and trying to close them down. The CRT was told that it was a "very dark difficult time". Morale was low and support was needed to identify the problems and implement an action plan to improve care. However, many of the midwives were asking what more they could have done and they wanted to know what the problems were in order to learn from them.

8.4.12 The CRT was informed at interview that the multidisciplinary team-working was not as effective as it should have been on the labour ward. Some of the NCHDs (registrars) had been working in PUH for a number of years and it appeared that there were limited opportunities for career progression. The CRT found little evidence in its review of the training records, of training having been made available or provided to the NCHDs in new advances in care. New initiatives, such as Fetal Blood Sampling (FBS), had only been introduced into regular clinical practice in the labour ward in PUH in mid-2014 and had not yet been integrated into routine care. The CRT were informed that during the time under review there was sometimes a lack of confidence in the experience of some of the NCHDs (registrars), which resulted in the midwives not calling them often enough. In addition, the midwives informed the CRT that they also felt that it could be quite difficult to escalate problems to some obstetric consultants, a problem that had built up over the years. They felt that this was now improving but not been totally eliminated.

8.4.13 When the midwives were asked if they thought the problems of 2014 would occur now, they believed that they would not due to heightened responsibilities and new practices. Specifically, there is a midwife manager now in the labour ward at all times. There is also a Director of Midwifery on each hospital site to provide strong local leadership. This will allow a hub and spoke arrangement and development of a centre of excellence, setting up specialist services so that women do not have to travel far in order to access maternity services.

8.4.14 The CRT was told that the inter-disciplinary relationship between the midwifery team and the obstetric consultant body had been difficult. Obstetric Consultants were not always present or supporting when required and some did not do regular ward rounds. Even since the incidents of 2014, little had changed until the new obstetric consultant appointments were made which has produced greater input and collaboration. It was the impression of the CRT that at the time under review, the obstetric consultants in PUH were not integrated as part of the team and did not feel they needed to be, which was the traditional, deferential model. This is changing and the midwives feel more empowered to involve the consultant at every level.

8.4.15 The CRT believe that there are good plans in place to progress the service and they need a strong lead midwife to work with a lead consultant obstetrician to develop the service to the level expected.

8.5 **Anaesthetists**

8.5.1 The anaesthetists informed the CRT that they were overwhelmed with the work load they had to cover. They reported that at times the workload was very heavy but this is the nature of acute care in a small hospital. When any safety concerns arose they were able to (and did) raise these issues directly with the consultant obstetricians. In 2014, they had 4 anaesthetic consultants and 6 anaesthetic registrars in their team covering the whole hospital not just the maternity unit. Out of hours (9-5) there was just 1 resident registrar and 1 consultant at home, covering the whole hospital.

Grade	2014
Consultant	4
Registrar	6
SHO	0

Table 11: Anaesthetic staffing

8.5.2 The hospital, to serve its adult population, including women who are critically ill around the time of delivery, has a 7 bed unit, made up of two ICU beds (Intensive Care Unit), two HDU (High Dependency Unit) and three coronary care beds. This provides acute intensive care management, including ventilation. More complex patients or those requiring prolonged ventilation would be transferred out in line with local policy. Occasionally the ICU provides care to paediatric patients.

8.5.3 The CRT were informed that there was an organised educational program within the department of anaesthesia which covered obstetric anaesthesia topics. These did not appear to be multi-disciplinary.

8.5.4 The anaesthetic service covered the elective obstetric service as well as general surgical lists. The CRT were informed that the anaesthetists could be servicing up to 3-4 epidurals per day in the labour ward but, due to lack of staff, they could not provide full follow-up care after delivery. They were not involved in the morning hand-over in labour ward to highlight at-risk patients or problems that may arise during the day and the anaesthetists did not carry an emergency obstetric page. Since there was just one full theatre team available out of hours, they felt the system was very vulnerable if the team were in theatre with ruptured appendix as the theatre and team were not available for an emergency CS. It is theatre nurses that scrub for caesarean sections not midwives which is good practice. The CRT was informed by the anaesthetists that the service was very dependent on staff good will when calling staff in from home to cover extra theatre needs. They felt this was not sustainable. According to the evidence, this problem was compounded by the regular misuse of the emergency theatre for elective work.

8.5.5 The CRT was told of cases where the anaesthetist was called by midwives to ill post-natal women 3 or 4 days after they should have been involved, or cases at 35 weeks gestation with pre-eclampsia that should have been transferred out. They felt that there was a reluctance on the part of the obstetricians to send these specialist cases to bigger units at the appropriate time. There was no risk stratification policy for women at high risk for anaesthesia and, with no antenatal reviews, this made the system inherently unsafe. When an inter-hospital transfer of a critically ill child or adult occurred, the anaesthetic registrar went with the patient, leaving the anaesthetic consultant on their own covering the whole hospital.

8.5.6 The anaesthetists also felt that some of the obstetric registrars were less experienced and needed a greater consultant input. The lack of obstetric consultant support, in their view, had led to an increase in the CS rate.

8.5.7 Although the 2014 cases referred for TH were put onto Q-Pulse by PUH staff, it was felt generally by the persons interviewed by the CRT that senior professional staff were not involved in the clinical governance process. The anaesthetists specifically informed the CRT that they were not involved in influencing obstetric practice. There was a lack of Multi-Disciplinary Team (“MDT”) reviews and meetings which would have provided a forum for discussion. Formal reporting of case reviews was not in place. The anaesthetists felt a lack of team ownership and practice in clinical care within the unit.

8.6 **Paediatricians**

8.6.1 The paediatricians were keen to meet the CRT in 2016 and have the opportunity to let them know how they felt about the situation in 2014 and what changes have been brought in over the previous two years. They are totally committed to good care and feel that they have a good relationship with obstetricians and the midwives in labour ward.

8.6.2 The paediatricians would have expected around 2-3 babies with Hypoxic Ischaemic Encephalopathy (HIE) per year. So the cluster of 6 cases of TH in 2014 was definitely higher than normal. While the initial cases were reported on Q-Pulse in PUH, the Paediatric team advised the CRT that they presented the first two cases at the hospital peri-natal meetings. However, it was not until the third and fourth cases that detailed investigations were undertaken.

8.6.3 They felt that they were understaffed with a variable level of experience from the locum agency registrars (NCHDs) who are often on contracts for only six months. This made the service cover they were expected to provide a significant challenge. Locums were engaged to cover gaps in the consultant rota. There was no paediatrician with a sub-specialty training in neonatology in PUH, as is the case in most units of that size, but they have had the opportunity to update their neo-natal skills and have good working relationships with other units. One of the Paediatric Consultants has spent some time in GUH to ensure that they were up to date and has taken on the lead role for neonatology. During the course of the feedback process, the CRT were informed that the Paediatricians continue to update their neo-natal skills, including their Neonatal Resuscitation Programme (NRP) training.

Grade	2014	Since 2014
Consultant	3	4
Registrar/NCHD)	6 (1 SpR)	6+(1 more SpR planned)
SHO	6 (1 BST)	6 (1 BST)

Table 12: Paediatric staffing

8.6.4 The documentation reviewed and the interviews completed by the CRT indicated that there had been occasional problems in getting emergency paediatric support to the labour ward, caused in part by failure of clinical escalation and difficulties in communication but this has improved with the introduction of an emergency bleep call through switchboard in January 2015. This has appeared to work well. Overnight can be more problematic as there were just 2 Neonatal Unit (NNU) nursing staff on duty at night, and therefore getting the appropriate people to emergency deliveries in good time can be difficult. The CRT were informed by SAOLTA management that there were guidelines for maternity and neonatal care. The paediatricians interviewed informed the CRT that they are reviewing the paediatric attendance at emergencies and wanting to produce set criteria for paediatric attendance similar to the Rotunda Hospital (Dublin) guidelines. They also informed the CRT that there was an unwritten guidance regarding paediatric attendance at emergencies during the period under review but they felt that there needs to be more work on templates for all the SAOLTA sites rather than each site doing their own thing. They now review all NNU admissions and issues are discussed and any transfers out investigated. There have been changes in baby criteria for transfer particularly with babies from 28 weeks to 32 weeks and the

decision of who is managed on site and who is transferred out[58]. This is evidenced by an antenatal transfer policy of < 30 weeks gestation in 2011 and subsequently amended to antenatal transfer at < 32 weeks gestation in 2013.

8.6.5 The paediatricians reported that they have had protected time for teaching. They are working on the development of scenario teaching and team training. They have developed a registry of neonatal resuscitation program (NRP) training for nurses, midwives and doctors with a lead paediatric consultant overseeing this.

8.6.6 The analysis of cases, service user feedback and a review of complaints has made PUH realise that it needs to develop a liaison person for parents to allow a single contact for families to get the support and information they deserve.

8.6.7 In interview, it was acknowledged that the clinical governance processes in PUH had been sub-optimal up to 2014, as reported earlier in this Report, but this was evolving in conjunction with local initiatives. One of the challenges was the level of knowledge and training of junior staff coming through the system. The paediatricians report that they are trying to address this with regular teaching sessions and scenario training. They also realise that it is important to have regular meetings with obstetric consultants to discuss cases of concern both before delivery and after an incident. Regular MDT meetings are planned with monthly reviews with obstetricians and neonatal nurses. They have changed the time of perinatal meetings to 9-10am rather than lunchtime on the third Tuesday of every month to try to improve attendances.

8.6.8 The CRT was told that the paediatricians feel that there should be more SAOLTA group developments with a Managed Clinical Network to help in the development of guidelines, clinical practices and governance. New developments, such as delayed cord clamping, and when this is appropriate, need to be agreed.

8.6.9 The paediatricians highlighted to the CRT, the significant impact this review and the SAI process has had on their own morale and that of their staff. The CRT recognise that the paediatric team have put in place significant measures to improve deficits outlined in the Preliminary Review.

8.7 Staffing

8.7.1 There was a chronic shortage of staff both at midwifery and consultant level with a lack of consistent midwifery management presence to supervise the labour ward during the period under review. This was compounded by the national moratorium in the public sector implemented by the Department of Finance in 2009[59]. During interviews and feedback, the CRT were informed of various attempts to address staff shortages within PUH. This lack of senior permanent staff meant that, although the day to day normal working continued to a high quality in the labour ward, there was no support if things went wrong.

8.7.2 The standards of training and experience of obstetric registrar level doctors varied and PUH did not have the obstetric consultant numbers required to compensate for this which sometimes led to a lack in obstetric consultant presence. This meant that the important team structure that needs to be in place at times of emergency was sometimes absent. The anaesthetic staff covered the whole hospital and therefore could not cover all emergencies out of hours if more than one problem was occurring at one time.

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[58] National Clinical Programme for Paediatrics and Neonatology, *Model of Care for Neonatal Services in Ireland*, November 2015

[59] HSE HR Circular 015/2009 Moratorium on Recruitment and Promotions in the Public Services – Revised Employment Control Framework for the Health Services 15th May 2009

8.7.3 When any service is stretched, it is the quality factors that suffer. There is an inability to give the level of supportive care at a time of crisis, both to the families and the staff. There can be a failure to report incidents, a failure to review incidents and a failure to learn from them. This can result in the failure of individuals knowing what good standards are and what was expected of them. The system may, then fail to educate and support the individuals to work as a team for the benefit of all. If people, systems or hospitals work in isolation, they stay rooted in the past. Practice becomes embedded and fails to progress.

8.7.4 In PUH, significant increases have been made in both medical and midwifery staffing to the apparent benefit of day to day working but appointing new people is the start of this journey, leadership and culture change is required to make change sustainable.

8.8 **Training**

8.8.1 Training initiatives described to the CRT appeared to suggest that such initiatives were introduced in a sporadic way over the last few years and there was little multidisciplinary training and a lack of overall leadership and coordination. The CRT were informed at interview and noted from the review of the training logs that the consultant obstetricians and the NCHDs did not generally attend the multidisciplinary training but the CRT understands that low staffing levels may have been a major factor in this. The records of the mandatory training shown to the CRT revealed some staff had little or no record of training. There is CTG training 5 times per year in Galway but not all staff were able to attend, partly due to the distance and also the time required. PROMPT[60] training had been carried out in PUH for a number of years but the CRT was informed that at the time of these events, this was not multidisciplinary (which is the whole point of PROMPT training). The CRT has been informed that this has now changed.

8.8.2 As previously noted, while incidents were recorded on to Q-Pulse and referred to the SIMT, there was no timely detailed reviewing of incidents and poor feedback to staff allowing learning and prevention. Specific problems found during the review included, CTG misinterpretation, poor escalation procedures and multiple instrumental deliveries were all known about but no training or supervision was put in place to overcome this and stop them happening again. There was an acceptance of the problems as unfortunate one-off outcomes and not problems to overcome.

8.8.3 There have been changes made and more are planned to develop the training programme within SAOLTA. There needs to be a combination of local, multidisciplinary training and regional modular training using modern technology to maximise availability of it over the geographical area. The environment needs to be developed to allow staff to be informed of new clinical advances, guidelines and recommendations as well as the training required to keep skills relevant to current expected practice.

8.9 **Clinical Governance**

8.9.1 Clinical governance is a framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (An Organisation With a Memory[61]). Errors are rarely the fault of one individual but a series of faults that fail to identify and correct the error (Swiss Cheese Model, Reason 2000). This is the responsibility of the organisation.

[60] Practical Obstetric Multi Professional Training www.promptmaternity.org
[61] An Organisation with a Memory, Department of Health UK. 2000

8.9.2 Although, problems were noted within PUH and reported on to Q-Pulse and SIMT, the system that was in place at the time under review did not lend itself to allow in depth timely review and learning from individual incidents. There was an acceptance of occasional poor outcomes as part of clinical practice but the organisation appeared to be reassured that their overall outcome figures were not outside the national average.

8.9.3 Of the cases the CRT reviewed from before 2014, in only three of the ten incidents was any form of report or review carried out. All three appeared to be carried out sometime after the events and were largely inadequate in their findings and recommendations. They were factual descriptions of events rather than an analysis of cause. These were missed opportunities to learn and put into place changes to prevent recurrence. Repeated errors made in 2014 were a direct result of these missed learning opportunities earlier.

8.9.4 With the formation of Galway Roscommon Hospitals Group in 2012 and subsequently SAOLTA in 2014, there were a lot of changes in the organisation and management reporting structures[62] At that time, there appeared to be a blurring of governance roles. In 2014, incidents were logged onto local (Q-pulse) and national systems[63] by the PUH local Quality and Risk Manager. There appeared to be no culture of timely detailed reviewing of incidents and poor feedback to allow learning and prevention of individual cases. There was no internal guidance about when and how an internal review should be carried out.

8.9.5 The CRT were told and saw evidence of regular monthly SAOLTA group risk management meetings. Minutes from these meetings showed that the attendees were mostly from Galway with some video or telephone input from elsewhere including PUH, but not at every meeting. There were discussions about cases of concern but little documentation or apparent action taken. According to the SIMT log, the case which occurred on 26th April 2014 (Case 2) was reported by PUH staff to the Clinical Director of Women's and Children's Directorate, who received the notes to review on 11th June 2014. It is not apparent from the SIMT log that further action was taken until after a total of four cases were logged and a trend was then noted. This led to an escalation and subsequent internal review (the Preliminary Review) which produced interim recommendations.

8.9.6 On 5th December 2014, there was a meeting of the Group Women and Children's Director, SAOLTA group management, PUH Management and senior maternity staff in PUH at which, the findings of Preliminary Review were highlighted following the review of the six cases. Agreement was reached on the corrective measures to immediately be put in place. On the 16th December 2014 a programme of planned audits were initiated to look for any ongoing problems within the labour ward in PUH. Protective measures were put in place with a clear directive sent out by email, by the SAOLTA Chief Clinical Director on the 23rd December 2014. The Chief Clinical Director escalated the Preliminary Review to the HSE and this external review was commissioned. At interview, the CRT were told that locally in PUH, there were audit and perinatal meetings held but attendance was inconsistent at consultant level. Whilst there was a local Quality and Risk Advisor in PUH, communication between sites needed to improve with a re-establishment of more local clinical involvement to help take ownership of the incidents as they occurred. The governance structures are getting better, with more regular meetings, but the group structures are still developing.

8.9.7 There was no robust obstetric clinical handover involving all relevant clinical staff so that the potential problems could be discussed and management plans made. Since the obstetric consultant ward rounds generally occurred first thing in the morning, any patient who was

[62] Appendix 6 – Organisational Structures
[63] Starwebs from 2008 or NAEMS from 2014-HSE, Safety Incident Management Policy, May 2014

admitted after that was not known to the consultant unless they returned to the labour ward or the case was escalated to them. This allowed some of the cases to deteriorate without medical awareness until they became critical. In feedback, the CRT noted that during normal working hours additional visits to the labour ward by the consultant on call may have taken place however, many of the cases reviewed in this Report occurred outside normal working hours.

8.9.8 In the reviewing of the cases and from the family interviews, the CRT learned that there was a general lack of pastoral care, counselling facilities and open disclosure. It is to be noted that these were mostly in the cases dating from before 2014 and things have improved since that time.

9. REVIEW OF THE WIDER DELIVERY OF SERVICES AT PUH MATERNITY UNIT BETWEEN 2008 AND 2014

9.1 The Environment

(a) When reviewing the service and the incidents that have occurred, it is important to look at the environment in which the care is provided. Whilst PUH perinatal outcomes were in line with national averages, there has been a general change nationally over the last 10 to 20 years. These include increased co-morbidities of patients[64], increasing skills required and an increased expectation of the women attending for care. A hospital like PUH cannot be expected to provide all levels of care, but should be part of a Managed Clinical Network of units, where this expertise can be provided either regionally or nationally[65]. Government agencies need to help in these developments and organisation as they are ultimately responsible.

(b) A good example of this changing environment was demonstrated by this review:

Therapeutic Hypothermia ("TH") is described in detail in Appendix 4. It is a treatment used when a baby is thought to be at risk of hypoxic ischemic brain injury around the time of birth. Lowering of their body temperature to 33C-34C for 72 hours significantly reduces the risk of long term damage, disability or death.

A number of clinical trials were conducted in the late 1990's and early 2000's showing a direct benefit from TH. A Cochrane review published in 2007[66] provided further evidence of its benefits. This treatment was available in Cork University Maternity Hospital in 2008 (as a centre involved in one of the international clinical trials[67]) and in the three tertiary level neonatal intensive care facilities in Dublin in 2009 when it became the standard treatment for babies with moderate to severe hypoxic ischaemic neonatal encephalopathy at these institutions.

A training day was held in the Rotunda in March 2009 open to all paediatricians in Ireland, with further dissemination at the national Irish Paediatric Association meeting in Cavan in May 2010. The National Transport Study day on 18th June 2010 focused on Cooling on Transport, Neonatal transport guidelines for TH[68] were developed by the National Transport Service in conjunction with the Faculty of Paediatrics (RCPI) in September 2011 and

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[64] Perinatal Mortality in Ireland NPEC Annual Report 2012

[65] National Clinical Programme for Paediatrics and Neonatology, *Model of Care for Neonatal Services in Ireland*, November 2015

[66] Jacobs S, Hunt R, Tarnow-Mordi W, Inder T, Davis P. Cooling for newborns with hypoxic ischaemic encephalopathy. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD003311. Review. Update in: Cochrane Database Syst Rev. 2013;1:CD003311

[67] Azzopardi DV, Strohm B, Edwards AD, Dyet L, Halliday HL, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thoresen M, Whitelaw A, Brocklehurst P; TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. N Engl J Med. 2009 Oct 1;361(14):1349-58. doi: 10.1056/NEJMoa0900854

[68] Transport of Infants Referred for Cooling Treatment: NNTP Clinical Guideline Cooling on Transport. September 2011

subsequently the Neonatal Clinical Advisory Group of the Royal College of Physicians of Ireland (RCPI) when this was established. The National Neo-natal Transport Service (NNTP) was available from 9am to 5pm during the time of this review with an onus on local sites to transfer outside of these hours. Since 2014, the National Transport Service is available 24/7.

The process of transfer for TH evolved over the time period between 2009 and 2013. Babies were initially transferred promptly to these centres for TH, later passive cooling began in local centres and on transport, with active cooling on transport available from 2013.

The time period 2009-2011 reflected a transition period where cooling was evolving nationally and it was not fully established nationally until 2012 when the NNTP guidelines were fully implemented having been introduced in September 2011. However the CRT is of the view that TH was the standard of care in Ireland from 2010[69] onwards[70] with a recognised method of referral and transfer to one of the four tertiary centres established by some regional centres. However, this appeared to occur only if the local paediatric staff were aware of TH, knew the indications for TH and organised the transfer of the baby to one the four units where TH was available. A publication in 2010[71] provides some insight into this process. The publication states that 100% of Paediatric Consultants in Ireland were aware of TH in 2010, all felt it was effective, and most were aware of the appropriate indications, but only 3 out of 12 Level II units, such as PUH, had a definitive plan to transfer patients. All clinical leads felt that parents should know about the potential benefits of TH. Appendix 5 details the evolution of Therapeutic Hypothermia in Ireland.

In 2010 PUH was still a stand-alone hospital. Only one newborn was recorded as having neonatal encephalopathy in the PUH 2010 Annual Report. However in that year the CRT reviewed three definitive cases of hypoxic ischaemic encephalopathy. Only the first case of the three identified cases was referred for TH. One of the other two cases was referred for further management beyond the TH window and the third case was not transferred. The fact that only one baby was transferred from PUH prior to 2011 probably reflected a combination of a lack of a definitive local clinical practice guidelines to transfer infants and the national system that was evolving and took time to establish. Notwithstanding, processes should have been in place in PUH to ensure shared learning of new developments such as transfer for TH, which may have resulted in the transfer of these additional two babies. This demonstrates a lag between new clinical developments, implementation nationally and the development of local clinical guidelines in PUH, as in other similar sized units, at that time.

[69] The CRT received feedback disagreeing with this section, in particular the view of the CRT that TH had become the standard of care from 2010 onwards. The CRT remain of the opinion that TH had become the standard of care in Ireland from 2010. In addition, The CRT noted in this Report that PUH transferred one baby for TH in 2010 but not another two who fitted the criteria.
The CRT were also informed in feedback that *"the CRT seems to imply that the onus for the safe introduction of radical changes in clinical practice should lie with individuals as opposed to a national approach"*. The CRT is of the opinion that the onus is both at local level as well as at national level where there should be leadership and development of national systems.

[70] In feedback, CRT were informed that the date of publication of the Transport of Infants Referred for Cooling Treatment: NNTP Clinical Guideline Cooling on Transport. September 2011 was the key point in time in terms of national practice and the standard of care. The CRT agrees that the NNTP was significant in terms of national practice and access to transport facilities, however the CRT is of the view that TH was the optimal standard of care in Ireland from 2010.

[71] Nicholas M Allen, Adrienne Foran and Donough J O'Donovan, Arch Dis Child Fetal Neonatal Ed2011 96: F233 originally published online December 1 2010.

9.2 **Maternity Services at PUH between 2008 and 2014**

9.2.1 During these changing times, normal midwifery practice within a unit can remain at a high standard, as long as all remains normal. The CRT's impression was that most women who went through pregnancy with no major complication, received a very good standard of care at PUH. Generally, when there are incidents in maternity units, it does not involve routine care, it is about what happens when things go wrong, as was the case in PUH. It is the modern governance processes that were lacking. The CRT found, following its review of the 18 SAI reports and the HCRs that, in a number of the cases there was one or a combination of the following:

(i) a lack of risk assessment at booking;

(ii) a lack of ownership of women with problems;

(iii) a lack of appreciation when things were beginning to go wrong;

(iv) a lack of escalation to the NCHD or the obstetric consultant;

(v) a lack of supervision of the NCHD and lack of consultant input at the appropriate times.

9.2.2 The aim in modern maternity care is getting it right first time, with early escalation and action allowing the appropriate intervention to occur within an appropriate timescale to try and minimise the possibility of damage to the mother or baby. In most of the 18 SAI reports and HCRs reviewed there was one or a combination of the following:

(i) a failure to notice deterioration in the mother or baby,

(ii) a failure to escalate the problem

(iii) a failure of the registrar to act appropriately

(iv) a failure of the consultant to be involved.

These delays resulted in much of the complications that were seen.

9.2.3 Although the 6 individual cases referred for TH in 2014 were identified and reported through the local governance mechanisms in PUH and recorded on Q-Pulse as part of the SAOLTA, SIMT governance process, it appeared to the CRT that detailed investigations did not occur until after the third and fourth cases happened. The collecting of incidents and reviewing them is only the beginning of the process. There needs to be a full cycle of reporting, reviewing, recommending, learning and implementing if care is to be improved. "*To err is human …… to fail to learn is inexcusable*" (An Organisation with a Memory).

9.2.4 From interviews held, the CRT believe that there were major problems in the staff structure at PUH. In some cases, there appeared to be a poor inter-disciplinary relationship between the midwives and obstetricians. There was an unfilled position for a training grade obstetric registrar (SpR). As previously noted, the importance of having training doctors in any hospital is that they are part of a training and research programme overseen by a training college which requires strict standards in the delivery of its specialist post-graduate training including the most up to date practices. This meant that, at the relevant time, the opportunity for the stimulation and learning that such a post would bring, was missed. Some of the obstetric NCHDs were engaged through agencies, they had no prior experience of working within the hospital and had no established relationships with the midwives or consultants. It appears to the CRT from a review of the 18 SAI

reports and the HCRs that the obstetric NCHDs were often left on their own with little or no supervision to assist them in making decisions and to take the appropriate action in circumstances where they may not have had the necessary skill or knowledge. The CRT noted that there were cases of multiple instrument delivery which displayed a lack of appropriate decision-making.

9.2.5 The CRT also noted from the SAI reports that when things did go wrong, there was a lack of communication to the relevant decision maker in order to appropriately manage the situation. The obstetric consultants relied on being contacted by the staff in order to be informed about cases when required and did not appear to take ownership of the labour ward. The CRT was informed that because of this, there was a perception amongst the families that the CRT spoke to, that private patients got better consultant input than public patients. A common question was; *"would this have happened if I was under private care?*"

10. EXAMINE THE CORRECTIVE MEASURES PUT IN PLACE DURING THE PRELIMINARY REVIEW

In the Autumn of 2014, further concerns were raised following the third and fourth cases referred for TH, after which, an internal review ("the Preliminary Review") was commenced.

The Preliminary Review process involved a group of clinicians from the SAOLTA group management who undertook a desktop review of the 6 cases reported to SIMT in 2014. Based on this, they produced the Preliminary Review report which assessed the causation of a poor outcome, concluding whether or not there had been a problem with the quality of the care and if so, why.

The individual maternal case notes were reviewed by a team from Galway University Hospital	
Ms. Dawn Johnston	Group Director of Midwifery
Professor Declan Devane	Professor of Midwifery
Dr. Geraldine Gaffney	Consultant Obstetrician & Gynaecologist and Group Clinical Director for the Women's and Children's Directorate
Dr. Donough O' Donovan	Consultant Neonatologist regarding neonatal resuscitation following delivery.

10.1 List of issues that were identified by the Preliminary Review[72]:

(a) "Poor interpretation of intrapartum CTG tracings;

(b) Failure to investigate a suspicious CTG with fetal blood sampling;

(c) Failure to ensure that there was an adequate CTG recording by using fetal scalp electrodes when the abdominal recording was inadequate;

(d) Inappropriate use of oxytocin during labour when there was an abnormal CTG trace. Furthermore, oxytocin was used without medical review of the patient, without prescription and when the indication was sometimes unclear;

[72] Dr. Geraldine Gaffney, Ms. Dawn Johnston, Dr. Donough O'Donovan and Professor Declan Devane, Preliminary Review of Adverse Perinatal Events at Portiuncula Hospital, Ballinasloe, 21st December 2014

(e) The position of the fetal head was not recorded prior to performing an instrumental delivery;

(f) In one case there was poor performance of an instrumental delivery;

(g) There was delayed escalation to the paediatric team following birth by the labour ward staff;

It is noted cases were not attributable to any one member of staff or team."

10.2 **Immediate Corrective actions taken after the Preliminary Review**

10.2.1 A joint plan of immediate corrective actions between SAOLTA group management and PUH key clinical personnel was agreed upon at a meeting on 5th December 2014 including:

(a) There should be improved interpretation of CTGs during labour and that the education required to do so should be implemented.

(b) The inability to obtain an adequate CTG recording abdominally mandates that a fetal scalp electrode should be used.

(c) Abnormal CTGs in labour should be referred for obstetric review and assessed further by fetal blood sampling unless immediate delivery is indicated.

(d) Oxytocin needs to be used appropriately during labour and should be prescribed by at least a registrar. The registrar should have discussed the care of a primigravida in the first stage of labour with the attending midwife, and have performed a clinical assessment on a multigravida in the first stage of labour and all women in the second stage of labour before starting oxytocin.

(e) Oxytocin should not be used in the presence of abnormal fetal heart rate patterns.

(f) Vaginal examinations should record the position of the fetal head.

(g) An attempt should be made to obtain an umbilical cord blood sample at an assisted delivery, CS, meconium staining of the liquor or where there is concern about fetal well-being (e.g. an abnormal fetal heart rate pattern or unexpected compromise at birth).

(h) Instrumental deliveries should be supervised by a consultant.

(i) Assistance from Galway University Hospital ("GUH") to provide senior midwifery support on the labour ward where possible.

10.2.2 This was followed by site visits to PUH in December 2014 and on the 16th December 2014, 22 further births were selected and were reviewed as part of a programme of planned audits performed by the team from SAOLTA in order to assess the compliance with the original recommendations. From these 22 cases, the intrapartum management of 4 cases gave some cause for concern. The similar issues of concern were identified previously:

(a) The interpretation of CTGs (including escalation of care)

(b) No use of fetal scalp electrodes when there was loss of contact with an abdominal transducer.

(c) No fetal blood sample to assess an abnormal CTG

(d) No cord blood sample at birth following delivery for an abnormal CTG

(e) Delay in escalation of resuscitation to paediatric team

10.2.3 These findings from the Preliminary Review and the subsequent audits led to the implementation of corrective measures as directed by the Group Clinical Director on the 23rd December 2014 and subsequent audits of compliance were carried out as set out below.

10.2.4 The CRT learned from the minutes of clinical governance meetings at SAOLTA that subsequent audits were conducted on the, 29th, 30th and 31st December 2014 and the 9th and 13th January 2015. These showed uniform compliance with the recommendations and no cause for concern. Over 200 sets of notes now have been audited by the SAOLTA group and no concerns have been noted in respect of the above criteria. The December 2014 audits showed many examples of good practice and well-managed cases.

10.2.5 The CRT considered the Preliminary Review to have made reasonable conclusions but due to the limitations of a desk top review it was not very deep in its assessments. The recommendations were good and correct but were instructive and not educational. To imbed change within the system requires extensive leadership and cultural changes with regular educational sessions that all staff can attend and take ownership of those changes. The CRT have no further information on clinical outcomes since the beginning of 2015 and how successful the ongoing developments have been. It was not part of the Terms of Reference to assess clinical practice from 2015 onwards, the CRT was therefore only in a position to assess the implementation of the corrective measures by analysing the audits undertaken by the SAOLTA group and from documentation, interviews and feedback. The CRT was satisfied with the processes undertaken to implement the corrective measures.

11. EXAMINE THE IMPLEMENTATION OF NATIONAL HSE POLICIES IN RELATION TO PATIENT SAFETY, RISK MANAGEMENT, INCIDENT MANAGEMENT, REPORTING, INVESTIGATION AND OPEN DISCLOSURE

The CRT considered in detail, the HSE policies[73] in relation to patient safety, risk management, incident management, reporting, investigation and open disclosure. The CRT also considered the findings of the 18 SAI reports for specific references to the above policies together with the information provided by the families in relation to open disclosure, for the purposes of analysing the extent to which these policies had been implemented. However, there were limitations in the CRT's ability to fully examine the implementation of these policies against each of the individual cases comprehended under this review within the period 2008-2014. Many of the relevant policies post-dated the cases under review. The timescale within which this Report was to be delivered did not allow for further analysis on a case by case basis. However, where the policies did apply, the CRT relied upon the analysis undertaken in the SAI reports.

As noted in Section 6 of the Report, the CRT accepted that the 18 SAIs were each carried out in accordance with the HSE's Guideline for Systems Analysis Investigation of Incidents and Complaints (2012, updated 2016) and for that reason the CRT have not examined the implementation of that policy (as amended) in this section specifically.

The CRT also analysed the relevant prevailing policies, reports and guidelines from its consideration of the themes which emerged from a review of the 18 SAIs in aggregate in relation to patient safety, risk management and incident management.

In completing this section, the CRT has reviewed the following documents:

- HSE Open Disclosure Policy 2013 (and Guidelines)
- HSE National Consent Policy 2013
- HSE Safety Incident Management Policy 2014
- National Standards for Bereavement Care Following Pregnancy Loss & Perinatal Death (September 2016)
- Irish Multidisciplinary Obstetric Emergency Training (IMOET) 2014
- National Consultant Workforce Planning 2015 (Supplementary Report)
- Irish Maternity Indicator System (IMIS) National Report 2015
- Final Report of the HSE Midwifery Workforce Planning Project 2016
- Creating A Better Future Together, National Maternity Strategy, 2016-2026
- Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16

[73] Health Service Executive (2012) Guidelines for the Systems Analysis Investigation of Incidents and Complaints;
Health Service Executive (2014) Safety Incident Management Policy
Health Service Executive (2016) Guidelines for the Systems Analysis Investigation of Incidents.
Health Service Executive. (2016). National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (pp. 86): Health Service Executive.
Health Service Executive National Intercultural Health Strategy 2007-2012

11.1 HSE Open Disclosure Policy 2013 (and Guidelines)

(a) The concept of open disclosure in clinical practice is a theme dealt with at various points throughout this Report. The CRT recognise, however, that it was not formally implemented until the later part of the period under review (2008-2014) by way of the HSE Open Disclosure Policy 2013 (and Guidelines) which were formally introduced by the HSE in October 2013[74].

(b) The Open Disclosure Policy (and Guidelines) formalised a practice expected of clinical staff in 2013, although good practice in open disclosure would have been expected prior to this.

(c) Some of the Incidental Findings of the 18 SAIs analysed by the CRT noted:

(i) The failure of SAOLTA to ensure that all staff are aware of and comply with the HSE Open Disclosure Policy; and that the related Open Disclosure Guidelines are implemented in the hospital and;

(ii) Failure to implement and audit compliance with National Open Disclosure Policy and relevant governance/Q&S Committee need to consider and address findings of audit.

(d) From the CRT's analysis of the 18 cases reviewed, together with its meetings with some of the affected families, its findings in relation to the presence of open disclosure are as follows:

	No. of cases where open disclosure was deemed satisfactory	**No. of cases where open disclosure was deemed unsatisfactory**	**Unsatisfactory 2008-2013[75]**	**Unsatisfactory 2014[76]**
Total (18 cases)	1 (2014)	17	10	7

Table 13: The CRT's findings in relation to open disclosure in the cases under review

It is important to note that of the 17 cases where open disclosure was deemed unsatisfactory, in 8 of those cases it had a significant effect on the family and in 9 cases, the communication could have been better.

11.1.1 Implementation Measures

(a) The CRT have reviewed records of training initiatives and implementation plans in PUH which shows that the HSE Open Disclosure Policy 2013 (and Guidelines) were on the agenda for PUH staff as evident from the Minutes of PUH Patient Safety Group Meetings in early 2014. An initial phase of implementation measures appeared to have been rolled out in PUH by July 2014 and continued to be on the training agenda after that. The Minutes of the Quality and Safety Governance Meeting in August 2014 references training in open disclosure.

[74] Health Service Executive Open Disclosure Policy, October 2013 Document Reference Number: QPSD-D-062-1
[75] Prior to the implementation of the HSE Open Disclosure Policy (October 2013)
[76] Subsequent to the implementation of the HSE Open Disclosure Policy (October 2013)

(b) The Multi-Disciplinary Training and Education Programme in PUH indicates that two Clinical Midwife Managers have trained as open disclosure trainers and are involved in providing training locally. The CRT notes from feedback received that additional obstetric staff have also trained in Open Disclosure.

(c) The Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16 states that two Clinical Midwife Managers have trained as open disclosure trainers and are involved in training locally. There is now on-going staff training on Open Disclosure.

11.2 **HSE National Consent Policy 2013**

The Incidental Findings of some of SAIs reviewed by the CRT, noted problems on the level of compliance with the National Consent Policy which needed to be considered and addressed by relevant governance/Q&S Committee.

11.2.1 **Implementation Measures**

The CRT has reviewed the meetings of the PUH Patient Safety Group Meetings (March 2014) which shows evidence of an initiative to roll-out the National Consent Policy. By July 2014, the initial phase of National Consent Policy had been rolled out in PUH.

11.3 **HSE Safety Incident Management Policy 2014**

(a) The HSE Safety Incident Management Policy 2014 outlined the principles that should be followed in relation to the identification, reporting and investigation of safety incidents.

(b) Some of the Incidental Findings of the 18 SAIs analysed by the CRT noted:

(i) Issues related to the initial management of the incident and implementation of the requirements for incident management as outlined in the Health Service Executive (2014) Safety Incident Management Policy and;

(ii) The failure of SAOLTA to ensure that all relevant staff attend **Incident Management Training** (0.75 day) and **Systems Analysis Investigation of Incidents** (3 days) training and that these trainees are assigned investigations which are reviewed and quality assured to ensure that competency in investigations is achieved

(c) The Safety Incident Management Policy came into effect in May 2014 and therefore it was not in place at the time of the cases occurring between January 2008-May2014. However, the CRT notes from the findings of the SAI reports that the policy did not appear to have been followed fully in 2014, as there was a failure to investigate the initial cases referred in 2014 in accordance with the policy after they were referred to the SIMT.

(d) The CRT identified a need for SAOLTA to ensure that the governance structures and processes within the group and individual hospitals regarding all aspects of incident management including investigation are fully aligned to the requirements as set out in the HSE Safety Incident Management Policy (2014).

(e) One of the CRT's Key Recommendations is the development of training in incident recognition and reporting and incident management and review.

11.3.1 **Implementation Measures**

(a) The CRT notes the establishment of the SAOLTA Serious Incident Management Team "SIMT" in March 2014. It is a SAOLTA group-wide incident review and management team.

(b) The CRT notes the contents of the Serious Reportable Events (SREs) - HSE Implementation Guidance Document in January 2015 However, as this guidance document was not introduced until 2015, the CRT was not able to comment on its implementation but acknowledged its importance in the further development of the Clinical Governance processes in the SAOLTA group.

(c) The Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16 states that all serious incidents should be documented on morning and evening Nursing Administration Reports. All incidents should be discussed and recommendations made if necessary to adjust clinical practice where appropriate. For incidents of a major or extreme impact, preliminary assessment reviews are compiled and subsequently submitted for discussion at the monthly Serious Incident Management Team meetings where these incidents are discussed.

11.4 National Standards for Bereavement Care Following Pregnancy Loss & Perinatal Death (September 2016)

(a) The CRT notes the Incidental Findings of the 18 SAIs where it is noted that PUH/SAOLTA had not implemented policy and guidance in relation to the maternity indications for the retention of organs and/or tissue samples for histological examination as outlined in the draft HSE Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (September 2016[77]);

(b) All relevant staff should be aware of, and use, the guidelines appropriately. This needs to include focus on the retention and use of placenta. The CRT noted this Guidance but as it was introduced in 2016 the CRT was not able to comment on its implementation but acknowledged its importance in the further development of the Clinical Governance processes in the SAOLTA group.

11.4.1 Implementation Measures

(a) During the timeframe under 2008-2014 review, the CRT noted that support was given to bereaved families through the Pastoral Care Department, however there was no dedicated bereavement midwife.

(b) PUH indicated that it works closely with support groups such as Féileacáin.

(c) The Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16 states that the hospital has established a multi-disciplinary Perinatal Bereavement Group with representation from across all disciplines. The role of the group is to facilitate a standardised approach to the provision of individualised quality care for women following miscarriage, stillbirth and neonatal death. The group is working towards the implementation of the National Standards in Perinatal Bereavement Care Following Pregnancy Loss published in September 2016. During this investigation, the hospital indicated that it is approved for a 0.5 Whole Time Equivalent (WTE) Perinatal Bereavement Midwife.

[77] https://www.hse.ie/eng/about/who/acute/bereavementcare/standardsbereavementcarepregnancyloss.pdf

11.5 Irish Multidisciplinary Obstetric Emergency Training (IMOET) 2014

(a) This initiative held its inaugural meeting in September 2014. Its aim was the 'Standardisation of multi-disciplinary obstetric emergency training across all of the maternity units in Ireland.'

(b) It highlighted 10 multidisciplinary obstetric emergency training topics, with videos, to help in improving safety in labour wards in Ireland. The ten topics are:

(i)	Maternal sepsis
(ii)	Major postpartum haemorrhage
(iii)	Maternal collapse
(iv)	Eclampsia
(v)	The management of pulmonary embolism
(vi)	Early pregnancy vaginal bleeding
(vii)	Shoulder dystocia
(viii)	Intrapartum fetal monitoring CTG
(ix)	Cord prolapse
(x)	Teamwork and obstetric emergencies

Table 14: The 10 initial training topics of the Irish Multidisciplinary Obstetric Emergency Training

Topics (vi), (viii) and (x) above have particular relevance to the 18 cases reviewed and topics (i) and (ii) 2 were also associated with some of the cases but not major factors. It highlights that these are rare events that all maternity staff should regularly train to maintain skills. This is particularly true in the smaller units that come across these situations even less often than the bigger units.

11.5.1 Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16

The implementation of this plan includes the following in response the IMOET:

(a) Two clinical midwife managers have been trained to facilitate the roll out of CTG multidisciplinary training in house. CTG master classes have been run with 8 midwives and one consultant and two NCHDs attending. Further master classes were planned.

(b) K2, a computer based fetal monitoring training system, is in place and the plan is for all staff to be trained annually. PROMPT, a multidisciplinary training programme for labour ward, is now delivered three times a year.

(c) A sepsis management education session is delivered regularly including the use of the Sepsis In-patient Screening Form. Training in the use of IMEWS and ISBAR are provided on an ongoing basis to aid in the diagnosis of the deteriorating patient and effective communication, both problems highlighted in the cases reviewed.

11.5.2 **Multi-Disciplinary Training And Education Programme in PUH**

This programme provides for:

(a) Weekly C-section audits.

(b) Multidisciplinary team CTGs reviews held weekly and multi-disciplinary CTGs teaching scheduled once a month.

(c) Two Clinical Midwife Managers trained as CTG trainers to facilitate courses locally.

(d) Multidisciplinary CTG training workshops scheduled for September.

(e) National and Group Guidelines are presented at weekly meetings.

(f) Supplementary sessions provided on maternal sepsis and IMEWS weekly clinical meetings.

(g) Four (additional) staff members have trained as facilitators for PROMPT and there are 3 courses per year onsite. Theatre staff are planning to participate in future PROMPT sessions. In feedback received, the CRT understands that additional staff members are now actively involved in PROMPT training.

(h) Monthly perinatal multidisciplinary meetings. Obstetricians, Paediatricians, Midwives and the Clinical Risk Manager (or equivalent) attend these meetings. All cases of perinatal mortality and morbidity are discussed.

(i) Staff trained as Caring Behaviour Assurance System (CBAS) facilitators. CBAS Champions in the Maternity Unit and roll out of the CBAS programme on the Maternity Unit.

(j) Two Clinical Midwife Managers have trained as open disclosure trainers and are involved in providing training locally. The CRT notes from feedback received that additional obstetric staff have also trained in Open Disclosure.

(k) Staff midwife trained in hypno-birthing, funding received to provide training for 10 further midwives; this will facilitate specialist hypno-birthing classes and up-skilling for labour ward staff.

(l) Four Staff Midwives have completed the module in High Dependency Care, a further four are applying for the 2016 course.

(m) There is on-going staff training provided regarding incident identification, reporting and management. Information sessions are also provided with regard to developing and populating a departmental level risk register.

(n) The Neonatal Resuscitation Program training (NRP).

Table 15: The Multi-disciplinary Training and Education programme currently in PUH

The training record for 2015/16 shows that many staff have attended the training sessions but the CTG and K2 uptake is disappointing considering the fact that CTG misinterpretation is such a common theme in the cases reviewed.

Training Records for 2015/2016	% Midwives Trained	% Doctors Trained
IMEWS/ISBAR	87%	100%
SEPSIS	96%	100%
PROMPT	80%	100%
CTG	79%	73%
K2	88%	83%

Table 16: The training record for staff in PUH for 2015/16

These training programmes need to be regionally driven with various options available for staff to access the training in a multidisciplinary environment. This is a great improvement and, by implementing this initiative fully, it will go a long way to help maintain the skills of their clinical staff.

11.6 **Irish Maternity Indicator System (IMIS) National Report 2015**

These figures show that the number of births is declining throughout Ireland and, PUH which delivers just under 2000 births a year, is well below the mean (The CRT acknowledges the fact that, with the skewed distribution, a median and range would be preferable but this is the data as presented).

	Total mothers delivered			**Total Births**		
	2014(n)	**2015(n)**	**Change**	**2014(n)**	**2015(n)**	**Change**
All Maternity Units	65,987	64,435	↓1,552 (-2.4%)	67,263	65,680	↓1,583 (-2.4%)
Mean Per Hospital	3,473	3,391	↓82 (-2.4%)	3,540	3,457	↓83 (-2.4%)

Table 17: The number of mothers delivered and births in Ireland in 2015

The report gives a lot of other data but this is at national level and it is not possible to comment on the local PUH figures.

11.7 **National Consultant Workforce Planning 2015 (Supplementary Report)**

(a) This report stated that "There is no one definitive and accurate source of information for the number of obstetricians and gynaecologists practising in Ireland which can be used for workforce planning." However, they used various sources to produce an accurate estimate.

(b) Using various calculations and assumptions, it states that Ireland has the lowest number of practicing obstetricians, including trainees, per 1000 births of all the OECD countries[78].

[78] Organisation for Economic Co-operation and Development

The result of 3.95/1000 births is less than half the figure of 9.22/1000 for the UK. They then conclude that Ireland needs another 100 new consultant posts but these should be recruited on a phased basis to maintain quality and continued renewal and replacement.

(c) On the basis of the information provided to the CRT, PUH had 4 obstetric consultants in place in 2014 when they delivered 1983 babies giving a ratio of 2/1000 births, nearly half the national average. The increase of 1 permanent consultant, now in post, and a slight reduction in deliveries to 1853 for 2015 gives a ratio of 2.7/1000 births, which is still less than the national average. The obstetric consultants felt that 7 consultants are required to provide the cover expected in modern obstetrics with consultant presence in labour ward during the day. This would give a ratio of around 3.5/1000 still less than the national average and below the national aspirations.

11.7.1 **Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16**

(a) The implementation of this plan includes the following in response to IMIS and the National Consultant Workforce Planning 2015 (Supplementary Report):

(b) As a result of increased consultant numbers, there is currently a dedicated consultant available to the Labour Ward. This is the consultant on-call for the day. This consultant is involved in and receives the morning hand-over from the consultant on-call overnight. This consultant is involved in safety huddles and the supervision of Registrars in the Labour Ward. The CMMI/II in charge can ring the consultant on call at any stage, including when they feel uncomfortable with the decisions or actions of NCHDs on call. The Consultant on-call can seek a 2nd consultant opinion at all times in relation to difficult cases.

(c) The CRT acknowledges that this is a great improvement on what went on before but it remains to be seen how well this is implemented. The new consultant appointment has certainly changed the atmosphere and input into the labour ward. There still needs to be an increase of consultant numbers. A total of 7 would bring the numbers up to the national average. Innovation in the appointments could bring joint posts with GUH allowing sharing of knowledge and experience.

11.8 **Final Report of the HSE Midwifery Workforce Planning Project 2016**

(a) This report goes into great detail on what the problems were in midwifery numbers and the methodology designed to assess the needs of a modern workforce. The assessment of need was based on Birthrate Plus® (BR+), which takes into account not only the number of deliveries but also the varying requirements based on clinical need. The cases are classified into 5 categories of complexity from 1 – low complexity to 5 – highly complex case requiring greater midwifery input. Inevitably the larger hospitals look after a greater percentage of complex cases than the smaller ones.

Hospital	Large	Small
Category I	3.6%	7.8%
Category II	8.8%	16.8%
Category III	12.6%	14.5%
Category IV	47.6%	36.5%
Category V	27.4%	24.5%

Table 18: The percentages by degree of complexity in large and small hospitals in Ireland

(b) What is interesting about these figures is that although there is a trend for the smaller hospitals to have less complicated cases, the differences are not that great suggesting that there is not a good risk categorisation within the maternity networks. This is important for hospitals like PUH where risk categorisation is essential to make sure the women get the best care in the best place.

(c) The study shows that PUH actually has 2.41 excess midwives per BR+ calculation compared with the larger hospitals studied, which all had a deficit. However, after the additional midwife roles such as clinical governance and risk is taken into account, PUH had a deficit of 0.55 of a midwife.

(d) The CRT felt that the evidence from the review was that an increase in senior midwifery staff was required to provide a safe service along the lines as outlined in the PUH QIP.

11.8.1 **Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16**

The implementation of this plan was largely completed by 2016 and includes the following:

(a) A new Director and Assistant Director of Midwifery have been appointed to provide the kind of leadership within the unit that is required. However, it is the opinion of the CRT that it is important that their role both within the hospital and the SAOLTA group is clearly defined. If this is not done, the unit will remain isolated and unsupported.

(b) There are now Clinical Midwife Manager CMM Posts on duty in the labour wards at all times, including overnight to provide support and leadership. There is an increase of CMM posts giving a total of 3 CMM1, 6 CMM2 posts to provide mentorship and support. There is an Information Technology Midwife to assess the data being collected including incident reports. A regular review of these results will be produced to monitor performance. They are planning positions of Midwifery Practice Development and Midwifery Clinical Skills facilitator. In feedback received, it is noted by the CRT that these positions are now in place. The CRT are of the opinion that these are good development positions for midwifery staff to advance themselves and be kept up to date.

(c) There are also plans to improve the supportive specialties of paediatrics, anaesthetists (including an intensivist) and physicians. Some of these posts are joint appointments with GUH and will hopefully help to improve the infrastructure to support best care.

(d) It is also important, however, to maintain morale, training quality and full integration into the SAOLTA group.

11.9 **Creating A Better Future Together, National Maternity Strategy 2016-2026**

(a) The National Maternity Strategy is an ambitious aspirational document that outlines where the Irish Maternity Services should be in the years to come.

(b) The size of the 19 maternity hospitals/units varies significantly, with 9,261 births in the National Maternity Hospital in 2014 compared with 1,100 births in South Tipperary General Hospital in the same period.

(c) PUH is in the 2000 births per year group. It is to be noted that half of all units in Ireland fall into the group that deliver 2000 babies or less per year. Therefore, it may be the case that challenges that existed in PUH may also exist to some degree in at least half the units of Ireland.

(d) The National Maternity Strategy highlights much of what is in this report and has been in others before it. The importance of the document is not what it says but whether it is implemented. This needs leadership, planning and support both financially and practically.

(e) **The Strategy states:** "Maternity services are appropriately resourced, underpinned by strong and effective leadership, management and governance arrangements, and delivered by a skilled and competent workforce, in partnership with women"

(f) **The Strategy states:** "It is clear that maternity services must be in a position to respond to increasingly diverse and complex population needs in order to provide safe, evidence-based, accessible care to all mothers, babies and their families in Ireland".

(g) **The Strategy states:** "Smaller maternity services cannot, and should not, operate in isolation as stand-alone entities. They cannot sustain the breadth and depth of clinical services that the populations they serve require without formal links to larger units. It is envisaged that through the establishment of maternity networks within hospital groups, and the sharing of expertise within those networks, the operational resilience of smaller units can be strengthened and such units can be supported to provide safe quality services.

11.9.1 **The Portiuncula Hospital Maternity Quality Improvement Plan (QIP) 2015/16:**

(a) The QIP outlines how it plans to deliver this within the hospital itself. New staff appointments, training and support are being put into place but the overall management structure needs to be strengthened and work with a clinical network.

Key Components of these Networks Include:

- A clinical service under a single governance framework;
- A common system of clinical governance; clinical and management policies, audit meetings, quality assurance, incident reporting, incident management, risk management etc.;
- Quality assurance on the basis of one single maternity service, although operating at different geographical sites; this will require data to be pooled across the network;
- Risk stratification of mothers attending the managed clinical network to ensure that higher risk pregnancies are dealt with at the most appropriate facility within the network;
- The ability for all medical and midwifery staff working within the network to rotate between sites to meet training and service requirements;
- The ongoing training of all doctors and midwives takes place at all sites within the network on a rotational basis;
- A co-operative approach to service delivery which ensures that each hospital site within the network delivers care appropriate to the resources, facilities and services available on that site;
- Planned support for families who will need to have their care transferred a long distance from their homes.

Table 19: Key Components of a Maternity Network

(b) Any solution to the problems found and progress in developing the service must follow these recommendations. It would appear from the CRT's review of the SAIs and interviews with PUH staff that PUH has suffered from the isolation of practice and culture even though it exists within the SAOLTA group. True integration and support is required with leadership at all levels if the improvements planned are to be fully implemented and sustained. The new appointments and plans begin to address the recommendations but further work is required.

(c) The Strategy states: "We fail to collect robust data on outcomes, fail to detect patterns, fail to learn from serious incidents, fail to disclose. We need a structure with explicit lines of who holds responsibility and accountability. We can no longer blame an inanimate 'system'".

(d) This Report is the result of governance systems detecting areas of concern in PUH but it is not the first report into problems of this kind in the Irish maternity system. It is important that it is the last. We know the problems, we know the solutions. It is the implementation and sustainability that is lacking.

REVIEW OF INDIVIDUAL INVESTIGATION OF 18 CASES IN ACCORDANCE WITH THE TERMS OF REFERENCE AND METHODOLOGY

12. THE REVIEW OF 18 INDIVIDUAL CASES

12.1 The methodology adopted for Part II of this review is as set out at Sections 6 and 7 earlier in the Report.

13. THE CASES REVIEWED BY THE SAI TEAMS

13.1 The original Preliminary Review included 6 cases which were referred for cooling reported onto SIMT by PUH in 2014.

Brief detail of event by investigators following investigation	Outcome	KCF (Yes/No)
Delivery by Spontaneous Vaginal Delivery following induction of labour. Umbilical cord was wrapped around the baby's neck and shoulders. Shoulder dystocia.	Baby doing well	No
Delivery by emergency CS following identification of a pathological CTG.	Baby doing well	Yes
Pathological CTG	Baby doing well	Yes
Failed instrumental delivery, emergency caesarean section	Baby doing well	Yes
True knot in umbilical cord.	Baby diagnosed with grade III HIE. Current state unknown.	Yes
Previous CS. Uterine rupture with sudden fetal distress.	Baby death	No

Table 20: Outline of the SAI results of the six cases which occurred in 2014. All were referred for TH.

13.2 Of these 6 cases, 4 appear to have had a good outcome. In one case, the long term outcome is unknown although the baby was discharged home with the parents and one baby sadly died. This implies that overall in 2014, the neonatal care system worked in that the problems were identified and appropriate interventions implemented. However, as can be seen in 4 of the cases Key Causal Factors were found in obstetric care that impacted on the initial hypoxia that led to transfer for TH as is described in Appendix 5. It is an example of how the final good outcomes can obscure some care concerns.

13.3 As stated before, there were 12 additional cases relating to 10 families[79], comprising of a range of different perinatal events at PUH dating from the seven year period from 2008 to 2014 and which were identified through a patient help line.

2008	2009	2010	2011	2012	2013	2014
1 case	1 case	5 cases	0 cases	2 cases	1 case	2 cases

Table 21: The year of delivery of the 12 additional cases reviewed

[79] Two of the families involved had two separate cases reviewed each.

Brief detail of event by investigators following investigation	Outcome	KCF? (Yes/No)
Unexpected deterioration after delivery	Baby doing well.	No
Unexpected deterioration after delivery	Baby doing well.	No
Failed instrumental delivery. Emergency CS.	Baby doing well. Some developmental delays	No
Vaginal delivery. Shoulder Dystocia.	Physically good, Developmental delays and learning difficulties	No
Fetal Distress, Emergency CS.	'infantile spasms'.	No
Fetal distress. Emergency CS	mild cerebral palsy and 60% hearing loss.	No
Failed instrumental delivery x 2 resulting in a crash caesarean section	Skull fracture, asphyxia. Baby has Epilepsy	Yes
VBAC. Delivery by caesarean section due to non-reassuring CTG.	Baby death	Yes
Quick labour with periods of non-reassuring CTG. Shoulder dystocia.	Baby death	No
Intrauterine death while an in-patient	Stillbirth	Yes
Intrauterine death (IUD) on scan. A concealed placental abruption was confirmed during the Caesarean Section.	Stillbirth	Yes
Baby non-responsive following delivery by emergency CS.	Macerated Still birth	No

Table 22: Outline of the SAI results for 12 additional cases relating to a range of perinatal events from 2008 – 2014 identified through a help-line

13.4 These are a different group of cases but they have a lot of similarities in the problems identified. It is noteworthy that 7 of these 12 cases occurred before 2012. During the time period 2009-2011 there was a transition period where transfer for TH was evolving, dependent predominantly on the local sites and it was not fully established nationally until 2012[80]. Many, if not most of these cases may have benefited from TH and resulted in potentially improved outcomes. This is a reflection of advancing medicine improving outcomes and the need to implement new advances in a timely manner on a national basis, by developing clinical networks and the appropriate training to provide the available benefits nationally to all.

13.5 In 4 of the 12 cases Key Causal Factors were found by the SAI teams, although there were many contributing and incidental factors. The biggest difference that appears between these 12 cases and the original 6, as detailed in the SAIs, was the handling of the cases by the hospital after the events. It is the view of the CRT that poor support at the time of the delivery and poor follow-up and lack of open disclosure were the main reasons that these families referred themselves for review. The SAI results confirm that the clinical handling of these 12 cases was no worse than in the original 6 cases as reflected by the lower incidence of Key Causal Factors found. It is clear that early follow-up and timely open disclosure can help families dealing with adverse events.

[80] Appendix 5 Therapeutic Hypothermia in Ireland

14. KEY CAUSAL FACTORS IDENTIFIED BY THE INVESTIGATORS IN THE INDIVIDUAL SAI

14.1 Key Causal Factors (KCFs) are defined as issues that arise in the process of delivering and managing care that the investigators consider contributed to the eventual adverse outcome as set out in the HSE Investigation Guidelines. In all KCFs were identified in 44.44% of the cases reviewed (N=8/18).

Summary of the 13 Key Causal Factors (KCFs) Identified in 8 out of the 18 SAI Reports
Failure to recognise and act on the abnormal antenatal CTG trace in a woman with pre-eclampsia resulting in: An incorrect decision to defer fetal assessment (it was a holiday weekend) Failure to carry out biophysical profile and Doppler studies Failure to expedite delivery of the baby
Failure to adhere to guidelines related to prompt and effective management of abnormal CTG's during labour on 5 occasions Poor interpretation of intrapartum CTGs Failure to investigate suspicious CTG with Fetal Blood Sampling (7) Failure to escalate abnormal intrapartum CTG findings Failure to expedite delivery of the baby
Incorrect use oxytocin infusion in the presence of an abnormal CTG
Failure to escalate cases to the consultant on four occasions leading to Delay in delivery of the baby Difficult operative vaginal delivery
Failure to follow the guidelines for the management of Vaginal Birth After Caesarean (VBAC)
Failure to consider and recognise the signs and symptoms of a placental abruption at 30 weeks gestation and intervene to expedite the delivery the baby

Table 23: Details of the 13 Key Causal Factors (KCFs) identified in 8 out of the 18 SAIs. More than one KCF were found in some cases.

14.2 In some cases more than one KCF was found and similar KCFs were repeated in several different cases.

14.3 The majority of the KCFs related to poor assessment of fetal wellbeing and escalation of care. This is not unusual and is the finding in most reviews of this kind. It is therefore important to look for factors that allow these errors to continue to occur and how they can be prevented. It is also important to look at other contributory factors.

15. CONTRIBUTORY FACTORS IDENTIFIED

15.1 The literature and the SAI Guidelines state that Key Causal Factors must be analysed to identify the underlying causes (i.e. Contributory Factors). Therefore, for the eight of the 18 individual investigations that identified Key Causal Factors, each was analysed using the Framework of Contributory Factors (See Appendix 3) to identify the contributory factors. The Contributory

Factors Framework[81] consists of seven broad contributory factor types; and 39 contributory factors sub-types.

15.2 26 broad contributory factor types were identified within the eight investigation reports that identified KCFs. These 26 broad contributory factor types fell into six of the seven broad contributory factor categories listed in the Contributory Factors Framework. The only broad contributory factor type that was not identified was the "Institutional Context Factor" type.

15.3 The most commonly occurring broad contributory factor type was "Task and technology factors" occurring 30.77% (N=8) of the time. Please see Table 21 below for further details of the broad contributory factor types that occurred in these eight cases.

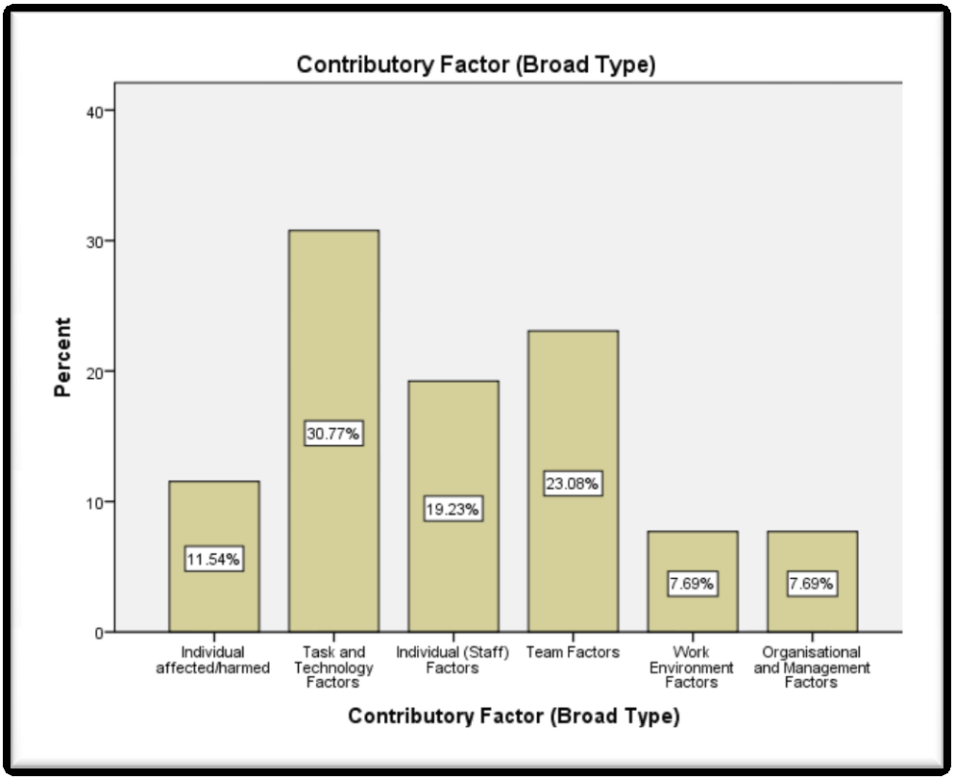

Figure 5: Showing the broad contributory factor types identified in the 8 out of the 18 individual SAIs that identified Key Causal Factors.

15.4 What this analysis shows is that in the 8 cases where the 13 KCFs were identified, nearly 54% of them were due to either failure to follow accepted guidelines or failure in team working. Individual error contributed to a fifth of cases. This emphasises the importance of the team culture and leadership and a multidisciplinary training environment.

15.5 The 26 broad contributory factor types were further analysed to identify contributory factor subtypes and were found to fall within 12 of the 39 available contributory factor sub-types.

15.6 The most commonly occurring contributory factor subtype was *"Task and technology factors: Availability and use of protocols, policies and standards"* occurring 16.1% (N=5) of the time. Please see Table 22 below for further details of the contributory factor subtypes that were identified in the eight cases that identified Key Causal Factors.

[81] From Health Service Executive (2012) Guidelines for the Systems Analysis Investigation of Incidents and Complaints

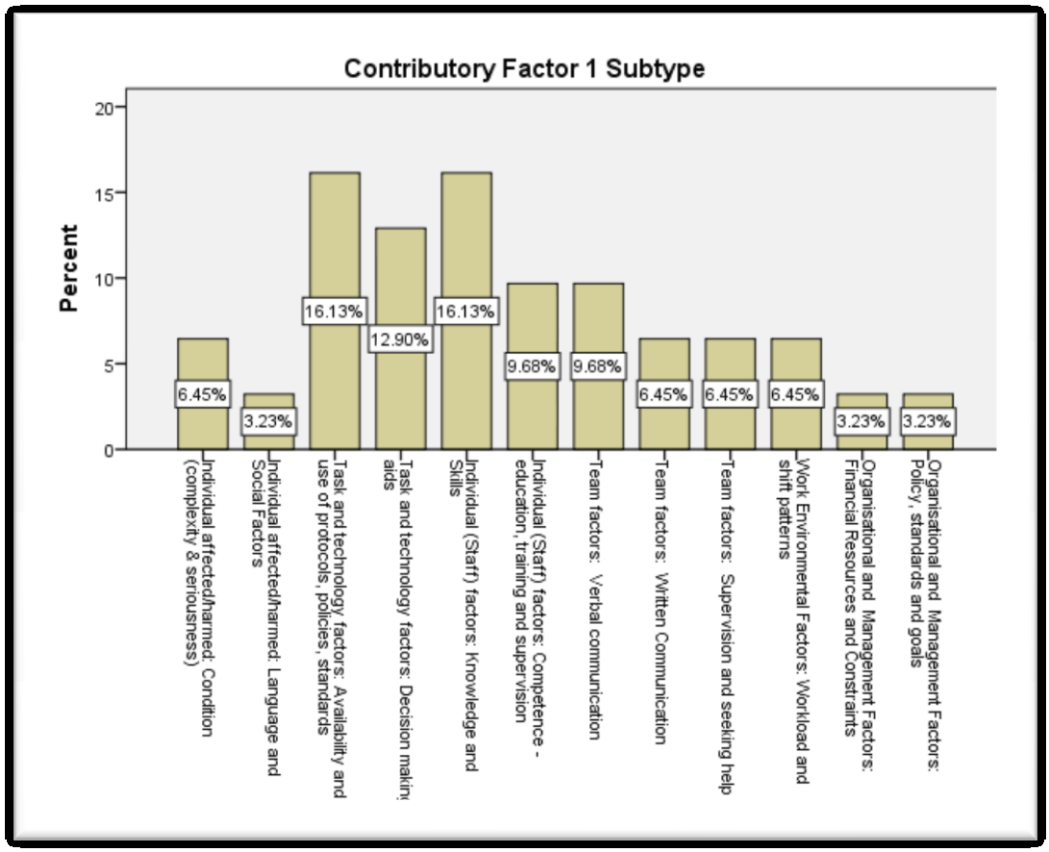

Figure 6: Showing the contributory factor subtypes identified in the eight out of the 18 individual investigations that identified key causal factors.

15.7 These findings highlighted the problems related to individual skills and knowledge, particularly when using equipment such as CTGs and the poor spoken and written communication that was apparent making it more difficult for teams to function.

15.8 Specific details of the contributory factors identified in the individual SAI reports are shown in Table 24 below.

Details of Contributory Factors Identified in 18 SAIs
(a) Poor obstetric clinical handover including processes for conveying clinical concerns and formal handover between on-call medical staff. (i) Contact with Registrars and Consultants to discuss cases of concern and when planning a trial operative vaginal delivery. (ii) Absence of a Multidisciplinary Training to managing cases within the Labour Ward which would improve team working.
(b) Need for one-to-one midwife mother ratio: (i) Need to adhere to practice of one midwife being assigned to one patient in the labour ward in accordance with "NICE CG. 190 (2014)".
(c) Need for local guidelines and training on intra-partum Fetal Heart Rate Monitoring: (i) Need for midwifery and medical staff to attend CTG and K2 training annually on a mandatory basis and for attendance to be monitored; (ii) Learn how to manage reduced variability on the CTG; (iii) Learn how to manage suspicious or pathological CTG's; (iv) Need for CTG skills to be verified; (v) Develop an escalation policy in response to a suspicious or pathological CTG; (vi) Need for the Obstetric and Midwifery leads to ensure that staff are aware of "Guidelines on Fetal Heart Rate Monitoring" and for all staff to comply with these guidelines; (vii) Need for routine audits of training and compliance with "Guidelines on Fetal Heart Rate Monitoring".
(d) Lack of use of decision making tools such as: (i) Guidelines on clinical indications for undertaking biophysical profiling; (ii) Lack of availability of Doppler ultrasound and general ultrasound support; (iii) Fetal blood sampling.
(e) Management of Ante-Partum Haemorrhage: (i) Need for routine audits of compliance with the "Guideline and Procedure for the Management of Ante-Partum Haemorrhage RCOG GG 63(2011)";
(f) Vaginal Birth after Caesarean Section (VBAC) protocol: (i) Need for the Obstetric and Midwifery leads to ensure that staff are aware of the current guidelines in the Hospital in relation to Trial of Labour (VBAC) and that it is implemented in practice; (ii) Need for staff to ensure that they are aware of and comply with current guidelines in the Hospital in relation to Trial of Labour (VBAC); (iii) Need for routine audits of compliance with current guidelines in the Hospital in relation to Trial of Labour (VBAC) and results reviewed by the relevant Governance Committee.

(g) Seeking consent where the patient does not speak English: (i) Need where the patient does not speak English as their first language, for Medical staff to consider and be satisfied that the patient has fully understood all of the information provided to them including related to consent to proceed with a procedure, particularly in situations where verbal consent is being sought; (ii) Need to ensure that effective translation services are engaged and partners are not used as translators in line with recommendations from the HSE's National Intercultural Health Strategy 2007-2012[82]; (iii) Need to follow Royal College of Obstetrics Guidelines regarding the principles of obtaining valid consent during labour being followed in all cases.
(h) Recruitment: (i) Need for risk assessment regarding recruitment and employment of locum clinical staff particularly those situations where locum staff are required on a short term basis and where the post needs to be filled within a short timeframe; (ii) The risk assessment should be included in the relevant hospital level Risk Register and should be reviewed and updated in line with the governance arrangements in place.
(i) Induction of locum medical staff: (i) Need to ensure that the relevant and appropriate induction information is available for all Medical specialities within the hospital including the Maternity Unit and that locum Medical staff are provided with access to relevant clinical protocols; (ii) Need to ensure that local clinical staff receive appropriate induction that clearly outlines their clinical roles and responsibilities for the period of their employment and that outlines the supervision structure in place for the locums; (iii) Need for guidance similar to UK Guidance "Guidance on the appointment and employment of NHS locum doctors (2013)".

Table 24: Details of the Contributory Factors (CF's) identified.

Again the main factors found in the SAI reports were poor assessment and escalation of CTG abnormalities, poor team working and poor communication. There were also deficiencies in skills and knowledge demonstrating the importance of multidisciplinary training, guideline development and adherence to these guidelines.

16. AN ANALYSIS OF INCIDENTAL FINDINGS IDENTIFIED IN 18 SAI

16.1 Incidental Findings are defined in the SAI Guidelines as:

"Issues that arose in the process of delivering and managing services identified during the course of an investigation which the Investigation Team consider did not impact on the outcomes but which serve to identify issues for system improvement". These were assessed in all 18 cases and the summary of these are in Table 23 below.

[82] HSE, National Intercultural Health Strategy 2007-2012

Summary of Incidental Findings (IF's) Identified in 18 SAIs
(a) Documentation Issues: (i) There were several instances where there was poor documentation and non-compliance with HSE Standards and Recommended Practices for Healthcare Records; (ii) There was one example of changes made in the Apgar score without explanation given.
(b) Staffing issues identified particularly staffing levels in the labour ward and in the SCBU. (i) Due to a lack of staffing numbers, there was not the appropriate midwifery leadership or shift leaders who could work in a supervisory capacity in labour ward; (ii) Concerns about the risk assessment of practice of nursing staff from the SCBU attending neonatal resuscitation in theatre; (iii) Problems with workflow interruptions interfering with the process and management of admissions, inductions of labour, and self-presenting patients in labour to the labour ward, with a the result of lack of continuity of care and person centred care. (iv) One to One midwifery Policy not adhered to.
(c) Communication issues: (i) Poor communications with families during labour and after an event; (ii) Options for birth not adequately discussed with the mother; (iii) Women and partner reported that they were not asked for consent to proceed with an instrumental delivery; (iv) Problems with compliance with National Consent Policy which needs to be considered and addressed by relevant governance/Q&S Committee; (v) Poor support for families prior to transportation to secondary units, one partner was sent around local shops looking for a cooler bag to transport EBM; (vi) The need for provision of open disclosure to family in relation to: • The circumstances of the birth of baby, the baby's clinical condition immediately following delivery; • Lack of an identified point of contact to liaise with families at these difficult times. To provide a link between different sites and to organise follow-up appointments in a manner sensitive to the needs of the families involved; • Inappropriate/insensitive arrangements of follow-up appointments where parents who have experienced the loss of their baby had to wait for over an hour in a waiting room surrounded by expectant women.

(d) Provision of care issues

(i) Identified issues with the management of policies at the hospital;

(ii) Lack of multidisciplinary training and maintenance of skills;

(iii) Lack of training in ultrasound scanning techniques and lack of access to routine anomaly scanning;

(iv) Pain management not adequately managed;

(v) Poor monitoring of patients within the Maternity Unit who are admitted for Vaginal Birth after Caesarean Section (VBAC);

(vi) Need for consideration of how the fetal heart rate might be monitored during the period an epidural was being sited if the baby is thought to be high risk;

(vii) Training in fetal blood sampling and when to carry it out;

(viii) Non-adherence to guidelines in relation to reporting a suspicious (non-reassuring) CTG to registrar/consultant for review, further management and intervention as needed.

(e) Particular problems related to Oxytocin use:

(i) Need for the hospital to review the policy developed in relation to the use of oxytocin to ensure that the following aspects have been addressed;

(ii) Qualifications of staff authorised to administer and amend oxytocin regimens;

(iii) Indications for the use of oxytocin to augment labour;

(iv) Methods of preparation and administration of oxytocin;

(v) The level of initial dose and subsequent doses;

(vi) Methods of managing complications should they develop;

(vii) Definition of hyper stimulation.

(f) Management of intervention:

(i) Lack of training and use of simulators, in order to teach and develop skills required for operative vaginal delivery and to maintain such skills;

(ii) Improve decision to delivery time for emergency Caesarean Section;

(iii) Problems resulting from the distance from labour ward to theatre taking into account availability of porters; lifts; staff for transfers; and impact on labour ward while staff are absent in theatre for prolonged periods;

(iv) Lack of guidance available to medical staff to assist them in making clinical assessments required to determine the timing of cord clamping, i.e. whether "early" or "deferred" clamping should be used;

(v) Failure to contact the Paediatric Team to attend the Labour Ward prior to delivery in circumstances where a decision had been made to perform an operative vaginal

delivery;

(vi) Problems in contacting the Paediatric Team to attend a high risk delivery;

(vii) Failure to comply with hospital/group policy (2012) regarding resuscitation of the new-borns in relation to significant meconium staining, with particular reference to the requirement that a paediatrician is present at such deliveries;

(viii) Failure to use standardised descriptors for meconium staining as per NICE/National Collaborating Centre for Women's and Children's Health Clinical Guidelines Intra-partum Care (2014);

(ix) Absence of paired samples for umbilical artery and umbilical vein blood gas as per Royal College of Physicians of Ireland (RCPI) Guidelines on intrapartum monitoring.

(g) Neonatal resuscitation issues:

(i) Ensure Neonatal Resuscitation Program (NRP) training compliance of appropriate staff;

(ii) Issues related to the difficulties identified in establishing baby's O2 saturation levels during the resuscitation;

(iii) Need for management of aspects of resuscitation of a baby particularly in relation to enhanced resuscitation training drills related to the use of equipment that maybe required during resuscitation such as aspirators; and the need to focus on early use of objective heart rate monitoring technology so as to enhance the process of clinical heart rate assessment.

(h) Problems with delays in post-mortem (PM)reports:

(i) Failure to follow post mortem standards in the hospital, in line with the HSE's standards and recommended practices for post mortem examination services (2012);

(ii) Failure of formal PM examination reports to be available within the shortest duration of time possible following the completion of the PM;

(iii) Parents should receive detailed information in relation to the hospital post mortem examination in an information leaflet written in appropriate and accessible language;

(iv) Each family should have an identified contact person within the hospital that is responsible for follow-up contact with them following completion of the hospital PM examination;

(v) The family should be informed that, at their request, the report of the hospital PM examination will be made available to them when completed;

(vi) The family should be informed that it may not be possible to give a definitive timeline as to when the PM report will be completed as timeframes vary depending on circumstances such as what laboratory tests or expert opinion may be required;

(vii) Need to develop hospital level Key Performance Indicators in relation to post mortem reporting, supported by an audit process to monitor the adherence to the

KPI targets by all relevant departments.
(i) Clinical Governance issues: (i) A lack of an agreed annual audit plan for the maternity unit including; • co-operation in national audits; • schedule of prioritised local audits; • targeted audits conducted in line with service requirements and priorities. (ii) routine audits related to the implementation of the requirements for requesting paediatric presence at high risk deliveries; (iii) Issues related to the initial management of the incident and implementation of the requirements for incident management as outlined in the Health Service Executive (2014) Safety Incident Management Policy; (iv) Lack of an investigation following an intrauterine death or serious incident; (v) The failure of SAOLTA to ensure that the governance structures and processes within the group and individual hospital regarding all aspects of incident management including investigation are fully aligned to the requirements set out by the Health Service Executive (2014) Safety Incident Management Policy; (vi) The failure of SAOLTA to ensure that all relevant staff attend Incident Management Training (0.75 day) and Systems Analysis Investigation of Incidents (3 days) training and that these trainees are assigned investigations which are reviewed and quality assured to ensure that competency in investigations is achieved; (vii) The failure of SAOLTA to ensure that all staff are aware of and comply with the HSE Open Disclosure Policy; and that the related Open Disclosure Guidelines are implemented in the hospital; (viii) Failure to implement and audit compliance with National Open Disclosure Policy and relevant governance/Q&S Committee need to consider and address findings of audit; (ix) Failure of the PUH/SAOLTA to develop and implement policy and guidance in relation to the maternity indications for the retention of organs and/or tissue samples for histological examination as outlined in the draft HSE Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (June 2015); and based on existing best practice evidence. All relevant staff should be aware of, and use, the guidelines appropriately. This needs to include focus on the retention and use of placenta; (x) Relevant governance committee should consider need for an "Event recorder".

Table 25: Details of the Incidental Findings (IF's) identified

The SAI reports helped to highlight not only the Key Causal Factors and the Contributory Factors but also a large number of Incidental Findings that guided the CRT on its assessment of the care provision in the hospital and the needs for improvement.

	Incidental Findings Identified	Contributory Factors Identified	Cases with Key Causal Factors
Total (18 cases)	84	26	8

Table 26: Summary of factors identified from the SAIs

Of 84 incidental findings in the 18 cases, many were the same. This suggests a wider systems failure in PUH, making the environment unable to respond to developing incidents. It demonstrates the importance of not just looking at Key Causal Factors and the Contributory Factors of individual cases but the overall care provided. However, it has to be remembered that these cases go back over a number of years and many of the recommended changes are already in place as described previously in this Report.

17. THE CRT'S REVIEW OF THE 18 CASES

In assessing the care given in PUH between 2008 and 2014, the CRT took into account the findings from the SAIs, a review of the HCRs and interviews with the families. This informed the CRT as to the nature and level of the support given after the events had occurred.

17.1 Materials on Which The CRT Relied for Their Review

For the purposes of the analysis of the individual cases, the CRT undertook a documentation review of all 18 individual cases using the following materials. For the purpose of this documentation review, the CRT members had access to the following documentation as needed for each case:

(a) The patient's healthcare records;

(b) A good quality long copy of the CTG trace (both of these became available to the CRT in August 2015 and were reviewed at that time);

(c) All of the SAIs as they were completed and became available;

(d) The CRT used a Desk Top Scoring System modified from a similar system used in the Morecambe Bay Investigation (described at Paragraph 7.5) to rate cases according to the following three parameters:

  (i) Obstetric Clinical Care;

  (ii) Immediate Neonatal Clinical Care;

  (iii) Patient Perceived Support (Including general communication, practical support, and feedback related to the incident).

(e) The CRT also used the SAIs to complement their assessments. Although there were some differences between how the SAI investigators and the CRT graded problems highlighted in specific cases, there was widespread agreement on the problems and concerns found and the solutions needed.

18. **OBSTETRIC CARE**

Obstetric Clinical Care Score		A	B	C	
		Different management would have made no difference to the outcome	Different management *might* have made a difference to the outcome	Different management would have reasonably been expected to have made a difference to the outcome	Total No. Cases
3	Major	0	2	9	11
2	Moderate	0	1	1	2
1	Minor	1	1	0	2
0	Appropriate care	3	0	0	3
	Total No. Cases	4	4	10	18

Table 27: Results of CRT review of obstetric clinical care

18.1 Whereas the SAIs only found 8 cases where there were Key Causal Factors, using the slightly different methodology, the CRT found 9 cases where major errors of management occurred and 1 where moderate errors of management occurred that would have probably made a difference to the outcome of the case (10 in all, 2 additional cases to the 8 others that were in agreement). In addition, the CRT found 2 cases where there were major errors in management but they *might* not have made a difference to the outcome. In 5 cases the CRT found none or only minor problems in patient care.

18.2 On review of the 18 cases, the CRT formed the opinion that there was a general lack of skills and training among frontline staff. Care when things were progressing normally appeared to be of a high standard but the response to a deteriorating situation was often slow and deficient. Particular concerns are the lack of skills in the assessment of CTGs and the response to the findings and the lack of access to quality ultrasound scanning and training.

18.3 The CRT formed the opinion, following a review of the 18 cases, that there was a lack of Obstetric Consultant supervision in the labour ward, particularly of the NCHDs, when this was required. The consultants appeared to wait to be called and did not take ownership of the clinical care being given. As a result of this, there did not appear to be an appropriate handover of care, risk assessment of those in the wards or on the labour ward and the care provided was generally reactive rather than preventative.

18.4 This was demonstrated by the lack of consultant input into the management of a woman with severe pre-eclampsia over a holiday weekend. There was a lack of counselling and risk assessment of women undergoing vaginal birth after caesarean section (VBAC). The appropriate monitoring and assessment was not in place. There was a lack of appreciation of the possibility of a concealed abruption that could have led to the appropriate monitoring and intervention.

18.5 As previously noted there were numerous cases where the assessment of an abnormal CTG, escalation of this and failure to act appropriately was of particular concern. There was a failure in the appreciation of the significance of meconium staining. There was a failure in carrying out fetal blood sampling with a lack of training in its use.

18.6 On review of the 18 cases the CRT noted that the SAI reports found in a number of the cases that the midwife would escalate the problems but there were delays in the NCHDs attending and/or failures of the NCHDs to act appropriately. In some cases the CRT also noted that there were

failures of the midwives to jump call to the consultant if they were concerned and then often a delay in the consultant attending.

18.7 When decisions were made to intervene, these were inappropriate in some cases resulting in failed multi-instrumental deliveries. There was a failure in consultant supervision in these cases and at difficult caesarean sections.

18.8 When a caesarean section was decided upon, there was sometimes a significant delay in achieving the delivery, which was partly due to the time it took to get from the ward to theatre and also due to delays from arrival in theatre to the operation beginning.

18.9 From its review of the 18 SAI reports and the HCRs it appeared to the CRT that, the actual decision making was often correct but delays in escalation, delays in NCHDs attending, delays in making the appropriate decision, delays in consultant attendance and delays in decision to delivery intervals meant that a worse outcome resulted than might otherwise have occurred had decisions and actions been carried out promptly.

18.10 The paediatricians reported to the CRT, that there were cases of delayed cord clamping when it did not appear to be appropriate and the baby needed resuscitation.

18.11 In two cases reviewed by the CRT, a caesarean section was carried out after the baby had already unfortunately died. The CRT noted that in these cases, the supervising obstetric consultants were not involved in the decision to carry out a caesarean. It is the CRT's opinion that a supervising obstetric consultant ought to be involved in such decisions since a caesarean section is not without risk to the mother and can cause additional problems in future pregnancies.

18.12 Another common finding by the SAI investigation teams and the CRT was the inappropriate use of oxytocin, often without medical approval. In many hospitals, midwives can use oxytocin, without medical consultation, as they are independent practitioners, but this is following the appropriate training and agreements. There did not appear to be an appreciation of the risk of hyper stimulation and there was a failure to recognise it in a number of cases.

18.13 After events occurred, there did not appear to be any debriefing sessions for staff to be able to discuss the cases and learn from events. Also, of the 12 additional cases added to the review, only 3 had any form of prior review carried out, and these were generally inadequate in their nature and stated outcomes. There was a failure to involve the parents in these reviews. Therefore, an opportunity to learn how communication could have been improved, both in terms of facilitating informed decision making and debriefing for parents after a traumatic event, was missed.

19. **IMMEDIATE NEONATAL CLINICAL CARE**

19.1 In addition to the review of the obstetric care given, the CRT looked at the neonatal care at birth. There were 3 Stillbirths and therefore 15 cases to review.

Neo-natal Clinical Care Score		A No. of Cases where different management would have made no difference to the outcome	B No. of Cases where different management *might* have made a difference to the outcome	C No. of Cases where different management would have reasonably been expected to have made a difference to the outcome	**Total No. Cases**
3	Major	0	3	0	**3**
2	Moderate	0	5	0	**5**
1	Minor	0	1	0	**1**
0	Appropriate care	6	0	0	**6**
	Total No. Cases	**6**	**9**	**0**	**15**

Table 28: Results of CRT review of immediate neonatal clinical care

19.2 The CRT found no cases where different immediate management would have reasonably been expected to have made a difference to the outcome. In 9 cases the CRT concluded that there might have been some benefit to the baby if the care had been different. In 6 cases there was appropriate care.

19.3 The CRT observed in the cases where different management might have made a difference to outcome, one of the factors was the delay in the attendance of the resuscitation team due to a failure to prospectively call them to the delivery. This would appear to be partly due to the method of calling previously used which is now overcome by an emergency bleep being put in place. A delay in initiating manual ventilation due to delayed clamping of the umbilical cord was also noted.[83]

19.4 When the paediatric team arrived, there was generally good care given, but on occasion normal guidelines were not followed and there was at times a slowness to intubate and give adrenaline when indicated.

19.5 The main discussion point was those babies born in 2010 who may have benefited from TH but they were not referred, although it had been used for 1-2 years in Cork and Dublin. The need to develop systems to implement advances throughout Ireland needs to be put in place. However there is an onus on the local service also. It was noted that one baby was sent in early 2010 for TH, a second baby was subsequently referred but outside of the therapeutic window and a third baby later in the year was not sent. Only one case of hypoxic ischaemic encephalopathy was recorded in the PUH Annual Report 2010. Appropriate governance and leadership at paediatric consultant level within the institution and the development of local guidelines might have led to a difference in

[83] During feedback, the consultant paediatricians commented that "Our message to obstetricians was always clear and consistent that in the event of a baby requiring resuscitation, the baby should be brought immediately to the resuscitaire".

outcome.[84]However, it is to be noted that 9 of 12 Level II units in Ireland surveyed in April 2010 reported that they did not have a definitive plan to transfer infants for TH.[85]

20. PATIENT PERCEIVED SUPPORT (INCLUDING GENERAL COMMUNICATION, PRACTICAL SUPPORT, AND FEEDBACK RELATED TO THE INCIDENT)

As part of the CRT's remit they assessed the support given to the families after the events. This included the communication both verbal and written, the practical support they received in the days following the event, such as travel and logistical support, and the feedback they received about the outcome for their baby, both at the time and in the long term.

This assessment did not include the hospital's responses to the event such as internal reviews etc., but purely the interaction with the families. Although the CRT expected that the 6 more recent cases that were picked up by the governance system would fare better, it found equally poor family support in both groups.

PATIENT PERCEIVED SUPPORT	No of cases deemed Satisfactory	No of cases that could have been better and might have alleviated problems	No of cases with very poor and aggravated the problems
Communication (Verbal and written)	1	9	8
Practical Support	8	7	3
Feedback[86]	2	8	8
Total	11	24	19

Table 29: Results of the CRT assessment of patient perceived support.

(a) All 18 cases were assessed for all three domains (Communication; Practical Support; and Feedback). In only 20% of domains was the provision assessed as satisfactory. In 44% it could have been better and helped the families cope and recover from the events that occurred and in 35% it was poor and may have aggravated the stress and upset to the families and made their recovery more difficult.

(b) Most of the problems concerned the communication during the pregnancy and delivery and communication and feedback about the cases after the events had occurred.

(c) Women described not being listened to or communicated with about their concerns during the antenatal period and during labour. They felt that they did not get full explanations of the purpose of certain tests and interventions or the opportunity to consent to them. They felt their concerns were dismissed by staff. When they requested to see a consultant, this was not always possible. There were problems accessing translation services and sometimes partners were used as the best available translator. The womens' comments mirrored the findings of the CRT in the lack of clinical ownership and risk assessment that were seen when reviewing the cases.

[84] Please refer to Appendices 4 and 5.
[85] Nicholas M Allen, Adrienne Foran and Donough J O'Donovan, Arch Dis Child Fetal Neonatal Ed2011 96: F233 originally published online December 1 2010.
[86] Feedback in this context referred to feedback in relation to the adverse event and/or concerns conveyed by the family.

(d) After the events, some families reported that they were not always informed what was happening, why things had turned out the way they had and how sick their baby was and why. Some partners also reported that they were not allowed to stay with their wives to support them when their baby was very unwell or had died.

(e) Some women reported that they had to discharge themselves from hospital to go with their baby to another hospital and partners often had to travel on alone.

(f) The CRT has concluded that in some cases there was a failure to timely debrief the family. There were also problems relating to information on when a post-mortem would be available. There was no single point of contact and a lack of openness when dealing with families.

(g) When families did come for follow-up they often waited for a long time, did not feel that they were being told the truth and often received contradictory information. Some families reported receiving no feedback at all.

(h) The CRT agrees with the concerns expressed by families about the absence of a peri-natal mental health care pathway for women experiencing post-natal depression and anxiety and the lack of a system of referral and support.

20.1 **Issues Conveyed by Families During Meeting with CRT**

20.1.1 The CRT met with families who wished to meet them on the 10th October 2016. Eight families accepted this offer and during this meeting families raised the following issues with the CRT.

20.1.2 The CRT noted that some families conveyed their thanks to investigators during the factual accuracy checking process and for the fact that investigators took the time to reflect the family's experience in such thorough detail in the individual investigation reports.

20.1.3 However, the CRT also received feedback from other families reflecting that they experienced frustration during the factual accuracy process and making sure their experience was accurately reflected in the SAI reports was extremely challenging and laborious.

20.1.4 The CRT notes that the SAI Guidelines require that investigators reflect all feedback from families and staff in investigations except in the following two circumstances:

(a) Including the feedback in the report would detract from the factual accuracy of the report;

(b) Including the feedback in the report causes the investigators to stray outside of the Terms of Reference for the investigation.

20.1.5 The CRT understands that almost all feedback contributed by both families and staff was reflected in the 18 SAI reports. It also understands, having met the families, that there were a number of families who gave feedback in relation to actions and/or statements of staff, which was not included because the staff member was not available to check the matter from a factual accuracy point of view. The CRT was informed in cases where this occurred, and where it was considered that the feedback could be considered to reflect adversely on an individual, the feedback was excluded in SAI reports as fair procedures stipulate that individuals have a right to check for factual accuracy any information that reflects adversely on them, prior to its inclusion in a report. The CRT notes that there was no situation where not including feedback from a family prevented the investigators from achieving the purpose of a SAI namely, to identify whether there were any key causal factors in the case (i.e. issues that arose in the process of delivering and managing care that the investigators considered contributed to the eventual harm).

20.1.6 In other situations the CRT was informed by families that some of their feedback was not included in the SAI reports where their accounts were at odds with the SAI report. The CRT is of the opinion that to have a full assessment of the service in all situations, this should be clearly indicated with all available accounts included and noted.

20.1.7 The CRT suggested that the HSE might consider recording of family interviews in any future investigation so as to ensure that family experiences are accurately reflected in SAI reports. The CRT notes that the SAI Guidelines states the following in relation to recording interviews in section 7.2.4.13 "Recording of interviews by investigation teams":

(a) "It is recommended that interview notes are only recorded in writing

(b) Tape recording of interviews by the Investigation Team is not recommended for the following reasons:

(i) The risk of confidentiality breaches is increased due to the increased processing requirements of taped interviews;

(ii) The process to be implemented in relation to tape recording interviews will considerably add to the investigation timeline e.g. the requirement to fully transcribe the interview from the recording;

(iii) There is potential for considerable cost and resource implications in relation to transcribing tape recorded interviews;

(iv) There is no evidence that the quality of investigation reports where interviews were tape recorded is better than the quality of those investigation reports where interviews were documented in writing."

20.1.8 The CRT also notes that in its meetings with families, some indicated that where they were satisfied with how their experience was reflected in the SAI reports, their satisfaction was not recorded.

20.1.9 **Recommendation**

The CRT recommends that, as a matter of urgency, the HSE commences collecting information about families' satisfaction in relation to how their experience of adverse events is reflected in investigation reports with a view to determining the factors that influence family satisfaction in this regard. This should in turn improve how family experiences are reflected in investigation reports, and the families satisfaction with this process. Since the family's version of events plays a considerable role in seeing the full picture, it is therefore important that this is captured as accurately as possible.

20.2 **Families Receiving Draft Chronologies With Elements Redacted**

20.2.1 The CRT noted that one family conveyed their frustration at receiving a draft chronology for factual accuracy checking with sections redacted. The CRT acknowledges that this was a frustrating experience for the family in question.

20.2.2 It has been confirmed to the CRT that, according to HSE Investigation Guidelines, families and staff should not receive draft reports with redactions for factual accuracy checking, and that no other family that had an individual SAI which fell under this review, received a draft chronology with sections redacted.

20.2.3 **Recommendation**

The CRT recommends that, as a matter of urgency, the HSE commences auditing compliance with the SAI Guidelines as they relate to the circulation of draft chronologies to patients/families for factual accuracy checking, specifically checking that they do not have sections redacted when circulated to patients/families for factual accuracy checking.

20.3 **Communication with families in aftermath of incidents/their expression of concerns**

20.3.1 Some families advised the CRT that they were informed in the aftermath of the adverse events/expressions of their concerns:

(a) That their case was very unusual and that they learned subsequently that this was not the case.

(b) Other families advised, that they only received information a significant time after the baby's birth (weeks, months or years later), regarding events during delivery, such as shoulder dystocia.

20.3.2 The CRT acknowledges that it is frustrating for families to feel that they are not getting important information about their cases in an open, transparent and timely manner. The CRT also acknowledges that healthcare professionals may not always have access to accurate and/or complete information to answer family queries and concerns at the time they are raised and that giving information prematurely, while often done with good intentions, can result in apparently conflicting information being given to families. The challenge for healthcare professionals is to be facilitated and supported to convey what information is available to answer family queries and concerns at any given time and to ensure that they provide accurate and complete information to families in as timely a manner as is possible.

20.3.3 **Recommendation**

The CRT recommends that, as a matter of urgency, monitoring of compliance with the HSE Open Disclosure Guidelines to ensure that families get accurate and complete information in relation to their adverse event. This information should be communicated in as timely a manner as is possible after such information becomes available to healthcare workers. The CRT recommends that an identified contact person be appointed in order to ensure that families receive accurate and timely information recognising that some information is qualified until such time as all the relevant information is available.

20.4 **Incomplete Healthcare Records Issued To Families**

20.4.1 Some families advised the CRT that they received initial copies of their healthcare records and that they then subsequently received a more complete set of healthcare records.

20.4.2 The CRT acknowledges that this could be related to filing or other issues related to the administration of information requests, never-the-less, the CRT also acknowledges that this is frustrating for families and could create an impression of lack of transparency and, even, the deliberate withholding of information.

20.4.3 **Recommendation**

The CRT recommends that, as a matter of urgency, an audit of compliance with the relevant legislation and guidelines is conducted related to the release of Healthcare Records to families.

20.5 **Lack of Thorough Investigation of Serious Incidents**

20.5.1 Some families expressed concerns to the CRT related to the fact that it appeared that a large number of incidents had to occur before a thorough investigation was conducted.

20.5.2 The CRT has outlined in other sections of the Report that the SAOLTA group had undertaken an Preliminary Review when the rate of referral of babies for TH in 2014 appeared to have increased, and that they commissioned this external independent review when the Preliminary Review identified concerns. The CRT has also outlined that PUH and the SAOLTA group needs to comply with HSE policy in relation to conducting thorough investigations of serious incidents as they arise.

20.5.3 The CRT also acknowledges that Health Systems in industrially developing countries all over the globe struggle to conduct thorough investigations of serious incidents.

20.5.4 The Parliamentary and Health Service Ombudsman in the UK (2015)[87] found that:

20.5.5 "We have found that NHS trusts are not always identifying patient safety incidents and are sometimes failing to recognise serious incidents....The process of investigation is not considered reliable or good enough... In 41% of cases inadequate explanations were given to complainants for what went wrong and why."

20.5.6 Similarly, the recent UK Quality Care Commission report entitled "Learning, candour and accountability: A review of the way NHS trusts review and investigate the deaths of patients in England" (2016[88]) identified the following:

20.5.7 "Over a four-year period, fewer than 1% of deaths in Southern Health's learning disability services and 0.3% of deaths in their mental health services for older people were investigated as a serious incident requiring investigation.... the quality of investigations is variable...."

20.5.8 The CRT further acknowledges that 18 thorough investigations of the cases that fell under this review have now been conducted, and that many of the themes related to Key Causal Factors/incidental findings identified in the recent cases, also appeared in the earlier cases. This indicates the existence of factors which may have been identified earlier and not repeated, had timely investigation occurred. The CRT emphasises the need for the SAOLTA group to build its capacity and capability to implement the HSE's policy in relation to thorough and timely investigations of serious incidents when they occur.

20.5.9 **Recommendation**

The CRT recommends that, as a matter of urgency, the SAOLTA Governance Committee arranges an audit of compliance with the HSE policy related to the investigation of Serious Incidents (HSE 2014[89]) and arranges expeditious implementation of the learning derived from this audit to achieve satisfactory compliance with this policy. This may require increased resource provision to support quality and safety.

[87] 'A Review into the quality of NHS complaints investigations where serious of avoidable harm has been alleged,' The Parliamentary and Health Service Ombudsman, 2015

[88] Learning, candour and accountability - A review of the way NHS trusts review and investigate the deaths of patients in England." CQC December 2016

[89] Safety Incident Management Policy, HSE May 2014

20.6 **Insensitive Communications With Bereaved Families**

20.6.1 Some families advised the CRT that they received calls from PUH seeking information about the welfare of the baby after the baby had sadly died and on one occasion, on the day of the baby's funeral.

20.6.2 The CRT acknowledges that this is deeply distressing for families. It also acknowledges that such calls were likely made by staff with good and well-meaning intentions.

20.6.3 **Recommendation**

The CRT recommends that, as a matter of urgency, development, implementation and audit of compliance with processes to ensure appropriate communications throughout the healthcare system in relation to complicated pregnancies so as to ensure sensitive communications with families in the aftermath of these tragic experiences.

20.7 **Families Have Requested Information About When Therapeutic Hypothermia ("TH") Was Rolled Out Nationally**

20.8 The CRT has provided this information within this review[90]. It is acknowledged that there was some confusion about referring babies for TH, especially in 2010 and this added to the distress that families felt at the time and subsequently in the following years.

20.8.1 **Recommendation**

The CRT recommends that, as a matter of urgency, systems are developed to roll out new therapeutic techniques as quickly as possible throughout Ireland with the appropriate, infrastructure, guideline development and training. This should be conducted through established networks of care in a hub and spoke model.

21. COMPARISON BETWEEN THE FINDINGS OF THE PRELIMINARY REVIEW, THE SAI AND THE CRT REVIEWS

21.1 The Preliminary Review of cases 1 - 6 was a desktop exercise that considered the documentation related to each case only. It did not involve interviews with families or staff that had observed the events pertinent to each case. The Preliminary Review identified issues in relation to each of the six cases. However, it did not classify whether these issues could be considered to be Key Causal Factors (i.e. issues that arose in the process of delivering and managing health services that the investigators/reviewers considered had an effect on the eventual harm in each case) and/or incidental findings (issues that arose in the process of delivering and management of health services which the investigators/reviewers considered did not impact on the outcomes but which serve to identify issues for system improvement).

21.2 The SAIs took a more formal approach, interviewing the families and staff involved and assessing whether the issues found in the care were causative and pertinent to the outcome.

21.3 The CRT review took both into account by assessing the case records, CTGs and also using the SAIs to obtain a richer knowledge of the cases, the staff involvement and the families' experiences.

[90] See Appendix 5

21.4 In general, the findings of the Preliminary Review, SAIs and the CRT analysis were broadly concordant with some notable differences as outlined within this Report. These differences are to be expected when comparing the findings of a documentation review on the one hand, with the findings of a detailed systems analysis investigation where the documentation is considered along with information gathered at interview and this in turn is analysed using standard methodology and definitions to identify Key Causal Factors, Contributory Factors and Recommendations.

21.5 In general, The Preliminary Review did not find any clinical problems that the SAIs did not identify but the SAIs and the CRT noted a wider range of concerns often related to the families anxieties about the management of the clinical care, the review and investigation processes. By comparing the clinical practices with the standards expected, it was possible to have a more robust critique of the care provided. It also allowed a better assessment of the needs required to improve management in the future and to try and prevent recurrences of such incidents.

21.6 Also, the SAIs took a deeper look at the factors associated with the outcomes rather than the more superficial assessments a desk top review can make. Further, it was apparent that the voice of the parents was more evident in some SAI reports than in others. This may have been due to the experience of or the time available to the investigators. Investigators need to be given adequate time to investigate cases of adverse events. The CRT concludes that closer involvement of clinicians in the SAIs would have made the reports more robust and relevant. The purpose of these reviews is not only to find out if something went wrong, but also to give answers to the families, learn from mistakes made and prevent them being repeated.

22. CONCLUSION

This Report was commissioned following the reporting of 6 babies referred for Therapeutic Hypothermia from PUH in 2014. This was then added to, with the addition of 12 further cases with varied outcomes ranging over a longer period between 2008 and 2014. This changed the structure of the review by widening the remit and adding 12 individual SAI reports to the overall review process. This meant that the process became far more complex and protracted. However, the additional 12 cases offered the CRT a wider review of the care provided over a longer period of time and for that reason, the CRT welcomed the opportunity to review these cases.

The prolongation of the process has meant that the families, particularly those related to the 12 additional cases, have had to endure further delays for the answers they have sought. Many of the staff have been interviewed several times and found the process very stressful at a time when they were continuing to provide a high level of care to women in PUH.

The CRT found that the care provided in PUH was of a high standard for the majority of women who had normal labours. However, the staffing levels were insufficient, making it difficult to provide care to women when things went wrong. There was a lack of senior midwifery support in the labour ward and a lack of a consultant presence. The CRT observed insufficient multidisciplinary training and team-working as well as poor communication between midwives and obstetricians and paediatricians. Timely comprehensive reviews of incidents were not carried out, resulting in missed opportunities to learn from them and to help prevent future occurrences. In the 12 additional cases, there was a failure to provide appropriate support and follow-up to the families after the incidents.

The reconfiguration of the hospitals that formed the SAOLTA group added to the problems by creating an unsettled atmosphere within PUH, resulting in a failure to manage change and a blurring of roles and responsibilities which is common in such reconfigurations.

These findings possibly suggest a general problem for many hospitals in Ireland where staffing, incident reporting and training may be insufficient. Also the move towards hub and spoke networks may lead to long term improvements but, as seen in SAOLTA, they may aggravate

problems in the short term. This emphasises the need for change management to be designed into any plans for reconfiguration.

There also needs to be a robust monitoring of the service user experience during the transitional period and their voices included in the reconfiguration of services at all levels. Monitoring of both the staff and service user experience can highlight problems before they become serious adverse events.

In general, the CRT found that staff welcomed the findings of this Report and there was a willingness to learn and move on from the incidents which prompted this Report. The CRT feels that the fundamental structures are in place and with the appropriate support, both monetarily and structurally, the staff at PUH can provide care at the highest level.

We would like to take this opportunity, again, to express our sympathies to everyone affected by the events which gave rise to this Report. We understand that this process has been extremely difficult for all concerned and we recognise the impact that these events have had on individuals and the community. It is important to understand that this is a learning process, not a blame exercise. The aim is to help the hospital and the community to come through this, understand what occurred and help the hospital become the best it can be.

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APPENDIX 1: GLOSSARY OF TERMS AND ABBREVIATIONS

Term	Definition
Active Whole Body Therapeutic Hypothermia (TH)	Whole body TH (cooling) is typically implemented via a cooling blanket placed under the baby that circulates cold effluent to achieve homogenous cooling of the entire body. Target rectal temperature during whole body hypothermia is 33.5 °C. The cooling device has automatic control modes where the device monitors the baby's temperature with an attached temperature probe placed in the rectum and maintains the desired target temperature, programmed by the user, by changing the temperature of circulating effluent. Security features, such as alarms and screen prompts notify users of unexpected changes in temperature. The desired temperature is maintained for 72hrs and then the patient is rewarmed at 0.5°C every 2 hours over the next 14hrs.
Adverse Event	An incident which resulted in harm.
AHD	Acute Hospital Division.
Antenatal	The period before birth, during or relating to pregnancy.
APGAR score	An objective score of the condition of a baby after birth. This score is determined by scoring the heart rate, respiratory effort, muscle tone, skin colour, and response to stimulation.
Birthrate Plus® (BR+)	Birthrate Plus is based upon the standard on one to one care from a midwife for a woman during labour and delivery, together with the care of the newborn infant(s). A classification system was developed which uses clinical indicators to place mother and baby in one of five outcome categories changing the acuity and therefore the numbers of midwives required.
BW	Birth Weight
CIP	Cost Improvement Program
Clinicians	Qualified clinicians including doctors, midwives and nurses.
CME	Continuing Medical Education
CMMI/II/III	Clinical Midwife Manager (Grades I, II and III)
Contributory Factor	A circumstance, action or influence which is through to have played a part in the origin or development of an incident or to have increased the risk of an incident.
CRT	Clinical Review Team.
CS	Caesarean Section
CTG	Cardiotocography is a technical means of recording the fetal heartbeat and the uterine contractions during pregnancy.
Delayed Cord Clamping	Delayed cord clamping is when the cord is not clamped for at least 1 minute after birth and before 5 minutes unless there is a reason to do otherwise. This is done to increase the amount of blood the baby gets at birth.
DIC	Disseminated Intravascular Coagulation is a serious disorder in which the proteins that control blood clotting become consumed resulting in too few clotting factors, these leads to an increased risk of bleeding.
Doppler	An ultrasound test that uses high frequency sound waves to measure the

	amount of blood flow through arteries and veins
EBM	Expressed Breast Milk
FBS	Fetal Scalp Blood Sampling is when a sample of blood (FBS) is taken from the baby's scalp with an electrode during labour it is to assess the level of acidosis within the baby's blood. The procedure is usually triggered by an abnormal CTG pattern.
Gestational Diabetes	Gestational diabetes is diabetes that is first recognised in women during pregnancy because the mother's body is not able to produce enough insulin due to placental hormone production antagonising the action of insulin.
GUH	Galway University Hospital
HCR	Health Care Records
HIE	Hypoxic Ischemic Encephalopathy has many causes and is essentially the reduction in the supply of blood or oxygen to a baby's brain before, during, or even after birth.
ICU	Intensive Care Unit.
IMEWS	The Irish Maternity Early Warning System (IMEWS) is a nationally agreed system developed for early detection of life threatening illness in pregnancy and the postnatal period.
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include **adverse events** which result in harm; and **near-misses** which could have resulted in harm, but did not cause harm, either by chance or timely intervention.
Intrapartum	The period during labour and birth
IOL	Induction of Labour is a method of artificially or prematurely stimulating childbirth in a woman.
ISBAR	ISBAR stands for **I**dentify, **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation. It is a mnemonic created to improve safety in the transfer of critical information.
K2 Fetal Monitoring Training System	K2 Fetal Monitoring Training System is an interactive computer based training system covering a comprehensive spectrum of learning that can be accessed over the internet.
Key Causal Factor (KCF)	Issues which arose in the process of delivering and managing health services which the investigators considered contributed to the eventual adverse outcome.
Level II Unit	This is a categorization of a neonatal unit that provides high dependency and short-term ventilation care services. They would normally transfer out very premature babies and those requiring specialist care to a Level III Unit.
Maternity Dashboard	The Maternity Dashboard is a tool that can be employed to monitor the implementation of principles of clinical governance 'on the ground'. It can be used to benchmark activity and monitor performance against the standards agreed locally for the maternity unit on a monthly basis
MDT	Multi-Disciplinary Team
Meconium	Meconium is the greenish-black sticky material passed from the baby's bowels

	before, during or after birth. In some instances, the foetus will pass meconium into the amniotic fluid while still in the womb, indicated by the presence of meconium staining of the liquor after the membranes have ruptured. Meconium staining is more common approaching and after term. It may indicate the presence of fetal distress in labour, but not universally so.
Model 3 Hospital	Hospitals which provide 24/7 acute surgery, acute medicine, and critical care.
Multigravida	A woman who is pregnant, in her second or subsequent pregnancy.
NAEMS	National Adverse Events Recording System (NAEMS) (previously known as STARSWeb) is the national system to electronically record all reported incidents
NCHD Non-Consultant Hospital Doctor	An NCHD is a Non-Consultant Hospital Doctor appointed directly by the hospital and may be part of a training programme. They can act at SHO (first tier) or Registrar (second tier) level depending on their experience. Where they are not in a national training position, they do not have the same protected time for training which a training SHO or registrar is allowed. A training grade doctor is part of a recognised training programme, overseen by a training college which allows the trainee to develop their training and progress through the different grades and is expected to become a consultant in due course. Although it is possible by experience and assessment of equivalence of training for a NCHD to become a consultant, this is not the norm.
Neonatologist	A doctor specialising in the care of the newborn
Neonate	A new-born infant, or neonate, is a child under 28 days of age
NIMLT	National Incident Management and Learning Team.
NRP	Neonatal Resuscitation Program
NPEC	National Perinatal Epidemiology Centre
Obstetrician	A doctor who specialises in the care of pregnant woman and their births.
Preliminary Review	A desktop review conducted by the SAOLTA group delivered on 21st December 2014 and completed in January 2015, relating to six cases at PUH where the babies were referred for therapeutic hypothermia during 2014.
Open Disclosure	An open, consistent approach to communicating with patients when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and steps taken to prevent a recurrence of the adverse event.
Oxytocin	Oxytocin is a medication administered to induce or augment labour, usually in conjunction with amniotomy (surgical rupture of the fetal membrane to induce labour).
PAR	Preliminary Assessment Review
Passive Therapeutic Hypothermia (TH)	Passive TH allows for the early initiation of TH at the referral site prior to transfer to the TH centre. Passive TH was found to be a simple and efficient way to initiate TH as long as appropriate temperature monitoring was used concurrently. Passive cooling is often initiated by turning off overhead heating devices and removing hats, clothing, and blankets. Serial monitoring of rectal temperatures every 15 minutes during passive cooling should be done to prevent the temperature from getting too low.

Perinatal	The World Health Organisation defines the perinatal period as commencing at 22 completed weeks (154 days) of gestation and ending seven completed days after birth.
PUH	Portiuncula Hospital Ballinasloe.
PM	Post-Mortem is a medical examination of a dead body to determine the exact cause of death.
PMA	Post Menstrual Age
Pneumothorax	The presence of air or gas in the cavity between the lungs and the chest wall, causing collapse of the lung
Postnatal	The period after birth
PPPG's	Policies, procedures, protocols and guidelines
PROMPT	(Practical Obstetric Multi-Professional Training) is an evidence based multi-professional training package for obstetric emergencies.
Primigravida	A woman in her first pregnancy
Q-Pulse	Incident Management System (IMS)
QIP	Quality Improvement Program
RCOG	Royal College of Obstetricians and Gynaecologists
RCPI	Royal College of Physicians of Ireland
RCSI	Royal College of Surgeons in Ireland
Registrar	A registrar is a doctor working on the second tier in the hospital. There will be an SHO below them (first tier doctor). The registrar is the first decision maker who is allowed to make decisions and carry out procedures depending on their ability and experience. There are usual local rules, as well as national guidance, on when they should contact the consultant for help and guidance. The consultant is a fully trained doctor who is the most senior and has ultimate responsibility for patient care. A registrar could be a SpR (specialist training registrar) if appointed nationally or a NCHD if appointed locally.
SAOLTA	Saolta University Healthcare Group
SCBU	Special Care Baby Unit. The role of SCBU is caring for all infants delivered who are sick or who have more than routine care requirements.
Serious Incident	An incident that resulted in death or serious harm.
STARSweb	National Clinical Incident Reporting System, superceded by NAEMS in 2014
STAT	Medication given immediately as a single dose
SHO	Senior House Officer A Senior House Officer is a non-consultant hospital doctor in the Republic of Ireland. SHO's are supervised in their work by consultants and registrars. In training posts, these registrars and consultants oversee training and are usually their designated clinical supervisors
SIMM	Severe Maternal Morbidity

SIMT	Serious Incident Management Team. A SAOLTA group-wide incident review and management team and was established in March 2014
SpR	Specialist Registrar An SpR is a non-consultant hospital doctor in the Republic of Ireland. SpRs are training posts and are supervised in their work by consultants. As they are training posts, consultants oversee training and are usually their designated clinical supervisors
Stillbirth	The definition of stillbirth recommended by the WHO for international comparison is a baby born with no signs of life at or after 28 weeks' gestation.
Systems Analysis Investigation (SAI)	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.
TH	Therapeutic Hypothermia (Appendix 4)
Therapeutic Hypothermia	Therapeutic Hypothermia, induced by cooling a baby to around 33 °C for three days after birth, is a treatment for Hypoxic Ischemic Encephalopathy (See HIE below). It has recently been proven to be the only medical intervention which reduces brain damage, and improves an infant's chance of survival and reduced disability.
TNA	Training Needs Analysis
Urodynamics	Urodynamics is a study that assesses how the bladder and urethra are performing their job of storing and releasing urine. Urodynamic tests can help explain symptoms such as: incontinence and recurrent urinary tract infections
VBAC	Vaginal Birth After Caesarean

APPENDIX 2: TERMS OF REFERENCE

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

Terms of Reference[91]:

Introduction

A Preliminary Review[92] into the care of 7 women who had adverse perinatal events between February and November 2014 at Portiuncula Hospital, Ballinasloe was undertaken in December 2014 by Dr. Geraldine Gaffney, Professor Declan Devane and Ms Dawn Johnston. The results of this preliminary Review were reported on the 19th Jan 2015.

Scope of the Review

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

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

Review Team

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

Review Commissioner

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

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

Purpose of the Review

The purpose of the Review is to:

Part 1: Review of maternity services at Portiuncula Hospital

[91] Date of Terms of Reference for this review: 20th February 2015, as amended May 2015
[92] These refer to the Preliminary Review set out in the review

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

Part 2: Review of individual cases

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

(Should any immediate safety concerns arise during the course of the Review the Chair of the Review Team will convey the details of these safety concerns to the Commissioner as soon as possible)

Membership of the Review Team

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

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

Professor Sean Daly: Consultant Obstetrician/Gynaecologist Coombe Hospital, Dublin

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

Dr Adrienne Foran**:** Consultant Neonatologist, Rotunda Hospital

Dr Paul Hughes: Obstetrician & Gynaecologist, University Hospital Kerry

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

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

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

Support for the Review Team

The Review Team will;

- Be afforded the assistance of all relevant staff and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Review methodology

The Review will follow the HSE Investigation policy and will be cognisant of the rights of all involved to privacy and confidentiality; dignity and respect; due process; and natural and constitutional justice.

The Review will commence immediately and will be concluded in the shortest timeframe necessary to achieve the purpose of the Review. It is anticipated that a maximum of 5 month will be required.

Following completion of the Review, an anonymised draft report will be prepared by the Review Team outlining the findings and recommendations. All who participated in the investigation will have an opportunity to give input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

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

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

Communications

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

Dr. Pat Nash

Chief Clinical Director, SAOLTA University Health Care Group

Appendix 3: Framework of Contributory Factors

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

Individual affected/harmed

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

Task and Technology Factors

- Task design and clarity of structure
- Availability and use of protocols, policies, standards
- Policies etc. relevant, unambiguous, correct and realistic
- Availability and accuracy of test results
- Decision-making aids

Individual (Staff) Factors

- Knowledge and skills
- Competence – education, training, supervision
- Physical, psychological and mental health illness

Team Factors

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

Work Environmental Factors

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

Organisational & Management Factors

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

Institutional Context Factors

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

Appendix 4: THERAPEUTIC HYPOTHERMIA (COOLING)

What is Cooling?

Therapeutic Hypothermia (TH) has been shown to improve neurologic outcomes in new-borns with moderate or severe hypoxic-ischemic encephalopathy (HIE). TH aims to lower the temperature of the vulnerable deep brain structures. Two methods are available in new-born infants with HIE: whole body cooling and selective head cooling with mild systemic hypothermia. In Ireland the standard approach is whole body cooling. This therapy, which involves lowering the body temperature to 33.5 degrees Celsius for 72 hours, is now the standard therapy for babies who have sustained a hypoxic ischaemic injury and who display signs consistent with moderate or severe encephalopathy. A number of trials were conducted in the late 1990's and early 2000s showing a direct benefit from TH. The most relevant European study was the TOBY trial[93], performed predominantly in the UK and included one Irish recruiting centre. The most recent meta-analysis of randomised controlled trials of TH shows that the therapy is beneficial. This is evidenced by the low number needed to treat (NNT) of 6. The NNT is the average number of patients who need to be treated to prevent one additional poor outcome.

How does it work?

Neuronal death occurs in two phases following a reversible hypoxic ischaemic insult. There may be immediate "primary neuronal death" related to cellular hypoxia with exhaustion of the cells high-energy stores (primary energy failure). After a latent period of at least six hours, the secondary phase of "delayed neuronal death" begins. The mechanisms involved in delayed neuronal death include increased blood flow, cytotoxic oedema, mitochondrial failure, accumulation of excitotoxins, active cell death. This is the biphasic injury described. Hypothermia for 72 hours ideally initiated within 6 hours from delivery is thought to minimise brain injury during this secondary phase.

Criteria to Warrant consideration for TH:

The general criteria considered for neonatal hypoxic ischaemic encephalopathy are outlined below. These are derived from a number of the clinical trials that have taken place to date. The criteria are characterised by their consistency in:

(i) gestational age and birth weight criteria;

(ii) evidence of fetal distress and;

(iii) clinical evaluation in the newborn period.

Inclusion Criteria: all three of the following

1. Post Menstrual Age (PMA) ≥ 36 weeks and Birth Weight (BW) ≥ 1.8 Kgs

2. Evidence of fetal distress or neonatal distress as evidenced by one of the following:

   - History of acute perinatal event (e.g. placental abruption, cord prolapse, severe fetal heart rate abnormality)
   - pH ≤ 7.0 or base deficit ≥ 16 mmol/L in cord gas or postnatal blood gas obtained within 1st hour of life

[93] TOBY Trial: Azzopardi DV, Strohm B, Edwards AD, Dyet L, Halliday HL, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thoresen M, Whitelaw A, Brocklehurst P; TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. N Engl J Med. 2009 Oct 1;361(14):1349-58. doi: 10.1056/NEJMoa0900854

- 10-minute Apgar score of ≤ 5
- Assisted ventilation initiated at birth and continued for at least 10 minutes

3. Evidence of moderate to severe neonatal encephalopathy by exam and/or aEEG, as follows:

    - Primary method for determining neonatal encephalopathy is physical exam.
    - If exam shows moderate or severe encephalopathy, amplitude integrated EEG/Cerebral Function Monitor (aEEG/CFM) should be performed to provide further assessment and monitoring.
    - In circumstances in which physical exam is unreliable (e.g. muscle relaxants), an aEEG/CFM should be performed to determine if there is encephalopathy.
    - Patterns on aEEG/CFM that indicate moderate or severe encephalopathy include the following, with a minimum of 20 minutes recording time:
        - Severely abnormal: upper margin < 10 µV
        - Moderately abnormal: upper margin >10 µV and lower margin < 5 µV
        - Seizures identified by aEEG

Exclusion Criteria: Any of The Following

- Presence of lethal chromosomal abnormality (e.g., Trisomy 13 or 18)
- Presence of sever congenital anomalies (e.g., complex cyanotic congenital heart disease, major CNS anomaly)
- Symptomatic systemic congenital viral infection (e.g., hepatosplenomegaly, microcephaly)
- Symptomatic systemic congenital bacterial infection (e.g., meningitis, DIC)
- Significant bleeding diathesis
- Major intracranial haemorrhage

Special Circumstances

TH has continued to evolve over the last number of years. Current clinical standards for TH as described above are based on RCTs that used strict study entry criteria. Most centres offering TH for neonates with HIE adhere to treatment protocols based on similar criteria developed from these published trials. However as evidence and understanding continues to evolve, TH may be considered in additional situations also.

Evaluation for TH for the following circumstances:

- Gestational age 35 to 36 weeks: based on degree of prematurity, birth weight, coagulation risk and other risk factors.
- Age > 6 hours: consider cooling up to 9 and even 12 hours of age, although goal remains to cool as soon as possible.
- Post-natal collapse resulting in hypoxic-ischemic injury (i.e. near-SIDS type event).
- Missing data, e.g. Apgar scores from home birth - still consider hypothermia if other conditions present.
- There is little evidence presently to support TH in situations of mild neonatal HIE.

CANDIDACY CHECKLIST FOR NEONATAL THERAPEUTIC HYPOTHERMIA (COOLING)

PATIENT'S NAME: _____ **HOSP. NO:** _____

TIME of BIRTH: _____:_____ hrs. **CURRENT AGE in hours /minutes:** _____ hrs._____ mins.

If current age is greater than 6 hours, call tertiary cooling centre before proceeding.

Directions for the use of this checklist: Start at the top and work through each numbered component. When directed to proceed to the exam, refer to the exam found on page 2. If there is missing data, (such as a known perinatal event and / or Apgar scores) and you are in doubt as to whether or not the patient qualifies for cooling, consult with the tertiary cooling centre promptly to discuss the patient.

**Note: If patient is < 6 hours old and meets the gestation, weight and blood gas criteria and has a witnessed seizure, patient is eligible for 'COOLING' regardless of additional exam findings. Consult the tertiary cooling centre to discuss any questions or concerns.*

Clinical Information	Criteria *(place a tick in the box that corresponds to the patient information)*	Instructions
Gestation	1 ≥ 36 weeks gestation ☐	Go to → 2 **Weight**
	= 35 weeks gestation ☐	May not be eligible *Contact cooling centre*
	< 35wks gestation ☐	Not Eligible
Weight	2 ≥ 1800 grams ☐	Go to → 3 **Blood Gas**
	< 1800 grams ☐	Not Eligible
Blood Gas pH = _____ Base Excess = _____ Source: Cord ☐ *Or* 1st infant blood gas at <1hour of life ☐ Arterial ☐ Capillary ☐ Venous Time Obtained: _____:_____	3 pH < 7.0 *or* Base excess ≥ -16 ☐	Criteria met thus far. Go to **EXAM***
	No gas obtained ☐ *or* pH 7.0 to 7.15 ☐ *or* Base excess -10 to -15.9 ☐	Go to → 4 **History of acute perinatal event**
	pH >7.15 or Base Excess < 10 ☐	May not be eligible; Go to → 4 **History of acute perinatal event**
Acute Perinatal Event *(tick all that apply)*	4 Variable / late foetal HR decelerations ☐ Prolapsed / ruptured / tight nuchal cord ☐ Uterine Rupture ☐ Maternal haemorrhage / placental abruption ☐ Maternal trauma (eg. vehicle accident) ☐ Mother received CPR ☐	Any ticked, Go to → 5 **Apgar score**
	No perinatal event *or* Indeterminate what the event was because of home birth or missing information	May not be eligible; Go to → 5 **Apgar score**
Apgar Score at 1 minute _____ 5 minute _____ 10 minute _____	5 Apgar ≤ 5 at 10 minutes (yes) ☐	Criteria met thus far. Go to **EXAM***
	Apgar ≤ 5 at 10 minutes (no) ☐ *(no, was 6 or greater at 10 minutes)*	Go to → 6 **Resuscitation after delivery**
Resuscitation after Delivery *(tick all that apply)* _____ PPV/intubated at 10 minutes _____ CPR _____ Adrenaline administered	6 Continued need for PPV or Intubated at 10 minutes?(yes) ☐	Criteria met thus far. Go to **EXAM***
	PPV/Intubated at 10 minutes?(no) ☐	May not be eligible Go to **EXAM***

This checklist, adapted from the 'STABLE Program', 6th edition, 2013, has been produced by the National Neonatal Transport Programme (NNTP) and endorsed by the Faculty of Paediatrics, Royal College of Physicians, Ireland, in March 2014.

Circle findings for each domain

PATIENT IS ELIGIBLE FOR COOLING WHEN 3 OR MORE DOMAINS HAVE FINDINGS IN COLUMNS 2 OR 3

Domain	1	2	3
Seizures	**None**	**Seizures common:** (focal or multifocal seizures) (Multifocal: clinical activity involving > one site which is asynchronous and usually migratory) Note: If the patient is < 6 hours old and meets the gestation, weight and blood gas criteria and has a witnessed seizure, patient is eligible for cooling regardless of the rest of this exam	**Seizures uncommon:** (excluding decerebration) ***Or*** Frequent seizures
Level of Consciousness	**Normal** **or** **Hyperalert**	***Lethargic*** Decreased activity in an infant who is aroused and responsive **Definition of Lethargic:** • Sleeps excessively with occasional spontaneous eye opening • Responses are delayed but complete • Threshold for eliciting such responses increased • Can be irritable when disturbed	**Stuporous / Comatose** Demonstrates no spontaneous eye opening and is difficult to arouse with external stimuli **Definition of Stuporous:** • Aroused only with vigorous and continuous stimulation **Definition of Comatose:** • No eye opening or response to vigorous stimulation In both stupor and / or coma, the infant may respond to stimulation by grimacing / stereotyped withdrawal / decerebrate posture
Spontaneous activity when awake or aroused	**Active** **Vigorous, doesn't stay in one position**	**Less than active, not vigorous**	**No activity whatsoever**
Posture	**Moving around and does not maintain only one position**	**Distal flexion, complete extension or "frog-legged" position** Term infants with HIE often exhibit • Weakness in hip-shoulder distribution (eg proximal part of extremities) • Distal joints, fingers and toes often exhibit strong flexion • Thumbs strongly flexed and adducted. • Wrists often flexed • Above postures are enhanced by any stimulation	**Decerebrate with or without stimulation (all extremities extended)**
Tone	**Normal** • Resists passive motion **Hypertonic, jittery** • Lowered threshold to all types of minimal stimuli eg light touch, sudden noises • Infant may even respond to his/her own sudden movements	**Hypotonic or floppy,** • Axial hypotonia (ie. head lag) and/or limb hypotonia	**Completely flaccid like a rag doll**
Primitive reflexes	***Suck:*** Vigorously sucks finger or ETT ***Moro:*** Normal: Limb extension followed by flexion with stimulus	***Suck:*** Weak ***Moro:*** Incomplete	***Suck:*** Completely absent ***Moro:*** Completely absent
Autonomic system	***General Activation of Sympathetic nervous system*** ***Pupils:*** • Normal size (-1/3 of iris diameter) • Reactive to Light ***Heart Rate:*** • Normal, > 100bpm ***Respirations:*** • Regular spontaneous breathing	***General Activation of Parasympathetic nervous system*** ***Pupils:*** • Constricted (< 3mm estimated) • but reactive to light ***Heart Rate:*** • Bradycardia (< 100bpm, variable up to 120) ***Respirations:*** • Periodic, irregular breathing effort • Often have more copious secretions and require frequent suctioning	***Pupils:*** • Skew gaze, fixed, dilated, • not reactive to light ***Heart Rate:*** • Variable, inconsistent heart rate, irregular, may be bradycardic ***Respirations:*** • Completely apnoeic, requiring PPV & / or ET intubation and ventilation

Neurological Exam to evaluate candidacy for cooling: If in doubt as to whether patient qualifies for cooling, consult with the cooling centre promptly to discuss the patient.

Appendix 5: Therapeutic Hypothermia in Ireland

Therapeutic Hypothermia is performed in four centres nationally, one centre in Cork and three centres in Dublin. TH was commenced in Cork University Maternity hospital in 2008 for babies who sustained a hypoxic ischaemic insult and 7 babies received TH that year (2008). This therapy was subsequently commenced in the three tertiary neonatal centres in Dublin from 2009 onwards and was the standard of care for babies with moderate to severe HIE at these institutions from 2009 onwards.[94]

The criteria to determine encephalopathy have been highlighted in Appendix 4. It is important to note that the clinical criteria to determine encephalopathy have remained unchanged and is principally based on the classic Sarnat[95] staging. Sarnat staging is a classification scale for hypoxic- ischaemic encephalopathy of the newborn (HIE) which manifests as altered consciousness, altered muscle tone and seizures. HIE is graded based on the infant's clinical presentation, examination findings, including the presence or absence of seizures into mild, moderate or severe.

These four centres are tertiary neonatal intensive care centres staffed by fulltime neonatologists. TH should only be carried out in units experienced in the care of severely ill neonates, by staff that have been specifically trained in the use of TH. These centres have access to additional expertise including paediatric neurophysiology, neurology, neuroradiology and neurodevelopmental follow up, all important components of a centre capable of performing TH[96].

However for the therapy to gain maximum benefit it should be commenced as soon after birth (6 hour window) as possible where there is evidence suggestive of hypoxic ischaemic encephalopathy. Whilst cooling takes place in these four centres, passive cooling should take place at the transferring hospital. This consists of initiating a number of environmental measures to lower the baby's body temperature prior to transfer to the referring hospital. This includes turning off overhead heaters, managing on an open top bed and measuring the rectal temperature intermittently prior to transfer.

The time period 2009-2011 reflected a transition period where cooling was evolving nationally and it was not fully established nationally until 2012[97]. In Ireland the first study day was held in Rotunda in March 2009. The National Transport Study day on 18th June 2010 focused on Cooling on Transport. The evidence for TH as a standard of care was very convincing in 2010. As stated above the most convincing evidence at the time was published in a Cochrane review in October 2007[98], and a subsequent clinical trial published in October 2009 (TOBY Trial)[99]. The review showed a reduction in mortality and a reduction in brain injury as evidenced by improved outcome at 18 months of age. The TOBY trial published its results in October 2009 again supporting the therapy. This therapy was one of the main areas of new-born care, topical in the latter years of the decade.

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[94] In feedback the CRT's attention was drawn to the fact that the perspective of the general paediatrician was not represented on the CRT and that this was not taken on board in the CRT's conclusions around TH in Ireland in 2010. Whilst the paediatric specialists on the CRT are neonatologists, they considered carefully the perspective of the general paediatrician in undertaking this review in relation to TH.

[95] Sarnat HB, Sarnat MS. Neonatal encephalopathy following fetal distress. A clinical and electroencephalographic study. Arch Neurol 1976;33: 696-705.

[96] National Clinical Programme for Paediatrics and Neonatology, *Model of Care for Neonatal Services in Ireland*, November 2015

[97] In feedback, the CRT were requested to acknowledge the failings at a national level with regard to the delay in the national implementation of TH. The CRT acknowledges that it took 2 years from the implementation of TH in Dublin and Cork before National Guidance was published on transportation.

[98] Jacobs S, Hunt R, Tarnow-Mordi W, Inder T, Davis P. Cooling for newborns with hypoxic ischaemic encephalopathy. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD003311. Review. Update in: Cochrane Database Syst Rev. 2013;1:CD003311

[99] TOBY Trial: Azzopardi DV, Strohm B, Edwards AD, Dyet L, Halliday HL, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thoresen M, Whitelaw A, Brocklehurst P; TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. N Engl J Med. 2009 Oct 1;361(14):1349-58. doi: 10.1056/NEJMoa0900854

All the consultants in the centres caring for new-born infants in Ireland were aware of this possible therapy in a national survey conducted in 2010[100]. Some had established referral pathways in place. Transport for TH during this time period was conducted by either the national service or by a local transport service. Some centres in Ireland had transferred infants to tertiary sites for this therapy in 2009 and 2010. The national transport service transported three newborns in 2009 to these referral centres for TH. In February 2010, an infant was transferred from PUH by the local transport service for TH.

Centres incorporating structured teaching sessions for junior doctors such as journal clubs or grand rounds would have encountered TH as a treatment option from 2007 onwards. There were over 110 references to TH in PubMed[101] in 2008, and over 130 references to TH in new-born infants in 2009. The Cochrane review[102] cited the published clinical trials at that time and the other various reviews published during these years provided insight into the criteria for TH, all of which were consistent and are outlined in Appendix 4. The letter entitled "Neonatal therapeutic hypothermia: practice and opinions in the Republic of Ireland" published in December 2010, sets out the position in Ireland at that time.[103] Although each centre at the time this survey was performed was aware of TH, only 25% had a documented referral pathway in place.

Transport for Cooling

When transport for TH occurred from 2009 onwards, the initial approach to transfer consisted of a rapid transport to the tertiary site for commencement of cooling. In 2009 the national transport service transferred three newborns for TH. Transportation subsequently evolved to passive cooling on transport and more recently active cooling on transport from 2013 onwards. Today transportation of new-borns in Ireland consists of passive cooling at the referring site prior to the arrival of the transport team, then active cooling thereafter and on transport. The first national seminar on cooling and transportation took place on 18th June 2010. The National Neonatal Transport Programme (NNTP) 'Transport of Infants Referred for Cooling Treatment' Guideline, endorsed by the RCPI, was produced on 23rd September 2011. There was a roll-out of National Outreach Sessions on Therapeutic Hypothermia during Neonatal Transport from May 2012 onwards.

[100] Nicholas M Allen, Adrienne Foran and Donough J O'Donovan, Arch Dis Child Fetal Neonatal Ed2011 96: F233 originally published online December 1 2010.
[101] U.S National Library of Medicine, National Institutes of Health https://www.ncbi.nlm.nih.gov/pubmed/
[102] Jacobs S, Hunt R, Tarnow-Mordi W, Inder T, Davis P. Cooling for newborns with hypoxic ischaemic encephalopathy. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD003311. Review. Update in: Cochrane Database Syst Rev. 2013;1:CD003311
[103] Nicholas M Allen, Adrienne Foran and Donough J O'Donovan, Arch Dis Child Fetal Neonatal Ed2011 96: F233 originally published online December 1 2010.

LETTERS

Neonatal therapeutic hypothermia: practice and opinions in the Republic of Ireland

Therapeutic hypothermia (TH) improves mortality and neurological outcome for neonates affected by hypoxic-ischaemic encephalopathy.[1] In the Republic of Ireland there are 20 maternity units, with over 50% of units having an annual delivery rate of 2500 or less. Neonatal care is provided in all maternity units but only the eight largest units have a consultant neonatologist. Smaller neonatal units would rarely encounter suitable candidates for TH and presently there is no national strategy in place for the provision of TH. In addition, the neonatal transport service in the Republic of Ireland is lacking 24-h cover. Therefore, we carried out a survey to determine current practice regarding TH as well as opinion regarding development of a nationwide strategy.

In April 2010, a web-based questionnaire (using http://surveymonkey.com) was sent to the clinical lead of each neonatal unit (n=20). An overall response rate of 100% was eventually achieved. Twelve units (60%) were classified as Level II and eight units (40%) classified as Level III according to current American Academy of Pediatrics definitions of care.

All consultants (100%) were aware of TH, felt it was effective and most understood appropriate indications. Six Level III units provided TH locally, five of which would consider becoming national referral centres. Fourteen units did not provide TH, of which only four had a clearly defined plan for transferring neonates to a TH centre. The 10 units without a current TH protocol would potentially consider offering TH by transferring to a TH centre or by local provision in future.

Regarding a nationwide strategy, all consultants felt there should be national referral centres for TH. Most felt there should be more than one centre, protected 'neurocots' and an out-of-hours transport team with expertise in 'cooling'. Ninety per cent felt there should be a consistent cooling protocol across units. Table 1 outlines the main findings of the survey.

This study clearly identified an awareness of TH and its benefits with the majority of large neonatal units in the Republic of Ireland now providing TH. However, smaller units do not and many lack protocols for transferring infants to cooling centres. It would be questionable whether the numbers of cooling centres that have already developed are justifiable when considering the birth population of the Republic of Ireland. Based on our survey the majority of clinicians desire a national approach to neonatal TH. In our opinion, without a cohesive national strategy it is likely that the optimum benefit of this treatment will not be achieved in our patient population and such a strategy should now be developed.

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Competing interests None.

Provenance and peer review Not commissioned; internally peer reviewed.

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1. **Edwards AD**, Brocklehurst P, Gunn AJ, *et al*. Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischaemic encephalopathy: synthesis and meta-analysis of trial data. *BMJ* 2010;**340**:c363.

Table 1 Knowledge, practice and opinions regarding neonatal therapeutic hypothermia in the Republic of Ireland

	Units	Level III	Level II
Overall response (%)	20 (100%)	8 (40%)	12 (60%)
Responders practicing role			
Neonatologist	8 (40%)	7 (35%)	1 (5%)
Paediatrician	11 (55%)	–	11
Both	1 (5%)	1	–
Delivery rates per annum			
1000–3000	13 (65%)	1	12
3000–5000	2 (10%)	2	–
5000–10 000	5 (25%)	5	–
Level of knowledge of TH (100% response)			
Aware of TH as therapy	20 (100%)	8	12
Felt it was effective	20 (100%)	8	12
Effect on mortality			
Effective enough to consider treatment	12 (60%)	5	7
Not effective	6 (30%)	3	3
More data needed	1 (5%)	–	1
Don't know	1 (5%)	–	1
Effect on neurological outcome			
Effective enough to consider treatment	17 (85%)	8	9
Very effective	1 (5%)	1	–
More data needed	2 (10%)	–	2
Experience and practice of Neonatal Unit			
Provide TH on-site	6 (30%)	6	–
Local access to relevant investigations			
aEEG	5/6	5	–
EEG	6/6	6	–
Cerebral ultrasound	6/6	6	–
MRI	6/6	6	–
MRS	3/6	3	–
Do not provide TH on-site	14 (70%)	2	12
Feel parents should know about potential benefit	14/14	2	12
Have definitive plan to transfer infants	4/14	1	3
Plan involves passive cooling	3/4	1	2
Do not have a definitive plan to transfer infants	10/14	1	9
Opinions relating to a national plan (100% response)			
TH can be realistically achieved for all eligible infants	15 (75%)	8	7
TH cannot be realistically achieved for all eligible infants	5 (25%)	–	5
Feel there should be referral hospitals for infants affected	20 (100%)	–	–
Support a central register for babies undergoing TH	20 (100%)	–	–

aEEG, amplitude-integrated EEG; HIE, hypoxic ischaemic encephalopathy; MRI/S, magnetic resonance imaging/spectroscopy; TH, therapeutic hypothermia.

Neonatal therapeutic hypothermia: practice and opinions in the Republic of Ireland

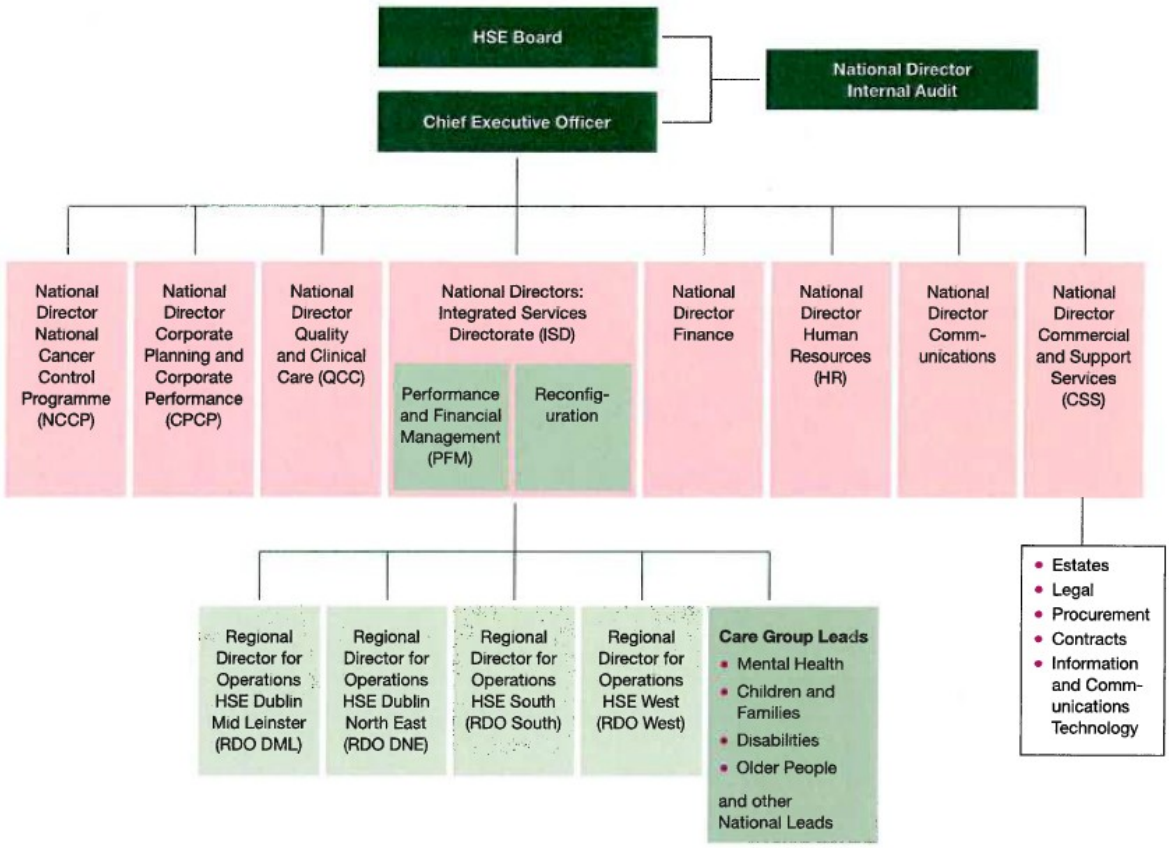
Nicholas M Allen, Adrienne Foran and Donough J O'Donovan

*Arch Dis Child Fetal Neonatal Ed*2011 96: F233 originally published online December 1, 2010
doi: 10.1136/adc.2010.195354

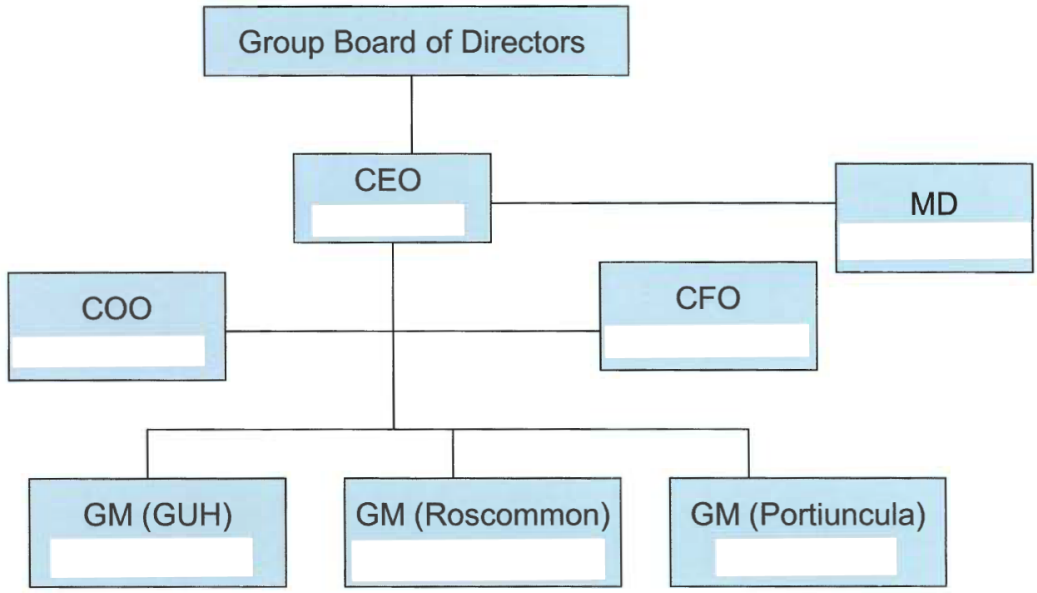
APPENDIX 6: ORGANISATIONAL STRUCTURES

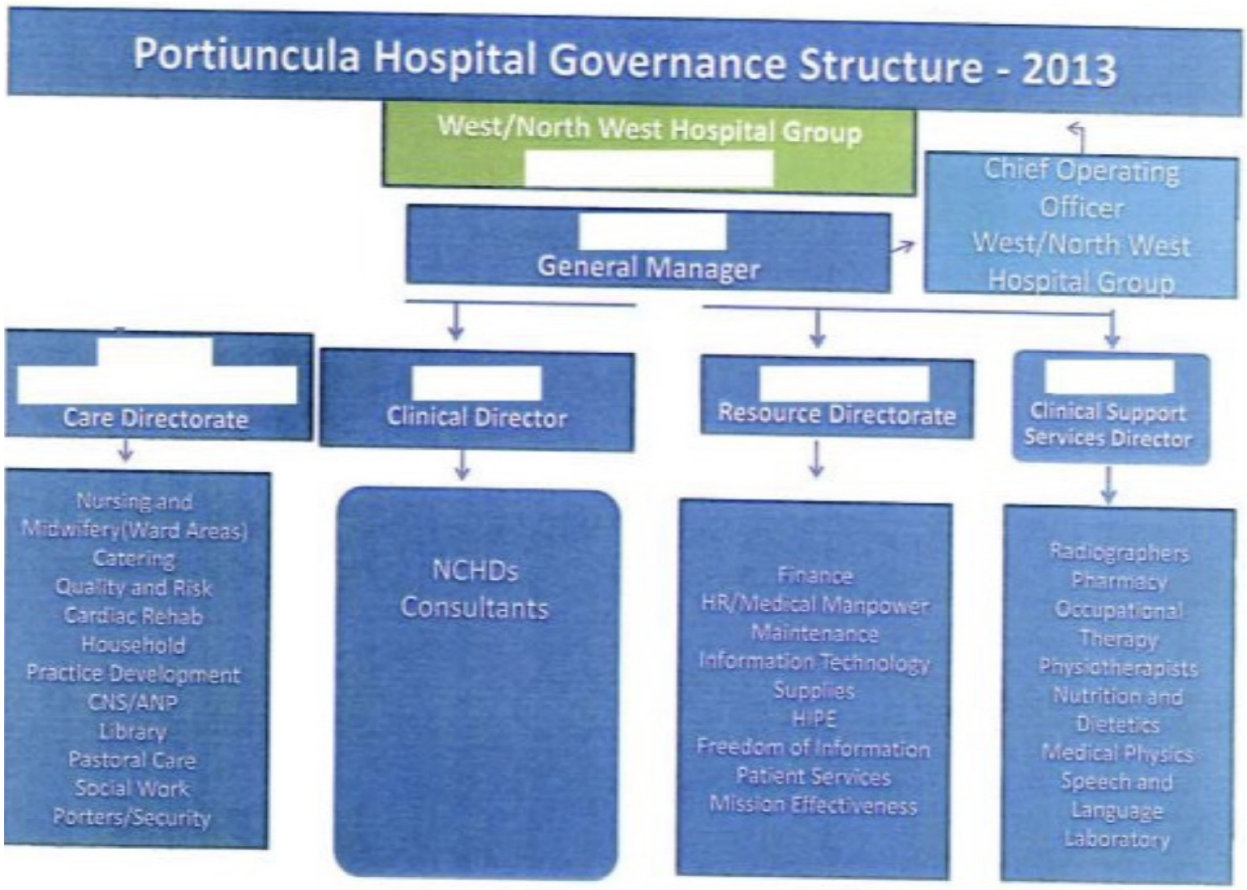
Appendix 1: Organisational Structure

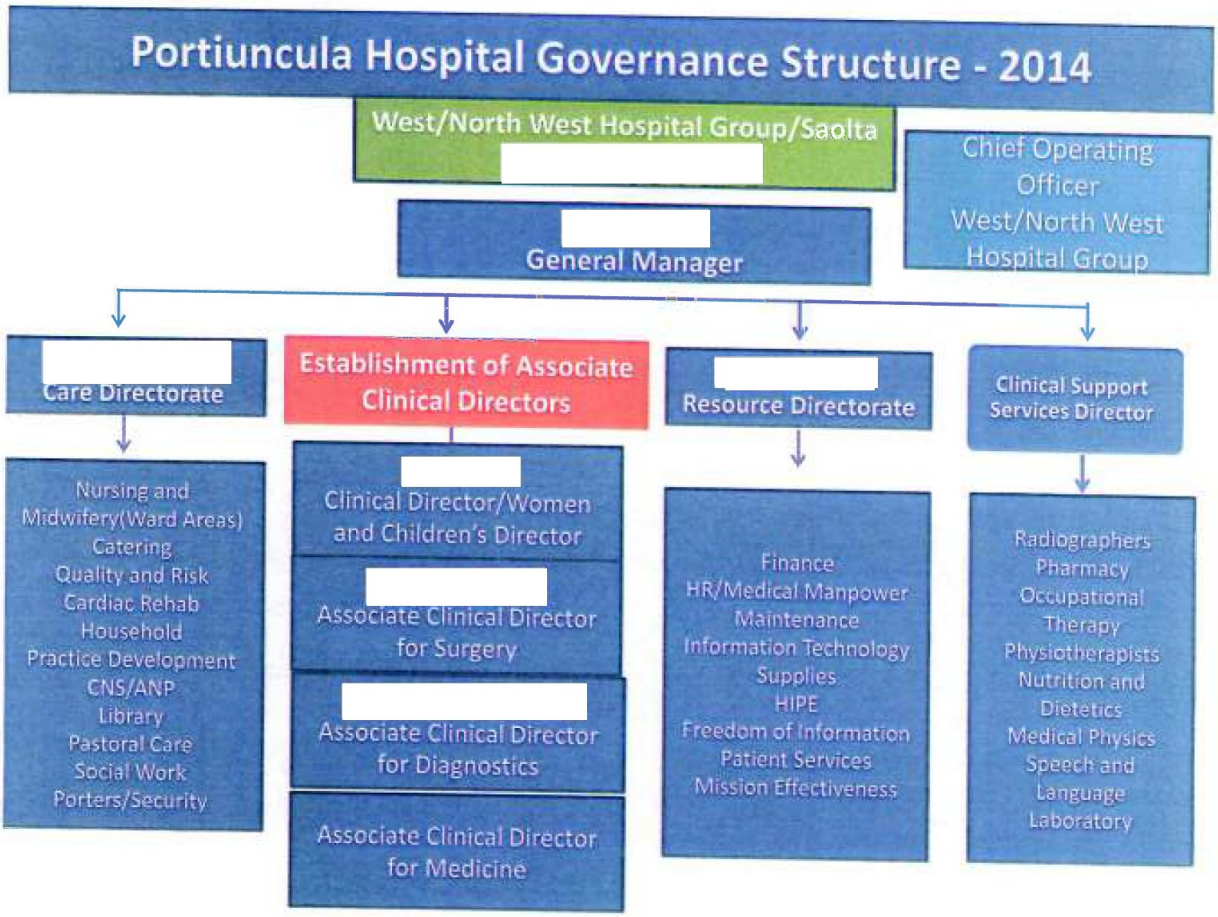
As at 31st December, 2010



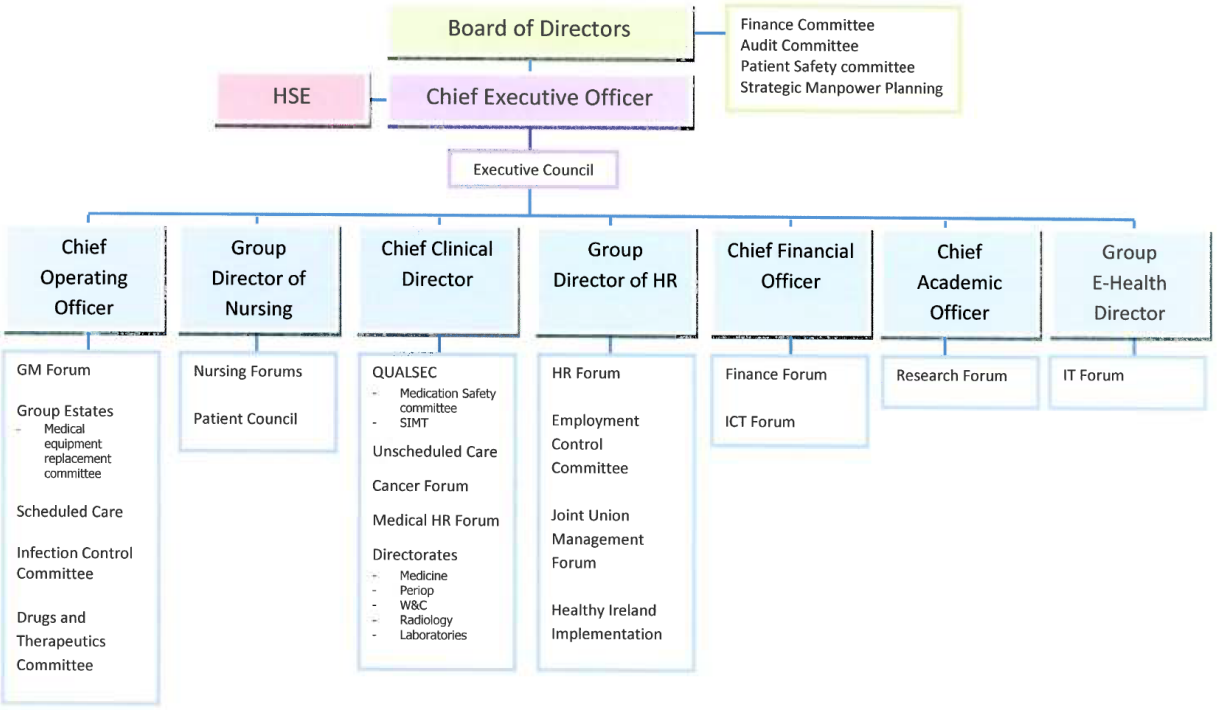
Group Management Team Organisational Structure



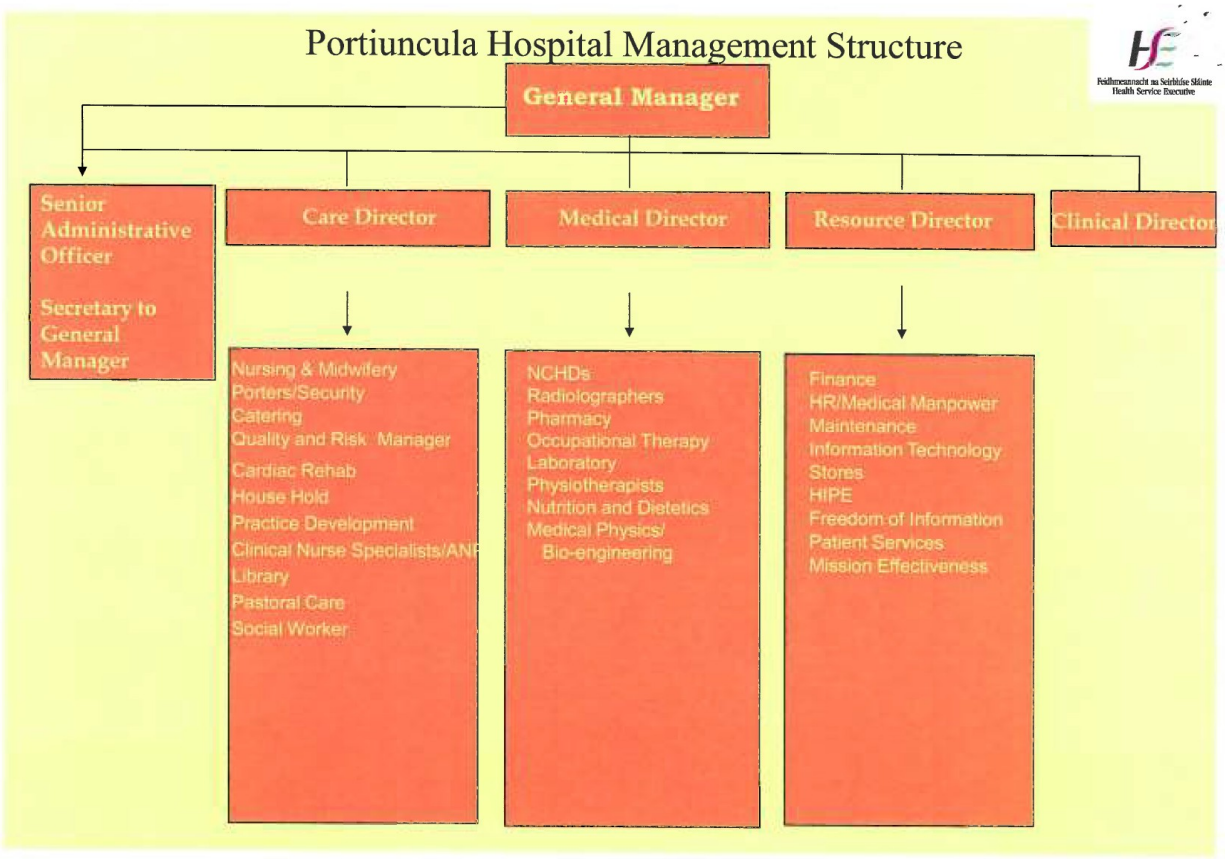

Portiuncula Hospital Governance Structure - 2013
West/North West Hospital Group
Chief Operating Officer West/North West Hospital Group
General Manager
Care Directorate
Clinical Director
Resource Directorate
Clinical Support Services Director
Nursing and Midwifery(Ward Areas)
Catering
Quality and Risk
Cardiac Rehab
Household
Practice Development
CNS/ANP
Library
Pastoral Care
Social Work
Porters/Security
NCHDs
Consultants
Finance
HR/Medical Manpower
Maintenance
Information Technology
Supplies
HIPE
Freedom of Information
Patient Services
Mission Effectiveness
Radiographers
Pharmacy
Occupational Therapy
Physiotherapists
Nutrition and Dietetics
Medical Physics
Speech and Language
Laboratory


Portiuncula Hospital Governance Structure - 2014
West/North West Hospital Group/Saolta
Chief Operating Officer West/North West Hospital Group
General Manager
Care Directorate
Establishment of Associate Clinical Directors
Resource Directorate
Clinical Support Services Director
Nursing and Midwifery(Ward Areas)
Catering
Quality and Risk
Cardiac Rehab
Household
Practice Development
CNS/ANP
Library
Pastoral Care
Social Work
Porters/Security
Clinical Director/Women and Children's Director
Associate Clinical Director for Surgery
Associate Clinical Director for Diagnostics
Associate Clinical Director for Medicine
Finance
HR/Medical Manpower
Maintenance
Information Technology
Supplies
HIPE
Freedom of Information
Patient Services
Mission Effectiveness
Radiographers
Pharmacy
Occupational Therapy
Physiotherapists
Nutrition and Dietetics
Medical Physics
Speech and Language
Laboratory

Saolta University Health Care Group Governance Structure



Final 29.2.16 amended 31.7.17


Portiuncula Hospital Management Structure
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive
General Manager
Senior Administrative Officer
Secretary to General Manager
Care Director
Medical Director
Resource Director
Clinical Director
Nursing & Midwifery
Porters/Security
Catering
Quality and Risk Manager
Cardiac Rehab
House Hold
Practice Development
Clinical Nurse Specialists/ANP
Library
Pastoral Care
Social Worker
NCHDs
Radiographers
Pharmacy
Occupational Therapy
Laboratory
Physiotherapists
Nutrition and Dietetics
Medical Physics/
Bio-engineering
Finance
HR/Medical Manpower
Maintenance
Information Technology
Stores
HIPE
Freedom of Information
Patient Services
Mission Effectiveness

Clinical Directorate Development and Support Programme:

The 4 clinical directors and the 16 associated clinical directors are the key clinical leaders across the hospital group as well as being the key business unit managers (directorate). They require key skills to successfully manage these important roles. Many will be taking up these roles without prior senior management experience and a clinical director education/support programme will be developed to ensure that all are supported in developing and enhancing the required skills in management, communication and leadership for these key roles.

Each CD will have a monthly review with the Group CD (termed POA – plan of action), to review progress and assess any deficits and discussion any relevant issues.

In addition a "10+5" approach to strategic performance management will be overseen by the group CD for all CDs.

It is expected that the CD will arrange POAs and 10+5 performance assessments with the relevant aCD and clinical leads.

Future:

As the group transitions from 7 individual hospital sites to one integrated hospital group on 7 sites, the critical role of the 4 directorates as the key business management units will increase. It is essential that the directorates are given the **authority** to make decisions about their clinical services that they have **responsibility** over. The interaction between the individual hospital managers their roles and responsibilities and the clinical directors/directorates roles, authority and responsibilities will need clarification. It will be important to process map and manage the transition from the traditional governance model to the clinical directorate model carefully to ensure that this change will enhance the quality of care and improve patient safety. Redistribution of resources to mirror these changes will be required. This is a key objective of the Integration team that has been established to oversee the group integration. It is chaired by the Group Clinical Director

Group Clinical Director
West/Northwest University Hospitals Group

APPENDIX 7: MIDWIFERY STAFFING

Assistant Director of Midwifery/ Nursing Role

As per Job Description circa 2009 (Appendix 1) The role of the ADON/ADOM had a functional role in managing units of care, bed management and practice development co-ordination. The Primary role was one of professional leadership and co-ordination and management of resources within clinical areas. Principal duties included Managerial, Personnel, Management, Professional, Educational, and Quality development.

Experience in first line clinical nursing management was an essential criteria for the role (approx 5 years).

Management training was also a criteria for ADON/ADOM roles from 2008.

Direct reporting line was to the Director of Nursing and Midwifery.

Divisional Responsibility of ADON/ADOM Womens and Children's Division

It is important to note for the period in question that initially the ADOM for Women and Childrens Division was responsible for the division and also operational site management for at least 25% of the time which included 1 weekend in four on operational site duties.

From 2010 the ADON/M for Womens and Childrens services also took over responsibility for Infection Prevention and Control and he Nursing Practice Development unit.

Clinical Midwifery Manager 3 (CMM3) Role

The first CMM3 was appointed to the Maternity Floor in August 2006.

As per Job Description 2006 (Appendix 2) The role of the CMM3 was to 'Manage the Midwifery Service, to include the efficient management of human and financial resources to ensure high quality of service'. The Primary role was one of management including the development of departmental policy, quality assurance and professional standards, interdisciplinary and team building, appropriate use of resources as well as clinical and professional leadership. The CMM3 role was developed to contribute to the strategic development of the Maternity service. Therefore essential qualification criteria for this position was minimum 5 years post registration midwifery experience 3 of which must have been at clinical manager level. Management training was also a desirable criteria for CNM3 role. Direct reporting line is to the ADON/ADOM

The CMM 3 also covered for the ADON/M while she was on sick leave/admin leave.

Clinical Midwifery Manager 2 (CMM2) Role

As per job description Appendix 3 The CMM2 has a pivotal role in the Service planning, co-ordination and day to day management of activities, services and resources within the direct clinical area. As such the CMM2 has operational management day to day management of the department. The CMM2 provides a high level of clinical leadership, participates to some degree in hands on clinical practices as well as facilitating and co-ordinating across teams and services. Clinical supervision and ensuring safe and optimum delivery of care are central to the role. The CMM2 should play a central role in the development of the service plan, deputise for the CMM3 and in consultation with the CMM3 disciplines, implement and assess quality management systems.Direct reporting line is to the CMM3

Essential qualification criteria for this position was minimum 5 years post registration midwifery experience .

Clinical Midwifery Manager 1 (CMM1) Role

As per job description circa 2012 (Appendix 4) The CMM1 during the period under review was to provide clinical leadership and effectively manage the activities of the ward in the absence of the CMM2 . The role had a strong clinical focus in the promotion of women centred maternity care.

Essential qualification criteria for this position was minimum 3years post registration midwifery experience .

In terms of this role in Portiuncula, all CMM1s rotated to night duty in the to always have a CMM1 in the labour ward.

Staff Midwife.

See Job description Circa 2012 (appendix 5)

Core function of the Staff Midwife role is the hand s on practice of Midwifery, working within the multidisciplinary team in providing safe, effective, high quality midwifery services to women babies and their families. Operating under the Code of professional conduct as independent practioners Midwives has a duty to ensure their practice was kept up to date.

Senior Staff Midwife: Nurses and Midwives who have completed 20years experience are graded as Senior staff Midwives (https://www.inmo.ie))

This grade was developed to acknowledge experience at staff midwife/nurse grade and to utilise this experience to support nurse managers in clinical practice and enable CMMs to ressign duties to include short term acting up to CMM duties for periods of up to three months. (See appendix 6).

Protocol for covering labour ward 2008 -2015

Strategic management of the department was by the CMM 3.

Up until 2015 there was only 1WTE CMM 2 and 3WTE CMM1's

There were 3 CMM1s allocated to the labour ward. All CMM1's rotated through night duty roster. However this was not enough to provide 24 hour cover, this would require 4.4WTEs. Applications submitted since 2012 to increase the level of CMM1&2 cover was not achieved until March 2015.

When a CMM 1 was available they were always allocated to the labour ward. At times the CMM3 took over the management of the floor which includes antenatal, postnatal and EPU and the CMM2 covered the labour ward.

In the absence of a CMM1 or 2 being available a senior midwife was allocated as in charge in the labour ward. The roster was written according to seniority and the lead for the labour ward was indicated on the roster

Staffing

In 2012 the WTE Midwifery Count on the Maternity Floor was reduced to 39WTEs total as follows

CMM3 X 1 WTE

CMM2 X 1WTE

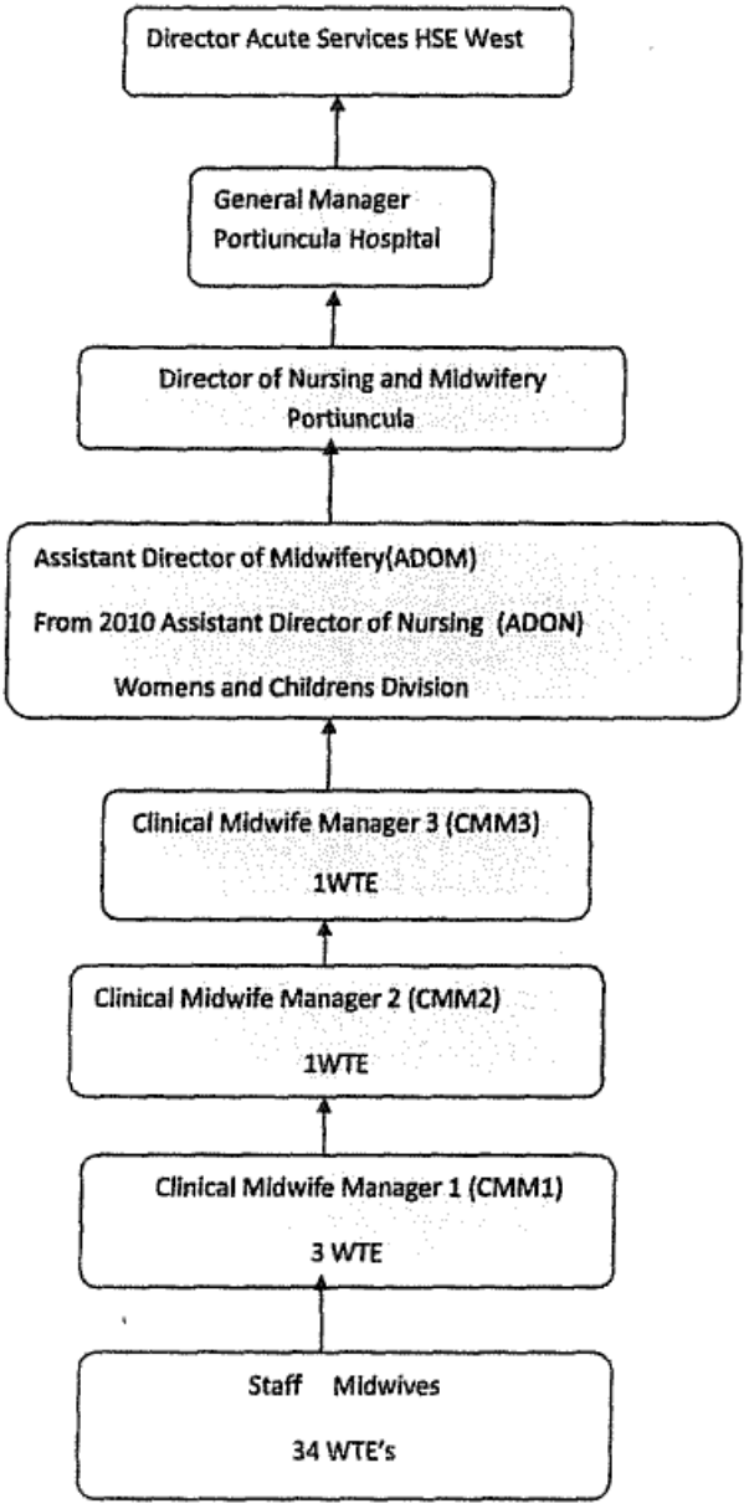
CMM 1 X3 WTE's

Staff Midwives 34

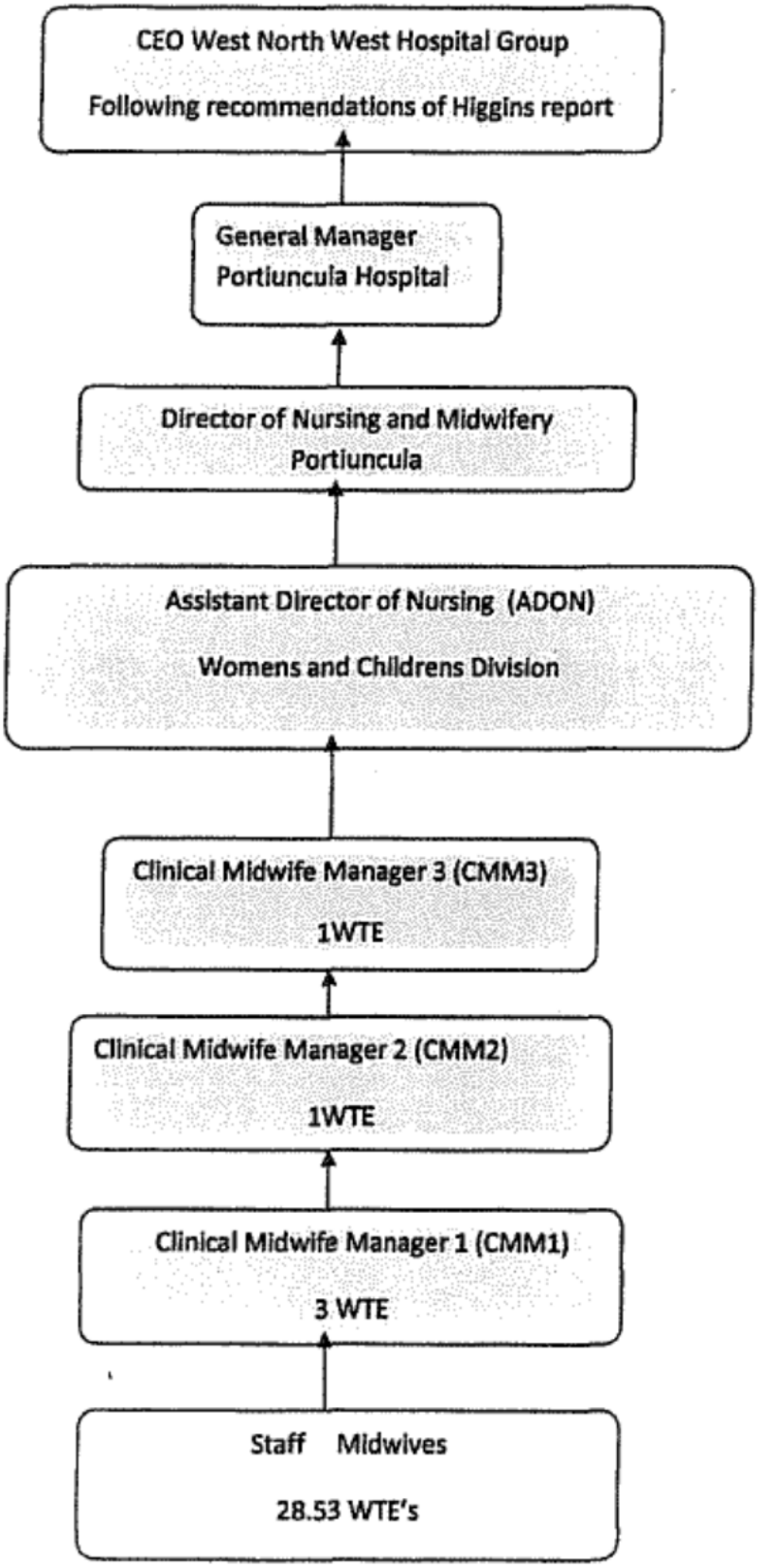
The maternity floor midwives also covered the Early Pregnancy Unit, the outpatient maternity service and outreach clinics. During this period due to the moratorium there was no replacement of sick leave or maternity leave. All qualified Midwives in the hospital who were working in the general areas were

It is worth noting that current Staff in Midwifery department is 46.5 WTE's

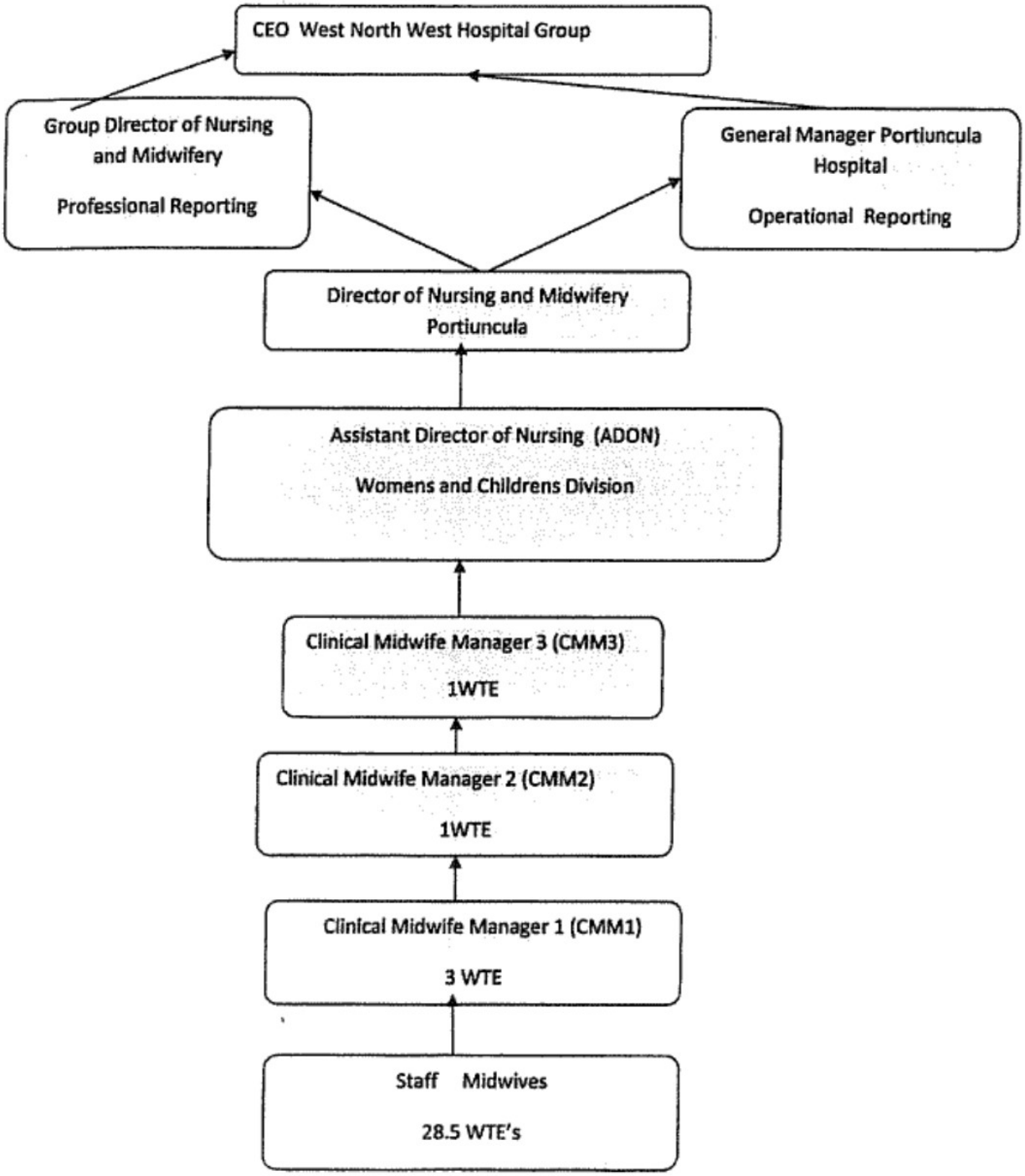
Organisational Management of Midwifery Staff 2008 to Feb 2012



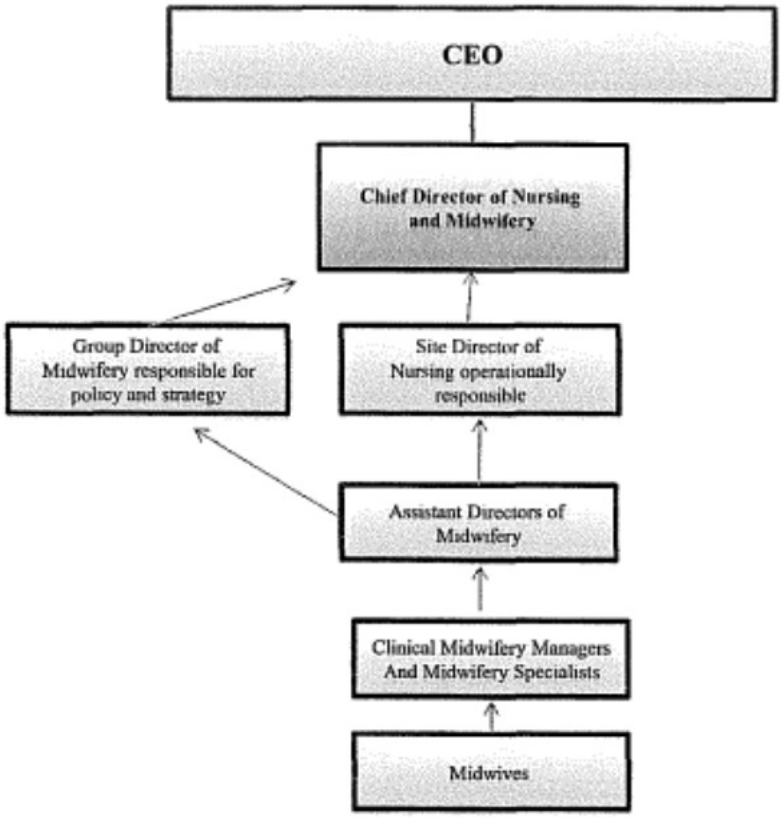
Organisational Management of Midwifery Staff Feb 2012 to Sept 2012



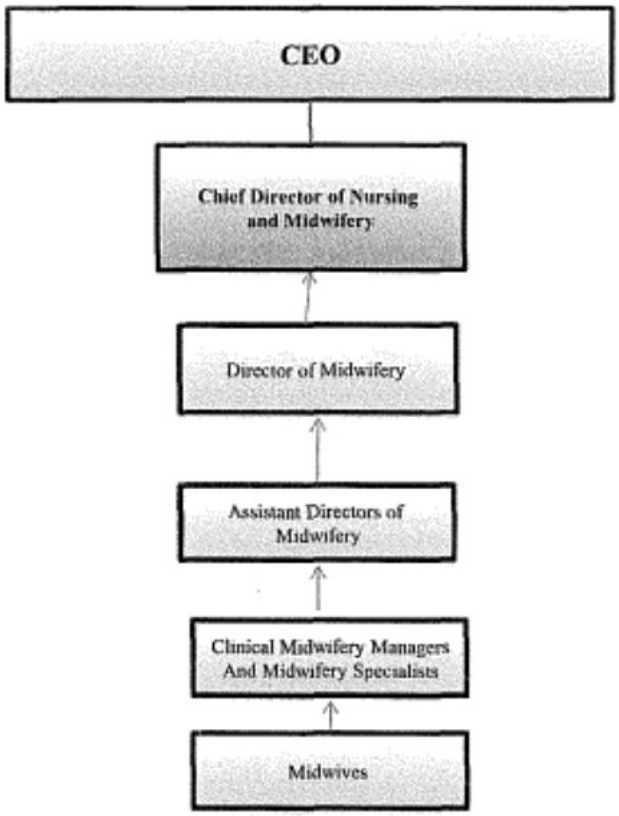
Organisational Management of Midwifery Staff Sept 2012 to June 2013



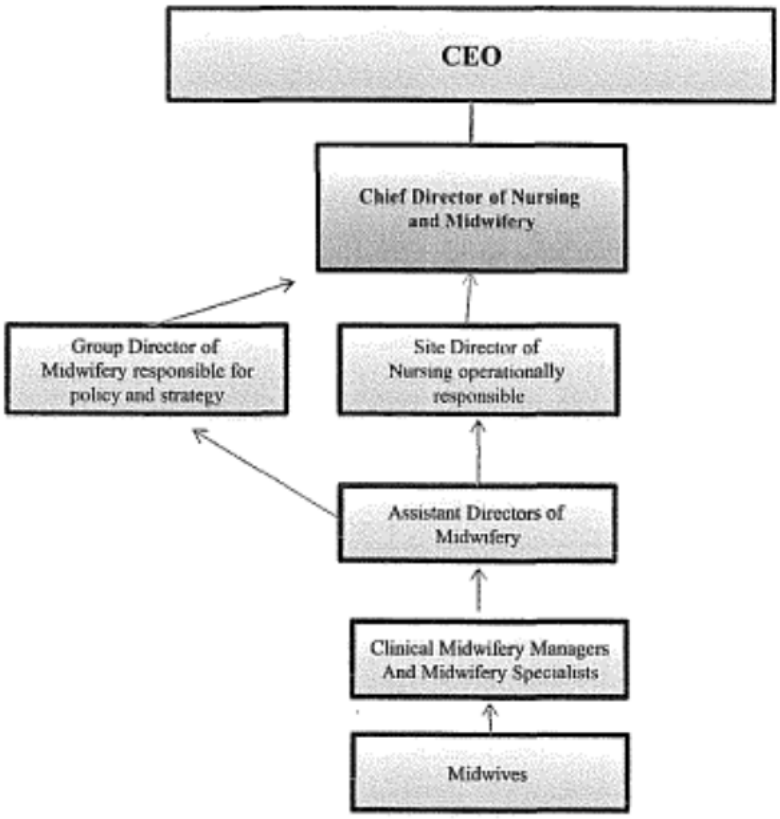
Group Midwifery Governance Structure 2014/16



Group Midwifery Governance Structure 2016/18



Group Midwifery Governance Structure 2014/16



	Maternity Staffing WTE Data													
Year	Month	ADON	CMM3	CMM2	CMM1	CMM SL	S/M	SL	ML	UPL	Admin Leave	Actual S/M	Total CMM2 CMM1 S/M	Actual CMM2 CMM1 S/M
2010	March	1	1	1	3	0	35.63	1.66	0	.5	0	33.47	39.63	37.47
	Sept	1	1	1	3	0	32.94	1.66	1	0	0	30.28	36.69	34.28
2011	March	1	1	1	3	0	32.94	.92	1	0	0	31.02	36.94	35.02
	Sept	1	1	1	3	0	32.5	.64	2.42	0	0	29.44	36.5	33.44
2012	March	1	1	1	3	0	31.82	1.29	1	1	0	28.53	35.82	32.53
	Sept	1	1	1	3	0	31.07	2.85	1	0	0	27.22	35.05	31.22
2013	March	1	1	1	3	1	33.8	2.69	1	0	0	30.11	37.8	33.11
	Sept	1	1	1	3	1	34.31	2.57	1.71	0	.69	29.34	38.31	32.34
2014	March	1	1	1	3	1	40.06	1.57	3.92	.88	.69	33.01	44.06	36.01
	Sept	1	1	1	3	2	39.9	1.71	1	1	.69	35.5	43.9	37.5
2015	March	1	1	4	2	1	36.1	.75	0	1	.69	33.66	42.1	38.66

In addition the following staff have been in place:

- .5 WTE CMS Neonatal Resuscitation
- .5 WTE Clinical Placement Co-ordinator Maternity
- 1 WTE IT Project Midwife
- 1 WTE CMS Lactation
- Jan 2014 Intern Midwife x 2WTE joined the staff (not included in figures above)
- March 2015 Pre-reg S/M x 2 WTE working on Maternity Unit (not included in figures above)
- March 2012 Early Pregnancy Unit operational 2.24 WTE S/M allocated to same

APPENDIX 8: TIMELINE OF THE REPORT PROCESS

2014	
February - November 2014:	The initial escalation of concerns relating to 6 cases referred for Therapeutic Hypothermia from PUH in 2014
23rd December 2014:	Results of the Preliminary Review were presented by the Dr. Pat Nash, SAOLTA Group Clinical Director (the "Commissioner"), and a decision to escalate nationally and undertake an independent external review.
2015	
16th February 2015:	First approach from Royal College of Obstetricians and Gynaecologists (RCOG) to Professor James Walker to be nominated to chair the external review.
16th February 2015:	Professor James Walker (the "Chairperson") agreed to chair the independent external review.
16th February 2015:	Initial communication from Cora McCaughan, HSE National Incident Management and Learning Team to the Chairperson by both phone call and email concerning the external review into the 6 cases in 2014 stating:- • The work is due to commence with immediate effect. • It is foreseen to be completed in 5 months unless unforeseen circumstances arise that require the timeline for completion of the work to be extended. • It is expected that most of the work of the review team could take place by WebEx/Teleconferences probably occurring on an approximately weekly basis lasting approximately 1 hour. • A small number of face-to-face meetings may be required and will occur at a venue in the South of Ireland. Every effort will be made to choose locations that are as convenient as possible for the members of the review team. • At least one site visit to the maternity services at Portiuncula Hospital in Balinasloe, Co. Galway will be required. • The entire review team will be required to review the

	draft systems analysis investigation reports of the 7(6 in actuality) individual investigations to determine whether the draft investigation reports address all pertinent clinical issues satisfactorily; and whether they are in line with HSE guidelines (NIMLT will assist with this piece). In our experience, it takes approximately 3 hours to conduct such a review of an individual investigation so this is approximately 21 hours work for each nominee. • The review team will oversee an aggregate analysis of the completed investigation reports. They will have supports from the NIMLT who has experience in doing this; and they will need to confirm that the analysis is as required by the terms of reference. • The review team will need to conduct items 3 – 7 of the terms of reference. Much of the work for this will be covered in the 7 (6 in actuality) individual investigations which will be conducted by experienced NIMLT investigators - but outstanding elements of this need to be conducted by the review team. Local hospital group resources will help with collecting the relevant data. It is difficult to estimate the amount of time that this might take the nominees but to be helpful it is estimated to be approximately 10 days work over the course of the review. • It is envisaged that a more detailed plan of the phasing/scheduling of work and allocation of tasks will be developed by the Chairperson when the review team is fully established and has its first meeting.
17th February 2015:	Confirmation of the HSE approval of Professor James Walker as Chairperson of the Clinical Review Team (CRT).
20th February 2015:	Executive Council meeting in SAOLTA - outline of plan for the independent external review on the 7 cases in 2014 and initial Terms of Reference drafted.
18th March 2015:	First contact between the Commissioner and the Chairperson by telephone call.
20th March 2015:	Formal letter of invite from the Commissioner to the Chairperson to chair the external review.
15th April 2015:	Board of Directors Meeting, SAOLTA Group • Update on the review process noting that there are only 6 cases to be reviewed from 2014 but a further 12 cases had been added to the review (18 in total). • The external review will review the individual System Analysis Investigations (SAIs) of each of the 18 cases as well as a review of maternity services at PUH.

	• It was still envisaged that the work would be completed within 5 months from commencement.
Wednesday 22nd April 2015 (full day):	First meeting of Clinical Review Team (CRT) in PUH • CRT meeting with the Commissioner. • Discussed outline of plan for the external independent clinical review and agreed amendment to the Terms of Reference (with the exclusion of item 7 from the Terms of Reference, being the neonatal care beyond referral). • Confirmed the expansion of the review to include the additional 12 cases (10 families) which were self-reported through a dedicated patient help line.
28th April 2015:	Email from the Chairperson to the Commissioner about concerns regarding the likely length of time required to complete the 18 SAIs.
May 2015:	Amended Terms of Reference provided.
5th May 2015 (1pm-2pm):	Teleconference of full CRT to follow-up and discuss plans.
5th June 2015(11:30-12pm):	Telephone call between the Chairperson and the Commissioner to discuss process.
8th & 9th June 2015 (Two Full days):	Meeting of full CRT to include: (a) Tour the Portiuncula University Hospital (PUH); (b) Interview staff; (c) Review of all the 18 clinical cases. All case notes were reviewed by an obstetrician, midwife, paediatrician and lay representative from the CRT.
24th July 2015:	Email from the Chairperson to the Commissioner raising concerns about time required for completion of SAIs.
14th August 2015:	Further email from the Chairperson to the Commissioner about concerns regarding the time required for completion of the SAIs.
17th August 2015:	The first draft SAI submitted to the CRT for review.
8th-9th September 2015:	Full meeting of CRT postponed as too few SAIs had been completed and submitted for review.
16th September 2015:	Telephone conversation of the Chairperson with the Commissioner about ongoing concerns and plans for service review.
16th September 2015:	Email from the Chairperson to the Commissioner about delays and process issues.

24th September 2015:	Email from Cora McCaughan to the Chairperson updating the Chairperson on the SAI process.
2016	
20th January 2016:	Telephone call between the Chairperson and the Commissioner about progress in the review process.
1st February 2016:	Full CRT meeting in PUH to interview further staff members
9th March 2016:	Chairperson meeting with Patrick Lynch, National Director of Quality Assurance and Verification in relation to a process update due to the complicated nature of the review process.
18th March 2016:	Telephone call between the Chairperson and the Commissioner about progress in the review process.
21st March 2016:	Email from Patrick Lynch about appointing further investigators to expedite outstanding SAIs.
23rd May 2016:	Full meeting of CRT in Galway for further interviews with staff.
9th September 2015 (16:15):	Telephone call between the Chairperson and the Commissioner about progress in the review process.
10th October 2016:	CRT group meeting arranged with families in Athlone to meet with and talk to the families involved in this review in an open forum setting.
11th October 2016:	CRT meeting at Adelaide Road, Dublin to discuss the SAIs to hand and agree structure of the Main Report.
12th-13th December 2016:	Full CRT Meeting in Dr Steevens' Hospital to discuss SAIs to hand and discuss structure of the Main Report.
2017	
23rd February 2017:	Second last SAIs submitted to the CRT for review.
10th April 2017:	Last of the 18 SAIs submitted to Commissioner and CRT. (See Figure A below setting out dates on which SAI reports were commenced, received in draft and in final form)

April 2017:	Mini Reports drafted on foot of review of the SAIs to hand
Tuesday 18th - 20th April 2017:	Individual private meetings conducted with a number of the families affected by this review to provide feedback on the CRT's findings on their individual cases.
April 2017:	Minutes of meetings with individual families prepared
30th May 2017:	Telephone call between the Chairperson and the Commissioner about progress in the review process.
4th June 2017:	Initial draft report sent by the Chairperson to the CRT for review.
5th June 2017:	Provisional draft report sent to the Commissioner for fact checking purposes.
17th June 2017:	The CRT engaged with legal advisors for support in the legal review and fair procedures process (as detailed in Appendix 9: Fair Procedures Methodology).

FIGURE A

No	Date of Commencement of the Investigation	Date of Submission of Draft Report	Date of Final Submission to Commissioner and CRT
1	01/05/2015	17/08/2015	03/06/2016
2	01/05/2015	27/08/2015	27/06/2016
3	01/05/2015	09/09/2015	11/07/2016
4	01/05/2015	11/09/2015	31/05/2016
5	01/05/2015	24/09/2015	02/06/2016
6	01/05/2015	08/10/2015	19/05/2016
7	01/05/2015	13/10/2015	14/07/2016
8	26/05/2015	20/11/2015	04/08/2016
9	26/05/2015	29/11/2015	04/08/2016
10	26/05/2015	01/09/2016	23/02/2017
11	26/05/2015	28/02/2017	10/04/2017
12	02/06/2015	04/11/2015	30/01/2017
13	02/06/2015	04/12/2015	05/10/2016
14	13/07/2015	23/10/2015	30/03/2017
15	28/07/2015	25/10/2015	05/10/2016
16	28/07/2015	25/03/2016	25/10/2016
17	11/08/2015	08/04/2016	15/11/2016
18	13/08/2015	25/03/2016	22/11/2016

APPENDIX 9: FAIR PROCEDURES METHODOLOGY

The First Fair Procedures Process	
July/August 2017	The initial draft main report ("Main Report") was reviewed by the legal advisors and further information was sought in relation to the process undertaken.
21 September 2017:	The CRT met for its first joint review session to consider the draft Main Report and provide detailed instructions in relation to the process. The CRT informed the legal advisors of the existence of the Mini Reports and the minutes of the individual meetings with the families. It was agreed that the CRT would provide the aforementioned documents and the 18 SAI reports to the legal advisors for consideration of the overall requirement for fair procedures in the process.
3 October 2017:	The CRT provided the legal advisors with copies of the 18 SAIs and the 18 Mini Reports and 9 sets of minutes of meetings with the families.
5 October 2017:	The CRT met for the second joint review session to conclude the Main Report review. The CRT were advised generally on the fair procedures process in relation to the Main Report. The CRT was also advised that the Mini Reports and the minutes of the meetings with the families were required to undergo a fair procedures review.
October 2017:	Administrative assistance was provided by SAOLTA in order to allow the CRT to identify the persons to whom the draft Main Report, the Mini Reports and the minutes of the meetings with the families should be provided in accordance with fair procedures.
October/November 2017:	Relevant extracts of the draft Main Report/Mini Reports and were prepared for review by affected parties. In addition the Mini Reports and the minutes of the meetings with the families Minutes. The relevant documents were prepared in the form of sealed and confidential 'packs' with a unique identifier number given to each recipient. In a total of one hundred and nine individuals were identified as being entitled to comment on either, the draft Main Report and/or the Mini Reports and/or the minutes of the meetings with the families.
8 & 9 November 2017:	One hundred and three packs were brought to PUH for the purposes of delivery to individual recipients. To ensure confidentiality, all persons were invited to confirm their preferred method of delivery and in that regard, packs were either delivered by hand, registered post or email. Individuals were given 28 days in which to provide their responses. Given the volume of individuals to be located and provided with packs, this part of the process was not completed until 8 December 2017. The CRT was unable to deliver packs to six individuals because those individuals either did not wish to engage with the process or could not be located. For those persons who could not be located, continuing efforts were made throughout the first fair procedures process to try to contact them through the Medical Council, the Nursing and Midwifery Board of Ireland and through further enquiries. The CRT would like to acknowledge the very helpful administrative support provided by the staff in PUH and SAOLTA in identifying the relevant persons and assisting in the delivery of the document packs to the relevant individuals.

11 & 12 December 2017:	A total of 59 individual responses were received by the CRT in relation to the relevant documents. The CRT met for its third joint review session to consider the responses.
December 2017:	In correspondence, an additional person identified themselves to the CRT as potentially being relevant to the review.
8 & 9 January 2018:	The responses received were extensive and the CRT was required to meet again to consider the balance of feedback received. During the course of its consideration of the feedback, it became apparent to the CRT that there were some factual inconsistencies in terms of the information provided to the CRT during the feedback process. In that regard, the CRT requested clarifying information from the Commissioner and additional documents were provided to the CRT by the Commissioner on the 7/8/9 January 2018. At the same time, the CRT considered the correspondence from the newly identified person ("additional person"), and agreed that they were relevant to the review process and should be given an opportunity to comment on the relevant extracts of the draft Main Report.
25 January & 2 February 2018:	The CRT convened again for its fifth and sixth joint review sessions to consider the documentation provided by the Commissioner and to incorporate certain factual accuracy changes into the draft Main Report. Over the course of the CRT's consideration of the feedback received from the various affected persons at the third, fourth, fifth and sixth joint review sessions, the CRT incorporated amendments and footnotes to the draft Main Report, Mini Reports and noted the relevant feedback as footnotes to the minutes of the meetings with the families. Thereafter, the CRT commenced a second round of fair procedures.
The Second Fair Procedures Process	
9 February 2018:	A second round of fair procedures was undertaken to allow the additional person and those recipients who engaged in the first fair procedures review an opportunity to review the amended draft Main Report and/or Mini Reports and/or minutes prior to finalisation.
9 February 2018:	A total of 44 persons were provided with extracts of the draft Main Report and/or Mini Reports and/or minutes of the meetings with the families and were given until the 23 February 2018 to consider same.
20 February 2018:	The CRT conducted a telephone interview with the additional person to receive their feedback. The additional person also provided their written feedback to the CRT for consideration and requested sight of any revisions made to the draft Main Report on foot of their feedback.
23 February 2018:	23 responses were received as part of the second round of fair procedures. Some recipients requested in their second round feedback to be provided with the relevant extracts of the amended draft Main Report for a third time.
26 February & 2 March 2018:	The CRT convened again to consider the feedback from the additional person and all responses received as part of the second round of fair procedures. Following consideration of this feedback, some further amendments were made to the draft Main Report and the Mini Reports.

The Third Fair Procedures Process	
15 March 2018:	The CRT provided the additional person with sight of the relevant extracts of the draft Main Report for a second time. However there were time constraints in relation to the receipt of the further response of the additional person and in that regard, it was agreed with the additional person that their second round feedback would be provided by them to a member of the CRT by telephone on the 16 March.
16 March 2018:	While the CRT was satisfied that the fair procedures process had been complied with and it was not deemed necessary to undertake a third round fair procedures review. The CRT consulted with the Commissioner in relation to the timeline for delivery of the Main Report and then agreed, that in order to address the further feedback received from some of the recipients of the draft Main Report in the second round fair procedures, a telephone call between those recipients (the "parties to the call") and a member of the CRT would take place. The phone call between the additional person and the CRT member also took place on the 16 March.
20 March 2018:	A further letter was received from the parties to the call requesting further sight of the draft Main Report. The CRT contacted the Commissioner again in relation to the timeline for the delivery of the Main Report and it was agreed that the parties to the call would be provided with the relevant extracts of the draft Main Report.
26 March 2018:	The parties to the call were provided with extracts of the draft Main Report for factual accuracy checking only and were given until 3 April 2018 to respond.
29 March 2018:	Response received from the parties to the call and considered by the CRT. This response included a further request for sight of the draft Main Report.
10 April 2018:	The extracts of the report in which the further feedback of the recipients to the call was incorporated was sent with a final letter.
CRT Communications	
September 2017 – April 2018:	Throughout the legal review process and in particular when it became clear that the fair procedures and factual accuracy checking process was more complex than had originally been envisaged, the CRT, through its legal advisors, provided regular updates to the Commissioner and his advisors as to the timeline for the completion of the Main Report and status of the fair procedures process. During this time, the CRT was cognisant that the families had anticipated the release of the Report at a number of different junctures from September 2017 onwards. Accordingly, when it became apparent that the fair procedures process was more complex than first anticipated, the Chair of the CRT wrote directly the families in order to keep them apprised of the developments in relation to the timeline for the completion of the Main Report. The Chair of the CRT wrote to the families on three occasions during the fair procedures process.