



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

# HSE MATERNITY CLINICAL COMPLAINTS REVIEW

FINAL REPORT | MAY 2017

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## INTRODUCTION

This final report of the Maternity Clinical Complaints Review concludes the review process commissioned by the HSE in 2014.

Two hundred and three patient complaints were received. These patients were written to and asked to consent to a review of their health care records as a first step in determining the nature of care they received. One hundred and fifty three patients consented to participate in the review process. This report describes the outcome of the external clinical review of these complaints which related to events over a period of 40 years. One hundred and thirty complaints related to maternity services in the Midland Regional Hospital Portlaoise and 23 complaints related to services in 8 other hospitals, including The Rotunda Hospital, The Coombe Women and Infants University Hospital, University Hospital Limerick, Cork University Maternity Hospital, Kerry General Hospital, Midland Regional Hospital Mullingar, Midland Regional Hospital Tullamore and Galway University Hospital.

Over the course of the entire process the patient complaints were reviewed in two ways. In Phase I this only involved a review of the healthcare record, while Phase II included an initial screening review and individual meetings with the families. The addition of individual meetings was recommended as part of the Phase I report and in response to the strong desire by many families who wanted to share their personal experiences.

The complaints reviewed related to perinatal death, maternal death, communication, access to information, autism, gynaecology issues, health care record issues, infant after care and management of labour.

This report summarises the screening process undertaken by the external clinical expert team in order to review the complaints received and outlines the findings of the process and recommendations arising for all maternity services nationally.

The recommendations contained in this report are drawn from the individual experiences as described by patients and their families who brought forward complaints.

The sensitivity of this report is emphasised by the fact that the reviewers considered a number of complaints which related to a perinatal death, amongst other issues or concerns. Each baby death represents a huge loss for the individual parents and families. The loss experienced by the parents will endure.

This review considered complaints spanning 40 years of service provision at the Midland Regional Hospital Portlaoise and other maternity hospitals in Ireland. The external expert clinical reviewers attributed perinatal deaths to a range of causes occurring in multiple different circumstances. Specific conclusions cannot be drawn in this context.

## ACKNOWLEDGEMENTS

On behalf of the Management Team of the Maternity Clinical Complaints Review, the authors of this report would like to acknowledge that this has been a difficult and stressful process for many of the participants. We are aware that the length of time it took to complete the complaints review for the large number of participants has been hard on those who were anxious to have their complaints heard.

We have learned a great deal about maternity services from our patients' experiences and we hope that we have done our best to answer questions and identify issues that needed further review or investigation.

We would like to thank all of the patients and families for their participation and for their patience. As a Health Care Service, we have learned from conducting this large complaints review, these lessons are continuing to be addressed across our National Maternity and Infants Services.

We would also like to thank our external Obstetrician/Gynaecologists, Midwifery experts and Paediatrician/Neonatologist who participated in the review processes. The commitment of their time has been an essential element of providing expert insight to the patients' personal experiences and the documented medical and midwifery care in the Hospitals.

We would like to thank Patient Focus for their continuous support for women and their families and for their attendance at many of the meetings with the external reviewers.

## EXECUTIVE SUMMARY

On the 30th January 2014, a Prime Time Investigates programme, “Fatal Failures”, aired on RTÉ television. The programme reported on the tragedies of the families whose babies had died around the time of birth at the Midland Regional Hospital Portlaoise (MRHP). Immediately following the programme, many patients contacted helplines established by the Patient Focus advocacy group or the MRHP with concerns in relation to their maternity care.

On February 24th 2014, the report to the Minister of Health from the Chief Medical Officer, Dr. Tony Holohan, entitled “The HSE Midland Regional Hospital Portlaoise, Perinatal Deaths (2006 – to Date)” was published. The Health Information and Quality Authority (HIQA) also began its investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the MRHP.

In the months that followed, a growing number of maternity related complaints were referred to the Health Service Executive, Acute Hospital Division, which resulted in the establishment of a Maternity Clinical Complaints Review in line with the National Incident Management and Learning Team (NIMLT) guidelines to evaluate these complaints. Two hundred and three patient complaints were received. These patients were written to and asked to consent to a review of their health care records as a first step in determining the nature of care they received. This was to provide guidance on whether or not further investigation or other actions were necessary in relation to individual patient complaints. Ultimately, 153 patients consented to a review of their health care records.

By the end of May 2014, the Maternity Clinical Complaints Review Management Team had been established, chaired by the Commissioner of the Review, Mr. David Walsh.

### Phase I of the Complaints Review

The Commissioner of the Review, Mr. Walsh, established a Clinical Review Team of 7 Consultant Obstetrician/Gynaecologists, of which Dr. Peter Boylan, a senior Obstetrician/Gynaecologist, was appointed Chair. They committed to review up to a maximum of 40 health care records of those patients who had consented and to decide what, if any, further action was required.

Twenty eight health care records were examined by the Clinical Review Team of which 23 were from the MRHP and 5 were from other hospitals (University Hospital Limerick, and Midland Regional Hospital Mullingar). This report entitled “A Review of Twenty Eight Maternity Case Notes” was published in June 2015. Each of the patients involved received a copy of the report and a copy of a summary of their case notes. Fourteen of the 28 complaints related to stillbirths or neonatal deaths. In 2 cases, there were full systems analysis in progress. In 11 cases, the Clinical Review Team concluded that there were possible issues relating to the care and in 9 of these cases they recommended the patients be offered a full systems analysis. The Clinical Review Team’s report made 10 recommendations, the first of which was that the Commissioner of the Review, or a person nominated by the Commissioner, should meet with the patients/families to relay the conclusions/recommendations in their individual cases.

Following the publication, a number of patients contacted the Commissioner's Office or Patient Focus to indicate their wish to meet reviewers and describe their experience. In February 2015 governance of the review and consequently the role of the Commissioner transferred to Dr. Susan O'Reilly, CEO of the newly formed Dublin Midlands Hospital Group (DMHG). The Management Team for the Complaints Review and Dr. Peter Boylan, the Chair of the Clinical Review Team, decided to offer a meeting with an external Obstetrician/Gynaecologist and/or Paediatrician/Neonatologist and an experienced Midwife to each of the patients in this review.

All patients except the 2 already proceeding with a full systems analysis were offered meetings either with an externally appointed Obstetrician/Gynaecologist and/or a Paediatrician/Neonatologist and an experienced Midwife (21 MRHP patients) or with a clinical review team established by the relevant hospitals (5 patients). The purpose of these meetings was to provide each patient with an opportunity to discuss the recommendations of their individual reviews, their concerns in the context of the patient health care record and to provide an opportunity for discussion of their own experience.

### **Phase II of the Complaints Review**

Based on Phase I recommendations the approach to Phase II of the review changed and the review methodology was revised. A new Terms of Reference was developed for this enhanced complaints screening process which involved meetings between external clinical experts and individual patients from the outset.

One hundred and seven of these patients received their maternity care at the MRHP and the other 18 had care in other hospitals (The Rotunda Hospital, The Coombe Women and Infants University Hospital, University Hospital Limerick, Cork University Maternity Hospital, Kerry General Hospital, Midland Regional Hospital Mullingar, Midland Regional Hospital Tullamore and Galway University Hospital). On an initial screen of health care records, 12 MRHP patients did not require a meeting with an external reviewer and these patients were written to and advised to contact the Commissioner's office if they had any further questions.

Ninety five MRHP patients were offered meetings with an external Obstetrician/Gynaecologist and/or a Neonatologist/Paediatrician and an expert Midwife. Seven patients from other hospitals (The Rotunda Hospital, Coombe Women and Infants University Hospital, Midland Regional Hospital Tullamore and Cork University Maternity Hospital) also met with the expert review teams in Portlaoise or Dublin between August 2015 and July 2016. If needed, some patients had additional meetings e.g., where a Paediatrician/Neonatologist opinion was required or a second meeting with the Obstetrician/Gynaecologist and Midwifery expert, or in some cases, where a second opinion was requested. The remaining 11 patients from other hospitals, were offered a clinical complaints review through their own Hospital Group and local hospital.

After each meeting with patients, the external review teams provided a note to the Commissioner (a proforma) advising whether no further action was required, whether additional support services such as counselling were requested or whether the patient's complaint be referred to the Commissioner. In these referred cases, a further discussion took place between the Review Team Members and the Commissioner to determine whether any further action was indicated.

The nature of the complaints received in Phase II related to perinatal deaths (17), maternal death (1), management of labour (34), communications (28), health care records (17), care of the mother (11), infant aftercare (7), Autism (4) and gynaecological issues (2). There were also 4 patients who did not attend for a meeting where no specific complaint was identified. The complaints related to care delivered between 1975 and 2015.

A single point of contact with the Commissioner's Office was provided to schedule all meetings and to respond to any enquires.

Throughout the screening process, a single point of contact with community support services was also provided. Twenty four patients accessed counselling or physiotherapy services and 14 received other community services.

### **Phase I and Phase II Outcomes**

In Phase I, 4 patients from the MRHP who had been recommended for a full systems analysis chose not to proceed. Two further patients from MRHP were referred to the Commissioner for a decision in their specific cases. Three patients, from other hospitals, who had been recommended for a full systems analysis, were referred to their Hospital Group to proceed.

As part of Phase I, the Clinical Review Team recommended the Commissioner provide 5 apology letters in cases where the care received was not consistent with best clinical practice. All 5 cases involved a perinatal death.

At the end of the Phase II review process, there were 16 MRHP patient complaints referred to the Commissioner which were individually discussed with the expert reviewers. These complaints related to: perinatal deaths (2); communications (4); communications associated with a perinatal death (3); care of mother (2); health care records (2); management of labour (1); management of labour associated with perinatal death (1); and health care records associated with a perinatal death (1). One of these cases from MRHP was referred to a full systems analysis.

As part of Phase II, the Clinical Review Team recommended the Commissioner provide 9 apology letters. Four of these apologies were for care that was not consistent with best clinical practice, 3 of these involved a perinatal death and 1 related to cerebral palsy. Three apologies were related to communications and two further apologies related to lost or delayed health care records.

### **Phase III of the Complaints Review**

In the course of the meetings with families and the review of their health care records, 3 cases of perinatal deaths at MRHP were observed which were linked to a finding of pathological cardiotocographs (CTG) (grossly abnormal recordings of the baby's heartbeat) which had not been acted on. In addition, the care of a fourth baby came to the attention of the review team. The care of this baby had not been reviewed previously. This information prompted the external Obstetrician/Gynaecologists participating in the expert review to advise the Commissioner that it would be prudent to do a formal historical review of CTGs from the mid-1980s to 2014 in the MRHP. The purpose of the review was to identify whether any other perinatal deaths were related to this serious problem and whether or not there had been any persistence of this practice beyond the 1980s and 1990s when these four babies were delivered at MRHP.

This historical review resulted in scrutiny by expert Obstetrician/Gynaecologists and Midwives of the CTG recordings in health care records. There were 90 cases of perinatal deaths identified at the MRHP from 1985 to the end of 2014 which met the review criteria. No evidence of any similar failure to react to pathological CTGs that might have been a contributory factor in these outcomes was identified.



## Overview of the Review

A high level overview of the phases and outcomes of the review are outlined in the Figures 1 and 2 below.

**Figure 1**

### SUMMARY

- 203 complaints were received.
- 50 patients did not return their consent forms and thus did not proceed.
- 28 patient complaints were reviewed in Phase I.
- 125 patient complaints were reviewed in Phase II.

### PHASE 1 - HEALTH CARE RECORD REVIEW

- 28 health care records reviewed.
- A recommendation following the review was to offer each patient a meeting with an external Obstetrician/Gynaecologist and/or Paediatrician/Neonatologist and an experienced Midwife.

### PHASE 2 - COMPLAINTS SCREENING REVIEW

- 107 complaints received related to MRHP.
- 95 MRHP patients were offered a meeting with the Expert Review Team.
- 12 MRHP patient files were reviewed and it was determined no further action was required.
- 18 complaints were received that related to other Hospitals.
- 7 patients were offered a meeting with the Expert Review Team.
- 11 patients were referred to the originating Hospital Group.

### PHASE 3 - HISTORICAL CTG REVIEW

- In the course of Phase I and Phase II, 3 perinatal baby deaths and the care of 1 baby at MRHP were linked to pathological CTGs. This prompted a historical review of CTGs in relation to 90 perinatal deaths between 1985 to 2014 in MRHP.
- The 90 baby deaths were determined based on defined criteria (see terms of reference, Appendix 4c).

Figure 2

**OUTCOME - PHASE 1**

- Each patient received a copy of the report and their individual case notes.
- 6 MRHP patients met with experts and no further action required.
- 6 MRHP patients chose not to meet with experts.
- 5 MRHP patients met with experts and further action was recommended.
- 4 MRHP patients were recommended for a FSA but chose not to proceed.
- 2 MRHP patients were already partaking in a FSA.
- 3 patients from other Hospital Groups were recommended for FSA.
- 2 patients from other Hospital Groups met with their local hospitals and no further action was required.
- 5 of these patients received letters of apology.

**OUTCOME - PHASE 2**

- 66 MRHP patient complaints concluded following the Clinical Expert meeting.
- 25 MRHP patients did not request a meeting or to proceed with the review.
- 16 MRHP patients were referred to the Commissioner for discussion.
- 1 MRHP patient proceeded to a FSA.
- 7 patients from other Hospital Groups met with the Clinical Expert Review Team.
- 2 patients were recommended for a FSA.
- 11 patient complaints were dealt with by the originating Hospital Group.
- 9 of these patients received letters of apology.

**OUTCOME - PHASE 3**

- No evidence of any similar failure to react to pathological CTGs that might have been a contributory factor in the 90 baby deaths were identified during the review in MRHP.
- The Commissioner and the Expert Review Team are reassured that the findings noted in the care of these babies have not led to the discovery of any similar events.

## COMMON THEMES

The common themes emerging from Phase I and Phase II of the review are as follows:

1. CTG monitoring emerged as a very serious issue in 3 baby deaths in the review and another baby delivered in MRHP and identified by the reviewers who had not been the subject of a specific complaint.
2. Patients highlighted a lack of communication around their care. This was particularly difficult for patients and families who needed support and answers to their questions following a baby death.
3. Patients frequently felt that they had not been treated with respect or their dignity had not been preserved.
4. A lack of bereavement support was again highlighted.
5. There were delays in response to complaints or in response to clinical issues experienced by mothers post-delivery.
6. Patients encountered difficulties accessing copies of their health care records.

## PHASE II AND PHASE III RECOMMENDATIONS

The Reviewers concurred with the recommendations published in the Phase I Review. The following are the recommendations arising from Phase II and Phase III.

1. Each hospital must ensure a robust clinical governance system is in place with a clearly identifiable individual with the accountability and authority to ensure quality of care and to implement improvements.
2. CTG interpretation training must be mandatory and updated every 2 years in all maternity units. This must apply to all Midwives, Non Consultant Hospital Doctors and Consultant Obstetrician/Gynaecologists.
3. The CTG monitoring equipment must be serviced and maintained in good working order including accuracy of time and date.
4. There should be immediate communication with the patient and family when they have a concern or an adverse event has occurred or have suffered a bereavement. Communications across the spectrum of maternity and infant care remains an area of concern for families and one which the Hospitals and professional staff will need to invest additional time and commitment. A culture of empathetic care for patients needs to be fostered across the spectrum of maternity and obstetrical care.

5. Timely open disclosure to patients and families is mandatory in the event of a possible adverse experience.
6. There should be experienced staff available to provide immediate support to each patient who has suffered a pregnancy loss. There should also be access to bereavement support and counselling to each patient who has suffered a pregnancy loss. Additionally a quiet and private environment should be provided for patients who are remaining in hospital during their immediate bereavement.
7. There should be a single point of contact for a patient who has a complaint or a poor outcome from a pregnancy so that they don't experience undue difficulty in having their questions addressed or engaging with hospital services.
8. The availability of perinatal mental health services is recommended and desirable for patients who are suffering grief, depression or other mental health problems relating to their pregnancy and delivery. Specialised psychiatric expertise should be made accessible through the larger Hospital Groups networks.
9. Counselling and access to community services should be provided if ongoing support is required.
10. In the event of a perinatal death every effort should be made to gain consent for a post mortem by a Perinatal Pathologist experienced in these examinations.
11. Hospitals should provide both support and on-going education to their obstetrical staff to enhance their professional development and coping strategies in their demanding roles.
12. External oversight should be provided in order to assure the public of the quality of maternal services. The National Women and Infants' Health Programme (NWIHP) should develop a model to ensure external oversight is applied across each hospital group. The Irish Maternity Indicator System (IMIS) currently provides information for local scrutiny of clinical maternity activity. The NWIHP will expand the role of IMIS to provide for Group and National level oversight, as well as local.

## BACKGROUND

### RTÉ Prime Time Investigates Programme

On the 30th January 2014, a Prime Time Investigates programme “Fatal Failures” aired on RTÉ television (ref 1). The programme outlined the personal tragedies of families whose babies had died around the time of birth and raised significant questions with regard to clinical governance in the maternity unit at the MRHP, where the deaths had occurred.

The effects of the programme resounded across the health service, had a considerable impact on maternity services and was the impetus for a number of actions and improvements.

As part of the HSE response, the maternity clinical complaints review process was commissioned to review the complaints of those who contacted helplines established by the Patient Focus advocacy group and the MRHP.

### Chief Medical Officer and HIQA Reports

‘HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)’ – was prepared for the Minister for Health and Children, Dr James Reilly, by the Chief Medical Officer (CMO), Dr Tony Holohan (ref 2). This was published on 24th February 2014.

The CMO report also recommended that HIQA should be requested to undertake an investigation of the hospital. A statutory investigation was announced by HIQA on 6th March 2014, its terms of reference published on 21st March 2014, and its report ultimately published on 8th May 2015 (ref 3).

The CMO and HIQA reports outlined similar operational and clinical governance, patient and quality safety, communications and staff training and education requirements. The recommendations of these reports are included in Appendix 3.

### The Complaints Review Process

This final report documents an overview of complaints and outcomes of the Maternity Clinical Complaints Review.

Immediately following the Prime Time programme and the subsequent report of the Chief Medical Officer (CMO) in February 2014 (ref 2), the National Director of the Acute Hospitals Division instigated the complaints review in line with HSE policy and under National Incident Management and Learning Team (NIMLT) guidelines.

By the end of May 2014, the Maternity Clinical Complaints Review was in place. All patients who had submitted a complaint were written to and asked to give their consent to a review of their health care records. Mr. David Walsh, the Regional Director for Performance Integration was appointed as Commissioner for the review.

The review was conducted in three phases and overseen by the Maternity Clinical Complaints Review Management Team. Each phase is reported separately in this report.

Terms of Reference for each of the three phases in the Maternity Clinical Complaints Review are available at Appendix 4(a-c).

The membership of the Management Team for Phase I is included in Appendix 5.

The Management Team sourced clinical expertise through the Post Graduate Training Forum of the Royal College of Physicians in Ireland. Dr. Peter Boylan was nominated by the Forum and appointed as the Clinical Chair to lead the team of 7 Consultant Obstetrician/Gynaecologists (referred to as the Clinical Review Team, see Appendix 6a) who participated in the review process. Two externally sourced Midwifery experts were appointed to contribute to reviews of specific cases as required

## THE PATIENTS

In total, 203 complaints were received (Table 1). These patients came into the review from multiple sources, including:

- Patient Focus helpline
- MRHP helpline
- Contacts to HSE/MRHP
- Contacts to Department of Health
- Contacts to HIQA
- Referred from MRHP directly
- Referred from other hospitals
- Contacts with the new DMHG from 2015 onwards

The first 28 patients were reviewed in Phase I ("A Review of 28 Maternity Case Notes by a Clinical Review Team undertaken at the request of the HSE" published in June 2015) (ref 4).

In Phase II, there were 125 patients. One hundred and seven patients from MRHP and 18 patients from other maternity hospitals (The Rotunda Hospital, The Coombe Women and Infants University Hospital, University Hospital Limerick, Cork University Maternity Hospital, Kerry General Hospital, Midland Regional Hospital Mullingar, Midland Regional Hospital Tullamore and Galway University Hospital).

On an initial screen of the 107 MRHP health care records, 12 did not require a meeting with the external reviewers. These patients were written to and advised to contact the Commissioner's office if they had further questions. Ninety five patients from MRHP and 7 patients from other maternity hospitals were written to and offered meetings with external reviewers. Eleven remaining patients from other Hospital Groups had meetings arranged through their local hospital and Hospital Group.

Fifty patients did not return consent forms to participate in the review. It should be noted that a number of these patients had already had their concerns addressed.

Table 1: Summary of All Complaints Received	
Description	No.
Complaints reviewed as part of Phase I	28
Complaints from MRHP patients reviewed in Phase II	107
Complaints related to other hospitals reviewed in Phase II	7
Complaints relating to other hospitals reviewed by relevant Hospital Group in Phase II	11
Complaints where consent form not returned	50
<b>Total</b>	<b>203</b>

The advocacy group, Patient Focus, was aware that the RTÉ Prime Time Investigates broadcast called Fatal Failures (ref 1) was scheduled for January 30th 2014 and understood that patients were likely to be distressed and concerned as a result of its content.

In expectation that some patients would need access to information and advice after the programme Patient Focus gave their contact details to RTÉ who provided this at the end of the programme along with an invitation to patient and families to contact them if they had been affected by any of the issues discussed. Patient Focus reported a high volume of phone calls in the days following the RTÉ Prime Time Investigates "Fatal Failures" programme.

Patient Focus encouraged patients to engage with the Maternity Clinical Complaints Review once it was instigated, while also continuing to provide these clients with support and advocacy services.

The MRHP also set up a helpline immediately after the broadcast.

## PHASE I METHODOLOGY

While 203 contacts had been logged from patients, consents to a review of health care records had been received from smaller numbers within the timeframe which would allow their inclusion in Phase I. This phase comprised the first 28 patient complaints from 3 maternity hospitals.

The Clinical Review Team was tasked with making recommendations based on a review of the healthcare records. This initial review did not include patient participation.

The Terms of Reference (see Appendix 4a) charged the team to:

- Review the health care records relating to complaints arising from patient contacts following the RTÉ programme of 30th January 2014
- Conduct a review leading to a decision that:
  - an appropriate investigation had occurred, or not
  - more extensive investigation or full systems analysis required
  - no further action required

The Phase I report was published on 18th June 2015 (ref 4). Each of the patients involved received a copy of the report and a copy of a summary of their case notes. The report made a series of recommendations.

## PHASE I RECOMMENDATIONS

1. The Commissioner of this review, or a person nominated by the Commissioner, should meet with each of the patients to relay the conclusions/recommendations in their individual case.
2. Each hospital in the State should implement a formal system of audit of pregnancy outcome classified according to the Ten Groups Classification as recently endorsed by the World Health Organisation (WHO). This audit should take place on a monthly basis and involve all relevant clinicians. Each hospital needs to supply relevant administrative support.

Using data from individual maternity units an annual audit of Irish maternity services should be implemented without delay.

Ongoing audit in this manner will allow a pattern of adverse outcomes to be identified in a timely fashion so that appropriate action can be taken.

3. Each hospital should have in place a formal system of review of adverse outcomes. The results of these reviews should be shared with the patients in a timely fashion. We recommend within two months of the incident. This timeline is subject to any relevant legal issues, external investigations or inquiries external to the hospital which might arise.
4. In the event of a perinatal death every effort should be made to gain consent for a post-mortem examination and examination of the placenta by a perinatal pathologist experienced in these examinations.
5. Each hospital should ensure the appointment of a number of Midwives trained in ultrasonography such that high quality obstetrical ultrasound is available on a routine basis during the working week and on an on-call basis at other times.
6. Each hospital should appoint bereavement counsellors trained to deal with perinatal deaths.
7. Each hospital should ensure that Midwifery staffing levels are at an adequate and internationally accepted level.
8. Each hospital should ensure that every Non-Consultant Hospital Doctor position is part of a recognised training scheme.
9. Each hospital should ensure that Consultant Obstetrician/Gynaecologist staffing levels are at an adequate, internationally accepted level.
10. Each hospital should implement ongoing mandatory training programmes for all clinical staff in respect of day-to-day care of pregnant women where such programmes do not already exist.



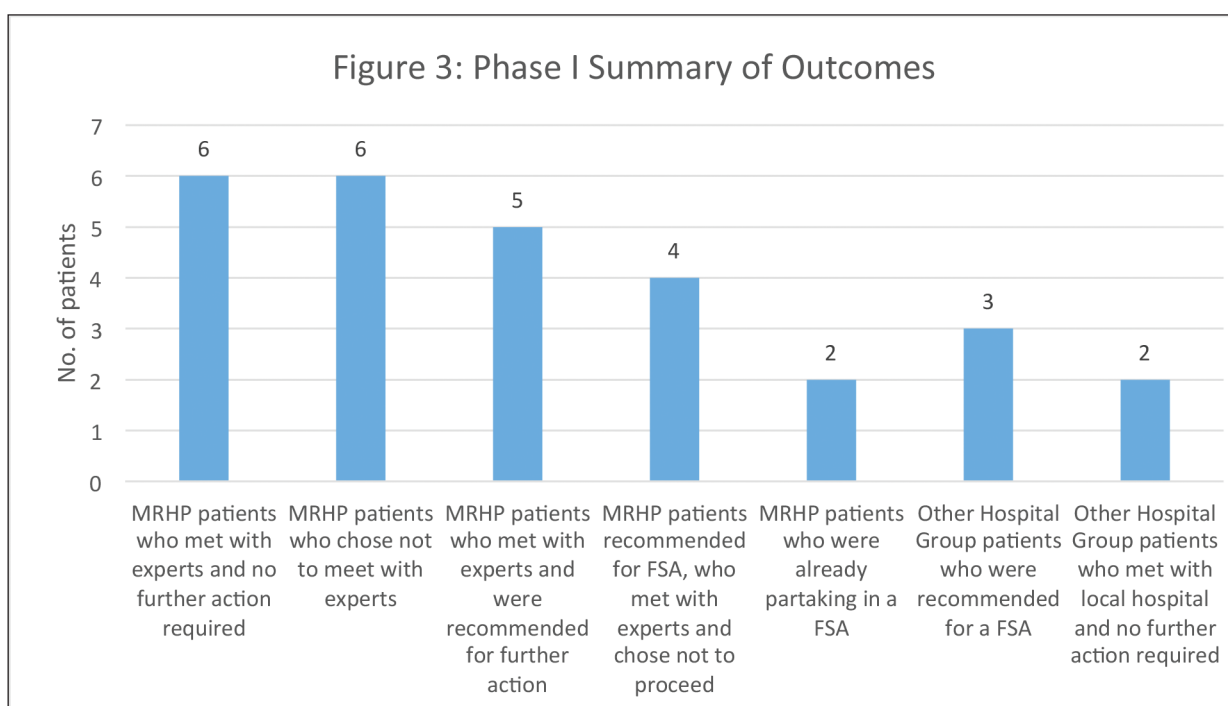
## PHASE I FOLLOW UP

In compliance with Recommendation 1, patients were offered a meeting with an external Obstetrician/Gynaecologist, a Midwifery expert and in some cases a Paediatrician/Neonatologist. The purpose of these meetings was to provide each patient with an opportunity to discuss the recommendations of their individual reviews, their concerns in the context of the patient health care record and also to provide an opportunity for discussion of their own experience. Fifteen patients and their families from the MRHP attended these meetings.

Two additional patients from the MRHP were already participating in a full systems analysis and thus did not require meetings with the external reviewers.

Six patients either did not respond to the letter from the Commissioner offering a meeting or decided not to proceed. In most of these 6 cases, meetings or telephone calls had already taken place between the patients and the hospital and their questions were responded to.

Finally 5 patients were from other hospitals. The Commissioner of the review wrote to the relevant Hospital Group CEO and requested that they arrange to offer meetings for these patients with their local hospital team and conduct a full systems analysis in 3 of these cases, if required.



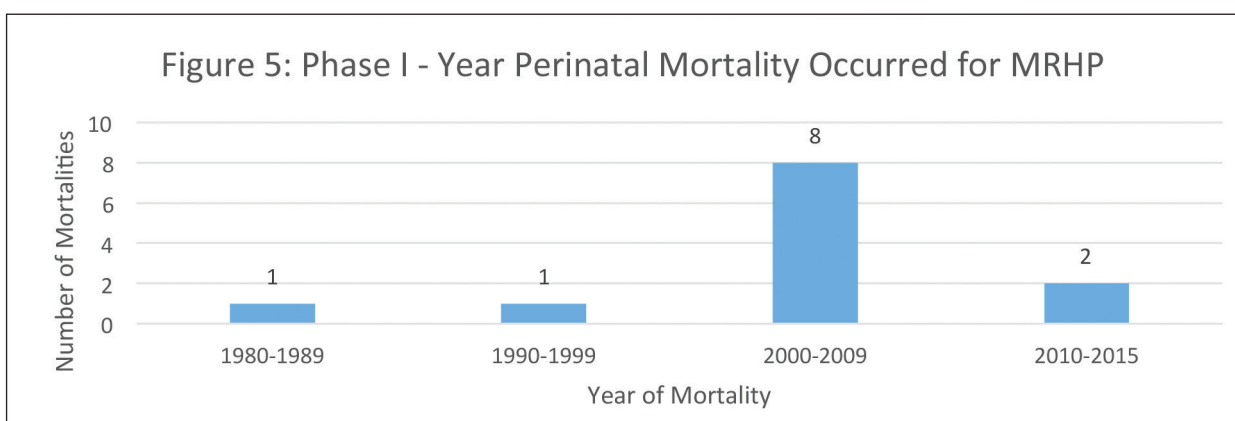
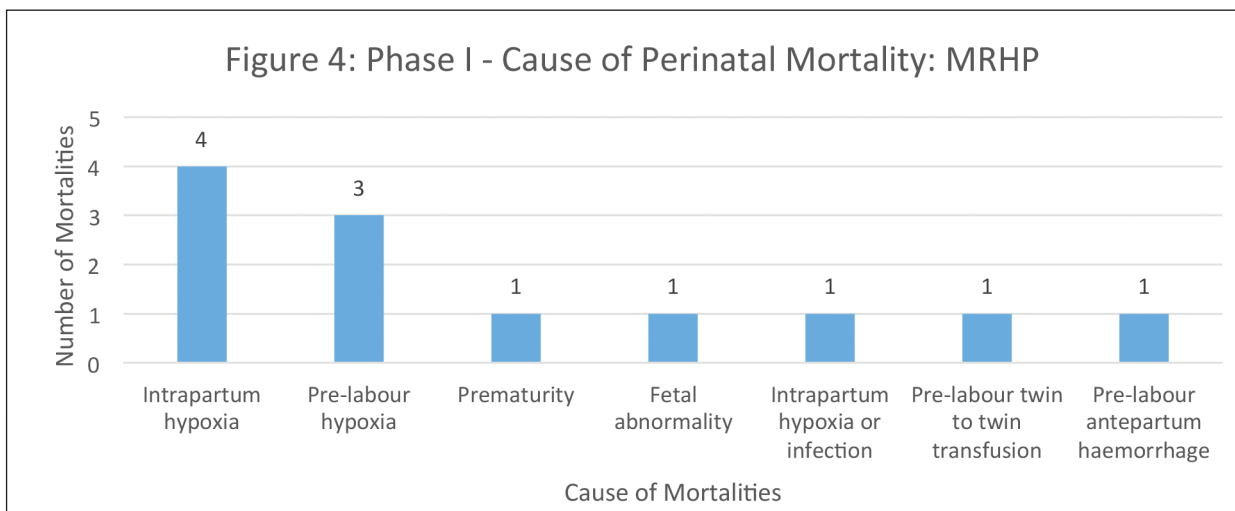
The Phase I Review referred 9 complaints to the Commissioner for consideration of a full systems analysis. Two of these were already in process prior to publication of the Phase I review, these have been completed; 4 patients from the MRHP who initially were recommended for a full systems analysis but chose not to proceed following their meetings with the external review team; 3 further patients were recommended for a full systems analysis in Maternity Hospitals in other Hospital Groups, 2 of these reviews have now been completed.

Following the conclusion of Phase I, the Clinical Review Team recommended the Commissioner provide 5 apology letters to MRHP patients in cases where the care received was not consistent with best clinical practice. All 5 cases involved a perinatal death.

## PHASE I PERINATAL MORTALITY: MRHP

The nature of the complaints varied, in some cases they related to communications, grief counselling and support, in others they related to a perinatal death. The external clinical reviewers noted that deaths occurred under a range of circumstances and were attributable to a variety of causes.

For Phase I, information relating to complaints which occurred in MRHP and involved a baby death was compiled. This information included the clinical cause of the mortality and the year in which the mortality occurred. There were 12 such complaints in Phase I as summarised in Figures 4 and 5.



This review considered complaints related to service provision at MRHP and other maternity hospitals in Ireland. The external reviewers attributed perinatal deaths to a range of causes occurring in multiple different circumstances. Specific conclusions cannot be drawn in this context.

## PHASE I IMPLEMENTATION OF RECOMMENDATIONS

All recommendations specific to the MRHP have been implemented. Recommendations relevant to other Maternity Hospitals or to the Acute Hospitals Division were referred to that Division for review and consideration of implementation. Progress on the implementation of recommendations is detailed later in this report (Appendix 2).

## PHASE II

### PHASE II GOVERNANCE

In February 2015 responsibility as the Commissioner of the Maternity Clinical Complaints Review transferred from Mr. David Walsh, Regional Director of Performance and Integration, to the CEO of the newly formed Dublin Midlands Hospital Group (DMHG), Dr. Susan O'Reilly. This was subsequent to her appointment as CEO of the Hospital Group, which included the MRHP. Formal handover of the Review's documents and records took place at this time.

### PHASE II METHODOLOGY

By the time the Phase I Report was published in June 2015, the HSE had received consent from additional patients and it was decided that the original process should be amended to provide an enhanced screening review that would include meetings with external clinical experts. Based on the recommendation from Phase I, the approach to Phase II of the review changed and the review methodology was revised to offer all patients an opportunity to meet with external clinical experts (see Appendix 4b for Terms of Reference). Community supports such as counselling were also offered to all participants. The patient advocacy group, Patient Focus, were also available for support and attendance at meetings. Additional management and expert clinical resources were provided to co-ordinate and support the Phase II review process.

In this new format, patients had scheduled meetings with either an Obstetrician/Gynaecologist and Midwifery expert and/or a Paediatrician/Neonatologist. Concerns were discussed in the full knowledge of the original complaint and having reviewed the health care record. This gave patients the opportunity to explore issues and outline their experience, if they so wished. In addition, the requirement to provide community and other supports, including counselling, to the patients involved in the review was acknowledged and implemented.

An initial screen at MRHP of these complaints identified 12 patients who did not require a meeting. These patients were written to outlining that there was no deficit in care and no incident had occurred. If the patients were still concerned about their care they were invited to contact the Commissioner regarding any questions. All other patients were written to and invited to attend a meeting with one of the two types of external review team i.e., Obstetrician/Gynaecologist and Midwifery Expert and Obstetrician/Gynaecologist, Midwifery Expert and Paediatrician/Neonatologist

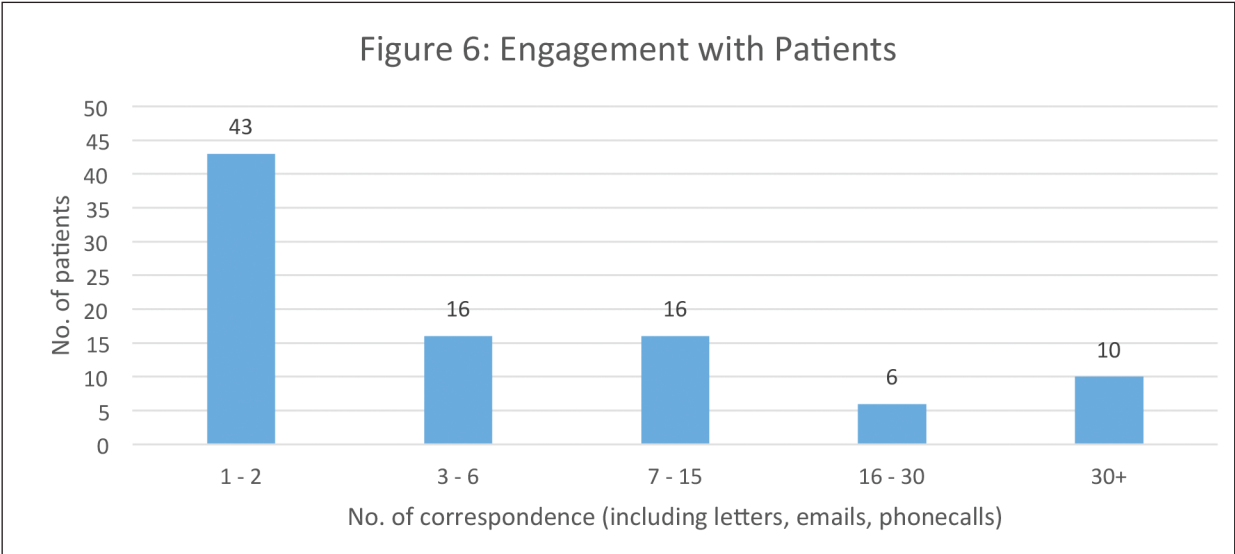
Meetings took place on dates between August 2015 and July 2016, with the majority of these taking place between August and December 2015. The later meetings were in some cases second meetings and in some cases reflected scheduling challenges.

An assessment was made by the Clinical Review Team as to any further action required e.g., the need for further meetings or information; the need for community or other services; referral to the Commissioner for discussion with expert reviewers and consideration of further action, organisational learning/training, or need for an apology from the HSE.

The proforma was a short note completed by the reviewers after the meeting, specifically for the information of the Commissioner, to record the recommendations arising from the meeting. These proformas were provided to patients, if requested.

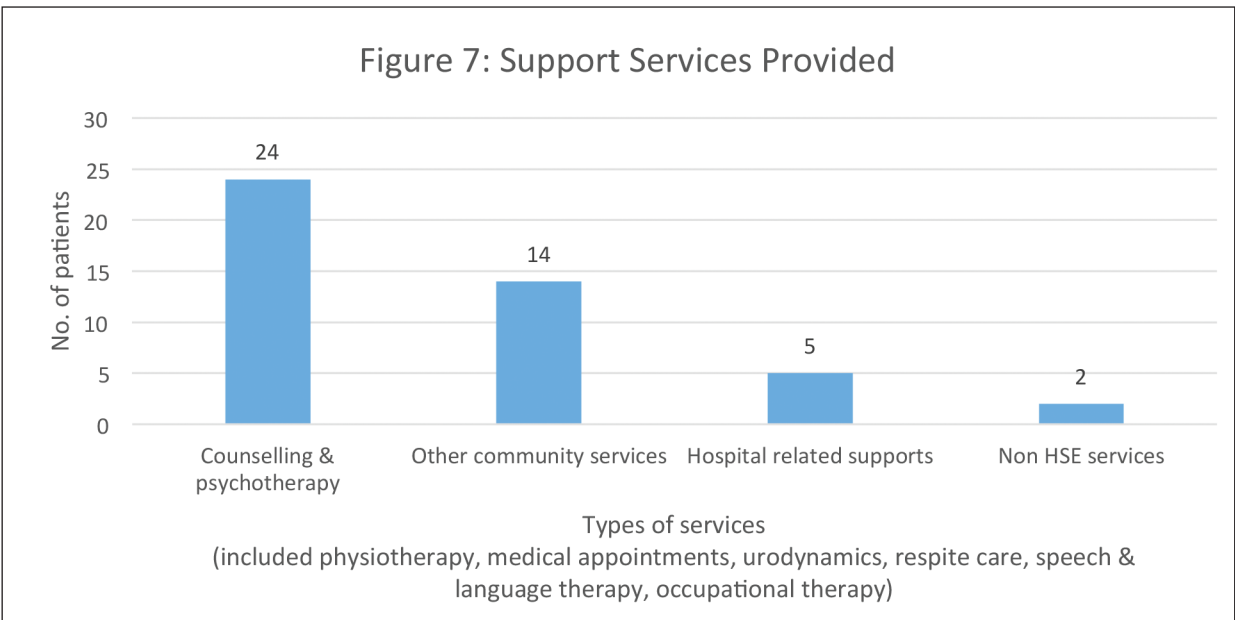
## COMMUNICATION WITH PATIENTS

Patients involved in Phase II were provided with a point of contact from the external review team, this being the DMHG General Manager. The nature and range of communication varied from patient to patient, and every effort was made to respond to individual requirements. The single point of contact provided telephone, email and mail responses to queries and requests. Figure 6 outlines the engagement with patients throughout the review process.



## ACCESS TO COMMUNITY SERVICES

Patients were offered a range of community services on foot of their expressed needs during the review. These supports were offered throughout all phases of the process to address the considerable stress and difficulties some patients experienced. The number of additional supports requested and reported are shown in Figure 7.



## CLINICAL REVIEW OUTCOMES

In line with the Phase II Terms of Reference, where investigators assessed that an incident may have occurred or whether additional information was required, these complaints were referred to the Commissioner for discussion with the external reviewers and a decision was made regarding further action.

## PHASE II FINDINGS

One hundred and twenty five patients whose cases were eligible for the screening review consented to participate in Phase II. The distribution of patient complaints in relation to the age of the patient, year in which event occurred and the nature of the complaints are shown in Figures 8, 9 and 10 below.

Figure 8: Age of All 125 Patients at Time of Event

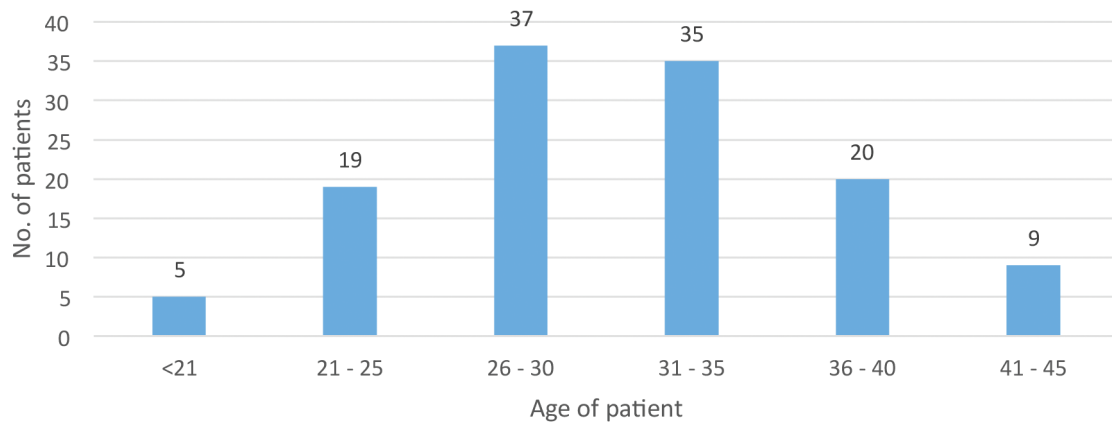
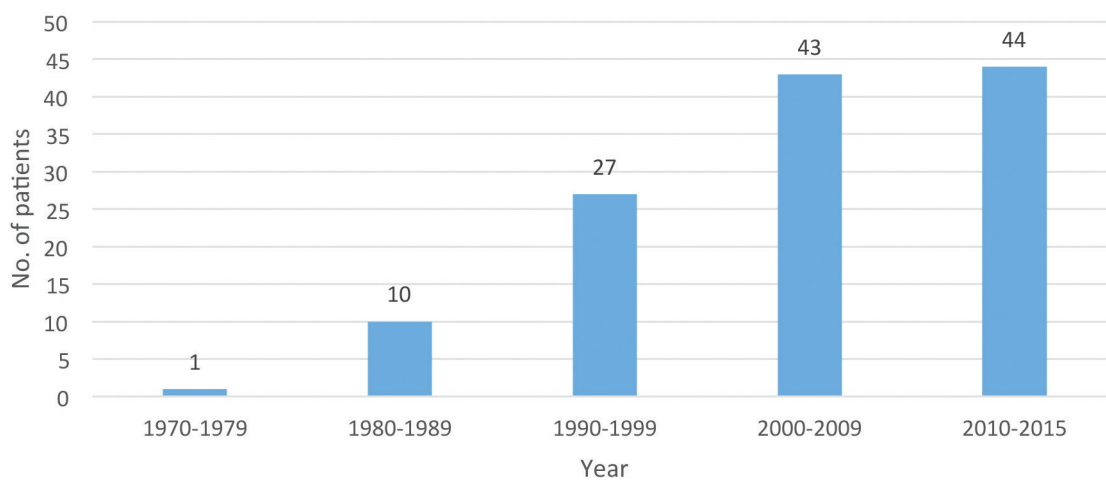
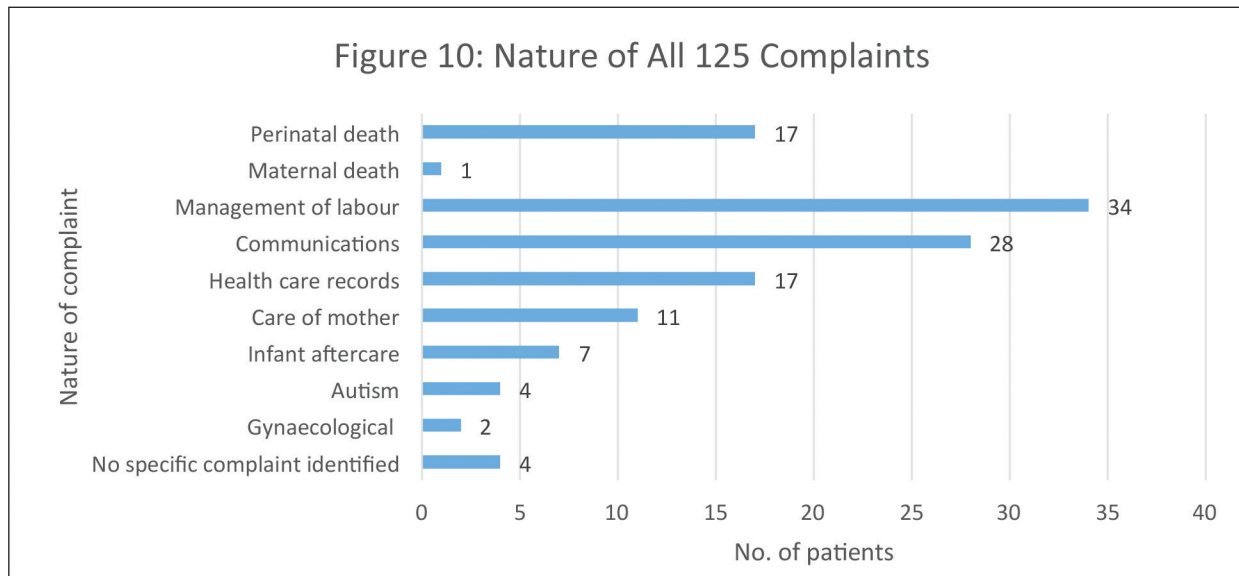


Figure 9: Year All 125 Complaints Occurred





Of these 125, 107 patients were from MRHP. The remaining 18 patients had complaints relating to other Hospital Groups and maternity services. Seven of these patients from other hospitals were offered meetings with the external reviewers either at the request of their own hospital or due to patient preference. The remaining 11 patients were referred by the Commissioner of the Complaints Review to the relevant Hospital Group CEO for meetings to take place at their local hospital.

Of the 107 MRHP patients, 82 proceeded to meet with an external Obstetrician/ Gynaecologist, Midwifery expert and where required a Paediatrician/ Neonatologist (Appendix 6b). For 12 patients from MRHP, on preliminary screen, a meeting with the external review team was not deemed necessary. These patients were written to and advised to contact the Commissioner's office if they had any further questions. Thirteen patients who were offered a meeting with the experts chose not to proceed. Where requested, access to health care records was facilitated for these patients.

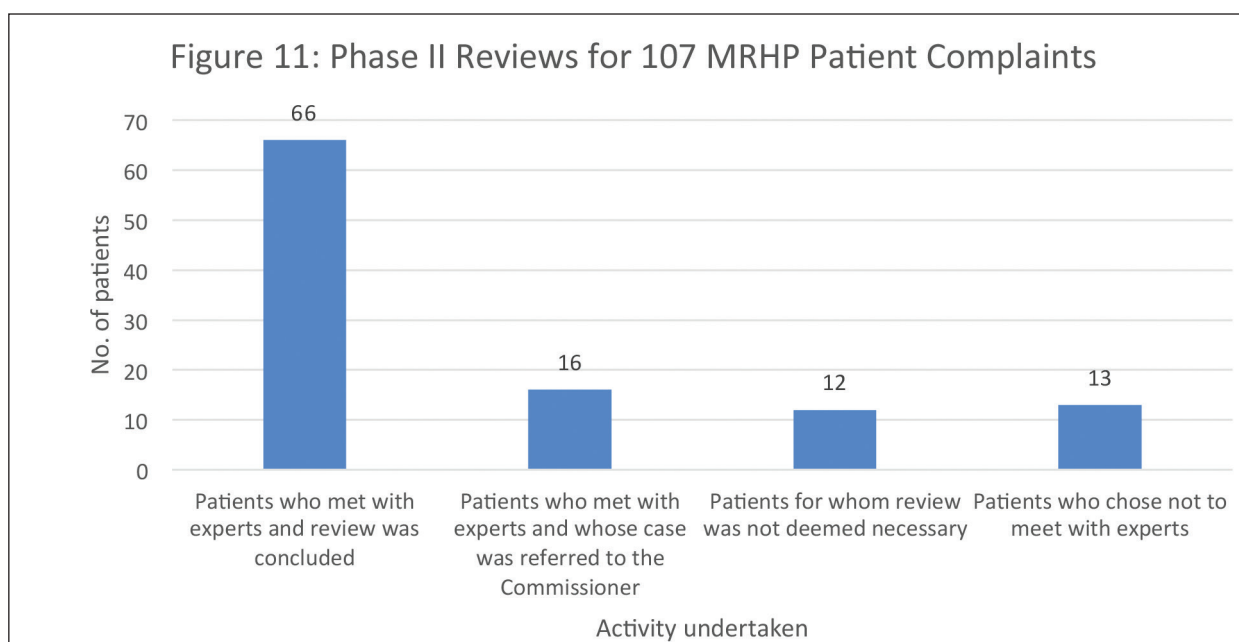
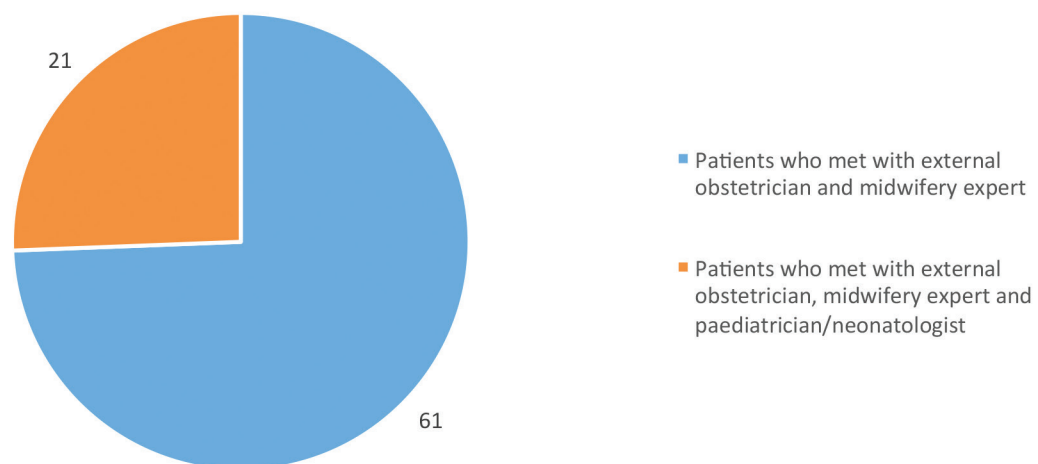


Figure 12: MRHP Patient Meetings with Expert Reviewers

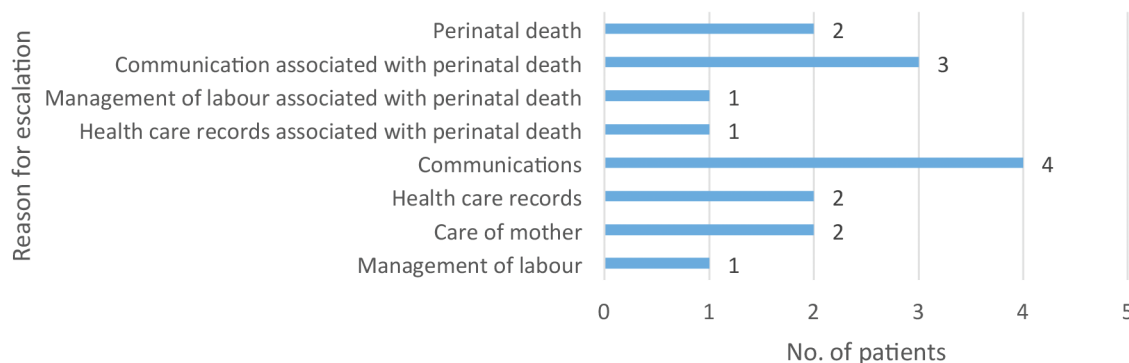


Note: During the process 102 meetings were held with MRHP patients, 18 patients had 2 or more meetings and Patient Focus were in attendance for 55 meetings.

All MRHP meetings were conducted between August 2015 to July 2016. Patients had scheduled meetings with either an Obstetrician/Gynaecologist and Midwifery expert and/or a Paediatrician/Neonatologist. Concerns were discussed in the full knowledge of the original complaint and having reviewed the health care record. This gave patients the opportunity to explore issues and outline their experience, if they so wished.

For 66 MRHP patients, the meeting with the external reviewers was the conclusion of their complaints review. Sixteen complaints were referred for further review and discussion with the Commissioner and external reviewers. The reasons for referring complaints are summarised in Figure 13 below.

Figure 13: Summary of MRHP Cases Referred to the Commissioner



Of the cases referred to the Commissioner for further discussion, 1 complaint from MRHP was referred for a full systems analysis and a range of actions were carried out to address the questions and concerns of these patients.

Community supports and/or counselling continued to be offered to all patients.



Following the conclusion of the Phase II review, the Clinical Review Team recommended the Commissioner provide 9 apology letters. Four of these apologies were for care not consistent with best practice, 3 of these involved a perinatal death and 1 related to cerebral palsy. Three apologies were related to communications and two further apologies related to lost or delayed health care records.

The external clinical reviewers advised the Commissioner that they did not identify any trends in clinical practice in individual staff currently working at MRHP, which would require referral to disciplinary processes. They did identify general themes and practices where further education, training and support for staff were needed. These are described in the section on common themes and recommendations.

## PHASE II PERINATAL MORTALITY

This review considered complaints spanning 40 years of service provision at MRHP and other maternity hospitals in Ireland. The nature of the complaints varied, in some cases they related to communications, grief counselling and support, in others they related to a perinatal death. The external clinical reviewers noted that deaths occurred under a range of circumstances and were attributable to a variety of causes. Specific conclusions cannot be drawn in this context. The recommendations arising from this review are based on the individual experience of each patient who participated.

Complaints from the 107 MRHP patients were reviewed. Where a miscarriage or perinatal death had occurred, the external review team provided an opinion in relation to the cause of each death. For these patients there were 34 complaints related to 35 baby deaths attributed to 9 different categories of clinical causes.

The clinical cause of mortality for Phase II in MRHP is shown in Figure 14 and the year these mortalities occurred is shown in Figure 15 below.

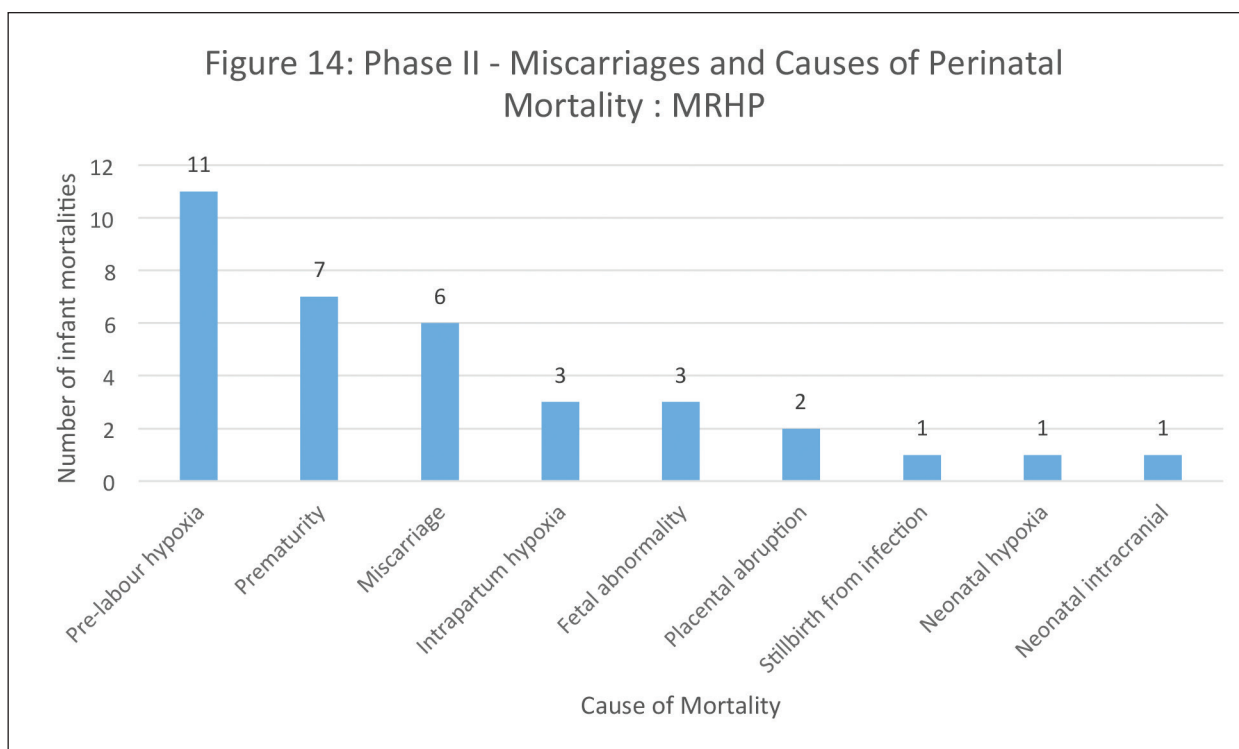
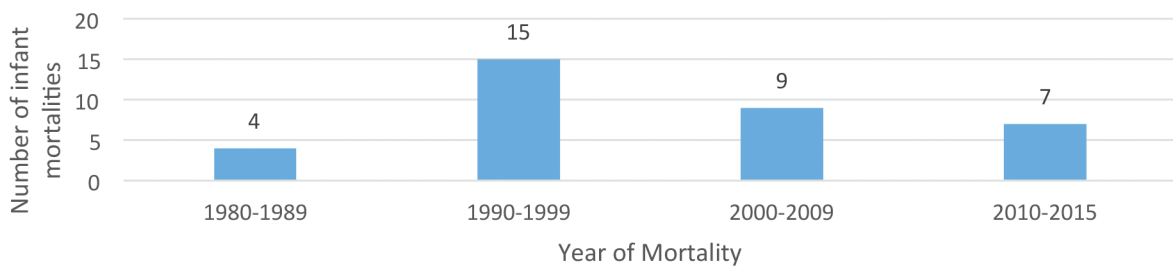


Figure 15: Phase II - Year Perinatal Mortality Occurred for MRHP

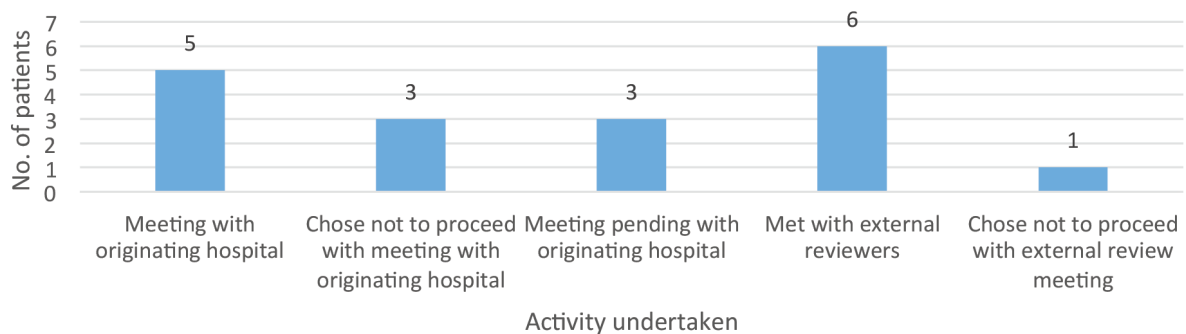


To provide a national context, in 2013, the third report of the National Clinical Audit on Perinatal Mortality in Ireland (ref 5) recorded a perinatal mortality rate of 6.7 per 1,000 births, comprising a total of 500 perinatal deaths arising from 69,146 births of infants of at least 500g birthweight or at least 24 weeks gestation. Stillbirths, early neonatal and late neonatal deaths accounted for 301 (60.2%), 162 (32.4%) and 37 (7.4%) of the 500 deaths, respectively. In MRHP in 2013 there were 1,987 births and 8 perinatal deaths resulting in a perinatal mortality rate of 4 per 1000 births.

## PHASE II REVIEWS FOR PATIENTS FROM OTHER HOSPITALS

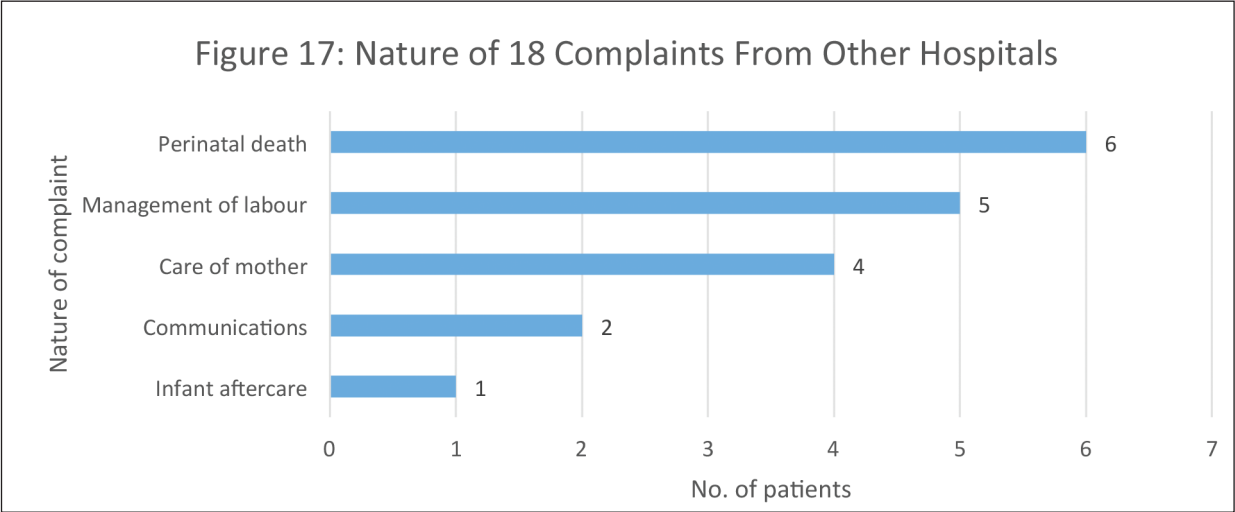
Complaints related to maternity services were received from 18 patients whose care had been delivered in other hospitals (The Rotunda Hospital, The Coombe Women and Infants University Hospital, University Hospital Limerick, Cork University Maternity Hospital, Kerry General Hospital, Midland Regional Hospital Mullingar, Midland Regional Hospital Tullamore and Galway University Hospital). Eleven patients were referred to the relevant Hospital Group for the complaints review to be conducted at that hospital. In some circumstances, either from patient preference or requests from the originating hospital, the Commissioner of the review was asked to arrange for these complaints to be reviewed and patients to meet the external reviewers who were also conducting the meetings with patients from MRHP.

Figure 16: Phase II Reviews for 18 Patient Complaints from Other Hospitals

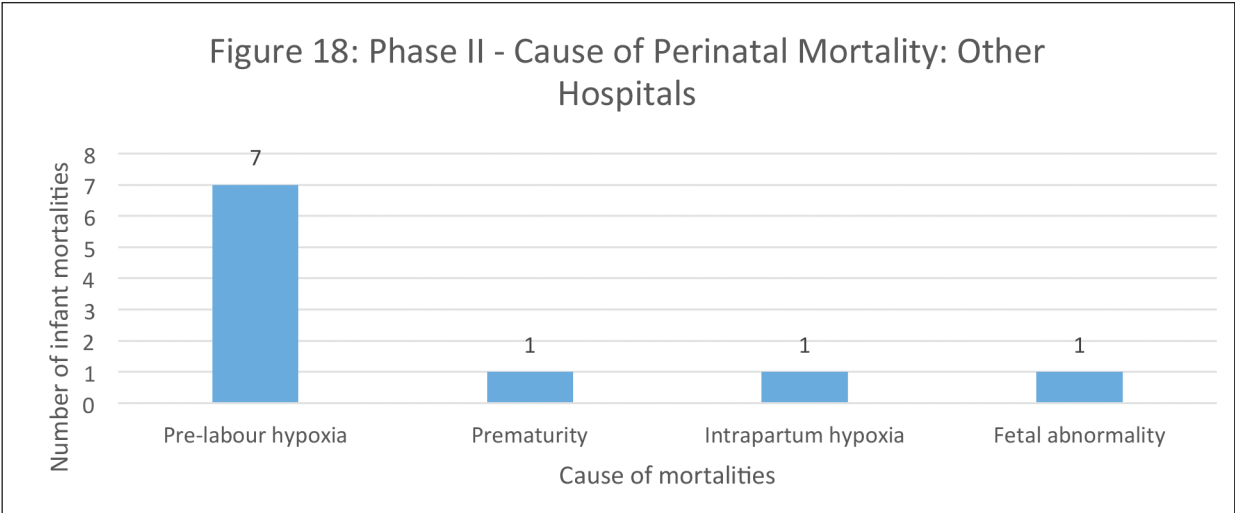


## CLINICAL REVIEW OUTCOMES FOR PATIENT FROM OTHER HOSPITALS

Of these 18 complaints, 6 related to perinatal deaths, 5 to the management of labour, 4 to the care of the mother, 2 to communications and 1 to infant care.



Altogether there were 10 perinatal deaths. The cause of perinatal mortality is shown in Figure 18.



The external clinical reviewers noted that deaths occurred under a range of circumstances and were attributable to a variety of causes. The context of this report is that it covers a period of 40 years and no specific conclusions can be drawn from the number of perinatal deaths occurring over this time frame.

Subsequent to the review of these complaints 2 patient complaints were recommended for a full systems analysis. Another 2 patients had already completed a full systems analysis at the relevant hospital.

## PHASE II COMMON THEMES

Similar themes were noted in the Phase II review to those highlighted in Phase I. In Phase II, 125 complaints that were reviewed revealed concerns in the following areas:

1. CTG monitoring emerged as a very serious issue in 3 baby deaths in the review and another baby delivered in MRHP and identified by the reviewers who had not been the subject of a specific complaint.
2. Patients highlighted a lack of communication around their care. This was particularly difficult for patients and families who needed support and answers to their questions following a baby death.
3. Patients frequently felt that they had not been treated with respect or their dignity had not been preserved.
4. A lack of bereavement support was again highlighted.
5. There were delays in response to complaints or in response to clinical issues experienced by mothers post-delivery.
6. Patients encountered difficulties accessing copies of their health care records.

## PHASE III

In both Phase I and Phase II the reviewers raised concerns regarding the failure to respond to the pathological (grossly abnormal) CTGs in 3 of the MRHP cases referred to the Commissioner. In addition, the care of a fourth baby came to the attention of the review team. The care of this baby had not been reviewed previously. All of these families were advised by the reviewers of their opinion that the delay in responding to these pathologically abnormal CTGs may have been a contributory factor in 3 perinatal deaths and 1 live birth. The 4 cases described above occurred in MRHP in the 1980s and 1990s.

As a consequence, the external review team recommended to the Commissioner of the Review that a historical review of CTGs in MRHP between 1985 and 2014 be undertaken in line with the specific Terms of Reference for a Historic Review of CTGs at MRHP (Appendix 4c).

## PHASE III METHODOLOGY

The purpose of this review was to identify perinatal deaths and cases of cerebral palsy attributable to a delay in identifying and responding to pathological changes on CTG tracings at the MRHP between 1985 to the end of 2014 or whether there was any persistence of this practice into recent years.

The scope of the review comprised all perinatal deaths and identifiable cases of cerebral palsy occurring from 1985 to the end of 2014 at MRHP. Very premature infants, those with foetal abnormalities, deaths where there has already been an expert review and any injuries or deaths where the States Claims Agency has completed their formal processes were excluded.

This historical review was carried out in November 2016 by a team of 12 external expert Midwives and 2 external Consultant Obstetrician/Gynaecologists (Appendix 6c). None of these experts were associated with the MRHP.

## PHASE III FINDINGS

A total of 90 cases of perinatal deaths, fitting the review criteria, were identified at MRHP. Communication with the State Claims Agency did not identify any cases of cerebral palsy which met the review criteria. A review confined to the CTGs in the health care records of these 90 babies did not reveal any further pathological CTGs that might have been a contributory factor in these outcomes.

The Commissioner is reassured that the deficits noted in the 4 cases described above which took place in the 1980s and 1990s were not replicated and the CTG review has not led to the discovery of any similar cases.

## PHASE II AND PHASE III RECOMMENDATIONS

The Reviewers concurred with the recommendations published in the Phase I Review. The following are the recommendations arising from Phase II and Phase III.

1. Each hospital must ensure a robust clinical governance system is in place with a clearly identifiable individual with the accountability and authority to ensure quality of care and to implement improvements.
2. CTG interpretation training must be mandatory and updated every 2 years in all maternity units. This must apply to all Midwives, Non Consultant Hospital Doctors and Consultant Obstetrician/Gynaecologists.
3. The CTG monitoring equipment must be serviced and maintained in good working order including accuracy of time and date.
4. There should be immediate communication with the patient and family when they have a concern or an adverse event has occurred or have suffered a bereavement. Communications across the spectrum of maternity and infant care remains an area of concern for families and one which the Hospitals and professional staff will need to invest additional time and commitment. A culture of empathetic care for patients needs to be fostered across the spectrum of maternity and obstetrical care.
5. Timely open disclosure to patients and families is mandatory in the event of a possible adverse experience.
6. There should be experienced staff available to provide immediate support to each patient who has suffered a pregnancy loss. There should also be access to bereavement support and counselling to each patient who has suffered a pregnancy loss. Additionally a quiet and private environment should be provided for patients who are remaining in hospital during their immediate bereavement.
7. There should be a single point of contact for a patient who has a complaint or a poor outcome from a pregnancy so that they don't experience undue difficulty in having their questions addressed or engaging with hospital services.
8. The availability of perinatal mental health services is recommended and desirable for patients who are suffering grief, depression or other mental health problems relating to their pregnancy and delivery. Specialised psychiatric expertise should be made accessible through the larger Hospital Groups networks.
9. Counselling and access to community services should be provided if ongoing support is required.
10. In the event of a perinatal death every effort should be made to gain consent for a post mortem by a Perinatal Pathologist experienced in these examinations.
11. Hospitals should provide both support and on-going education to their obstetrical staff to enhance their professional development and coping strategies in their demanding roles.

12. External oversight should be provided in order to assure the public of the quality of maternal services. The National Women and Infants' Health Programme (NWIHP) should develop a model to ensure external oversight is applied across each hospital group. The Irish Maternity Indicator System (IMIS) currently provides information for local scrutiny of clinical maternity activity. The NWIHP will expand the role of IMIS to provide for Group and National level oversight, as well as local.

## CONCLUSION

This review of complaints relating to maternity services has added to the understanding of the needs of mothers and babies for high quality and safe care in a supportive environment. The complaints that precipitated this review and a number of reports referenced in this document have led to improvements in maternity services in Ireland.

The provision of expert clinical care requires many qualities of compassion, sensitivity and understanding, in addition to clinical and communication skills. For many of the complaints reviewed as part of these processes, these qualities were not always demonstrated.

This complaints review began with the intent to clarify the nature of the complaint, determine whether the complaint required a referral to the Commissioner of the Review for consideration of further action, and to facilitate essential learning from complaints to inform future performance and behaviour of management and Clinical Staff. The review was then expanded to provide patients with the opportunity to meet external clinical experts in order to have their questions addressed in the context of their health care record and to provide the opportunity for them to describe their personal experiences.

The experience of conducting this large scale historical complaints review provides the health services with an insight into how we must provide compassionate care and timely communications in a manner which appreciates the personal experiences lived by parents who attend our maternity services. It is hoped that this report will help the HSE have a greater understanding of the challenges and difficulties of conducting such a retrospective complaints review and how reviews of this nature might be managed in the future. A number of lessons learned relating to the management and governance of any future large scale reviews are described in Appendix 1.

To the parents, their families and loved ones, we would like to acknowledge that this has been a difficult and stressful process for many. We are aware that the length of time it took to complete the complaints review for the large number of participants has been hard, particularly for those who have lost a baby and who were seeking answers and anxious to have their complaints heard.

## GLOSSARY

- **Clinical Review Team** – A Group of Obstetrician/Gynaecologists set up to review a number of health care records as part of the Phase I Complaints Review process.
- **CMO** – Chief Medical Officer
- **Commissioner of the Review** – The Commissioner of an investigation differs across the health system, but is typically the senior accountable officer in a service, division or care group that commissions an investigation of a clinical or non-clinical safety incident.
- **CTG** – Cardiotocography is a technical means of recording the baby's heartbeat and the contractions of the uterus during pregnancy.
- **DMHG** – Dublin Midlands Hospital Group
- **Referred Cases** – Complaints brought to the attention of the Commissioner following meeting(s) with external reviewers.
- **Full Systems Analysis (FSA)** – 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.
- **HIQA** – Health Information & Quality Authority
- **Historical Review** - This is a historic review of CTGs, arising from concerns raised during the review. The clinical investigators identified cases where there was a delay in identifying and responding to pathological changes on CTG tracings.
- **Intrapartum hypoxia or infection** - Lack of oxygen supply or development of foetal infection during labour.
- **Intrapartum hypoxia** - Lack of oxygen supply to the foetus during labour.
- **IMIS** - Irish Maternity Indicator System
- **Miscarriage** - Any pregnancy which ends with the death of the embryo or foetus before 24 weeks of pregnancy.
- **MRHP** – Midland Regional Hospital Portlaoise
- **Neonatal hypoxia** - A newborn experiencing lack of oxygen supply which may have begun before delivery.
- **Neonatal intracranial haemorrhage** - Bleeding in the brain in the newborn period.
- **NIMLT** – National Incident Management and Learning Team



- **NWIHP - National Women and Infants' Health Programme**
- **Pathological CTG:** A CTG that has one abnormal feature or two non-reassuring features.
- **Patient Focus:** Patient Focus is one of Ireland's leading national patient advocacy organisations. Formed in 1999, Patient Focus provides a point of contact and other supports to patients who have been damaged by the Healthcare system. We assist people to try and resolve difficulties as early as possible after they arise. We also aim to ensure the preservation and enhancement of patient rights in all healthcare settings.
- **Placental abruption -** Acute separation of a placenta (afterbirth).
- **Prelabour antepartum haemorrhage -** Vaginal bleeding in pregnancy before the onset of labour.
- **Prelabour hypoxia -** Lack of oxygen supply to the foetus before the onset of labour.
- **Prelabour twin to twin transfusion -** Transfusion of blood from one identical twin to the other before the onset of labour.
- **Prematurity -** A baby born before 36 weeks of pregnancy.
- **Pro Forma –** Written note/form completed after the meeting with families to advise the Commissioner whether further action was required.
- **SIMT –** Serious Incident Management Team
- **Stillbirth from infection -** A baby who is born dead where the death has been due to infection.
- **World Health Organisation - Ten Group Classification –** This classification system allows for the analysis of all births and is used primarily in the analysis of caesarean section deliveries. The classification system is based on characteristics of pregnancy according to whether the pregnancy is a singleton or multiple (twins etc.), nulliparous (first pregnancy), multiparous (second and subsequent pregnancy), or multiparous with a previous caesarean section. The classification details whether the baby is presenting head first (cephalic), by the breech or other mal-presentation. The system classifies labour as either spontaneous or induced and birth as either term or pre-term.

## REFERENCES

1. RTÉ Prime Time Investigates: Fatal Failures; aired January 30th 2014
2. 'HSE Midland Regional Hospital Portlaoise, Perinatal Deaths (2006-date)' Report to the Minister for Health, Dr James Reilly; Dr. Tony Holohan; 24th February 2014
3. Report on the Investigation into the Safety, Quality and Standards of Services Provided by the Health Service Executive to Patients in the Midland Regional Hospital Portlaoise HIQA; 8th May 2015
4. A Review of 28 Maternity Case Notes by a Clinical Review Team undertaken at the request of the HSE; Dr. P. Boylan; June 2015
5. Perinatal Mortality in Ireland Annual Report 2013; Manning E., Corcoran P., Meaney S., Greene R.A., on behalf of the Perinatal Mortality Group; 2015
6. Performance Diagnostic Report (May 19th 2014) on the Midland Regional Hospital Portlaoise Dublin: Acute Hospital Division, HSE; I. Carter; 2014
7. Creating a better future together; National Maternity Strategy, 2016-2026: Department of Health: 2016.
8. National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death; HSE; August 2016

## APPENDICES

### APPENDIX 1

#### Managing a Large Scale Review - Lessons Learned

This complaints review began with the intent to clarify the nature of the complaint, determine whether the complaint was sufficiently serious to require referral to the Commissioner of the Review for consideration of further action, and to facilitate essential learning from complaints to inform future performance and behaviour of management and Clinical Staff. It was expanded to provide patients with the opportunity to meet independent clinical experts in order to have their questions addressed in the context of their health care record and to provide the opportunity for them to describe their personal experiences.

#### FEEDBACK

Our learning has been informed by feedback gathered from various sets of interactions, including:

- Patients
- Independent clinical reviewers
- Clinical Review Team workshop
- Patient Focus
- Safety Incident Management Team Steering Committee Meetings
- Series of meetings with the Chief Medical Officer and Department of Health officials
- Collaborative meetings with HSE, Department of Health and Safety Incident Management Team representatives

#### ISSUES IDENTIFIED

1. Where a large volume of complaints need to be addressed, it is vital to invest time in engaging with patients, advocacy groups, expert reviewers, the steering committee for the project, the relevant HSE national divisions, e.g. the Acute Hospital Division, Hospital Groups, the Quality Assurance Verification Division, the relevant National Clinical Programme and where relevant, legal advice, to develop optimal terms of reference and procedures to conduct the review at the outset. The Phase I review process was limited to a clinical chart review. The expert reviewers' opinions were not informed by an interaction with the patients. The process therefore focused on the care as documented in the health care record and did not include engagement with the patients. It became clear from feedback from patients and Patient Focus that some had expected they would have a personal meeting to address their complaint.

2. One of the key recommendations from the Phase I Report is that patients and families should be invited to participate in the review and that they should meet the Commissioner or his or her designate to relay the conclusions and recommendations in their individual case. This knowledge informed the complaints review process adopted for the remaining 125 patients in Phase II, whereby patient meetings with independent experts were integrated into the review.
3. Some patients remained dissatisfied with the complaints process particularly in relation to the time it took to schedule meetings and their preference to have formal written reports on each individual case which was not part of the terms of reference. This may have been avoided if patients were involved in, and had a better understanding of the review process as already discussed.

Not all patient complaints required the same approach, some of the concerns related more to the manner in which care was delivered rather than issues relating to the quality of care itself. This indicated the need for a more differentiated approach to the review which should be informed by better understanding the perspective of the patient.

A further issue identified was that, unknown to the Commissioner, a small number of the patients included in Phase I were already involved in a full systems analysis of their care. This resulted in duplication of effort and from the perspective of the patient the impression that there was a lack of coordination in the overall processes. Patients should be asked from the outset if they were already participating in other formal review processes in order to make a decision to progress their complaint through a single management route.

These issues may also have been addressed by direct and earlier communication with the patients

4. The Commissioner and reviewers noted that this complex process would have benefited from more support, for instance:
  - a. Communications with patients would have been improved if a patient advocacy expert had been included as a member of the team and been available to patients to explain the timelines and processes that were ongoing.
  - b. Investment in data management, report writing and analysis throughout the review, dedication of additional staff for patient engagement, triage of complaints and development and design of appropriate methodologies to streamline such a high volume of historical complaints is essential.
5. The Phase II review process was inevitably protracted by the requirement to schedule personal meetings for patients and expert reviewers. It proved challenging to balance the demands of timely complaint reviews with the necessity to provide appropriate opportunities to meet the experts engaged in the process.
6. Very early in the course of Phase I Review, it became clear to the first Commissioner of the Review that patients were finding it extremely difficult and distressing to re-live some of the experiences that related to their maternity care. Psychological support and counselling was offered at an early date to all patients. A specific HSE point of contact was provided for psychological counselling or other community

supports. Patient Focus was available to patients throughout the process and their contact information was also provided. Likewise a single point of contact was offered for any questions about the complaints review processes, scheduling of appointments with reviewers or any of their needs that related to hospital services. This was provided through the Office of the Commissioner. The provision of these liaison personnel were communicated in all correspondence to the patients and are a very important element of management of patients' understandable distress and concerns in the course of their complaints review. We recommend this for any future reviews of a similar nature.

7. If patients required further meetings with the same review team to address their questions or a second opinion from a different review team, this was facilitated. Flexibility relating to additional meetings or second opinions is a helpful element to note for future reviews. Patients should be appraised at the outset that the review process may take considerable time to complete.
8. The external reviewers noted that the volume of work involved was considerable and that scheduling the large number of appointments was challenging. The demand on Obstetric and Gynaecological staffing resources in Ireland was considerable and this must be borne in mind when tailoring further complaints' reviews in the future. Ideally the majority of complaints should be dealt with promptly and immediately by the hospital in question and external reviewers only invited to participate if it is deemed essential to the complaints review process or to any recommended full systems analysis. Improved governance arrangements in maternity units facilitate more timely and appropriate response to complaints. All hospitals must practise open disclosure to patients and families and implement prompt complaints reviews and/or incident management reviews.
9. The external reviewers expressed their appreciation of Patient Focus volunteers accompanying the patients to their meetings with the clinical experts. These experts recommended that in future, availability of a Social Worker would be helpful during meetings if patients did not bring other supports (e.g., Patient Focus).

## APPENDIX 2

### CURRENT STATUS OF IMPLEMENTATION OF ALL RECOMMENDATIONS

The RTÉ Prime Time Programme, Fatal Failures, in January 2014 highlighted failures of care in the MRHP which resulted in a range of reviews by the Chief Medical Officer, HIQA and this complaints review. The patients who related their experiences have helped the HSE to develop significant changes in maternity and infants services, both in the MRHP and nationally. These developments are summarised below.

#### Midland Regional Hospital Portlaoise

- General Manager for Maternity Services and Director of Midwifery was appointed in February 2014.
- The DMHG implemented a new clinical and operational governance model including maternity services.
- Training Needs Analysis completed and implemented including mandatory K2 (on-line training) and workshops on CTG training.
- A Clinical network between MRHP and the Coombe Women and Infants University Hospital (CWIUH) began in 2014 and continues. A Memorandum of Understanding was signed off in March 2015 between the Board of the CWIUH and the DMHG.
- The Medical Director of Clinical Integration was appointed in 2015.
- A process of streamlining care pathways has been completed. These care pathways are in line with the CWIUH.
- Two additional Obstetric Consultants and two Neonatologists in place. These are shared posts between the CWIUH and Maternity Services Portlaoise. Recruitment for a Neonatal Psychiatrist and Pathologist is ongoing.
- The Maternity Governance Multidisciplinary Committee meets weekly and oversees the management of the Maternity Services at MRHP. This committee reports into the Senior Management Team of MRHP.
- Multidisciplinary Clinical Audit Committee put in place at MRHP.
- Multidisciplinary Guideline Development Committee in place at MRHP.
- HSE Open Disclosure Policy fully implemented at MRHP.
- National Standards for Bereavement Care following Pregnancy (August 2016) implemented at MRHP.
- Bereavement Specialist in place at MRHP.
- Bereavement education days were provided, by the Irish Hospice Society.
- Bereavement room to be completed by Quarter 3 2017 at MRHP.

- Creating a Better Future Together, National Maternity Strategy 2016 -2026. The Maternity Service are progressing with its implementation at MRHP.
- The National Incident Management System (NIMS) implemented and reports incident trends.
- A Quality and Patient Safety Action Plan was developed and a Serious Incident Management Team is in place at MRHP.
- Midwifery staffing in accordance with international recommendations and Birthrate Plus staffing tools at MRHP.
- Workforce plan developed and midwifery shift-leaders in place 24/7 at MRHP.
- Clinical Skills Facilitator Maternity in place at MRHP.
- Florence Nightingale Leadership Programme undertaken by midwifery managers at MRHP.
- Caring Behaviour Assurance System –Ireland programme implemented. This programme engages individuals, teams and Executive Boards in achieving quality and safe care for patients and families and for staff.
- Tailored customer care programmes were provided for all staff at MRHP.
- Patient/ Staff satisfaction surveys were carried out at MRHP.
- Staff experience – we seek and value feedback and ideas for improvement, through open forums and staff meetings at MRHP.
- Fibronectin Point of Care Test will be introduced Quarter 2 2017. This test identifies women who are in pre-term labour and who may require transfer to a tertiary hospital. It also reduces unnecessary transfer of pregnant women from MRHP.
- A Capital Project to provide new ambulatory facilities for obstetrics and gynaecology has been approved and is awaiting funding at MRHP.

## PROGRESS ON NATIONAL MATERNITY SERVICES

### National Acute Hospitals Division

#### Context

The Health Information and Quality Authority (HIQA) published a report of the investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients in the MRHP (8th May 2015).

The report contained eight separate recommendations. The Department of Health had responsibility for recommendations one to four and HSE had specific responsibility for recommendations four to eight inclusive.

In July 2015, the HSE established an Implementation Group chaired by Mr Liam Woods, Interim National Director Acute Hospitals Division with multidisciplinary membership including the Clinical Care Programme for Obstetrics and Gynaecology and service user representation. The purpose of the Implementation Group was to develop and oversee the Plan to deal with the recommendations pertaining to MRHP and their wider implications across the acute hospital system.

The HSE Implementation Group also included within its remit the relevant recommendations from the following reports:

- HSE Midland Regional Hospital Portlaoise, Perinatal Deaths (2006 –date) Report to the Minister of Health, Dr James Reilly TD from Dr Tony Holohan, Chief Medical Officer (CMO Report) February 2014 (ref 2);
- HSE Midland Regional Hospital Portlaoise, Performance Diagnostic (Carter Report) May 2014 (ref 6);
- A Review of 28 Maternity Case Notes by a Clinical Review Team, undertaken at the request of the HSE (“A Review of 28 Maternity Case Notes by a Clinical Review Team undertaken at the request of the Health Service Executive” Phase I) May 2015 (ref 4).

#### Governance and Oversight

From August 2015, the Implementation Group has met frequently, reports monthly (19 reports to date) and is held to account by the HSE Director General and Leadership Team. Multiple meetings of sub groups and other relevant stakeholders took place to progress the broad range of recommendations.

Separately the Minister for Health put in place a Department of Health Oversight Group (which oversees implementation of all eight HIQA recommendations) chaired by Dr Tony Holohan, Chief Medical Officer. That Group met on 15 occasions to date from June 2015 with HSE invited and in attendance on 12 occasions since September 2015. Once approved by HSE Leadership, the HSE submits a comprehensive status report each month to the Office of the Chief Medical Officer, Department of Health setting out:



- a) The status of implementation of the recommendations from the above referenced Reports.
- b) The status of the specific issues arising from the Ministers meeting with families in Portlaoise on 13 May 2015 and his subsequent visit in January 2016 are also reported monthly.
- c) Phase I and Progress of Phase II

### Ongoing Oversight

Significant progress has been made in implementing the recommendations within the referenced reports and work will continue to improve the quality and safety of the maternity services in line with Maternity Strategy. The recently established National Women & Infants Health Programme which is nested within the HSE National Acute Hospitals Division will play a key role in overseeing the implementation and completion of any remaining recommendations. The Programme will work closely with all relevant stakeholders including the Clinical Programme for Obstetrics and Gynaecology to develop further plans for maternity services and seek resources to give effect to their implementation.

Tables 1 & 2 provide summaries of the progress made to date in relation to implementing the recommendations across the acute hospitals system. In addition it is important to highlight the following:

- **National Maternity Strategy**

In January 2016, the first National Maternity Strategy, Creating a Better Future Together (ref 7), was published by the Health Minister and provides the blueprint for the maternity services for the next 10 years. The recently established National Women & Infant Programme which was a recommendation within the above Reports will lead out on developing the Implementation Plan to give effect to the Maternity Strategy.

- **National Bereavement Guidelines following Perinatal Death and Baby Loss**

The National Bereavement Guidelines following Perinatal Death and Baby Loss were launched in July 2016 (ref 8). These new standards clearly define the care parents and families can expect to receive following a pregnancy loss or perinatal death. The standards will be implemented and applied across the health service in all appropriate hospitals and settings.

All Maternity Hospitals/Units will now establish or further develop Bereavement Specialist Teams to assist and support parents, families and professionals dealing with pregnancy loss. These teams will comprise staff members who have undertaken specialist and extensive education in bereavement care and will include a dedicated clinical midwife specialist in bereavement care for each maternity unit.

- **Funding in 2016**

€3 million additional funding was provided by the Government for maternity services within the HSE 2016 Service Plan. This enabled the HSE to approve the recruitment of additional staff to support the work of current staff in the provision of safer and more comprehensive services. These include:

- an additional 100 midwives
- 14 Directors of Midwifery to ensure all 19 Maternity Units has senior midwifery management
- 14 bereavement specialists
- Other additional clinical posts such as Consultant Neonatologists, Perinatal Pathologist, and Patient Advocacy.

- **Establishing Obstetric Clinical Networks**

A number of Clinical Networks are already established and clinical oversight and governance within the Hospital Groups has been strengthened. For example the DMHG has an established clinical network lead by the Coombe Women and Infant University Hospital and incorporating MRHP (MRHP). The RSCI Hospital Group has a similar network in place incorporating Our Lady of Lourdes Hospital Drogheda, Cavan General Hospital and the Rotunda Hospital. Saolta Hospital Group already has a Women and Childrens Directorate and the development of a clinical network will be developed as part of the Groups Five year strategy. The development of clinical networks remains a high priority for all hospital groups.

**Table 1- National Acute Hospitals Division - Status of Recommendations**

Ref	HIQA (Portlaoise) Recommendation	Progress Update
1-4 (& 9)	Are owned by DOH.	HIQA recommendations one through four are owned by the Department of Health.  (Note Minister is currently progressing administrative Boards for Hospital Groups)
5	The Health Service Executive (HSE) should ensure the appointment of a director of midwifery, before September 2015, in all statutory and voluntary maternity units and Hospitals in Ireland that currently do not have such a post.	Six vacancies remain and further competitions to fill remaining posts will be scheduled for April 2017.
6	<p>The Health Service Executive (HSE), along with the chief executive officers of each Hospital Group, must ensure that the new Hospital Groups prioritise the development of strong clinical networks underpinned by:</p> <p>A group-based system of clinical and corporate governance informed by the National Standards for Safer Better Healthcare.</p> <p>A clearly defined, agreed, resourced and published model of clinical service delivery for each Hospital within the group. This must be supported by clearly defined, agreed and documented patient care pathways to ensure that patients are managed in or transferred to the most appropriate Hospital.</p> <p>Regular evaluation and audit of the quality and safety of services provided.</p> <p>Systems to support a competent and appropriately resourced workforce.</p> <p>A system to proactively evaluate the culture of patient safety in each Hospital as a tool to drive improvement.</p>	<p>It is envisaged formal guidance from Department of Health will assist Hospital Groups in finalising the development of Strategic Plans. The establishment of Hospital Group Boards are required to give effect to HG Strategic Plans</p> <p>Each Hospital Group produced a report setting out their risk concerns in the context of the HIQA Report (with a view to identifying and stratifying immediate risks and mitigating actions). A consolidated report was discussed at HSE Leadership on two occasions in June 2016 and a copy shared with DOH in July 2016.</p> <p>Hospital Groups strategic plans will reflect improvement plans. These Plans will include inter alia a clear delineation, role and function for each hospital within the Group. The findings and risk concerns identified by the Hospital Groups will inform configuration and organisation of services within each Group.</p> <p>The National Women &amp; Infants Health Programme Office was established in January 2017. Its main primary objective in 2017 is to develop an Implementation Plan arising from the publication of the Maternity Strategy in 2016.</p>

Ref	HIQA (Portlaoise) Recommendation	Progress Update
6	<p>Systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted, as per the National Standards for Safer Better Healthcare.</p> <hr/> <p>Effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions.</p> <hr/>	<p>The HSE Midwifery Planning report was finalised in April 2016. Birth rate plus methodology used to undertake a workforce analysis of the midwife to birth ratio within Maternity services. 2016 Service Plan provided 100 posts and 2017 NSP will endeavour to address gaps in manpower to incrementally address the staffing requirements.</p> <hr/> <p>Ten priorities are identified for on-going mandatory clinical training for all clinical staff in respect of day-to-day care of pregnant women. (Maternal Sepsis, Vaginal Breech Delivery, Early Pregnancy and Vaginal Bleeding, Major Postpartum Haemorrhage, Cord Prolapse, Shoulder Dystocia, Management of Pulmonary Embolism, Maternal Collapse, Eclampsia, Intrapartum Fetal Monitoring CTG).</p> <hr/> <p>Guidance prepared for 9 of the 10 priorities. A national Steering group established to oversee the implementation of the training programme. Assessment of existing compliance with existing training programmes is underway across the hospital system.</p> <hr/> <p>Reporting and publication of monthly Maternity Patient Safety Statement commenced in February 2016. A national Oversight Group established which includes service user representation seeks assurance &amp; tracks and trends the information reported to support performance improvement.</p> <hr/> <p>Reporting and publishing monthly Hospital Patient Safety Statement is anticipated to commence in April 2017.</p> <hr/>

Ref	HIQA (Portlaoise) Recommendation	Progress Update
6		<p>An annual Clinical Audit Plan, in line with the National Clinical Effectiveness Committee (NCEC) model of national clinical audit, is finalised.</p> <hr/> <p>National Director of HR has established a working group to develop leadership capability and capacity within Hospitals and ensure that clinical staff have the necessary skills and capacity to undertake their assigned roles.</p> <hr/> <p>Business case for a National Patient Safety Culture Survey among staff in each Hospital is finalised in consultation with DOH.</p> <hr/> <p>National Patient Experience Survey launch April 2017. Survey goes live in May with publication of reports due in December 2017.</p> <hr/> <p>An acute national complaints process has been developed by the HSE, each Hospital has a complaints officer and each Hospital Group has a person responsible for complaints.</p> <hr/> <p>There are now named Complaints Officers for all Hospitals published on the HSE website. Acute national complaints process has been developed by the HSE. Each Hospital has a complaints officer and each Hospital Group has a person responsible for complaints.</p> <hr/> <p>Report on analysis complaints is published annually. Learning from complaints continues at local service level and National capacity to learn from complaints is being developed.</p> <hr/>

Ref	HIQA (Portlaoise) Recommendation	Progress Update
6		<p>Significant progress has been made to develop a system to measure and report incidents across the Acute Hospital Division which will provide visibility to investigations underway and investigation status. A Special report on Serious Reportable Events (SREs) reported between March 2014 and September 2015 was published on the 26th November 2015.</p> <p>Specific immediate resource requirements from the Phase I report were progressed under 2016 Service Plan. Medium term capital and revenue requirements are subject to ongoing discussion with the DOH within context of ongoing Service Planning.</p>
7	<p>The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin Midlands Hospital Group should:</p> <p>Review all of the findings of this investigation and address the patient safety concerns at the Midland Regional Hospital, Portlaoise.</p> <p>Immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital.</p>	<p>There is a continuous improvement plan in place for audit and quality assurance for NEWS.</p> <p>100% of staff involved in clinical service delivery are fully trained and new staff appointed have NEWS training incorporated into their induction.</p> <p>100% of Midwifery and Obstetric staff have attended the IMEWS training to date and all new staff including NCHDs are trained at induction.</p> <p>Protocol formalised to ensure named Consultant responsibility for each patient within ED.</p> <p>An Advanced Nurse Practitioner was appointed to support appropriate treatment and discharge of patients.</p> <p>A formal ambulance bypass protocol for paediatric trauma was reissued in April 2015 by the National Ambulance Service and is fully operational.</p>

Ref	HIQA (Portlaoise) Recommendation	Progress Update
7	<p>Publish an action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services. This action plan should include a named person or persons with responsibility and accountability for implementation of recommendations and actions in internal and external reviews and investigation reports, and be continuously reviewed and updated in order to drive improvement and mitigate risk.</p>	<p>Substantial progress has been made towards establishing appropriate paediatric triage through provision of additional staff. Creation of a dedicated space for paediatric triage underway.</p> <hr/> <p>The action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services is in the final stages of development and under discussion within HSE and DOH with a view to being finalised publication.</p> <hr/> <p>Significant additional staffing provided (i.e. via Birthrate Plus, and 2016 Service Plan)</p> <hr/> <p>Clinical Network with Coombe established.</p>
8	<p>Develop, Agree and Implement a Memorandum of Understanding between HSE &amp; State Claims Agency (SCA)</p>	<p>Statement of Partnership finalised and approved by SCA and HSE</p>

**Table 2 - National Acute Hospitals Division - Status of Recommendations (Phase I)**

REC No	Phase One Report - Recommendation	Comment
1	The commissioner of this review, or a person nominated by the commissioner should meet with each of the patients to relay the conclusions/recommendations in their individual case.	Completed as part of the Maternity Complaints Review
2	<p>Each hospital in the State should implement a formal system of audit of pregnancy outcome classified according to the Ten Groups Classification as recently endorsed by the WHO. This audit should take place on a monthly basis and involve all relevant clinicians. Each Hospital needs to supply relevant administrative support.</p> <p>Using data from individual maternity units an annual audit of Irish maternity services should be implemented without delay.</p> <p>Ongoing audit in this manner will allow a pattern of adverse outcomes to be identified in a timely fashion so that appropriate action can be taken.</p>	This recommendation is being progressed within the Hospital Groups with the establishment of the Obstetric and Clinical Networks
3	Each Hospital should have in place a formal system of review of adverse outcomes. The results of these reviews should be shared with the patients in a timely fashion. We recommend within two months of the incident. This timeline is subject to any relevant legal issues, external investigations or inquiries external to the hospital which might arise	Reviews are currently being undertaken in line with HSE Policy. This will be further developed by the National Women & Infant Programme Office
4	In the event of a perinatal death every effort should be made to gain consent for a post-mortem examination and examination of the placenta by a perinatal pathologist experienced in these examinations.	A manpower review will be undertaken by the National Women & Infant Programme Office and it is envisaged that each Obstetric Network will have access to a Perinatal Pathologist



REC No	Phase One Report - Recommendation	Comment
5	Each Hospital should ensure the appointment of a number of midwives trained in ultrasonography such that high quality obstetrical ultrasound is available on a routine basis during the working week and on an on-call basis at other times.	This recommendation is also set out in the Maternity Strategy and will form part of the Implementation Plan
6	Each hospital should appoint bereavement counsellors trained to deal with perinatal deaths.	<p>Funding provided in HSE National Service Plan 2016 for 14 bereavement specialists. Hospital Groups are progressing appointment.</p> <p>The National Bereavement Guidelines following Perinatal Death and Baby Loss were launched in July 2016.</p>
7	Each hospital should ensure that Midwifery staffing levels are at an adequate and internationally accepted level.	The HSE Midwifery Planning report was finalised in April 2016. In addition to the 100 midwives provided, a further review will be undertaken to reflect midwifery requirements to deliver the Maternity Strategy.
8	Each hospital should ensure that every Non-Consultant Hospital Doctor position is part of a recognised training scheme.	The National Women & Infants Health Programme will engage with the relevant colleges to progress this recommendation
9	Each hospital should ensure that Consultant Obstetrician staffing levels are at an adequate, internationally accepted level.	A full manpower review will be undertaken by the National Women & Infant Health Programme as part of identifying resources required to deliver the Maternity Strategy
10	Each hospital should implement on-going training programmes for all clinical staff in respect of day to day care of pregnant women where such programmes do not already exist.	Guidance prepared for 9 of the 10 clinical priorities. A national Steering group established to oversee the implementation of the training programme. Assessment of existing compliance with existing training programmes is underway across the hospital system.

## APPENDIX 3

### CMO Report

Below are the recommendations contained within the CMO report 'HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)' published on 24th February 2014.

The CMO report also recommended that HIQA should be requested to undertake an investigation of the hospital. A statutory investigation was announced by HIQA on 6th March 2014, its terms of reference published on 21st March 2014, and its report ultimately published on 8th May 2015.

1. Families and patients were treated in a poor and, at times, appalling manner with limited respect, kindness, courtesy and consideration.
2. Information that should have been given to families was withheld for no justifiable reason.
3. Poor outcomes that could likely have been prevented were identified and known by the hospital but not adequately and satisfactorily acted upon.
4. The PHMS service cannot be regarded as safe and sustainable within its current governance arrangements as it lacks many of the important criteria required to deliver, on a stand-alone basis, a safe and sustainable maternity service.
5. Many organisations, including PHMS, had partial information regarding the safety of PHMS that could have led to earlier intervention had it been brought together.
6. The external support and oversight from HSE should have been stronger and more proactive, given the issues identified in 2007.

### HIQA Report

Below are the recommendations contained within the HIQA report 'Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise' published on 8th May 2015.

1. The Department of Health should commence discussions with the Health Service Executive (HSE) to establish an independent patient advocacy service, with a view to having a service in place by May 2016. This service's role would be to ensure that patients' reported experiences are recorded, listened to and learned from. Such learning needs to be shared between hospitals within hospital groups; between hospital groups; nationally throughout the wider health system; and published. In the interim, the Department of Health and the HSE should provide regular updates on their websites to inform the public on the progress of establishing this service.
2. The Department of Health should, in line with its published Profile Table of Priority Areas, Actions and Deliverables for the Period 2015-2017, ensure implementation of the recommendations contained in this investigation report and previous investigations undertaken by the Authority.

## 3. The Department of Health:

- a. must now develop a national maternity services strategy for Ireland, as specified in recommendation N7 of the Authority's October 2013 Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar.
- b. should provide regular updates on its website to inform the public of progress with developing and implementing this national maternity strategy.
- 4. In line with the Department of Health's policy to develop independent hospital groups, the Department should expedite the necessary legal framework to enable the group boards of management and chief executive officers of each hospital group to comprehensively perform their governance and assurance functions.
- 5. The Health Service Executive (HSE) should ensure the appointment of a director of midwifery, before September 2015, in all statutory and voluntary maternity units and hospitals in Ireland that currently do not have such a post.
- 6. The Health Service Executive (HSE), along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by:
  - a. group-based system of clinical and corporate governance informed by the National Standards for Safer Better Healthcare.
  - b. a clearly defined, agreed, resourced and published model of clinical service delivery for each hospital within the group. This must be supported by clearly defined, agreed and documented patient care pathways to ensure that patients are managed in or transferred to the most appropriate hospital.
  - c. regular evaluation and audit of the quality and safety of services provided.
  - d. systems to support a competent and appropriately resourced workforce
  - e. a system to proactively evaluate the culture of patient safety in each hospital as a tool to drive improvement.
  - f. systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted, as per the National Standards for Safer Better Healthcare.
  - g. effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions.
- 7. The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin Midlands Hospital Group should:

- a. review all of the findings of this investigation and address the patient safety concerns at the Midland Regional Hospital, Portlaoise
  - b. immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital
  - c. publish an action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services. This action plan should include a named person or persons with responsibility and accountability for implementation of recommendations and actions in internal and external reviews and investigation reports, and be continuously reviewed and updated in order to drive improvement and mitigate risk.
8. The HSE and hospital group CEOs must now ensure that every hospital undertakes a self-assessment against the findings and recommendations of this investigation report, and develop, implement and publish an action plan to ensure the quality and safety of patient services.
  9. The Health Service Executive (HSE), the chief executive officer of each hospital group and the State Claims Agency must immediately develop, agree and implement a memorandum of understanding between each party to ensure the timely sharing of actual and potential clinical risk information, analysis and trending data. This information must be used to inform national and hospital-group patient safety strategies.

## APPENDIX 4A

The Terms of Reference (Phase I) in relation to the review were drafted after the Clinical Review Team was appointed in mid-May 2014 and were finalised in October 2014. Terms of Reference are as follows:

1. "The Clinical Review Team will review a maximum of forty cases arising out of patient contacts to the HSE following the Primetime Investigates documentary broadcast on 30 of January 2014 - referred to them by the HSE".
2. "For cases that are referred to the Clinical Review Team the review team will conduct a preliminary review leading to the following decisions/actions;
  - a) Where local investigations have been conducted, the Clinical Review Team will review the local investigation and either confirm that it is satisfactory or not. If the team feel the investigation has not been satisfactory they may recommend a more extensive investigation guided by HSE protocols.
  - b) Where no local investigation has been conducted, the Clinical Review Team may request that a systems analysis investigation to be conducted by HSE investigators
  - c) The review team may decide that no further action is required. This finding, and the reasons behind it, will be conveyed to the family".
3. "The Clinical Review Team will receive and check the draft system analysis investigation reports against the audit tool in the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE 2012). Where the investigation is deemed to be compliant with HSE guidelines and otherwise satisfactory to the Clinical Review Team - it will be released by the investigation commissioner to the family concerned. Where investigations are not deemed to be satisfactory, they will be returned to the investigators with feedback about the issues that need to be addressed in the report for re-submission to the Clinical Review Team. Once the clinical review team is satisfied that the outstanding issues are addressed - the report may be released by the commissioner to the family".
4. "The Clinical Review Team will provide a report of the methods and the findings of their review to the commissioners (i.e. the National Director for Acute Hospital Services) via the Acute Hospitals Office Nominee on the Clinical Review Team".
5. "Indemnity arrangements and payments for the external independent nominations from the Forum of Post-Graduate Training Bodies will be as per the forms of request for nominations from the HSE and as per agreements between the HSE. and the Forum".
6. "The work of the Clinical Review team will not conflict with the work of the HIQA investigation into the safety, quality and standards of services provided by the HSE to patients in the Midland Regional Hospital, Portlaoise".

In relation to No. 3 above, the CRT has been advised that it would not be appropriate for it to check the draft system analysis investigation reports against the audit tool in the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE 2012) and/or give an opinion on the release of the report/review to the investigation

commissioner and/or to the patient/family concerned. These are issues for the HSE or the individual Review Teams appointed in each case. The HSE has accepted that this is the correct position.

## APPENDIX 4B

### NIMLT 50554 Phase II Terms of Reference

#### Background to NIMLT 50554 Phase II Clinical Review:

#### Screening Review of Approximately 130 cases

NIMLT 50554 is a group of cases where concerns were raised by families in relation to care delivered at Maternity Services throughout the country following the Primetime Investigates Documentary about maternity services at Midland Regional Hospital Portlaoise, broadcast on the 30th January 2014. The Phase I process involved a Clinical Chart Review of 28 cases from various hospital locations in the country, not only Portlaoise, carried by out Dr. Peter Boylan and a team of 6 Obstetricians. This report, known as the Phase I Report, was published in June 2015.

The NIMLT 50554 Phase II Review of approximately an additional 102 cases was commissioned by the National Director of the Acute Hospital Services Division. These 102 complaints are going through a similar process as Phase I to address the volume of complaints. This process involved the hospital, where the complaint arose, conducting a clinical chart review by the lead Obstetrician, Director of Midwifery and the Quality and Safety Manager. 90% of these complaints arose from Portlaoise Hospital. The MRHP review identified a number of complaints for which no further action was required. However patients were advised they could write to the Commissioner of the review, Dr. Susan O'Reilly, if they had any further questions.

There were three other categories of patients identified. The second category was offered a meeting with an external Obstetrician (nominated by the Institute of Obstetricians and Gynaecologists) to discuss their concerns. The third category is where there were paediatric issues which required a Paediatrician or Neonatologist (nominated by the Faculty of Paediatrics) to participate in the discussion as well as an Obstetrician. The fourth category comprised 17 cases where significant concerns had been identified and where two external Obstetricians, conducted further scrutiny of the patient's records before a proposed meeting with the patients

This process is outside the Phase I process. All patients in the Phase II process have given their consent. The Acute Hospital Nominee Co-chairing the Safety Incident Management Team reports to the National Director of the Acute Hospital Services Division in relation to the work of the Phase II Screening Review of the additional 102 (approximately) cases.

Terms of reference:

The reviewer(s) of the Phase II Clinical Review Team will:-

- 1 Meet approximately 59 families with a Consultant Obstetrician, a Senior Midwifery Expert and/or a Paediatrician/Neonatologist to ensure that all concerns raised by these families have been fully addressed.

- 1.1 Receive the chart of the patients concerned, in addition to information about the concerns that have been raised; the date the event causing concerns occurred; and any incident investigation that has been conducted along with the outcome of the NIMLT review of any investigation. The reviewer (s)) will complete the proforma following this review.
- 1.2 Will make the following decision about each case:-
  - 1.2.1 An incident appears to have occurred (i.e., issues appear to have arisen in the process of delivering and managing health services which the reviewer(s)) considers may have had an effect on the eventual outcome of care), but it has been satisfactorily investigated.
  - 1.2.2 An incident appears to have occurred, but it was not satisfactorily investigated. **Action required:** Reviewer(s)) to refer incident back to the Commissioner of 50554 Phase II for further appropriate action by the HSE.
  - 1.2.3 An incident does not appear to have occurred
  - 1.2.4 An incident does not appear to have occurred, but it appears that there may be issues related to how the family were communicated with/ supported.
  - 1.2.5 It is not possible to tell from the information available whether an incident occurred or not. **Action required:** Seek further information. The reviewer(s) to refer this to the Commissioner of 50554 Phase II for further action.
  - 1.2.6 Due to the time that has elapsed, it is not possible to tell from the information available whether an incident occurred or not, nor is it possible to conduct a useful investigation.
- 1.3 The Commissioner of 50554 Phase II will follow up on all actions/ recommendations from these meetings.
- 1.4 Written responsibilities to any of the families will lie with the Commissioner of 50554.
- 2 Perform a screen (i.e. a clinical chart review) of 17 additional cases where the initial screen has identified concerns about maternity services as follows:
  - 2.1 The reviewer(s) receives the chart of the patients concerned, in addition to information about the concerns that have been raised; the date the event causing concerns occurred; and any incident investigation that has been conducted along with the outcome of the NIMLT review of any investigation. The reviewer(s) will complete the proforma following this review.
  - 2.2 Meeting with the 17 families and a Director of Nursing & Midwifery



Services to be in attendance.

- 2.3 Make the following decisions about each case after meetings with the families:
  - 2.3.1 If an incident appears to have occurred (i.e. Issues appear to have arisen in the process of delivering and managing health services which the Reviewer(s) considers may have had an effect on the eventual adverse outcome. Action required: Reviewer(s) to refer incident back to the Commissioner of 50554 Phase II for appropriate escalation within the HSE.
  - 2.3.2 In the event that negligence of care may of occurred the reviewer(s) will notify the Commissioner of 50554 Phase II for appropriate action within the HSE.
- 2.4 The Commissioner of 50554 Phase II will follow up on all actions/ recommendations from these meetings.
- 2.5 Written responsibilities to any of the families will lie with the Commissioner of 50554.
- 3 Those remaining cases not specifically identified in the Phase II Screening process to be referred back to the Hospital Group concerned for action at local level in conjunction with the family concerned.

Aggregate analysis of the findings of the above Phase II Screening Review will be reflected in the final report of the NIMLT 50554 incident (including the reports of the Phase I Clinical Review Team; the Phase II Screening Review and any individual investigations related to cases referred to each review).

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Dr. Susan O'Reilly  
MB, BCh, BAO, FRCPC, FRCPI  
Chief Executive Officer  
16th September 2015

## APPENDIX 4C

### Terms of Reference for a Historic Review of CTGs at MRHP

#### Ref - NIMLT 50554

Date: 14th March 2016

#### Introduction

This is a historic review of CTGs, arising from concerns raised during Phase 1 of NIMLT 50554 Review. The clinical investigators identified cases where there was a delay in identifying and responding to pathological changes on CTG tracings.

#### Purpose

The purpose of this review is to identify:

- perinatal deaths and cases of Cerebral Palsy attributable to a delay in identifying and responding to pathological changes on CTG tracings the Midland Regional Hospital Portlaoise between 1985 to the end of 2014.

#### Scope

All Perinatal deaths, stillbirths and identifiable cases of Cerebral Palsy occurring from 1985 to the end of 2014 at MRHP.

The time frame of the Review will be one month.

#### The Review Team members

Dr. Peter Boylan Consultant Obstetrician

Dr. Peter McKenna Consultant Obstetrician

Team of 10 Midwifery Experts to review charts in consultation with obstetricians

This review team falls under the governance of the SIMT established for 50554 chaired by Dr. Susan O'Reilly who is the commissioner for this review.

Prior to the commencement of this review the Commissioner will inform the SCA of the commencement of the initial review to identify affected cases and the subsequent review of these cases.

## Methodology

The review team will initially conduct a review of charts to identify affected cases prior to reviewing each affected case.

### Exclusion Criteria:

Very premature infants (<32weeks gestation) or those with foetal abnormalities.  
Deaths where there has already been an external expert chart review in NIMLT 50554.  
Injury or death where the States Claims Agency has completed the formal claims process

### Perinatal Deaths

90 cases of perinatal deaths have already been identified  
Review CTG of these 90 cases  
Select Pathological CTGs  
Review charts in Pathological CTG cases  
Determine if adverse outcome is attributable to misinterpretation of CTG

### Cerebral Palsy (CP)

Engage with SCA to identify all CP cases logged with them for time period under investigation  
Review Cases currently in process or pending  
Exclude:  
cases which have been settled, finalised or been through judicial process

Upon completion of the initial stage the review team will produce a report and make recommendations.

### Note:

CTGs are usually graded as:

Normal  
Non reassuring or suspicious  
Pathological.

The Review will follow the methodology as outlined above and will be cognisant of the rights of all involved to privacy and confidentiality. The review team will also be cognisant of outcome and hindsight bias in the context of this review. Due process, natural and constitutional justice will be adhered to during the course of this review.

The Review will commence in early 2016 and will be expected to last for a period of approximately 4 weeks, provided unforeseen circumstance do not arise.

The Review Team will advise the Commissioner on the follow-up required, which may include:

No further action required;  
Further action required which necessitates contacting affected patients  
Any other further action, to be determined.

The review may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the initial review (i.e. not identified previously) should be considered for further investigation in accordance

with the current HSE Safety Incident Management Policy and HSE Guidelines for the Systems Analysis Investigation of Incidents.

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a review process will be fully protected from legal discovery and / or disclosure.

Through the Commissioner the Review Team will:

Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.

Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, Dr. Peter Boylan and Dr Peter McKenna will convey the details of these safety concerns to the Commissioner as soon as possible.

Should the Historical Review Team require external expert input, Dr. Boylan and Dr McKenna will discuss and agree this with the Commissioner.

#### Communication Strategy:

A communication strategy will be determined for each stage of the Review Process. Helen Stokes, Group General Manager, Dublin Midlands Hospital Group will be appointed to co-ordinate communications, subject to a predetermined strategy

#### Reference:

HSE Safety Incident Management Policy (2014)

Signed:

Date: 14th March 2016

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Dr. Susan O'Reilly  
MB, BCh, BAO, FRCPC, FRCPI  
Chief Executive Officer

## APPENDIX 5

### Membership of Maternity Clinical Review Management Team:

The membership of the Management Team for Phase I comprised the following members:

- Mr. David Walsh, Co-Chairperson and Commissioner, Regional Director of Performance and Integration (RDPI)
- Ms. Cora McCaughan, Co-Chairperson, Quality and Patient Safety HSE
- Dr. Peter Boylan, Clinical Lead of the Review Team, Royal College of Physicians in Ireland (RCPI)
- Ms. Lucy Nugent, Head of Quality Assurance and Risk Management, Acute Hospitals Division
- Ms. Val Wade, Business Manager, Office of the RDPI
- Mr. Michael Knowles, General Manager, MRHP
- Ms. Angela Dunne, Director of Midwifery, MRHP
- Ms. Deirdre O’Keeffe, Assistant National Director, NIMLT
- Ms. Maria Lordan Dunphy, Assistant National Director, Quality Improvement Division
- Ms. Sheila O’Connor, Patient Focus
- Ms. Kirsten Connolly, Communications Lead HSE

The membership of the Management Team for Phase II comprised the following members:

- Dr. Susan O’Reilly, CEO Dublin Midlands Hospital Group (Commissioner)
- Mr. Michael Knowles, General Manager, MRHP
- Dr. Peter McKenna, Consultant Obstetrician/Gynaecologist
- Dr. Peter Boylan, Consultant Obstetrician/Gynaecologist
- Ms. Angela Dunne, Director of Nursing, MRHP
- Ms. Sheila O’Connor / Ms. Bridget Doherty, Patient Focus
- Dr. Orla Healy, Director of Quality, Governance and Patient Safety
- Ms. Eileen Whelan, Chief Director of Nursing and Midwifery, DMHG
- Ms. Helen Stokes, General Manager, DMHG
- Ms. Arlene Crean, Communications Manager, DMHG
- Ms. Deirdre Carey / Ms. Deirdre O’Keeffe, QPS, Acute Hospital Division Quality and Safety

## APPENDIX 6A

Phase I - A Review of 28 Maternity Case notes by a Clinical Review Team Undertaken at the Request of the Health Service Executive

### Obstetrician/Gynaecologists:

- Dr. Peter Boylan MAO, FRCPI, FRCOG, Chair of the Clinical Review Team, Chairman of Executive Council of the Institute of Obstetricians and Gynaecologists (2015-2018) at the Royal College of Physicians in Ireland, National Maternity Hospital, Dublin
- Dr. Paul Hughes, MB, FRCOG, Kerry General Hospital, Tralee, Kerry
- Dr. Elizabeth Dunn, MRCOG, MRCPI, Wexford General Hospital, Wexford
- Prof. Louise Kenny, MB, ChB, PhD, MRCPG, Cork University Maternity Hospital, Cork
- Dr. Peter McKenna, FRCPI, FRCOG, Rotunda Hospital, Dublin
- Prof. John Morrison, MD, FRCOG, FRCPI, Galway University Hospital, Galway
- Dr. Michael Robson, FRCS, FRCOG, National Maternity Hospital, Dublin

## APPENDIX 6B

### Phase II Obstetrician/Gynaecologists, Paediatrician/Neonatologist & Midwifery Experts

#### Obstetrician/Gynaecologists:-

- Dr. Peter Boylan, Chair of the Clinical Review Team, Chairman of Executive Council of the Institute of Obstetricians and Gynaecologists (2015-2018) at the Royal College of Physicians in Ireland, National Maternity Hospital, Dublin
- Dr. Peter McKenna, Rotunda Hospital, Dublin
- Prof. John Bonnar
- Dr. Elizabeth Dunn, MRCOG, MRCPI, Wexford General Hospital, Wexford
- Dr. John Murphy

#### Paediatrician/Neonatologist:-

- Dr. John Murphy, National Maternity Hospital, Dublin

#### Midwifery Experts:-

- Ms. Angela Dunne, Midland Regional Hospital Portlaoise, Laois
- Ms. Ann Rath, National Maternity Hospital, Dublin
- Ms. Maeve Dwyer
- Ms. Rosa Dignam
- Ms. Mary Byrne

## APPENDIX 6C

### Phase III - Historic Review of CTGs at MRHP

#### Obstetrician/Gynaecologists:-

- Dr. Peter Boylan, National Maternity Hospital, Dublin
- Dr. Peter McKenna, Rotunda Hospital, Dublin

#### Midwifery Experts:-

- Ms. Ann Rath, National Maternity Hospital, Dublin
- Ms. Ann Fergus, Coombe Women & Infant's University Hospital, Dublin
- Ms. Ann Moyne, Coombe Women & Infant's University Hospital, Dublin
- Ms. Colette McCann, Lady of Lourdes Hospital, Drogheda, Co. Louth
- Ms. Siobhan Weldon, Lady of Lourdes Hospital, Drogheda, Co. Louth
- Ms. Deirdre Naughton, University Hospital, Galway
- Ms. Juliana Henry, Sligo General Hospital, Sligo
- Ms. Karen Crowley, Midland Regional Hospital Mullingar, Westmeath
- Ms. Martha Murtagh, Midland Regional Hospital Mullingar, Westmeath
- Ms. Mary Bolger, University Hospital Limerick, Limerick
- Ms. Suzanne Jackman, University Hospital Limerick, Limerick
- Ms. Rachel Conaty, National Maternity Hospital, Dublin





