An Roinn Sláinte
Department of Health

Perinatal Mortality

National Clinical Audit No. 2

April 2022

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

This National Clinical Audit (NCA) has been developed by the Perinatal Mortality National Clinical Audit Governance Committee (PMNCAGC) supported by the National Perinatal Epidemiology Centre (NPEC).

Using this National Clinical Audit

This NCA of perinatal mortality in Ireland is relevant to all healthcare professionals working in maternity units, caring directly for women and their babies, as well as all those healthcare professionals who work within the wider maternity services in Ireland.

Disclaimer

National Clinical Effectiveness Committee (NCEC) National Clinical Audits do not replace professional judgment on cases, whereby the clinician or health professional decides that individual audit findings are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommended course of action in their care or treatment plan. In these circumstances the decision should be appropriately recorded in the patient's healthcare record.

Users of the NCEC National Clinical Audits must ensure they have the current version by checking the relevant section in the National Patient Safety Office on the Department of Health website at: gov.ie - Clinical Effectiveness (www.gov.ie)

Users are also directed to the webpages of the audit providers where further information, including annual reports and other documents are available. For audits conducted by the NPEC these are available at: https://www.ucc.ie/en/npec/npec-clinical-audits/

Quality assurance appraisal against the NCEC criteria was conducted on the NPEC Perinatal Mortality in Ireland Annual Report 2016 and is referred to in the text of this document. Since then, the NPEC has published subsequent reports in 2017 and 2018/2019, which are available at: https://www.ucc.ie/en/npec/npec-clinical-audits/perinatalmortality/perinatalmortalityreportsandforms/

Whilst every care has been taken to ensure that all information contained in this publication is correct, the Department of Health cannot accept responsibility for any errors or omissions which may have occurred.

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Membership of the Perinatal Mortality National Clinical Audit Governance Committee

The PMNCAGC is chaired by Professor Richard Greene (2008 to date), Consultant Obstetrician and Gynaecologist at Cork University Maternity Hospital and Director of the NPEC.

Membership nominations were sought from a variety of clinical and non-clinical backgrounds to be representative of all key stakeholders, and geographical spread within the maternity services. PMNCAGC members included those involved in maternity clinical practice, education, administration, research methodology, clinical risk, and quality assurance as well a person representing patients and the public.

Members were recruited and invited to partake in the PMNCAGC on the provision that they provided justifiable expertise and/or viewpoints to the committee, offering valuable contributions based on their extensive knowledge in the field of obstetrics, and/or professional experience of working in maternity services, and/or knowledge of a healthcare sector.

Membership of the PMNCAGC is outlined in Table 2 of this report. The PMNCAGC Terms of Reference (TOR) are included in Appendix 1. The TOR are reviewed regularly and were last updated in March 2020 by the PMNCAGC. Members were not compensated for their involvement or contribution to the PMNCAGC and were informed that it was on a voluntary basis.

Credits

The role of the NCEC is to prioritise, quality assure and recommend clinical audits to the Chief Medical Officer (CMO) for endorsement by the Minister for Health. It is intended through Ministerial endorsement that full implementation of the audit will occur through the relevant service plans. The NCEC and the Department of Health acknowledge and recognise the Chair and members of the PMNCAGC for development of the audit. The NCEC and Department of Health wish to express thanks and sincere gratitude to all persons contributing to this National Clinical Audit; especially those that have given of their time on a voluntary basis and those that seek to input the voices of patients, their families, and the public.

Acknowledgements

The NPEC acknowledges continued hard work and commitment of many people both within the maternity units and the NPEC team that collaborate on this audit.

It is with sincere thanks and appreciation that the NPEC would like to acknowledge the many healthcare professionals who contribute to the NPEC audit on perinatal mortality. In particular, we would like to thank the perinatal mortality data coordinators who co-ordinate the collection of perinatal mortality data at centre level, many of whom do so without protected time for clinical audit. The NPEC would like to acknowledge members of the PMNCAGC, for their guidance in the continual optimisation of the NPEC NCA of Perinatal Mortality.

We would also like to extend thanks to the NPEC Governance Committee, who represent a diverse range of key stakeholders from maternity centres and universities throughout the country, for their support and guidance as the centre continues to evolve.

We thank all the NPEC staff members past and present for their hard work and dedication to the mission of the centre.

We thank the National Office of Clinical Audit (NOCA), whose endorsement of the NPEC annual report is an element of the audit process. The NPEC would also like to acknowledge the National Perinatal Reporting System (NPRS) for their continued collaboration in consolidating national data on perinatal deaths thus ensuring that both agencies represent the most accurate and complete record of Irish perinatal mortality data annually as recommended by the CMO.

We thank Clare Fitzgerald and Brendan Kennelly for their assistance with the Economic Evaluation piece for this submission.

Finally, we thank the office of the NCEC for the opportunity in submitting this application and for their assistance in providing support and guidance throughout the process.

Signed:

_____ Date: 06/04/2022

Professor Richard Greene
Director of the National Perinatal Epidemiology Centre

The National Perinatal Epidemiology Centre

The NPEC works with the maternity services in Ireland. The NPEC is a team of midwives, researchers, administrators, clinicians and is directed by Professor Richard Greene. The NPEC produces annual reports on perinatal mortality in Ireland, maternal morbidity in Ireland, home births in Ireland and neonatal care of very low birth weight babies in Ireland and therapeutic hypothermia in Ireland, subject areas that constitute key indicators of quality of maternity and neonatal care. At local hospital level, the NPEC provides customised feedback to individual hospitals on how they compare against the national average. The NPEC makes recommendations in its annual audit reports. However, it recognises that recommendations are ineffective if they are not implemented. The NPEC has always strategically aimed to close the audit loop and since the establishment of the National Women and Infants Health Programme (NWIHP) in January 2017, several of the NPEC recommendations have been progressed. The NPEC works in collaboration with the NWIHP and acknowledges the key relationship that has developed between the two organisations. The NPEC is funded by the Department of Health through the Health Service Executive (HSE) and is based at Cork University Maternity Hospital in the Department of Obstetrics and Gynaecology, University College Cork. In Dáil Éireann on 8th March 2006, the then Minister for Health and Children, Mary Harney stated that 'Every time a mother gives birth in Ireland, the important interventions, the good outcomes and the complications are recorded and analysed at a national specialist centre'.

The specific roles of the centre are:

- To collaborate with government agencies to collate outcome data from maternity hospitals in Ireland.
- To contribute to the development of clinical protocols and guidelines based on analysis of data.
- To translate outcome data for mothers and children into improved clinical practice.
- To act as a resource for the Minister of Health and the Department of Children and Youth Affairs.
- To publish annually an analysis of national perinatal data.
- To develop research thematic areas in the perinatal space.
- To encourage the development of a national uniform obstetrics chart/record.
- To establish appropriate expert sub-committees to assess and review material and sign off on reports (e.g. maternal mortality, prenatal mortality, birth defects).
- To enhance public and patient involvement in NPEC activities and to foster awareness of NPEC outputs amongst patients and the public.

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The National Clinical Effectiveness Committee

Providing standardised clinical care to patients in healthcare is challenging. This is due to several factors, among them diversity in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to allow delivery of safe and high-quality care. The NCEC is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high-profile health service system failures at home and abroad.

The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines (NCG) and NCAs.

The aim of the suite of NCEC NCAs is to progress quality and safety using measurement against clinical standards. The implementation of these NCAs will support the use of rigorous data for evaluation and quality improvement in Irish healthcare services.

The NCEC is a partnership between key stakeholders in patient safety. The mission of the NCEC is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care.

The NCEC Terms of Reference are:

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for NCGs and NCAs.
5. Prioritise and quality assure NCGs and NCAs.
6. Commission NCGs and NCAs.
7. Align NCGs and NCAs with implementation levers.
8. Report periodically on the implementation and impact of NCGs and the performance of NCAs.
9. Establish sub-committees for NCEC workstreams.
10. Publish an Annual Report.

Information on the NCEC and relevant documentation is available at:
www.health.gov.ie/patient-safety/ncec

National Clinical Audit

National Clinical Audit is a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis.

Clinical audits endorsed by the Minister will be titled *'National Clinical Effectiveness Committee National Clinical Audit'*. Endorsement will mandate that the appropriate services engage with the NCEC NCA, thereby superseding all other NCAs on the topic.

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Introduction to the Perinatal Mortality National Clinical Audit

Perinatal mortality is a significant measurement of the outcome of obstetric and neonatal care. For this reason, in 2011, the National Perinatal Epidemiology Centre (NPEC) established the first national clinical audit (NCA) of Perinatal Mortality in Ireland. Since 2009 the NPEC, in collaboration with the multidisciplinary Perinatal Mortality National Clinical Audit Governance Committee (PMNCAGC), has conducted a NCA of Perinatal Mortality annually. The fundamental aim of this clinical audit, and a core function of the NPEC, is to improve the care of mothers and babies in Ireland through the provision of key epidemiological evidence and monitoring of adverse perinatal outcomes. It is acknowledged that ongoing monitoring of quality and safety data is essential to continually drive improvements in the maternity services. High quality perinatal mortality auditing has an important role to play in reducing perinatal loss, lessening the personal suffering, and monetary expense experienced by those affected by bereavement. The Lancet *Stillbirths Series* (2016): *Ending Preventable Stillbirth*s, and the British Journal of Obstetrics and Gynaecology (2018) both advocate for high quality perinatal mortality audits and reviews (Flenady, 2016, Siassakos et al., 2018).

Total expenditure on clinical claims in maternity services was 54% of all clinical care related claims in 2014. Total expenditure on maternity related claims has increased 80% from €32 million in 2010 to €58 million in 2014 (State Claims Agency, 2015). Some of these costs are associated directly with perinatal losses. There were 32 claims finalised in the period 2016-2019 (relating to neonatal death/stillbirths) that amounted to €12,448,735 this included legal costs (data supplied by the State Claims Agency, 2021). There is also evidence that improvements in detection of risk factors that can be used to reduce stillbirths may also reduce the risk of neonatal brain injury – a significant contributor to the medico legal costs in the maternity services.

The information provided in this report contributes to a body of evidence that will guide future clinical practice, counselling of bereaved parents, public health interventions and inform policy makers within the health services. Regular audit of perinatal mortality can identify modifiable risk factors which decrease the risk of perinatal death and inform clinical practice. Over the past decades, the rate of perinatal mortality has decreased substantially in high-resource countries and has been partly attributed to the proliferation of regular perinatal mortality audits. The information for this submission is based on data from 2016 in which it was encouraging to see a clear reduction in perinatal mortality. While this finding was just for one year, the NPEC hope that this trend continues in the future. However, it is important that we do not focus on rates and numbers alone. The NCA of perinatal mortality has led to improved investigations including use of a standardised pathology terminology and increased monitoring of factors associated with perinatal loss as identified within the audit (e.g. fetal growth assessment). This has led to a reduction in the perinatal mortality rate in Ireland and the audit provides standard information for families. This is a key element for families as the economic burden of perinatal mortality extends far beyond the healthcare setting.

We should remember that each perinatal death has a profound effect on a mother, a father, and the extended family. Perinatal deaths are devastating for families and staff involved. Failure to examine perinatal deaths for substandard care prevents learning and may lead to recurrence of events, as well as prolonged morbidity in bereaved families and hospital staff.

1 Focus of the Perinatal Mortality National Clinical Audit

1.1 Aim of the Perinatal Mortality National Clinical Audit

Since 2009, the NPEC, in collaboration with the PMNCAGC conducted a NCA of Perinatal Mortality annually. The fundamental aim of this clinical audit, and a core function of the NPEC, is to improve the care of mothers and babies in Ireland through the provision of key epidemiological evidence and monitoring of adverse perinatal outcomes. It is acknowledged that ongoing monitoring of quality and safety data is essential to continually drive improvements in the maternity services. The information provided aims to contribute to a body of evidence that will guide future clinical practice, the counselling of bereaved parents, public-health interventions, and inform policy makers within the health services.

For the purpose of this report, the NPEC followed the National Clinical Effectiveness Committee (NCEC) document *Framework for Endorsement of National Clinical Audit* (2015) and were mindful of the criteria set out.

NCEC criteria:

1. Patient Safety Issue
2. Burden of Clinical Topic
3. Clinical Standard Availability
4. Variability in Practice High
5. Economic Impact
6. Potential for Improved Health
7. Clinical Audit Implementation.

1.2 Scope of the Perinatal Mortality National Clinical Audit

There are 19 maternity units in Ireland. Within each maternity unit, perinatal mortality data coordinators with the responsibility of submitting perinatal mortality data to the NPEC have been identified. Each year pseudonymised data on perinatal deaths from births that occurred between 1st January and 31st December are submitted to the NPEC by all 19 units using a standardised notification dataset either electronically, via the secure online NPEC database, or alternatively by paper format. The notification dataset is completed using data on fetal and maternal characteristics recorded in the clinical records. Implemented nationally in 2011, the NPEC notification dataset was based on the validated Centre for Maternal and Child Enquiries (CMACE) Perinatal Death Notification Form and has been endorsed by the Clinical Advisory Group at the Institute of Obstetrics and Gynaecology (IOG), the Faculty of Paediatrics, and the Health Service Executive (HSE) National Obstetric Programme Working Group. There has been a steady improvement in the overall quality of data reported by all maternity units since the implementation of the Perinatal Mortality National Clinical Audit (PMNCA) dataset in 2011. To ensure completeness and accuracy of information, all data is validated directly with the respective maternity units. The NPEC also undertakes extensive reconciliation of its annual perinatal mortality dataset with that of the National Perinatal Reporting System (NPRS). This consolidation with the NPRS is in response to recommendations by the Chief Medical Officer (CMO) and ensures that both agencies' datasets represent the most accurate record of perinatal mortality annually.

2 Rationale for the Perinatal Mortality National Clinical Audit

2.1 Need for the Perinatal Mortality National Clinical Audit

The World Health Organisation (WHO) states that 2.6 million stillbirths and 2.7 million neonatal deaths occur every year worldwide. Unfortunately, some perinatal deaths are inevitable, but others may be preventable. Congenital abnormalities account for around 8% of stillbirths, which are rarely avoidable. Worldwide modifiable risk factors include maternal infection, non-communicable diseases (e.g. diabetes, hypertension), nutrition and lifestyle factors (e.g. obesity), prolonged pregnancy and advanced maternal age (Lawn et al., 2016). In developed countries around 10% are intrapartum stillbirths (Lawn et al., 2016). Up to 75% of neonatal deaths can be prevented with high quality maternity, intrapartum and neonatal care according to the WHO. The death of a baby is devastating for parents, families and all healthcare staff involved. It can lead to anxiety, depression, post-traumatic stress disorder and relationship difficulties for the bereaved parents (O'Connell et al., 2016). For the healthcare staff involved in an intrapartum fetal death in particular, it can have lasting emotional and professional effects (McNamara et al., 2017). To society, perinatal deaths represent many years of life lost, as by definition they occur at the beginning of life compared to deaths at advanced age (Deeny, 1955, Kirkup, 1991). There is now a significant effort being made internationally to reduce the numbers of perinatal deaths including initiatives such as the WHOs *Every Newborn Action Plan* (ENAP) and *Each Baby Count*s in the United Kingdom (UK) (Robertson et al., 2017, Lawn et al., 2016, Kerber et al., 2015a).

There is consensus in the literature that it is essential to learn from previous substandard maternity care to prevent mistakes recurring (British Medical Journal, 1957, Drife, 2006, Kerber et al., 2015a, Robertson et al., 2017). Perinatal mortality reviews take place to identify factors contributing to suboptimal care and to identify weaknesses in health care services (Pattinson et al., 2005, Buchmann and Velaphi, 2009). These reviews can be carried out in several ways at institutional (e.g. perinatal reviews), regional (e.g. confidential enquiry), national or international level (e.g. audits) with input by clinicians, experts and more recently the bereaved parents.

2.2 Defining Perinatal Mortality

Differences in definition and classification of perinatal deaths impede international comparison of data (Deeny, 1955, Kirkup, 1991, Drfe, 2006, Gissler et al., 2010, Lawn et al., 2011b, Kerber et al., 2015a, Flenady et al., 2016b, Lawn et al., 2016). Perinatal mortality can be subdivided into stillbirths and neonatal deaths as illustrated in Figure 1.

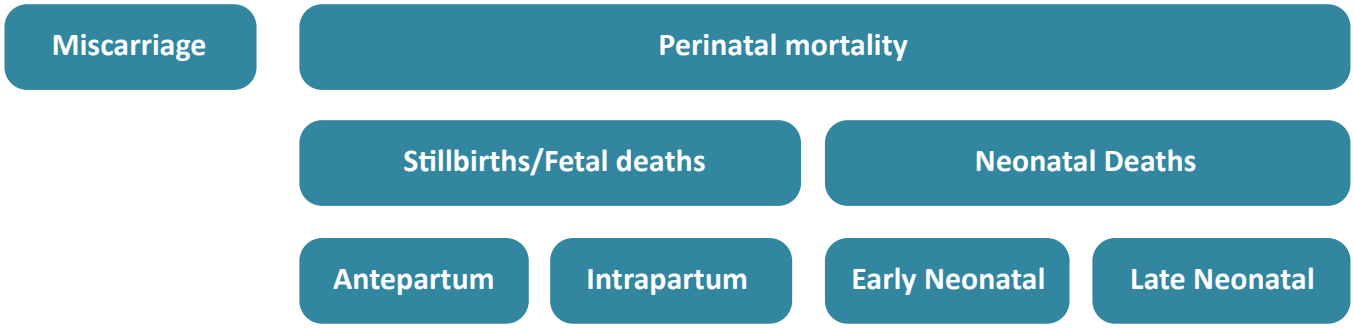

Figure 1: Perinatal Mortality Definitions

Stillbirth generally refers to a viable baby born with no signs of life (Lawn et al., 2011b). However, currently there is no consensus internationally on the lower limit of gestation that is included for stillbirths, it varies from 20 to 28 weeks gestation of pregnancy (Flenady et al., 2016b, Lawn et al., 2016). For international comparison of stillbirth rates, the WHO recommends 28 weeks gestation as the lower gestational limit (Lawn et al., 2016, Lawn et al., 2011b).

The International Classification of Diseases 10th revision (ICD-10) refers to fetal death instead of stillbirth from 22 weeks gestation, and fetal death at less than 22 weeks gestation is classified as a miscarriage (Lawn et al., 2016, Lawn et al., 2011b). The EURO-Peristat Network recommended the recording of all fetal deaths after 22 weeks as part of their perinatal health indicators for Europe, although varying lower limits of gestational age are included in the recording of stillbirths across the European Union (EU) (Gissler et al., 2010). An intrapartum stillbirth refers to the death of a baby after the onset of labour but before the birth (Lawn et al., 2016, Lawn et al., 2011b). Internationally, neonatal deaths are divided into early (first 7 days of life) and late death (after the 7th day and up to 28 completed days of life) of a baby born alive (Lawn et al., 2011b, Manning E, 2018, Elizabeth S Draper, 2018).

2.3 Perinatal Mortality Rates

The perinatal mortality rate (PMR) is the number of stillbirths and neonatal deaths per 1000 total births (live births and stillborn) (Manning E, 2018). International PMR comparison is significantly hindered by using different lower gestational limits for the definition of stillbirths (Robertson et al., 2017). In 2016, Australia and New Zealand used a classification of stillbirth with a gestational limit of 20 weeks, whereas Ireland and UK classified their stillbirths as those born with more than 24 weeks gestation (including weight of 500gram (g) in Ireland). In line with the WHO, Northern American countries used 28 weeks gestation as the lower gestational limit for classification of stillbirths in 2016. Additionally, the difference in the inclusion or exclusion of late neonatal deaths in the calculation also hampers the possible comparison of PMRs.

Perinatal mortality rates are stated as an indicator of the standard of maternity and perinatal care and/or services provided to women and infants (Pakter et al., 1955, Baird, 1969, Atrash et al., 1992, Mancey-Jones and Brugha, 1997, Kent et al., 2009, Flenady et al., 2010, Eskes et al., 2014). The 2011 *Stillbirth Series* published in The Lancet also suggested that intrapartum stillbirth rates are an indicator and measure of the quality of intrapartum care (Lawn et al., 2011b); these are assessed in the PMNCA. Intrapartum deaths usually occur in term, viable babies and are often associated with suboptimal care in labour (Lawn et al., 2011b, Flenady et al., 2016b). Inadequate fetal monitoring during labour, risk assessment and management of labour are recurring contributory factors identified for intrapartum stillbirths (Robertson et al., 2017). These themes have been identified in a number of reviews of perinatal events in Ireland – Mark Molloy Report, HSE Report of Maternity Services In Portiuncula, Health Information and Quality Authority (HIQA) Review of Portlaoise Implementation (Health Service Executive, 2013, 2015, HIQA, 2015).

Information on pregnancies, labour, birth outcomes and neonates are collected to monitor maternity services (Gissler et al., 2010). Without basic information on perinatal and maternal mortality, it is difficult to identify problems, initiate change and examine progress (Pattinson et al., 2005, McIlwaine et al., 1979).

This issue was recognised in Ireland with the establishment of the NPEC, announced in Dáil Éireann on 8th March 2006 by then Minister for Health and Children, Mary Harney T.D. in the Lourdes Hospital Inquiry Statement:

'This means that every time a mother gives birth, the important interventions, good outcomes and complications will be recorded and analysed at a national specialist centre. Unusual trends will be easily and quickly observed and, most importantly, acted on. The centre has been designed based on models from Australia and its immediate priorities are to devise a single identical maternity chart for every maternity hospital in the country. This is the first very important step in re-establishing trust and ensuring that services to mothers and their babies born here are based on the best possible research'

(Harney, 2006).

The subsequent Service Level Agreement (SLA) between the HSE and University College Cork outlined the various expectations including:

1. To establish the specific functions of the NPEC as follows:
    a. Act as an independent source of advice for the HSE
    b. Inform Department of Health and Children in creation of policy
    c. Collect outcome data from maternity hospitals in Ireland and to collaborate with government agencies in same
    d. Evaluate this data, including, inter alia, data relating to:
        i. parent and child mortality
        ii. birth defects
    e. Publish annually an analysis of national perinatal data
    f. Develop clinical recommendations based on these analyses.
2. To encourage the development of a national uniform obstetrics chart/record:
    a. Harmonise data collection from different hospitals
    b. Facilitate patient movement between hospitals
    c. Create a professional and accurate record chart
    d. Co-ordinate a perinatal epidemiology monitoring service.
3. To establish appropriate expert sub-committees to assess and review material and sign off on reports (e.g. maternal mortality, prenatal mortality, births defects).

2.4 Perinatal Mortality Audits and Reviews

Data on mortality cases can be collected to compare numbers, categorise causes of deaths or to identify and address potentially avoidable factors (Pattinson et al., 2005). This data can be collected in many ways; local perinatal reviews, clinical audits and confidential enquiries are all methods of assessing perinatal mortality cases.

Perinatal mortality audits are important to collect data and identify recurrent or modifiable contributory factors that have adverse effects on perinatal outcomes and highlight local and/or national issues (Manning E, 2018, Pattinson et al., 2005). National audit aids the comparison of results between different maternity units and allows the creation of national perinatal mortality figures for international comparison (Manning E, 2018). National perinatal mortality audit can generate clinical recommendations directly

affecting quality of maternity care (Eskes et al., 2014). Audit is a process of ongoing data collection, assessment, implementation of change and re-evaluation i.e. a continuous cycle (Kerber et al., 2015a, Drife, 2006, Mancey-Jones and Brugha, 1997). Helps et al comment that the International Classification of Diseases-Perinatal Mortality (ICD-PM) and the International Classification of Diseases 11th revision (ICD-11) will hopefully facilitate the agreement of one international model of classification and definition of perinatal deaths (Helps et al., 2020).

An important part that may be missed in the audit cycle is the development of recommendations linked to action plans with clear targets and feedback to staff (Kerber et al., 2015a, Flenady et al., 2010). The 2011 *Stillbirth Series* published in The Lancet states that this final step of action and re-evaluation is the most important (Lawn et al., 2011b). This step of re-evaluating the implementation of recommendations, may not be completed in a local hospital-based perinatal mortality review that lacks a formal audit structure (Drife, 2006). This is achieved and under regular review in PMNCA undertaken by the NPEC (working with the National Office of Clinical Audit (NOCA)) through the management structure for maternity services-the National Women and Infants Health Programme (NWIHP).

The benefit of perinatal mortality reviews was recognised in the 1950s (Gruenwald, 1955). The aim of these earlier reviews was mostly to establish and agree on cause of death of stillborn and new-born infants. However, studies published in Canada recognised the benefit of *'an objective viewpoint in the assignment of preventability'* and *'the application of lessons learned to the saving of future infant lives'* (Briggs et al., 1956, Wallace, 1959). During this time the importance of the collaboration between different specialities in obstetrics, neonatology, and pathology, as well as the discussion of perinatal mortality cases at regular conferences was deemed valuable (1957, Drife, 2006, Chalmers, 1985).

To achieve comprehensive local perinatal mortality reviews, funding for protected time for the multidisciplinary clinical staff involved is required (Flenady et al., 2016b). In these reviews the standard of care examined is measured against predetermined guidelines, protocols and policies (Buchmann and Velaphi, 2009). This has been a consistent recommendation in the NPEC perinatal mortality reports (Manning E, 2018). The PMNCA does have 100% coverage in all 19 maternity units. Whilst the analysis of the audit is funded, data collection at unit level is done over and above everyday work. This is extremely challenging within busy maternity units and is not a sustainable model. With protected time, data could be submitted in a timelier manner which would enable reports to be produced within 18 months of the year's end. Timely reports allow for timely care quality initiatives that may be identified within recommendations in the report. Further, the PMNCAGC have noted they would like other areas of perinatal loss to be investigated intensively to inform clinical practice, for example, fetal deaths occurring in utero after 22 weeks and before 24 weeks gestation (referred to as *'late miscarriages'*). However, the units do not have the capacity to take on this additional work without protected time.

For comparison of PMR, there needs to be international consensus on the lower gestational limit of stillbirths to be included in the calculation (Robertson et al., 2017). The NPEC audits use the legislative definition for still birth as babies greater than or equal to 24 weeks gestation and/or greater than or equal to 500g in birthweight as the lower limit but collect adequate data to assess against other definitions used nationally and internationally.

Additionally, education on audit and quality improvement skills should become part of training for all clinicians (Flenady et al., 2011b, Robertson et al., 2017). Awareness of the importance to review perinatal mortality cases for substandard care is increasing (Flenady et al., 2016b). However, the review process is standardised in few countries at national level (Flenady et al., 2016b). Establishment of multi-disciplinary review committees (including clinical staff (midwifery, obstetrics), relevant experts {e.g. perinatal pathology, neonatology, anaesthesia, haematology, microbiology} and patients/parents), and

development of specific perinatal mortality review tools and/or guidelines will enable a more regulated, structured approach to this process. This is achieved through the PMNCAGC and through the data collection tools (including web-based data collection tools) and review processes in place.

The involvement of bereaved parents in the review process is still mostly unexplored (Kerber et al., 2015a). The NPEC have public/patient representation on their governance committees, the impact has been positive towards the ongoing improvement in the audit and in identifying lessons for recommendation (National Advisory Group on the Safety of Patients in England, 2013) (Metcalfe D, 2018).

National perinatal mortality audits compare results between different maternity units and identify important modifiable key findings to generate national clinical recommendations to improve maternity services. Reliable national perinatal mortality data facilitates international comparison. For a deeper understanding of the care provided to pregnant women with poor perinatal outcome a more detailed impartial, multidisciplinary examination like a confidential enquiry is required. The care provided is thus measured against predetermined standards, and recommendations are made at system level. This has been a recommendation from the NPEC and is now being actioned through the NWIHP.

To achieve the ultimate goal of reducing the number of stillbirths and neonatal deaths, the perinatal mortality review cycle needs to be closed with re-evaluation of recommended changes in maternity services, this requires longitudinal on-going audits as encompassed in the NPEC PMNCA.

2.5 Financial Impact of Perinatal Mortality

The cost of perinatal mortality to a health service is not known with any clarity. For this NCEC application, a systematic review was conducted to evaluate the economic impact of perinatal mortality (Annex 1). This report makes an economic assessment of perinatal mortality by identifying the main costs. The full report (Annex 1) first sets out the economic review strategy and outlines any existing evidence. This is followed by known costs of the PMNCA, which are formed mainly from direct costs associated with the administration of the audit rather than capital costs or costs associated with clinical staff involvement. An analysis of the benefits of a PMNCA in the Irish context is then made.

The year 2016 saw a total of 250 stillbirths, 124 early neonatal deaths and 33 late neonatal deaths resulting in a total perinatal mortality of 407 in Ireland (Manning et al, 2016). A country's perinatal mortality levels are a critically important marker for both maternal health, and the ease of access to high quality care in pregnancy (Blencowe et al., 2017). Inadequate data collection in relation to perinatal loss ignores its impact on women, families, and society, and underestimates the benefits of investments in maternity care. This situation has led to accumulating failures to invest in reducing perinatal death statistics (Blencowe et al., 2017, Stenberg et al., 2014).

Without accurate data to assess the current economic impact of perinatal mortality, it is impossible to assess the cost-effectiveness of prevention programmes, or cost-benefit of auditing in this field (Mistry et al., 2013). Despite the substantial emotional, financial and far-ranging costs placed on women, families and healthcare professionals, the amount of research examining the economic effect of perinatal mortality remains miniscule (Campbell et al., 2018).

The NPEC has been publishing its annual PMNCA report since 2011. Dunn and McIlwaine define perinatal audits as:

'The systematic, critical analysis of the quality of perinatal care, including the procedures used for diagnosis and treatment, the use of resources and the resultant outcome and quality of life for women and their babies' (Dunn and McIlwaine, 1996).

The findings of Ireland's PMNCA are intended to highlight the critical need for ongoing auditing to identify the main factors impacting on adverse perinatal outcomes. Maternal and perinatal mortality auditing is supported by the *WHOs Every Newborn Action Plan* where two of the five objectives are to address quality of care at birth, and to generate data for decision making and action (WHO, 2018). In lower income countries, evidence suggests these strategies have been effective with a reduction of poor outcomes and better resource use reported (Pattinson et al., 2009a). However, in higher income countries, the beneficial effects of auditing have been muted, in part due to the lack of robust economic analysis that is conducted in tandem with reporting derived from its findings. This has resulted in continued undervaluation of perinatal loss, and results in this issue remaining invisible to policy makers (Lawn et al., 2011a).

The WHO Every Newborn Action Plan To End Preventable Deaths has set a stillbirth target of 12 per 1000 births or less by 2030 (Newborn, 2018). The current global average reduction rate (ARR) of 2% needs to more than double if this target for reduction in stillbirth is to be accomplished (Newborn, 2018). A study published for The Lancet's 2016 *Ending Preventable Stillbirths Series* found that Ireland had an ARR of 3.5% over the 15-year period of 2000-2015. While this figure is above average compared to the other 49 high-income countries included in the study, it does fall below the 4% target necessary to achieve the goals set within the ENAP (Flenady et al., 2016a).

Despite calls in The Lancet *Stillbirths Series* for a uniform approach to the definition and classification of perinatal mortality, continued use of disparate approaches across countries renders interpretation between countries difficult (Flenady et al., 2016a). However, Ireland has been commended in this regard for its standardised approach to auditing, and the most recent PMNCA saw perinatal death rate fall from 6.9 per 1000 in 2015 to 5.8 in 2016 (Kerber et al., 2015b). Similarly, in New Zealand, stillbirth rates at term have reduced since its national perinatal audit began. These national programmes have been credited with creating better cooperation between hospitals and swifter implementation of nationwide protocols all accumulating in better communication, increased efficiencies, and greater quality of care (Flenady et al., 2016a, Kerber et al., 2015b).

3 Evidence-Base for the Perinatal Mortality National Clinical Audit

3.1 Clinical Standards and/or Clinical Guidelines for Perinatal Mortality National Clinical Audit

For many years, clinicians have been reviewing case notes and compiling perinatal mortality statistics for their own units and comparing with other units. Perinatal death audit is an essential part of all obstetric services (Gardosi, 2010). Worldwide, few countries collect routine high quality perinatal data. Therefore, even in high income countries, analysis of individual perinatal death cases is not always possible. To better understand deaths in fetuses, babies, and infants from 20 weeks of pregnancy to 1-year after birth, the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) was established in the UK in 1992. The CESDI set a standard for quality assessment in the field of obstetrics worldwide (BergsjØ et al., 2003). Further information on the relevant clinical guidelines and standards is also included in section 3.7 and outlined in Appendix 2.

3.2 Perinatal Mortality Audit in Other High-Income Countries

United Kingdom

The CESDI was established in 1992, after the Department of Health directed that the 14 regions of England should undertake perinatal mortality surveys. The process identifies approximately 10,000 deaths annually in England, Wales, and Northern Ireland. Public recommendations for action are made based on the findings of the enquiries. The additional social and political pressure of public reports has mobilised national attention and resulted in channeling more resources to the problems identified. The Confidential Enquiry into Maternal and Child Health (CEMACH) was established in April 2003 to replace the CESDI. CEMACH has combined with the National Institute for Health and Clinical Excellence (NICE), and more recently is being run by the National Patient Safety Agency.

Netherlands

In the Netherlands nationwide perinatal audits are conducted through a joint effort by the government and oppressional colleges across all 90 obstetric units in the country.

Norway

In Norway, multidisciplinary perinatal audit has been implemented since 1986.

United States

In the USA, several Fetal and Infant Mortality Review (FIMR) programmes have been established to review these deaths and make recommendations for improvements in health care and public health in general. However, these programmes are not uniform in approach and, although many suggestions for improvements in care have been defined, no structured assessment of efficacy has been reported.

Australia

In Australia, while a national perinatal audit programme is yet to be implemented, state committees produce regular reports on rates and causes of perinatal mortality and in Victoria and Western Australia health departments routinely undertake perinatal mortality audits (Flenady et al., 2010).

New Zealand

In New Zealand, maternal and perinatal audit (including in-depth review for substandard care) has been in place since 2006 with all mortality review committees under the auspices of the Health Quality and Safety Commission since 2009 and funded by the national Department of Health, which follows bi-national guideline recommendations.

3.3 Evidence from Studies on the Impact of Perinatal Mortality Audit

Although perinatal audit is accepted as a vital component of obstetric care, more high quality studies are needed to identify its value in improving practice and health outcomes (Pattinson et al., 2005). To date, only one systematic review examining the impact of introduction of perinatal audit in developing and middle-income countries has been carried out (Pattinson et al., 2009b). This systematic review by Pattinson et al. was a meta-analysis of before-and-after effects associated with the introduction of perinatal audits and showed a 30% reduction in perinatal mortality. Pattinson et al. found that that no randomised control trials were conducted in this area. Findings from observational studies based in high income countries have also found positive findings. Flenady and colleagues in The Lancet (2013) *Stillbirths Series* have shown that in 30-70% of stillbirth cases substandard care factors contributed to or caused the death (Flenady et al., 2011a). In Norway, the PMR has decreased from 13·8 to 7·7 per 1,000 births since the introduction of the national perinatal audit in 1986 (Bergsjo et al., 2003). In New Zealand, stillbirth rates at term have declined over the seven years since national perinatal audit was implemented.

While perinatal mortality audit is accepted as an essential component of care and case studies across countries highlight the yield in terms of identifying substandard care factors, further high-quality studies are needed to determine its value in improving practice and health outcomes. Research to identify the optimal approaches to classification of perinatal deaths is also needed. Additionally, outcomes associated with involving parents in perinatal mortality audit and methods to improve autopsy counselling and consent requires further research (Perinatal Society of Australia and New Zealand (PSANZ), 2018).

3.4 Perinatal Mortality Audit in Ireland

Before the establishment of the PMNCA, there was no nationally agreed dataset of perinatal mortality from a clinical perspective and definition of such deaths varied across maternity units. Further, most maternity units did not have an electronic data reporting system. The Harding Clarke Report, 2006 stated that:

'If every maternity unit was obliged each day to fill in key details of mother and baby into a computer programme and the data thus received was regularly analysed, there would be much benefit to the health system'. It was also noted that *'consideration to reporting sentinel events into a national integrated monitoring system'* was warranted and *'this system will be in addition to, but separate from clinical incident reporting'* (Clark, 2006).

Like other high-resource countries, stillbirths constitute a larger proportion of the overall perinatal death rate in recent decades. This has been attributed to advancements in intensive neonatal care. Thus, the capacity to identify clinical risk factors associated with stillbirths is critical. However, to date, there is no international consensus on how to best classify perinatal deaths despite the development of many perinatal death classification systems over the past three decades. Given the importance of regular perinatal mortality audit using a robust data collection tool and classification system the NPEC established the PMNCAGC in 2009 to develop a national audit system of perinatal mortality in Ireland from a clinical perspective. The fundamental aim of this programme is to improve Irish perinatal outcomes through the provision of key epidemiological evidence and clinical audit data.

After reviewing the international evidence, the PMNCAGC adapted an audit methodology in 2010 based on the validated CMACE Perinatal Death Notification Form and Classification System on cause of death, (CMACE, 2010). A strength of this classification system is that it was developed following a meta-analysis of existing, classification systems. To ensure the feasibility of this new data collection tool, a pilot study was conducted in three maternity units between 1st January 2010 and 31st December 2010. Following the pilot study, the dataset was further developed with the PMNCAGC, and the data and findings were analysed.

Findings from this pilot study demonstrated that using the NPEC Classification System rather than the Wigglesworth Classification System (a classification system widely used in Irish maternity units at the time) substantially reduced the proportion of unexplained stillbirths (Manning E, 2013).

Further, detailed data on a wide breadth of clinical factors provided the capacity to improve clinical interpretation of perinatal deaths. Collection of anonymised perinatal mortality data using the new NPEC Perinatal Death Notification Form was initiated at a national level in January 2011.

This audit methodology allows for international comparison and has been endorsed by the Clinical Advisory Group at the IOG, the Faculty of Paediatrics and the HSE National Obstetric Programme Working Group.

3.5 National Perinatal Epidemiology Centre Perinatal Mortality Clinical Audit Tool

The suitability of a measure for inclusion in a NCA depends on several explicit criteria: validity, fairness, sufficient statistical power, and adequate technical specification. In addition to these criteria, it is also important for a set of audit measures to be balanced. In other words, the audit should cover various dimensions of care to give a complete overall picture of the service.

The NPEC Perinatal Mortality Clinical Audit Tool enables data collection, validation, analysis and reporting of stillbirths and neonatal deaths. The NPEC produces annual perinatal mortality reports outlining national and hospital specific PMR in addition to maternal socio-demographic factors, clinical characteristics of mothers and babies, causes of death and post-mortem uptake. The report outlines indicators that are clinically relevant and of use to our audience of women and families, clinicians, policy makers, commissioners, and stakeholder groups. In addition to the clinical measures, the audit also provides contextual information describing the characteristics of women and babies cared for by the Irish maternity services. Embedded within the audit data collection tool is a cause of death classification system which is used as part of the audit process in the classification of the causes of stillbirths, neonatal and perinatal death.

3.6 Analysing the Causes: Causes of Death Classification Systems

Analysis of deaths by cause is essential for useful lessons to be learned. To improve our understanding of the causes and events leading to the perinatal deaths and, where an underlying cause cannot be identified, to describe in detail and in terms of what happened are two non-mutually exclusive principal purpose for classification of perinatal death. Classification of death is not standardised across countries and the type of classification tool varies from country to country. Whilst the Wigglesworth and Aberdeen Classification Systems are widely used, they are often considered sub-optimal given the large proportion of stillbirths which are attributed to non-specific or unexplained causes. This inherent lack of information limits the clinical lessons that could be learned, inhibits the identification of public health interventions and may impact on counselling of bereaved parents (Gardosi, 2005). To better elucidate risk factors associated with perinatal death, audit tools would ideally capture information on antecedent maternal, infant, and clinical conditions.

For example, CESDI uses three systems of classification, the Extended Wigglesworth Classification, Obstetric (Aberdeen) Classification and Fetal and Neonatal Factor Classification.

The Obstetric (Aberdeen) Classification (1969)

Similarly, to the extended Wigglesworth Classification, the amended Aberdeen Classification also explores the maternal and the fetal contributing factors with a probable cause and events leading to the perinatal death. The classification is based on presented clinical criteria in both the maternal and fetal factors. It includes congenital anomaly, isoimmunisation, pregnancy hypertension, antepartum haemorrhage, trauma, maternal disorder and unknown, in the classification of perinatal death. In addition, infection of the fetus or neonate, toxaemia, serological incompatibility and mechanical causes were included in the amended classification in 1969 (Chan et al., 2004).

Fetal and Neonatal Factor Classification (1986)

The Fetal and Neonatal Factor Classification allowed for most probable cause of death based on both clinical and pathological findings, and focuses on the fetus and neonates as a separate individual (Flenady et al., 2009) in understanding perinatal deaths. Classification groupings investigate fetal and neonatal conditions which includes congenital abnormalities, severe pulmonary immaturity, hyaline membrane disease, asphyxia before birth (antepartum or intrapartum), birth trauma, intracranial haemorrhage, infection, and isoimmunisation.

The Extended Wigglesworth Classification (1989)

The functional groupings in the Extended Wigglesworth Classification targets the cause of stillbirth and neonatal deaths with each grouping requiring, different strategies to understand the reasons for and, for prevention of perinatal deaths. The classification groupings include lethal congenital anomalies, maceration in antepartum stillbirths, asphyxial deaths (intrapartum stillbirths and neonatal deaths), immaturity associated deaths (neonatal deaths), and specific causes of deaths such as congenital infection or iso-immunisation, accident or non-intrapartum trauma, and sudden infant death syndrome (SIDS) (Gardosi, 2010, Flenady et al., 2009).

The NPEC Classification System (2007)

The NPEC data collection form requests contributors to identify maternal, fetal, and neonatal conditions, using specific categories, which caused or were associated with the death. The unit contributor is also requested to assign the principal cause of death with reference to the post-mortem and placental pathology if performed. Briefly described, categories include both pathophysiological entities and clinical conditions present at time of death including placental pathology and intrauterine growth restriction (IUGR). Classification of stillbirths was made using the NPEC Maternal and Fetal Classification System. In the case of neonatal deaths, the NPEC Neonatal Classification System was used to attribute the main neonatal cause of death and the NPEC Maternal and Fetal Classification System was used to identify the underlying obstetric condition/sentinel event associated with the death.

Despite the large number of perinatal classifications, there remains the absence of a standardised global classification tool. Therefore, the definition of the terms should be considered when classifying the fetal and neonatal factors involved in perinatal death despite the similarities in some of the classification groupings.

3.7 Clinical Guidelines and Standards

Clinical guidelines

Many countries do not have their own National Clinical Guidelines (NCG). In Ireland, at the time the PMNCA was being set up, clinical guidelines in the field of obstetrics and gynecology were not yet developed. However, clinical guidelines have now been developed by the IOG, Royal College of Physicians of Ireland (RCPI) and the Directorate of Strategy and Clinical Care, HSE. Further revisions and establishment of new guidelines is being overseen by the NWIHP. The PMNCAGC use these to guide and benchmark the audit. The following clinical guidelines are of note and key recommendations are outlined:

- **Investigation and management of late fetal intrauterine death and stillbirth (IUFD)** (Institute of Obstetricians and Gynaecologists, 2014)

  https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2016/05/4.-Investigation-and-Management-of-Late-Fetal-Intrauterine-Death-and-Stillbirth.pdf

  - Real-time ultrasonography is essential to diagnose IUFD accurately.
  - Management may involve awaiting spontaneous labour or planned medical induction.
  - It is usual clinical practice to recommend medical induction provided that this can be undertaken safely.
  - Vaginal birth is the recommended mode of delivery for most women, but caesarean birth may need to be considered in individual cases.
  - Clinical assessment and laboratory tests for post-mortem should be recommended to assess maternal wellbeing and to determine the cause of the death and provide information relevant to prevention of such. This must be undertaken by a trained senior obstetrician.

- **Recognition, diagnosis and management of fetal growth restriction** (Institute of Obstetricians & Gynaecologists, 2014)

  https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/fetal-growth-restriction.pdf

  - Recognition should include comprehensive medical and obstetric history from every patient at booking to assess risk of fetal growth restriction (FGR) (Hallgren Elfgren et al.).
  - Abdominal palpation and fundal height (FH) measurement in centimeters and plotting on a customised FH chart, if available, shows an improved, but still low, detection of FGR antenatally when compared with conventional methods. Use of such customised charts may be considered.
  - For diagnosis, every woman should undergo a comprehensive evaluation of the fetal anatomy (by a sonographer or clinician who is experienced in ultrasound) between 20- and 22-weeks gestation to rule out structural abnormalities and to assess for soft markers as a sign of chromosomal abnormalities. Referral to a fetal medicine specialist should occur as per local protocol.
  - Once FGR is diagnosed, 2-weekly assessment of fetal growth is recommended. In addition, amniotic fluid volume and umbilical artery doppler assessment should be carried out.
  - Management of FGR: timing of delivery should be individualised, depending on the suspected underlying cause of FGR.
  - For severe and very preterm infants, the optimal timing of delivery, requires a careful clinical balance between the risk of antepartum stillbirth due to delaying delivery and iatrogenic prematurity potentially causing significant morbidity or neonatal death by early intervention.

- The optimal mode of delivery should be determined following a multidisciplinary case discussion involving fetal medicine specialists. Caesarean section is likely when absent or reversed end-diastolic flow (AREDF) umbilical artery (UA) doppler waveforms are present, or in very preterm gestations. Induction of labour should be offered for all other women.
- Histopathological examination of the placenta is strongly recommended in all cases where FGR is diagnosed prenatally or at birth to understand the underlying causes and guide management in a subsequent pregnancy.

- **Model of care for neonatal services in Ireland bereavement** (Royal College of Physicians of Ireland, 2015)

  https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/model-of-care-for-neonatal-services-in-ireland.pdf

  - All relevant hospital staff sensitively communicate bad news to parents in a quiet and private environment and with special consideration.
  - The *'no chance'* and *'no purpose'* situations should be applied to newborns whose status deteriorates irretrievably despite intensive care.
  - An agreement on the importance of proceeding slowly and allowing parents and families plenty of time is essential and staff must explain about examinations and results of investigations that demonstrate poor outcome.
  - When intensive care is withdrawn, parents must be given time and privacy with their child. In protracted cases, the palliative care team should be consulted.
  - A bereavement counsellor should be available in all units.

- **Guideline for post-mortem consent and retention of samples** (Faculty of Pathology of the Royal College of Physicians of Ireland, 2000)

  https://www.hse.ie/eng/services/publications/hospitals/rcpiguidelinespm.pdf

  - Consent must be sought from the family of the deceased for all hospital post-mortem examinations and retention of organs.
  - Consent from the family of the deceased is not required if a post-mortem examination is ordered by the coroner.
  - Consent is required from the family of the deceased for the continued retention of organs for any purpose once the coroner's post-mortem examination and any other legal functions are complete.

- **Obesity and pregnancy clinical practice guideline** (Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland and Clinical Strategy and Programmes Directorate, Health Service Executive, 2013)

  https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/obesity-and-pregnancy.pdf

  - A low threshold fetal assessment and monitoring should be used with ultrasound or cardiotocography in women who are obese.
  - All women with Body Mass Index (BMI) greater than 29.9 kg/m^2 (where kg is a person's weight in kilograms and m^2 is their height in metres squared) at booking should be screened at 24 to 28 completed weeks gestation for gestational diabetes.

International consensus

As the audit is evolving the PMNCAGC are mindful of international practices. The below international consensus was proposed by PMNCAGC member nominated by the faculty of pathology. The group agreed with the proposal following discussion.

Classification of abnormal placental histology

Abnormal placental findings have been classified and presented under the following broad categories: maternal vascular malperfusion, fetal vascular malperfusion, cord pathology, cord pathology with distal disease, delayed villous maturation defect, chorioamnionitis, villitis and other placental condition. This is in keeping with recommendations in a publication from an international consensus meeting of pathology (Khong TY, 2015). It is envisaged that this will optimise classification of placental conditions causing or contributing to perinatal loss (Manning E, 2018). It will also allow for international comparison of pathological placental histology associated with perinatal loss.

3.8 Economic Assessment of the Perinatal Mortality National Clinical Audit

An economic assessment of the PMNCA has been conducted and the report is published as an annex to this document (Annex 1). The assessment highlights that the costs identified should be regarded as a conservative valuation, as the data available for many cost categories were lacking or absent. Research finds perinatal mortality auditing plays an important role in reducing perinatal loss, lessening the personal suffering, resulting in decreased monetary expenses and greater healthcare efficiencies.

4 Perinatal Mortality National Clinical Audit Implementation

4.1 Adherence to Clinical Audit Quality Performance Measures

Since 2011 the NPEC has conducted the PMNCA in Ireland using the methodology described in this report. The audit is led by the Director of the NPEC and supported by a multidisciplinary team, including a research midwife audit manager, perinatal epidemiologists and administrative support funded by the NPEC. Under the auspices of the NPEC, a multidisciplinary PMNCAGC was established in 2008 to develop a surveillance programme on perinatal mortality with the overall aim of contributing to improvement in perinatal outcome in Ireland. They represent a diverse range of clinical expertise and key stakeholders from maternity centres throughout the country as well as a public representative. The core function of the PMNCAGC is to ensure the integrity, success, and continual optimisation of the NCA process within the Irish maternity service. Whilst developing a comprehensive clinical dataset on perinatal mortality, the NPEC, in collaboration with the PMNCAGC, has collected and analysed perinatal mortality data from Irish maternity units since 2008.

After reviewing the international evidence, the PMNCAGC adapted an audit methodology in 2010 based on the validated CMACE Perinatal Death Notification Form and Classification System on cause of death (CMACE, 2010). This audit methodology allows for international comparison and has been endorsed by the Clinical Advisory Group at the IOG, the Faculty of Paediatrics and the HSE National Obstetric Programme Working Group.

There are defined criteria for inclusion in the PMNCA, based on the type of perinatal death, specifically stillbirths and neonatal deaths. Neonatal deaths are defined by the WHO and the Births and Deaths Registration Act. Stillbirths are defined by the Irish Stillbirths Registration Act (Houses of the Oireachtas, 1994). The conventions for calculating PMR are also based on international and national guidelines. The NPEC perinatal mortality notification dataset includes data on maternal and fetal characteristics, model and pathway of care, management of delivery, investigations into cause of death and factors associated with or causing the perinatal death. The NPEC PMNCA Perinatal Death Notification Form 2016, which was used for data collection, is included in Appendix 3.

To ensure feasibility of the NCA methodology in the Irish context, a pilot study was carried out in three maternity units in 2010 and following a national multidisciplinary response forum the PMNCA was implemented nationally in 2011. Since 2014, the NPEC aligns its audit governance structures to the NOCA audit governance standards for audit governance committees, monitoring & escalation of outliers and national reporting.

Prior to the implementation of the PMNCA nationally in 2011, all maternity units were visited by the NPEC, and training was provided for perinatal mortality data coordinators to support data capture and completion of the NPEC perinatal mortality dataset, both in paper format and online via the NPEC online portal. A reference manual (Appendix 4) is provided to support data quality and completeness with further support available by telephone. Training videos are provided on the NPEC website demonstrating access and use of the perinatal mortality online database. The NPEC also provides support to hospital-based clinicians and perinatal mortality data coordinators through facilitating information and educational meetings via webinars and in person. Resources, experiences, quality improvement initiatives and solutions are shared across units which promotes a culture of shared learning and data quality assurance. Accreditation from

the relevant faculties was achieved for these meetings enabling allocation of continuous professional development rewards for clinical practitioners in attendance (e.g. from the Nursing and Midwifery Board of Ireland and the RCPI).

4.2 Hospital Aspects of the Perinatal Mortality National Clinical Audit

In 2011, all maternity units in the Republic of Ireland (ROI) were invited to participate in the PMNCA. A template of the perinatal mortality dataset was disseminated to all units. The senior management team (Obstetric Lead, Director of Midwifery/ Nursing and Hospital Manager) in each maternity unit were requested to nominate the following:

- Perinatal mortality data coordinator with the responsibility of submitting data to the NPEC
- Senior clinicians to support the perinatal mortality data coordinator.

The NPEC advocates multidisciplinary involvement in the audit process at unit level to ensure complete case ascertainment and quality data. Further, in the context of identifying the main cause of perinatal death, the support and expertise of a senior obstetrician, midwifery, paediatrician, and pathologist are invaluable.

Since 2011, all maternity units in the ROI have contributed their data on perinatal deaths to the NPEC. The contribution of data to the NPEC is voluntary and many perinatal mortality data coordinators who collate data at unit level do so without protected time for clinical audit. There is no funding by the HSE for clinical audit on perinatal mortality at unit level. This has been recommended by the NPEC in successive annual perinatal mortality reports. In the 2018/2019 Perinatal Mortality National Clinical Audit Biennial Report all individual maternity hospitals/units were identified. This move to ensure transparency within the maternity service was taken by engagement with all senior management and discussions with the NPEC Governance Committee.

4.3 Data Collection Strategy

Within each of the 19 maternity units, data on perinatal deaths from births that occurred between 1st January of each year and 31st December of the same year are pseudonymised and submitted to the NPEC by perinatal mortality data coordinators using a standardised notification dataset either electronically, via the secure online NPEC database (15 maternity units), or by paper format in 4 maternity units. Data required to complete the perinatal mortality notification dataset is obtained from the following sources: maternal and neonatal clinical records, placental histology reports, post-mortem reports, and cytogenetic analysis reports.

Hospital access to the secure online NPEC database is restricted to the appointed hospital perinatal mortality data coordinators and clinical leads as nominated by senior hospital management. Access to the database is password protected and is only accessible after installation of a security certificate unique to the perinatal mortality data coordinator's computer. Individual usernames and passwords are issued directly by the NPEC. Within the NPEC, all perinatal mortality data is maintained on a high-security server with access limited to the relevant NPEC personnel only. The NPEC online database allows the NPEC to access data in a timelier manner, in addition to providing a specific dataset for local use and assisting hospital audit at local level. Users of the NPEC database can view data from their own unit only.

The NPEC data collection and management processes for the PMNCA are detailed in Appendix 5.

Data quality checks

Data can be considered to be of good quality when the correct reliable data is available in a timely manner (HIQA, 2018). The NPEC Data Quality Strategy outlines NPECs adherence to good practice regarding data quality as outlined in the *HIQA Guidance on a Data Quality Framework for Health and Social Care*, 2018. The NPEC strategy encompasses data quality polices that include:

- Data Collection Policy - including online and paper collection policy
- Data Processes Policy
- Data Validation Policy
- Data Storage Policy
- Data Dissemination Policy

Data quality is an inherent aspect of the PMNCA methodology and is defined and assessed here using the internationally accepted dimensions recommended by HIQA (HIQA, 2018):

1. Relevance
2. Accuracy and reliability
3. Timeliness and punctuality
4. Coherence and comparability
5. Accessibility and clarity

Relevance

Processes are in place to regularly monitor the relevance and use of existing data in meeting the needs of data users and other stakeholders. Regular consultation with data users and other stakeholders is undertaken. These are structured consultation activities focusing on the content and the quality of the data collected, the outcomes, continuous operational improvements, future direction, and potential needs.

Accuracy and reliability

All perinatal mortality data coordinators are provided with training prior to data collection commencement. Specific instruction on data quality and definitions is provided in the PMNCA Reference Manual. Internal procedures and guidelines for data quality assessment exist and include data cleaning and validation procedures regarding data submitted through both the online and paper formats.

The NPEC online database incorporates a suite of validation checks for accuracy. Data cleaning and correction processes are consistently applied. These include checks on the structure and integrity of the data, checks for missing data, checks that the data conforms to data source specifications and checks for outliers.

The NPEC undertakes extensive reconciliation of its annual perinatal mortality dataset with that of the NPRS. This consolidation with the NPRS is in response to recommendations by the CMO and ensures that both agencies' datasets represent the most accurate record of perinatal mortality annually. The NPRS dataset is based on the HSE Civil Registration Service Birth Notification Form which is a legal requirement for all births in Ireland.

Timeliness and punctuality

The NPEC works closely with the perinatal mortality data coordinators to ensure timely submission of data. The NPEC makes data providers aware of submission dates. Planned releases occur within a reasonable period of time from the end of the reference period.

Coherence and comparability

Assessments of compliance with terminology standards are regularly undertaken to ensure the data collection is compliant with international and national standards, including clinical guidelines and current best practice.

Divergences originating from different sources are identified and reasons are clearly and publicly explained. For example, stillbirth and perinatal morality rates are calculated differently by various countries and institutions based on the definition of stillbirth used.

Geographic variation limitations that impact analysis and interpretation are documented for users.

Accessibility and clarity

The Annual Report for the National Clinical Audit of Perinatal Mortality is publically available on the NPEC website. Research output from the audit is catalogued according to individual staff members and publicly available on Institutional Research Information System (IRIS), Research Gate and other research information systems.

The NPEC operates a data access policy available on the NPEC website in which clear policies and procedures are outlined for data users in relation to the process of accessing and requesting data. The data access policy is available on the NPEC website at: https://www.ucc.ie/en/npec/dataaccesscommittee/

Data quality continuous improvement

The NPEC ensures that a continuous improvement review cycle is followed in the PMNCA. Reviews and updates are carried out on an annual basis to ensure issues arising are addressed and possibilities for improvement considered whilst being cognisant of maintaining comparable trend data. Yearly governance meetings are held with the PMNCAGC in which aspects related to the audit data and current relevant clinical guidelines are reviewed, for example for the reporting year 2017 of this audit, the NPEC collected data on whether a woman underwent an anatomy scan. This followed a recommendation made by the IOG, noting that second trimester fetal anomaly ultrasound scanning should be universally available for all pregnant women in Ireland. Additionally, an annual review meeting is carried out by the internal NPEC audit team.

4.4 Classification of Perinatal Death

The capacity to identify clinical risk factors associated with perinatal death is critical. However, to date, there is no international consensus on how to best classify perinatal deaths despite the development of many perinatal death classification systems over the past four decades. Whilst the Wigglesworth and Aberdeen Classification Systems are widely used, they are often considered sub-optimal given the large proportion of stillbirths which are attributed to non-specific or unexplained causes. This inherent lack of information limits the clinical lessons that could be learned, inhibits the identification of public health interventions, and may impact on counselling of bereaved parents (Gardosi, 2005). To better elucidate risk factors associated with perinatal death, audit tools would ideally capture information on antecedent maternal, infant, and clinical conditions (Smith GC, 2007).

An integral part of the PMNCA is the use of the NPEC Classification System on cause of perinatal death. Based on the CMACE Classification System, this classification system includes two new categories (specific placental pathology and IUGR) which were formally labelled as unexplained in the historically used Extended Wigglesworth Classification (CMACE, 2010). Consequently, the findings from the Perinatal Mortality Audit Pilot Study in 2010 demonstrated that using the NPEC Classification System rather than the Wigglesworth Classification System substantially reduced the proportion of unexplained stillbirths (Manning E, 2013).

The NPEC perinatal mortality notification dataset requests perinatal mortality data coordinators to identify maternal, fetal, and neonatal conditions, using specific categories, which caused or were associated with the death. The perinatal mortality data coordinator is also requested to assign the principal cause of death with reference to the placental pathology and post-mortem if performed.

Once all information is received, cause of death is coded centrally within the NPEC using the classification system, thus ensuring uniformity and consistency. Classification of stillbirths is made using the NPEC Maternal Fetal Classification System. In the case of neonatal deaths, the NPEC Neonatal Classification System is used to attribute the main neonatal cause of death and the NPEC Maternal and Fetal Classification System is used to identify the underlying obstetric condition/sentinel event associated with the death.

4.5 Reporting Process for the Perinatal Mortality National Clinical Audit

The NPEC produces an annual national report on perinatal mortality and unit specific reports for all 19 maternity units. Every year an expert in their field is invited to provide an invited commentary on a specific topic. A list of resulting topics that have featured in the perinatal mortality annual reports is outlined in Appendix 6. Following data analysis and report writing, the audit findings are reviewed and endorsed by the PMNCAGC. Prior to publication, the PMNCA Annual Report is reviewed and endorsed by the NOCA. The NPEC aligns its audit governance structures to the NOCA audit governance standards for audit governance committees, the monitoring and escalation of outliers (Appendix 7), and the standard for national reporting (Appendix 8). The NOCA endorsement letter for the PMNCA Annual Report 2016 is included in Appendix 9.

4.6 Extract from National Perinatal Epidemiology Centre Perinatal Mortality in Ireland Annual Report 2016

How to read this section

This section 4.6 is an extract from the NPEC Perinatal Mortality in Ireland Annual Report 2016. This is the sixth report of the PMNCA in the ROI, using the NPEC data collection tool and classification system. It provides information on perinatal deaths arising from births occurring in the ROI during 2016. For Perinatal Mortality in Ireland Annual Report 2016 denominator data on the number of live births and stillbirths were provided directly by the Healthcare Pricing Office (HPO). The full report is available on the NPEC website at: https://www.ucc.ie/en/npec/npec-clinical-audits/

The extract is presented in italicised text. Table and figure numbers, and references may not follow the sequence set out in the remainder of this report.

Comparison of perinatal mortality, 2011-2016

Table 1.2 compares the perinatal mortality outcomes for 2016, based on the criteria of birthweight greater than or equal to 500g or gestational age greater than or equal to 24 weeks, with those of the previous five years. There was a notable decrease in perinatal mortality in 2016 compared to 2015, the largest year-to-

year change observed during 2011-2016. PMR were higher in the period before 2011-2016. Thus, 2016 is the year with the lowest PMR ever recorded in Ireland. The largest relative year-to-year decrease was the 23% fall in the early neonatal death rate which was statistically significant (rate ratio (RR)=0.77, 95% confidence interval (CI)=0.61-0.97). The 15% decrease in the total PMR was also statistically significant (RR=0.85, 95% CI=0.74-0.97). The corrected PMR had a similar 16% decrease (RR=0.84, 95% CI=0.71-1.01) and the stillbirth rate was 11% lower in 2016 (RR=0.89, 95% CI=0.75-1.06). The time trend in each of the PMR is illustrated in Figure 1.2 below. The notable decreases in the rates in 2016 have reversed the effects of the smaller increases observed since 2011.

Table: 1.2 Comparison of perinatal statistics, 2011 - 2016

		2011	2012	2013	2014	2015	2016	RR (95% CI)
Total Births	N	74,265	71,755	69,146	67,663	65,904	64,133	
Stillbirths	n	311	299	294	325	288	250	0.89 (0.75-1.06)
	rate	4.2	4.3	4.2	4.8	4.4	3.9	
Early neonatal deaths	n	137	141	162	141	166	124	0.77 (0.61-0.97)
	rate	1.9	2.0	2.4	2.1	2.5	19	
Perinatal deaths	n	448	440	456	466	454	374	0.85 (0.74-0.97)
	rate	6.0	6.1	6.6	6.9	6.9	5.8	
Corrected perinatal deaths	n	296	292	296	315	279	229	0.84 (0.71-1.01)
	rate	4.0	4.1	4.3	4.7	4.2	3.6	

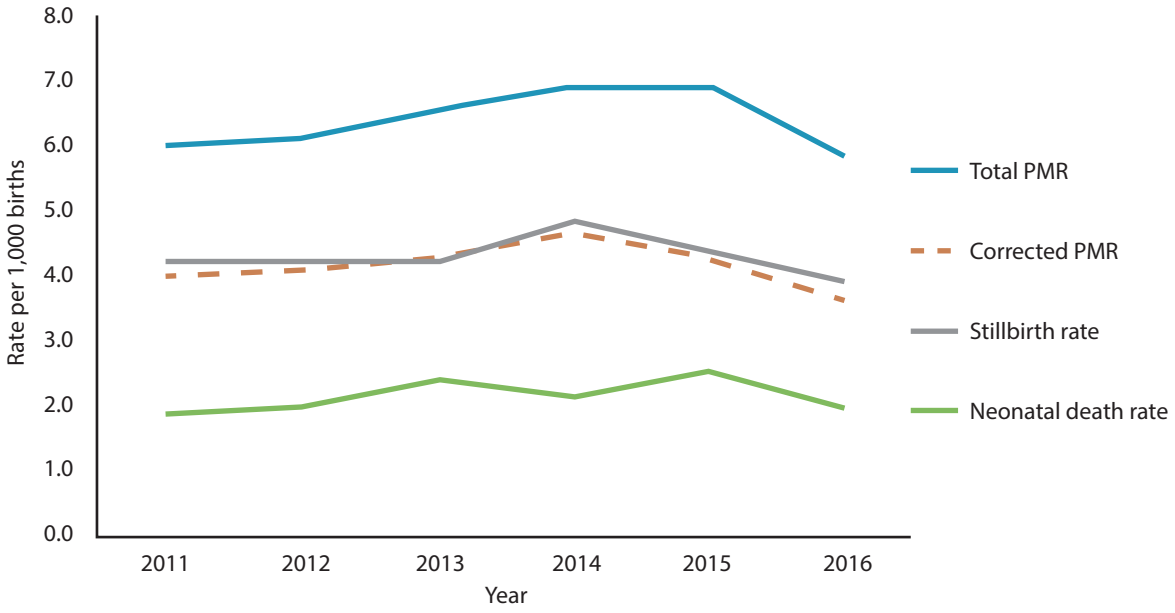

Figure 1.2: Trend in perinatal mortality rates in Ireland, 2011 - 2016

Note: Rates per 1,000 births; PMR = perinatal mortality rate; Corrected PMR excludes deaths due to a congenital malformation.

Variation by maternity unit

Based on birthweights greater than or equal to 500g and/or gestation at delivery greater than or equal to 24 weeks, the uncorrected PMR across the Irish maternity units ranged from 4.0 to 7.8 per 1,000 births (Table 1.3); the corrected PMR ranged from 2.0 to 5.9 per 1,000 births. This level of variation across units is lower than that observed in recent years. There was also a positive correlation between the 2015 and 2016 unit specific corrected PMR, which has not been evident in recent years. As reported earlier, there was a 17.1% decrease in the corrected PMR at the national level from 4.3 per 1,000 births in 2015 to 3.6 per 1,000 births in 2016. Year-to-year changes at the level of individual units are volatile due to the smaller numbers involved, however, there was a decrease in corrected PMR for 12 of the 19 units and the decrease exceeded 20% for eight units.

Table: 1.3 Perinatal mortality rates across Irish maternity units in 2015 and 2016.

Unit	Uncorrected PMR (95% CI)	Corrected PMR (95% CI)	
	2016	2016	2015
1	7.8 (3.6-11.9)	4.4 (1.3-7.6)	2.7 (0.5-5.0)
2	7.6 (5.7-9.4)	5.2 (3.7-6.8)	5.1 (3.6-6.7)
3	7.5 (4.5-10.6)	4.7 (2.3-7.1)	6.1 (3.4-8.8)
4	7.4 (2.7-12.0)	5.9 (1.7-10.0)	5.9 (1.7-10.1)
5	7.2 (3.0-11.3)	3.6 (0.7-6.5)	3.5 (0.6-6.3)
6	6.7 (3.0-10.4)	4.6 (1.5-7.7)	3.4 (0.8-6.0)
7	6.3 (2.5-10.1)	4.0 (1.0-7.1)	5.1 (1.7-8.5)
8	6.3 (4.6-8.0)	3.8 (2.5-5.1)	4.3 (2.9-5.6)
9	6.0 (3.2-8.8)	3.7 (1.5-5.9)	4.4 (1.9-6.8)
10	5.6 (2.0-9.1)	3.3 (0.6-6.1)	58 (2.3-9.4)
11	5.5 (1.8-9.2)	3.1 (0.3-5.8)	5.0 (1.5-8.5)
12	4.8 (0.5-9.2)	2.9 (0-6.3)	2.8 (0-6.1)
13	4.7 (3.2-6.2)	2.6 (1.5-3.7)	3.6 (2.3-4.9)
14	4.7 (2.6-6.7)	2.0 (0.7-3.3)	3.6 (1.9-5.4)
15	4.6 (3.0-6.1)	2.5 (1.3-3.6)	4.8 (3.3-6.3)
16	4.3 (1.1-7.6)	3.1 (0.3-5.8)	2.9 (0.3-5.5)
17	4.3 (1.4-7.1)	3.3 (0.8-5.8)	5.0 (2.0-8.0)
18	4.3 (0.8-7.7)	2.8 (0.5.7)	2.8 (0-5.7)
19	4.0 (0.7-7.3)	2.7 (0-5.4)	1.9 (0-4.0)
All	5.8 (5.3-6.5)	3.6 (3.1-4.1)	4.3 (3.8-4.8)

Note: Rates per 1,000 births based on birthweights ≥500g or gestational age ≥24 weeks; PMR = perinatal mortality rate; 95% CI = 95% confidence interval; Corrected PMR excludes deaths due to a congenital malformation; Two perinatal deaths were born outside of the maternity care and, therefore, were not included in the rates of any of the 19 units.

In utero transfer

In Ireland, women with high-risk pregnancies may be transferred to the care of tertiary maternity units with facilities for specialist fetal medicine and high-level neonatal intensive care. Of the 374 perinatal deaths in 2016, there were 36 cases (9.6%) where the care of the pregnant woman was transferred in utero.

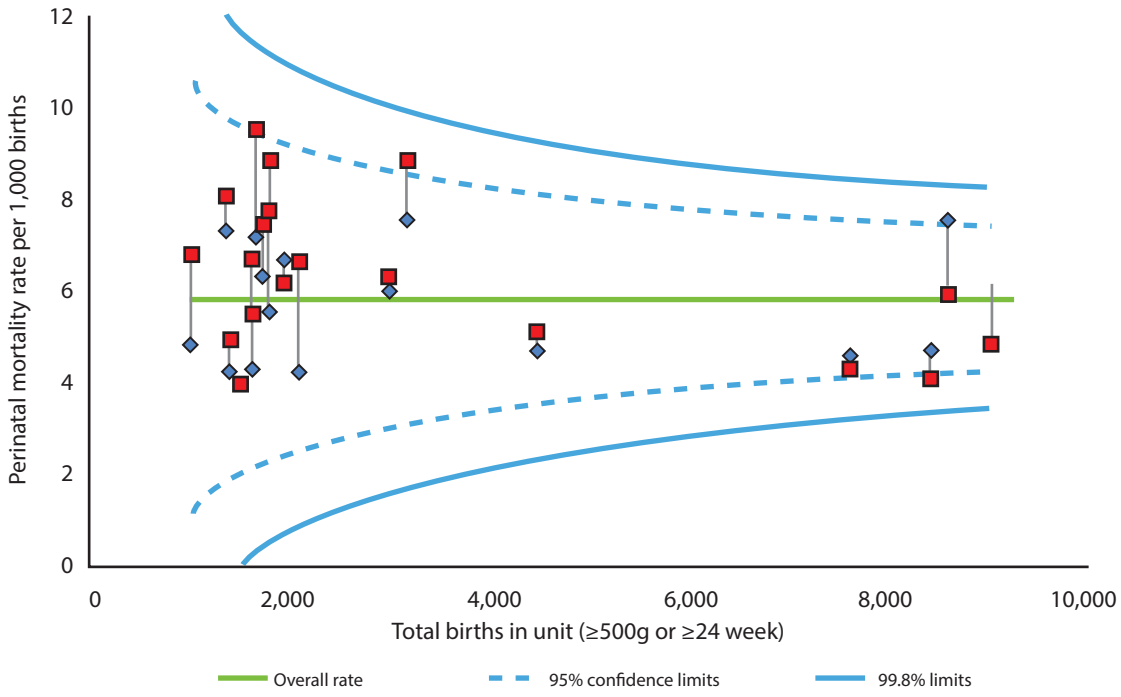

Figure 1.3: Funnel plot of the uncorrected perinatal mortality rate (PMR) for Irish Maternity Units, 2016

Note: The blue diamond markers indicate the unit-specific PMR that was observed in 2016 and the red square markers the PMR that would have been observed if in utero transfer cases had remained at the unit where the booking appointment had taken place.

Corrected perinatal mortality rate

The solid horizontal line in Figure 1.4 below represents the national corrected PMR in 2016 (3.6 deaths per 1,000 births). The curved dashed blue lines represent the 95% confidence limits around the national rate and the curved blue lines represent the 99.8% confidence limits. Statistically, one in 20 observations (i.e. 5%), can be expected to be outside the 95% confidence limits whereas an observation outside the 99.8% confidence limits is especially rare (i.e. approximately one in 500 observations). In 2016, the corrected PMR of all but one unit was within the 95% confidence limits indicating that they were consistent with the national rate. The exception had a corrected PMR that was higher than the national rate though it was not outside the 99.8% confidence limits. This unit was one of the maternity hospitals noted earlier as having a high proportion of perinatal deaths following in utero transfer. If perinatal deaths following in utero transfer were excluded from the corrected PMR for this unit, it would be reduced by 13.3% and would be within the 95% confidence limits.

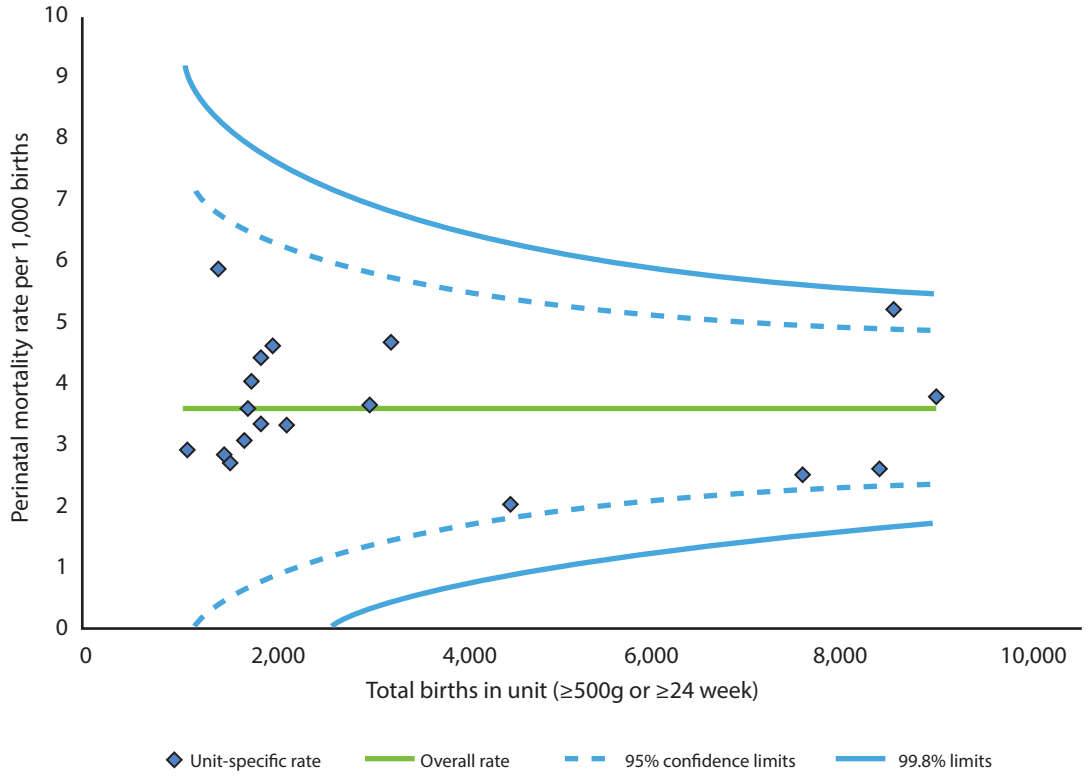

Figure 1.4: Funnel plot of the corrected perinatal mortality rate for Irish maternity units, 2016.

Note: Two units have similar rates of 3.06 and 3.08 (represented by overlapping diamonds.

International comparison of the rate of stillbirth

An article published in 2016 in The Lancet's *Ending Preventable Stillbirths Series*, compared the stillbirth rate across 48 high-income countries. The criterion for the stillbirth rate was gestational age greater than or equal to 28 weeks (Flenady V, 2016). Based on this criterion, Figure 1.5 illustrates the 2016 Irish total stillbirth rate and the corrected Irish stillbirth rate, which excludes cases due to a congenital malformation in comparison to the reported stillbirth rate for the other 47 high-income countries.

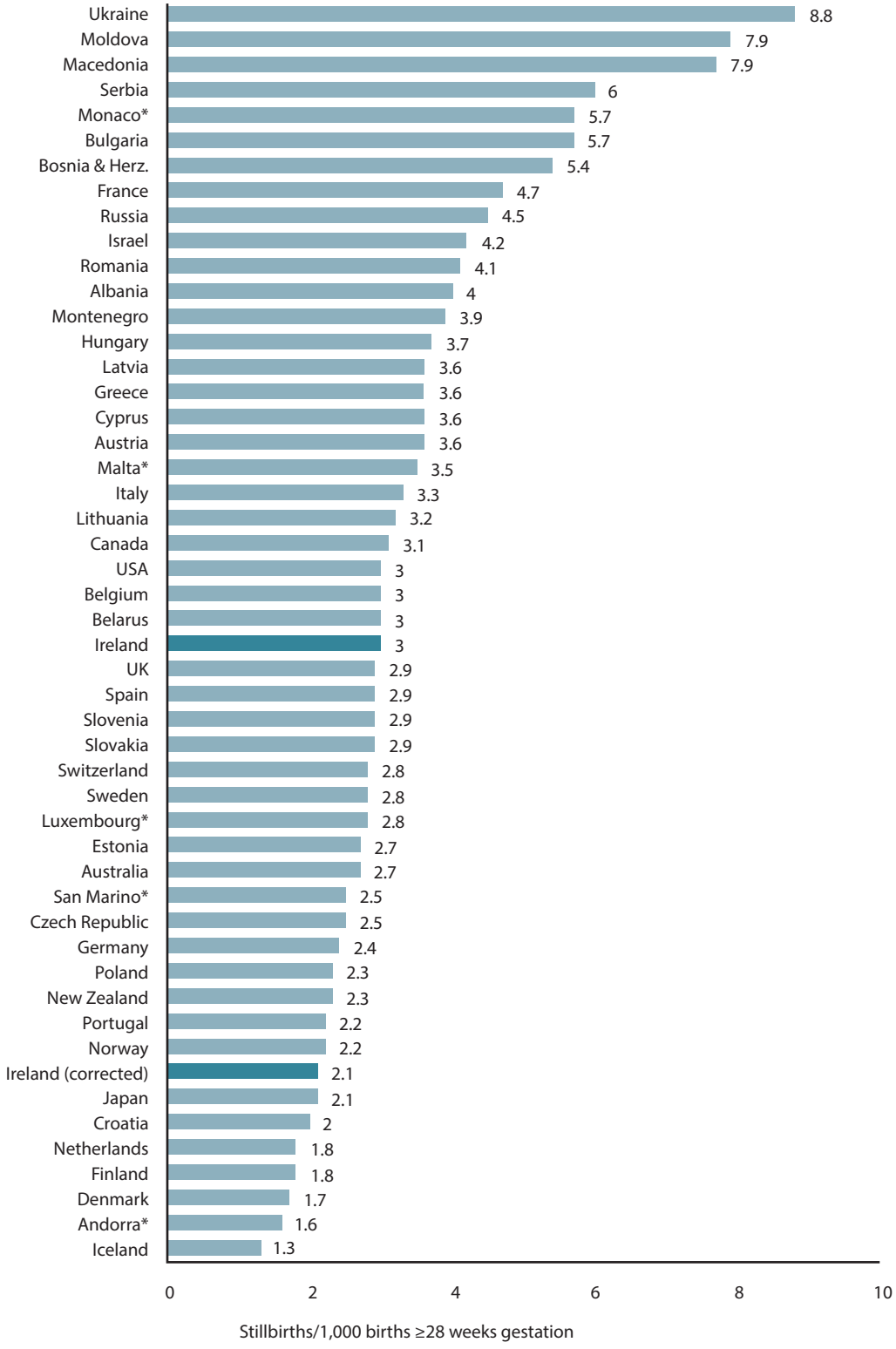

Figure 1:5: Irish stillbirth rate in 2016 compared to the stillbirth rate for 47 other high-income countries

Note: Rates based on stillbirths among births with ≥28 completed weeks of gestation. The Irish stillbirth rate, when corrected by excluding cases due to a congenital malformation, is adjusted to 2.1. *Indicates countries with fewer than 5000 births.

4.7 Communication and Dissemination of the Perinatal Mortality Annual Report

A 'lay summary' of the PMNCA Annual Report 2016 has been made available since publication of the full report and this summary contains commentary from the Patient Representative on the PMNCAGC. The lay summary is available at: https://www.ucc.ie/en/npec/npec-clinicalaudits/perinatalmortality/perinatalmortalitylaysummaries/

The Annual Report for the PMNCA is disseminated to various stakeholders including the Department of Health, HSE Chief Clinical Officer, NWIHP, Royal College of Obstetrics and Gynaecology, Midwifery Educational Programmes, and the public. Reports are available on the NPEC website at: https://www.ucc.ie/en/npec/

Following publication of the Annual Report for the PMNCA the NPEC facilitates a webinar to provide perinatal mortality data coordinators and clinicians an opportunity to discuss audit findings and recommendations. These webinars also provide a forum to discuss relevant issues impacting on data quality (e.g. timeliness and availability of post-mortem reports in the event of a coroner's inquiry).

The NPEC is committed to informing clinical practice to improve care in the maternity services. Audit findings are disseminated widely at various educational forums both nationally and at unit level. PMNCA findings have also been disseminated at numerous international conferences. A list of abstracts, presentations, and posters from the PMNCA has been included in Appendix 10.

4.8 Implementing and Sustaining Improvement

In Ireland, the PMNCA measures perinatal deaths from a clinical perspective. Maternal and fetal conditions associated with the perinatal death, and management processes, are examined to drive quality improvement at hospital and national level. Since its establishment, the NPEC has worked with all maternity units to promote an open culture of shared learning. The participation of all 19 maternity units in PMNCA reflects their commitment to go beyond clinical care and contribute to this national audit to help improve perinatal outcomes for mothers, babies, and their families.

In acknowledgment of the HSE's Accountability Framework (2016), the NPEC engages directly with senior management in maternity units and hospital groups regarding significant audit findings and audit outliers. The NPEC aligns to the NOCA escalation process in the event of an outlier and actions taken are detailed in the PMNCA Report while preserving anonymity of the unit. The NOCA Monitoring & Escalation Policy is outlined in Appendix 7. Working to these defined governance structures will improve clinical outcomes and patient safety nationally. The NPEC will continue to work with all stakeholders to ensure its active monitoring of clinical audit is aligned to the HSE Accountability Framework in the areas of safety and quality improvement (HSE, 2015). Since the inception of the PMNCA no maternity units have deviated as a statistical outlier from the national average PMR.

Perinatal mortality audit has been integral and influential to the strategic development of maternity services in the UK (CMACE, 2010). Similarly, in Ireland, recommendations to improve maternity services based on the PMNCA findings are being progressed by the NWIHP. These recommendations include:

- Establishment of an enquiry into unexpected intrapartum related deaths.
- Development of a national pathology service.
- Development of a multidisciplinary working group to address a national standardised approach to the detection of FGR (Hallgren Elfgren et al. 2016).

- Further engagement with the Coroner Society of Ireland to explore the timeliness of autopsy reports reported to maternity units.

Other quality improvements have evolved from the PMNCA recommendations. These include:

- The use of standardised terminology for presenting placental pathology as per the international consensus. This terminology is presented in the PMNCA Annual Report (Khong et al., 2016).
- Implementation of the Growth Assessment Protocol (GAP) Tool in an Irish maternity unit which enhanced surveillance and detection of FGR impacting on stillbirth rates. This quality improvement project was carried out by Our Lady of Lourdes Hospital, Drogheda and presented at the NPEC Study Day by Director of Midwifery, Grainne Milne.

The recommendation regarding a national standardised approach to the detection of FGR has led to improved awareness of this issue, reducing the risk of neonatal mortality and morbidity. This in turn can lead to earlier intervention in the later stages of the pregnancy and in the delivery stage.

The PMNCA highlights the care provided in units and the continued monitoring of outcomes. The awareness of the audit and the work of the NPEC has led to an increased knowledge of perinatal mortality and the associated risks. Enhanced risk assessment has now been shown to improve care and reduce adverse outcomes. The development and use of the PMNCA is an invaluable tool in identifying and monitoring areas that need to be addressed.

The use of standardised terminology for assessing placental pathology ensures that there is assessment of the placenta and enhanced knowledge of causation. This ensures better information for parents that may help to explain their loss and assist in planning care for future pregnancies for example, the need for folic acid, aspirin.

Research is the process that advances clinical knowledge and is essential to optimise the care in the maternity services. An objective of the PMNCA is to provide high quality data, enabling peer reviewed research, thereby driving clinical change. To date, data accrued by the PMNCA has provided a vital source of data in a number of research projects including the examination of intrapartum related deaths and the impact of placental pathology on perinatal death (K. McNamara 2018). Further research using PMNCA data is in progress exploring the impact of placental pathology, FGR and congenital heart conditions on perinatal deaths.

A very welcome development in the PMNCA is the collaboration between the NPEC and the Northern Ireland Maternal and Child Health (NIMACH) office. In Northern Ireland, surveillance and reporting of perinatal mortality is carried out by NIMACH using a comparable dataset and audit methodology. Collaboration between both agencies in producing this and future reports has allowed us to compare and learn more about perinatal mortality across the island of Ireland as we continue to work closely with colleagues in the UK and internationally. The NPEC continues to investigate how they can compare rates internationally. The lack of standardised international definitions does cause issues, the PMNCAGC extended the audit to capture cases of late neonatal deaths (i.e. death of a live born baby occurring from the 7th day and before 28 completed days after birth) and requested that if a baby born at less than 2 completed weeks is being registered as a neonatal death, that it is reported to the NPEC. These cases are reported in the annual reports available on the NPEC website at: https://www.ucc.ie/en/npec/

In the 2018/2019 PMNCA Biennial Report all individual maternity hospitals/units were identified. Transparency in clinical audit is recognised as a key factor which builds trust in healthcare systems and trust is critical for system learning and improvement (National Advisory Group on the Safety of Patients in England, 2013). In a recent Cochrane Review, it was suggested that the public release of performance data in healthcare may slightly improve outcomes for patients whilst concomitantly leading to little or no difference in the services that patients choose to access (Metcalfe D, 2018). Working with units the NPEC, the PMNCAGC and the NPEC Governance Committee helped ensure units were confident with the change.

The PMNCA is now well established with all 19 maternity units contributing data, albeit without protected audit time for contributors in some units. Perinatal mortality audit data has contributed to a body of evidence and a series of outputs which have informed clinicians, bereavement midwife counselors, policy makers, public health initiatives and the public. Endorsement by the NCEC will help strengthen the position of the PMNCA and the NPEC mission to translate clinical audit data and epidemiological evidence into improved maternity care for families in Ireland.

5 Perinatal Mortality National Clinical Audit Governance

The NPEC was established in 2006, by then Minister for Health and Children Mary Harney. The centre was established following the publication of the Lourdes Hospital Inquiry Report carried out by Judge Maureen Harding Clark. The NPEC operates under a SLA between University College Cork and the HSE. The primary purpose of the NPEC is to collaborate with Irish maternity services to translate clinical audit data and epidemiological evidence into improved maternity care for families in Ireland. The NPEC functions through the Director and a team that provide managerial, operational, research and epidemiological support to deliver the objectives of the centre. The NPEC aligns the perinatal mortality audit governance structures to the NOCA audit governance standards for audit governance committees, the monitoring and escalation of outliers and for national reporting.

5.1 The National Perinatal Epidemiology Centre Governance Structures

The NPEC Governance Committee oversees the strategic direction for evaluation of quality in maternity services. The NPEC Governance Committee is a multi-disciplinary committee and Table 1 outlines membership. The responsibilities of the NPEC Governance Committee members are outlined below as per the terms of reference of the group:

1. Advise and support the NPEC in the achievement of its defined mission and

   objectives by:

   a. Advising on content and implementation of its strategy, business plan, and relevant policies and procedures

   b. Ensuring that it reflects the views of service users and health care professionals

   c. Taking into account best practice on monitoring the outcome of maternity care nationally and internationally.
2. Retain key function and responsibility for the strategic direction of NPEC audits (the operational management of individual audits is overseen by the relevant NPEC audit working groups).
3. Shape the strategic direction of specialty specific audit streams.
4. Ensure that national audit complies with all legal and statutory requirements.
5. Advise and support the NPEC on issues in relation to access to NPEC data and secondary research.
6. Support and facilitate consultation and information exchange between the NPEC and key stakeholders in support of the centre's mission and objective.
7. Present annual reports of national audits to the NOCA Governance Board prior to publication.
8. The Chair to the NPEC Governance Committee will endeavour to secure consensus decisions. Where this is not possible, the Chair will present views to the Director of NPEC who will take the ultimate decision on the issue.

Table 1: Membership of National Perinatal Epidemiology Centre Governance Board (October 2018)

Role/Representing	Name
Chair Consultant Obstetrician and Gynaecologist, National Maternity Hospital	**Dr Michael Robson**
Deputy Chair Consultant Neonatologist, Rotunda Hospital (Retired)	**Professor Tom Clarke**
Institute of Obstetrics and Gynaecology Representative	**Dr Sharon Cooley**
Patient Representative, University College Cork	**Ms Marie Cregan**
Chair of Midwifery, National University of Ireland, Galway	**Professor Declan Devane**
Senior Lecturer, National University of Ireland, Galway	**Dr Geraldine Gaffney**
Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital Director of the National Perinatal Epidemiology Centre	**Professor Richard Greene**
Consultant Obstetrician and Gynaecologist, Sligo General Hospital	**Dr Heather Langan**
Master, National University Hospital	**Dr Rhona Mahony**
Master, The Rotunda Hospital	**Professor Fergal Malone**
Faculty of Paediatrics Representative	**Professor Eleanor Molloy**
Clinical Midwife Manager III, St. Luke's General Hospital	**Ms Connie McDonagh**
Specialist in Public Health Medicine, HSE	**Dr Mary O'Mahony**
Master, Coombe Women and Infants University Hospital	**Dr Sharon Sheehan**
National Lead Midwife, Office of the Nursing & Midwifery Services	**Ms Sheila Sugrue**
NOCA Executive Director, National Office of Clinical Audit	**Ms Collette Tully**
Chair of the National Designated Midwifery Officer Group - Home Births	**Ms Ann O'Byrne**

The PMNCA is governed by the PMNCAGC, which makes executive decisions regarding the NCA. It is comprised of obstetrics, neonatology, midwifery, pathology, and patient representatives who have been nominated to the group by their respective professional bodies. Table 2 outlines the members of the group. The NPEC Governance and Management Structure for the PMNCA is outlined in Appendix 11.

Table 2: Membership of Perinatal Mortality National Clinical Audit Governance Committee

Role/Representing	Name
Chair Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital *Director of the National Perinatal Epidemiology Centre*	**Professor Richard Greene**
Assistant Director of Midwifery, Coombe Women & Infants University Hospital *Nominated by the Deputy Nursing Services Director, HSE*	**Ms Bridget Boyd**
Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick *Nominated by the Institute of Obstetricians & Gynaecologists, RCPI*	**Dr Gerry Burke**
Consultant Neonatologist, Rotunda Hospital *Nominated by the Faculty of Paediatrics, RCPI*	**Dr David Corcoran**
Senior Lecturer in Perinatal Epidemiology, National Perinatal Epidemiology Centre *National Perinatal Epidemiology Centre contributor*	**Mr Paul Corcoran PhD**
Project Manager, National Perinatal Epidemiology Centre *Perinatal Mortality Project Manager*	**Ms Edel Manning**
Consultant Paediatrician, Our Lady of Lourdes Hospital *Nominated by the Faculty of Paediatrics, RCPI*	**Dr Siobhan Gormally**
Research Officer, National Perinatal Epidemiology Centre *National Perinatal Epidemiology Centre contributor*	**Ms Sarah Meaney PhD**

Consultant Obstetrician & Gynaecologist, University Hospital Galway *Nominated by the Institute of Obstetricians & Gynaecologists, RCPI*	**Professor John Morrison**
Consultant Pathologist, National Maternity Hospital *Nominated by the Faculty of Pathology, RCPI*	**Dr Eoghan Mooney**
Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital *Nominated by the Institute of Obstetricians & Gynaecologists, RCPI*	**Professor Keelin O'Donoghue**
Clinical Midwife Manager III, University Hospital Waterford *Nominated by the National Lead Midwife Office of the Nursing & Midwifery Services Director*	**Ms Breda O'Donovan**
Clinical Midwife Manager III, National Maternity Hospital *Nominated by the Deputy Nursing Services Director, HSE*	**Ms Ann Rath**
Consultant Neonatologist, National Maternity Hospital *Nominated by the Faculty of Paediatrics, RCPI*	**Dr Anne Twomey**
Assistant Director of Midwifery, Sligo General Hospital *Nominated by the Deputy Nursing Services Director, HSE*	**Ms Oonagh McDermott**
Assistant Director of Midwifery, Rotunda Hospital *Nominated by the Deputy Nursing Services Director, HSE*	**Ms Patricia Williamson**
Patient Representative	**Ms Siobhan Whelan**

Management of conflict of interest

The NPEC acknowledges that from time to time, a conflict of interest (COI) may exist and that to avoid or eliminate them entirely is unlikely to be possible. If they are not managed effectively, however, and the NPEC is seen or perceived to be abusing its influence, likely consequences include loss of confidence by healthcare professionals and the public. Actual COI that are identified, acknowledged, and appropriately managed will ensure transparent and good decision making by the NPEC.

Audit monitoring and escalation

The NPEC aligns its audit governance structures to the NOCA audit governance standards for audit governance committees, the monitoring and escalation of outliers and for national reporting. The NOCA was established in 2012 to create sustainable clinical audit programmes at a national level. The NOCA Monitoring and Escalation Policy states that: *'That National Office of Clinical Audit produces annual national clinical audit reports across multiple areas of clinical care that aim to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis'* (NOCA, 2017) (Appendix 7).

The NPEC engages directly with hospitals to examine if data quality issues have arisen. Where statistical audit outliers are identified, the NPEC requires the hospital Chief Executive Officer (CEO)/Manager to identify a Senior Accountable Person to investigate and complete a report detailing the findings of the investigation and the associated corrective action plan; the outline and learning of which is included in subsequent PMNCA Annual Reports.

Information governance

This section outlines the policies that the NPEC adhere to regarding information governance. The NPEC is mindful of the sensitive data and ensure that all requirements are met. The NPEC is obligated to abide by all relevant Irish and European legislation relating to data. The relevant regulations and directives include:

- General Data Protection Regulation 2018 (GDPR)
- *Data Protection Act (2018)*
- *The Data Protection Act (1988/2003)*
- *European Communities Data Protection Regulations (2001)*
- *European Communities (Data Protection and Privacy in Telecommunications) Regulations (2002)*
- *Data Protection EU Directive 95/46/EC (1995)*

These regulations and directives provide the legislative basis for the approach of the Office of the Data Protection Commissioner about personal data across all sectors of society including the health service. The Data Protection Commissioner (2007) recommends that identifiable personal data should be either anonymised or pseudonymised as an optimal approach to clinical audit. Pseudonymisation involves removal of identifiable aspects of personal data and replacement with use of code for a look–up list by the data controller. To ensure confidentiality to patients and clinicians alike and to enable access to third parties all personal data is pseudonymised at hospital level, meaning no identifiable patient data leaves the hospital, as recommended by the Data Protection Commissioner (2007). THE NPEC Data Protection Policy (available on the NPEC website at: https://www.ucc.ie/en/npec/) guides management of privacy and confidentiality of individuals. Each employee and contractor of the NPEC is obligated to preserve confidentiality. To ensure this, all NPEC employees, students, contractors and other third parties are required to sign a confidentiality agreement. As the NPEC was formed under a SLA between the HSE on behalf of the Department of Health and University College Cork, the NPEC policies are underpinned by the Office of Corporate and Legal Affairs, University College Cork.

Freedom of Information requests

The Freedom of Information (FOI) Act 2014 was signed into law on 14 October 2014. Under the FOI Act 2014, individuals are entitled to apply for access to information held in records that are not otherwise publically available. The NPEC informs the requestor of the names of any other FOI body who hold the data requested. In this instance, individual requests to the NPEC will be referred to the treating hospital. The PMNCAGC and the NPEC Governance Committee will be informed of all FOI requests.

Access to NPEC PMNCA data by third parties

The NPEC Data Access Committee membership outlined in Table 3 below has policies governing access by third parties to data including perinatal mortality. These policies cover requests for access to data for:

- Service provision or quality initiatives
- Anonymised data for research purposes.

Access to perinatal mortality data is granted following a detailed application and then a review and approval by the NPEC Data Access Committee. The NPEC polices and application form are available from the NPEC website at: https://www.ucc.ie/en/npec/dataaccesscommittee/dataaccesscommittee/

Like the details outlined in the NOCA GDPR Guidance for Clinical Audit, data submitted to NPEC is pseudonymised by the hospitals prior to disclosure to NPEC and NPEC cannot identify individual patients. In addition, when the NPEC provides data to third parties for research studies it is fully annoymised, those third parties cannot identify any individuals from the data and have no means of re-identifying individuals from any other data or sources. This means that, in the possession of the NPEC or third-party researchers, this data is not personal data (NOCA, 2019).

Table 3: Membership of the National Perinatal Epidemiology Centre Data Access Committee

Chair Professor Richard Greene, Director of the National Perinatal Epidemiology Centre
Professor Eleanor Molloy, Consultant Neonatologist, National Maternity Hospital
Professor Declan Devane, Chair of Midwifery, National University of Ireland, Galway
Dr Geraldine Gaffney, Senior Lecturer, National University of Ireland, Galway
Dr Michael Robson, Consultant Obstetrician and Gynaecologist, National Maternity Hospital

Public reporting

The NPEC is committed to national reporting of clinical audit data to ensure continual learning, transparency of process, and quality improvement of health care. The NPEC is committed to ensuring that audit output is published and disseminated with appropriate timeliness, clarity, and detail, to facilitate change in clinical practice, and in a form suitable for its audience, health care professionals, service users and general public. The NPEC Dissemination and Communications Workplan for the PMNCA Annual Report 2016 is outlined in Appendix 12. Audit findings are published nationally once the NOCA Governance Board has endorsed the audit output. The findings are presented to the Department of Health, HSE Chief Clinical Officer, HSE representatives, and units can review their data in their individual hospital reports.

5.2 Roles and Responsibilities of Perinatal Mortality National Clinical Audit Implementation

The NPEC through the Director is responsible for the operational delivery of the PMNCA. This team is supported by the multi-disciplinary PMNCAGC. The Director is chair of the PMNCAGC. From its inception, representation from various stakeholder groups was invited to participate in the PMNCAGC. These include representatives from several disciplines and specialities across maternity services including the IOG, neonatologist and paediatricians, midwives, pathologists researchers and patient advocates.

The PMNCAGC is responsible to oversee the audit meet its aim and objectives and is accountable to the NPEC Governance Committee.

This includes periodic review of the perinatal mortality dataset to ensure relevance to the Irish context. A key deliverable is the NPECs ability to build local support at hospital level for both implementation and sustainability. The NPEC Director and team visit the hospitals on regular basis. Webinars and regular catch-up calls also ensure the sustainability of the audit in units. The PMNCA is well embedded in the 19 maternity units. At hospital level a perinatal mortality data coordinator is nominated, and this person works with a local multidisciplinary team. The NPEC continues to recommend protected time for perinatal mortality data coordinator in units.

The NPEC supports the perinatal mortality data coordinator in their role through:

- Individual hospital reports are sent to the senior management and auditor of each unit. Feedback has indicated the reports are discussed at local level and are used for training purposes. The NPEC ensure to include key indicators for units and request regular updates to allow units to benefit from the individual reports.
- Webinars and teleconferences following release of national reports. The webinars allow for an interactive session with the unit multidisciplinary teams.
- Regular individual telephone calls and face-to-face support is also offered.
- The NPEC also holds an annual study day providing an opportunity to meet with all perinatal mortality data coordinators engaged in NPEC audits. Every second year the NPEC holds a feedback forum for all coordinators. These events allow the coordinators to come together and discuss positive steps taken with the units.

5.3 Procedure for Review of Perinatal Mortality National Clinical Audit

The NPEC works with the PMNCAGC to review the data that is being collected. Changing clinical standards are monitored to ensure that key areas are monitored and added if required.

An example of one area that has evolved is the classification of abnormal placenta histology. The terminology now used is in keeping with recommendations in a publication from an international consensus meeting of pathology. It is envisaged that this will optimise classification of placental conditions causing or contributing to perinatal loss (Khong et al., 2016). Data collection is also monitored to ensure the quality of data is continually improved. The NPEC publically lists both associated research as well as publications arising from use of NPEC perinatal mortality data. All updates to the NPEC perinatal mortality dataset are approved by the PMNCAGC which is chaired by the Director of the NPEC.

6 Appendices and References

Appendix 1: NPEC Perinatal Mortality National Clinical Audit Governance Committee Terms of Reference

Appendix 2: Clinical Guidelines and Standards used in the NPEC Perinatal Mortality National Clinical Audit

Appendix 3: NPEC Perinatal Mortality National Clinical Audit Perinatal Death Notification Form 2016

Appendix 4: NPEC Perinatal Mortality National Clinical Audit Reference Manual 2016

Appendix 5: NPEC Perinatal Mortality National Clinical Audit Data Collection and Management Processes

Appendix 6: List of Invited Commentaries that Feature in the NPEC Perinatal Mortality National Clinical Audit Annual Reports

Appendix 7: NOCA Monitoring & Escalation Policy

Appendix 8: NOCA Standard for Annual Reports Template

Appendix 9: NOCA Endorsement Letter for the NPEC Perinatal Mortality National Clinical Audit Annual Report 2016

Appendix 10: List of Abstracts, Presentations and Posters from the Perinatal Mortality National Clinical Audit

Appendix 11: NPEC Governance and Management Structure for the Perinatal Mortality National Clinical Audit

Appendix 12: NPEC Dissemination and Communications Workplan for the Perinatal Mortality National Clinical Audit Annual Report 2016

Appendix 13: List of Acronyms and Abbreviations

Appendix 1: NPEC Perinatal Mortality National Clinical Audit Governance Committee Terms of Reference

NATIONAL PERINATAL EPIDEMIOLOGY CENTRE

Perinatal Mortality National Clinical Audit Governance Committee

Terms of Reference

Version: October 2009; Revised: March 2020

I. To maintain a surveillance programme on perinatal mortality with the overall aim of contributing to improvement in perinatal outcome t¬hrough the provision of key epidemiological evidence.

II. To collect and report information on all babies delivering without life from 24 weeks and/or ≥ 500g, and any live born baby dying within 28 days after delivery (irrespective of the baby's weight or gestational age, as per Vermont Oxford Network guidelines), as part of its mortality surveillance work.

III. To develop a nationwide surveillance programme on intrapartum deaths.

IV. To develop a surveillance programme to investigate all fetal loss after 22 completed weeks

V. Provide timely data on perinatal deaths in the form of an annual national perinatal mortality report for hospitals with maternity services, within 18 months of the year end. To monitor and report on all perinatal deaths and their causes in the Republic of Ireland, in a format that is meaningful to the relevant health bodies e.g. HSE, DOHC, professional organizations (RCPI, IOG, Faculty of Pathology, Academy of Paediatrics) and other organizations (Irish Perinatal Society).

VI. To contribute to activities working to improve perinatal mortality through the provision of key epidemiological evidence – as follows;

   i. Provide ongoing quality, timely epidemiological data on perinatal deaths, for the purposes of informing health policy, service planning and further research, and benchmark at a local, regional and national level

   ii. Maintain a national model for perinatal mortality review and surveillance and allow for international comparison;

   iii. Examine clinical care prior to perinatal death and use this information to make recommendations for the improvement of clinical care, where appropriate

   iv. Provide findings relating to perinatal mortality that can assist national guidelines and clinical advice via partnerships with the Institutes, Colleges, HSE and other guideline or audit development groups

   v. To provide data to researchers, planners, healthcare organizations and policy makers in public health on the major "clinical" and "non-clinical" risks associated with perinatal death

   vi. To identify and promulgate areas for further research on perinatal mortality and morbidity.

Appendix 2: Clinical Guidelines and Standards used in the NPEC Perinatal Mortality National Clinical Audit

Clinical Standards	specific measure	Source	Description
Fetal growth restriction	Fetal growth, amniotic fluid volume and umbilical artery oppler	https://www.hse.ie/eng/services/publication s/clinical-strategy-and-programmes/fetal- growth-restriction.pdf	Patients who had gestational age of the fetus estimated by ultrasound at or prior to 20 weeks (20 weeks initially estimated by date of LMP)
BMI	Weight and Height; Ultrasound or cardiocography in mobidly obese patients.	https://www.hse.ie/eng/about/who/acute- hospitals-division/woman-infants/clinical- guidelines/obesity-and-pregnancy.pdf https://www.hse.ie/eng/about/who/acute- hospitals-division/woman-infants/clinical- guidelines/nutrition-during-pregnancy.pdf	Patients who had at booking been identified as being overweight or obese based on the Body Mass Index (BMI)> 29.9 kg/m2
Smoking	None	There are no national guidelines for smoking during pregnancy. Services are available for cessation of smoking in all maternity hospital. https://www.lenus.ie/bitstream/handle/10147/44841/6501.pdf?sequence=1 https://www2.hse.ie/quit-smoking/support- services/ http://imj.ie/a-national-audit-of-smoking- cessation-services-in-irish-maternity-units/	Patients who at booking were identified through self-reporting as using tobacco product
Gestational Age	Physical examination: Abdominal palpation and fundal height (FH)	https://www.hse.ie/eng/services/publication s/clinical-strategy-and-programmes/fetal- growth-restriction.pdf	Important in determining perinatal outcome at delivery along with birth weight. It is used to determine the prospect of survival at birth and guides the timing of delivery(Baschat et al., 2007)

Clinical Standards	specific measure	Source	Description
Gestation Weight	Estimated fetal weight , abnormal umbilical artery doppler measurement, FH	https://www.hse.ie/eng/services/publication s/clinical-strategy-and-programmes/fetal- growth-restriction.pdf	Estimated fetal weight below the 10th centile. The interpretation based on gestational age relies on accurate dating of pregnancies and customized growth standard (Unterscheider et al., 2013)
Hypoxic-Ischaemic Encephalopathy (HIE)	Core body temperature	https://www.hse.ie/eng/services/publication s/clinical-strategy-and- programmes/neonatal-therapeutic- hypothermia-summary-nov-18.pdf	A reduced oxygen or blood supply before or during birth, evidenced by abnormal neurological behavior after birth in some infants.

Appendix 3: NPEC Perinatal Mortality National Clinical Audit Perinatal Death Notification Form 2016

NATIONAL PERINATAL EPIDEMIOLOGY CENTRE

For NPEC Office use only:
CASE NUMBER

PLACE OF DEATH:

PERINATAL DEATH NOTIFICATION FORM
2016

CHOOSE Type of Case *(TICK)*

☐ **STILLBIRTH:** *A baby delivered without signs of life* from 24 weeks' gestation and/or with a birth weight of ≥ 500g.

*If the birth occurred unattended and there was no lung aeration seen at Post Mortem (PM) and no other circumstantial evidence of life at birth, it should be assumed that the baby was stillborn.

OR

☐ **EARLY NEONATAL DEATH:** *Death of a live born baby occurring before 7 completed days after birth.*

OR

☐ **LATE NEONATAL DEATH:** *Death of a live born baby occurring from the 7th day and before 28 completed days after birth.*

* For the purpose of reporting, a 'live born' baby is defined as any baby born with evidence of life such as breathing movements, presence of a heart beat, pulsation of the cord or definite movement of voluntary muscles.

If a baby born at <22 completed weeks is being registered as a neonatal death, please report same to NPEC.

The National Perinatal Epidemiology Centre is sincerely grateful for your contribution to this audit.

Guidance for completing this form, with specific reference to Sections 11, 12 and 13 on Cause of Death, is outlined in the accompanying reference manual.

The National Perinatal Epidemiology Centre also acknowledges with thanks the Centre for Maternal and Child Enquiry (CMACE) UK for permission to modify and use its Perinatal Mortality Notification Proforma for use in the Irish context.

SECTION 1. WOMANS' DETAILS

1.1. Mother's age ☐☐

1.2. Ethnic group:

☐ White - Irish ☐ Irish Traveller

☐ Any other White background ☐ Please specify country of origin_____

☐ Asian or Asian Irish ☐ Black or Black Irish

☐ Other including mixed ethnic backgrounds: Please specify _____

☐ Not recorded

1.3. Marital status: ☐ Married ☐ Never married ☐ Separated/Divorced ☐ Widowed ☐ Unknown

1.4. Living with partner / spouse? ☐ Yes ☐ No ☐ Unknown

1.5. Woman's employment status at booking?

☐ Employed or self-employed (full or part time) ☐ Unemployed (looking for work)

☐ Student ☐ Home maker ☐ Permanently sick/disabled

☐ Other_____ ☐ Unknown

1.7. Height at booking (round up to the nearest cm): ☐☐☐

1.8. Weight at booking (round up to the nearest kg): ☐☐☐

If weight is unavailable, was there evidence that the woman was too heavy for hospital scales? ☐ Yes ☐ No

1.9. Body Mass Index at booking (BMI): ☐☐.☐

1.10. a. Did the woman smoke at booking? ☐ Yes ☐ No ☐ Unknown

specify quantity smoked per day_____

1.10.b. Did she give up smoking during pregnancy? ☐ Yes ☐ No ☐ Unknown ☐ N/A

1.11. Is there documented history of alcohol abuse?

☐ None recorded ☐ Prior to this pregnancy ☐ During this pregnancy

1.12. Is there documented history of drug abuse or attendance at a drug rehabilitation unit?

☐ None recorded ☐ Prior to this pregnancy ☐ During this pregnancy

SECTION 2. PREVIOUS PREGNANCIES

2.1. Did the woman have any previous pregnancies? *If yes, please complete questions 2.2-2.4* ☐ Yes ☐ No

2.2. No. of completed pregnancies ≥24 weeks and or with a birth weight ≥ 500g (all live and stillbirths): ☐☐

2.3. No. of pregnancies <24 weeks and with a birth weight < 500g: ☐☐

2.4. Were there any previous pregnancy problems? *If yes, please tick all that apply below* ☐ Yes ☐ No

☐ Three or more miscarriages ☐ Pre-term birth or mid trimester loss ☐ Stillbirth, *please specify number* ☐

☐ Infant requiring intensive care ☐ Baby with congenital anomaly ☐ Neonatal death, *please specify number* ☐

☐ Previous caesarean section ☐ Placenta praevia ☐ Placental abruption

☐ Pre-eclampsia (hypertension & proteinuria) ☐ Post-partum haemorrhage requiring transfusion

☐ Other, please specify _____ ☐ Unknown

SECTION 3. PREVIOUS MEDICAL HISTORY

3.1. Were there any pre-existing medical problems? *If yes, please tick all that apply below* ☐ Yes ☐ No ☐ Unknown

☐ Cardiac disease (congenital or acquired) ☐ Epilepsy

☐ Endocrine disorders e.g. hypo or hyperthyroidism ☐ Renal disease

☐ Haematological disorders e.g. sickle cell disease ☐ Psychiatric disorders

☐ Inflammatory disorders e.g. inflammatory bowel disease ☐ Hypertension

☐ Diabetes ☐ Other, please specify _____

SECTION 4. THIS PREGNANCY

4.1. Final Estimated Date of Delivery (EDD): ☐☐/☐☐/☐☐☐☐ Unknown

Use best estimate *(ultrasound scan or date of last menstrual period)* based on a 40 week gestation, or the final date agreed in the notes.

4.2. Was this a multiple pregnancy at the onset of pregnancy? ☐ Yes ☐ No

4.3. Was this pregnancy a result of infertility treatment? ☐ Yes ☐ No ☐ Unknown

If yes, please specify method of fertility treatment _ _____ ___

4.4 Gestation at first booking appointment: ☐☐ weeks + ☐ days ☐ Not booked ☐ Unknown

4.5 Intended place of delivery at booking: Name of unit _____

Please specify the type of unit

☐ Obstetric Unit ☐ Alongside Midwifery Unit ☐ Home ☐ Unbooked

4.6 What was the intended type of delivery care at booking?

☐ Midwife ☐ Obstetric-Led Care ☐ Midwifery-Led Care ☐ Self-Employed Community

☐ Home c/o Hospital DOMINO Scheme

4.7a Was the care of the mother transferred from another unit with the fetus in utero? ☐ Yes ☐ No
If yes please answer question 4.7 b

4.7b Gestation at time of in-utero transfer: ☐☐ weeks + ☐ days ☐ Unknown

SECTION 5. DELIVERY

5.1. Onset of labour:

☐ Spontaneous ☐ Induced ☐ Never in labour

5.2. Intended place of delivery at onset of labour: Name of unit_____

Please specify the type of unit

☐ Obstetric Unit ☐ Alongside Midwifery Unit ☐ Home

5.3. What was the intended type of care at onset of labour?

☐ Obstetric-Led Care ☐ Midwifery-Led Care ☐ Self-Employed Community Midwife

☐ Home c/o Hospital DOMINO Scheme

5.4. Was the intended mode of delivery a planned caesarean section? ☐ Yes ☐ No

5.5. Place of delivery: Name of unit _____

Please specify the type of unit

☐ Obstetric Unit ☐ Alongside Midwifery Unit ☐ Other, please specify_____

5.6. What was the type of care at delivery?

☐ Obstetric-Led Care ☐ Midwifery -Led Care ☐ Born Before Arrival (BBA) - Unattended

☐ Self-Employed Community Midwife ☐ Home c/o Hospital DOMINO Scheme

5.7. Date and time of delivery/birth: **Date:** ☐☐/☐☐/☐☐ **Time:** ☐☐:☐☐

5.8.* What was the lie of the fetus <u>at delivery</u>*?

☐ Longitudinal ☐ Oblique ☐ Transverse

***5.9.* What was the presentation *<u>at delivery</u>*?**

☐ Vertex ☐ Breech ☐ Compound *(includes transverse and shoulder presentations)* ☐ Brow ☐ Face

5.10. What was the mode of delivery? (Please tick all that apply)

☐ Vaginal cephalic delivery ☐ Ventouse ☐ Forceps ☐ Assisted Breech delivery

☐ Vaginal Breech delivery ☐ Pre-Labour Caesarean Section ☐ Caesarean Section After Onset of Labour

CAESAREAN SECTIONS ONLY

5.11. What was the type of *or* indication for Caesarean Section?

☐ Elective - At a time to suit woman or maternity team ☐ Urgent - Maternal or fetal compromise which is not immediately life threatening

☐ Emergency - Immediate threat to life of woman or fetus ☐ Failed instrumental delivery

SECTION 6. ALL BABY OUTCOME

6.1. Sex of fetus/baby: ☐ Male ☐ Female ☐ Indeterminate

6.2. Number of fetuses/babies in this delivery: *(all identifiable including papyraceous)* ☐

Birth order of this fetus/baby:

☐ Singleton

☐ Twin 1 ☐ Twin 2

☐ Triplet 1 ☐ Triplet 2 ☐ Triplet 3

☐ Other multiple birth pregnancy, please specify_____ Birth Order ☐

***6.3.* If from a multiple delivery, what was the chorionicity?** *Please tick all that apply*

☐ Dichorionic diamniotic ☐ Monochorionic diamniotic ☐ Monochorionic monoamniotic ☐ Trichorionic

☐ Singleton ☐ Not known

6.4. Birth weight (kg): ☐.☐☐☐

6.5. Gestation at delivery: ☐☐ weeks + ☐ days ☐ Unknown

6.6. Was this a termination of pregnancy? ☐ Yes ☐ No
Please refer to the reference manual

6.7. Was a local hospital review of this case undertaken? ☐ Yes ☐ No
Please refer to the reference manual

SECTION 7. MATERNAL OUTCOME

7.1. Admission to HDU: ☐ Yes ☐ No

7.2. Admission to ICU: ☐ Yes ☐ No

7.3. Maternal Death: ☐ Yes ☐ No

SECTION 8. STILLBIRTH (If not a stillbirth, please go to Section 9)

8.1. At what gestation was death confirmed to have occurred? ☐☐ weeks + ☐ days

If known, what date was death confirmed? ☐☐/☐☐/☐☐☐☐

8.2. Was the baby alive at *onset of care* in labour? ☐

☐ Yes ☐ No ☐ Never In Labour ☐ Unattended ☐ Unknown

SECTION 9. NEONATAL DEATH ONLY

9.1. Was spontaneous respiratory activity absent or ineffective at 5 minutes? ☐ Yes ☐ No

If a baby is receiving any artificial ventilation at 5 minutes, the assumption is absent/ineffective activity: a 0 Apgar score indicates absent activity.

9.2. Was the heart rate persistently <100bpm? (i.e. heart rate never rose above 100bpm before death)

☐ Persistently <100bpm ☐ Rose above 100bpm

9.3. Was the baby offered *active resuscitation in the delivery room? ☐ Yes ☐

*active resuscitation includes BMV, PPV, intubation, cardiac massage)

9.4. Was the baby admitted to a neonatal unit? (Includes SCBU and ICU) ☐ Yes ☐ No

9.5a. Was the baby transferred to another unit after birth? ☐ Yes ☐

If yes please answer 9.5 b

9.5 b. Date and Time of Transfer to other unit after birth: Date ☐☐/☐☐/☐☐ **Time** ☐☐:☐☐

9.6. Date and Time of Death: Date ☐☐/☐☐/☐☐ **Time** ☐☐:☐☐

9.7. Place of Death*: ☐ Labour Ward ☐ Neonatal Unit ☐ Ward ☐ Theatre ☐ In Transit ☐ Paediatric Centre ☐ Home

Name of unit:_____

*This question refers to where the baby actually died, e.g. 'ICU, 'at home' or 'in transit'.
Babies are deemed to have died 'at home' if there are no signs of life documented in the home even if resuscitation is attempted.
A baby is deemed to have died 'in transit' if signs of life are documented prior to transfer but the baby was either declared dead on arrival to the hospital or showed no subsequent signs of life in the hospital, despite attempted resuscitation..

SECTION 10. POST-MORTEM INVESTIGATIONS

10.1. Was this a coroner's case? *If yes, please complete question 10.2.* ☐ Yes ☐ No

10.2. Has the post-mortem report been received from the coroner's office? ☐ Yes ☐ No

10.4. Was a post-mortem performed? ☐ Yes ☐ No

If no, please complete question 10.5.

10.5. Was a post-mortem offered? ☐ Yes ☐ No

10.6. Were any of the following procedures carried out after death?

Please tick all that apply

☐ MRI ☐ X-Ray ☐ CT ☐ External Examination ☐ Genetic testing

10.7. Was the placenta sent for histology? ☐ Yes ☐ No

SECTION 11. CAUSE OF DEATH AND ASSOCIATED FACTORS - STILLBIRTH & NEONATAL DEATH

11. Please TICK ALL the maternal or fetal conditions that were present during pregnancy or were associated with the death. ***PLEASE REFER TO THE REFERENCE MANUAL.***

11.1.1. MAJOR CONGENITAL ANOMALY:

☐ Central nervous system ☐ Cardiovascular system ☐ Respiratory system ☐ Gastro-intestinal system

☐ Musculo-skeletal anomalies ☐ Multiple anomalies ☐ Urinary tract ☐ Metabolic diseases

☐ Other major congenital anomaly, please specify _____ _____

☐ Chromosomal disorder*, please specify _____ _____ _____ _____

*** In the event of a chromosomal disorder how was the diagnosis made?**

☐ Clinically ☐ Genetic analysis * ☐ Ultrasound

**See reference manual*

11.1.2. HYPERTENSIVE DISORDERS OF PREGNANCY:

☐ Pregnancy induced hypertension ☐ Pre-eclampsia ☐ HELLP syndrome ☐ Eclampsia

11.1.3. ANTEPARTUM or INTRAPARTUM HAEMORRHAGE:

☐ Praevia ☐ Abruption ☐ Other, please specify _____ _____ _____

11.1.4. MECHANICAL:

Cord compression: ☐ Prolapse cord ☐ Cord around neck ☐ Other cord entanglement or knot

Uterine rupture: ☐ Before labour ☐ During labour

Mal-presentation: ☐ Breech ☐ Face ☐ Compound

☐ Transverse ☐ Other, please specify _____

Shoulderdystocia: ☐

11.1.5. MATERNAL DISORDER:

☐ Pre-existing hypertensive disease ☐ Diabetes ☐ Other endocrine conditions (excluding diabetes)

☐ Thrombophilias ☐ Obstetric cholestasis ☐ Uterine anomalies

☐ Connective tissue disorders, please specify _____ _____ _____ _____

☐ Other, please specify _____ _____ _____ _____ _____ _____

11.1.6. INFECTION: (confirmed by microbiology/placental histology)

Maternal infection: ☐ Bacterial ☐ Syphilis ☐ Viral diseases

☐ Protozoal ☐ Group B Streptococcus

☐ Other, please specify organism _____ _____

Ascending infection:

☐ Chorioamnionitis ☐ Other, please specify _____ _____ _____

11.1.7. SPECIFIC FETAL CONDITIONS:

☐ Twin-twin transfusion ☐ Feto-maternal haemorrhage ☐ Non-immune hydrops ☐ Iso-immunisation

☐ Other, please specify _____

11.1.8. SPECIFIC PLACENTAL CONDITIONS:

PLEASE REFER TO THE REFERENCE MANUAL, PAGE 10, BEFORE COMPLETING THIS SECTION

☐ **No abnormal histology reported**

☐ **Chorioamnionitis** → ☐ Mild ☐ Moderate ☐ Severe

☐ **Fetal vasculitis** → ☐ Arterial ☐ Venous ☐ Both

☐ **Maternal vascular malperfusion (uteroplacental insufficiency)**
Please specify pathology:

☐ Distal villous hypoplasia ☐ Placental hypoplasia

☐ Accelerated villous maturation ☐ Ischaemic villous crowding

☐ Placental infarction → Please specify approximate percentage involved _____

☐ Retroplacental haemorrhage → Please specify approximate percentage of maternal surface involved _____

☐ **Fetal vascular malperfusion:**
Please specify pathology

☐ Patchy hypoperfusion ☐ Scattered avascular villi ☐ Thrombosis in fetal circulation ☐ Fetal thrombotic vasculopathy

☐ **Cord pathology as sole finding**
Please specify pathology

☐ Hypercoiled cord ☐ Hypocoiled cord ☐ Meconium associated vascular necrosis

☐ Vasa praevia ☐ Velamentous cord ☐ Other , please specify _____

☐ **Cord pathology associated with distal disease**
please specify associated distal disease:

☐ Delayed villous maturation ☐ Thrombosis in fetal circulation

☐ **Villous maturation defect (distal villous immaturity/ delayed villous maturation)**

☐ **Villitis** → ☐ Low grade ☐ High grade ☐ With stem vessel obliteration

☐ **Other**, please specify_____

_____

11.1.9. INTRA-UTERINE GROWTH RESTRICTION DIAGNOSIS MADE: YES ☐

What was this based on? *Please tick all that apply*

☐ Suspected antenatally ☐ Observed at delivery ☐ Observed at post-mortem

11.1.10. ASSOCIATED OBSTETRIC FACTORS: *Please tick all that apply*

Birth trauma ☐ Intracranial haemorrhage ☐ Subgaleal haematoma

☐ Fracture, please specify_____

☐ Other, please specify_____

Intrapartum fetal blood sample result < 7.25 ☐ Yes ☐ No

☐ Polyhydramnios ☐ Oligohydramnios ☐ Premature rupture of membranes

☐ Prolonged rupture of membranes (> 24hours) ☐ Amniocentesis

☐ Spontaneous premature labour ☐ Other, please specify_____

11.1.11. WERE THERE ANY ANTECEDENT OR ASSOCIATED OBSTETRIC FACTORS PRESENT? YES ☐ NO ☐

11.1.12. UNCLASSIFIED: *Please use this category as sparingly as possible* ☐

SECTION 12. MAIN CAUSE OF DEATH: STILL BIRTH & NEONATAL DEATHS

12.1. **Which condition, indicated in Section 11 as being present, was the MAIN condition or sentinel event causing or associated with the death.** *Please refer to the post-mortem and placental histology reports.*

(NB "non-MAIN" conditions are best described as the "Other clinically relevant maternal or fetal conditions/ factors that were associated with but not necessarily causing the death").

12.2. Sources of information used to determine cause of death?

Please tick all that apply

☐ Post Mortem ☐ Placental Histology ☐ Other, please specify_____

SECTION 13. NEONATAL DEATH ONLY: NEONATAL CONDITIONS ASSOCIATED WITH THE DEATH

13.1. Please TICK ALL the neonatal conditions causing and associated with the death.
PLEASE REFER TO THE REFERENCE MANUAL.

13.1.1. MAJOR CONGENITAL ANOMALY:

☐ Central nervous system ☐ Cardiovascular system ☐ Respiratory system ☐ Gastro-intestinal system
☐ Musculo-skeletal anomalies ☐ Multiple anomalies ☐ Urinary tract ☐ Metabolic diseases

☐ Other major malformation, please specify _____

☐ Chromosomal disorder*, please specify _____

*** In the event of a chromosomal disorder how was the diagnosis made?**

☐ Clinically ☐ Genetic analysis * ☐ Ultrasound
**See reference manual*

13.1.2. PRE-VIABLE: (less than 22 weeks) ☐

13.1.3. RESPIRATORY DISORDERS:

☐ Severe pulmonary immaturity ☐ Surfactant deficiency lung disease ☐ Pulmonary hypoplasia ☐ Meconium aspiration syndrome

☐ Primary persistent pulm. hypertension ☐ Chronic lung disease / Bronchopulmonary dysplasia (BPD)
☐ Other (includes pulmonary haemorrhage), please specify _____

13.1.4. GASTRO-INTESTINAL DISEASE:

☐ Necrotising enterocolitis (NEC) ☐ Other, please specify _____

13.1.5. NEUROLOGICAL DISORDER:

☐ Hypoxic-ischaemic encephalopathy (HIE)

☐ *Intraventricular / Periventricular haemorrhage, please specify highest grade (0 – 4) ☐ *

☐ Hydrocephalus*, please tick all that apply:

* ☐ Congenital ☐ Acquired ☐ Communicating ☐ Obstructive ☐ Other _____

☐ Other, please specify_____

13.1.6. INFECTION:

☐ Generalised (sepsis) ☐ Pneumonia ☐ Meningitis Please specify specific organism _____

☐ Other, specify _____

13.1.7. INJURY / TRAUMA: (Postnatal) ☐

Please specify_____

13.1.8. OTHER SPECIFIC CAUSES:

☐ Malignancies / Tumours ☐ In-born errors of metabolism, please specify _____

☐ Specific conditions, please specify _____

13.1.9. SUDDEN UNEXPECTED DEATHS:

☐ Sudden Infant Death Syndrome (SIDS) ☐ Infant death – Cause unascertained

13.1.10. UNCLASSIFIED: (Use this category as sparingly as possible) ☐

13.2. **Which condition, indicated in Section 13.1 as being present, was the MAIN condition causing or associated with the death.** *Please refer to the post-mortem report. In the absence of a post-mortem report, please refer to the death certificate.*

(NB "non-MAIN" conditions are best described as the "Other clinically relevant maternal or fetal conditions/ factors that were associated with but not necessarily causing the death").

13.3. Sources of information used to determine cause of death?

Please tick all that apply

☐ Post Mortem ☐ Placental Histology ☐ Other, please specify _____

SECTION 14. DETAILS OF REPORTING UNIT (Please print)

14.1. Name of reporting unit: _____

14.2. Completed by

Name: _____

Staff Grade: _____

Work address: _____

_____

Telephone Number: _____

E-mail Address: _____

Date of Notification: ☐☐/☐☐/☐☐

Thank you very much for taking the time to complete this form

Please return all completed forms to:

Ms Edel Manning, Project manager perinatal mortality audit,
National Perinatal Epidemiology Centre
Department of Obstetrics and Gynaecology
5th Floor
Cork University Maternity Hospital
Wilton
Cork

If you have any queries regarding the Perinatal Death Notification Form, please contact us at the National Perinatal Epidemiology Centre

Tel: (0)21 420 5042
E-mail: npec@ucc.ie

Appendix 4: NPEC Perinatal Mortality National Clinical Audit Reference Manual 2016

REFERENCE MANUAL

For completion of Perinatal Death Notification Forms

2016

If you have any queries regarding the Perinatal Death Notification Form, please contact us at the National Perinatal Epidemiology Centre

Tel: (0)21 420 5042

E-mail: npec@ucc.ie

Please return all completed forms to:

Ms E. Manning, Project Manager Perinatal Mortality Audit National Perinatal Epidemiology Centre

Department of Obstetrics and Gynaecology 5th Floor

Cork University Maternity Hospital Wilton

Cork

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Reportable perinatal deaths

The National Perinatal Epidemiology Centre (NPEC) kindly requests that units submit completed perinatal death notification forms on the following perinatal deaths:

Stillbirths

All stillbirths when:

(i) the baby was delivered in the reporting maternity unit;

(ii) the reporting unit was the intended place of delivery but the baby was born before arrival;

(iii) the mother had not booked to deliver in any maternity unit but presented to the unit after unattended delivery in the community.

Neonatal deaths

(i) The death of any live born infant delivered in your unit occurring within 28 completed days of birth. This includes babies who were transferred and died in another unit (e.g. tertiary maternity unit, paediatric hospital or at home).

(ii) All neonatal deaths occurring in your unit, regardless of place of delivery.

Please note that the above request will not result in duplication of reporting on neonatal deaths nationally, or an increase of perinatal mortality rates in individual units, but is necessary to ensure complete case ascertainment.

Calculating Perinatal Mortality Rates (PMR) for individual units

Perinatal deaths are included in a maternity unit's PMR if:

(i) the baby was delivered in the maternity unit

(ii) the unit was the intended place of delivery but the baby was born before arrival

The overall PMR is based on the number of stillbirths and neonatal deaths per 1,000 births (live births and stillbirths from 24 weeks gestation or weighing >500g). For consistency with the Irish Healthcare Pricing Office reporting of perinatal statistics, we also report the PMR using the criterion of birthweight >500g.

Neonatal deaths occurring in babies with a birthweight < 500g and delivered before 24 weeks are not included in the PMR. However, the collation of data on these perinatal events by the NPEC provides vital information surrounding adverse pregnancy outcomes in all registered live births.

Definitions

Stillbirth: Baby delivered without signs of life from 24 weeks gestation or with a birthweight ≥500g.[1]

Early neonatal death: Death of a live born baby occurring within 7 completed days of birth.

Late neonatal death: Death of a live born baby occurring after the 7th day and within 28 completed days of birth.

Live birth: Live birth refers to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life - e.g. beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles - whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered live born.[2]

Booking: Some data sought by the NPEC relate to the time of booking. Booking in this regard relates to the mother's first antenatal visit at the maternity unit.

Parity: The number of completed pregnancies, whether live birth or stillbirth, of at least 24 weeks gestation or with a birthweight ≥500g. The NPEC refer to parity prior to the pregnancy that resulted in a perinatal loss.

In utero transfer: The care of the mother was transferred, with the fetus in utero, to the care of another maternity unit where the baby delivered.

Genetic analysis: The study of the fetal chromosomes using varying techniques in the antenatal or post natal period. Sampling techniques include: Amniotic fluid analyses, Chorionic Villus Sampling (CVS), Percutaneous umbilical blood sampling (PUBS), Fetal tissue/organ sampling and Extra-fetal tissue analysis, such as placental or umbilical cord biopsy .

Guidance for completion of the notification form

- Please complete the notification form using the information available on the maternity case notes, the post mortem report and the placental histology report.
- 'Not known' codes should be used as sparingly as possible.
- Please complete all dates in the format DD/MM/YY; and all times using the 24hr clock e.g. 17.45.

[1] Stillbirths Registration Act, 1994.

[2] World Health Organisation. Available at: http://www.who.int/healthinfo/statistics/indmaternalmortality/en/

Guidance for completion of specific questions within sections

Most questions are self-explanatory but the following notes give guidance to specific questions within sections of the notification form.

Section 1: contains questions on maternal characteristics.

Q 1.7, Q 1.8 and Q 1.9: Maternal weight, height and body mass index (BMI) must be completed to enable the NPEC to calculate customised birth weight centiles for infants.

Section 4: contains questions on clinical and hospital details related to the pregnancy.

Q 4.1 Final Estimated Date of Delivery (EDD): please use the final date agreed in the clinical notes based on best estimate EDD (from ultrasound scan or date of last menstrual period based on a 40 week gestation). **Q 4.5** Intended place at delivery at booking: Place in this regard relates to the maternity unit where the mother intended to deliver at her first antenatal visit.

Q 4.7 (b) Gestation at time of in-utero transfer: This refers to the gestation of the pregnancy at the time when the hospital where the delivery took place, received care of the mother.

Section 6:

Q 6.6: 'Was this a termination of pregnancy?' Termination of Pregnancy refers to all cases where either:

(a) The pregnancy was medically ended in the interest of the maternal health, with the expected outcome of fetal or early neonatal death, OR

(b) Intrauterine Death (IUD) occurred following fetal reduction.

Q 6.7: 'Was a local hospital review of this case undertaken?'

Hospital review includes in depth case review, review by risk management and clinical case presentation at multidisciplinary meetings.

Section 8: refers to stillbirths only

Q 8.1 Refers to the date when a diagnosis of perinatal death was made.

Q 8.2 Was the baby alive at onset of care in labour? Responses to this question identifies whether the death of the baby occurred during labour under the care of a health professional.

Section 9: refers to neonatal deaths only.

Q 9.1 Was spontaneous respiratory activity absent or ineffective at 5 minutes? If a baby is receiving any artificial ventilation at 5 minutes, the assumption is absent/ineffective activity: a 0 Apgar score indicates absent activity.

Q 9.3 Was the baby offered active resuscitation in the delivery room? Active resuscitation includes BMV, PPV, intubation, cardiac massage.

Q 9.7 Place of neonatal death. This question refers to where the baby actually died, e.g. 'ICU, 'at home' or 'in transit'. Babies are deemed to have died 'at home' if there are no signs of life documented in the home even if resuscitation is attempted. A baby is deemed to have died 'in transit' if signs of life are documented prior to transfer but the baby was either declared dead on arrival to the hospital or showed no subsequent signs of life in the hospital, despite attempted resuscitation.

Sections 11, 12 and 13: Cause of Death and Associated Factors, Stillbirths and Neonatal Deaths

The main cause of death and conditions/ events associated with the perinatal death are identified in sections 11, 12 and 13.

- The post-mortem and or placental histology report should be referred to when completing sections 11, 12 and 13. In the absence of a post-mortem and / or placental histology report, please refer to the death certificate.
- For completion of sections 11, 12 and 13 (cause of death and associated factors), please refer to Table 1 and Table 2 for guidance on definitions and associated subcategories.
- For completion of Question 11.1.8 'Specific Placental Conditions', please refer to Table 3.

Cause of death, Stillbirths:

Please complete Section 11 and 12.

Section 11: Please **TICK ALL** the maternal or fetal conditions that were present during pregnancy or were associated with the death. Table 1 (page 8) outlines definitions of terms.

> **Q 11.1.8** Specific Placental Conditions. Guidance notes on reporting placental histology results are available in Table 3 (page 10). An alternative to completing this question is to submit an anonymised copy of the placental histology report to the NPEC.

Section 12: Q 12.1. Please specify the condition, indicated in Section 11, that was the MAIN condition or sentinel event causing or associated with the death. "Non-MAIN" conditions are best described as the "Other clinically relevant maternal or fetal conditions / factors that were associated with but not necessarily causing the death".

Cause of death, Neonatal Deaths:

Please complete sections 11, 12 and 13.

Please note that completion of all sections is important and not a duplication of data points.

- Section 11 and 12 allows for classification of maternal and fetal factors associated with the death.
- Section 13 allows for classification of 'specific neonatal conditions' associated with the death.

Section 11: Please TICK ALL the maternal or fetal conditions that were present during pregnancy or were associated with the death. Table 1 (page 8) outlines definitions of terms.

Q 11.1.8: Specific Placental Conditions

- Guidance notes on reporting placental histology results are available in Table 3 (page 10). An alternative to completing this question is to submit an anonymised copy of the placental histology report to the NPEC.

Section 12: Q 12.1.

Please specify the condition, indicated in Section 11, that was the MAIN condition or sentinel event causing or associated with the death. "Non-MAIN" conditions are best described as the "Other clinically relevant maternal or fetal conditions / factors that were associated with but not necessarily causing the death".

Section 13. Q 13.1.

Please TICK ALL the neonatal conditions causing and associated with the death.

Q 13.2. Which condition, indicated in Section 13.1 as being present, was the MAIN condition causing or associated with the death. “Non-MAIN” conditions are best described as the “Other clinically.

SECTION 11: STILLBIRTHS AND NEONATAL DEATHS

Table 1 Definitions and associated subcategories in Section 11 that will help you choose the relevant maternal and fetal conditions causing and associated with perinatal death.

DEFINITION OF TERMS	Subcategory
MAJOR CONGENITAL ANOMALY Any genetic or structural defect **arising at conception or during embryogenesis** incompatible with life or potentially treatable but causing death	Central nervous system Cardiovascular system Respiratory system Gastro-intestinal system Musculo-skeletal anomalies Multiple anomalies Chromosomal disorders Metabolic diseases Urinary tract Other
HYPERTENSIVE DISORDERS OF PREGNANCY	Pregnancy induced hypertension Pre-eclampsia HELLP syndrome Eclampsia
ANTEPARTUM OR INTRAPARTUM HAEMORRHAGE After 20 w gestation, whether revealed or not. If associated with PET, APH will be a secondary diagnosis. Ignore minor degrees of haemorrhage (e.g. 'shows', cervical polyps etc). Recurrent bleeding of uncertain origin followed by preterm labour should not be ignored.	Praevia Abruption Uncertain
MECHANICAL. Any death attributed to uterine rupture, deaths from birth trauma or intrapartum asphyxia associated with problems in labour such as cord compression, malpresentation, shoulder dystocia etc. Antepartum deaths associated with cord entanglement in the absence of strong circumstantial evidence that cord compression caused death should be classified as having no associated factor.	**Cord Compression** Prolapsecord Cord around neck Other cord entanglement or knot **Uterine Rupture** Before labour During labour **Mal-presentation** Breech / Transverse Face / Compound Other **Shoulder dystocia**

DEFINITION OF TERMS	Subcategory
MATERNAL DISORDER. Specify hypertensive disease present before pregnancy or any other maternal disease or condition sufficient to jeopardise the baby such as diabetes, cardiac disease etc. Infection is classified separately.	Pre-existing hypertensive disease Diabetes Other endocrine conditions Thrombophilias Obstetric cholestasis Drug misuse Uterine anomalies Connective tissue disorders / Other
INFECTION. Confirmed by microbiology / placental histology. Specify maternal infections sufficient to have compromised the baby which may be associated with congenital infection of the baby. Trans-placental transmission may have occurred such as CMV, toxoplasmosis etc. Specify only those ascending infections that are a significant factor in death. Chorioamnionitis sufficient to cause preterm birth may be specified for some neonates but evidence of fetal infection may be required as an explanation of stillbirth.	**Maternal infection** Bacterial / Viral diseases Syphilis /Group B Streptoccus Protozoal Other **Ascending infection** Chorioamnionitis Other
SPECIFIC FETAL CONDTIONS. Document only those specific conditions **arising in the fetal period**.	Twin-twin transfusion Feto-maternal haemorrhage Non-immune hydrops Iso-immunisation Other
SPECIFIC PLACENTAL CONDITIONS. Specific placental conditions sufficient to cause death or be associated with fetal compromise such as IUGR. Cord problems associated with compression will normally be classified under 'Mechanical'. **Please refer to guidance notes prior to completing this section (Page 10). Alternatively, an anonymised placental histology report can be attached to the Perinatal Mortality Notification form.**	Chorioamnionitis Fetal vasculitis Maternal vascular malperfusion Fetal vascular malperfusion Cord pathology Villous maturation defect Villitis Other
INTRA-UTERINE GROWTH RESTRICTION DIAGNOSIS MADE. IUGR may be suspected antenatally by abdominal circumference (AC) less than the centile threshold used to define IUGR locally, or decreased AC growth velocity, +/- oligohydramnios.	Suspected antenatally Observed at delivery Observed at post mortem

DEFINITION OF TERMS	Subcategory
ASSOCIATED OBSTETRIC FACTORS. Factors recorded as Other Associated Obstetric Factors will be important clinical or pathological features of the pregnancy or baby but may not be an explanation of the death; they will often be secondary to other maternal or fetal conditions. Birth trauma and/or Intrapartum asphyxia should normally be classified primarily by the underlying cause (e.g Mechanical). Birth Trauma and/ or other antenatal/intra-partum factors can be recorded here either as a secondary factor or when there is no underlying explanation.	**Birth Trauma** Intracranial haemorrhage Birth injury to scalp Fracture Other **Intrapartum fetal** **blood sample <7.25** **Other** Polyhydramnios Oligohydramnios Premature rupture of membranes Spontaneous premature labour Other
NO ANTECEDENT OR ASSOCIATED OBSTETRIC FACTORS. Deaths with no explanation or significant associated factor.	
UNCLASSIFIED. Cases where little or nothing is known about pregnancy or delivery and which cannot be fitted into any of the above categories. **Use as sparingly as possible.**	

PLACENTAL PATHOLOGY

Table 2 Guidance notes for completion of question 11.1.8: Placental pathology

CATEGORY OF PLACENTAL PATHOLOGY	GUIDANCE NOTES
NO ABNORMAL HISTOLOGY REPORTED	No abnormal pathology reported.
CHORIOAMNIONITIS	Please specify if the finding of chorioamnionitis was reported as mild, moderate or severe.
FETAL VASCULITIS	Please specify if the finding of fetal vasculitis was arterial, venous or in both vessels.
MATERNAL VASCULAR MALPERFUSION (UTEROPLACENTAL INSUFFICIENCY)	Refers to the spectrum of findings related to shallow implantation of the placenta, often found in conjunction with PET and IUGR. Please specify the conditions associated with this finding: **Distal villous hypoplasia** is an early/severe form of maternal vascular malperfusion and is often accompanied by absent or reduced end-diastolic flow. This usually occurs at less than 32 weeks gestation. **Accelerated villous maturation, ischaemic villous crowding and placental infarction** are other findings associated with maternal vascular malperfusion. **These conditions are listed in increasing order of severity in question 11.1.8, please tick the most severe finding.** **Retroplacental haemorrhage** frequently occurs with a background of maternal vascular malperfusion, but may occur in isolation with no other identified placental disease. **Placental hypoplasia:** the placenta may be small in cases of maternal vascular malperfusion. While no standards for Ireland currently exist, placental weight <350g at term is taken to be the 10th centile and warrants use of the term hypoplasia. The finding of a small histologically normal placenta should be reported here.
FETAL VASCULAR MALPERFUSION	Refers to thrombosis or the effect thereof in the fetal circulation. It may be difficult to distinguish arterial from venous vessels, and pathology may be present in both. The findings of fetal vascular malperfusion are listed in order of severity: patchy hypofusion, scattered avascular villi and fetal thrombotic vasculopathy. Please tick the most severe finding

CATEGORY OF PLACENTAL PATHOLOGY	GUIDANCE NOTES
CORD PATHOLOGY	Cord pathology may exist by itself, or may be accompanied by evidence of other disease. Abnormal cord insertion (marginal/velamentous) may be seen in cases of shallow implantation. **Cord hypercoiling** A diagnosis of cord hypercoiling should be supported by measurement of an umbilical coiling index (number of coils/length of the cord in cm) of 0.3 or more. Cord stricture should be sought in these cases. Where delayed placental maturation is accompanied by a hypercoiled cord, it suggests that the latter may have caused the former. Other effects of impaired fetal flow include multiple non- occlusive thrombi in chorionic plate or fetal stem vessels.
VILLOUS MATURATION DEFECT	Villous maturation defect is a term used synonymously with distal villous immaturity.
VILLITIS	The term is used to mean villitis of unknown aetiology, and assumes that the reporting pathologist has excluded infection where appropriate.
OTHER	Please specify any other pathological findings reported by the pathologist e.g. maternal floor infarction.

Placentas may have more than one pathologic finding.
If placental disease was the main condition associated with the perinatal death, please specify in Section 12: Q 12.1, which placental pathological finding was most likely to have caused the pregnancy loss.

Please note that an alternative to completing question 11.1.8 is to submit an anonymised copy of the placental histology report to the NPEC.

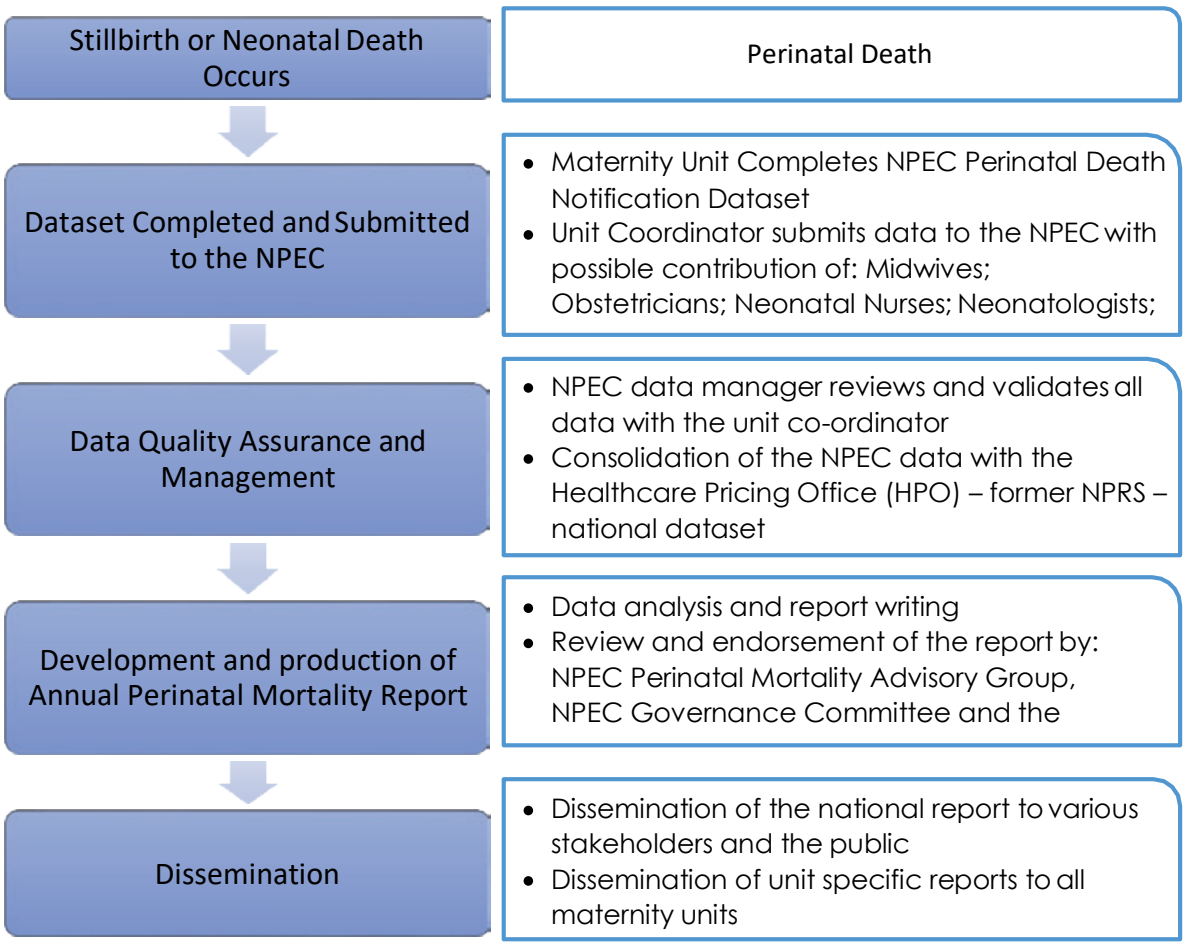
SECTION 13: NEONATAL DEATH ONLY

Table 3 Definitions and associated subcategories in Section 13 that will help you choose the relevant neonatal conditions causing and associated with death.

DEFINITION OF TERMS	Subcategory
MAJOR CONGENITAL ANOMALY Any genetic or structural defect arising at conception or during embryogenesis incompatible with life or potentially treatable but causing death.	Central nervous system Cardiovascular system Respiratory system Gastro-intestinal system Musculo-skeletal system Multiple anomalies Chromosomal disorders Metabolic disorders Urinary tract Other
PRE-VIABLE Babies (less than 22 weeks) who are non-viable at birth because of gestation but who show signs of life.	
RESPIRATORY DISORDERS Severe pulmonary immaturity will encompass those babies where structural lung immaturity is so gross as to mean ventilatory support is unsustainable at the outset. Surfactant Deficient Lung Disease may include babies with clinical or pathological evidence of hyaline membrane disease. Please note that neonatal deaths previously attributed to prematurity, would most often be captured under the subcategory of 'severe pulmonary immaturity'.	Severe pulmonary immaturity Surfactant deficiency lung disease Pulmonary hypoplasia Meconium aspiration syndrome Primary persistent pulmonary hypertension Chronic lung disease / BPD Other (includes pulmonary haemorrhage)
GASTRO-INTESTINAL DISEASE Many babies with NEC will have associated sepsis which may be given as a secondary cause.	Necrotising enterocolitis (NEC) Other
NEUROLOGICAL DISORDER HIE includes those babies with severe hypoxic-ischaemic brain injury before birth. If possible, please specify if HIE was primarily of intrapartum or antepartum origin. Specify periventricular leukomalacia only if this is a significant factor in the infant death. Birth Trauma will usually be classified here.	Hypoxic-ischaemic encephalopathy (HIE) Intraventricular / Periventricular haemorrhage Other

DEFINITION OF TERMS	Subcategory
INFECTION Where possible specify the location of infection and whether due to bacteria, virus, fungus or other specific organism. If infection was the main cause of death please specify whether infection is congenital (i.e. acquired ante or intrapartum acquired) or neonatal in origin.	Generalised (sepsis) Pneumonia Meningitis Other
INJURY / TRAUMA Post natal trauma only including iatrogenic injury. 'Birth Trauma' will usually be classified under neurological disorder e.g. HIE; the obstetric classification identifying the timing of the injury.	
OTHER SPECIFIC CAUSES Death due to specific fetal and neonatal conditions such as isoimmunisation or unexplained hydrops. Neonatal conditions will include aspiration, unexplained pulmonary haemorrhage.	Malignancies/Tumours Specific conditions
SUDDEN UNEXPECTED DEATHS SIDS should conform to the accepted definition. Unascertained are those unexpected deaths that are not explained despite a full investigation including autopsy, but do not conform to the accepted definition of SIDS.	Sudden Infant Death Syndrome (SIDS) Infant deaths – cause unascertained
UNCLASSIFIED. Cases where little or nothing is known about the pregnancy or delivery and which cannot be fitted into any of the above categories. **Please use this category as sparingly as possible.**	

Appendix 5: NPEC Perinatal Mortality National Clinical Audit Data Collection and Management Processes



Appendix 6: List of Invited Commentaries that Feature in the NPEC Perinatal Mortality National Clinical Audit Annual Reports

Invited commentaries

2011 -- Perinatal pathology Dr Eoghan Mooney, Perinatal Pathologist, National Maternity Hospital

2012 -- Fetal growth restriction and the risk of perinatal mortality - Dr Julia Unterscheider, Maternal Fetal Medicine Fellow at the Royal College of Surgeons in Ireland

2013 -- The Impact of Stillbirth – Professor Keelin O'Donoghue, Senior Lecturer, Department of Obstetrics and Gynaecology, UCC and Consultant Obstetrician at the Cork University Maternity Hospital

2014 -- Can we reduce the incidence of stillbirth? --Professor Richard A Greene, Consultant Obstetrician and Gynaecologist at Cork University Maternity Hospital and Director of the NPEC

2015 – Early Neonatal Death in Ireland and Congenital Anomalies -- Professor Eleanor Molloy, Chair and Professor of Paediatrics and Child Health, Trinity College Dublin, and Dr Bob McDonnell of the HSE Registry of Congenital Anomalies, Health Intelligence Unit

2016 -- Reducing the Burden of Intrapartum Fetal Deaths -- Dr Karen McNamara, Specialist Registrar and Clinical Research Fellow in Obstetrics and Gynaecology at the Cork University Maternity Hospital

2017 -- The Impact on Prematurity on our Perinatal Mortality Rate -- Dr Anne Twomey, Consultant Neonatologist at the National Maternity Hospital

2018/2019 The contribution of Twin Pregnancy to Perinatal Mortality -- Dr Sieglinde Mullers; Consultant in Obstetrics and Gynaecology at the Rotunda Hospital

Appendix 7: NOCA Monitoring & Escalation Policy

Policy Name:	NOCA Monitoring and Escalation Policy
Policy No:	NOCA-GEN-POL014
Effective Date:	1st January 2017
Review Date:	1st February 2018

Policy Title	National Office of Clinical Audit (NOCA) - Monitoring & Escalation Policy		
Authors	Collette Tully, Executive Director, NOCA Marina Cronin, Hospital Relations Manager, NOCA Kenny Franks, Operations Manager, NOCA		
Internal Review	Mary Baggot, National Intensive Care Unit Audit Coordinator, NOCA Louise Brent, National Irish Hip Fracture Database Audit Coordinator, NOCA Aisling Connolly, Senior Administrator, NOCA Deborah McDaniel, Hospital Relations Coordinator, NOCA Bríd Moran, Information Manager, NOCA NOCA Audits Clinical Leads NOCA National Clinical Audit Governance Committee's		
External Review	Health Service Executive (HSE) Acute Hospitals Division (AHD) HSE Quality Improvement Division HSE Quality Assurance & Verification Division Hospital Group Chief Executive Officers National Clinical Effectiveness Committee (NCEC) Quality Assurance Review Teams		
Approved by	NOCA Governance Board		
Issue Date	1st January 2017	Revision Due	12 Months from issue
Change Log	Page	Heading	Change
	1-14	Headings 1-13	All Sections Revised
Version	2.1		

Table of Contents

1.0 Policy Statement

That National Office of Clinical Audit (NOCA) produces annual national clinical audit reports across multiple areas of clinical care that aim to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis.

2.0 Purpose

The purpose of the policy is to ensure that:

2.1 The NOCA Audit Coordinator and the NOCA Audit Clinical Lead continually monitor clinical audit data and informs a hospital of any data quality issues in a timely manner

2.2 The Hospital Audit Clinical Lead and the Hospital Data Coordinator/Nurse will investigate and resolve all data quality issues in a timely manner so as to ensure their data is complete and accurate for inclusion in the national clinical audit reports

2.3 The NOCA Audit Clinical Lead notifies a Hospital, Group and relevant National Director of a statistical outlier in a timely manner.

2.4 There is an identified Senior Accountable Person in each hospital who will ensure that all statistical outliers arising from national clinical audit are reviewed and any required actions taken within agreed timelines.

2.5 NOCA escalates to the appropriate accountable level in the HSE, as defined in the HSE Accountability Framework

2.6 NOCA will share key learnings and recommendations with the relevant HSE National Director and other key stakeholders

3.0 Scope of this Policy

This policy applies to all audits under the governance of NOCA regardless of policy date.

4.0 Glossary of Terms and Definitions

Terms	Definition
Quality Indicators	Also known as Key Performance Indicators (KPIs) - Quality Indicators are specific and measurable elements of practice that can be used to assess quality of care. Indicators are quantitative measures of structures, processes or outcomes that may be correlated with the quality of care delivered by the healthcare system (HSE, 2013).
Statistical outlier	Each Audit stream will have pre-determined quality indicators, which are primarily process and outcomes measures. An outlier is a result that is statistically significantly further from the expected value of an agreed quality indicator than would occur by chance alone. The definition of an outlier therefore is based on setting an expected value for an indicator and defining what level of variation / acceptable limits from the expected value is acceptable, based on statistical probability and / or clinical judgement. The expected value may come from the data itself (such as the mean/ median value) or from external sources such as research evidence or national targets such as all patients with a traumatic hip fracture should have surgery within 48 hours. The expected value should be established by the Audit Governance Committee or Audit Provider. Acceptable limits for the observed outcomes are statistically calculated as follows: • a deviation more than 2 standard deviations from the ('target' / 'expected' is an 'alert'; • more than 3 standard deviations is an 'alarm' (UK Department of Health, Healthcare Quality Improvement Partnership (HQIP), 2011). Statistical outliers are defined as results that fall: • two standard deviations on or above the expected value across two consecutive reporting periods; or • three standard deviations on or above the expected comparator value in one or more reporting period (ICNARC, 2015). A finding of a statistical outlier does not in the first instance indicate a problem with the quality of care, but rather a difference between the expected value and a result that is unlikely to have arisen from random variation. This should trigger further analysis and review in the hospital. It is in this context that statistical outliers will be identified by NOCA audit specific governance committees.

Terms	Definition
Data Quality	The quality of data can be determined through assessment against a number of dimensions which include accuracy, validity, reliability, timeliness, relevance, legibility and completeness (HIQA, 2013). When accessing statistical outliers, at a minimum the following criteria should be considered: • Case ascertainment (also called coverage): the number of patients included compared to number eligible, derived from external data sources for example from HIPE. This can impact on the generalisability (representativeness) of the results. • Data completeness: in particular performance indicator data and data on patient characteristics required for case-mix adjustment. • Data accuracy: tested using consistency and range checks, and if possible external sources. National clinical audit governance committees should acknowledge that new audit sites will require consideration in terms of "bedding down" their data quality and this should always be the first point of analysis and review of a statistical outlier.
Patient Safety Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near- misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include, but are not limited to, incidents associated with harm to: • patients, service users, staff and visitors • the attainment of national quality objectives • Information and communications technology (ICT) systems • data security e.g. data protection breaches • the environment (HSE, 2014). **It is the responsibility of the service provider to log all patient safety incidents on the National Incident Management System (NIMS)**

5.0 About the National Office of Clinical Audit (NOCA)

NOCA was established in 2012 as a key enabler of clinical effectiveness which is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent. Clinical effectiveness processes include guidelines, audit and practice guidance.

6.0 Clinical Audit Definition

"Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery." (Principles of Best Practice in Clinical Audit endorsed by HQIP/National Institute for Health and Care Excellence (NICE)/Care Quality Commission (CQC) (UK).

National Clinical Audit is a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis. Clinical audit endorsed by the Minister will be titled 'NCEC National Clinical Audit'. Endorsement will mandate that the appropriate services engage with the NCEC National Clinical Audit, thereby superceding all other national clinical audits on the topic. (NCEC Framework for Endorsement of National Clinical Audit October 2015)

7.0 Benefits of Clinical Audit - Improvement and Assurance

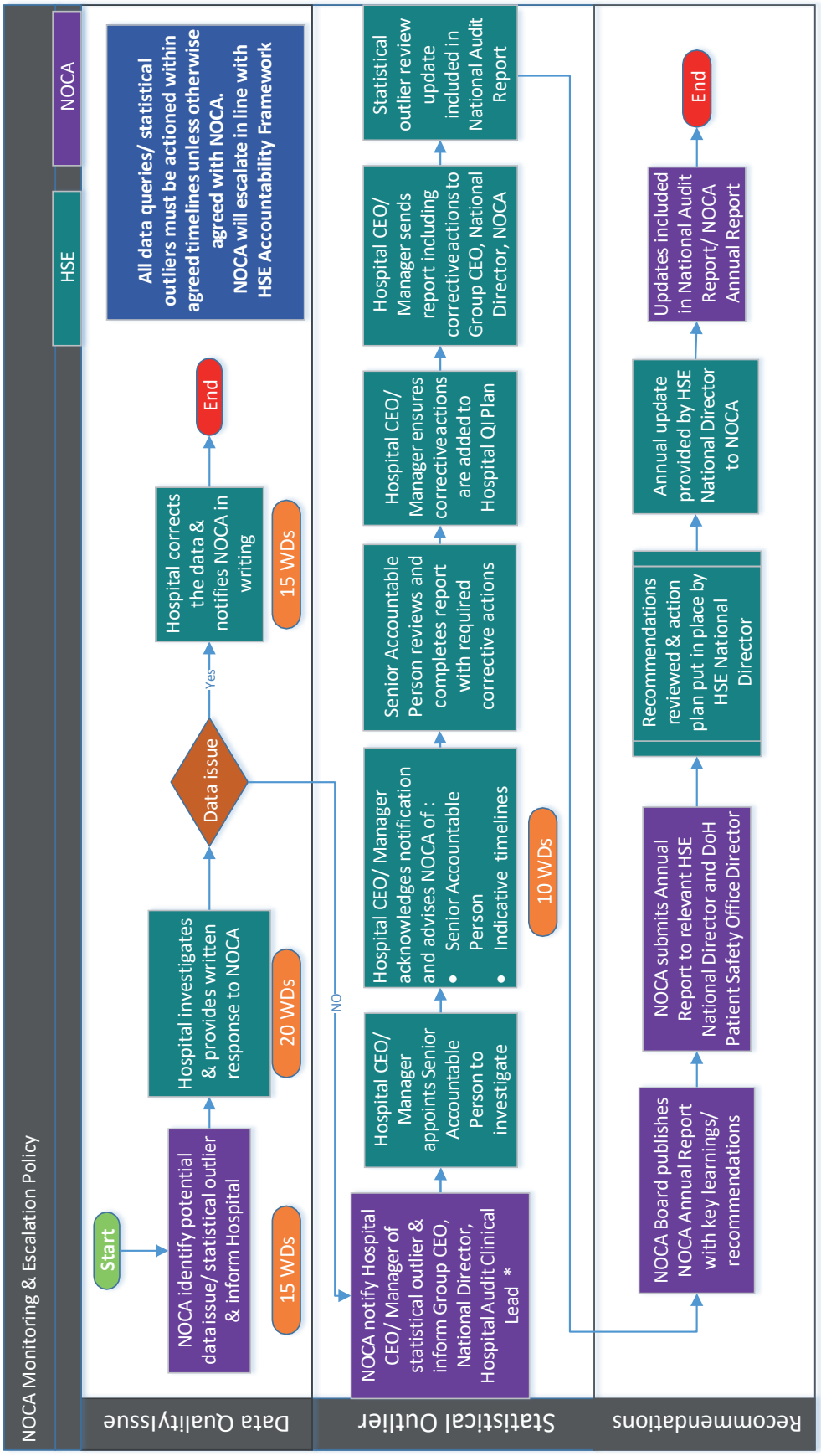
NOCA supports the view that Clinical Audit is fundamentally a quality improvement process, rather than data collection per se (although data analysis is an essential element of the clinical audit cycle). Clinical audit also plays an important role in providing assurances about the quality of services.

National clinical audit measures against national and international benchmarks, identifying areas of excellence and of concern. Recommendations for improvements are also provided. The benefits of national clinical audit include:

- Improved patient outcomes by identifying centres with good outcomes and implementing their good practices elsewhere
- Decreased poor outcomes by changes in practice in centres where suboptimal outcomes are identified
- Reduction in variation in practice and outcomes
- Enhanced culture of transparency, improvement and accountability - report openly on issues identified and measures taken locally and nationally to improve.
- Increased motivation of staff, as they can see improvements happening by documenting changes in quality measures
- Increased economic benefit e.g. reduced length of stay, rehabilitation care, state claims
- Reliable data for activity and performance reporting , research, case studies

However, NOCA is also clear that clinical audit is not an appropriate mechanism for investigating matters relating to the performance of individual healthcare professionals.

8.0 NOCA Monitoring & Escalation Process



*Required minimum. Others may be added on a case by case basis

9.0 NOCA Monitoring & Escalation Process

Ref	Process Step	Details	Responsible Person
1.	NOCA identify data issue/ statistical outlier & inform Hospital	The NOCA Audit Coordinator/NOCA Audit Clinical Lead email the Hospital Audit Clinical Lead and Audit Co- ordinator, regarding a data quality issue e.g. change in trend, statistical outlier indicator in quarterly reports, within **15 working days.** NOCA will add to their data quality action log and track for resolution within **35 working days**.	NOCA Audit Coordinator NOCA Audit Clinical Lead
2.	Hospital investigates & provides written response to NOCA	The Hospital Audit Clinical Lead and Hospital Data Coordinator investigate and inform the NOCA Audit Coordinator in writing of the outcome within 20 working days unless otherwise agreed with NOCA.	Hospital Audit Clinical Lead and Data Co- ordinator
3.	Data Quality Issue?	**Decision** **Step 4** **Yes** – Hospital corrects the data & notifies NOCA in writing. **Step 5** **No** – The NOCA Audit Clinical Lead will notify Hospital CEO/ Manager of statistical outlier & inform Group CEO, National Director, Hospital Audit Clinical Lead	
4.	Hospital corrects the data & notifies NOCA in writing	The Hospital Audit Clinical Lead and Hospital Data Coordinator correct the data & notifies the NOCA Audit Coordinator in writing within 15 working days unless otherwise agreed with NOCA. The NOCA Audit Coordinator may carry out additional statistical analysis to verify correction of the data quality issue.	Hospital Audit Clinical Lead and Data Coordinator

Ref	Process Step	Details	Responsible Person
5.	NOCA notify Hospital CEO/ Manager of statistical outlier & inform Group CEO, National Director, Hospital Audit Clinical Lead *	The NOCA Audit Clinical Lead will write to Hospital CEO/Manager notifying them of a statistical outlier. NOCA will also inform the: • Hospital Group CEO • National Director e.g. AHD • Hospital Audit Clinical Lead • Hospital Audit Data Coordinator The **NOCA notification letter** will outline the details of the statistical outlier and required next steps **(See Appendix 1)**. ***Required minimum**. Others may be added on a case by case basis eg Professional Bodies, Clinical Programmes The NOCA Audit Coordinator will maintain a log of all statistical outliers and will also inform the relevant governance committee.	NOCA Audit Clinical Lead, NOCA National Clinical Audit Governance Committee
6.	Hospital CEO/ Manager appoints Senior Accountable Person to review	The Hospital CEO/ Manager will nominate a Senior Accountable Person to lead on the review and analysis of the statistical outlier.	Hospital CEO/ Manager
7.	Hospital CEO/ Manager acknowledges notification and advises NOCA of : • Senior Accountable Person • Indicative timelines	Within **15 working days** of receipt of the **NOCA notification letter**, the Hospital CEO/ Manager will in writing acknowledge receipt of the NOCA notification letter and provide details of: **1.** Name and contact details of Senior Accountable Person. **2.** Indicative timelines for completion of review.	Hospital CEO/ Manager
8.	Senior Accountable Person reviews and completes report with required corrective actions	Senior Accountable Person will complete a review and analysis of the statistical outlier and prepare a report outlining the key findings and required corrective actions. See **Appendix 2 – National Clinical Audit Outlier Report Guidance**.	Senior Accountable Person (Hospital)

Ref	Process Step	Details	Responsible Person
9.	Hospital CEO/Manager ensures corrective actions are added to Hospital QI Plan	Hospital CEO/ Manager is accountable for ensuring that the required corrective actions are added to the Hospital QI Plan and implemented within agreed timeframes.	Hospital CEO/ Manager
10.	Hospital CEO/Manager sends report including corrective actions to Group CEO, National Director, NOCA	Hospital CEO/ Manager or a nominee sends the statistical outlier report with associated corrective actions to: • Hospital Group CEO • Relevant HSE National Director • Relevant NOCA National Clinical Audit Governance Committee via NOCA Audit Coordinator so as to include update in next national report.	Hospital CEO/ Manager
11.	Statistical outlier review update included in National Audit Report	An update on the findings/ progress of the statistical outlier review carried out by the hospital in the relevant annual national clinical audit report.	NOCA Audit Coordinator NOCA Audit Clinical Lead
12.	NOCA Board publishes NOCA Annual Report with key learnings/ recommendations	A summary of key learnings and recommendations arising from national clinical audits will be included in the NOCA Annual Report.	NOCA Executive Director
13.	NOCA submits Annual Report to relevant HSE National Director and other Key Stakeholders	The NOCA Annual Report will be shared with the HSE National Directors and other key stakeholders as appropriate e.g. Department of Health (DoH), HIQA, Specialty Organisations and Academic Institutions.	NOCA Executive Director
14.	Recommendations reviewed & action plan put in place by HSE National Director	The relevant HSE National Director will review the NOCA recommendations and determine a suitable action plan. This action plan will be monitored at National Directorate Level.	HSE National Director

Ref	Process Step	Details	Responsible Person
15.	Annual update provided by HSE National Director to NOCA	The relevant HSE National Directorates will provide an end of year status to the NOCA Board via NOCA Executive Director on the progress to date to implement recommendations put forward by NOCA.	HSE National Director
16.	Updates included in National Audit Report/ NOCA Annual Report	NOCA will include the progress updates on recommendations provided to HSE / DoH in: • Relevant National Clinical Audit Report • NOCA Annual Report	NOCA Executive Director/ NOCA Audit Coordinator

10.0 Escalation - HSE Accountability Framework

NOCA will utilise the existing levels within the HSE Accountability Framework if the following arise:

- A data issue is not resolved within 30 working days unless otherwise agreed with NOCA
- A statistical outlier is not actioned by the hospital within agreed timelines unless otherwise agreed with NOCA

The levels identified in the HSE Accountability Framework (2016) are as per the Table below:

Level	Escalate to
Level 1	Minister for Health
Level 2	Director General
Level 3	National Director
Level 4	Hospital Group CEO/ CHO Chief Officer
Level 5	Hospital CEO/ Manager/ CHO Chief Officer

11.0 Medical Devices Escalation of Statistical Outliers

The Irish National Orthopaedic Register (INOR) has a separate process for the management of statistical outliers relating to Medical Devices and the subsequent reporting to the Health Products Regulatory Authority (HPRA) using the Medical Device Incident Report Form or alternative as determined but HPRA.

12.0 Applicable Standards

HIQA Standards Safer Better Healthcare. Available at https://www.hiqa.ie/standards/health/safer-better-healthcare

13.0 Policy Revision and Audit

A planned review of this policy will take place in 1 year from date of approval.

14.0 References

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Health Services Executive (2013), A practical guide to Clinical Audit. Available at: http://hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Audit/clauditfilespdfs/practicalguideclaud it2013.pdf [Accessed 25/06/2014].

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15.0 Appendix 1 - NOCA Notification of Statistical Outliers

NOCA Audit	
Hospital Group	
Hospital	
To:	Hospital CEO/ Manager
Date	

Dear Hospital CEO,

Please be advised that the following statistical outlier has been identified for your hospital.

Details of the Audit findings outside the norm **(Personal Data is not used in these reports.)**	

Your hospital is now required to review this statistical outlier and complete a written report to include key findings and required action plan. Please refer to attached "National Clinical Audit Outlier Report Guidance" (Appendix 1).

This report should be sent to NOCA, your Group CEO and the relevant National Director. Can you please provide us with the following information in writing by DD/MM/YYYY:

1. Name of Senior Accountable Person who will lead on the review of this statistical outlier
2. Indicative date for completion of report

Should you require further information on this, please contact your NOCA National Audit Coordinator [name, email, and phone]

Kindest regards,

NOCA Audit Clinical Lead

XXX Audit

- Hospital Group CEO
- National Director e.g. AHD
- Hospital Audit Clinical Lead
- Hospital Audit Data Coordinator
- Others can be included on a case by case basis eg Professional Bodies, Clinical Programmes

16.0 Appendix 2 – National Clinical Audit Statistical Outlier Report Guidance

The Senior Accountable Person is responsible for preparing a report outlining the review approach, key findings and required corrective actions.

Personal Data should not be used in this report.

The report should include the following sections

- NOCA Audit Title
- Hospital
- Report prepared by
- Date Issued
- Review Team
- Background - A brief summary of the statistical outlier
- Approach taken to review statistical outlier
- Time to complete the review
- Key findings
- Summary of any required hospital escalations arising from the review. This might include but not be limited to…
    - Patient Safety Incident– Raised on NIMS
    - Poor practice reported to relevant regulator
- Action Plan (included in Hospital QI Plan)
    - Summary of actions
    - Responsible Person
    - Responsible Manager
    - Timelines
    - Mechanism to be put in place to monitor implementation

Appendix 8: NOCA Standard for Annual Reports Template

Audit:

This NPEC Annual Report was prepared in line with NOCA Standard for Annual Reports.

Development of the Report	✓
Membership of the Report Core Writing Group included at least Clinical Lead, Audit Coordinator, Statistician.	✓
• The Report Writing Group included Subject Matter Expertise	✓
Data validation was carried out	✓
Supporting / additional comments	

Structure of the Report	✓
Report Information Page is included	✓
A Forward / Preface Is included	✓
Patient Story / Experience is included	In Lay Summary
A Table of Contents is included	✓
• A Tables of Tables is included	✓
• A Table of Figures is included	✓
• Tables of Contents / Figures /Tables is consistent with the Report text	✓
An Executive Summary Is included	✓
• Key Findings & Recommendations are included	✓
A Report introduction is included	✓

• Aim and Objectives s of the national clinical audit are included	✓
Body of the Report presented in chapters	✓
• Audit Methods are presented	✓
• There is a section on data quality	✓
• Audit Findings are clearly presented	✓
• Key findings are highlighted	✓
• Key Recommendations are highlighted	✓
Conclusion or Evaluation Chapter	✓
Reference List is included	✓
Appendices are included	✓
Supporting / additional comments	

Format within the Report	✓
Individual chapters are divided clearly and developed logically	✓
Information clearly displayed using tables, graphs, info graphics	✓
• Data in Tables, Figures and Infographics is clearly explained & is consistent with that in report	✓
• All Tables and Figures are sequentially numbered	✓
Attention has been paid to referencing of material in the text in reference list	✓
• Reference Style- Harvard Style	✓
During the preparation of this report, attention was to ensure clarity of the end report.	✓
Supporting / additional comments	

Content within the Report	✓
Information content is of appropriate depth and contributes to development of key findings and recommendations	✓
Recommendations are based on the audit findings and/or the process of carrying out the audit	✓
• Recommendations are clearly and concisely presented	✓
Considerations / Learning points are clearly presented	✓
The report identifies opportunities for improvement	✓
Discussion and conclusions should relate to content and have a summative quality	✓
Appendices	✓
• A Glossary of Terms/Definitions is included	✓
• NCA Governance Committee Membership and Meeting Attendance for Reporting Year is included	Membership not attendence
Acknowledgements are included in the Report	✓
Supporting / additional comments	

The Summary Report was prepared in line with NOCA Standard

Summary Report	✓
The Public/ Patient Representative on the NCA Governance Committee contributed to development of this Summary Report	✓
This Report is developed from the Annual Report; it is presented in a manner suitable for a non-clinical audience.	✓
There is a focus on Key findings and Recommendations	✓
Information is presented in a visual format	✓
Supporting / additional comments	

Assurance from the National Office of Clinical Audit	✓
Reports meet the NOCA Standard	
NOCA Executive Director (or nominee) Name:	
NOCA Executive Director (or nominee) Signature:	
Date:	

Assurance from the National Office of Clinical Audit	✓
This NOCA Report was approved by the NOCA National Clinical Audit Governance Committee	
The NOCA Summary Report approved by the NOCA National Clinical Audit Governance Committee	
National Clinical Audit Governance Committee Chair Name: NPEC Perinatal Mortality Group: Professor Richard Greene	
National Clinical Audit Governance Committee Chair Signature:	
Date:	

Appendix 9: NOCA Endorsement Letter for the NPEC Perinatal Mortality National Clinical Audit Annual Report 2016

NOCA National Office of Clinical Audit

Professor Richard A. Greene
Director
National Perinatal Epidemiology Centre
5th Floor, Cork University Maternity Hospital Wilton
Cork

01st June 2018

Perinatal Mortality in Ireland, Annual Report 2016

Dear Professor Greene,

I write to thank you and your colleague Dr Paul Corcoran for your detailed presentation to the NOCA Governance Board, 24th May 2018 of NPEC's Perinatal Mortality in Ireland – Annual Report 2016.

You and your NPEC colleagues are to be congratulated for the quality of the report and manner in which you continue to engage with maternity services to maintain this work.

The NOCA Board and Executive Team will continue to support NPEC governance efforts and in particular highlight the national requirement for resource commitment to ensure sustainable clinical audit of perinatal and maternal outcomes.

Please accept this as formal endorsement from the NOCA Governance Board of the Perinatal Mortality in Ireland Annual Report 2016.

Yours sincerely,

Professor Conor O' Keane FFPath FRCPI
Chair
National Office of Clinical Audit Governance Board

National Office of Clinical Audit
2nd Floor
Ardilaun House, Block B
111 St Stephen's Green
Dublin 2, D02 VN51
Tel: + (353) 1 402 8577
Email: auditinfo@noca.ie

Appendix 10: List of Abstracts, Presentations and Posters from the Perinatal Mortality National Clinical Audit

List of NPEC Abstracts, Presentations and Posters (Topic: Perinatal Mortality):

1. ABSTRACTS:

Title:	First Author:	Where Submitted:
Island of Ireland Perinatal Mortality Report 2014 and 2015.	O'Farrell IB	Irish Perinatal Society
Perinatal Mortality in Ireland, 2014 – A national clinical audit into perinatal mortality in Ireland.	Corcoran P	British Maternal & Fetal Medicine Society (BMFMS)
Perinatal Mortality in Ireland, 2014 – A national clinical audit into perinatal mortality in Ireland.	Corcoran P	National Health Services Research Conference
Perinatal Mortality in Ireland, 2014 – A national clinical audit into perinatal mortality in Ireland.	Corcoran P	National Patient Safety Conference
Fetal Growth Restriction (FGR) and perinatal mortality in Ireland 2011- 2013.	Manning, E	24th European Congress of Obstetrics and Gynaecology, Torino, Italy.
Fetal Growth Restriction (FGR) and perinatal mortality in Ireland	Manning, E	Fetal Growth Conference
The incidence of perinatal mortality in Ireland according to the Robson Ten Groups Classification System (TGCS).	Corcoran P	British Maternal & Fetal Medicine Society (2017)
Perinatal Mortality in Ireland – 2008. An ascertainment of the national picture.	Manning E	Irish Congress of Obstetrics and Gynaecology

2. PRESENTATIONS:

Title:	Presenter:	Where Presented:
NPEC Hospital Visit Perinatal Mortality & Severe Maternal Morbidity	Edel Manning	University Hospital Galway
Island of Ireland: Perinatal Mortality Report 2014 and 2015	Edel Manning	Department of Health
NPEC National Clinical Audit – Perinatal Mortality and Severe Maternal Morbidity	Edel Manning	NPEC Feedback Forum
Island of Ireland: Perinatal Mortality Report 2014 and 2015	Edel Manning	ICOGPM
Fetal Growth Restriction and Perinatal Mortality in Ireland 2011-2013	Edel Manning	24th European Congress of Obstetrics and Gynaecology, Torino.
Perinatal Mortality in the Republic of Ireland	Edel Manning	Meeting between NIMACH and NPEC
Fetal Growth Restriction and Perinatal Mortality in Ireland	Edel Manning	Fetal Growth conference 2014, Oxford,
Perinatal Mortality in Ireland Annual Report 2013	Edel Manning,	NPEC Governance Committee
National Audit : Improved Care Marking 10 years of NPEC & Clinical Audit in the maternity services	Paul Corcoran	CUH Grand Rounds
Perinatal Mortality in Ireland Annual Report 2015	Paul Corcoran	NOCA Governance Board Meeting
Perinatal Mortality in Ireland Annual Report 2014	Paul Corcoran	NPEC Webinar
Perinatal Mortality in Ireland Annual Report 2014	Paul Corcoran	NOCA Governance Board Meeting
Severe Maternal Morbidity Annual Report 2012 and 2013	Paul Corcoran	NOCA Governance Board Meeting
Findings from the perinatal mortality and severe maternal morbidity audits	Paul Corcoran and Edel Manning	17th Annual Western Obstetrics and Gynaecology Society Conference
Perinatal mortality in Ireland 2008-2012	Paul Corcoran and Edel Manning	NPEC Annual Study Day 2014
Perinatal mortality in Ireland: A national clinical audit	Paul Corcoran	The 2014 International Conference on Stillbirth, SIDS and Baby Survival; Global Action Needed, Amsterdam

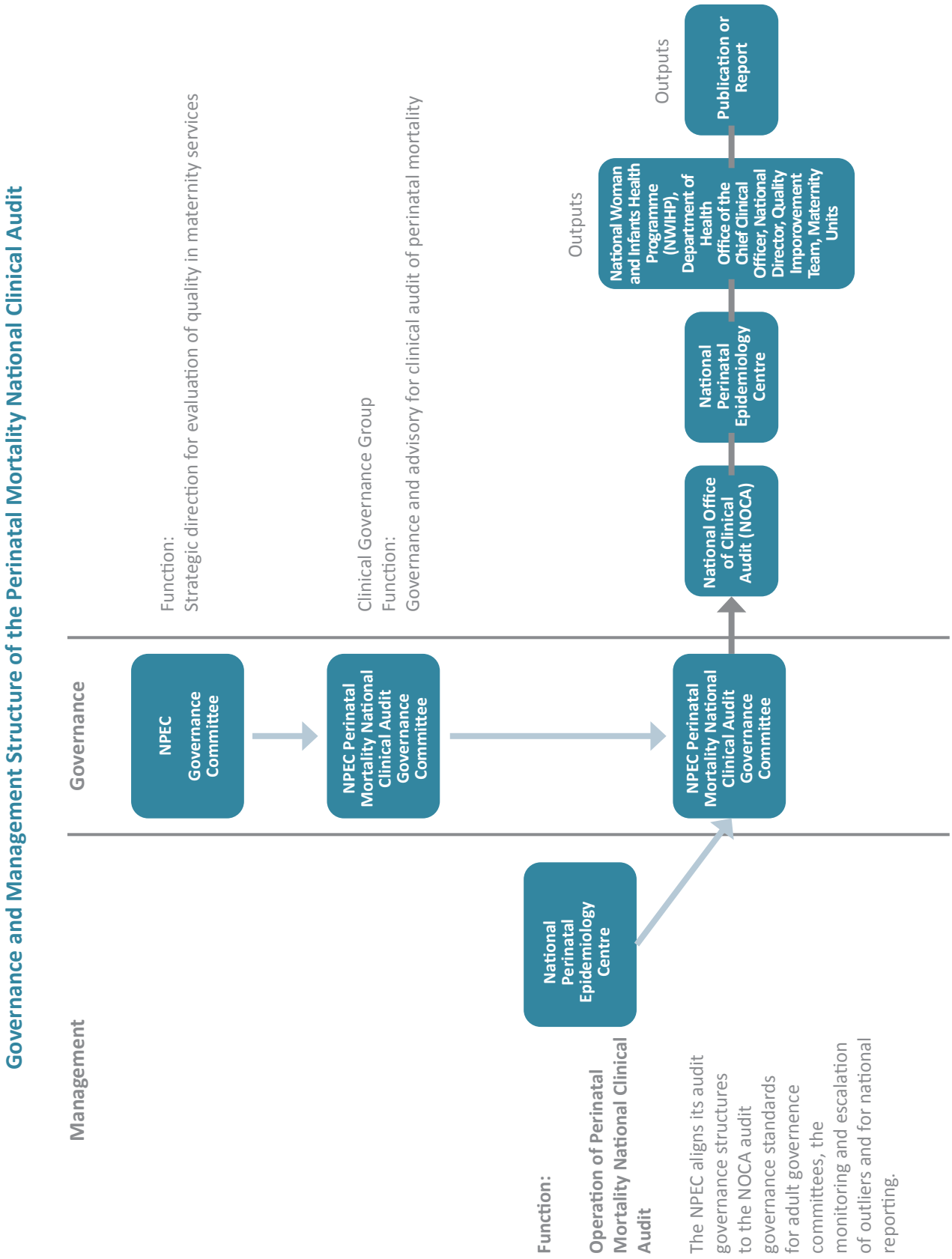
Title:	Presenter:	Where Presented:
National Audit: Improved Care Marking 10 years of NPEC & Clinical Audit in the maternity services.	Professor Richard Greene	NOCA Annual Conference 2019, RCSI
NPEC Hospital Group Visit Ireland East Hospital Group	Professor Richard Greene	Wexford General Hospital
Using National Audit to learn lessons from Perinatal Mortality	Professor Richard Greene	Maternity Bereavement Forum March 2018
The Inaugural Institute Clinical Reports Meeting – Perinatal Mortality 2015	Professor Richard Greene	IOG
Clinical Audit in Maternity Services; the numbers and beyond.	Professor Richard A Greene	National Maternity Hospital
Perinatal Mortality in Ireland	Professor Richard A Greene	Department of Health
How can we Reduce the incidence of Stillbirth?	Professor Richard Greene	CUMH Grand Rounds
Perinatal Mortality in Ireland Annual Report 2013	Richard A Greene	NOCA Governance Board Meeting
NPEC Report Outputs for Practice in Ireland	Professor Richard A Greene	All Ireland Midwifery Conference
Clinical Audit in the Irish Context: the Experience of the National Perinatal Epidemiology Centre	Richard A Greene	Inaugural NOCA Conference Managing what we measure, RCSI, Dublin
How can we Reduce the incidence of Stillbirth?	Professor Richard Greene	Irish Congress of Obstetrics, Gynaecology & Perinatal Medicine
Are our maternity hospitals safe?	Professor Richard Greene	Mid-Western Regional Maternity Hospital, Limerick
Are our maternity hospitals safe?	Professor Richard A Greene	Letterkenny Hospital Visit
Are Our Maternity Hospitals Safe? – Maternal and Perinatal Mortality in Ireland	Professor Richard Greene	Cork university Maternity Hospital General Practitioners Study Day
The National Perinatal Epidemiology Centre	Professor Richard Greene	Royal College of Physicians of Ireland Conference
Clinical Audit in Maternity Services; the numbers and beyond	Professor Richard Greene	The 20th Western Obstetrical and Gynaecological Society Meeting
The role of perinatal audit and confidential enquiries	Professor Richard A Greene	International Stillborn Alliance Conference

Title:	Presenter:	Where Presented:
NPEC Hospital Visit Lunchtime presentation (Perinatal Mortality	Professor Richard A Greene	2nd Nursery Gallarus Ward, UHK
'Development of Midwifery-Led Units represents the way forward for Maternity Services in the Republic of Ireland' Against the Motion.	Professor Richard Greene	Irish Perinatal Society
NPEC Annual Reports 2016	Professor Richard Greene	Department of Health
What influences parents' decision to have a perinatal autopsy?	Sarah Meaney	The Impact of Stillbirth Conference
Lessons from the National Perinatal Epidemiology Centre national audits	Sarah Meaney	3rd Irish Congress of Obstetrics, Gynaecology and Perinatal Medicine, Dublin
Translating Clinical Audit Data and Epidemiological Evidence into Improved Maternity Care for Families in Ireland	Professor Richard Greene	CUH Grand Rounds

3. POSTERS:

Title:	Presenter:	Where Presented:
Perinatal Mortality in Ireland, 2015 – A national clinical audit into perinatal mortality in Ireland	O'Farrell IB	BMFMS
Island of Ireland: Perinatal Mortality Report 2014 and 2015	O'Farrell IB	NPEC Study Day
Perinatal Mortality in Ireland, 2016 – A national clinical audit into perinatal mortality in Ireland	Manning E	NPEC Study Day
Congenital anomalies in a cohort of stillborn infants; A review from 1996- 2010 in the Cork and Kerry Region	Meaney S	ISA 2017
The Incidence of Fatal Fetal Anomalies associated with Perinatal Mortality in Ireland.	Power S	ISA 2017
Modifiable risk factors for stillbirth: a literature review, 2018	Escañuela Sánchez T	ISA 2017
Critical discourse analysis on the influence of media commentary on fatal fetal anomaly in Ireland.	Power S	ISA 2017
Perinatal Mortality in Ireland, 2014 – A national clinical audit into perinatal mortality in Ireland	Corcoran P	Patient Safety Conference
Perinatal Mortality in Ireland in 2008: a National Perspective.	E Manning	N/A

Appendix 11: NPEC Governance and Management Structure for the Perinatal Mortality National Clinical Audit



Appendix 12: NPEC Dissemination and Communications Workplan for the Perinatal Mortality National Clinical Audit Annual Report 2016

NATIONAL PERINATAL EPIDEMIOLOGY CENTRE

NPEC Perinatal Mortality Annual Report 2016
Dissemination and communications work plan

Date	Action	Details
Pre-launch:	Strictly embargoed report sent to DOH and NWIHP	As agreed
Prior to report launch	Nominate report spokespeople	Richard Greene, Edel Manning
	Department of Health & HSE Meeting	NPEC Representatives, NWIHP Representatives NOCA Representative
Prior to report launch	Individual Hospital Reports emailed to stakeholders	Hospital Management Audit Coordinators
Day of report launch	Tweet Release	Tweets will be sent thought out the day highlighting key findings and recommendations.
	Report available on NPEC website	Published at 15.00hrs
	Email to all stakeholders with link to report	Hospital & Hospital Group Management Hospital Clinical Leads & Audit Coordinators Relevant Clinical Programmes Department of Health HSE Patient Advocacy Groups Libraries – healthcare and academic.
Following publication	Printed reports	Printed copies will be sent to all units including audit co-ordinators, senior management and risk managers
Two weeks following publication of report	Webinar	Audit co-ordinators and hospital management will be invited to a webinar to discuss findings of the report and for feedback.
Early September	Webinar	All contacts will be invited to webinar a request will be sent out through the Faculty and neonatal nurses networks also.

NATIONAL PERINATAL EPIDEMIOLOGY CENTRE HSE NOCA National Office of Clinical Audit UCC

Appendix 13: List of Acronyms and Abbreviations

List of Acronyms and Abbreviations

AREDF	Absent or reversed end diastolic flow
ARR	Average reduction rate
BMI	Body mass index
CESDI	Confidential Enquiry into Stillbirths and Deaths in Infancy
CEO	Chief Executive Officer
CI	Confidence interval
CEMACH	Confidential Enquiry into Maternal and Child Health
CMACE	Centre for Maternal and Child Enquiries
CMO	Chief Medical Officer
COI	Conflict of interest
ENAP	Every Newborn Action Plan
EU	European Union
FGR	Fetal growth restriction
FH	Fundal height
FIMR	Fetal and Infant Mortality Review
FOI	Freedom of Information
g	Gram
GAP	Growth Assessment Protocol
GDPR	General Data Protection Regulations
HIQA	Health Information and Quality Authority
HPO	Healthcare Pricing Office
HSE	Health Service Executive
IOG	Institute of Obstetrics and Gynaecology
IUFD	Intrauterine fetal death
IUGR	Intra-uterine growth restriction
IRIS	Institutional Research Information System
NCA	National clinical audit
NCEC	National Clinical Effectiveness Committee

NCG	National Clinical Guideline
NICE	National Institute for Health and Care Excellence
NIMACH	Northern Ireland Maternal and Child Health
NOCA	National Office of Clinical Audit
NPEC	National Perinatal Epidemiology Centre
NPRS	National Perinatal Reporting System
NWIHP	National Women and Infants Health Programme
PMNCA	Perinatal Mortality National Clinical Audit
PMNCAGC	Perinatal Mortality National Clinical Audit Governance Committee
PMR	Perinatal mortality rate
PSANZ	Perinatal Society of Australia and New Zealand
RCPI	Royal College of Physicians of Ireland
ROI	Republic of Ireland
RR	Rate ratio
SIDS	Sudden Infant Death Syndrome
SLA	Service level agreement
TOR	Terms of reference
UA	umbilical artery
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

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