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Study of methods, systems, recommendations and bereaved parents' involvements in perinatal death reviews, inquiries and audits

Thesis presented by

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for degree of

Doctor of Philosophy to College of Medicine and Health

Research conducted at the National Perinatal Epidemiology Centre and the Pregnancy Loss Research Group, Department of Obstetrics and Gynaecology, Cork University Maternity Hospital, Cork.

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10th December 2021

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List of abbreviations

CMS	Clinical Midwife Specialist
GP	General Practitioner
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
ICD	International Classification of Diseases
IOG	Institute of Obstetrician and Gynaecologists
MBRRACE	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries
MDT	Multidisciplinary team
MERT	Maternity Event Review Tool
NCHD	Non-consultant hospital doctor
NIMF	National Incident Management Framework
NPEC	National Perinatal Epidemiology Centre
NWIHP	National Women and Infants Health Programme
PMMRC	Perinatal and Maternal Mortality Review Committee
PMRT	Perinatal Mortality Review Tool
PSANZ	Perinatal Society of Australia and New Zealand
RCOG	Royal College of Obstetricians and Gynaecologists
RCPI	Royal College of Physicians of Ireland
SIMT	Serious Incident Management Team
SRE	Serious Reportable Event
TOP	Termination of Pregnancy
WHO	World Health Organisation

Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism and intellectual property.

Helps, Ä. 2021. Study of methods, systems, recommendations and bereaved parents' involvements in perinatal death reviews, inquiries and audits. PhD Thesis, University College Cork.

Please note that pages. xii-xiv are unavailable due to a request by the author.

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Research Outputs

The following manuscripts published or submitted for publication form the chapters in the current thesis.

Published Peer Review Articles:

Helps Ä, Leitao S, Greene R, O'Donoghue K. Perinatal mortality audits and reviews: Past, present and the way forward. Eur J Obstet Gynecol Reprod Biol. 2020 Jul;250:24-30. doi: 10.1016/j.ejogrb.2020.04.054. Epub 2020 Apr 30. PMID: 32371247.

Helps Ä, Leitao S, O'Byrne L, Greene R, O'Donoghue K. Irish Inquiry Reports Relating to Perinatal Deaths and Pregnancy Loss Services. Ir Med J. 2020 Feb 13;113(2):21. PMID: 32401451.

Helps Ä, O'Donoghue K, O'Byrne L, Greene R, Leitao S. Impact of bereavement care and pregnancy loss services on families: Findings and recommendations from Irish inquiry reports. Midwifery. 2020 Dec;91:102841. doi: 10.1016/j.midw.2020.102841. Epub 2020 Sep 10. PMID: 32956983.

Helps Ä, Leitao S, O'Byrne L, Greene R, O'Donoghue K. Governance of maternity services: Effects on the management of perinatal deaths and bereavement services. Midwifery. 2021 Oct;101:103049. doi: 10.1016/j.midw.2021.103049. Epub 2021 May 28. PMID: 34126337.

Helps Ä, Leitao S, Gutman A, Greene R, O'Donoghue K. National perinatal mortality audits and resultant initiatives in four countries. Eur J Obstet Gynecol Reprod Biol. 2021 Oct 30;267:111-119. doi: 10.1016/j.ejogrb.2021.10.012. Epub ahead of print. PMID: 34749039.

Articles currently under review:

Helps Ä, Greene R, O'Donoghue K, Leitao S. Implementation of a national incident management framework: how does it apply to local perinatal death reviews? Under review in Maternal and Child Health Journal

Helps Ä, O'Donoghue K, O'Connell O, Leitao S. Bereaved Parents Involvement in Maternity Hospital Perinatal Death Review Processes: "Nobody even thought to ask us anything" Under review in Health expectations.

Published abstracts

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Helps Ä, Leitao S, O'Byrne L, Greene RA, O'Donoghue K. Analysis of Irish inquiry reports relating to perinatal deaths and pregnancy loss services (2005 – 2018). Irish Medical Journal; Book of abstracts published online 2020 (#33; p51)

Helps Ä, Leitao S, O'Donoghue K, Greene RA. Perinatal death notification and local reviews in the 19 Irish maternity units. Irish Medical Journal; Book of abstracts published online 2020 (#34; p52)

Gutman A, **Helps Ä**, Leitao S, O'Donoghue K. Review of the National Perinatal Epidemiology Centre Perinatal Mortality Audit Reports (2009-2016). Irish journal of Medical Science 2019; 188 (suppl 12), s360-s360

Helps Ä, O'Byrne L, Leitao S, O'Donoghue K. Analysis of irish inquiry reports relating to pregnancy loss services (2005–2018). Society for Social Medicine and Population Health Annual Meeting, Cork, 4-6 September 2019. J Epidemiol Community Health 73 (Suppl 1), A80-A81

Helps Ä, Leitao S and O'Donoghue K. The way forward in perinatal mortality reviews. RCOG World Congress, London, 11-19 June 2019. BJOG: An International Journal of Obstetrics & Gynaecology 2019;126 (Issue S2)

Collaboration in articles not part of this thesis:

Leitao S, **Helps Ä**, Cotter R, O'Donoghue K. Development and evaluation of TEARDROP - a perinatal bereavement care training programme for healthcare professionals. Midwifery. 2021; 98(102978).

Research dissemination

Oral presentations:

"The evolution and current status of perinatal mortality reviews", Trinity Health and Education International Research Conference, Trinity College, Dublin. 6th and 7th of March 2019.

"Analysis of Irish inquiry reports relating to perinatal deaths and pregnancy loss services (2005 – 2018)", ANU research meeting, University College Cork. 21st June 2019

"Irish inquiry reports on pregnancy loss services: recommendations on management of information and maternity services governance", ISA International Stillbirth Alliance Conference, Madrid, 4th – 6th October 2019.

"Analysis of Irish inquiry reports relating to perinatal deaths and pregnancy loss services (2005 – 2018)", Irish Congress of Obstetrics, Gynaecology and Perinatal Medicine, Galway Bay Hotel, Galway, 29th November 2019.

Thesis in 3, INFANT research day, Cork. 12th December 2019.

Invited oral "Analysis of Irish inquiry reports relating to perinatal deaths and pregnancy loss services (2005 – 2018)", 4 posters, NPEC annual study day, Cork. 17th January 2020.

"Governance of Maternity Services: Effects on the Management of Perinatal Deaths and Bereavement Services", JOGS 2020 (online/pre-recorded), 27th November 2020.

"National Perinatal Mortality Audits and Resultant Initiatives in Four Countries". ISA-ISPID Digital Conference, Brisbane, Australia. (Online format), 11th – 13th November 2021.

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Poster presentations:

"How do we best review perinatal deaths?", Junior Obstetrics & Gynaecology Society (JOGS) Annual Scientific Meeting, RCPI, Dublin. 23th November 2018.

"Perinatal mortality reviews in Ireland and internationally", National Perinatal Epidemiology Centre annual study day, Aviva stadium, Dublin. 18th January 2019.

"The way forward in perinatal mortality reviews" Published in BJOG. RCOG World Congress, London. 17th – 19th June 2019.

Analysis of 10 published national inquiry reports relating to Irish pregnancy loss services (2005 – 2018)", RCOG World Congress, London. 17th – 19th June 2019.

"Analysis of Irish inquiry reports relating to pregnancy loss services (2005 – 2018)", Society for Social Medicine & Population Health and International Epidemiology Association European Congress, University College Cork, 4th – 6th September 2019.

"Analysis of Irish inquiry reports relating to pregnancy loss services (2005 – 2018)" International Stillbirth Alliance, Madrid, 4th – 6th October 2019. **Awarded runner-up in poster presentations**

"Analysis of Irish inquiry reports relating to pregnancy loss services (2005 – 2018)" MBRRACE-UK Perinatal Surveillance Launch Meeting, London, 15th October 2019.

"Perinatal death notification and local reviews in the 19 Irish maternity units", MBRRACE-UK Perinatal Surveillance Launch Meeting, London, 15th October 2019.

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"The effects of maternity services governance on the management of perinatal deaths and bereavement services", New Horizons, UCC (online format), 3rd December 2020.

“The effects of maternity services governance on the management of perinatal deaths and bereavement services”. Poster presentation, NPEC annual study day (online), 22/01/2021

“The effects of maternity services governance on the management of perinatal deaths and bereavement services”, Stillbirth Summit 2021, Star Legacy Foundation, (online format). 23th – 24th June 2021.

“National Perinatal Mortality Audits and Resultant Initiatives in Four Countries”, International Federation of Gynecology and Obstetrics, World Congress (online format). 21st – 28th October 2021

“National Perinatal Mortality Audits and Resultant Initiatives in Four Countries”, JOGS Annual Scientific Meeting 2021 (online format). 26th November 2021.

Abstract

Background

An estimated 5.3 million perinatal deaths occur worldwide each year. In Ireland, there were 335 perinatal deaths reported in 2019. These deaths are devastating for the parents, families and, if unexpected, for the healthcare staff involved, with long-lasting emotional consequences. Some of these deaths are unavoidable, but many are preventable. To investigate these deaths and identify contributory factors, local hospital-based perinatal death reviews as well as national perinatal mortality audits are carried out. In certain circumstances, for example if a higher than expected intrapartum perinatal death rate is recorded, an external inquiry may be commissioned to investigate events of public concern. Reports with recommendations are published after local perinatal death reviews, perinatal audits and external inquiries. In Ireland, there is currently no standardised format to the recommendations or their implementation. Further, the involvement of bereaved parents in local maternity hospital-based perinatal death reviews is poorly explored.

The aim of this thesis is to analyse the methodology and structure of perinatal mortality audits, local reviews and inquiries, as well as recurrent themes in the recommendations of the published reports and the inclusion of bereaved parents in reviews.

Methodology

Both qualitative and quantitative methods were employed for this thesis. A topic can be explored with flexibility and in depth by using a mixed methods approach. An integrative literature search was carried out focussing on the types and evolution of perinatal mortality audits and reviews in high-income countries. Further, an integrative review using quantitative and qualitative methods to identify established national perinatal mortality audits in four high-income countries and national initiatives addressing recommendations from these audits

was done. Content analysis of the audits' recommendations was performed organising them into themes according to topics covered. Additionally, a service evaluation of the local maternity hospitals' perinatal death reviews in Ireland was carried using an electronic survey. The quantitative and qualitative data collected from all 19 maternity units were analysed to identify and compare current local review processes.

In the analyses of the ten Irish inquiry reports relating to perinatal deaths and pregnancy loss services in the maternity services quantitative and qualitative data were collected by two clinicians using a specifically designed review tool. Descriptive analyses of the main characteristics of the reports gave an overview of the terms of reference and inquiry review process, and identified recurring themes in the recommendations. Qualitative content analysis of the reports' findings and recommendations was used to identify key domains. An inductive thematic analysis with a semantic approach following the steps of familiarising, coding, identifying, grouping and revising themes identified the main themes and subthemes for each domain. Lastly, purposeful sampling was used to recruit bereaved parents in Ireland to take part in semi-structured interviews to examine how parents may be appropriately involved in the local hospital-based review in a way that is beneficial to them and the review process itself. Reflexive thematic analysis using a five-phase process (familiarisation, open coding, generating themes, developing themes, refining themes) was carried out on the collected data by three researchers.

Results

Internationally, differences in perinatal mortality classifications, audits and reviews, as well as barriers to the implementation of recommendations were noted. Common and recurrent themes of recommendations from four established national perinatal mortality audits suggested a lack of progression of recommendations that is shared between countries. These four countries have

adopted varying national initiatives and programmes to address the audits' recommendations.

A lack of standardisation for the methods of local perinatal mortality reviews and external inquiries in Ireland was highlighted within this thesis. Recommendations from ten inquiry reports were numerous and repetitive suggesting a lack of clear ownership for the implementation process. An analysis of the findings of the ten inquiry reports showed that that elements of governance of Irish maternity services (workforce, leadership, management of risk, work environment) impacted negatively and directly on the management of perinatal deaths and bereavement services. Further, three elements (hospital oversight, national documents, data collection) identified from the inquiry reports in turn affected governance structures in the management of perinatal deaths. Examination of these inquiry reports highlighted shortcomings in the perinatal bereavement care and pregnancy loss services provided to families in the Irish maternity services and the short- and long-term effects this can have. Interviews with bereaved parents revealed that parents want a more inclusive and open process that allows them to be included in the local hospital perinatal mortality review. However, this parental involvement needs to be carefully considered, flexible and appropriately resourced.

Conclusion

The culture in the maternity unit determines how bereaved families and hospital staff cope after an adverse event like an unexpected perinatal death. A lack of open disclosure can have negative effects on how bereaved parents process events and cope with their grief after the death of their baby. Recently many reports with multiple recommendations have been published to improve safety standards in the Irish maternity services; however, implementation thus far has been slow and incomplete. The focus is currently on collecting data and highlighting issues, and less on progressing recommendations to implement

changes and prevent similar events recurring. To overcome barriers to successful recommendation implementation and advance perinatal mortality audits and reviews, suggestions based on examples from the international literature were identified and provided as part of this thesis.

Perinatal mortality processes, including reviews, need to be standardised across the 19 maternity units. Suggestions to achieve this include the adaptation of the national Incident Management Framework specifically to the maternity setting, the implementation of an electronic review tool such as MERT (Maternity Event Review Tool) for perinatal deaths and an assessment of the feasibility of a national perinatal (and/or paediatric) Coroner for Ireland. The inclusion of parents in perinatal mortality reviews needs to be addressed urgently yet carefully considered and resourced, in order for it to be beneficial to them and the review process itself. A collaborative process between staff and parents can highlight clinical areas in need of change, enhance lessons learned, and may prevent future perinatal deaths.

Chapter 1 - Introduction

Chapter 1 – Introduction

1.1 Introduction

The death of their baby in pregnancy or soon after birth is a devastating experience for parents with long-lasting consequences.[1–4] The manner of bereavement and clinical care the parents and their family receive at this time and throughout their bereavement journey can have significant positive or negative influences on their healing.[3–5]

Any perinatal death, and especially an unexpected death in labour or soon after birth due to labour complications, impacts healthcare staff emotionally and professionally.[2,6,7] The manner of staff debriefing and support after these deaths, as well as the reviewing and reporting of events, can have far-reaching consequences on general staff well-being, morale, clinical functioning and retention in a maternity hospital.[6,8] Further, the hospital and/or health service can be impacted by litigation and intrusive media attention.[9,10]

Reporting of adverse perinatal events in the media can influence the public's opinion and trust in the national maternity services.[9,10] Self-imposed social isolation by the bereaved parents, and possibly by the affected healthcare staff, may affect friends, family members and their community.[2,8] Unrealistic and unhelpful expectations by society of recovery after a perinatal death can amplify the feeling of isolation for bereaved parents.[2] For the parents unsupportive employers and/or restrictive parental leave policies result in reduced/loss of employment and earnings.[2] Governments that offer tangible supports to bereaved parents (and hospital communities) in the form of paid leave, structured psychological supports and healthcare expenses can make a difference to the recovery of the parents.[2]

According to the World Health Organisation (WHO) an estimated 5.3 million perinatal deaths occur worldwide every year.[11] There is now significant effort being made worldwide to reduce the number of perinatal deaths and thus their

burden on families, hospitals and society.[11–16] Counting and recording the number of perinatal deaths and identifying contributory factors is one step towards this.[11] The WHO (2016) published a guide titled "Making Every Baby Count" to achieve reliable audits and reviews of stillbirths and neonatal deaths.[11] By learning from these deaths through national audits and local reviews to inform changes in policies and clinical practice appropriately, future preventable deaths can be avoided.[11,12]

In Ireland there were 360 perinatal deaths reported by the National Perinatal Epidemiology Centre (NPEC) in 2019, giving a perinatal mortality rate of 6 deaths per 1000 births.[17] Since 2009 NPEC carries out an annual national perinatal mortality audit (as well as others). As part of this audit national recommendations are made.[18]

Multiple local and national perinatal mortality (and adverse event) reviews are carried out, however follow-up processes to ensure that recommended changes are implemented are not consistently in place.[11,12,19] There is little literature comparing perinatal mortality audits and reviews to each other (especially in the Irish setting) and what effects they have had on maternity care and bereaved families, therefore these topics were explored to form part of this thesis.

This chapter gives an overview of maternity care and services, including perinatal bereavement services, in Ireland. The definitions and rates of perinatal mortality are described. In addition, information on different types of perinatal mortality reviews including established national audits, hospital-based reviews and standalone inquiry reports in Ireland are presented. The involvement of bereaved parents in these types of reviews internationally and in Ireland is examined. Finally, the thesis' aims and objectives, as well as an overview of the individual chapters is provided.

1.2 Maternity services in Ireland

1.2.1 Structure and standards

The maternity services in Ireland are managed by the Health Service Executive (HSE) and funded through the Department of Health. There are 19 maternity units in Ireland, 15 are co-located within general hospital grounds and four currently are stand-alone hospitals (three of which are voluntary hospitals with their own board of management contracted by the HSE to provide maternity services).[20] There is a plan to move these maternity units to be co-located with acute general hospitals by 2040.[21,22] The maternity units vary significantly in size, delivering between 1,000 and 8,000 babies per annum (Table 1.1).[21] The 19 units are divided into six hospital groups/networks (Table 1.1).[23] The aim of these networks is to facilitate the sharing of clinical services and expertise between smaller and larger units.[21,23–25] There were 59,352 births in Ireland in 2019.[26] The majority of births in Ireland occur in the hospital setting, with less than 0.3% of births occurring through the national homebirth service at home.[21,27]

The Irish Maternity and Infant Care Scheme provides free maternity care to the mother and her infant during the pregnancy and up to six weeks after birth.[21,28] As part of this scheme the care is shared between the maternity unit and the General Practitioner (GP).[21,28,29] Most antenatal care is provided this way, combining consultant-led care from the hospital with GP visits.[21] The midwifery-led care options include DOMINO (Domiciliary in and out) in seven maternity units and two midwife-led units (co-located with consultant-led units). In 2014, these types of midwifery-led births accounted for approximately 4% of total births in Ireland.[21] According to the National Women and Infants Health Programme (NWIHP), in 2019, 52% of women had a spontaneous vaginal delivery, 34% a caesarean section birth and 14% an operative vaginal delivery in Ireland.[26] The majority of women attend the GP rather the maternity unit for their six week post-natal check.[21]

A National Maternity Experience Survey (3204 women took part) was carried out in Ireland by the National Care Experience Programme (a joint initiative by HIQA, HSE and the Department of Health) for women who gave birth in October/November 2019 and the findings were published in 2020.[30] Nationally, 60% of the women surveyed were offered different choices of maternity care, with midwifery-led services less commonly offered. The survey showed that 85% of participants had a good or very good experience and 15% had a fair or poor experience of maternity care in Ireland.[30] The women were asked if they knew how to give feedback or make a complaint about the care they received: 30% answered yes, 47% answered no, and 23% said they did not wish to give feedback.[30] Almost one third of the women stated they did not have the opportunity to ask questions about their labour and birth post-natally.[30] The mothers of babies that had to be admitted to a neonatal unit (n=561, 18% of the total) rated the neonatal care as good or very good (90%), however 24% stated they did not receive enough emotional support from professionals.[30] This survey did not include parents that had experienced a perinatal death. HIQA (in collaboration with HSE and Department of Health) is planning to distribute a National Maternity Bereavement Experience Survey in 2022.[31]

There are 300 neonatal unit cots across Ireland, with three levels of care depending on the size and number of births in the maternity unit.[21] The four largest maternity units (Table 1.1) provide tertiary, complex neonatal care. Four units provide intermediate level of care and the remaining eleven units provide routine neonatal care.[21] The National Neonatal Transport Programme commenced in 2001 (and is available as a 24/7 service since 2013), to transport infants between hospitals for treatment as required.[21,32,33].

Table 1. 1: Maternity hospitals in Ireland in 2019

Hospital Group	Maternity Hospital/Unit	No of births (2019)
Ireland East Hospital Group	National Maternity Hospital	7776
	Regional Hospital Mullingar	1874
	St Luke's General Hospital Kilkenny	1454
	Wexford General Hospital	1935
Royal College Of Surgeons Ireland (RCSI) Hospital Group	Rotunda Hospital	7925
	Our Lady of Lourdes Hospital Drogheda	2901
	Cavan Monaghan Hospital	1358
Dublin Midlands Hospital Group	Coombe Women and Infants University Hospital	7614
	Midland Regional Hospital Portlaoise	1490
University Limerick Hospital Group	University Maternity Hospital Limerick	4152
South/South West Hospital Group	Cork University Maternity Hospital	7197
	University Hospital Waterford	1728
	University Hospital Kerry	1194
	South Tipperary General Hospital	902

Saolta University Health Care Group (West/North West)	University Hospital Galway	2837
	Letterkenny University Hospital	1644
	Mayo General Hospital	1708
	Portiuncula Hospital Ballinasloe	1529
	Sligo University Hospital	1368

The current proposed governance model for the Irish maternity service includes the NWIHP within the HSE having overall accountability, and maternity units within each of the six hospital groups operating under a single governance framework.[21] An identified individual has accountability in each maternity unit and is supported by a multi-disciplinary management team that shares the responsibilities for the management and functioning of clinical services.[21]

1.2.2 National Maternity Strategy

The first Irish National Maternity Strategy titled "Creating a better future together" was published in 2016 to cover the period 2016 to 2026.[21] It is centred around four strategic priorities: health and wellbeing; safe, quality and women-centred care; choice; governance and workforce.[21]

The first priority describes opportunities for maternity services to help women reduce harmful lifestyle behaviours (e.g. smoking) and encourage protective measures (e.g. improved nutrition, breastfeeding). The second priority requires each maternity unit to have leadership oversight to encompass both maternity quality (e.g. standards, audits) and patient safety elements (e.g. complaints, incident management). The third priority states that women and their families should be involved in the decision-making around their care, including the model or level of care they require and how this may change during the ante-, post-natal and intrapartum periods. As part of the third priority the Strategy proposed three new care pathways for mothers and babies: supported care pathway which is

midwifery-led; assisted care pathway which is obstetrician-led and delivered by a multidisciplinary team; specialised care pathway for high-risk mothers and babies involving specialist services as required.[21] The final priority emphasises that the maternity services need to be adequately resourced and structured, in relation to workforce, leadership and management.

The NWIHP are responsible for the implementation of the Strategy. The implementation plan was launched in October 2017, though limited written information is available on the progress of implementing the Strategy.[34]

1.2.3 National Women and Infants Health Programme (NWIHP)

The NWIHP was established in January 2017 within the HSE "to lead the management, organisation and delivery of maternity, gynaecology and neonatal services" in Ireland.[21] As well as overseeing the implementation of the Maternity Strategy, NWIHP monitor conformity across the 19 maternity units to the HSE's National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death *(to be discussed in section 1.2.8.)*, and the Health Information and Quality Authority's (HIQA) Safer Better Health Standards for Maternity Services. NWIHP monitors maternity service outcome metrics through the Irish Maternity Indicator System (IMIS) and publishes an annual IMIS report with data from the 19 units *(further detail on IMIS is provided in section 1.2.5.)*.[26]

NWIHP collaborate with NPEC and the National Clinical Programme for Paediatrics and Neonatology since 2016 to examine the incidence and risk factors for infants requiring therapeutic hypothermia as a treatment for neonatal encephalopathy.[35] An annual report on the infants that survived and those that died (14% between 2016 and 2019) is produced including recommendations based on the key findings.[35] Further, NWIHP established the National Neonatal Encephalopathy Action Group in a partnership with the State Claims Agency and the Department of Health to implement strategies to reduce the risks relating to neonatal encephalopathy.[36]

NWIHP is staffed by a National Programme Director, Clinical Director, Director of Midwifery, Quality & Safety Lead, Data & Quality Improvement Systems Manager, Project Manager, General Managers and Administrative Officer.[20] It is supported by a range of other HSE programmes e.g. the National Clinical Programme for Paediatrics and Neonatology, Mental Health Programme, among others.[20]

1.2.4 Role of the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority is an independent Irish statutory authority established under the Health Act 2007. It endorses safety and quality in health care provision, by inspecting and reviewing health services and developing standards.[22] HIQA published the National Standards for Safer Better Maternity Services in December 2016, as a result of a number of investigations and reviews (by the HSE, the Department of Health and HIQA itself) highlighted service deficits in the Irish maternity services.[37] The Standards are based around eight themes (person-centred care and support; effective care and support; safe care and support; better health and wellbeing; leadership, governance and management; workforce; use of resources; use of information) to promote a culture of quality and safety, as well as minimising and preventing harm.[37] Further, the Standards highlight the importance of reliable workforce and resources, in addition to clear accountability, decision-making and risk management within the maternity services.[37] Audit activities should include monitoring the care (risks and care outcomes) provided to women and infants locally, and the participation in national audit programmes.[37] Delivering multidisciplinary perinatal morbidity and mortality meetings in all maternity units (or at maternity group level) and sharing any learning with the relevant staff is a feature of the Standards.[37]

Between August 2018 and September 2019 HIQA inspected all 19 maternity units, taking a risk-based approach to monitor programmes against its Maternity Standards and the findings were published in a report in February 2020.[22] HIQA found good compliance in 17 units with most aspects of the Maternity Standards; the other two units had follow-up inspections which indicated progress was being

made to address key issues such as leadership, staffing, training and audit activities.[22] The main issues identified at national and hospital group level included the incomplete formalisation of care pathways for women (as outlined in the Maternity Strategy[21]), substandard infrastructure of units, unsatisfactory staffing arrangements, inadequate attendance by staff at multidisciplinary training and the lack of shared learning from adverse events.[22] These were reflected in the eight recommendations made in the report, which also included the need for a "time-bound and fully costed" implementation plan for the Maternity Strategy.[22] HIQA found good compliance with participation in national audit activities such as NPEC's perinatal mortality database.[22] However, seven units required improvement regarding the monitoring of implementation of local audits' recommendations.

1.2.5 Outcome data monitoring

Maternity outcomes from all 19 units have been captured and monitored using the Irish Maternity Indicator System since 2014.[20,26] In 2019, 40 multidisciplinary metrics including (but not limited to) births, perinatal deaths, obstetric complications and hospital activities were collected.[26] IMIS is a national management tool that aims to bring consistency to data collection and facilitates national comparisons of outcomes, as well as the tracking of monthly and annual trends.[26]

Data entered into IMIS also populates the data (17 metrics including total births, perinatal mortality rate, number of clinical incidents reported) for the monthly publicly-available Maternity Patient Safety Statements (MPSS) from individual units published on the HSE website since 2015.[20] According to the HSE, the objective of publishing these MPSS is to "provide public assurance that maternity services are delivered in an environment that promotes open disclosure".

The National Perinatal Epidemiology Centre (NPEC) based in Cork was established in 2007 and commenced data collection from 2008. [18] The objective of NPEC (as stated on their website) is to "collaborate with Irish maternity services to translate

clinical audit data and epidemiological evidence into improved maternity care for families in Ireland". NPEC collects national perinatal mortality data in Ireland directly from each unit for its annual perinatal mortality audit, which was the first audit to be commenced by NPEC *(further information on this audit is detailed in section 1.4.5.).* The other national audits currently being carried out by NPEC on an ongoing basis include: Severe Maternal Morbidity; Planned Home Births; Very Low Birth Weight Infant; Preterm Rupture of Membranes; National Therapeutic Hypothermia.[38]

1.2.6 Ongoing issues in the maternity services

Oversight

HIQA stated in 2020 that greater clarity between various national HSE offices was needed to succeed with the implementation of the Maternity Strategy.[22] Up to 2019 the governance role of NWIHP within the HSE was unclear.[22] Issues in relation to the functioning of hospital networks are covered in the section '*Hospital networks/groups'* below. At local maternity unit level management structures are generally well laid out, however HIQA found two units not fully compliant with the following standard: "maternity service providers have effective management arrangements to support and promote the delivery of safe, high-quality maternity services".[22] On a positive note, since 2019, all the 19 maternity units have a Director of Midwifery in post as part of arrangements for senior management teams in each unit.[22]

Hospital networks/groups

The Institute of Obstetricians and Gynaecologists (IOG) of the Royal College of Physicians of Ireland (RCPI) recommended the formation of maternity networks to integrate smaller and larger units in 2006.[39] Six maternity hospital groups (Table 1.1) were formed in 2014 (according to the Higgins report) to share clinical services and expertise, as well as function under an overarching governance structure.[23] During their 2018/9 inspections HIQA found that none of the hospital groups had

established a single, clear governance structure, though some were more advanced than others.[22]

The current six hospital groups (Table 1.1) differ from those proposed in 2006, as well as the six health regions originally proposed for the implementation of Sláintecare.[23,25] Sláintecare is a ten-year plan launched in 2017 to restructure and renovate the Irish health and social care services to facilitate the delivery of "the right care, in the right place, at the right time".[25] Further changes and potential disruptions to group governance structures are likely, as six new Regional Health Areas (based on geographical boundaries this time) were approved by the Government in 2019 as part of the implementation of Sláintecare.[40] The newest Sláintecare implementation plan covering the period 2021 to 2023 includes the development of a business plan and change management programme to progress to these new Regional Health Areas.[40]

Workforce planning

The Maternity Strategy implementation plan (2017) includes a section on workforce planning to "scope out the multi-professional staffing requirement" in the maternity services.[34] However, national workforce planning reports for midwifery or medical staff in the maternity services are still outstanding. According to NWIHP a national midwifery workforce baseline report is due to be published in 2021.

The Medical Council of Ireland reported that that Ireland produces a high number of medical graduates compared to other countries, but has a low number of specialists per population compared to other European countries.[41]

The HSE National Doctors Training and Planning division publishes an annual report of the medical workforce in the Irish health service (including all specialities).[42] In 2020, there were 93 trainees on the Higher Specialist Training (HST) scheme for obstetrics and gynaecology; and 189 consultant obstetricians

and gynaecologists in Ireland, 40% of whom were over the age of 55 years and therefore likely to retire within ten years.[42]

Staffing and training

The maternity service in Ireland has been chronically understaffed.[39] Ireland had the third lowest number of consultant obstetricians per female population in the Organisation for Economic Co-operation and Development (OECD) in 2013.[43] The shortage of staff is affecting the care women receive[30] and also staff morale, and is a factor in the ongoing emigration of medical staff from Ireland.[44]

The training structure for Obstetrics and Gynaecology in Ireland is overseen by the IOG (established in 1968) of the RCPI. The current training structure consists of a three year Basic Specialist Training scheme (BST, Senior House Officer leading to Registrar post/s), followed by a five year HST scheme (Specialist Registrar posts).[45] During the two schemes non-hospital consultant doctors (NCHDs) rotate through different posts in teaching accredited maternity units (19/19 for BST, 13/19 units for HST).[45]

NCHDs not on recognised training schemes fill the remaining posts in maternity units. Of note, this reliance on non-training posts is not unique to the maternity system in Ireland, but widespread throughout the HSE. In 2020, 35% of NCHDs working in Ireland were not part of recognised training schemes.[42] HIQA highlighted that NCHDs not on training schemes lacked a recognised training and career pathway[22], which is unsatisfactory for themselves as well as the maternity services.

Staffing shortages are equally a concern in the midwifery workforce; an ongoing legacy from a substantial exodus of newly qualified midwives during the recession.[46] A 2018 survey completed by 417 final year nursing and midwifery students showed that over 70% felt that staffing levels at the time were not sufficient to facilitate training on clinical placements and were also considering leaving Ireland.[47] Training to become a midwife in Ireland is possible via two

routes.[46,48] Either a four year undergraduate programme (BSc Midwifery) facilitating direct entry into midwifery or a 18 months post-graduate programme for registered general nurses.[46,48]

Maternity units' physical infrastructure

Four maternity hospitals are still stand-alone hospitals, with no onsite medical and surgical specialities or intensive care facilities, these have to be accessed remotely in acute hospitals as required. HIQA, in their 2018/19 report found that 15 maternity units had inadequate and outdated infrastructure to provide services.[22] Access to toilet facilities and storage for equipment were issues in assessment areas, ante-, post-natal and labour wards across many of the units.[22] Overcrowding of beds/cots was noted as a problem in ante-, post-natal and neonatal wards.[22] The upgrading of all maternity units in Ireland will take significant time and funding.[21,22] *Further information on maternity units' physical infrastructure in relation to perinatal deaths is detailed in section 1.2.7. 'Facilities'.*

1.2.7 Perinatal bereavement care in the maternity services

Historically perinatal bereavement care in the Irish maternity services was under-resourced and under-appreciated, meaning that bereaved families received minimal support during and after pregnancy loss and perinatal deaths.[49–51] A number of reviews by the HSE and HIQA between 2005 and 2018 highlighted the need for consistent high-quality bereavement support in the Irish maternity services.[52–58] The National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were launched in August 2016 to standardise bereavement care in the 19 maternity units *(section 1.2.8. has further detail on these Standards)*. A National Maternity Bereavement Experience Survey for parents is currently being developed by HIQA and is due to be distributed in 2022.[31]

Bereavement Specialist Team

Clinical Midwife Specialists (CMS) in Bereavement and Loss have the specialised role of supporting women, partners and families during and after the time of pregnancy loss and perinatal death, and are thus central to providing consistent bereavement care and nurturing a compassionate culture in maternity units.[51,56] The CMS in Bereavement and Loss is a recognised specialist post in Ireland, with a specific university qualification in the area of bereavement.[56] In 2015 before publication of the Irish Bereavement Standards, 10 of the 19 maternity units did not have a CMS in Bereavement and Loss post. By September 2020, all units had CMS in Bereavement and Loss posts approved, with three units having unfilled posts.[51] The CMS in Bereavement and Loss should be assisted by a multidisciplinary Bereavement Specialist Team.[56,59] Members of the Bereavement Specialist Team (e.g. bereavement coordinator, chaplain, social worker) complement the CMS in Bereavement and Loss in supporting families according to their area of expertise and acting as key contacts for parents.[56,59]

Staff Training and Support

Appropriate bereavement care training is essential for all maternity unit staff and should be provided regularly.[56] It is essential that staff are made aware of acceptable language that is empathetic and are taught to take their cues from the terms used by the parents themselves.[4,59–61] Staff require training to communicate sensitively with bereaved parents about stillbirth and neonatal death diagnoses, post-mortem examination consent and coronial involvement into the death of their baby.[1,3,4,62,63] Further, staff need training on local policies and national guidelines regarding treatment pathways for stillbirths and neonatal deaths, including those babies with life-limiting conditions.[56]

The bereavement care audits carried out in 2017 and 2020 as part of the Bereavement Standards' implementation programme showed that in 2017, 6/19 units were providing regular- and 5/19 occasional education sessions. In 2020,

12/19 were providing regular- and 6/19 occasional education sessions.[51] These local education sessions were developed at unit-level, multidisciplinary and ran by the CMS in Bereavement and Loss, chaplain, social worker and/or centre of midwifery education. Further, as part of the Bereavement Standards' implementation programme it is recommended for all maternity units to include perinatal bereavement care in staff induction programmes.[51]

A multidisciplinary, interactive workshop called TEARDROP (Teaching, Excellent, pArent, peRinatal, Deaths-related, inteRactions, tO, Professionals) workshop was developed by the Pregnancy Loss Research Group based in University College Cork to address the educational needs of all health professionals involved in maternity and neonatal bereavement care.[60] This workshop was piloted and evaluated in one Irish maternity unit in 2019/2020 and the aim is to expand it nationally.[60]

Staff require support relating to bereavement care in the maternity units, especially after an unexpected perinatal death under distressing circumstances (e.g. an intrapartum term death).[6,56] This area of supporting staff after challenging and upsetting events has been neglected in the Irish maternity services, with only 28% of units offering formal support in 2015.[6,51] The HSE Employee Assistance Programme (EAP) is a free, confidential and independent service offering counselling and consultation to line managers for all staff.[64] In 2017, 10/19 units supported staff via HSE EAP, 2/19 provided internal support and 7/19 provided no structured support. By 2020, all units were providing support to staff (14 units via HSE EAP, 5 units internally).[51]

Facilities

A suitable, private environment and accommodation for bereaved families in maternity units is important to allow families to grieve, while not feeling isolated from staff and visitors.[56,65,66] An audit carried out in 2015 as part of the work on the Bereavement Standards showed that 98% of maternity units had single room available, however 76% and 59% of units accommodated pregnancy loss patients

on antenatal- and postnatal- ward respectively.[51] The Maternity Strategy (2016) stated that "women who experience miscarriage or receive bad news should be cared for in a private room, and should not be put in the same ward as pregnant women or newborns".[21] It acknowledged that there were problems due to the facilities at the time, however that "the capital investment in new maternity hospitals in the coming years should make it possible to stop this from happening at all in the future".[21] In 2017, only 6/19 units had a dedicated in-patient bereavement room, by 2020 this had increased to 11/19 units (and four further units had plans in development).[51]

Access to Pathology services including Post-Mortem Examination

Parents should be offered a full post-mortem examination of their stillborn infant or infant that died after birth.[18,62] Post-mortem examination may reveal the cause/s (and time in case of stillbirth) of death, and inform discussion regarding the risk of recurrence of risk factors in future pregnancies.[1,62,63,67] Previous studies showed that parents should be provided with appropriate and clear information regarding the post-mortem examination in a sensitive and respectful manner.[4,62,63] Some perinatal post-mortems, where the death is unexpected, will be directed by the designated Coroner, in which case parental consent is not required.[68] However, providing the parents with relevant, appropriate information if this is the case, is just as important.

The perinatal post-mortem examination should be carried out by a perinatal pathologist.[56,62,67] As this is a specialised area of pathology, not every maternity unit will have a perinatal pathologist on site. The Maternity Strategy (2016) acknowledged that access to perinatal pathology services was not consistent, and recommended that these services should be provided at group/network level.[21] In 2017, 4/19 units had local access to a perinatal pathologist and 15/19 relied on locum cover. By 2020, 14/19 units had access to a perinatal pathologist (5/19 local, 9/19 through the maternity group), while 5/19 still relied on locum cover.[51]

Support organisations

There are many excellent support organisations (including but not limited to A Little Lifetime Foundation, Féileacáin, Every Life Counts, First Light, Leanbh mo Chroí, Miscarriage Association of Ireland) in Ireland providing support to bereaved parents and families.[56] As well as filling any void in health service bereavement care, these support organisations provide essential peer-to-peer support following pregnancy and infant loss based on shared experiences.[56,69,70]

1.2.8 Bereavement Standards

The National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were published in August 2016.[56] There are four Standards described to enhance bereavement care in the maternity services (Figure 1.1).[56]

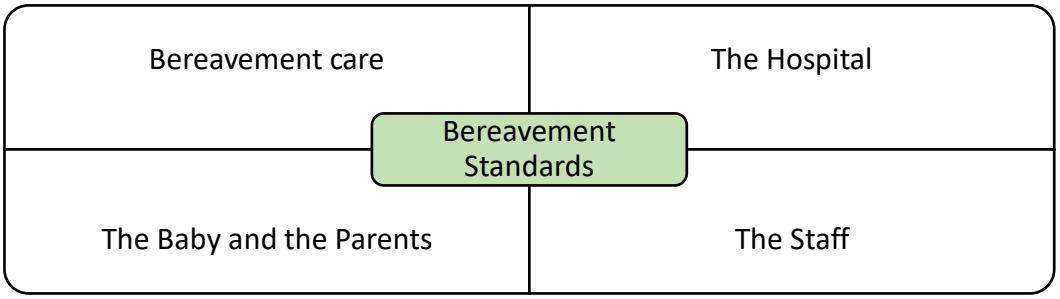

Figure 1. 1: The Irish Bereavement Standards

The four Standards set out that:

- bereavement care in the maternity unit/hospital is sensitive to the parents' values and individual needs, and consistent throughout their bereavement journey
- the hospital ensures compassionate bereavement care is central to the hospital, and reflected in the culture of the maternity unit, with adequate private facilities available for families

- the baby and parents receive suitable palliative and end-of-life care, as well as clear and accurate information

- the staff receive education and training so that they are competent in providing compassionate bereavement care at all times

The Standards state that all perinatal deaths should be reviewed at a monthly multidisciplinary perinatal mortality meeting.[56] Further, the role of the CMS in Bereavement and Loss includes staff education and involvement in audit and research to promote bereavement care, in addition to supporting families.[56]

The implementation programme for the Bereavement Standards ran for two years (March 2017 to 2019) and was facilitated by a National Implementation Group under six work streams: Quality and Service Improvement; Policies and Procedures; Information Technology; Referrals and Integration; Perinatal Palliative Care/TOPFA; Education, training and staff support. The National Oversight Group continues to oversee the implementation and development of the Bereavement Standards since 2019. Each maternity unit was visited by the Lead and the Programme Manager of the Implementation Group twice (once in 2017 and once in 2020) to audit bereavement care in each unit against the four Bereavement Standards outlined above.[51]

1.3 Perinatal mortality

1.3.1 Definitions

Stillbirth

Stillbirth (also known as fetal death) refers to a baby that could show signs of life (breathing, heart activity, umbilical cord pulsation and/or movement of voluntary muscles), being born with none.[71] An intrapartum stillbirth refers to the death of a baby after the onset of labour but before the birth.[71] Currently the lower limit

of gestation that is included for the recording of stillbirths varies from 20 to 28 weeks' gestation of pregnancy internationally.[13,27]

The World Health Organisation recommends 28 weeks' gestation as the lower limit for recording stillbirths, as in low-income countries even babies born alive before 28 weeks have a low chance of survival.[11,13] Some countries in Europe, including Ireland, use 24 weeks as the gestational limit for inclusion of stillbirths.[27,72] The Irish Stillbirth Act 1994, which still applies currently, specified a registrable stillbirth as an infant born weighing at least 500g or having a gestational age of 24 weeks.[18,27,73]

The EURO-Peristat network recommended a gestational limit of 22 weeks for the recording of stillbirth as part of their perinatal health indicators for Europe.[72] With advances in neonatal care more infants are surviving if born at 23 (up to one third) and even 22 weeks' gestation, and some countries (e.g. Sweden, Japan) have adapted their stillbirth definitions accordingly.[27]

The International Classification of Diseases 10th revision (ICD-10) uses the same cut-off of 22 weeks' gestation and refers to a stillbirth at lower gestations as a miscarriage.[13] ICD-11 was released in 2018 to come into effect from 2022. The WHO application ICD Perinatal Mortality (ICD – PM) was developed in 2016 to specifically classify perinatal deaths accurately and comprehensively.[11,74,75] ICD-PM separated perinatal deaths into three periods: antepartum, intrapartum and neonatal and included information on maternal conditions (e.g. maternal complication of pregnancy) at time of the infant's death.[74,75]

Neonatal death

Neonatal deaths can be divided into early (first 7 days of life) and late deaths (after the 7th day and up to 28 completed days of life) of a baby born alive.[11,71] Early neonatal deaths (if not due to congenital anomalies or extreme prematurity) frequently are related to events around the births, and therefore may suggest issues with intrapartum- and/or the immediate post-partum care.[11] The WHO

estimate that worldwide three-quarters of neonatal deaths are estimated to occur in the first 7 days of life.[11] In Ireland, all liveborn babies who die regardless of gestation are registrable, however only those weighing over 500g or are at least 24 weeks' gestation are currently included in perinatal mortality statistics.[18]

Perinatal mortality

Perinatal mortality refers to the addition of stillbirths and neonatal deaths (Figure 1. 2). The WHO defines perinatal mortality as the numbers of stillbirths from 28 weeks and early neonatal deaths.[11] NPEC in Ireland and MBRRACE in the UK classify perinatal deaths to include all stillbirths and early neonatal deaths from 24 weeks' gestation (or weighing >500g).[18] Perinatal mortality can be extended to include late neonatal deaths [11]. The differences described in definitions of perinatal deaths impede international comparison of perinatal mortality rates.[13,27]

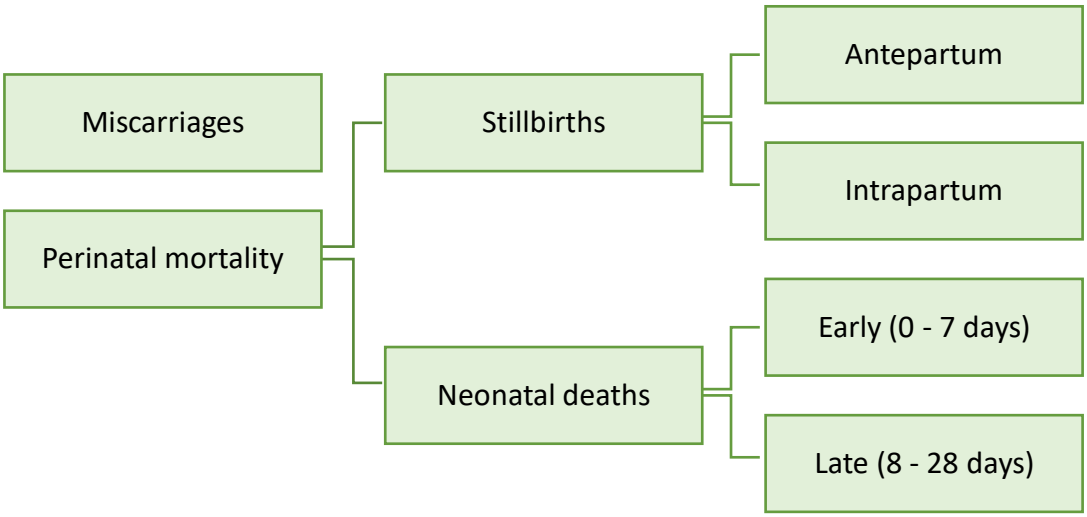

Figure 1. 2: Perinatal death components

1.3.2 Perinatal mortality rates

The stillbirth rate is calculated by dividing the number of stillbirths by the total number of (live and stillborn) births and is, generally, expressed as the rate per 1000 total births (during one calendar year).[11] The neonatal mortality rate is calculated by dividing the number of neonatal deaths by the number of total live births and is expressed as the rate per 1000 live births.[11] The perinatal mortality

rate is calculated by dividing the sum of the numbers of stillbirths and neonatal deaths by the number of total (live and stillborn) births, and is expressed as the rate per 1000 total births. Perinatal mortality rate calculations vary depending on the lower gestational limit included for stillbirths and the inclusion or exclusion of late neonatal deaths.[11]

Some countries include second trimester termination of pregnancies (TOP) in their rate calculations, others exclude them.[27,72,76–78] There is currently no standardisation for the reporting of TOP, with practices and legislation varying widely internationally, especially for second trimester TOP for fetal anomalies.[76,77] In Ireland, TOP for conditions likely to lead to the death of the foetus (either before or within 28 days of birth) was legislated for in 2018, and TOP services began in January 2019.[79]

Calculating local and national annual perinatal mortality rates facilitates the monitoring of rates in a country over time, as well as the benchmarking of individual maternity units.[18] Furthermore, if the rate calculation and death classification are standardised across countries, international comparison and benchmarking of rates is possible.[13,71,77,78,80–82] The intrapartum stillbirth rate has been suggested as a marker of quality of care during labour, therefore it is pertinent to collect the intrapartum stillbirth rate in addition or separately to the overall stillbirth rate.[11,71] Reliable data collection, including mortality rates, increases the visibility of perinatal deaths, therefore can aid decision-making for health policies and funding for maternity services.[11,82–84] The development of programmes addressing perinatal risk factors or augmenting perinatal data analysis (e.g. by commencing a Confidential Enquiry in addition to perinatal audit) may be prioritised by stakeholders based on static or rising perinatal mortality rates.[11,13,85]

1.3.3 Perinatal mortality rates in Ireland

The perinatal mortality rate in Ireland includes all stillbirths and neonatal deaths (≥500g or ≥24 weeks' gestation) per 1000 total births.[18] Late neonatal deaths or

neonatal deaths outside these parameters are not included in the perinatal mortality rate calculation.[18] NPEC also reports a corrected perinatal mortality rate for Ireland, which excludes deaths associated with or due to a major congenital malformation (Table 1.2).[18] Currently, the detail of information collected on intrapartum- or labour-related neonatal deaths by NPEC is insufficient to reliably identify whether changes in antenatal-, intrapartum- or neonatal care would have changed the outcome.[18,84,86]

Table 1. 2: Perinatal statistics in Ireland, 2013 - 2019[17,18]

	2013	2014	2015	2016	2017	2018	2019	RR (95%CI)*
Total births (n)	69,146	67,663	65,904	64,133	62,076	61,298	59,574	
Perinatal deaths (n)	456	466	453	374	346	325	360	1.15 (0.96-1.38)
Perinatal mortality rate	6.6	6.9	6.9	5.8	5.6	5.3	6.0	1.14 (0.98-1.32)
Corrected perinatal mortality rate	4.3	4.7	4.2	3.6	3.5	3.2	3.7	1.17 (0.96-1.41)

*RR=Rate ratio comparing rate in 2019 versus rate in 2018 (data from www.ucc.ie/en/npec/)

1.4 National perinatal mortality audits

1.4.1 The audit cycle

The National Institute of Clinical Excellence (NICE) defines audit in healthcare as "a quality improvement process that seeks to improve patient care and outcomes

through systematic review of care against explicit criteria and the implementation of change".[87] An audit cycle or upgoing spiral is formed by different, inter-dependent steps, where each cycle aspires to improve the quality of care.[87] The audit cycle can be divided into five separate steps (Figure 1. 3).[11,87] Each step is as important as the previous one and must follow on to the next.[88] To complete an audit successfully, each step needs to be carefully considered including providing appropriate time and resources (e.g. sustained funding) for staff.[11,12]

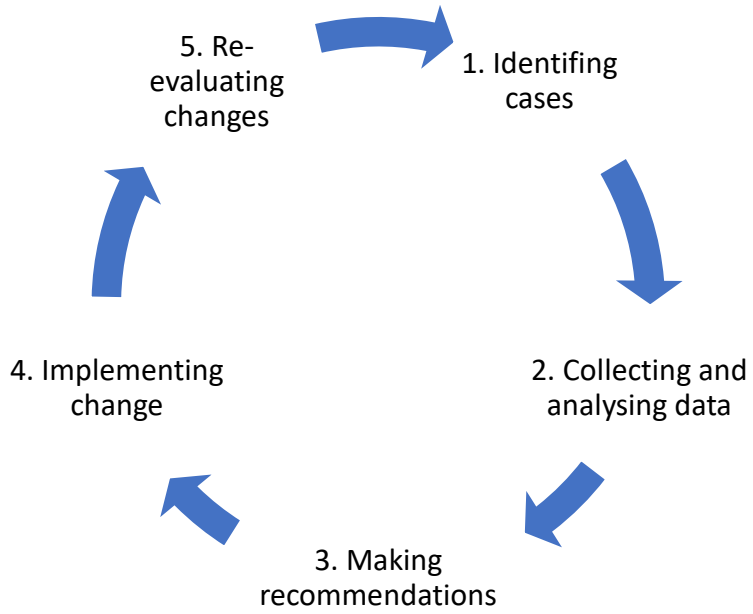

Figure 1. 3: The audit cycle

The Irish National Office of Clinical Audit (NOCA) was established in 2012 to monitor and improve standards of care in the healthcare system by systematically reviewing care against national and international criteria through sustainable clinical audits.[89,90] Other organisation managing national clinical audits in Ireland include the NPEC[38], RCPI and HSE (Sepsis Audit).[90] The Irish National Clinical Effectiveness Committee provides guidance and can commission further national clinical audits through NOCA.[90] NPEC has aligned its audit governance structures to NOCA.[18]

1.4.2 Implementation of audit recommendations

The final two steps of an audit cycle are implementing recommendations, evaluating and refining solutions. Recommendations that are consistently SMART (Specific, Measurable, Achievable, Realistic, Time-bound) are more likely to be successfully implemented.[11,91] The acronym SMART was first suggested by George Doran in 1981 for managers to write effective company objectives.[92] The concept of making SMART recommendations (objectives) has been adapted in healthcare systems, including audits and reviews, to promote the implementation of their recommendations.[91,93,94]

Appropriate recommendations with an identified person or team responsible for their implementation are more likely to result in the desirable action and change.[11,90] For national audits, the ownership of recommendations should be assigned to key stakeholders such as professional associations and/or government departments.[11,90] The implementation of recommendations is enhanced by several factors; the understanding by those delegated to progress the recommendations of the significance of the work undertaken, prioritised recommendations are disseminated within tangible programmes and that desired effects on patient outcomes are realistic (and achievable).[88] It is important to be aware of potential barriers to successful implementation at both national (e.g. availability of funding for new programmes) and local (e.g. limited resources, lack of appetite to change) levels and plan on how to overcome challenges at those levels.[87,88]

1.4.3 Aims of perinatal mortality audits

Currently there are four high-income countries with established ongoing perinatal mortality audits: Mothers & Babies Reducing Risk through Audits & Confidential Enquiries (MBRRACE) in the UK, Perinatal & Maternal Mortality Review Committee (PMMRC) in New Zealand, Perined in the Netherlands and NPEC in Ireland *(further information on these audit is detailed in section 1.4.4. and 1.4.5.)*.[18,95–97] National perinatal mortality audits provide a robust system for assessing and monitoring the burden, trends and causes of perinatal deaths.[11] This collation of outcome

data is an important source of information for individual hospitals, hospital networks/trusts, as well as government departments.[11,18,96] In addition to providing the causes of deaths, as part of a national perinatal audit fetal and maternal risk- and contributory factors for stillbirths and/or neonatal deaths are identified, analysed and collated.[11,18,96,98] This information enables the calculation of national mortality rates and statistical analysis of perinatal mortality data.[96] A detailed analysis can thus provide reliable key findings to facilitate the making of specific and targeted recommendations.

Data from perinatal mortality audit are disseminated to clinicians, managers, health- and government agencies to encourage the planning and pursue of quality improvement strategies based on the audit's key findings.[11] Targeted public health campaigns, specific risk reduction policies and interventions can then be developed. The aim is to achieve a reduction in perinatal mortality over time.[96] The prevention of future perinatal deaths means a reduction in parental bereavement and the associated morbidity, as well as the potentially damaging consequences on maternity staff and services.[2,6,11]

Finally, robust perinatal mortality audits can facilitate international benchmarking of mortality rates, trends and the sharing of successful initiatives and interventions.

1.4.4 Perinatal mortality audits internationally

A national perinatal mortality audit involves the identification and notification of all stillbirths and neonatal deaths, including the collection of demographic and clinical data across a whole country.[11,96] The identified perinatal deaths (either some or all) are reviewed in detail and based on these findings national recommendations are made as part of the perinatal mortality audit. The manner of progressing and implementing recommendations varies in countries depending on the establishment the audit is part of (the health service- or government department).

National maternal mortality audits have a longer history than perinatal mortality audits, the first maternal mortality audit was established in 1952 in the UK, the Confidential Enquiry into Maternal Deaths (CEMD).[99,100] The aim of CEMD was to assess the main causes of maternal deaths, identify modifiable factors and make recommended changes in clinical care as indicated, at the time significant fetal and infant losses were occurring and believed inevitable.[99] In 1958, the first British Perinatal Mortality Survey was carried out, collecting data on all perinatal deaths that occurred in March, April and May of that year. The national perinatal audit was established in 1993 in the UK, known as CESDI (Confidential Enquiry Into Stillbirths and Deaths in Infancy).[99,100] Since then some other high-income countries *(detailed below)* as well as some low/middle-income countries (e.g. the Perinatal Problem Identification Programme in South Africa[101]) have established national perinatal mortality audits. Below, the most established current perinatal mortality audits in high-income countries are briefly outlined.

United Kingdom

CESDI was established to address deaths from 20 weeks' gestation to one year after birth by identifying suboptimal clinical practices and making recommendations for improvement.[99,100,102] Data on all deaths was collected and a subset of deaths, relating to a predetermined topic (e.g. intrapartum related deaths >2.5 kg in 1993), were reviewed in detail.[99,102] In 2003 CESDI was combined with CEMD (to form the Confidential Enquiry into Maternal and Child Health (CEMACH).[99] CEMACH consisted of three sections: maternal deaths (previously CEMD), perinatal deaths and childhood deaths (28 days to 17 years).[103–105]

Since 2012 these confidential enquiries continue as Mothers & Babies Reducing Risk through Audits & Confidential Enquiries (MBRRACE-UK).[96] MBRRACE-UK collect, analyse and report national surveillance data on all perinatal deaths in the UK, and a Confidential Enquiry (i.e. multi-disciplinary, anonymous review) on a sample of defined cases under varying topics (e.g. intrapartum stillbirths and intrapartum-related neonatal deaths in 2016-2017) is carried out biennially. The

electronic, interactive Perinatal Mortality Review Tool (PMRT) was developed in 2017, as part of MBRRACE, to standardise perinatal death reviews, as well as ensure local and national learning.[106]

New Zealand

In New Zealand perinatal deaths are audited by the Perinatal & Maternal Mortality Review Committee (PMMRC) since 2005.[95] The PMMRC collect, review and report the deaths of babies from 20 weeks pregnancy to 28 days after birth.[95] An annual national report is published on these deaths, this report also includes maternal deaths and cases of neonatal encephalopathy.[95]

Netherlands

Perinatal deaths have been registered in the Netherlands by the Perinatal Registration Netherlands since 1999. Perinatal Audit Netherlands (PAN) commenced in 2010 after high rates of perinatal mortality were reported in the Netherlands compared to other high-income countries.[85,107] These two organisations merged in 2015 to form Perined. An online ACTion toolkit (www.actiontoolkit.nl) has been developed to encourage audit recommendation implementation throughout the Netherlands. Perined publish annual national data reports without recommendations (in Dutch).[97]

EURO-Peristat

The EURO-Peristat project was established in 1999 to monitor perinatal health and outcomes based on core indicators in 15 countries across Europe.[107] EURO-Peristat now has representation from 31 countries across Europe. Comparative statistics reports with recommendations based on the findings were published in 2008 (data from 2004), 2013 (data from 2010) and 2018 (data from 2015). The aim of EURO-Peristat is to highlight differences between populations, healthcare factors and maternity care policies, as well as monitor the role of bench-marking countries with each other.[107] Some issues with robust data collection remain,

including decentralised data collection systems and the differences in registration criteria (and definitions) of births/perinatal deaths in countries.[72]

1.4.5 Perinatal mortality audit in Ireland

The perinatal mortality audit in Ireland is one of the various audits carried out by the National Perinatal Epidemiology Centre.[38] The NPEC, funded by the HSE, publish a national perinatal mortality report including recommendations annually, as well as providing individual reports to the 19 maternity units, since 2009.[18] The reporting of perinatal mortality data to NPEC is voluntary, however all Irish maternity units contribute using the electronic data collection tool (Perinatal Death Notification Form).[18] Audit coordinators are established in each maternity unit and are responsible for submitting and validating data with NPEC.[18] The multidisciplinary NPEC Perinatal Mortality Group advises the centre on the optimisation of the perinatal mortality audit.[18] NPEC is collaborating with NWIHP to progress and follow-up on the implementation of the perinatal mortality audit's recommendations.[18]

1.4.6 Outcomes of perinatal mortality audits

Well executed audits (in general) can result in improved communication among stakeholders through a united aim.[108] Further, professional satisfaction may increase when the workforce feels issues are highlighted and addressed, resulting in appropriate resources and ultimately improved patient care.[108]

National perinatal mortality audits can highlight contributory factors and offer solutions in the form of recommendations. Publishing a national annual report including the rates, findings and recommendations requires dedicated staff and resources.[11,18] A report is helpful in tracking trends of outcomes and highlight recurring recommendations.[11] Sufficient funding and resources is required for the successful implementation of recommendations.[11]

An article from 2017 highlighted the effects audits can have, stating that national perinatal audits in New Zealand and the UK had shown "a reduction in the proportion of stillbirths classified as hypoxic peripartum or intrapartum death"

between 2007 and 2014.[98] Term perinatal mortality reduced by 16% in the Netherlands between 2010 and 2014, after the national audit (PAN at the time) focused on term outcomes during that period, demonstrating the impact national perinatal audits can have.[98]

For complex issues identified as part of a national perinatal mortality audit, multifaceted quality improvement programmes can be beneficial such as:

- the Safer Baby Bundle (from 2019 consisting of five elements: smoking cessation, management of fetal growth restriction, awareness of fetal movements, sleeping position, timing of birth) in Australia[109]
- the Saving Babies Lives Care Bundle (from 2016 consisting of five elements: smoking cessation, fetal growth restriction, fetal movements, fetal monitoring, prevention of preterm birth)[110]
- Each Baby Counts (from 2015 to 2020 bringing together the reports of local investigations into term intrapartum related perinatal deaths and brain injuries) initiative in the UK[111]

There are some challenges to consider for national perinatal mortality audits. Data collection for national audits requires resources at local unit level to access, enter and submit reliable information to the national office and staff need be provided with protected time for this activity.[11,112] Professionals may not be aware or appreciate either the audit's findings or the necessary changes in practice required to address them.[108] To overcome this barrier it is advisable to have a multidisciplinary audit team and aim for realistic rather than ideal standards.[112] Training for audit processes needs to be promoted and facilitated for local and national staff.[11,108,112] Lastly, the audit's methodology and recommendations need to be evaluated regularly to maintain momentum and achieve the desired outcomes.[108]

1.5 Hospital-based perinatal mortality reviews in Ireland

Local or hospital-based perinatal mortality reviews are carried out in many countries.[11,19,94,99,106,113,114] Some countries like the UK, Australia and New Zealand have national guidelines or structures developed to standardise these reviews.[94,115] In the UK the interactive, electronic Perinatal Mortality Review Tool (PMRT) was developed by MBRRACE-UK following a tender issued by the Healthcare Quality Improvement Programme (HQIP) to "support high-quality local perinatal reviews".[106,115] The PMRT was developed from Task and Finish Groups set up by the British Department of Health and Sands (the leading stillbirth and neonatal death charity in the UK), and has been in use since 2018.

The aim of the PMRT is to ensure that for all babies (after 22 weeks' gestation) all parts of care are examined, inclusive of the parents' perspective.[115] The Perinatal Society of Australia and New Zealand (PSANZ) have developed and updated the Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death (current version 3.3, December 2019) which includes a section on institutional perinatal mortality audit.[94] This section of the PSANZ guideline details the analysis of each perinatal death by a multidisciplinary team by collecting high-quality data on causes and contributory factors to explain to parents and improve clinical practice.[94]

In Ireland, though hospital-based perinatal mortality reviews are carried out, there is no standardisation at national level and not much is known about them. This section outlines the different types of hospital-based reviews currently being done in Ireland (Figure 1. 4).

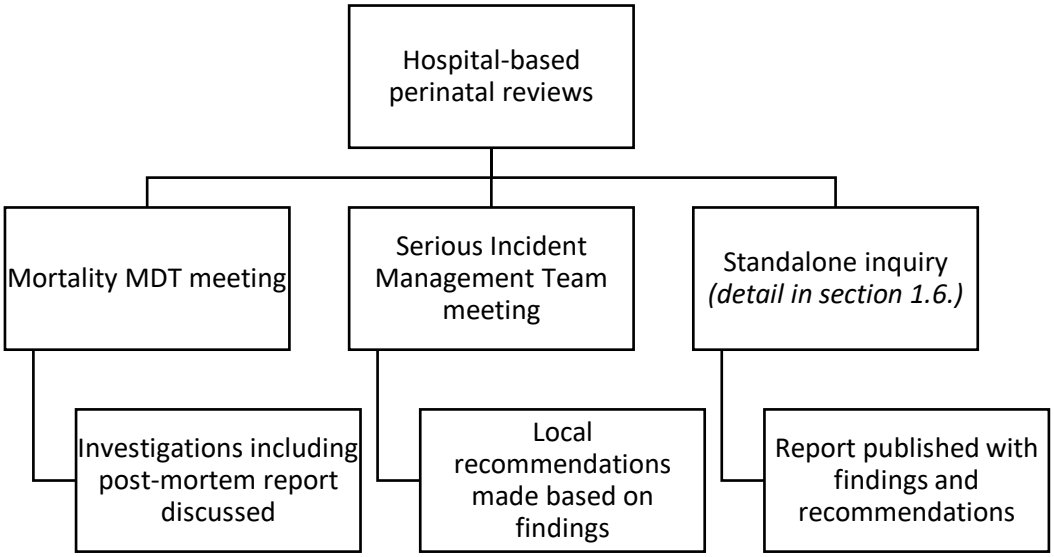

Figure 1. 4: Types of hospital-based reviews in Ireland

1.5.1 Perinatal mortality multidisciplinary team meetings

Mortality multidisciplinary team (MDT) meetings have a long-standing history. The function of these meetings is to identify causes of deaths and contributory factors, as well as monitor numbers and recurrent factors implicated in local perinatal deaths.[11,56,94] The information included in the reviews is gathered from medical records and presented in a summarised format.[116] All maternity staff, including students and junior staff, should be facilitated to attend perinatal mortality MDT meetings to promote honest discussion of the causes of deaths and the care provided.[11,12,56] Professionals from the pathology department to outline post-mortem examination and placental findings, as well as colleagues from midwifery, obstetrics and neonatology departments should be invited.[11,56,117] Appropriate follow-up arrangements and further investigations can be arranged for the parents, and valuable lessons can be learned if disseminated appropriately.[11,12,56,94] High clinical workload can be a reason for staff not attending meetings regularly.[11,12,117]

Despite a regular perinatal mortality MDT meeting being endorsed in the Irish National Standards for Bereavement Care, there is minimal information available on the functioning and variety of these in Ireland.[56,117] A recent study of 78 professionals in Ireland stated only 50% had attended the local perinatal mortality MDT meeting.[117] Apart from recommending a common system for audit and risk management meetings across maternity networks, there is no detail provided on holding these specific MDT meetings in the Maternity Strategy or the Strategy's Implementation plan.[21,34]

1.5.2 Changes in incident management policies over time

It is policy of the HSE that all safety incidents, also known as Serious Reportable Events (SREs), are identified, reported and investigated appropriately.[118] In 2014, the HSE Safety Incident Management Policy replaced the Incident Management Policy and Procedure (2008), as well as the Risk and Incident Escalation Procedure (2010). The 2014 Policy focussed on the incident management process including: prevention of incidents; management and type of investigation/review required; circulation of reports and recommendations; and national learning in the form of a national data reporting system.[118] While this policy described the importance of communicating appropriately with the patient/family (including appointing a point of contact), there was no mention of the involvement of families in the investigation/review, apart from providing them with the final review report.[118]

This Policy (2014) included "death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy" as a Serious Reportable Event.[118] In 2014 there was a suggestion in Ireland (from the Chief Medical Officer) regarding calling these serious reportable events 'never events'[50] much to the concern of healthcare professionals working in the maternity service.[8] In 2015, an updated guidance document was published, reinstating the term of serious reportable events.[119] These SREs were described as "serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers" and that caused serious harm. In the area of maternity services these included all maternal deaths and the "perinatal

death of a neonate occurring in a term infant or an infant weighing more than 2,500g" and the "death or encephalopathy of a normally formed neonate occurring in a term infant or an infant weighing more than 2,500g.[119]

In 2018, the HSE National Incident Management Framework (NIMF) replaced the 2014 Safety Incident Management Policy. It emphasised the need to support the service users (patients), families and staff after incidents, including Serious Reportable Events as described above, have occurred.[91] The NIMF is based on the following principles: person centred (service users and staff); all persons are treated in a fair and just manner; open and transparent communication; responsive actions are taken in a timely manner; improvement focused risk reduction; learning locally and within the wider service. There is no specific policy on reviewing perinatal deaths, which present specific and unique characteristics and circumstances, in the Irish maternity services.

1.5.3 Aims of the hospital-based perinatal reviews

Like the perinatal mortality MDT meetings, other hospital-based reviews (with a review team either from internally or externally to the hospital) aim to identify contributory factors and learn from incidents, to lead to improved services as indicated and educate staff.[91] To identify issues that go beyond individual accountability, policies, working conditions and systems need to be examined.[91] It is important to asses not just how but why an incident occurred. These factors can then be addressed through changes in systems, structures and local working conditions. By identifying all factors contributing to patient safety incidents, systemic flaws can be effectively managed for the benefit of all patients.[91]

1.5.4 Methodology of the hospital-based reviews

A hospital-based review takes place after an incident (such as a SRE described above) has occurred. The level of review (comprehensive, concise or aggregate) for the incident is decided based on its risk categorisation. The NIMF advised the management of any incident process should follow six steps: 1. Prevention, 2. Identification and immediate actions required, 3. Initial reporting and notification,

4. Assessment and categorisation, 5. Review and analysis, 6. Improvement planning and monitoring.[91]

Further, the NIMF stated that the terms of reference should be set out for each review. Family and staff liaison contacts should be identified. An independent, multidisciplinary review team with access to all relevant documentation and expertise is required. At the review meeting(s) it is important to: agree a chronology of events; identify key casual factors, incidental findings and good practice; address any questions raised by the family; and make recommendations. To complete the review process a report should be provided to all stakeholders (including the staff and family) and action plans are made to implement the recommendations.[91] The NIMF recommended all reviews should completed within 120 days.[91]

1.5.5 Serious Incident Management Team reviews

A Serious Incident Management Team (SIMT) has been established in each hospital (or at group level) in Ireland. Generally, this is a standing group, including members from management with scheduled meetings, that decides on the level of review required for each reported incident, including SREs.[91] Internal reviews may be carried out by some or all members of the SIMT, as well as other clinical experts as required, whereas external reviews commissioned by the SIMT are carried out by professionals outside of the unit/hospital.[91] There is paucity of information on SIMT reviews and shared learning from incidents in maternity units in Ireland.

1.5.6 Staff involvement

In accord with Irish research, the NIMF acknowledged that staff can be significantly affected (emotionally and functionally) by an incident, such as a perinatal death, and that appropriate supports need to be initiated as soon as the incident has occurred.[6,8,91] Further, the NIMF recommended staff to write a personal recollection of events as soon as possible after the incident, this can be used for the review process and may preclude the need for a formal staff interview.[91]

However, this personal recollection of events can also be used for other reviews (e.g. a Coroner's Inquest) and legal claims into the incident.[91]

According to the WHO, it is important that the local reviews focus on identifying modifiable contributory factors and getting answers for families rather than blaming individual professionals or their department.[11]

Any relevant key findings and learning points from hospital-based perinatal reviews should be shared with the appropriate staff, in order to improve policies and practices if indicated.[11,91]

1.5.7 Patient involvement

Generally, in Ireland patients and families have not been involved in local hospital based incident reviews, including perinatal mortality reviews. The NIMF (2018) aimed to address this and stated that the first response after an incident needs to be to the person affected.[91] Open and transparent communication (i.e. open disclosure) with the patient and her family must be part of this.[91] Due to controversies with open disclosure in the Irish healthcare system, including the maternity services, the HSE published an updated Open Disclosure Policy in 2019.[120] A Patient Safety Bill (2019) stipulating mandatory open disclosure in the health service is currently going through the process of becoming law in Ireland.[121]

Further, the NIMF recommended for a liaison person to be assigned to the patient and her family as support and key contact after an incident has occurred.[91] The role of the liaison entails communicating with the family regarding the management of the incident, including commissioning a review.[91] There is minimal information available about the inclusion of families in hospital-based reviews in Irish maternity hospitals and the information that is available in the form of two inquiry reports, highlighted multiple issues with the involvement of families in these reviews (e.g. ineffective communication).[50,58] *(Further information on the involvement of bereaved parents' in reviews internationally and in Ireland is detailed in sections 1.7.4. and 1.7.5. respectively.)*

Informing the family that a review is taking place should be the first step of involving them in the review process itself. The framework highlighted that it is important that queries or concerns raised by the family are addressed as part of the review.[91] Finally, families should be able to review a draft of the report before it is finalised.[91]

Since 2018, there is a free, independent, government-commissioned patient advocacy service available to families in Ireland to help them make a complain about care they received in hospital or as support during hospital-based reviews processes.[122]

1.5.8 Dissemination of findings and learning outcomes of reviews

Publishing a review report is one method to disseminate key findings, encourage learning and promote changes as indicated.[11,94] Plans for the implementation of review recommendations are essential.[115] Recommendations that follow the SMART (Specific, Measurable, Achievable, Reasonable/realistic, Time-bound) principle and assign ownership to an individual or department are more likely to be implemented.[91,94,115] The implementation of recommendations from similar reviews needs to be monitored to avoid repetitive recommendations being made and, most important, prevent avoidable events recurring.[22,115]

Furthermore, the WHO recommends that learning points should be collated and disseminated to all relevant staff in the hospital, for example through learning notices, a newsletter or at multi-disciplinary meetings.[11] A proactive organisational culture that promotes change by sharing learning outcomes from local reviews can help to improve the quality of care for patients and families.[11,115]

Hospital-based perinatal mortality review reports, such as those commissioned or produced by the SIMT, are generally not made available in the public domain in Ireland, unless publication is specifically requested by the family.

1.5.9 Coroners in Ireland

The role of the Coroner in Ireland is to investigate any sudden, unexpected death to determine the cause and circumstances around the death.[68] The Coroner can direct a post-mortem examination to be carried out on the deceased, which will not require consent from the next-of-kin.[68] The Irish Coroners Act 1962 was amended in 2019.[68] An addition to the amended Act was that any death of a stillborn child or infant death has to be referred to the district Coroner to consider if a post-mortem examination and an inquest into the death are indicated or not.[68] There are currently 34 Coroners listed in the Republic of Ireland (www.coroners.ie).

Qualitative research carried out at the NPEC and presented at the NPEC study day 2020 on 'parents' experience of the coronial process following perinatal death' (consisting of interviews with eleven parents) revealed three superordinate themes: a slow, uncaring bureaucracy with inquests taking up to two years to be completed; the unfamiliar environment of the formal court setting for parents; and the discomfort of parents regarding criminalisation and blame.[123] The conclusions of this research included the need for improved communication and transparency with and for parents around investigations and reviews after perinatal deaths.[123]

1.6 Standalone inquiry reports into adverse perinatal events in Ireland

An external inquiry or review into specific adverse event(s) is instigated to examine matters of public concern.[124] In maternity services, an unexpected, potentially preventable maternal death or an unexplained series of perinatal deaths or recurrent unexpected morbidities/adverse outcomes may result in an inquiry being established to investigate events. This type of investigation (meaning inquiry) may examine events in one hospital or concerns noted at national level. In Ireland, many external inquiries related to perinatal events in maternity services have been commissioned over the last two decades (Table 1.3). A report is

published at the end of the inquiry process including key findings and recommendations to address them.

Table 1. 3: Inquiries related to perinatal events in maternity services

	Title of the inquiry report	Year of publication
1	"Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures"	2005
2	"Report into the circumstances pertaining to the death of TMC and her infant son at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007"	2008
3	"National Miscarriage Misdiagnosis Review"	2011
4	"Investigation of Incident 50278 from time of patient's self referral to hospital on the 21st of October 2012 to the patient's death on the 28th of October, 2012"	2013
5	"Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration including those provided in University Hospital Galway…"	2013
6	"HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)"	2014
7	"Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise"	2015
8	"A review of the governance of maternity services at South Tipperary General Hospital."	2015
9	"HSE Maternity Clinical Complaints Review"	2017
10	"External Independent Clinical Review of the Maternity Services at Portiuncula Hospital, Ballinasloe (PUH) and of 18 perinatal events which occurred between March 2008 and November 2014."	2018

1.6.1 Methodology of inquiries

In Ireland, inquiries are usually commissioned by Irish government departments (ministers) or management within the HSE, at times in response to public pressure or to highlight healthcare services in need of attention.[124,125] There are multiple aims of inquiries including establishing of facts or a timeline of events, reassurance that events are investigated, holding professionals and organisations accountable, facilitating resolution and importantly learning essential lessons to prevent events recurring.[124,126]

An inquiry team or panel is selected to carry out the investigation into events and write a report upon its conclusion, the manner of selecting these individuals is generally not well described.[124] Ideally, the inquiry team should be multidisciplinary, have relevant experience and be independent to the service under scrutiny.[124]

In Ireland, there is no standardised approach or methodology for external inquiries.[124] Generally, inquiries involve the review of relevant medical files and documents, as well as statements or interviews with the appropriate staff and affected families.[124,126] A publicly- available report is published and provided to the commissioning department at the end of the inquiry process. Inquiries are usually carried out in isolation and rarely consider previous inquiry reports or recommendations.[124] To date, no research or analysis have been carried out on the methods, impact and implementation of recommendations from inquiries related to the Irish maternity services.

1.6.2 Staff involvement

The experience of an adverse incident in the maternity services, such as an unexpected intrapartum death, can have lasting detrimental personal and professional consequences on staff.[6,125] In addition, the stress of taking part in and the aftermath of the inquiry process examining such an incident, as well as

the ensuing media attention can have significant negative impacts on staff well-being and morale.[124]

As for any incident investigation, relevant health care staff should be able to contribute to the inquiry process.[91] However, there is no standard for the involvement of staff in inquiries and currently there are various ways for members of staff to be included in inquiry processes in Ireland. Some recent inquiries involved staff representatives rather than all relevant staff members.[50,127] Staff may be interviewed individually or as part of a group discussion.[58,128] Alternatively, at times staff members have submitted written statements.[58]

1.6.3 Patient involvement

As happens with staff involvement in the inquiry process, families affected by the events can be included in inquiries in various ways. If the inquiry is local to one hospital, all affected patients (and families) should be invited to participate, however there is no standardisation for patient involvement in inquiries in Ireland at present and patient involvement has varied significantly.[50,53,54,58,128] National inquiries investigating adverse perinatal events across all Irish maternity units, have in the past invited families to self-request their inclusion in the inquiry (e.g. through a helpline).[49,52,55] The families that have participated in inquiries related to perinatal events in maternity services were asked to provide a written statement or attend for an interview.[49,53,58] For families, the inquiry process can be a way of getting answers, however the protracted and/or adversarial nature of some inquiries can be difficult for them.

1.6.4 Media coverage and public perception

By their nature, events investigated in the maternity service through an external inquiry (e.g. series of perinatal deaths) attract public interest and media attention. Public opinions and conclusions are formed based on media coverage of these events, often at a time when the inquiry process is just beginning.[9,10,124] The media attention may unintentionally influence this process and force an acknowledgement of failures by organisations before all the facts are

established.[10,124] When the inquiry report is published, often months or years after the events, it can refuel the general distrust in maternity services created by initial media reporting of the original events. Some inquiries attract global media attention and can have far-reaching effects internationally.[10,124]

1.6.5 Implementation of recommendations

All inquiry reports include recommendations based on key findings to improve maternity services if necessary and prevent events recurring in the future. For affected families this is one of the most important reasons for taking part in an inquiry. However, in Ireland, as in the UK there is no official structure or standards for implementation of inquiry recommendations.[126] Sequential reports from different inquiries may include the same or similar recommendations if their implementation is not progressed successfully. To succeed the planning and costing for the implementation of inquiry recommendations is important, this includes involving key stakeholders and a supportive political and/or managerial environment.[124] Along with the report including key findings and recommendations, a publicly-available implementation plan would help to assess progress and hold the people responsible for it accountable.[124] Further, the individual or specific department (rather than general organisation) responsible for each recommendation must be clearly identified [124]. In Ireland, this has not been made clear in recent inquiries and reports related to maternity services.

1.7 Bereaved parents' involvement in local reviews and inquiries

1.7.1 Benefits for parents

When bereaved parents are meaningfully involved in reviews, they feel their concerns and opinions are listened to, they feel heard.[129] Further, by being involved the parents can understand and process events around the time of their baby's birth and death, which may help the grieving process.[129] They can alleviate their feelings of guilt, which may aid to bring some closure.[129] Knowing and understanding the cause of death of their child, may be important for counselling

for future pregnancies for couples.[130] For bereaved parents it is important to know that changes in care have taken place as a result of their child's death, if indicated.[131] Giving bereaved parents the opportunity to talk about their child, allows them to keep their child's memory alive and to know that their life mattered.[132]

1.7.2 Benefits to the review

There is growing evidence of the benefits of involving bereaved families in mortality reviews.[129–131,133–135] From bereaved parents useful, additional information can be gained for the perinatal mortality review.[129,134] Parents can highlight positive and negative areas of clinical and bereavement care, those that should be maintained and those that require improvement.[129,131] There can be sharing of learning between staff and bereaved parents to improve services for other parents, and if possible to prevent further perinatal deaths in the future.[134] Further, if bereaved parents are meaningfully involved in reviews, it may reduce the number of complaints and litigations for the hospital(s), which in turn can be cost-saving for the national health service.[134]

1.7.3 Challenges

There are some challenges to involving bereaved parents in reviews into their and their baby's care. If it is not an established local practice to engage parents in reviews, it requires support from management and endorsement from the clinical workforce to inaugurate. There are financial and organisational issues to consider, as extra resources and supports are necessary.[134] Meaningful parental involvement results in additional workload for the bereavement midwives, as both a point of contact and support for parents, as well as for clinical staff (consultants, midwives) to discuss the parents' questions and to facilitate follow-up appointments. In addition, appropriate psychological support for the parents and the staff needs to be available throughout the review process.[129,136] Timing the parental engagement to fit with the hospital schedule, ensuring they feel engaged with the review process while being sensitive to the parents' grief, can be a

challenge.[129] Relationship strain or breakup between the parents can pose a further challenge to involving both parents equally.[134]

1.7.4 Bereaved parent involvement in reviews internationally

Of 1104 healthcare professionals from six high-income countries (Australia, Canada, Ireland, New Zealand, UK and USA) surveyed in 2015, less than a third reported that bereaved parents were involved in their local perinatal mortality reviews.[133] Those that reported parental involvement stated that most commonly feedback was provided to the parents after the review was completed, with only 5% describing opportunities for the bereaved parents to contribute to the review process itself.[133]

In the USA the Maternal and Child Health Bureau together with the American College of Obstetricians and Gynecologists established the National Fetal and Infant Mortality Review (NFIMR) Program in 1990 "to serve as the national resource centre for information on local perinatal and infant mortality review".[130,137] NFIMR supports local, community based FIMR and central to these reviews are maternal or family interviews, which provide social and environmental information surrounding the fetal or infant death.[137] However, these reviews are organised at city or county level with minimal state oversight.[130]

In the Netherlands a law was passed in 2016 that mandates families to be involved in hospital incident investigations (including deaths).[135] The law does not specify the extent of the families' involvement in the hospital investigations (or reviews), it is up to individual hospital to determine the degree of familial engagement.[138]

In the UK the PARENTS (Parents' Active Role and ENgagement in The review of their Stillbirth/perinatal death) 1 and 2 studies have explored parental engagement in the perinatal review process since 2015.[129,131,134] A focus group with bereaved parents (PARENTS 1) showed that parents welcome the opportunity to contribute and be involved with reviews.[131] The views of healthcare professionals and stakeholders on parental involvement in reviews, including some of the benefits and challenges as outlined above (*sections 1.7.1-3*),

were explored through two further focus groups.[134] Material and pathways for parental engagement in reviews was developed and piloted (between November 2018 and May 2019), and post-intervention evaluations carried out.[129] The conclusion was that with the appropriate resources, meaningful parental engagement in the review process is achievable and is important for the collaboration between parents and staff, as well as improving future care.[129]

In the UK, parental involvement is now part of the reviews using the national Perinatal Mortality Review Tool, which was launched in 2018.[115] In the first report (2019) of 1500 cases, 84% of parents were told about the review and for 75% of reviews the parents' perspective was sought.[106] In the subsequent report (2020) 84% of parents were aware of and able to give their perspective to the review.[115]

In Australia and New Zealand, national guidelines recommend that all perinatal deaths are investigated in a formal manner locally.[138] Communicating with the bereaved parents and informing them of all the findings from the investigations is considered an essential step of the investigative cycle, however there is no information provided in the guidelines whether parents should be involved in the investigation beyond receiving information.[138]

1.7.5 Bereaved parent involvement in reviews in Ireland

Generally, patients, parents and families have not been involved in perinatal mortality reviews in Ireland.[55] Instead the results and findings of investigations, including the post-mortem examination, were provided to families by their GP or their hospital consultant.[3] From previous research, it is evident that sensitive and clear communication with parents around the post-mortem examination process in Ireland is essential.[1,3,63] Further, research carried out Ireland stated that parents found the wait to receive results, such as the post-mortem examination report too long.[3]

The National Incident Management Framework (2018) stated that communication with families needs to be open and honest.[91] The families must be informed if a review is going to be carried out and should be given the opportunity to give their

perspective of events.[91] A number of families were involved in some of the recent inquiries related to perinatal events in the maternity services (Table 1.3). However, this involvement has not been evaluated and there is currently no standardised method in Ireland for involving patients (and families) in inquiries. Further, no research has been carried out in Ireland to investigate the involvement of bereaved parents in maternity hospitals' perinatal death reviews.

The organising committee of the International Stillbirth Alliance Conference 2017 which was held in Ireland (Cork) consisted of both bereaved parents and staff.[139] Through this partnership "a deeper awareness on the part of clinicians of the needs of parents and on the part of parents of the challenges and realities for clinicians working in this challenging area" was fostered.[139] This conference held in Ireland highlighted the important links between the human experience, clinical care and scientific research around pregnancy loss.[139]

1.8 Summary

The Irish maternity service is still evolving, with many recent documents highlighting ongoing issues and others proposing changes and solutions.[21,22,30,34,37,56] Some of these documents were developed due to public and political pressure after inquiries into adverse perinatal events (including deaths) and negative media attention to Irish maternity hospitals.[10,50,128]

Though many inquiries have been carried out into adverse perinatal events in the Irish maternity services over the last two decades, no research has been carried out studying the structures and processes of these inquiries and, importantly, whether the recommendations stemming from these are implemented or recurrent.

The monitoring of outcomes, including perinatal deaths, in the 19 maternity units is now established through IMIS, MPSS and audits by NPEC. Perinatal deaths are audited by NPEC and a national annual report with recommendations is published.

The NIMF clearly outlines how SREs (including certain perinatal deaths) should be reviewed locally and how the affected families and staff should be involved in these reviews. However, no research has thus far examined the recurrence of recommendations from national audits or how the NIMF applies to local perinatal mortality reviews and if there is a standardised structure to these reviews across the 19 maternity units.

Further, emerging research from the UK highlights the importance of involving bereaved parents in these local reviews.[129,131,134] Meaningfully involving parents in their maternity hospital review can have positive impacts on mental wellbeing, provide closure and help to plan for future pregnancies.[129–131] Although Irish research has shown the importance of communicating clearly and sensitively with parents at the diagnosis of and after a perinatal death[1,3,61,63], there is an absence of knowledge within the Irish context regarding the inclusion of parents in perinatal mortality reviews, despite family involvement being widely advocated.

1.9 Thesis outline

This thesis consists of nine chapters, including seven scientific articles (Chapters 2 to 8) discussing various methods and aspects of perinatal mortality reviews, audits and inquiries. Five of these articles (Chapters 2, 3, 5, 6 and 7) have been published in peer-reviewed journals. An integrative literature review on the past, present and future of perinatal mortality audits and reviews is presented first (Chapter 2). This is followed by a study comparing and analysing the methods and recommendations of national perinatal mortality audits (in Ireland, New Zealand, United Kingdom, Netherlands), as well as resultant initiatives in these four countries (Chapter 3). Additionally, local perinatal death reviews in the 19 Irish maternity units are evaluated using an electronic questionnaire (Chapter 4).

Ten published Irish inquiry reports relating to perinatal deaths and pregnancy loss services published between 2005 and 2018 were analysed leading to three main pieces of work (Chapters 5, 6 and 7). The first article describes and compares the

inquiries' methods, structure and details of the recommendations of the ten reports (Chapter 5). The second article examines the effects of governance in the Irish maternity services on the management of perinatal deaths and bereavement services as described in the ten inquiry reports (Chapter 6). The third article explores the impact of bereavement care and pregnancy loss services on bereaved families as illustrated in the ten reports (Chapter 7). Lastly, the involvement of parents in maternity hospital reviews into their care and their baby's death is explored through semi-structured interviews with bereaved parents (Chapter 8).

For ease of reading, this thesis is presented as:

Chapter 1 Introduction and aims

Chapter 2 Original research; Perinatal Mortality Audits and Reviews: Past, Present and the Way Forward

Chapter 3 Original research; National perinatal mortality audits and resultant initiatives in four countries

Chapter 4 Original research; Implementation of a national incident management framework: How does it apply to local perinatal death reviews?

Chapter 5 Original research; Irish inquiry reports relating to perinatal deaths and pregnancy loss services

Chapter 6 Original research; Governance of maternity services: Effects on the management of perinatal deaths and bereavement services

Chapter 7 Original research; Impact of bereavement care and pregnancy loss services on families: Findings and recommendations from Irish inquiry reports

Chapter 8 Original research; Bereaved Parents' Involvement in Maternity Hospital Review Processes "Nobody even thought to ask us anything"

Chapter 9 Discussion and Conclusion

1.10 Thesis aims and objectives

The aim of this thesis is to analyse the methodology and structure of perinatal mortality audits, inquiries and local reviews in Ireland with comparison to the international literature. In addition, it aims to study recurrent themes in the audit and review reports' recommendations and assess the implementation of these recommendations and learning points to improve care and outcomes associated with perinatal mortality. A specific aim is to study the involvement of bereaved parents in reviews currently, and to inform and promote their involvement in reviews in the future.

Table 1. 4: Objectives of each chapter

Chapter	Title of article	Objectives
2)	Perinatal Mortality Audits and Reviews: Past, Present and the Way Forward	Outline the types of perinatal mortality audits and reviews from international literature, how these are carried out in high-income countries at present and how the processes may be improved
3)	National perinatal mortality audits and resultant initiatives in four countries	Examine national perinatal mortality audits' methodology in four high-income countries (UK, NZ, Ireland, Netherlands) to highlight different approaches taken
		Compare and discuss the recommendations made in the national perinatal mortality audit reports, from these countries from the last five years looking for any common or recurring themes
		Assess national initiatives and programmes addressing these recommendations to assess accomplishment of the audit's recommendations implementation
4)	Implementation of a national incident management framework: How does it apply to local perinatal death reviews?	Evaluate the current status of local perinatal death review processes in the 19 Irish maternity units
		Compare them to the National Incident Management Framework, as well as study other international perinatal mortality review procedures
5)	Irish inquiry reports relating to perinatal deaths and pregnancy loss services	Examine the general structure, methodology, findings and recommendations of ten Irish inquiry reports relating to perinatal deaths and pregnancy loss services to identify standardised inquiry procedures and highlight recurring recommendations in the reports

6)	Governance of maternity services: Effects on the management of perinatal deaths and bereavement services	Outline how Irish perinatal bereavement services and the management of perinatal deaths (including events leading up to the deaths) were affected by developments in maternity services governance as described in ten inquiry reports
		Provide ideas for changes in local and national maternity services governance to enhance perinatal bereavement services
7)	Impact of bereavement care and pregnancy loss services on families: Findings and recommendations from Irish inquiry reports	Describes the impact of bereavement care provided to families around the time of pregnancy loss or neonatal death as stated in ten inquiry reports related to Irish maternity services
		Discuss the issues with care encountered by bereaved parents and improvements to address them
8)	Bereaved Parents' Involvement in Maternity Hospital Review Processes "Nobody even thought to ask us anything"	Establish how bereaved parents may be best involved appropriately in maternity hospital reviews in Ireland, in a way that is both beneficial to them and the review process

Chapter 2 - Perinatal Mortality Audits and Reviews: Past, Present and the Way Forward

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Chapter 2 - Perinatal Mortality Audits and Reviews: Past, Present and the Way Forward

2.1 Abstract

Background

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. Perinatal mortality reviews can identify factors contributing to suboptimal care.

Methods

An integrative literature review was carried out to study the different types of perinatal mortality reviews currently being done internationally, establishing a comparison and examining promising new developments.

Results

The classification of perinatal deaths and the different types of perinatal mortality reviews carried out in high-income countries are outlined. We reflect on the challenges that are encountered in the current processes and we then comment on how these may be overcome.

Current literature shows that differences in classifications of perinatal deaths continue to impede important international comparisons. National perinatal mortality audits can provide reliable high-quality data to facilitate national and international benchmarking. Confidential enquiries give expert assessment on anonymised information to initiate system-wide improvements, but to provide local information on perinatal deaths unit-based multi-disciplinary team reviews are required. Additionally, there is a need to shift from a blame-culture to a focus on achieving best practice by learning from mistakes. Review tools and processes have been implemented in some countries to standardize perinatal mortality reviews, but there is still more work to be done. Involving the bereaved parents

in the perinatal mortality review process is important and ways to achieve this are progressing.

Conclusion

A structured approach to the perinatal mortality review process should be developed to facilitate sharing of experiences and challenges at national (or international) level. To achieve a reduction in the number of stillbirths and neonatal deaths, it is crucial to ensure that the perinatal mortality audit and review cycle is completed with implementation and re-evaluation of recommended changes in maternity services.

Keywords

Perinatal mortality review, audit, Confidential Enquiry, stillbirth classification, multidisciplinary team, bereaved parents' involvement

2.2 Introduction

The World Health Organisation (WHO) estimates that 2.6 million stillbirths and 2.7 million neonatal deaths occur every year worldwide.[13] Unfortunately, some perinatal deaths are inevitable, but others may be preventable. Stillbirth refers to a viable baby born with no signs of life.[71] An intrapartum stillbirth occurs after the onset of labour but before birth.[13,71] A neonatal death refers to the death of a baby born alive within the first 7 (early) up to 28 days of life (late).[71] In high-income countries around 10% are intrapartum stillbirths and 3.6% of neonatal deaths are related to intra-partum events.[13,140] Congenital abnormalities account for around 8% of stillbirths and 10% of neonatal deaths, which are rarely avoidable.[13,14] Modifiable risk factors in high-income countries include nutrition and lifestyle factors, prolonged pregnancy and advanced maternal age.[13,141]

The death of a baby is devastating for parents, families and staff involved. It can lead to anxiety, depression, post-traumatic stress disorder and relationship difficulties for the bereaved parents.[2,3] For the healthcare staff involved an intrapartum stillbirth in particular can have lasting emotional and professional effects.[6,7] There is now a significant effort being made internationally to reduce the numbers of perinatal deaths and adverse events including initiatives such as the WHO's Every Newborn Action Plan (ENAP) and "Each baby counts" in the United Kingdom (UK).[11–13,15,142]

There is consensus in the literature, that it is essential to learn from previous substandard maternity care to prevent mistakes recurring.[12,15,113] Perinatal mortality audits and reviews take place to identify factors contributing to suboptimal care, to identify weaknesses in healthcare services and make recommendations to facilitate learning and improvements in care.[11,114,143] These reviews can be carried out in a number of ways at local, national and international level with input by clinicians, experts and more recently including the bereaved parents.

The EURO-Peristat project was established in 1999, highlighting differences in perinatal health and outcomes in 31 countries across Europe.[107] Documenting and comparing national perinatal outcomes like this facilitates international collaboration and sharing of successes.[83] The recent stillbirth series in the Lancet (2016) and BJOG (2018) both advocate for high quality perinatal mortality audits and reviews.[16,144]

National perinatal mortality audit collects national statistics on all perinatal deaths in a country, the local perinatal mortality review examines local deaths for contributory factors and recommends changes accordingly, whereas a Confidential Enquiry is an independent in-depth examination by an expert panel of the care provided in defined cases and a report is produced highlighting learning points.

The aim of this article is to examine the different types of perinatal mortality reviews to understand which type of review may be most important to undertake in a high-income country. This article outlines the types and evolution of perinatal mortality audits and reviews, focusing on how and why these are carried out in high-income countries currently. Furthermore, the article studies each one of these processes, reflecting on what the challenges are in relation to each process and how they may be improved.

An integrative search was performed using various academic databases (e.g. Pubmed, Google scholar) between July 2018 and October 2019. An integrative search was chosen to include all relevant experimental and non-experimental (e.g. national reports) literature. Different combinations of the search terms “perinatal mortality”, “neonatal death”, “stillbirth” were used applying the Boolean terms “OR”, as well as “AND” to include the terms “audit”, “review”, “Confidential Enquiry” or “analysis” (e.g. “neonatal death” OR stillbirth AND audit OR analysis). The search progressed as the work was being completed. Articles were initially scanned by title and abstract to assess its relevance and most recent publications were prioritised (i.e. published from 2010 onwards). Scientific peer-reviewed

articles as well as published national and international perinatal mortality audit reports written in English were included. In the scientific literature the terms audit and review are often used inter-changeably, however in this article the terms are applied separately, where “audit” refers to national perinatal mortality audit and “review” to local perinatal mortality review.

2.3 Background

Medical advances and specialised antenatal and intrapartum care practices have contributed to improved pregnancy outcomes in high-income countries (e.g. recognition of maternal medical conditions, anti-D immunoglobulin prophylaxis and magnesium sulphate for eclampsia prevention).[145–147] Socioeconomic factors have also seen a change over time. Poor maternal nutrition and grand multi-parity have been replaced with rising maternal age and a higher obesity rate.[71,148,149] Other issues like maternal smoking and being part of an ethnic minority are ongoing risk factors for stillbirth.[98,141,150]

Literature on early maternal mortality reviews in Ireland, the UK and the USA, from 1920s-1940s, provide an insight into the perinatal care in this period, although these focused on identifying the causes of death rather than examining the standard of care. The outcome of the baby was often not mentioned as part of these reviews; significant fetal and infant losses were expected at the time.[148] In the 1950s with the introduction of the national Confidential Enquiry into Maternal Deaths (CEMD) in the UK, a more structured approach to maternal mortality reviews was established and adopted subsequently in many countries.[99,100]

The UK expanded its confidential inquiries to include perinatal deaths with the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) in 1992. Information on all perinatal deaths was collected by CESDI annually, and a defined anonymised subset of these cases (based on a varying, select topics e.g. intrapartum related deaths) was reviewed by an expert panel.[99,100] Since 2012

these confidential enquiries continue as Mothers & Babies Reducing Risk through Audits & Confidential Enquiries (MBRRACE-UK).[100]

2.4 Defining perinatal mortality

Perinatal mortality rates are stated as an indicator of the standard health care provided to women and infants.[19,85,148,149,151] The perinatal mortality rate is the number of stillbirths and early neonatal deaths per 1000 total births (live births and stillbirths).[18] Differences in definition and classification of perinatal deaths impede international comparison of data.[12,13,16,71,72,98,113,144] A systematic review carried out in 2016 identified 81 different perinatal death classification systems in use internationally, one-third of which were commonly used.[82] It is important to classify perinatal deaths accurately and comprehensively for national and international benchmarking, monitoring of rates and preventing future deaths by informing national and/or international policy, clinical practice and research.[152]

As illustrated in table 2.1, there is currently no consensus internationally on the lower limit of gestation for classifications of stillbirths, it varies from 20 to 28 weeks' gestation of pregnancy.[13,98,144] For international comparison of stillbirth rates, the WHO recommends 28 weeks' gestation as the lower limit.[13,71] 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).[72] The International Classification of Diseases 10th revision (ICD-10) refers to a fetal death at less than 22 weeks' gestation as a miscarriage.[13,71] The WHO application ICD Perinatal Mortality (ICD – PM) developed in 2016 to classify deaths accurately and comprehensively; it has three distinct features: 1. perinatal deaths are grouped into ante-, intra-partum or neonatal periods, 2. existing ICD codes are used, 3. contributing maternal conditions are linked to perinatal deaths. [11,74,153] The new revision ICD-11 was released in 2018 and is due to come into effect in 2022.

Variations in data collection and reporting methods still impede direct comparison of perinatal mortality causes and rates internationally.[15,81,144] EURO-Peristat noted that decentralised data collection systems hampered collection of national perinatal mortality data from different countries and monitoring perinatal health in Europe.[72] The inclusion or exclusion of late termination of pregnancies affects perinatal mortality rate calculations (table 2.1).[16,72]

Table 2. 1: Comparison of international perinatal mortality (PM) reporting

Location	National organisation publishing PM report	National PM audit and/or in-depth review (Confidential Enquiry)	Lower gestational limit included in national PM statistics 2016	Inclusion of termination of pregnancies in national PM statistics	WHO: Stillbirth rates 2015 from 28 weeks' gestation/1000 births[1]
Europe	Euro-peristat Project www.europeristat.com	Few countries only	Variable 20 - 28 weeks	Mostly excluded	1.3 – 4.7
Ireland	National Perinatal Epidemiology Centre www.ucc.ie/en/npec	National audit	>/= 24 weeks' gestation	Excluded, not legal until 2019	2.7
UK	National Perinatal Epidemiology Unit (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries) www.npeu.ox.ac.uk/mbrrace-uk	Both	>/= 24 weeks' gestation	Excluded	2.9

Netherlands	Perined (No English report published, some data in Dutch) www.perined.nl/	Both	>/=22 weeks	Included	1.8
USA	Centers for Disease Control and Prevention (National Center for Health Statistics) www.cdc.gov/nchs	Neither	>/= 28 weeks' gestation	Not clarified	3.0
Canada	Public Health Agency of Canada (Canadian Perinatal Surveillance System) www.canada.ca/en/public-health.html	Neither	>/=20 weeks gestation	Included	3.1
Australia	Australian Institute of Health and Welfare www.aihw.gov.au	Neither	>/= 20 weeks' gestation	Some included	2.7
New Zealand	Perinatal and Maternal Mortality Review Committee www.hqsc.govt.nz/our-programmes/mrc/pmmrc	Both	>/=20 weeks' gestation	Included	2.3

2.5 Types of perinatal mortality audits and reviews

Without basic information on perinatal mortality, it is difficult to identify problems, initiate change and examine progress in maternity care.[114,146] Perinatal mortality data is collected as part of local perinatal reviews, clinical audits and confidential enquiries to categorise causes of deaths and to identify potentially avoidable factors.[114] Standard of care should be examined for all perinatal deaths as 10-60% of stillbirths and neonatal deaths are reported to be associated with some suboptimal care.[106,144,150]

2.5.1 National audits

National audit aids the comparison of results between different maternity units and allows the creation of national perinatal mortality figures.[18,141] National perinatal mortality audit can generate clinical recommendations directly affecting quality of maternity care.[85]

Audit is a process of ongoing data collection, assessment, implementation of change and re-evaluation i.e. a continuous cycle.[12,113,151] The development of recommendations linked to action plans with clear targets for healthcare management and feedback to staff is a step often missed in the audit cycle.[12,19] The 2011 Stillbirth series published in the Lancet states that this final step of action and re-evaluation is the most important.[71] Each action plan should be assigned to a specific individual or department, with a specific timeframe stated for each.[11] A structured national implementation plan guided by a working group and involving relevant clinical (e.g. midwives, neonatologists, obstetricians) and non-clinical professionals (e.g. from the department of health, epidemiologists, health planners) is important to progress action plans.[11]

Both the WHO and the Perinatal Society of Australia and New Zealand (PSANZ) have developed detailed perinatal mortality audit guidelines.[11,19] The PSANZ Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death is used to

classify perinatal mortality causes in both Australia and New Zealand.[19] Perinatal deaths in Ireland have been audited by the National Perinatal Epidemiology Centre (NPEC) in the National Clinical Audit of Perinatal Mortality since 2008.[18] McNamara et al analysed all intrapartum fetal deaths and unexpected neonatal deaths reported to NPEC (2011 to 2014), and showed that only 63% of cases (without congenital anomaly) underwent a local hospital review.[86]

2.5.2 Local reviews

Local perinatal mortality reviews require lower costs and simpler organisational structures than those involved in national audit or confidential enquiries.[114] The benefit of local perinatal mortality reviews was recognised in the 1950s, at the time reviews were carried out to establish the cause of death of stillborn and newborn infants.[154] However, Canadian studies at the time 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".[155,156] From this time the importance of a collaboration between different specialities in obstetrics, midwifery, neonatology and pathology i.e. the multidisciplinary team (MDT), to discuss perinatal mortality cases was appreciated.[113,157] In the past, opposing views on standards of maternity care during perinatal mortality MDT reviews created conflict and confusion within hospital departments. Now standards are more clearly defined by guidelines and protocols.[113]

As part of the hospital-based perinatal mortality review, specific recommendations linked to key findings can achieve change and improve clinical care.[11,151] It is important that perinatal mortality reviews focus on improving healthcare rather than blame individuals or departments.[11] As with audits, the final step of re-evaluating the implementation of recommendations, may be missing in a local perinatal mortality review that lacks formal structure.[113] As part of, or in conjugation with, local perinatal mortality reviews, key findings and learning points should be disseminated to all relevant clinical staff e.g. in a regular report/newsletter, during a MDT meeting.[11,151]

Perinatal mortality meetings must be well managed, as staff may become demoralised and disinterested in the process if no actions are taken or recurrent unresolved issues persist.[12,151] The discussions arising from these meetings should focus on areas for improvement rather than criticising practices.[12] If conflict is generated at these discussions between specialists or departments, it can be counterproductive to the review process.[114] Nevertheless, all staff involved in maternity and neonatal care (including junior/support staff) should be facilitated to attend MDT meetings to promote open communication and learning, as well as identify good aspects of care and celebrate progress, as appropriate.[12,151] High clinical workload can present a barrier to staff for attending meetings regularly.[12] Perinatal mortality reviews should involve careful consideration of the clinical and emotional care provided to the bereaved parents.[158] Timely reviews can thus provide important answers and closure to parents.[114,158]

2.5.3 Confidential enquiries and other in-depth reviews

According to MBRRACE-UK, a Confidential Enquiry is an anonymous review of cases with a specific adverse outcome (e.g. intrapartum fetal deaths) by an expert MDT in a defined geographical area over a defined period of time.[140] These aim to examine cases for suboptimal care and/or avoidable factors, thereby creating recommendations to improve the quality of healthcare through policy and practice updates.[143,159] Usually, the case records are summarised into an anonymised pre-prepared structured format and distributed to a pre-defined MDT for analysis.[160] The management of care for set factors (e.g. standard of intrapartum monitoring) is assessed against predetermined guidelines and policies, not the outcome of the case.[143,160,161] The Lancet's 2011 Stillbirth series suggested that term unexpected intrapartum stillbirth rates are a measure of the quality of intrapartum care provided in a unit.[71] Inadequate fetal monitoring, risk assessment and management of labour are recurring contributory factors identified for term intrapartum stillbirths.[15,71]

In 1985, the Director of the National Perinatal Epidemiology Unit, UK stated that "one benefit of enquiries is the provision of good data describing perinatal

outcome".[157] He also stated that "the effort and cost involved in any enquiry process should be reflected in recognizable benefits".[157] Both statements are still relevant today.[159]

Examples from New Zealand and the Netherlands, illustrate how robust, in-depth perinatal mortality reviews can contribute to reducing stillbirth rates. The New Zealand multidisciplinary Perinatal and Maternal Mortality Review Committee (PMMRC) has conducted a comprehensive review of maternal and perinatal mortalities, and the standard of care from 2007.[162,163] A significant 11% decrease in stillbirth rates was registered since then, however the overall neonatal mortality rate has not changed in NZ since 2007.[163]

As a consequence of their above-average perinatal mortality rates in the 2000 and 2004 EURO-Peristat reports, the Netherlands initiated a national effort to reduce these.[107,141] In 2010 nationwide perinatal mortality audits [The Foundation Perinatal Audit in the Netherlands (PAN)] were implemented by the government and professional colleges.[85] This national audit and in-depth review is confidential and expert led; the care provided is benchmarked to guidelines or standards.[85] The Netherlands achieved the highest annual rate of reduction (ARR) of stillbirths from 2000 to 2015 when compared to 48 other high income countries.[144]

2.6 The way forward

2.6.1 Standardising perinatal mortality classifications and reviews

Reaching agreement on one international model of classification and definition of perinatal deaths is a priority.[12,13,16,82,150,153] To classify perinatal deaths accurately for international benchmarking the lower gestational limit included for stillbirths, as well as the inclusion/exclusion of late terminations of pregnancy needs to be agreed on. The ICD-PM and ICD-11 revision will hopefully facilitate this agreement. Comprehensive classification of cause of death can provide bereaved parents with much sought after answers, such as risk of recurrence.[158] Perinatal post-mortem and placental examination have long been recognised as important

to aid classification of cause of deaths as well as in the planning of future pregnancies.[19,113,150,155,156]

Education on audit and quality improvement skills should become part of training for all clinicians.[15,150] Awareness of the importance to review perinatal mortality cases for substandard care is increasing.[144] However, the review process is standardised in very few countries at a national level.[144] National perinatal mortality audits facilitate the collection of good-quality, reliable data and examine if national guidelines are being followed. However, to identify complex and interlinked contributory factors a more detailed systematic approach like a Confidential Enquiry is required (e.g. MBRRACE-UK, PMMRC-NZ, PAN).[85,100,163] More countries (e.g. Australia, Canada, Chile, Ireland, Italy, Poland) are now working towards establishing a national, standardised perinatal mortality review with in-depth analysis of cases.[144] As well as a national audit and Confidential Enquiry, local perinatal mortality MDT reviews and meetings should be carried out to facilitate staff involvement in local learning and change.[141,158]

2.6.2 Barriers to implementation of reviews and ways to overcome them

Barriers to implementation of local and national review/audit programmes include frequent clinical staff rotation between hospitals (which can affect continuity of care and review programmes) as well as lack of funding for protected time for staff.[11,12] Long-lasting improvements can be achieved by having permanent chairpersons or review committee members to advocate for regular, high-quality local reviews.[11]

Fear of repercussions and litigation are regularly stated as reasons for reluctance to participate in both local and national reviews.[114,157,161] Some advocate for legal protection of any opinions expressed on standard of care, while still ensuring the reporting of any gross malpractice.[12,159] There is a need to shift from a blame-culture to a focus on achieving best practice by learning from mistakes. With a supportive hospital and political environment at local and/or national level,

progress and improvements are more likely to be ongoing and widely distributed.[11,12]

Establishment of multi-disciplinary review committees, development of specific perinatal mortality review tools and/or guidelines will enable a more regulated, structured approach to the review/audit process.[11] A centralised electronic perinatal mortality data collection system facilitates rate and case comparisons.[72]

2.6.3 Web-based perinatal mortality review tools

Input of factual information into national web-based review tools will facilitate objective perinatal mortality or near-miss reviews, which can create clear action plans based on issues identified when compared to national guidelines. In the UK the Perinatal Mortality Review Tool (PMRT) has been launched as part of the MBRRACE-UK programme with the aim to standardise perinatal mortality reviews across the NHS maternity and neonatal units in Scotland, Wales and England.[106,140] The first published PMRT report (2019) showed that 7993 contributory factors were identified in the 1500 reviews, of these 38% required action to improve the standard of care. Furthermore, 3050 actions formed part of the action plans produced, while these were mostly specific, achievable and realistic, some were not measurable or time-bound (SMART).[106]

External review can provide unbiased opinions on the clinical care provided and may identify more contributory factors than local reviews.[161,162] While the PMRT report recommended to include an independent external professional to be part of each local review, less than 10% of the first 1500 cases using this tool included one.[106]

To expand the existing national perinatal mortality audit the Irish Maternity Event Review Tool (MERT) is due to be released by NPEC in the near future. The benefits of web-based review tools include standardising reviews nationally, as well as allowing the safe transfer and sharing of clinical information/data.

2.6.4 Bereaved parents' involvement

Methods of involving bereaved parents in the local review process are still mostly unexplored.[12] PARENTS 2 was a UK pilot study of parents' engagement in the review process, which highlighted the need for standardised continuity of care for parents through the review process.[134,164] Parents' involvement in their baby's review may help them to cope with their bereavement, answer some of their questions and for the hospital to obtain relevant factual information.[134]

This involvement allows parents to give and receive important clinical feedback.[16] Parental involvement in PARENTS 2 included a face-to-face explanation of the review process with written information in the hospital, followed by a meeting with the parents in a location of their choice with a nominated clinical advocate to complete a parental feedback form.[164] This form was discussed at the perinatal mortality meeting attended by the nominated advocate.[164] A plain English summary of the meeting was offered to the parents and discussed at a follow-up meeting.[164]

The first PMRT report (2019) states that in 75% of the first 1500 local reviews the perspective of parents was sought, however of these 55% indicated the parents had no concerns regarding their care which "may to some extent reflect the quality of parent engagement".[106]

2.7 Conclusion

Maternal and perinatal mortality rates have fallen significantly, especially in high-income countries. However, perinatal deaths still occur and are devastating for parents, families and healthcare professionals involved. Suboptimal care contributes to some of these cases. 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.

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 high-quality national perinatal mortality data facilitates international comparison.

Perinatal mortality reviews have evolved significantly with time; earlier reviews lacked structure and rarely commented on good aspects of care. Confidential enquiries give an impartial expert assessment on perinatal deaths and supply feedback at a system level, whereas local reviews identify unit-specific issues and provide essential feedback (to bereaved families and frontline staff).

By running structured local reviews and national audits, with in-depth examination of contributory factors (e.g. within a Confidential Enquiry) alongside one another, local lessons can be learned as well as ensuring that national policy and clinical practice is informed on key findings from all perinatal mortality cases.[152] Few high-income countries (e.g. UK, Ireland, New Zealand, Netherlands) carry out ongoing national perinatal mortality audits and only a minority of these have implemented in-depth examination of substandard care factors (e.g. within a Confidential Enquiry).[144]

In order to accomplish a factual, informative local perinatal mortality review, clinical staff and bereaved families should always be involved in local hospital reviews. This involvement can provide bereaved parents with essential answers, help them to process their bereavement and plan for future pregnancies. Further research is required to ensure the way parents are involved is beneficial to them and the review process itself.

Finally, to achieve the ultimate goal of reducing the number of stillbirths and neonatal deaths, the perinatal mortality audit/review cycle needs to be closed with re-evaluation of recommended changes in maternity services. In this cycle, making achievable perinatal mortality audit/review recommendations should be one of the first steps and not the last.

Chapter 3 - National perinatal mortality audits and resultant initiatives in four countries

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Chapter 3 - National perinatal mortality audits and resultant initiatives in four countries

3.1 Abstract

Background

It is important to examine perinatal deaths as part of a national mortality audit to identify risk factors. Implementing and re-evaluating recommendations from perinatal mortality audits completes the audit cycle, preventing similar deaths in the future. Lack of implementation results in recommendations recurring.

Objectives

In this study we examine national perinatal mortality audits' methodology in four high-income countries (United Kingdom, New Zealand, Ireland, Netherlands) to highlight different approaches taken. We compare the recommendations made in these audits' reports over the last five years, as well as review national initiatives and programmes addressing them.

Study Design

This study is an integrative review where two comprehensive literature searches were completed: on established national perinatal mortality audits in high-income countries; and on national initiatives addressing recommendations from these audits. Content analysis of the audits' recommendations was performed organising them into themes according to topics these focused on.

Results

Though the methodology of the national perinatal mortality audits varied, all four were state-funded and had standardised online data collection forms to report deaths.

The recommendations themes included: Raising public awareness of perinatal mortality risk factors, Detection of fetal growth restriction, Prevention of preterm birth, Resources for data collection and review.

Only the UK had various initiatives addressing perinatal mortality risk factors directly. New Zealand included stakeholders in the audit recommendations' development and provided updates on their implementation. The Netherlands developed a programme for audit recommendation implementation. Ireland created a group which is progressing some recommendations from the audit.

Conclusions

National perinatal mortality audits are important in identifying contributory factors and making recommendations to address these. Recurring recommendations suggest a failure to resolve the identified issues. This study shows how some challenges are common to high-income countries' audits, highlighting the need for shared learning of successful initiatives.

Keywords: Perinatal mortality audit; United Kingdom; Netherlands; New Zealand; Ireland

3.2 Background

Reporting national perinatal mortality rates is important, however examining these perinatal deaths further as part of a mortality audit will identify risk factors that can be addressed to prevent similar deaths in the future.[11] National perinatal mortality audits are carried out to identify modifiable factors, change clinical practice if indicated and improve the quality of perinatal care provided.[85,100,144,165] The WHO's perinatal mortality audit guide "Making Every Baby Count" states that detailed analysis of perinatal deaths, including risk factors and events leading to the deaths, can identify health-care and -system shortcomings and offer solutions to overcome them.[11] For national perinatal mortality audits to achieve a reduction in deaths, adequate resources must be available and relevant stakeholders (e.g. government health departments, maternity services management, professional associations) need to be engaged in coordinating and implementing audit recommendations.[11] Further, closing the audit cycle by evaluating and refining recommendations and implementation plans is key to "move from problems to solutions".[11]

In high-income countries there are currently three levels of assessment of national perinatal deaths: (i) collecting and reporting incidents and rates (done in many countries), (ii) collecting and analysing incidents and rates; reviewing a large clinical audit dataset and making recommendations based on these (as is done, for instance, in Ireland[18]), (iii) collecting and analysing incidents and rates; reviewing the deaths (either some or all) in detail and making recommendations based on these (as is done in the United Kingdom (UK), New Zealand (NZ) and the Netherlands[140,166,167]).

There is no previous research available comparing national perinatal mortality audits and the recommendations made as part of the audits. The aim of this study was to compare different national perinatal mortality audits to assess their strength, successes and limitations. In this study we examine national perinatal mortality audits' methodology in four high-income countries (UK, NZ, Ireland,

Netherlands) to highlight different approaches taken.[18,140,166] Further, we compare and discuss the recommendations made in the national perinatal mortality audit reports, from these countries from the last five years (i.e. reports published from 2015 to 2019, with data from 2013 to 2017) [18,84,140,163,166,168–171,172–177], looking for any common or recurring themes. National initiatives and programmes addressing these recommendations were examined to assess accomplishment of the audit's recommendations implementation.

3.3 Methods

This study is an integrative review where two separate literature searches were carried out using various academic (e.g. Pubmed, Google scholar) and non-academic databases between October 2020 and May 2021. An integrative search strategy was chosen to include all relevant experimental and non-experimental (e.g. national reports) literature. The first search aimed to identify literature from high-income countries with an ongoing national perinatal mortality audit including their methodology, funding and published reports. The second literature search identified national initiatives and programmes addressing the audits' recommendations. Different combinations of the search terms "perinatal mortality", "neonatal", "death", "stillbirth", "national", "audit", "review" and "analysis" were used applying the Boolean terms "AND" and "OR". Figure 3.1 illustrates the selection process for documentation on the national perinatal mortality audits which were included in this study, highlighting exclusion and inclusion criteria. Both searches included scientific and grey literature, including national public reports and websites, focussing on information from the identified audits covered in the five most recent audit reports (i.e. from 2013 onwards). The UK, NZ, Ireland and Netherlands were identified as performing and having information available on their national perinatal mortality audits.[18,140,144,165,166]

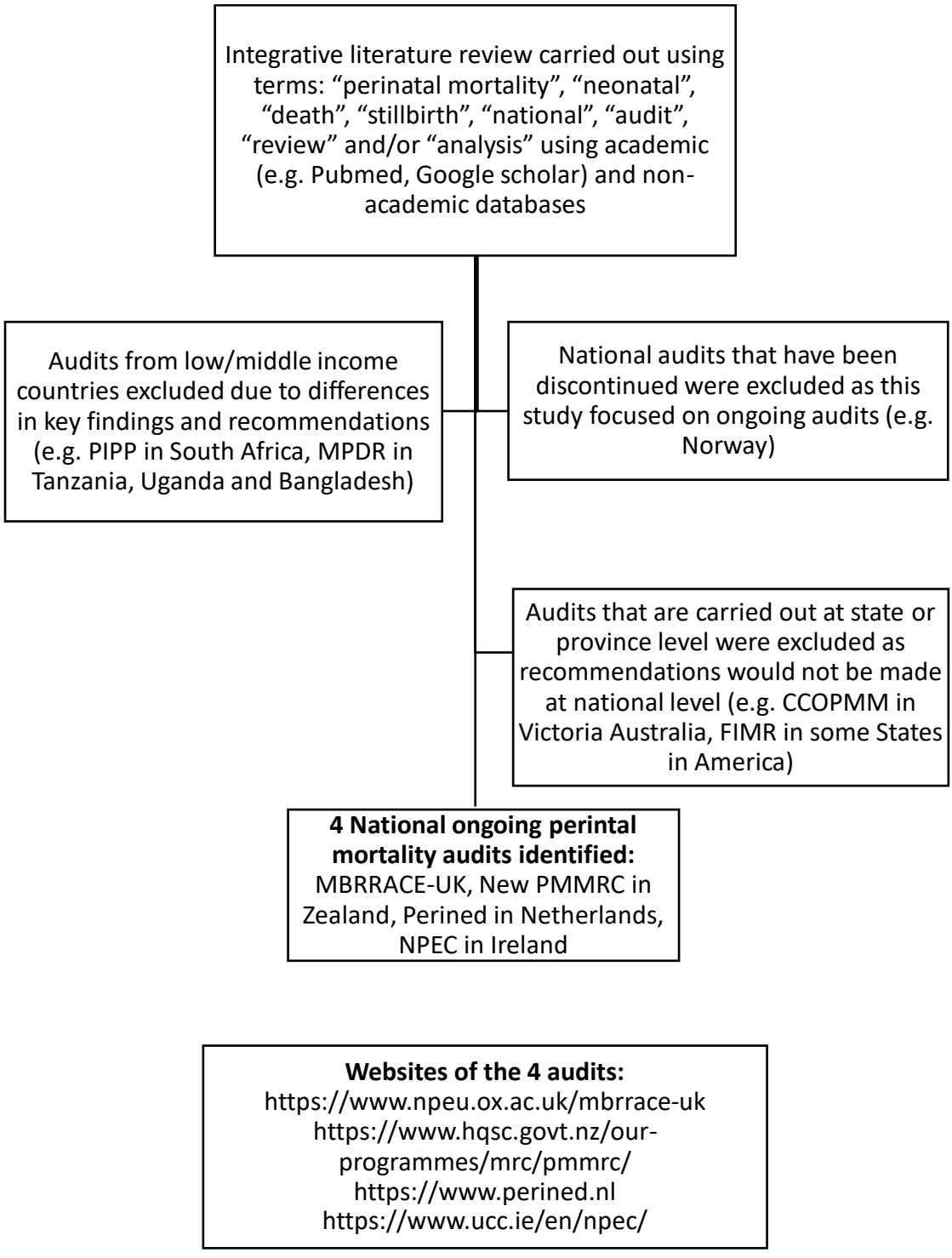

Figure 3. 1: Selection Process for National Perinatal Mortality Audits included in this study

Abbreviations:
Perinatal Problem Identification Programme (PIPP)
Maternal and Perinatal Death Review (MPDR)
Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM)
Fetal and Infant Mortality Reviews (FIMR)

Information collected on the methodology, funding and national recommendations of the audits allowed for a descriptive comparative analysis to be carried out on the perinatal mortality audits from these countries. Although the Netherlands have an established perinatal audit programme called Perined, unlike the UK, NZ and Ireland, the reports from Perined do not contain recommendations comparable to the other audits' reports. Therefore, it could not be included in the analysis of the audits' recommendations or related initiatives.

Content analysis of the recommendations of the audit reports from five years (2015 - 2019) was carried out following these steps: preparation (selecting the recommendations to include), organisation (recommendations into themes) and reporting (revising and finalising according to identified themes).[178] Two researchers discussed and collated the Tables of the recommendations according to different themes. Considering the vast number of recommendations and their broad themes, to make this comparative study feasible, only recommendations from the audits under a theme across all three countries were included for analysis.

Ethical approval was not required as the reports from the countries included are publicly-available documents published online.

3.4 Results

Four high-income countries (UK, NZ, Ireland, Netherlands) were found to currently have ongoing national perinatal mortality audits with reports and/or publications broadly available.[18,140,144,165,166] The results presented here focus on audit reports from five years (published from 2015 to 2019 with perinatal mortality data from 2013 to 2017[18,84,140,163,166,168–171,172–177]), with information on funding and methodology of the audits, as well as national initiatives and programmes related to preventing perinatal deaths.

3.4.1 Similarities and differences between the four perinatal mortality audits

Inception of the audits

Confidential enquiries into perinatal deaths commenced in the UK in 1993, which continue as "Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK" (MBRRACE-UK) since 2012[165] (Table 3.1). In NZ perinatal deaths have been monitored by the Perinatal & Maternal Mortality Review Committee (PMMRC) since 2005. In Ireland the National Perinatal Epidemiology Centre (NPEC) has audited perinatal deaths since 2008.[165] In the Netherlands Perined was founded in September 2015 when Perinatal Audit Netherlands (PAN, established in 2010) and Perinatal Registration Netherlands (PRN, from 1999) merged.

Funding

All four national audits were state-funded. The National Perinatal Epidemiology Unit (NPEU) leads MBRRACE-UK, which is funded through the Healthcare Quality Improvement Partnership (HQIP) on behalf of the UK's National Health Service (NHS). The current commissioning of MBRRACE-UK runs until September 2021 (www.npeu.ox.ac.uk/mbrrace-uk/service-users). The PMMRC is part of the Health Quality & Safety Commission New Zealand financed by annual Crown funding. Perined is funded through the Ministry of Health of the Netherlands, while in Ireland, the government-financed public health service (Health Service Executive, HSE) funds NPEC.

Methodology of the audits

All four countries have standardised online data collection forms to report perinatal deaths (Table 3.1). Lower gestational limits of the deaths included in the perinatal mortality audits varied between the four countries from 20 to 24 weeks' gestation, therefore the perinatal mortality rates are not comparable between these countries (Table 3.1).

In NZ individual coordinators within each District Health Board oversaw the collection of the perinatal mortality data from their district (20 in NZ in total) and initiated local reviews to classify causes of death and identify contributory factors.[170] These data were submitted to the PMMRC together with post-mortem and histology reports (Table 3.1). Using set queries, data were validated to complete missing information and correct inconsistencies.[170]

In the UK and Ireland each maternity unit nominated local staff to coordinate the collection and entering data. The Irish NPEC validated the collected data with the respective maternity units and reconciled the annual dataset with the National Perinatal Reporting System.[18] MBRRACE-UK internally validated the dataset, using set limits for each data item and not accepting values outside this range.[179]

In addition to the perinatal audit, in the UK a sample of defined cases under varying topics (e.g. intrapartum stillbirths and intrapartum-related neonatal deaths in 2016-2017) undergoes a multi-disciplinary, anonymous review (a Confidential Enquiry) every two years.

In the Dutch Perined regional audit teams (10 in total) liaise with local audit teams to discuss the results of the local audit meetings (Table 3.1). Anonymised cases (all or those related to a specific topic) are discussed by a multidisciplinary local team (at least two professionals from each discipline and an external chairperson). The data and findings from these cases are entered into a national database called Perinatal Audit Assistant (PAA), which forms the basis for national reporting of perinatal mortality data. Points for improvement or improvement actions are entered into the PAA by local audit teams, these points are assessed and approved by the national audit team.

Published audit reports

The UK (Perinatal Mortality Surveillance Report), NZ (Annual Report of the PMMRC), Netherlands (Perinatal care in the Netherlands) and Ireland (Perinatal Mortality in Ireland Annual Report) publish annual audit reports with data from

perinatal deaths from one to two-years prior.[18,97,140,166] Reports from three countries (UK, NZ and Ireland) included national recommendations (discussed in section 2). At time of researching for this article Perined had published its national data report, and was in the process of preparing special articles focussing on specific issues, which will include recommendations to address these.

The NZ PMMRC reports were peer-reviewed and consultations with stakeholders were carried out. These reports included maternal deaths and neonatal encephalopathy cases with specific recommendations; these cases are beyond the remit of this study. Only the PMMRC reports contained a dedicated section with detailed updates on recommendations from previous reports.

The Irish NPEC perinatal mortality audit reports included an invited commentary by clinicians on varying, topical issues. In Ireland, unit-specific reports were provided to each of the 19 Irish maternity units.

3.4.2 Comparison of the recommendation made and resultant initiatives

Over the five years of the audits (2013 to 2017) the UK reports made 46 recommendations in total (7-12 annually), the Irish reports 42 (8-10 annually), and the NZ reports included 28 recommendations (2-11 annually).[18,84,140,163,166,168–171,172–177] Several recommendations recurred over two or more years.

Some recommendations were specific to the country due to varying or specific national challenges e.g. induction of labour in NZ; the use of the Perinatal Mortality Review Tool in the UK; universal access to fetal anomaly ultrasound in Ireland. However, there were common and recurring themes in recommendations: Raising public awareness of perinatal mortality risk factors, Detection of fetal growth restriction, Prevention of preterm birth, Resources for data collection and review. These are discussed below and outlined in Tables 3.2 to 3.5, where they are grouped by theme, including associated national initiatives. Additional recommendations from the reports not included in this comparative study are listed in the supplementary data (Appendix I and Appendix II).

Raising public awareness of perinatal mortality risk factors

All three countries made recommendations on addressing public awareness regarding modifiable risk factors for perinatal deaths (Table 3.2). Risk factors mentioned in the reports included smoking, substance misuse, obesity, poor antenatal care attendance and lack of folic acid supplementation.[18,84,140,163,166,168–171,172–177] General advice on pregnancy health is available on official websites from the three countries (Table 3.2), however only NHS England commenced a national initiative ("Saving Babies' Lives Care Bundle", SBLCB) addressing smoking in pregnancy and reduced fetal movements (as well as detection of fetal growth restriction and effective fetal monitoring during labour).[180] In NZ different District Health Boards initiated varying local public health campaigns (outlined in Table 3.2).

Detection of fetal growth restriction

All three countries' reports included recommendations to improve detection of FGR during pregnancy, including identifying maternal and fetal risk factors (Table 3.3). In NZ, the 2017 perinatal mortality rate for small gestational age babies (>26/40, without congenital anomaly) was 9/1000 births compared to 2.3/1000 in appropriately grown babies.[166] Of the deaths in 2017 in Ireland, 37% had identified FGR, however only 39% of those were diagnosed as growth restricted antenatally.[18] The UK, Ireland and NZ have national FGR guidelines for management of babies at risk of FGR. The SBLCB Element 2 addresses the "risk assessment and management of babies at risk of fetal growth restriction" (Table 3.3).

Prevention of preterm birth

Recommendations from the three countries' reports included preterm birth prevention by identifying and addressing modifiable risk factors (Table 3.4). Of the neonatal deaths in 2017, 65%, 70% and 81% were born at less than 37 weeks' gestation in the UK, Ireland and NZ respectively.[18,140,166] Element 5 was added in

2019 to the SBLCB (Version2) to address the prevention of preterm births[110] (Table 3.4). New Zealand is aiming to reduce preterm birth "by a state-wide multifaceted program" (Table 3.4).

Resources and time for perinatal mortality data collection and review

All studied reports highlighted the importance of allocating time and resources to local staff for audit associated activities and the notification of deaths centrally (Table 3.5). MBRRACE highlighted incomplete maternal data variables for neonatal deaths as an ongoing problem.[140]

3.4.3 National programmes related to perinatal deaths

The perinatal mortality rate is trending downwards in all four countries. In England the stillbirth rate has fallen by 21% between 2010 and 2018, and the neonatal mortality rate by 5.1%.[181] Since the set-up of the PMMRC in 2007, the stillbirth rate in NZ has reduced by 11%, however the neonatal mortality rate has not changed significantly.[163] The Dutch perinatal mortality audit began in 2010 (as part of an effort to reduce the above-average national perinatal mortality rate when compared to other European countries), and the Netherlands achieved the highest annual rate of reduction of stillbirths between 2000 and 2015 when compared to 48 other high income countries.[85,144] As part of the Dutch audit a specifically-designed course called 'ACTion toolkit' has been developed (more information on www.actiontoolkit.nl) to help implement improvement points and changes locally, which are overseen and monitored by a national team.

Perinatal mortality audits highlight modifiable risk factors, make recommendations to address these, however national programmes and/or initiatives are required to progress these further. Since 2016 the Maternity Transformation Programme (NHS England) is bringing together different organisations and initiatives, including prevention with the Saving Babies' Lives Care Bundle (Tables 3.2-3.4) and after-event reviews with MBRRACE-UK, the Perinatal Mortality Review Tool (NPEU), Each Baby Counts (RCOG) and NHS

Resolution's Early Notification Scheme to "learn from adverse events through reports which summarise good practice and where action needs to be taken".[181]

The National Maternity Monitoring Group within the NZ Ministry of Health was established in 2012 to oversee and review national maternity standards and highlight areas in need of improvement. In 2020 the NMMG reported plans for a "national programme to reduce preterm birth and preterm-related perinatal death" including processes to follow-up women with previous preterm birth and engage early in future pregnancies[182] (further detail included in Table 3.4).

In Ireland, the National Women and Infants Health Programme (NWIHP) was established in 2017 within the health service (HSE) to lead the management, organisation and delivery of maternity services, as well as the implementation of the Maternity Strategy (covering the period 2016 to 2026). The Strategy's implementation plan contains a section on health and wellbeing during pregnancy [21]. NWIHP is progressing some of the recommendations made in the NPEC perinatal mortality audit reports, including the resourcing of perinatal pathology services (Appendix I) and the establishment of an enquiry for intrapartum perinatal deaths (Table 3.5).

3.5 Discussion

3.5.1 Principal findings

This study examined the similarities and differences between four national perinatal mortality audits in the UK (MBRRACE), New Zealand (PMMRC), Ireland (NPEC) and Netherlands (Perined). All four audits were state-funded, either through the public health service (MBRRACE, NPEC) or government departments (PMMRC, Perined) and had adopted online data collection systems, which increase the accuracy and speed of reporting perinatal deaths. All four audits publish annual reports.

The WHO "Making Every Baby Count" guide recommends that, as well as collecting national perinatal mortality data, all or a selected sample of perinatal deaths should be reviewed by one or more multidisciplinary committees to identify contributory modifiable factors at national level.[11] Unlike the UK, NZ and the Netherlands, Ireland has not commenced this in-depth review of perinatal deaths, despite recommendations in NPEC reports since 2015.[175]

The implementation of recommendations or learning points from perinatal mortality audits is key to adapting clinical practices and improving perinatal mortality rates.[85,100] Perined has prioritised the implementation of learning points from the audits. PMMRC reports include information on the progress of recommendations from previous reports, including national initiatives planned or commenced. Providing these updates gives a clear overview of which recommendations are being implemented and which require further attention.

The recommendations in the audits' reports on public health campaigns span the five-years (up to 2019). There is still limited public awareness and/or online advice about risk factors for perinatal deaths.[183–185] Far-reaching public health campaigns, as were carried out internationally for risk factors for Sudden Infant Death Syndrome (SIDS) in the 1990s[186], are needed.

FGR has been recognised as a risk factor for perinatal deaths since the 1960s[187,188], with significantly increased risk if remaining unrecognised antenatally, yet high proportions of babies that die in the perinatal period still have undiagnosed FGR in the four countries (e.g. 23% in Ireland in 2017).[189] An evaluation (SPiRE) of the implementation of Savings Babies Lives Care Bundle (SBLCB Version 1) in 19 NHS England trusts found a 59% increased antenatal detection of small for gestational age (SGA) babies over a four-year period.[110,180] However, there was an associated significant increase in ultrasound scans, inductions and caesarean sections, and therefore cost.[110,180]

Of the neonatal deaths in 2017, 65-81% were born before 37 weeks' gestation in the UK, Ireland and NZ. In 2015, the percentage of live preterm births were 6.5,

6.9 and 7.7% in Ireland, the Netherlands and the UK respectively.[83] The overall preterm birth rate has not reduced in Ireland/UK over the last 10 years, which is concerning considering the increased mortality rate in this group identified by perinatal mortality audits.[21,190]

To identify the trends and relation of FGR detection and preterm birth to perinatal deaths, robust perinatal mortality data collection and analysis is required. Recommendations in the reports from Ireland, the UK and NZ reflect the importance of providing resources to local hospital staff for audit activities. In order to receive accurate and complete perinatal mortality data for analysis, local staff need protected time to collect and enter data variables into the national electronic data portal.

National oversight of and engagement with progressing perinatal mortality audit's recommendation is essential to prevent issues and resultant recurrent recommendations recurring. The NZ NMMG, the Maternity Transformation Programme (NHS England) and the Irish NWHIP fulfil this function since 2012, 2016 and 2017 respectively. It takes considerable time (often years) for national programmes addressing audit recommendations to be developed, implemented and evaluated, thus adding to delays in changes to perinatal mortality figures and outcomes being noticed.

3.5.2 Strengths and limitations

This is the first study of its kind; comparing national perinatal mortality audits in four countries. By focussing on and comparing recommendations from the different audits and resultant national initiatives, this study encourages shared learning and highlights varying approaches taken, and may stimulate other countries, including Ireland, to develop effective methods of implementing perinatal mortality audit recommendations.

We reviewed five years (2013 - 2017) of the perinatal mortality audit recommendations, however we searched the literature extensively for updates on initiatives and related reports up to May 2021. Therefore, this article provides an

up-to-date overview of progression (or lack of) of the recommendations from the reports.

The information on the Dutch Perined audit and related ACTion method is limited by the limited publications to date. In general, more information and greater transparency regarding the methodology of different audits would be helpful to other countries planning to commence a national perinatal mortality audit. Further, a shortcoming in the potential for sharing of knowledge and information internationally is highlighted.

A cost-effectiveness analysis of perinatal mortality audits was beyond the scope of this study, this would be a valuable focus for further research on these audits. Further, based on this study we could not conclude which the 'gold standard' approach for perinatal mortality audits is.

3.5.3 Interpretation

A perinatal mortality audit, like all audits, should be carried out as an ongoing cycle, and ideally an upwards spiral where the standards of care improve with each cycle of the audit.[191] The essential steps in the cycle of implementing recommendations and evaluating the implementation process are key to a successful audit.[11] The recurrent nature of the audits' recommendations suggest gaps in the audit cycles. While the four different national organisations are responsible for collating and using national perinatal mortality data to make relevant recommendations, the progression of recommendations at national level is beyond their remit. Relevant national bodies and stakeholders should be involved in the development of recommendations, as in NZ.[170] Given their knowledge and resources to propose timelines, assess feasibility and measure progress, stakeholders should be accountable for implementing recommendations.

National perinatal mortality audits are important for highlighting issues such as the detection and management of FGR, the prevention of preterm births and the need for public health campaigns on risk factors for perinatal deaths, and

therefore promoting the implementation of national initiatives to reduce these deaths. Multi-agency involvement and varying but complimentary approaches addressing both public awareness and the clinical care provided in the maternity services can address multiple issues concurrently, as the SBLCB (2016) and the Safer Baby Bundle (2019) have done in the UK and Australia respectively.[109,110]

3.6 Conclusions

Perinatal mortality rates in high-income countries are falling, however preventable perinatal deaths still occur. National perinatal mortality audits play an important role in identifying risk factors and deficits in clinical care provision and in making recommendations for change. If these recommendations are not implemented, further preventable deaths may occur. This study highlights how some of the main issues identified in perinatal mortality audit reports are ongoing and common to several high-income countries. It is time to share the learning and successes from these audits and resultant health service initiatives internationally.

Table 3. 1: General Information on the National Perinatal Mortality Audits

Name of organization	**Country (year of inception)**	**National set-up**	**Standardised data collection**	**Total number of births in the country (from gestations included) 2018**	**Number of perinatal deaths (stillbirths + early neonatal deaths) 2018**	**Other information**
National Perinatal Epidemiology Unit (NPEU), Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK)	United Kingdom (since 1993)	1 central office and team, Nominated staff in each maternity unit to notify deaths	Yes, electronic (Perinatal and Infant Death data entry)	735,745 (>/= 24 weeks)	3403 (>/= 24 weeks)	Varying topic-based confidential case reviews (enquiry) carried out Electronic National Perinatal Mortality Review Tool in use to support high quality standardised local perinatal reviews
Perinatal & Maternal Mortality Review Committee (PMMRC)	New Zealand (since 2005)	1 national committee with a national coordinator, 1 or more designated local	Yes, electronic	59,258 (>/= 20 weeks)	566 (>/= 20 weeks)	As well as filling out the electronic forms, a local group will review the death and send extra information to the PMMRC

		coordinator(s) in each district health board				
Perined	Netherlands (since 2010)	1 central office and committee, 10 regional teams which intermediate with the approx. 85 local teams	Yes, electronic	162,464 (>/= 22 weeks)	1207 (>/= 22 weeks)	2-3 audit sessions per year per hospital, depending on the case load Teams are trained in multidisciplinary audit methodology and implementation skills (www.actiontoolkit.nl)
National Perinatal Epidemiology Centre (NPEC)	Ireland (since 2008)	1 national centre and Perinatal Mortality Group, 1 coordinator in each maternity unit	Yes, electronic (Perinatal Death Notification Form)	61,084 (>/= 24 weeks)	295 (>/= 24 weeks)	Data collected and analysed by the team in the national centre, unit-specific reports provided to each maternity unit

Table 3. 2: Public Health Campaign on Modifiable Risk Factors

Report	Year	Recommendation summary	National initiative or public information available
NPEC Perinatal Mortality in Ireland Report	2014, 2015 2016, 2017	A public health education programme on perinatal deaths and modifiable risk factors should be developed.	Health service website with general advice on pregnancy health: www2.hse.ie/pregnancy/ (as part of mychild.ie) And smoking cessation help: www2.hse.ie/quit-smoking/
MBRRACE-UK Perinatal Mortality Surveillance Report	2016	Public health initiatives should continue to be developed to reduce the impact of known risk factors for stillbirth and neonatal death; for example, smoking and obesity.	**Saving Babies' Lives Care Bundle (NHS England):** Element 1: Reducing smoking in pregnancy by testing carbon monoxide at booking appointment and refer as appropriate Element 3: Raising awareness of reduced fetal movement by providing advice leaflet to all pregnant women
	2017	Commissioning organisations should review mortality rates alongside their high risk population characteristics to facilitate the development of public health initiatives and to target focused interventions.	Health service website with general pregnancy advice: www.nhs.uk/conditions/pregnancy-and-baby/to-do-list-pregnant/ Our Chance safer pregnancy campaign: 25 short videos on important pregnancy issues (2016) https://www.bestbeginnings.org.uk/our-chance
Annual Report of the PMMRC, New Zealand	2013	That all maternity care providers identify women with modifiable risk factors including improving uptake of periconceptual folate, smoking cessation, advice to women and	The New Zealand Guidelines for Helping People to Stop Smoking (Ministry of Health, 2014) Alcohol and Pregnancy: A practical guide for health professionals (Ministry of Health, 2010)

		appropriate management of decreased fetal movements	Government website with general pregnancy advice: www.health.govt.nz/your-health/pregnancy-and-kids/pregnancy
		Offer education to all clinicians so they are proficient at screening women, and are aware of local services and pathways to care for smoking, alcohol and other substance use	
	2016	The Ministry of Health and DHBs to develop, in consultation with young mothers, acceptable and safe methods for mothers under 20 years of age to access and engage with care in order to achieve equitable health outcomes, including smoking cessation	**Update in 2014 report on previous recommendation:** District Health Boards are implementing strategies to address modifiable risk factors, strategies include early screening and encouraging women to: engage early with a lead maternity carer (LMC); take folic acid and iodine; eat well and be active; avoid alcohol, recreational drugs and smoking. Examples of programmes include: 5 Things to Do in the First 10 Weeks, SMILE Pregnancy Care Actions, Healthy Babies Healthy Futures

Table 3. 3: Detection of Fetal Growth Restriction (FGR)

Report	Year	Recommendation summary	National guidelines/initiatives
NPEC Perinatal Mortality in Ireland Report	2013 2014 2015 2016 2017	The generation of customized birth weight centile charts for every woman during pregnancy is recommended and concomitantly, staff should be trained to plot symphysial fundal height and scan weight estimates	Fetal Growth Restriction Guideline - Recognition, Diagnosis and Management (RCPI/HSE, 2014)
	2016 2017	A multidisciplinary working group should be developed to address a national standardised approach to the detection of FGR. A national approach should also evaluate the use of a standard growth curve across all Irish maternity units.	No update on this recommendation available
MBRRACE-UK Perinatal Mortality Surveillance Report	2015	Trusts and Health Boards should ensure that systems are in place to implement appropriate national guidance related to monitoring fetal growth.	The Investigation and Management of the Small-for-Gestational-Age Fetus (RCOG, 2013) **Saving Babies' Lives Care Bundle (NHS England) Element 2:** Risk assessment using a risk stratification algorithm and surveillance for fetal growth restriction using serial ultrasound scans as indicated

Annual Report of the PMMRC, New Zealand	2013	That all maternity care providers identify women with modifiable risk factors including the antenatal recognition and management of fetal growth restriction	Guideline for the Management of Suspected Small for Gestational Age Singleton Pregnancies after 34 Weeks' Gestation (New Zealand Maternal Fetal Medicine Network, 2013)
		Assessment of fetal growth should incorporate a range of strategies including: assessment and appropriate referral for risk factors for fetal growth restriction, ongoing assessment of fetal growth by measuring fundal-symphysial height; if fetal growth restriction is confirmed by ultrasound, appropriate referral and assessment of fetal and maternal wellbeing and timely delivery are recommended	The PMMRC supports the Ministry of Health initiative to explore the evidence and validate the use of customised growth charts, and to investigate the appropriate way to incorporate these into the national maternity record. **Update in 2014 report** on previous recommendation: The Ministry of Health supports the implementation of the UK Perinatal Institute's GROW (Gestation Related Optimal Weight) system for assessing fetal growth in New Zealand.
			Update in 2015 report: The Growth Assessment Protocol (GAP) (based on GROW) from the UK Perinatal Institute is being progressed, making the GAP application freely available to clinicians; however, they need to be trained and accredited to use it. The Ministry of Health is working on ensuring funding is also available for evaluation of the GAP.

Table 3. 4: Prevention of Preterm Birth

Report	Year	Recommendation summary	National initiative/guidelines
NPEC Perinatal Mortality in Ireland Report	2017	Establishment of a national working group to look at preterm birth and how it is best addressed	No update on this recommendation available
MBRRACE-UK Perinatal Mortality Surveillance Report	2015	Identify the extent to which deaths before 32 weeks' gestational age are avoidable and to try to develop practices and policies which could reduce potential variation in management across the UK	Preterm labour and birth guideline (National Institute for Health and Care Excellence, 2015)
	2017	Renewed efforts need to be focused on implementing existing national initiatives, emphasis should be placed on reducing preterm birth	**Saving Babies Lives Version 2 (NHS England, 2019) Element 5:** Assess all women at booking for the risk of preterm birth (including smoking cessation, need for aspirin, testing for bacteriuria); Pathway for women at risk of preterm birth (including appropriate cervical length surveillance and use of cervical cerclage); Optimising time and place of birth (including medications and multidisciplinary team involvement); Examine outcomes and pathways, demonstrating continuous improvement
Annual Report of the PMMRC, New Zealand	2013	That all maternity care providers identify women with modifiable risk factors including prevention of	

		preterm birth and management of threatened preterm labour	
	2016	The PMMRC recommends the Ministry of Health establish a multidisciplinary working group to review current evidence for implementation of a preterm birth prevention program such as that implemented in Western Australia	Reducing preterm birth by a state-wide multifaceted program: Counselling at the time of a preterm birth to outline the strategies likely to be recommended for their next pregnancy; Antenatal care is available to allow women to register early (including attention to modifiable risk factors); Referral for specialist consultation in the first trimester (including cervical surveillance, cervical cerclage or vaginal progesterone); Counselling around signs and symptoms of preterm birth
		Lead Maternity Carers and District Health Boards employ strategies to reduce preterm birth by targeting women with a previous preterm birth at less than 34 weeks	
	2017	The Ministry of Health should resource, support and facilitate the development of a national guideline for the provision of care of mothers and infants facing delivery at <25 weeks' gestational age	

Table 3. 5: Perinatal Mortality Data Collection and Review

Report	Year	Recommendation summary	National initiatives , Summary of initiative
NPEC Perinatal Mortality in Ireland Report	2013	A multidisciplinary approach, including perinatal pathology, is recommended in the audit of perinatal deaths at unit level.	
	2013 2014	Funding should be provided by the Health Service Executive (HSE) to ensure that staffing levels allow protected time for clinical audit.	Update of previous recommendation: All Irish maternity units now collect and submit data on perinatal deaths through the NPEC national audit on perinatal mortality (2017)
	2015 2016	All maternity units should continue to collect and submit anonymised data on perinatal mortality (2013, 2014, 2015)	
	2017	The establishment of an enquiry for stillbirth and neonatal deaths should be considered in order to enhance the lessons which may improve care.	This recommendation is being processed by the National Women and Infants Health Programme (from 2018)
MBRRACE-UK Perinatal Mortality Surveillance Report	2013 2014	All Trusts and Health Boards to provide data which is complete, accurate and reported in a timely manner	
	2015	All Trusts and Health Boards should endeavour to continue to improve the quality and completeness of data reported	
		Close monitoring of mortality rates is required to ensure that the decline in rates of stillbirth is continued	
	2016	All stillbirths and neonatal deaths should be notified via the web-based system as soon as possible following the death	

		Trusts and Health Boards should ensure that the data provided is of the highest quality and endeavour to improve the quality and completeness of data reported	
		A national forum should be established across the UK to agree an appropriate benchmark against which stillbirth and neonatal mortality rates should be monitored	No update on this recommendation available
	2017	Trusts and Health Boards should aim to notify all deaths within 30 days of the death occurring. Mechanisms for timely notification should be incorporated into local processes, and must have adequate staff, time allocation and resources.	In 2018 two-third of deaths were notified within the 30 day benchmark time (an improvement from 55% in 2017)
		Trusts and Health Boards should use the MBRRACE-UK real time data monitoring tool to monitor the completeness of their data.	
Annual Report of the PMMRC, New Zealand	2014 2015 2016	That district health boards with rates of perinatal related mortality significantly higher than the national rate review, or continue to review, the higher rate of mortality in their area and identify areas for improvement.	Update on initiatives relating to this recommendation from three districts (2017)
		Continued support and funding is required for District Health Boards for collection of complete perinatal mortality statistics.	This recommendation has been integrated into core work by the Ministry of Health.

Chapter 4 - Implementation of a national incident management framework: how does it apply to local perinatal death reviews?

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Article Under review in Maternal and Child Health Journal

Chapter 4 - Implementation of a national incident management framework: how does it apply to local perinatal death reviews?

4.1 Abstract

Objectives

Stillbirths and neonatal deaths are devastating for families (and health care staff involved), especially when the death is unexpected. Local perinatal death reviews aim to identify contributory factors and change maternity care to prevent recurrences. This study analysed the current local Serious Incident Management Team (SIMT) perinatal death review processes in Irish maternity units, comparing them to the National Incident Management Framework (NIMF), and international perinatal mortality review procedures.

Method

Quantitative and qualitative data on local SIMT reviews nationally were collected via an electronic questionnaire. Members (2-3) of the management teams in the 19 Irish maternity units were asked to participate (January-July 2019). All units responded. The characteristics of SIMT processes (e.g. cases reviewed, members, timeframe, parents' involvement) in the different maternity hospitals were analysed.

Results

Despite the NIMF, there was little consensus across the units regarding which cases were reviewed, the SIMT members and the timeline of reviews. Clinical midwifery managers and administrative staff were underrepresented at meetings, 27% and 13% of meetings respectively. Four units (22%) stated that reviews took >6 months to be completed. It was not standard practice to involve bereaved parents in local review processes in all units.

Conclusions

A nationally co-ordinated system would ensure that all local perinatal death reviews are of the same standard, with equivalent multidisciplinary review teams following an agreed timeframe and producing comparable reports with implementable recommendations. Delays in reviewing events and report dissemination represents long waits for answers for the affected families, and prevents local learning opportunities.

Significance

Perinatal death reviews are important to identify contributory factors, to recognise weaknesses in healthcare services and provide learning opportunities, thus prevent future deaths. Review teams should be multidisciplinary including administrative support. A thorough local incident review requires significant time and resources. Bereaved families should be at the centre of perinatal mortality reviews.

There currently is no standardised process for perinatal death reviews across Ireland. A nationally co-ordinated system should be used, adhering to agreed timeframes and producing comparable reports with implementable recommendations. A shift from a blame-culture is needed to focus on prevention, learning from adverse events and, thus achieving best-practice.

Keywords

Perinatal mortality, stillbirth, bereavement, parents, maternity hospital, incident management

4.2 Introduction

Pregnancy is a natural physiological process, thus outcomes are generally expected to be positive. While there are many minor pregnancy complications which can occur, outcomes such as unexpected term perinatal deaths (stillbirths + neonatal deaths) are uncommon and devastating. Therefore, it is key that these events (or incidents) are appropriately investigated, the bereaved families are fully informed and, if indicated, changes in maternity care are made.

Incident reviews in health care, such as mortality reviews, are carried out to establish what happened; how and why an adverse outcome occurred.[192] Local mortality reviews aim to identify any modifiable contributory factors, and to prevent recurrences of events if possible. There is general consensus that review teams should be multidisciplinary to allow identification of all contributory risk factors and optimise learning.[11,106,130,193] Administrative support is important to arrange local meetings and take minutes, thereby maximising time spent on discussing cases.[193] A thorough local incident review requires significant time and resources.[193]

The World Health Organization (WHO) published a comprehensive perinatal death review guide in 2016 (Making every baby count: audit and review of stillbirths and neonatal deaths), which outlined how to "review selected individual cases for systematic, critical analysis of the quality of care received, in a no-blame, interdisciplinary setting" as well as collecting statistics for comparison.[11]

To reduce the number of term birth-related perinatal deaths and brain-injuries (encephalopathy) in the United Kingdom (UK) the Royal College of Obstetricians and Gynaecologists commenced the quality improvement programme "Each Baby Counts" (EBC) in 2015.[15] This programme showed that midwives (98%) and obstetricians (95%) were most commonly present for local reviews in 2017, however senior management was involved in less than half of reviews.[194] Of the reviews from 2017 included in EBC, 82% used specific though varying review methodologies.[194] Furthermore, the Perinatal Mortality Review Tool (PMRT-UK)

has been launched within the MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries) program in 2018 to standardise local reviews across the UK.[106]

In the Netherlands, nationwide local perinatal audits were set up in 2010; local cases were reviewed systematically by a multidisciplinary team (including an external chairperson) to identify contributory factors and make recommendations to improve the quality of care.[85] A 2016 law in the Netherlands mandated the submission of investigation reports to the national regulatory body within 8 weeks of the incident, to ensure a timely local review takes place for all incidents (that have caused serious harm or death).[135] Furthermore, Dutch hospitals are mandated to involve families in all incident investigations since 2016.[135]

In 2017, there were 381 perinatal deaths (all stillbirths and neonatal deaths >24 weeks' gestation and/or weighing >500g) reported in Ireland.[195] The Irish Health Service Executive (HSE) recommended for a Serious Incident Management Team (SIMT) to be set up in all hospitals to review serious incidents (also called reportable events) locally. Since 2015, these include all perinatal deaths or encephalopathy of infants >37 weeks' gestation and/or weighing >2,500g.[119]

The 2018 Irish National Incident Management Framework (NIMF) was developed to provide all clinical services "with a practical and proportionate approach to the management of incidents and seeks to place a particular emphasis on supporting the needs of service users, families and staff".[91] According to this framework, any serious incident should be reported within one working day and discussed at the SIMT meeting (within 5 days of notification of the incident) including the review level and approach to be taken.[91]

Perinatal death reviews are important to identify modifiable, contributory factors, to recognise weaknesses in healthcare services and to provide learning opportunities, thus prevent future deaths, if possible.[11,130,196] Furthermore, these reviews are an important part in promoting and ensuring continuous quality improvement in maternity services.[196]

The hypothesis for this study was that the local perinatal death reviews in Irish maternity units differ currently between units. The aim of this study was to analyse the current status of SIMT perinatal death review processes in the 19 Irish maternity units and compare them to the NIMF, as well as study other international perinatal mortality review procedures.

4.3 Methods

A service evaluation of the local SIMT perinatal death reviews in Ireland was carried using an electronic survey. An electronic questionnaire regarding SIMT processes was sent to the management team (including the clinical director, director of midwifery, general manager, lead obstetrician and/or lead neonatologist as indicated) of all 19 maternity units using a web-survey platform, between January-July 2019. Two to three individuals were asked to participate in each of the units.

Questions (31 in total) on SIMT processes, parental involvement in reviews and personal professional practice were included (Table 4.1).

Table 4. 1: Sections and focus of the questions included in the survey

Section	**Questions regarding:**
Name of Maternity Hospital	
Serious Incident Management Team (SIMT) reviews	Local SIMT Members of SIMT Timeframe of review Report submission Type of cases reviewed External input Bereaved parents involvement
Professional practice	Personal views and opinion of review processes

The varying characteristics of SIMT meetings in the different maternity hospitals nationally were analysed using descriptive statistics according to: type of cases reviewed, members of the review team, timeframe of the reviews, dissemination of the final report, bereaved parents' involvement. Results were compared to standards outlined in the NIMF.

Participants were also asked to share their views on the local review meetings. These free text answers were grouped into positive, mixed and negative comments with a frequency count.

The study was approved by Clinical Research Ethics Committee of the Cork Teaching Hospitals (No: ECM 4 (q) 16/10/18, ECM 3 (ddd) 06/11/18).

4.4 Results

In total we received 25 responses (22 complete questionnaires, 3 partially-completed) from the 19 maternity hospitals. More than one questionnaire was received from 5 units; 2-3 participants responded from each of these units. Individual names or specialties were not recorded. Responses were grouped and cross-checked by hospital to examine potential conflicting answers within the same hospital. There were conflicting answers provided to only one question (referring to type of cases reviewed) by management of one hospital. Twenty-two individuals responded to the open-text question on their personal views of the local reviews.

4.4.1 Type of cases reviewed

When asked if all cases of encephalopathy, intrapartum deaths (the death of a baby during labour) and perinatal deaths without congenital anomaly were discussed at the SIMT meetings 12 hospitals replied Yes, five replied No, one did not respond, and for one hospital, two conflicting answers were recorded.

4.4.2 Members of the SIMT

Sixteen (84%) of the 19 Irish maternity units reported having their own SIMT. Two further units reviewed their cases in the wider hospital group SIMT and one unit was incorporated into the co-located general hospital SIMT. Clinical midwifery managers (Figure 4.1), doctors-in-training (1 unit only), consultant pathologist (1 unit only) and administrative staff (2 units only) were underrepresented at SIMT meetings. In 12 (63%) of the units, members varied depending on the incident (e.g. additional clinicians from neonatology/paediatrics or anaesthetic departments). In one unit the director of midwifery (DOM) was the only maternity service expert member of the SIMT and in a further two units this was also the case, with consultant obstetricians joining those SIMTs only as required.

Only three units (17%) reported frequently seeking expert external input (when required or requested by parents) into the local reviews. Thirteen units sought this input "sometimes" (72%) and two (11%) "rarely".

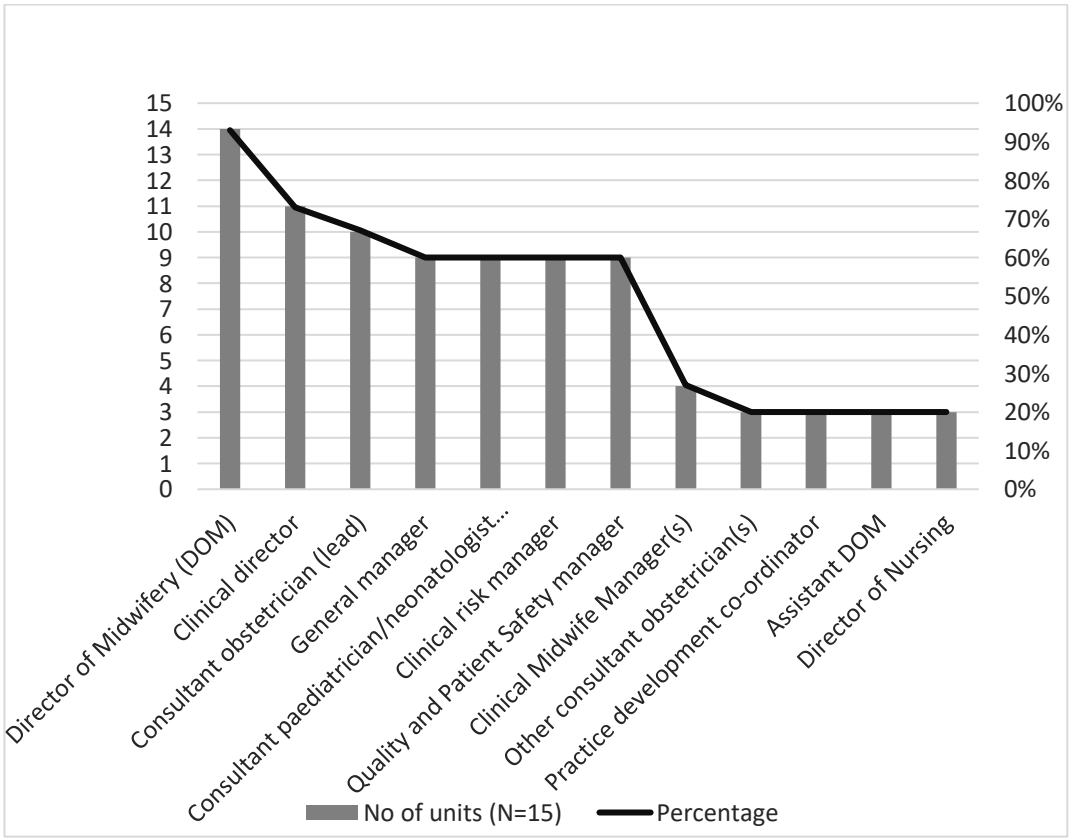

Figure 4. 1: Members of the SIMT in the maternity units

4.4.3 Timeframe of the SIMT reviews

The timeframe of SIMT meetings and reviews varied considerably between, and at times within, units (Figure 4.2). Timeframes varied depending on the type and complexity of the incident. Routine SIMT meetings were scheduled: weekly in 11%, fortnightly in 17%, monthly in 39% and variably in 33% of units, respectively. Four units (22%) stated that reports were published more than 6 months after the incident occurred (Figure 4.2).

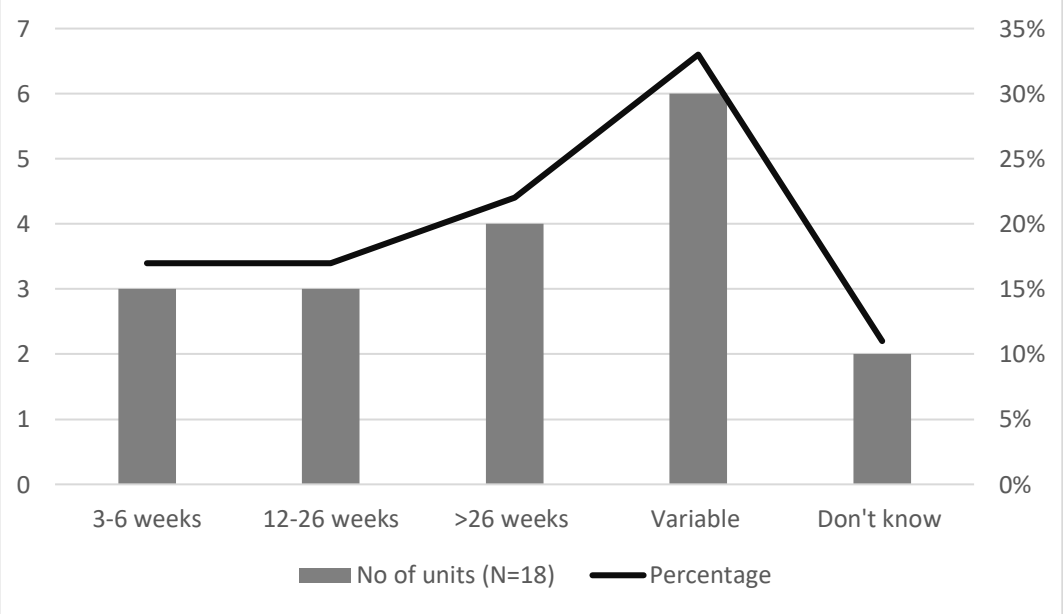

Figure 4. 2: Timeframe of SIMT reviews in the maternity units

4.4.4 Dissemination of the final report

Generally, reports were submitted to management personnel (16/18 units). In one-third of units the final review report was sent to the staff and patients involved. Two-thirds of units submitted reports to multiple recipients (e.g. local management and stakeholders or local quality/patient safety personnel). One unit uploaded reports onto the secure internal electronic hospital-management-information-system (Q-Pulse) to disseminate learning outcomes.

4.4.5 Bereaved parents' involvement

The bereaved parents were frequently informed of the review in 11 units (58%), sometimes in 4 units (24%) and rarely in one (6%). Three units (17%) stated that the final review report was provided to the bereaved parents.

4.4.6 Participants' views on the reviews

Twenty individuals gave comments on their own personal involvement on the local perinatal death review process and, their views and opinions on this (Table 4.2). Most participants (91%, n=20/22) found these meetings relevant to their personal clinical practice.

The overall opinion on the current review process varied. Some felt it was "working well", "robust" and "valuable", whereas others found it "difficult", "cumbersome" and "not particularly fit for purpose". Eight individuals had mixed feelings on the current reviews, stating that while the process was valuable for staff, the parents and/or the hospital, it required significant co-ordination and resolve. Six comments were positive and one negative (Table 4.2). Five individuals commented on the way they were involved in reviews only without providing their personal views.

The workload was described as being significant, including the identification, preparing and coordinating of cases/documents. While some felt the current process was comprehensive, lacking resources were highlighted as a concern. This, as well as the time commitment required, were described to add delays in completing the reviews in a timely manner.

It was noted that learning opportunities arise from the reviews, however at times these were not well disseminated or changes in clinical services not noticeable (Table 4.2). Furthermore, one person mentioned that implementing recommendations from the reviews was "often challenging".

Three individuals described the involvement in the review process as "stressful" for clinical staff; the importance of supporting, as well as debriefing staff, was

appreciated. Initiatives implemented to support staff after an event or during the review (e.g. After Action Reviews) were mentioned by three participants. Five individuals described meeting and debriefing bereaved parents as part of their role, sometimes more than once during the review process. Open disclosure was described to be part of this aspect of care. Supporting families after a perinatal death, giving them feedback after the review was felt to be “important”, “so worthwhile” and was said to help them in their grieving process (Table 4.2).

Table 4. 2: Personal opinions on the local perinatal death reviews

Positive	"We (Clinical Risk Managers) are involved in all SIMT reviews. We coordinate the Clinical Incident Review Group meetings where all priority incidents are reviewed by a multidisciplinary team and attend the Perinatal M&M discussion group meetings. The *hospital name* review process is evolving and continually reviewed and updated in accordance with national requirements and is currently working well." (Response 4)
Mixed	"Can be an intimidating situation. Better emphasis on supporting staff through reviews since clinical incident framework introduced in 2018" (Response 5) "I take a very keen interest into the care processes that are afforded to the families. I would be involved in the debriefing of some of the families. While the review process can be extremely long and time consuming it is so worthwhile to support the families in their grieving process and dealing with that loss of a life. Professionally I feel that the reviews need to be opened up to all staff for them to review so that the impact of findings whether good or bad can have a more widespread effect." (Response 18) "I feel it is a valuable process, difficult as it can be sometimes however, it can highlight clinical issues but also good practices. The actually process of writing up a review report is extremely time consuming and while it effects all the individuals involved with a specific case I'm not totally convinced that it changes the practices of others unless they have been directly affected. I think human factors get involved, particularly complacency within practice for some individuals especially if there is no impetus to improve or develop compliance with standards on an individual basis rather

	than an organisational one. e.g. 'that is someone else's job' " (Response 6) "They are a significant workload. They are stressful for the staff involved which has an impact on staff morale and retention of staff. The process of incident reviews has been comprehensive and robust. The quality of the recommendations is variable and often challenging to implement. There have been improvements in the quality of service provided arising from some reviews but there is a large emphasis on what has gone wrong within the department rather than what is being done well." (Response 12)
Negative	"The current review process as outlined in the HSE guidelines is incredibly cumbersome, time consuming and not particularly fit for purpose. It results in lengthy and unacceptable delays for parents and staff. It requires streamlining and a practical approach to be rolled out and adopted nationally to ensure consistency of process and outcomes. It relies on busy staff to undertake the reviews and often staff who have been involved in one don't want to undertake another as they've taken up huge amounts of time, with little resources." (Response 16)

4.5 Discussion

Our study showed that all 19 Irish maternity units discussed serious incidents at SIMT meetings, in line with the Irish National Incident Management Framework (NIMF). However, despite this framework, there was little consensus across the 19 units regarding which cases were reviewed, who were the participating members of the SIMT and the timeline of reviews from incident to completed report. By comparing our findings to examples from the international literature, we discuss how these processes can be standardised at a national level, using the NIMF.

Previous research has highlighted that, ideally, each member of the review team should have a defined role; either as an expert in their field or in investigation methods, or as part of management to create relevant learning opportunities.[197] The NIMF recommends SIMTs to include senior staff; a member of the management team, a human resources manager and other professionals (e.g. clinical expertise relating to the incident, Quality and patient safety (QPS) manager) as necessary.[91] In line with the NIMF, in our study, in 93% of SIMTs hospital management were included as members. However 20% of SIMTs did not consistently include more than one maternity service expert. Even though the NIMF states "it may be decided to involve others" the inclusion of clinical expertise is not mandated.[91] Shah et al compared local reviews with external reviews of 33 severe maternity incidents, and similarly to our study the local reviews did not consistently involve both midwives and obstetricians i.e. experts in their fields.[198]

The WHO guide (Making every baby count) explained how national guidelines may mandate that specified staff positions have responsibility to oversee the review system, and therefore the relevant tasks form part of their job descriptions.[11] Like the WHO, the 2019 British PMRT report recommended for clinical experts to have allocated time included in job plans to participate in reviews.[106] However, 22% of the British PMRT reviews were not multidisciplinary.[106] A multidisciplinary review

team is essential to identify and evaluate contributory factors from varying but complimentary professional angles.[199]

The lack of administrative support was also highlighted in our study. Administrative staff complete time-consuming but important tasks (e.g. gathering documentation, timely responses) essential for the adequate running of the review process.[193] The WHO guide states that "supportive administrators and health professionals can make all the difference between success and failure" of perinatal mortality reviews.[11]

An external person in reviews can provide unbiased opinions on the clinical care provided, including constructive criticism without blaming individuals.[198] Our study highlights that expert external input is not routinely sought for local SIMT reviews in Irish maternity units. Similarly, in the UK, external input was sought for less than <10% of reviews although the PMRT report recommends at least one external panel member to be part of each local review group.[106] In 2013, Ireland had the third lowest number of obstetricians/female population in the Organisation for Economic Co-operation and Development (OECD)[43], therefore recruiting experts as external reviewers may be difficult as this removes them from their own understaffed service. One individual in the study commented how their unit "struggles with expert external investigations due to the expertise and time commitment required". This was echoed by others in the published literature stating that external review panels are costly and labour intensive.[196,198]

External input into reviews can be time-consuming. The WHO guide recommended for deaths to be reviewed within one week of the event.[11] In Ireland, the timeframe advised by the NIMF from incident notification to submission of the final report to the review commissioner is a maximum of 125 calendar days (18 weeks).[91] Despite this there currently is no consensus across the maternity units regarding how often meetings occur or how long serious incident reviews take with 22% of units requiring more than 26 weeks.[91] For the UK-PMRT reviews the median time from death to report publication was 17 weeks,

which compares to the recommended maximum 18 weeks in the NIMF.[91,106] A delay in reviewing events and report dissemination means a long wait for answers and closure for both the affected families and staff. Conversely, with the short-commanded timeframe of 8 weeks to complete local reviews in the Netherlands, Kok et al noted difficulties with involving families appropriately amid their bereavement and practical needs.[135]

The WHO guide explains how collated review reports can be shared with local stakeholders and relevant local services, as well as national authorities, for dissemination and implementation of learning points.[11] The UK-PMRT has a build in function, where a report can be generated at the end of the review using the data entered into the tool.[106] This report can be included in the medical records for discussion with the parents, as reference for future pregnancies and for distribution of generated actions plans to the relevant health boards or committees.[106] Like the WHO guide, the NIMF emphasised the importance of shared learning by dissemination of findings and recommendations through discussions at the local QPS committees.[91] In our study, only a third of hospitals or less reported submitting the final reports to QPS personnel, relevant stakeholders and the hospital group SIMT. This suggests that currently the findings of reviews are not widely shared, therefore limiting local and national learning. In addition, the NIMF recommended for the final report to be provided to the family/affected person in a supportive manner (i.e. with contact by phone/in person).[91]

Findings and recommendations from the local reviews can be valuable to families, the maternity unit, as well as the staff involved. From the perinatal death reviews bereaved parents may get answers to questions regarding the cause of death, which can help them to process their bereavement and plan for future pregnancies.[130] In line with recent updated Irish legislation, the NIMF highlights the importance of immediate open communication (and disclosure) with the affected person and family after an adverse incident has occurred.[91] A named liaison person should be assigned to the family and the staff involved, so they can

be made aware and be part of the review undertaken.[91] It has been shown that patients can help to identify contributory factors from incidents affecting their care.[200]

Currently it is not standard practice to involve bereaved parents in the local review process in all Irish maternity units. Bereaved parents are debriefed after the review is completed to offer them the key findings; however, our study showed that the final review report was provided to the parents infrequently. Unfortunately, the above suggests that currently families are not consistently at the centre of reviews into their cases contrary to the recommendation made by the Lancet series on Child death.[130]

Patient satisfaction with the review process can vary depending on the level of involvement.[135] Kok et al described that families want to be involved in incident reviews, and that by involving families, trust in the health service can be restored and complaints avoided.[135]

4.1. Limitations

This study focussed on the maternity units in Ireland, gathering self-reported information from 1-3 managers on the local SIMT review structures. However, national data from all 19 units was obtained in this study, giving detailed information on the local review process and its main benefits and challenges (with only one unit providing <50% of the requested information).

Further research is required examining the challenges of implementing review recommendations, improvement planning and monitoring, and the involvement of bereaved parents in the local review process.

4.2. Conclusions for practice

Despite the NIMF, there currently is no standardised process to perinatal death reviews across the 19 Irish maternity units. A significant challenge to completing reviews in a timely and comprehensive fashion is a lack of resources, both in relation to staff and time. Additionally, clinicians (especially clinical midwifery

managers, doctors-in-training) and external experts were underrepresented at review meetings.

It is essential to promote parents' involvement in reviews; it allows them to give important clinical feedback, receive answers to questions regarding their clinical care while potentially restoring trust and confidence in the services.

To complete comprehensive reviews, the multidisciplinary review team needs to have the appropriate resources available (i.e. protected time, facilities, managerial and administrative support).

It is important to shift from a blame-culture to a focus of prevention by learning from adverse events, and thus achieving best practice. In line with research on child death reviews in the USA, England, Australia and New Zealand, and the WHO, we recommend a systematic local approach to reviews to identify the reason and circumstances of perinatal deaths.[11,130,199]

A nationally co-ordinated system (e.g. using a standard format/tool) based on the NIMF would help to ensure that all local perinatal death reviews in Ireland are of the same standard and follow the same structure/method. It is important that equivalent multidisciplinary review teams adhere to an agreed timeframe and produce comparable reports with recommendations, which are implemented. Appropriate national legislation (as in England, New Zealand, the Netherlands) could help to standardise review processes and ensure adequate resources are allocated for these processes.[130,135]

Chapter 5 - Irish inquiry reports relating to perinatal deaths and pregnancy loss services

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Chapter 5 - Irish inquiry reports relating to perinatal deaths and pregnancy loss services

5.1 Abstract

Objective

External inquiries are carried out following specific adverse events in healthcare, many in maternity care; to identify issues and make recommendations to improve standards of care.

Methods

Ten publically-available national inquiry reports published between 2005-2018 relating to pregnancy loss services, were reviewed by 2 clinicians, separately, examining the content and recommendations from each report.

Results

A total of 258 recommendations were made in 9 reports (90%). Five inquiries (50%) clearly stated that affected families were involved and four (40%) involved affected clinical staff. In 9 reports (90%) recommendations included: increase workforce staffing and/or training, strengthen clinical governance, enhance adverse incident management and comprehensive data collection e.g. maternity outcomes. Only two inquiry reports (20%) stated that feedback was sought from key stakeholders prior to publication.

Conclusions

A collaborative and standardised inquiry process involving and supporting all persons affected as well as key stakeholders would ensure that all relevant issues are identified, recommendations are implemented and essential lessons are learned.

5.2 Introduction

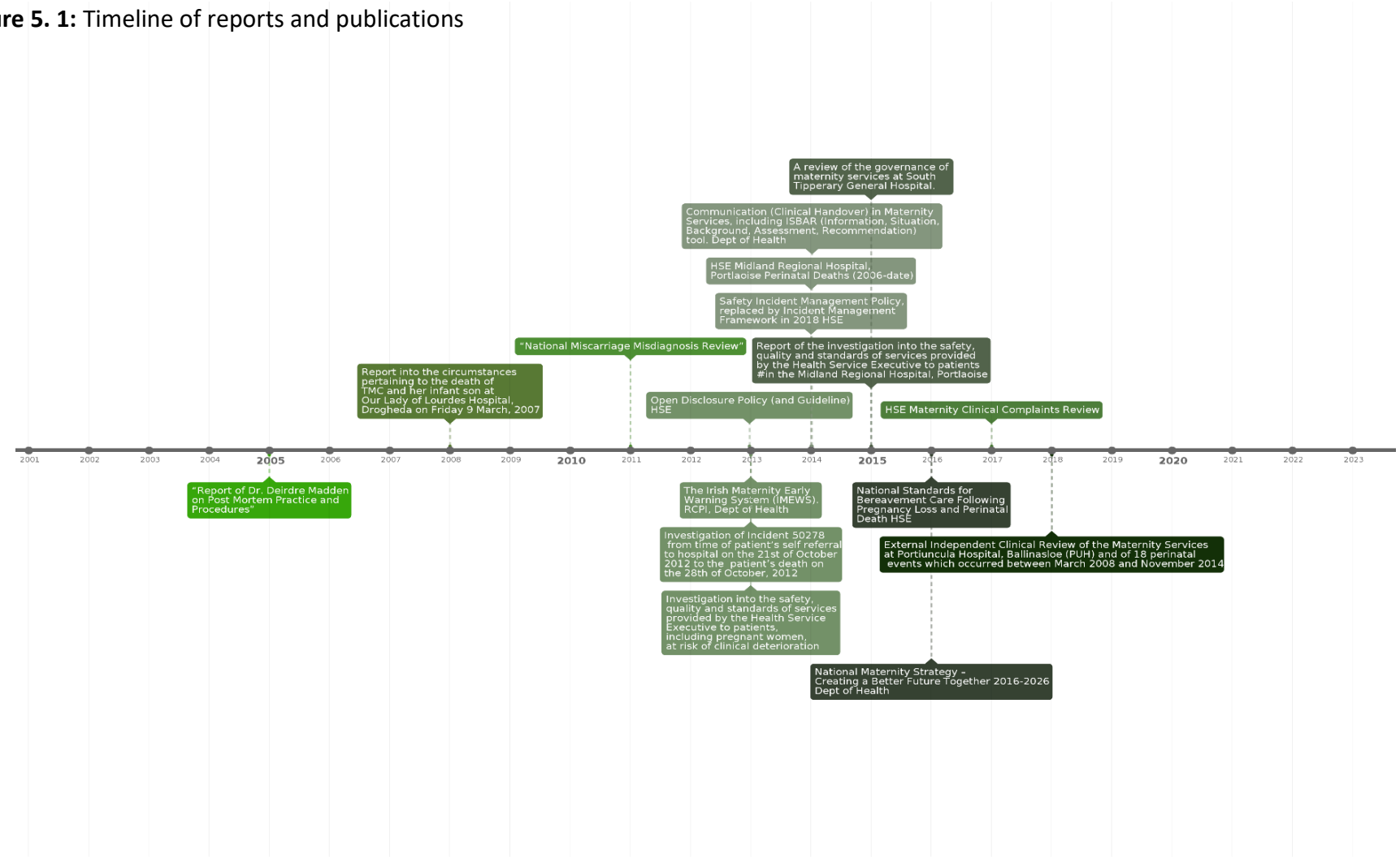
An external inquiry is established, when required, to examine issues of public concern or importance.[124] In the health services, inquiries aim to establish facts, identify modifiable factors after adverse outcome(s) and ensure essential lessons are learned, and thereby prevent a recurrence of the events.[126,201] An inquiry should always remain inquisitorial and avoid becoming adversarial.[201] For affected families and even the public, well-executed inquiries can contribute to restoring confidence and trust in health services, as well as providing resolution/closure.[126,201] Government and/or health service departments may commission an inquiry due to public pressure to respond to tragedy or to highlight areas of need for change.[126]

External inquiry teams or panels should be independent with no vested political or personal interest to the events under review.[124] Ideally, panels are made up of multidisciplinary teams with experts from various backgrounds (including healthcare professionals, risk or quality management personnel, support or patient representative groups and administrative support) with defined roles and access to all relevant documentation.[91] An external inquiry requires a significant commitment of time and resources; therefore it can be a costly endeavour.[126]

Many external inquiries related to maternity services in Ireland have been carried out over the last 15 years, often after negative media reporting of adverse events (e.g. maternal/perinatal deaths) that have occurred. The aim was to identify issues in the maternity care provided to pregnant women, and to make recommendations based on these findings to improve the standard of care. The Health Service Executive (HSE) Incident Management Framework – Guidance 2018 (which replaced the HSE Safety Incident Management Policy 2014) advocates for recommendations to apply the SMART (i.e. specific, measurable, achievable, realistic or time-bound) principle to facilitate the development of clear and relevant action plans.[91] However, generated inquiry recommendations assessed in previous Irish and British research have not been consistently or entirely

implemented.[124,126,202] We hypothesised and aimed to examine and compare the general structure, methodology, findings and recommendations of 10 Irish inquiry reports (published between 2005 and 2018 relating to perinatal deaths and pregnancy loss services), in order to identify standardised or variable inquiry procedures and highlight recurring recommendations in the reports (Figure 5.2).

Figure 5. 1: Timeline of reports and publications



5.3 Methods

Ten publically-available national inquiry reports, published between 2005 and 2018 relating to perinatal deaths and pregnancy loss services, were identified from national inquiries into the maternity services in Ireland.[49,50,52–55,57,58,127,128] The focus of each report is outlined in table 5. 1 and the timeline for the reports' publication, as well as other relevant publications related to Irish maternity services are presented in figure 5.1. The ten reports were reviewed and assessed by 2 clinicians, separately, to compare and examine the content and recommendations made in each report.

Quantitative and qualitative data was collected using a standardised and specifically designed review tool (based on the HSE Systems Analysis Review Report Checklist). The review tool has 21 items divided into 6 separate sections which cover aspects such as: terms of reference, general content, review methodology and recommendations (See Appendix III). Where applicable, the answers were scored: Yes, Partial or No. The two reviewers met on three occasions and discussed any differences between report assessments until agreement was reached. Descriptive analyses of the main characteristics of the reports were carried out to give an overview of the terms of reference and inquiry review process, and to identify recurring themes in the recommendations.

Table 5. 1: Report focus and year of publication

Report	Focus of report	Year of publication
1	National paediatric post-mortem practice and procedures [49]	2005
2	Inquiry into the case of a maternal and perinatal death at a regional hospital [53]	2008
3	Identification of trends about the causes of miscarriage misdiagnoses [52]	2011
4	Inquiry into the case of a maternal death at a regional hospital [54]	2013
5	The safety and quality provided to pregnant women at risk of deterioration (based on findings in one regional hospital) [57]	2013
6	Perinatal deaths and related matters in one regional hospital (over 8 years) [50]	2014
7	The safety and quality provided to patients at one regional hospital, including maternity care [128]	2015
8	Governance of maternity services at one peripheral hospital [127]	2015
9	Evaluation of 203 maternity related complaints received by the HSE [55]	2017
10	Maternity services and 18 perinatal deaths at one peripheral hospital (over 6 years) [58]	2018

5.4 Results

5.4.1 Structure of the inquiry reports

The layout and length of the 10 analysed inquiry reports varied significantly. All but one had clearly defined sections. The make-up of the inquiry teams, the report commissioner and the manner the affected clinical staff and patient and/or family were involved in the review process is outlined in table 5.2. Half of the reports (n=5) clearly explained the inquiry methodology used (including reference to review tools). International, as well as national guidelines, were used as reference standards in 6 reports (60%). Three reports (30%) used national guidelines as reference standards; one report (10%) does not mention any guidelines. Four of the inquiry reports (40%) describe clearly how the relevant clinical staff were involved in the review, one further inquiry held interviews with staff representatives and in one inquiry interviews were carried out, but it is unclear from the report with whom. All affected families were involved in 4 inquiries (40%) and one further inquiry involved some of the affected families (table 5.2). Three reports (30%) outlined how the outcome of the inquiry was communicated to the families directly. Four reports (40%) commented on good aspects of care provided; however, the reports focussed mostly on unfavourable issues.

Table 5. 2: Report structure

Report	Length (pages)	Inquiry team	Commissioned by	Timeframe of review	Clinical staff involvement	Patient/family involvement
1	143	Only the author of the report named (Deirdre Madden)	Government	8 months	Submissions from hospitals	Written accounts by families submitted
2	15	Multidisciplinary team (4 people)	HSE NE	Not stated	Interviews with 31 staff members	Interviews with 2 family members
3	57	Multidisciplinary team (14 people making up 2 teams)	HSE	10 months	No, anonymous case reviews	No, anonymous case reviews but cases identified through patient helpline
4	108	Multidisciplinary team (8 people)	Hospital, HSE	7 months	26 interviews with key staff	Offered and declined
5	31	Multidisciplinary team (published in separate document)	HSE (Director General)	11 months	No	No
6	86	Not stated	Minister for Health	Not stated	Meetings with staff representatives	Meetings with some families
7	210	Multidisciplinary team (6 people)	Minister for Health	13 months	Interviews, group meetings, observations	Meetings with 15 families

8	11	Only the author of the report named (David Flory)	HSE	Not stated	Interviews (number not stated)	No
9	66	3 phases to the review, 3 teams	HSE	3 years	No	Telephone, mail and email correspondence; Meetings with external clinical experts in phase 2
10	136	Multidisciplinary team (8 people)	Chief Clinical Director, Hospital Group	3 years	Interviews with senior clinicians and managers; 201 separate staff interviews relating to specific cases	Open forum meeting, followed by private meetings with 9 families; 16 families interviewed regarding 18 specific cases

5.4.2 Recommendations made in the reports

All reports made recommendations; these were in clear sections in 9 (90%) reports (Table 5.3). A total of 258 recommendations were made in 9 (90%) reports (Table 5.3). Nine reports (90%) made nationally applicable recommendations. The SMART principle (1. Specific, 2. Measurable, 3. Achievable, 4. Realistic, 5. Time-bound) for developing recommendations as advocated by the HSE Incident Management Framework was fulfilled in only one report (Table 5.3).[91] The SMART principle describes elements that recommendations should have to promote implementation.[91] The recommendations were scored 1 for each element, to give a score out of 5 (Table 5.3). Recommendations were either discussed with key stakeholders or the organisation named responsible for implementation of recommendations in three reports (30%). A clear timeline for implementation of all recommendations was set out in only one report (10%).

Table 5. 3: Report recommendations

Report	Specific section for recommendations	Number of recommendations	Linked to findings	SMART *	Actions necessary to reduce recurrence risks highlighted
1	Yes	50 within 7 themes	Yes	3/5 (not time-bound, not consistently specific)	Yes
2	Yes	27 divided into 3 categories based on priority	Yes	4/5 (not time-bound)	Yes
3	Yes	20 within 6 themes	Yes	3/5 (not time-bound, not consistently realistic)	Partial
4	Yes	9 divided into 2 groups	Yes	4/5 (not consistently time-bound)	Yes
5	Yes	34 divided into local and national	Partial	2/5 (not consistently specific, measurable, time-bound)	No
6	Yes	53 (11 of these labelled overall recommendations)	Partial	5/5	Partial
7	Yes	8	Yes	2/5 (not consistently specific, measurable, time-bound)	Yes
8	No	Embedded into main text not highlighted as recommendations	No	Not possible to assess as recommendations embedded into main text	No

9	Yes	22 divided into 2 phases	Partial	4/5 (not time-bound)	No
10	Yes	35 within 5 themes	Yes	4/5 (not time-bound)	Yes

*Specific, Measurable, Achievable, Realistic, Time-bound

Themes generated from the recommendations and the frequency (%) with which these were made in the reports are illustrated in figure 5.2. Other recommendation themes included: maintenance of professional competence (30%), reviewing legislation (e.g. Coroners Act, Civil Registration Act, Termination of pregnancy) (30%) and perinatal post-mortem consent and procedure (20%).

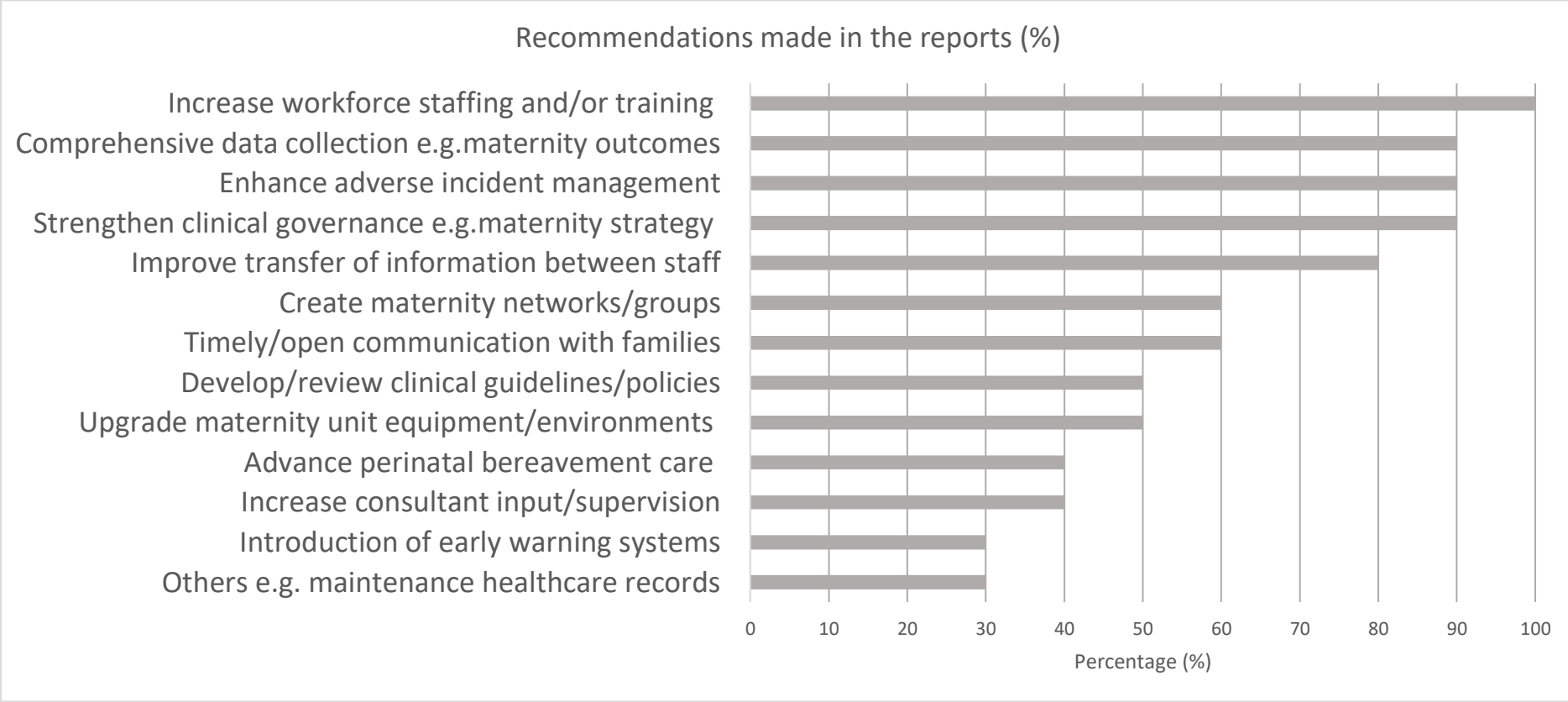


Figure 5. 2: Themes and frequency of recommendations

5.5 Discussion

We examined and compared the general structure, methodology, findings and recommendations of ten inquiry reports in detail. The inquiries were commissioned by the HSE or the Department of Health. Only 5 reports (50%) explained the inquiry methodology used clearly. It is not clear in the other 5 reports (50%) whether the method used is simply not outlined or no formalised method was used. The focus of the 10 inquiry reports varied significantly, but they were all related to the maternity services and adverse pregnancy outcomes. Generally, pregnancies are seen as having only positive outcomes and therefore adverse outcomes can generate significant public interest.[8,10] Inquiries take a significant time to be completed (7 months to 3 years in this cohort), this delay in report publication means that public opinion is often formed by immediate media coverage of events rather than inquiry findings.[10,124]

The reports under review varied from 11 to 210 pages in length. Lengthy reports are unlikely to be read in full, therefore having a comprehensive executive summary and recommendations section is essential to present the key learning points.[126] Seven of the inquiries (70%) were carried out by an appropriate multidisciplinary team, however, the selection process of the experts/professionals in the team is not clearly outlined. Ireland is a small country with a limited number of experts/specialists in its maternity service; appointing experts to lengthy inquiry processes reduces their time commitment to a service already under pressure.

Ongoing reliable internal adverse incident reviews may reduce the need for external inquiries, reserving their use for exceptional adverse events of public concern. Ninety percent of reports (n=9) advised enhancing adverse incident management in the maternity services. Of note the HSE Incident Management Framework 2018 has been published since the most recent inquiry was completed.[91] This Framework recommends that all persons affected by an

incident (i.e. service users, families and staff) should be aware of any review undertaken and ideally be involved in the process.[91] We suggest the same principle be applied to inquiries. Timely and open communication with families after an adverse event was recommended in 60% (n=6) of reports. Families value transparent, kind and compassionate interaction with hospital staff after adverse outcome, especially a perinatal death, whereas lack of information or explanation may exacerbate feelings of anger and frustration.[3]

Every inquiry or incident review report should include recommendations directly linked to the key findings. Clear and relevant recommendations are more likely to be implemented than non-specific and impractical recommendations.[202,203] Furthermore, appropriate and well-defined recommendations encourage the development of action plans. The HSE Incident Management Framework advocates the generation of SMART recommendations.[91] Out of the 10 reports only one (10%) fulfilled all 5 criteria, however in this report not all recommendations were directly linked to the key findings. The average score for the 9 reports was 3/5. Nine reports (90%) did not give a defined timeline for implementation of all the recommendations. It was not clearly described who had responsibility for implementation in 90% of reports (n=9). To support implementation of recommendations, the development of a standardised, systematic approach to inquiry recommendations would be beneficial.

Involving key stakeholders in the making of recommendations increases the chances of successful implementation.[124] This is especially important for hospital-specific recommendations. One possible method is to request feedback on draft recommendations over a defined period of time, before publishing the appropriately revised final report recommendations. Two of the 10 Irish inquiry reports (20%) stated that feedback was sought prior to publication of the report.

In Ireland, as in the UK there are no formal systems in place for following up recommendations made in inquiries.[126] Three of the reports (30%) highlighted a concern regarding the incomplete implementation of previous inquiry

recommendations. This raises the following questions: what responsibilities does the commissioning agency have in following-up on the implementation of recommendations made by the inquiry team they have put in place? And who is accountable if recommendations are not implemented? The inquiry report is just the first step in managing adverse incidents, as highlighted by Macrae (2016): "The search for safety starts, rather than ends, with incident reports".[192]

It is difficult to assess fully what impacts these inquiry reports have had on maternity services directly, as some changes may have occurred with policy improvements anyway. Of note, all 10 reports (100%) made recommendations in relation to workforce staffing and/or training. A service that is chronically under-staffed will not be able to facilitate protected time for important training and education of its workforce. However, in the time since the first report publication in 2005, pregnancy loss/perinatal bereavement care has improved nationally as recommended in 40% of reports. In 2016, the HSE National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were published (Figure 5.1).[56]

Since publication of reports 4 and 5 (Table 5.1) awareness of the deteriorating pregnant patient has increased. Early warning systems (recommended in 30% of reports) have been introduced and multidisciplinary sepsis training implemented. National maternity outcome reporting (Irish Maternity Indicator System) commenced in 2014 and reports 30 common indicators (e.g. miscarriage misdiagnosis) across the 19 maternity units annually.[204] Ongoing maternal and perinatal outcome data collection has been recommended by numerous National Perinatal Epidemiology Centre (NPEC) reports (including Perinatal Mortality Report 2016, Neonatal Therapeutic Hypothermia in Ireland 2016-2017 and Severe Maternal Morbidity Report 2014).[84,205,206]

In this cohort of reports, ninety percent (n=9) recommended comprehensive data collection in the maternity units to identify areas in need of improvement. However, it is important to also provide resources for addressing these

shortcomings and ensure duplication of data collection/reporting does not occur. Nine reports (90%) advocated for stronger clinical governance in the maternity service. Steps taken to date to strengthen the maternity service governance include: the publication of National Maternity Strategy (2016-2026), the establishment of the National Women & Infants Health Programme (NWIHP) and the evolving formation of maternity networks.

Strengths and limitations

Some strengths and limitations of using inquiry reports as source data were considered. There are many inquiry reports related to Irish maternity services available, these documents are publically-available and therefore readily accessible. Limitations of using these reports include restrictions due to the terms of reference of the inquiry itself and a general focus on reporting inadequacies in services mainly.

Conclusion

Inquiries are important to investigate rare, exceptional incidents of public concern, however they entail lengthy and sometimes complex processes; thus, a timely and robust internal inquiry might instead address local concerns in a more timely manner. Reliable, beneficial internal incident reviews require staff training in-and availability for incident management.

A collaborative inquiry process involving and supporting all persons affected, as well as key stakeholders would ensure that all relevant issues are identified, recommendations that can be implemented will be generated and essentials lessons are learned. The approach to recommendations and the process for implementation of these recommendations should be clearly documented, including who has responsibility to oversee implementation. Developing a standardised and systematic structure for inquiry methodologies and reports would be beneficial to this process, and encourage completion of the investigation cycle.

Chapter 6 - Governance of Maternity Services: Effects on the Management of Perinatal Deaths and Bereavement Services

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Chapter 6 - Governance of Maternity Services: Effects on the Management of Perinatal Deaths and Bereavement Services

6.1 Abstract

Background

External inquiries are carried out following adverse maternal/perinatal events, to examine the care provided and make recommendations to improve it. Clinical governance ensures that organisations promote high-quality care and are accountable for the care they provide, thus contributing to its improvement.

Objective

This study examined how Irish perinatal bereavement services and the management of perinatal deaths (including events leading up to the deaths) were affected by developments in maternity services governance as described in ten Irish inquiry reports published over 14 years (2005-18).

Methods

Two clinicians collected data from the ten inquiry reports by using a specifically designed review tool. Thematic analysis was carried out, following the steps of familiarising, coding, identifying, grouping and revising themes.

Findings

Seven main themes were identified: workforce, leadership, management of risk, work environment, hospital oversight, national documents, data collection. Eight reports noted shortcomings in staffing levels, with a workforce that was under-resourced, and at times carried excessive workloads. The absence of 24/7 midwifery-shift leaders in maternity units resulted in problems with care at times not being escalated appropriately. The absence of a widely-owned, understood strategic plan for the management of the maternity services was mentioned in the reports from 2013.

Conclusions and implications for practice

The National Bereavement Care Standards were published in 2016 to address deficiencies identified in the inquiry reports and to standardise perinatal bereavement care across Irish maternity units. Though the first Irish Maternity Strategy (2016-26) was published in 2016, its implementation is incomplete. Inconsistencies remain in the definition and collection of national perinatal data, as well as concerns regarding the lack of local audit activities on pregnancy outcomes. Greater focus on hospital oversight, implementation of national documents and reliable data collection is required. To be effective and initiate positive changes in clinical services, documents such as incident reviews, national strategies and national reports including inquiries, need to include realistic recommendations with clear timelines and responsibilities for implementation.

Keywords

Clinical governance, maternity services, national inquiries, perinatal deaths, bereavement services

6.2 Introduction

The aim of clinical governance is to ensure that organisations, and the individuals within them, promote and are accountable for the clinical care they provide, thereby continuously striving to improve the quality of care.[207,208] The Irish Department of Health stated that clinical governance "defines the culture, the values, the processes and the procedures" of a hospital that are necessary to provide consistent excellent care.[209] Clinical governance can be divided into various elements or "pillars" including but not limited to: leadership, adequate workplace, well-trained workforce, up-to-date guidelines, risk and incident management, information management, patient involvement.[208–210]

Using these pillars, standards for clinical services are regularly evaluated and updated to create a just and considerate hospital culture for both patients and staff.[208,211] Where there is ineffective clinical and non-clinical leadership and/or management this can be challenging.[208] Therefore, the oversight of clinical activities and clinical workplaces needs to be specified in governance structures with defined ranks of accountability and responsibility.[211]

Standards of maternity care are set out in Ireland by the Health Information and Quality Authority (HIQA) and the Department of Health, to ensure consistent, high-level maternity services nationally.[21,37] Then, outcomes can be monitored in line with these standards, and changes in services made to address and reduce outcome deviations from the expected standard e.g. the rate of intra-partum stillbirths.[208,212]

In Ireland, maternity outcomes from all 19 maternity units are monitored using the annual Irish Maternity Indicator System (IMIS) National Report, published since 2014, and the monthly published Maternity Patient Safety Statements (MPSS) from individual units since 2015.[213] National perinatal mortality data has been collected and published by the National Perinatal Epidemiology Centre (NPEC) for its annual audit since 2008.[18] Perinatal mortality is the combination of stillbirths and neonatal deaths.[18] In Ireland, these include infants from 24 weeks'

gestation and/or weighing more than 500g.[18] Pregnancy losses at lower gestations are considered first and second trimester miscarriages.

HIQA was established in 2007 under the Health Act 2007. The National Standards for Safer Better Healthcare were published by HIQA in 2012 to "promote responsibility and accountability for the quality and safety of services provided", followed by the National Standards for Safer Better Maternity Services in 2016.[37]

The first Irish National Maternity Strategy was published by the Department of Health in the same year to ensure that maternity and neonatal care "is safe, standardised, of high-quality and offers a better experience and more choice" to women and their families.[21] In Ireland, maternity care has been provided free under the Maternity and Infant Care Scheme since 1954. In maternity units, this care is provided under the remit of the Health Service Executive (HSE). Over 99% of births in Ireland occur in a maternity hospital, with 4% of these being midwifery-led while the remainder are obstetric (consultant)-led.[21] However, the primary care is provided by midwives and unless some intervention (e.g., operative vaginal delivery or caesarean section) becomes necessary, births are not routinely attended by medical staff. Since 2017, the National Women and Infants Health Programme (NWHIP) heads the management, organisation and delivery of maternity and neonatal services in Ireland, as well as oversees the implementation of the Maternity Strategy.

The aim of this study was to highlight the relationship between governance of maternity services and perinatal bereavement standards. This paper outlines how Irish perinatal bereavement services and the management of perinatal deaths (including events leading up to the deaths) were affected by developments in maternity services governance as described in ten inquiry reports published over 14 years (2005-18).

This study provides an overview of elements of maternity services which either were affected by or in turn affected governance structures. Additionally, it

suggests recommendations for changes in local and national maternity services governance to enhance perinatal bereavement services.

6.3 Methods

From all national inquiries into the maternity services in Ireland over the last 15 years, ten relevant health-service-commissioned inquiry reports relating to perinatal deaths and pregnancy loss services, were identified.[49,50,52–55,57,58,127,128] The reports covered issues in relation to paediatric post-mortem examinations; the management of pregnancy loss; maternal and perinatal deaths in different Irish maternity units (including events leading up to the deaths); miscarriage misdiagnoses; maternity services governance; maternity related complaints received by the HSE.

Ethical approval was not required as all the reports are publicly- available documents. The inquiry reports were assessed by two clinicians, separately, between October and December 2018, using a specifically-designed review tool to compare and examine the content and recommendations made in each report. The review tool was based on the Irish Health Service Executive (HSE) Systems Analysis Review Report Checklist and consisted of 21 items divided into 6 separate sections covering the terms of reference, review methodology, key findings, contributory factors, recommendations and action plans.[214] In a published review the characteristics of the ten reports are discussed in detail.[214] A further publication outlines the impact of perinatal bereavement care on families as described in the reports.[215]

Following on from data collection using the review tool, qualitative content analysis of the reports was used to identify the main domains. The domain of maternity services governance informed the following thematic analysis to identify the relevant themes. Thematic analysis with a semantic approach was carried out following the steps of familiarising, coding, identifying, grouping and revising themes, followed by writing this article.[216] Various issues relating to

maternity services governance were thus initially identified and coded. These codes were further explored and discussed by three authors with the assistance of a thematic mind-map until the seven governance-related themes were agreed on. By re-analysing the reports for clarification (focussing on the key findings and recommendations) these seven themes were finalised.

Two peer debriefing sessions, with a qualitative researcher and with an expert in perinatal medicine/pregnancy loss, were carried out to consider the analysis process and the themes. Of note, the authors collectively have considerable years of experience of working in the Irish maternity services, including in positions of authority.

6.4 Results

Seven main themes regarding perinatal bereavement services and management of perinatal deaths informed by maternity services governance were identified from the ten Irish inquiry reports. Table 6.1 shows the themes relating to elements which were affected by or in turn affected clinical governance structures. The number of reports in which each theme was mentioned is also highlighted. In the sections below we will explore each theme in detail.

Table 6. 1: Elements affected by or in turn affected governance structures in the management of perinatal deaths and bereavement services

Elements affected by governance structures	**Reports (N=10)**	**Elements that affected governance structures**	**Reports (N=10)**
Workforce	10	Hospital oversight and networks	8
Leadership "hospital culture"	10	National documents	8
Management of risk	9	Data collection	9
Work environment	6		

6.4.1 Elements affected by governance structures

The following four elements are affected by maternity services governance structures. Issues with these elements have a direct impact on the management of perinatal deaths and bereavement services.

Workforce

Staffing levels, staff training and professional competence were identified as parts of the theme workforce. Eight reports noted shortcomings in staffing levels, with a workforce that was under-resourced, and at times carried excessive workloads.[50,52,53,55,57,58,127,128] Relevant specialists (e.g. perinatal bereavement, perinatal mental health) were not always available resulting in varying supports being available to bereaved parents.[215] Understaffing was present at midwifery, non-consultant hospital doctor (NCHD) and consultant level as well as in management positions and administrative support (Table 6.2, Number 1).[50,52,53,55,57,58,127,128] This resulted in extensive use of agency and locum staff.

As previously advised in a national Consultant Workforce Planning report from 2015[217], the inquiry report from 2018 recommended that both midwifery and consultant obstetrician numbers needed to be increased to internationally accepted levels, allowing for a one-to-one ratio of midwife to woman in labour in

all units.[58] Furthermore, specialist services such as perinatal mental health and bereavement care needed to be expanded, to allow access for all women who require them.[55] Six reports included recommendations relating to the recruiting, reviewing and retaining of a clinical and managerial workforce that is fit for purpose.[49,52,53,55,58,128]

Four successive reports raised concerns regarding the lack of formal and mandatory training programmes for: induction of new staff, fetal monitoring and multi-disciplinary emergency training.[52,54,58,128] Hospitals under investigation were not consistently able to produce records of training for all staff. Access to training, both in relation to providing protected time and facilitating attendance at off-site courses, was reported as limited.

The maintenance and updating of clinical skills in-line with international best practice was reported as haphazard. Circumstances of unprofessional behaviour and lack of competence by staff were described, including non-disclosure of harm and lack of appreciation of changing clinical circumstances.[49,50,53–55,57,58,128]

Leadership "hospital culture"

Occasional accounts of an absence of a compassionate culture at individual or organisational level were recorded with "a system and culture that failed to take into account the views and feelings of parents".[49] Different staff groups were reported as having varying perceptions of the safety culture with some staff fearing challenging clinical situations, hence becoming either overcautious or too reactive to clinical incidents (Table 6.2, Number 2a).[127,128]

It was stated that in some units there were gaps in key management positions; elsewhere management structures did not function well due to hospital group governance changes with senior staff not feeling in charge of their own clinical environment.[50,58,127,128] Some senior staff in key leadership positions had unrealistic clinical and administrative workloads, lacking the time for informal

mentoring of colleagues where personal or organisational concerns could have been raised.

Without a director of midwifery in every maternity unit up to 2019, there was inconsistent senior midwifery input at some clinical governance meetings.[22,58,128] The absence of a 24/7 midwifery-shift leader in maternity units resulted in problems with care at times not being escalated appropriately.[58,127,128] One report highlighted that suitable midwifery-led care was not available, despite management having applied to develop this service.[58]

In some units the midwife-doctor relationship was described as very traditional, with poor multidisciplinary team-working and sub-optimal communications between professionals and specialities (Table 6.2, Number 2b). Uncertainty regarding patient-care responsibilities without clear communication and handover, as well as lack of senior clinical staff involvement, led to suboptimal care being provided at times. Eight reports advocated for improving the transfer of patient information between staff and four mentioned the need for increased consultant input/supervision into patient care.[50,52–55,57,58,128]

Management of risk

The management of risk includes risk recognition and incident investigation. Six reports, between 2008 and 2018, noted that lack of regular monitoring and inadequate risk assessments meant that at-risk or deteriorating maternity patients (both mothers and babies in-utero) were, at times, not identified early.[50,53,54,57,58,128] The need for an early warning score was mentioned in the reports in 2008, 2013 and 2015; the Irish Maternity Early Warning System (IMEWS) was introduced nationally in April 2013 (Figure 5.1, Table 6.3).[53,54,57,128] Furthermore, concerns regarding delays and lack of clarity in care escalation, were raised. In some maternity units risk escalation policies were not well developed at both clinical or managerial level, with poor tracking and/or poor monitoring systems of identified risks.[54]

Incidents (e.g., an unexpected perinatal death) were not consistently and/or comprehensively investigated. Incident investigations (reviews) that were carried out, were reported to be of varying quality and lacked timeframes and accountability for implementation of recommendations, as well as containing limited feedback to staff (Table 6.2, Number 3). There were significant delays in incident reviews and a lack of involvement of clinical staff and/or contact with the bereaved families during the review process.[50,58,128] Short-comings with open disclosure to families were highlighted, both immediately after an incident and regarding incident reviews taking place.

Work environment

Five reports published between 2011 and 2018 mentioned that some hospital buildings and equipment (e.g. fetal heart rate monitoring devices, ultrasound machines) were not fit for purpose (Table 6.2, Number 4a).[50,52,58,127,128] Inadequate facilities with lack of privacy were said to add to bereaved parents' distress.[49,128] Furthermore, absence of essential services, lack of space and the layout of some maternity units with significant distances between departments (i.e. the labour ward, operating theatres and the neonatal unit) posed additional risks.[50,58,128]

Sub-optimal introduction of new services (e.g. fetal blood sampling during labour, neonatal therapeutic hypothermia) was said to have resulted in additional adverse outcomes (Table 6.2, Number 4b).[55,58,128] Some necessary practices were unintentionally disrespectful, for example the type of transfer of deceased infants to another hospital for post-mortem examination in one unit.[50] The lack of appropriately trained staff to provide comprehensive antenatal ultrasound services was criticised in reports from 2011, 2015 and again from 2018.[52,58,128]

Table 6. 2: Quotes from the Inquiry reports

Number	Element	Quote
1	Workforce	"There was a chronic shortage of staff both at midwifery and consultant level with a lack of consistent midwifery management presence to supervise the labour ward during the period under review. This was compounded by the national moratorium in the public sector implemented by the Department of Finance in 2009." [58]
2a	Leadership "hospital culture"	"Poor standards of multidisciplinary communication were highlighted by a number of people who met with the Authority. Yet, these concerns were reported as far back as 2007 and had not been addressed. Multidisciplinary communication had also been highlighted as problematic in the safety culture assessment carried out as part of this investigation." [128]
2b		"There is an ongoing and critical discussion about maternity services playing out through the media. This contributes to a culture of fear of getting it wrong amongst some healthcare professionals who can become more cautious or even defensive in the course of their work. If this impacts upon the decisions about the care of patients then high quality appropriate care can be compromised." [127]
3	Management of risk	"No common process for development of recommendations was evident across the adverse incident reports. There was an absence of timeframes, identification of responsibility and

		accountability and evidence of completion for implementation of recommendations." [50]
4a	Work environment	"The Investigation Team found that staff are continuously challenged by the current infrastructure to deliver a person-centred service, particularly in the context of maintaining patient privacy and dignity." [128]
4b		"There were numerous cases where the assessment of an abnormal CTG, escalation of this and failure to act appropriately was of particular concern. There was a failure in carrying out fetal blood sampling with a lack of training in its use."[58]
5	Hospital networks	"Smaller hospitals… cannot operate in isolation as standalone entities either clinically or financially. They simply cannot sustain the breadth and depth of clinical services that the populations they serve require without formal links and networks with bigger, more specialist units." [127]
6	National documents	"The absence of clear guidelines regarding required observations and reactions and the lack of a structured format for recording vital signs contributed to the delayed medical intervention." [53]
7	Data collection	"At the time of the investigation, there was also no agreed national dataset of quality and safety measures for maternity services in Ireland and no consistent approach to reporting clinical outcomes."[57]

6.4.2 Elements affecting governance structures

Below three elements raised in the reports, which affect maternity services governance, are described. Issues with these elements have an indirect impact on the management of perinatal deaths and bereavement services due to the way they are closely linked to hospital practices, and therefore the way in which services are delivered.

Hospital oversight and networks

Five reports raised concerns regarding a lack of national oversight of the maternity services, by both the Department of Health and the HSE, regarding ongoing local and/or national identified clinical risks e.g. access to appropriate and the right level of care 24 hours per day for all pregnant women [49,50,57,58,128]. During the financial recession and until 2014 the main focus by senior HSE managers was on controlling health care expenditure [128].

The absence of a widely owned and understood strategic plan to guarantee high-quality of maternity care was mentioned in the reports published from 2013 (Table 6.3). The National Maternity Strategy was published in 2016 (Figure 5.1), however as the report from 2018 stated "the importance of the document is not what it says but whether it is implemented" [58].

Clinical maternity networks (groups) have been recommended by the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland since 2006 to integrate smaller and larger units.[39] While smaller hospitals are vital for their communities[218], the smaller units require efficient intergroup co-operation with the tertiary centres for specialist services (Table 6.2, Number 5).[23] In 2014 Irish hospital groups were recommended and formed for governance, training and clinical services including risk categorisation and sharing of clinical expertise.[23] These groups were different to the recommended networks in 2006 and the six health regions currently proposed for the implementation of Sláintecare, which is a ten-year programme to renovate the Irish health and social care services with a focus on delivering "the right care, in the right place, at the right time".[23,25,39]

Reports from 2015 and 2017 explained that hospital groups were going through ongoing "set up and development".[55,127]

Multiple changes in governance arrangements during the formation of hospital groups was said to have led to confusion regarding management roles and responsibilities. Furthermore, due to "cultural, behavioural, operational or financial barriers" not all units were consistently and/or effectively integrated into maternity clinical networks.[127] Some evolving group committee structures were reported to be overlapping and unnecessarily complicated, and some group meetings poorly attended by staff from the various units.[58,127,128]

While it was noted that some audit, incident and risk management processes could be consolidated within the hospital group to share information, the importance of local learning points being disseminated was highlighted.[58,127]

National documents related to maternity services

Table 6.3 describes the type of national documents discussed in the reports as not available, poorly implemented or not in use in maternity units, and in which year these were published. National guidelines provide clear information on managing clinical conditions. Standards and strategies define the clinical care required for consistent safe services. Both types of documents aim to standardise and ensure good quality of clinical care. From 2010 national clinical guidelines for maternity services in Ireland were published by the HSE's national clinical programme, and this role has been taken over by NWIHP since 2017.

Eight reports mentioned the absence or poor implementation of clear clinical guidelines or guidance documents e.g. open disclosure policy and guideline (Table 6.2, Number 6).[49,50,52–54,57,58,128] There were accounts of national and/or local guidelines not being used or not being adhered to in maternity units.[57,58,128] It was stated that deviation from an agreed guideline can arise from staff unawareness, poor communication of new guidelines or a new (not previously encountered) clinical situation.[52]

Data collection

Duplication and inconsistencies were reported in the collection of national perinatal data involving four separate state agencies.[50] There were data inconsistencies between the 19 units relating to the quality of maternity services. An inquiry in 2013 found that only 11 out of the 19 units produced an annual clinical report.[57] The lack of an agreed national dataset as well as clinical outcomes was highlighted at the time (Table 6.2, Quote 7).[57] In 2015 publically-available monthly Maternity Patient Safety Statements (MPSS) from all units were recommended and published by the HSE, in addition to the annual IMIS (Irish Maternity Indicator System) reports, which commenced in 2014.

Further, in 2017 it was recommended that "an annual audit of Irish maternity services" should be implemented.[55] Reports from 2011, 2013, 2015 and 2018 advocated for an audit of compliance with national policies/guidelines e.g. the Open disclosure policy.[52,57,58,128] In total, nine out of the ten reports made recommendations on improving comprehensive data collection.[49,50,52,54,55,57,58,127,128]

Concerns were raised in 2013, 2015 and 2018 about the lack of local audits on activities such as work-loads, adverse incidents and clinical outcomes.[54,58,128] Ineffective information technology structures and a shortage of dedicated staff members to oversee audit activities were stated as contributory factors.

Table 6. 3: Name/year of document and year (report) in which issues related to it were raised

Name of national guideline	**Year published**	**Year [report] in which issues related to guideline were raised**
The Irish Maternity Early Warning System (IMEWS) RCPI, Dept of Health	2013 (updated 2014, 2019)	2008 [53] Need for physiological observation, track and trigger type programme 2013 [54] Need to implement IMEWS 2013 [57] Need for mandatory induction and refresher training 2015 [128] Use of IMEWS for all maternity patients regardless of location in the hospital
Open Disclosure Policy (and Guideline) HSE	2013	2014 [50] Need to implement policy 2015 [128] Confirm policy is in use 2018 [58] Monitor compliance with policy
Communication (Clinical Handover) in Maternity Services, including ISBAR (Information, Situation, Background, Assessment, Recommendation) tool Dept of Health	2014	2013 [54] Adoption of appropriate communication tools such as ISBAR 2013 [57] Need for national guideline for effective communication 2014 [50] Need for standardised and structured communication 2018 [58] Need to introduce tools such as ISBAR to aid communication
Safety Incident Management Policy, replaced by Incident Management Framework in 2018 HSE	2014	2011 [52] Enhance capacity for hospitals to conduct investigations of incidents 2015 [128] Local practices were contrary to the policy 2017 [55] Each Hospital should have in place a formal system of review 2018 [58] Ensure incident investigations comply with policy

Name of standards/strategy	Year published	Year (report) in which issues related to standards/strategy were raised
National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death HSE	2016	2008 [53] Need for bereavement room, liaison person, staff training 2011 [52] Need for bereavement support 2013 [54] Need for availability of bereavement counselling nationally 2015 [128] Need for bereavement care 2017 [55] Need for bereavement support and counselling 2018 [58]
National Maternity Strategy – Creating a Better Future Together 2016-2026 Dept of Health	2016	2013 [57] Need for a Strategy to optimise maternity services 2014 [50] Recommendations from the report should be incorporated into the Strategy 2015 [128] Urgent need for a Strategy to implement standard, consistent maternity care 2015 [127] Absence of a clear Strategy 2017 [55] Need to develop implementation plan for the recently published Strategy 2018 [58] Need for national support to implement the changes proposed in the Strategy

6.5 Discussion

We examined how Irish perinatal bereavement services and the management of perinatal deaths (including events leading up to the deaths) were affected by developments in maternity services governance as described in ten inquiry reports around seven themes (workforce, leadership, management of risk, work environment, hospital oversight, national documents, data collection). The themes of workforce, leadership, management of risk and work environment related to elements that were directly affected by clinical governance structures. On the other hand, issues with hospital oversight, national documents and data collection had an indirect impact on the management of perinatal deaths and bereavement services.

To address deficiencies identified in the inquiry reports related to perinatal bereavement services, the HSE National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death were published in 2016 (Figure 5.1).[56] The aim of the Standards is to improve and standardise perinatal bereavement care across the 19 Irish maternity units.[56] In the same year the first Irish Maternity Strategy was published to cover the period 2016-26.[21] NWIHP (National Women and Infants Health Programme) oversee the implementation of this Strategy.

HIQA (Health Information and Quality Authority) carried out inspections in all Irish maternity units between August 2018 and September 2019 to assess compliance with the National Standards for Safer Better Maternity Services (2016) and implementation of the Maternity Strategy.[21,22,37] Findings in the current study highlight that the inquiry reports reflected similar concerns to those raised by HIQA who noted ongoing national shortfalls in: the formation of maternity networks, the formalisation of care pathways, the infrastructure of units, midwifery and medical staffing levels, uptake and recording of attendance at multidisciplinary training and measures to share learning (both good practice and

when things go wrong).[22] Furthermore, HIQA raised concerns regarding the level of progress of the implementation of the Maternity Strategy, which affects the provision of high-quality care in the maternity services and consequently perinatal bereavement services.[22]

Four of the 19 Irish maternity hospitals currently are stand-alone units. However, the plan is to move these maternity units to be co-located with acute adult hospitals by 2040.[22] In agreement with the inquiry reports, NWHIP acknowledged in 2018 that "the majority of the 19 maternity hospitals/units require investment to meet current hospital accommodation standards".[20] During their 2018/9 inspections HIQA found that none of the six Irish maternity hospital groups had completed the set-up of a single governance framework across their network, despite it being recommended since 2006 and pertinent concerns raised repeatedly in the inquiry reports from 2015.[22,39]

Even though it was highlighted in 80% of the reports, there is still an ongoing lack of continuous national workforce planning for the Irish maternity services, with ongoing reliance on agency staff and existing staff to work overtime to cover essential services.[22] However, since 2019 there is at least one Bereavement Clinical Midwife Specialist (CMS) employed in each maternity unit and perinatal mental health teams are in post in four of the six hospital groups.[20] Of note, the current COVID-19 pandemic has led to challenges with recruitment for the whole-time equivalent (WTE) specialist posts and some CMSs in post have been redeployed to other clinical areas.

While training for obstetric emergencies and fetal heart rate monitoring was being offered in all units in 2018/9, the attendance at these was suboptimal despite this being raised as a concern in the inquiry reports.[22] Units that are persistently under-staffed will not be able to facilitate staff to attend important training sessions, which in turn can affect staff morale.[219]

Clinical staff members, as well as management and leadership behaviour contribute to the hospital culture through their attitudes, actions or inactions.

Cohesive team behaviour and unified values have a positive impact on hospital culture, and if combined with supportive leadership, result in employees feeling valued and satisfied.[220] Unfortunately, a fragmented hospital or organisational culture can have detrimental effects on patient care as highlighted in the 2018 Inquiry report: "If people, systems or hospitals work in isolation, they stay rooted in the past. Practice becomes embedded and fails to progress".[58]

In Ireland, as internationally, there is a shift in health care provision including maternity services from paternalism to greater emphasis on patient autonomy and open disclosure.[221] While this is a welcome change, negative publicity of events described in the ten inquiry reports created a loss of trust by the public in the Irish maternity services, sometimes resulting in a division between staff and patients instead of the desired partnership.[10,125]

As a result of the inquiry reports from 2013 and 2014, the national guidelines on communication, including ISBAR, and IMEWS were published (Figure 5.1, Table 6.3). Using communication tools such as ISBAR (Identify, Situation, Background, Assessment, Recommendation) has been shown to improve the transfer of patient information between staff, thereby reducing the risk of not recognising the deteriorating patient because of missed vital clinical information.[222] Equally, having a structured method of recording vitals signs e.g. IMEWS can help to identify the deteriorating maternity patient early to prevent delays in required interventions e.g. expediting the delivery of the baby.[223]

If an adverse outcome, like an unexpected perinatal death, does occur it should be comprehensively investigated to identify any modifiable contributory factors.[224] Issues were raised in the reports from 2015 and 2018 regarding suboptimal local adherence to national incident policies. In 2018, the HSE Incident Management Framework replaced the previous national policy to provide guidance in the management of incidents while "supporting the needs of service users, families and staff in the aftermath of an incident" and facilitate learning from it.[91] Despite this Framework, in 2019, there was no consensus across the

Irish maternity units regarding the timeframe of incident reviews or how the findings were shared with the affected families and staff[225].

Ninety percent of the reports advocated for robust local and/or a national perinatal data collection, including the need to benchmark maternity outcomes. National Irish perinatal data is collected by both NPEC (National Perinatal Epidemiology Centre) and the Healthcare Pricing Office (HPO) of the HSE.[18,226] Irish maternity outcomes are collated by both IMIS (national annual data) and MPSS (monthly unit-specific data).[213] While all four reports allow for local, national and international benchmarking of Irish perinatal data, there is some overlap and duplication between reports.[18,213,226] Furthermore, only NPEC makes recommendations based on their findings in their audit; HPO, IMIS and MPSS present data without recommendations.[18,213,226]

Over 250 recommendations were made in the ten inquiry reports, these are discussed in further detail in a previously published review.[214] Three of the inquiry reports highlight the incomplete implementation of previous inquiry recommendations.[57,58,128] This concern was shared by the Irish public.[10]

Limitations

The foci and content of the ten inquiry reports differed considerably, however the reports all related to Irish maternity services covering different aspects of the management of perinatal deaths and bereavement services. In some reports the issues with the management of perinatal deaths were directly linked to maternity service governance, in others this link was not clearly stated. However, from the reports it was evident that governance of maternity services has a top-down effect on bereavement care.

Conclusion

Effective clinical governance is important to unite the managerial, organisational and clinical administration through clear structures and systems, thereby creating a just organisational culture and improving the quality of care.[208,211] This study

highlights that issues related to lack of leadership, workforce staffing levels, adequate infrastructures and effective risk management are still affecting the national maternity services. Furthermore, a greater focus on hospital oversight, implementation of national documents (e.g. guidelines, standards) and adequate data collection is required. The issues with all these elements of clinical governance must be brought together and addressed, to improve the quality of the investigation and management of perinatal deaths and the delivery of bereavement services.

To be effective and initiate positive changes in clinical services, documents such as incident reviews, national reports including inquiries, national standards and strategies need to include realistic recommendations. Furthermore, action plans have to be made and resourced for the implementation of these recommendations with clear timelines and responsibilities.[203] Locally, if new safety ideas or recommendations do not filter down to the frontline clinical staff, few or no visible improvements will be achieved for women and their families attending maternity units.

Recommendations

- Effective clinical governance is important to achieve clear structures and systems, with organisational and clinical administration creating a caring culture, thus it should be the priority for all maternity care.
- Outcomes of clinical care, including maternity care, should be monitored and improved according to agreed national standards. There is a need to bench-mark maternity outcomes nationally and internationally.
- Ways to strengthen pathways for local learning, sharing lessons within maternity networks, at national, and potentially global level, should be developed.
- National workforce planning in the maternity services, including progression plans, must be prioritised to reduce reliance on agency staff and overtime.

Chapter 7 - Impact of bereavement care and pregnancy loss services on families: findings and recommendations from Irish inquiry reports

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Chapter 7 - Impact of bereavement care and pregnancy loss services on families: findings and recommendations from Irish inquiry reports

7.1 Abstract

Background

Pregnancy loss and the death of their baby can be overwhelming for families, especially when the loss is unexpected. The standard of bereavement care families receive around the time of pregnancy or early infant loss can have a significant impact on their psychological recovery. At times external inquiries are carried out to identify issues in the maternity care provided and make recommendations to improve its' standard.

Objective

This study aims to describe the impact of bereavement care provided to families around the time of pregnancy and/or early infant loss as stated in ten published inquiry reports related to Irish maternity services.

Methods

Using thematic analysis, issues with care encountered by bereaved parents as outlined in the reports were identified. These focussed around five main themes (communication, healthcare staff skills, maternity unit environment, post-mortem/coronial process, local incident reviews).

Findings

Bereavement care, as described by families in the ten reports, was not consistently individualised or respectful, resulting in additional feelings of anger and upset. Problems with clear communication of complex issues, in a manner that is understandable to bereaved families, were identified in several reports. Recommendations from the inquiry reports included that experienced and skilled staff should always be available to provide immediate support to bereaved

families as appropriate, and assist families in understanding and processing information around the time of their loss.

Conclusions and implications for practice

Consistent, individualised bereavement care facilitates a seamless transition for bereaved families from diagnosis through the hospital stay to discharge and follow-up, allowing them to focus on their baby, their bereavement and their family's wellbeing. The process of consent for a perinatal post-mortem and associated concerns have evolved over the timeframe of the ten inquiries. We reflect further on this and the impacts of the other issues highlighted, as well as discussing possible improvements to address them as described in the scientific literature.

7.2 Introduction

External inquiries related to maternity services are carried out regularly; sometimes after negative media reporting of adverse events (e.g. maternal/perinatal deaths) that have occurred. Inquiries are commissioned by government and/or health service departments to examine events that are of public concern or importance.[3,124,126] In the healthcare context, inquiries aim to establish a timeline of these events, identify all modifiable risk factors and make recommendations to upgrade services and thereby avoid a recurrence of events.[126,201] Well-executed inquiries can help to provide answers and closure to families directly affected by unforeseen circumstances that resulted in an adverse outcome.[126] Inquires can contribute to re-establishing confidence in health services for the public by showing that events are "fully investigated and dealt with".[126,201] Unfortunately, at times inquiries have the opposite effect, adding to the general distrust society may have towards the service under scrutiny.

The loss of a pregnancy at any gestation is distressing for families. Recurrent loss or loss in advanced pregnancy is particularly devastating for parents and families, but also for the healthcare staff involved. The death of their baby can trigger anxiety, depression and relationship difficulties for the bereaved parents.[2,3] A baby dying unexpectedly during labour, or shortly after, can have lasting emotional and professional effects for the healthcare staff involved.[6] The manner of interactions between families and staff in these distressing circumstances is critical, and can have long-lasting positive or negative impacts on well-being.[4,5]

This article describes the impact of bereavement care provided to families around the time of pregnancy loss or early infant loss (neonatal) as stated in ten inquiry reports related to Irish maternity services.

Providing bereavement care is an important part of all maternity services as all bereaved families have bereavement care needs.[227] The adverse psychological effects of pregnancy loss on families, which also continue into subsequent pregnancies, can be reduced by providing individualised and supportive

care.[2,158] The issues with care encountered by bereaved parents and improvements to address them are discussed in this article.

7.3 Background

Bereaved families value kind and compassionate interaction with hospital staff around the time of the death of their baby, whereas lack of information or explanation may exacerbate feelings of anger and frustration.[3] Individualised continuity of care allows the parents to focus on their baby and address all questions or concerns to one person.[3] If they choose, parents can spend time with their deceased baby, which is limited by natural changes that occur after death. Therefore, "a lifetime of memories" has to be made in a few hours or days, and there is just "one chance to get it right" by staff and also the families themselves.[228] Above all, families value respect and empathy shown by healthcare professionals to themselves and their baby.[4,67,227]

The emergency room (ER), labour ward (LW) and post-natal ward are often busy, noisy maternity unit departments. In the maternity ER, it may not be possible to differentiate women experiencing pregnancy loss (miscarriage or stillbirth) until a diagnosis is made, therefore these women may be in the waiting room together with labouring or post-natal women. This case mix load and limited physical space in the ER can add to women's distress.[65,229] The LW can be a daunting environment for labouring women, especially if there are signs that their baby is distressed and interventions (e.g. caesarean section) become necessary.

In this clinical scenario, as well as others, pregnant women should be fully informed and involved in decision-making processes relating to their clinical care (patient autonomy) as much as possible.[230] Post-mortem examination of their baby should be offered to all parents after a perinatal death, however it is important to respect individual beliefs and choices.[67,227,231] Explanation about the post-mortem examination ought to include the option of limiting the post-mortem

to specific body systems and/or excluding the retention of specific organs, which may be necessary for detailed analysis.[231] Consenting to post-mortem examination can be a difficult decision for parents, who seek clarity on the cause of death but also wish to protect their child from any further intervention.[1,63]

Many countries have developed policies on obtaining consent for interventions, as well as practising open disclosure after an unexpected, adverse incident to provide reassurance and support to patients.[232] Open disclosure is the process whereby healthcare staff discuss events with patients/families openly following an unexpected negative outcome that occurred in hospital.[232] Bereaved parents value the opportunity to give and receive feedback regarding the clinical care provided around the time of their pregnancy loss.[131] Local adverse incident reviews are carried out by hospitals into unexpected events to identify any modifiable contributory factors. Including the patient and/or family's perspective and knowledge in this review can offer significant insight to the care received.[135]

The aim of this study was to highlight the impact the quality of bereavement care provided to families around the time of pregnancy and/or early infant loss has on them.

7.4 Methods

The ten relevant publicly-available national health-service-commissioned inquiry reports relating to perinatal deaths and pregnancy loss services published between 2005 and 2018, were identified from all national inquiries into the maternity services in Ireland over the last 15 years.[214] No ethical approval was sought as all the reports are publicly- available documents. Table 7.1 gives the titles of the reports and the purpose of each inquiry, as well as the year the inquiry report was published.

Quantitative and qualitative data were collected between October and December 2018 by two of the authors using a specifically designed review tool (based on the

Irish Health Service Executive's (HSE) Systems Analysis Review Report Checklist).[91] The review tool has 21 items divided into 6 separate sections which cover aspects such as: terms of reference, review methodology, general content including key findings, and recommendations.[214] This qualitative piece is part of larger body of work on the inquiry reports.[214] Further details on the characteristics of the inquiries and recommendations made in the reports were published in a previous article.[214]

Following on from the data collection using the review tool further qualitative content analysis of the reports identified the main domains. This informed the selection of the data to be included in the following thematic analysis. Therefore, an inductive thematic analysis with a semantic approach was carried out on the sets of data including any reference to patients or families following the steps of familiarising, coding, identifying, grouping and revising themes, followed by writing this article.[216] Relevant issues in relation to the impact of bereavement care provided to families as stated in the inquiry reports were thus identified, discussed and clarified by two of the authors with the assistance of a thematic mind-map. These issues were further explored by re-analysing the reports for clarification, focusing on the key findings and recommendations, until the five main themes were agreed on. During this process of analysis, two peer debriefing sessions were carried out discussing the analysis process and the themes with a qualitative researcher and with an expert in perinatal medicine/pregnancy loss. Of note, the authors have clinical experience of caring for families experiencing pregnancy or early infant loss.

Table 7. 1: Title and purpose of the Inquiries

	Title of the report and purpose of the inquiry	**Year of publication**	**Purpose of the Inquiry**
1	"Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures"	2005	It gave an overview of paediatric post-mortem practices in Ireland, how the associated information was communicated to bereaved parents and how practices may be improved.
2	"Report into the circumstances pertaining to the death of TMC and her infant son at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007"	2008	It examined the clinical and non-clinical circumstances around the two deaths.
3	"National Miscarriage Misdiagnosis Review"	2011	It discovered trends regarding the causes of miscarriage misdiagnoses.
4	"Investigation of Incident 50278 from time of patient's self referral to hospital on the 21st of October 2012 to the patient's death on the 28th of October, 2012"	2013	It identified key causal and contributory factors to the maternal death and made recommendations to address these locally and nationally.
5	"Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration…"	2013	It examined the services provided to pregnant women at risk of deterioration (based on findings in one regional hospital).

6	“HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)”	2014	It assessed the regional hospital concentrating on perinatal deaths and related matters over an eight year timeframe.
7	“Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise”	2015	It assessed the safety and quality of services provided to patients at one regional hospital, including maternity care.
8	“A review of the governance of maternity services at South Tipperary General Hospital.”	2015	It reviewed the governance of maternity services at one peripheral hospital.
9	“HSE Maternity Clinical Complaints Review”	2017	It evaluated 203 maternity related complaints received by the HSE related to events over 40 years.
10	“External Independent Clinical Review of the Maternity Services at Portiuncula Hospital, Ballinasloe (PUH) and of 18 perinatal events which occurred between March 2008 and November 2014.”	2018	It reviewed 18 perinatal deaths and the general maternity services at one peripheral hospital.

7.5 Results

The bereavements relating to miscarriage, stillbirth or neonatal death were acknowledged in seven of ten reports; one additional report described maternity services including bereavement care in one unit without reference to specific cases.

Bereavement care as described by families in the 10 Irish inquiries reports was not reliably patient-centred or respectful. Five main themes regarding the impact of bereavement care on families were identified in the inquiry reports: Communication, Healthcare staff, Maternity unit environment, Post-mortem/coronial process and Local incident reviews. In the sections below, we will explore these further and quotes from the inquiry reports are used to illustrate each theme.

7.5.1 Communication

Communication between health care professionals and patients or families is complex and is further complicated by stressful and/or tragic circumstances. The style and demeanour of these interaction may be perceived by different parties in different ways.

The influence of patient factors (e.g. language, culture, emotions) and staff factors (e.g. communication skills, lack of available time) on interactions were noted in the inquiry reports. It was observed that not appreciating and accommodating these different factors can have negative impacts on communication with bereaved parents.

> *"There was an unacceptable lack of consideration of the views and experiences of patients. It is clear that there are some difficult cultural issues at play in* the hospital *which must be addressed." Report 6*

"At the time when the issue of a post-mortem examination was raised with the parents, they were in a state of shock and grief. All parents who made submissions to the Inquiry related the fact that the discussion took place in circumstances of extreme stress." Report 1

"There were problems accessing translation services and sometimes partners were used as the best available translator." Report 10

Unfortunately, in five inquiry reports bereaved parents stated that they were treated with lack of empathy, dignity and respect.

"Families were not always given time to deal with their grief. They were not always provided with support and clear, unbiased information. They feel that they were not always treated with dignity and respect." Report 1

Problems with clear communication of complex issues that arise at a challenging and emotional time, such as pregnancy loss or perinatal bereavement, in a manner that is understandable to families were identified in several reports. In addition, it was reported that the use of medical jargon and lack of clear information (verbal and written) regarding interventions caused confusion, discomfort and anxiety; whereas clear explanations could have eased some of the distress felt.

"This (poor communication and language skills using unexplained medical jargon) *left parents feeling intimidated and unclear as to what was being said to them and some of them felt inadequate and uncomfortable about asking for a clearer explanation." Report 7*

"Some (parents) *praised the staff for explaining everything in detail so that they could understand the circumstances of their child's death. In contrast, others found that the information was conveyed in technical language that they did not understand." Report 1*

Situations where patient autonomy was disregarded were described, such as not offering all management options during labour or for early pregnancy loss. Sufficient information needs to be provided, so patients can be active

members regarding decisions in their care and make informed choices. The following quote from one inquiry illustrates how this was not the case:

> *"They* (patients) *felt that they did not get full explanations of the purpose of certain tests and interventions or the opportunity to consent to them." Report 10*

Six inquiry reports documented issues with the practice of open disclosure. Accounts of lack of openness or honesty from staff and management after unexpected adverse events were described; this adversely affected the trust patients had in health care professionals and/or the hospital system. In addition, this distrust or delays in receiving explanations was stated to complicate grief reactions.

> *"Patients highlighted a lack of communication around their care. This was particularly difficult for patients and families who needed support and answers to their questions following a baby death." Report 9*

> *"Parents found that such lack of openness in providing information and explanations compounded their feelings of fear and grief." Report 7*

Follow-up after pregnancy loss is important to discuss results of investigations, like the post-mortem examination findings, and to address any questions the bereaved parents may have [3]. One report clearly described how inappropriate or delayed arrangements were made for this follow-up visit. Further, some parents did not receive honest answers to their questions.

> *"When families did come for follow-up they often waited for a long time, did not feel that they were being told the truth and often received contradictory information. Some families reported receiving no feedback at all." Report 10*

7.5.2 Healthcare staff

Inquiries reported that in cases of stillbirths or neonatal deaths, trained staff can help parents to care for the deceased baby e.g. around time of post-mortem, making memories by taking photos and hand/foot prints. The time parents will have, to spend with their baby is limited, so every contact with the baby is precious. In this analysis, issues related to lack of bereavement support for families and absence of specialist trained staff were identified; in contrast, it was highlighted how those who did receive appropriate bereavement care valued this greatly.

> *"The parents who had experienced some kindness and compassion remarked at how supported they felt by this and how this approach had helped them get through a difficult time." Report 7*

It was noted that appropriately trained staff, such as Clinical Midwife Specialists (CMSs) in Bereavement, can provide this vital support such as practical advice and counselling to the bereaved families for all types of pregnancy loss. The 2011 inquiry report stated that CMSs were available to support women in 40% of Irish maternity units. This report describes how after a miscarriage CMSs can provide bereavement counselling and/or arrange further investigations and follow-up for parents.

> *"Clinical Midwife Specialists in bereavement and counselling are an under-utilised resource who can provide invaluable support for the women in their care." Report 3*

The lack of a single-point of contact was an aspect mentioned in many reports. Without knowing who to contact or approach, it can be difficult for families to direct their questions at the appropriate personnel.

> *"During the time of the cases for review, 2008-2014, although support was given through the Pastoral Care Department, there was no dedicated bereavement midwife or a single contact for families." Report 10*

7.5.3 Maternity unit environment

Accommodating bereaved couples or those with a pregnancy with uncertain outcome away from others with normal and ongoing pregnancies can be difficult. Mothers who have had a stillbirth or lost a baby soon after birth may find meeting or hearing other mothers and their newborns traumatic, as demonstrated by the following quote from one inquiry report:

> *"It was clear that inadequate facilities and equipment added to the trauma. Mothers were not necessarily accommodated away from other mothers who had delivered babies." Report 6*

Providing uninterrupted time to discuss sensitive and/or complex clinical situations in a quiet and private environment will help patients and families to understand and process the received information, and give them an opportunity to ask all relevant questions. Three reports described situations where unsuitable facilities (such as a hospital corridor or a busy post-natal ward) were used to explain distressing information about their baby to new parents. This was reported to add to the distress and trauma already experienced by these parents and families.

> *"Others* (parents) *described being told their baby did not survive, or being given other sensitive information, in an unsuitable environment such as the hospital corridor." Report 7*

Most parents appreciate receiving guidance and support through the grieving process, and spending time with their deceased baby and making lasting memories [66,233]. Two of the inquiry reports stated that appropriate offers to care for their deceased baby (such as washing and dressing) and creating lasting memories, were not consistently made to the bereaved parents.

> "*Practices with regard to handling, holding, dressing, bathing, and photographing their infants were at best variable; appropriately sized coffins were not always made available." Report 6*

7.5.4 Post-mortem/coronial process

From the inquiries it was clear that parents appreciated detailed information on the post-mortem process that was sensitive to their recent bereavement. Two inquiries reported that the information provided to parents was lacking in detail and there was no written material provided. Furthermore, parents were not consistently informed of the possibility of limiting the post-mortem and the need for organ retention for detailed examination.

> *"None of the parents recall being given written information about the post-mortem process. Discussions tended to be brief and lacked in-depth detail." Report 1*

For a coronial post-mortem no parental consent is required. Even though the coronial process is independent from the hospital, the bereaved parents need explanations regarding what it involves and the length of time it can take [234]. Lack of support through the coronial process was reported to contribute to further feelings of anger and upset as illustrated in the following quote:

> *"The families seemed particularly angry at their treatment in the process* (coronial)- *a process that they understood to be there to provide them with the answers to some of their questions. They described their surprise and discomfort at the extent of the adversarial nature of the process." Report 6*.

7.5.5 Local incident reviews

From the inquiry reports it is evident that families were not consistently involved in the local incident reviews surrounding their care, and sometimes were not aware of the existence of these reviews at all. Other families raised the issue that incidents were not appropriately investigated in the first place:

> *"Some families expressed concerns to the* inquiry team *related to the fact that it appeared that a large number of incidents had to occur before a thorough investigation was conducted." Report 10*

At times families had to wait many months or even years for reviews to be completed. Such delays can have negative impacts as highlighted in the following quote:

> *"A common factor in each of the serious adverse incident reviews is that they were conducted in a less than timely manner, often well after the incident had taken place. Delays of this nature deny families answers to critical questions and deny healthcare systems both locally and nationally the opportunity to derive learning and to implement recommendations." Report 6*

7.6 Language style used in the reports

Beside the main themes, the investigators noted how the language style used in the reports to describe impacts on families differed. Some reports used descriptive styles illustrating the emotions parents felt, e.g. as shown in the following quote on parent-staff interactions:

> *"Most parents who met with the* Investigators *during this investigation explicitly expressed the opinion that some staff who were involved in their care were uncaring and did not listen to what they were saying. This was a common theme running through the meetings with those met with by the* Investigators *with parents saying they felt they were being talked about, were being ignored, and that they felt invisible."*

Other reports used an informative, matter-of-fact style to report findings; e.g. in the following quote on patient perceived support (regarding communication, practical support and feedback):

> *"In only 20% of domains was the provision assessed as satisfactory. In 44% it could have been better and helped the families cope and recover from the events that occurred and in 35% it was poor and may have aggravated the stress and upset to the families and made their recovery more difficult."*

7.7 Discussion

Well-executed inquiries can help to provide answers and closure to families affected by pregnancy loss, as well as promote positive change through initiating policy and practice updates in the maternity services. The methodology of the inquiry and the language style of the published inquiry report can have significant positive or negative impacts on the families and healthcare staff involved. Therefore, the wellbeing of the families and of the healthcare staff ought to be taken into consideration during the inquiry process, while addressing the shortcomings identified in the clinical care received/provided.

Three of the analysed inquiry reports described national findings, whereas the other seven reports focused on individual hospitals. There are 19 maternity units in the Republic of Ireland, and local lessons from one hospital are often applicable to other maternity units; therefore, it is important to share local lessons at a national level.

There were over 250 recommendations made in this cohort of 10 inquiry reports. A number of these addressed standards of bereavement care in the Irish maternity units relating to communication practices, the healthcare staff, the maternity unit environment, the post-mortem/coronial process and local incident reviews. In response to deficiencies identified in some of the inquiry reports the HSE National Standards for Bereavement Care following Pregnancy Loss and

Perinatal Death were published in 2016 to address the bereavement care needs of families in Ireland.[227] As a result, there is at least one Clinical Midwife Specialist in Bereavement employed in each Irish maternity unit since 2019 to provide a single point-of-contact for the bereaved families. This is a very important and positive step in providing bereavement care in the maternity units, although, as the findings of this study highlight there is potential for further improvements to ensure the best quality care is provided to all bereaved parents.

Communication is at the core of most patient/healthcare staff interactions, and therefore can affect patient outcome either positively or negatively.[235] Difficult and complex clinical interactions, such as conveying bad news or open disclosure after an adverse experience, require careful and experienced communication practices.[235] Such communications skills need to be learned;[236] lack of confidence and/or training may mean communication practices are unintentionally crude or insensitive. Regardless of the circumstances it is important that bereaved parents are always communicated with in a compassionate manner.[227]

Our findings show that experienced staff should always be available to provide immediate support and counselling to bereaved families as appropriate; and to allow patients and families the opportunities to understand and process information at and around the time of a pregnancy loss. O'Connell et al (2016) reported that bereaved parents consistently rated a hospital-wide sensitive and considerate culture as highly important[3]. Furthermore, supportive staff can facilitate extended family members to meet the deceased baby, thereby strengthening his or her unique identity. The importance for bereaved parents to create a lasting identity for their stillborn baby was described by Nuzum et al (2018). Maternity unit staff are in a unique position to help bereaved parents to make lasting memories with their baby. This is an important process as evidenced in a systematic review by Kingdon et al (2015), which highlights the benefits of contact with their deceased baby for the parents' mental health (e.g. lower levels of anxiety and depression).

Lack of awareness of bereavement needs by care providers and deficient continuity of care results in varying levels of support and practical advice being available to families. Continuity of care describes the seamless and personalised provision of quality care to families by an individual or team; which is maintained during the entire time the family engages with the health service.[237] Bereavement specialist teams (BST) and especially CMSs, co-ordinate and provide clinical- as well as bereavement care (e.g. social work support, spiritual support and counselling) and liaise with community services (e.g. general practitioner, public health nurse) as required.[227] With good continuity of care, the transition for bereaved families from diagnosis through the hospital stay to discharge and follow-up should be seamless, allowing them to focus on their baby, their bereavement and their family's wellbeing. Hence, effective continuity of care is an essential part of the care provided to bereaved families and could have avoided certain difficulties as described by some of the bereaved families in the inquiry reports (e.g. when and where to attend for follow-up care).

Hartigan et al (2018) and Meaney et al (2017) describe how an unsuitable hospital environment and lack of privacy (such as a noisy ER) for breaking bad news regarding pregnancy loss can exacerbate the distress felt by women and partners. However, while allowing privacy to grieve, bereaved couples do not want to feel isolated by staff.[66] In line with the Irish National Standards for Bereavement Care (2016), recommendations for a quiet reserved environment for bereaved families, ideally in a dedicated room away from busy maternity unit wards, were made in the 10 Irish inquiry reports.

A suitable private space should be available both in the inpatient- and outpatient-setting to discuss diagnoses, necessary interventions and consenting to them. The process of consent (e.g. for post-mortem) requires a good understanding of the parents' background knowledge and expectations. Issues with post-mortem consent processes, as presented in this analysis, share similarities with other studies.[5,62,63] The amount and type of information provided should be guided by parents' preferences[62] The decision to proceed with, limit or decline a post-

mortem examination requires careful consideration, and may involve discussions with various members of the clinical team (midwives, doctors, bereavement specialists, social worker).[5,62] The healthcare staff need to acknowledge any distress caused during this consent process and offer further support as appropriate. Written information and sufficient uninterrupted time should be provided for this decision process, as highlighted by the first inquiry report of this cohort from 2005. Furthermore, this report recommended that public education and information available on post-mortem and coroner's processes need to be developed. In 2012 the Irish HSE published "Standards and Recommended Practices for Post Mortem Examination Services" which gives clear guidelines on the consent process and additional information families should receive.[231]

The reports analysed, stated that patient autonomy needs to be respected and open disclosure practiced in the event of an unexpected adverse experience. Since completion of the 10 inquiries, the Irish HSE Incident Management Framework 2018 has been published.[91] This document explains that incident management is informed by learning from the perspective of persons affected.[91] Our findings show that various recommendations have been made on improving local adverse incident reviews, e.g. including the family's experience of an adverse event in the incident report. One recommendation stated that each Irish hospital should have a formal system of review for adverse incidents in place; and that "the results of these reviews should be shared with the patients in a timely fashion". This can provide families with answers to questions they may have and help them to process their bereavement. The Irish Incident Framework recommends for all reviews to be completed within 18 weeks.[91] Despite this Framework there currently is no consensus across the 19 Irish maternity units regarding how quickly adverse incidents get reviewed or how the findings are shared with the affected families.

In the Netherlands a law was passed in 2016 that mandates family involvement in hospital incident investigations and investigation reports have to be submitted to the national regulatory body within 8 weeks.[135] In Scotland, Wales and England a

Perinatal Mortality Review Tool (PMRT) has been launched within the MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries) program. The aim is to standardise perinatal morality reviews across maternity and neonatal units in the NHS (National Health Service) UK using the PMRT and to ensure bereaved parents are always involved in the review of their baby's case.

Adverse incident reviews, as well as external inquiries, make recommendations to ensure lessons are learned and maternity care standards improve as a result. To complete the investigation cycle it is important to confirm key learning points have been disseminated and lessons shared with all staff and stakeholders, and that the implementation of recommendations is followed-up. If recommendations are not implemented adverse events may recur at the detriment of patients, families and also the healthcare staff involved.

7.7.1 Limitations

Even though the ten inquiry reports all related to maternity services in Ireland, the overall focus and content of the reports differed significantly. They covered varying aspects of pregnancy loss (miscarriage and stillbirth) and/or early infant loss. Some reports had a larger focus on issues not exclusively or directly related to the bereavement care needs of families. However from the information in these reports it is apparent that bereavement care standards can be indirectly affected by wider organisational and managerial decisions. The bereavement needs of the families are comparable and should be met unconditionally, regardless of the type of loss and the type of clinical management necessary.

7.7.2 Conclusion

Pregnancy loss or death of their baby can be overwhelming for families, especially if the loss is unexpected. The standard of bereavement care families receive around this time, can have a significant impact on their short- and long-term psychological recovery. Maternity units need to ensure that all staff and facilities are equipped to provide consistent excellent individualised perinatal bereavement care.

If short-comings in care or equipment are identified in local incident reviews or national inquiries, these should be resolved without delay. During the review or inquiry, families as well as the relevant clinical staff, should be involved in a manner that is beneficial both to the review process and the individuals themselves. It is important to shift from a blame-culture to a focus on achieving best practice through collaboration and implementation of inquiry recommendations.

Chapter 8 - Bereaved Parents Involvement in Maternity Hospital Perinatal Death Review Processes: “Nobody even thought to ask us anything”

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Under review in Health expectations

Chapter 8 - Bereaved Parents Involvement in Maternity Hospital Perinatal Death Review Processes: "Nobody even thought to ask us anything"

8.1 Abstract

Introduction

The death of a baby is devastating for parents, families and staff involved. Involving bereaved parents in their baby's care and in the maternity hospital perinatal death review can help parents manage their bereavement and plan for the future. In Ireland, bereaved parents generally have not been involved in this review process. The aim of our study was to assess parents' perception on how they may be appropriately involved in the maternity hospital perinatal death review in ways that benefits them and the review process itself.

Methods

Bereaved parents (n = 20) in Ireland were invited to take part in semi-structured interviews. Thematic analysis was carried out on the interview transcripts.

Results

Four main themes were identified based on the participants views and opinions on how they experienced the review process and how they feel this process may be improved on. The themes reflect the journey of the parents through the different stages of the review process: Throughout process; On leaving the hospital; Interaction with the hospital "waiting in limbo"; Review itself. Identified subthemes highlighted essential aspects in this process and care provided to parents. For the parents, open, honest communication with staff, as well as having a key hospital contact was essential. Parents wished to provide feedback on their experience and wanted to be included in the review of their baby's death, in a way that was sensitive to their needs and the hospital's schedule.

Conclusion

A respectful, flexible system that allows bereaved parents' involvement in their baby's perinatal death review and is tailored to their needs is essential. A collaborative process between staff and parents can highlight clinical areas in need of change, enhance lessons learned, improve bereavement services, and may prevent future perinatal deaths.

Public Contribution

Bereaved parents were interviewed for this study.

8.2 Introduction

The death of a baby during pregnancy or shortly after birth is devastating for parents, families and all the staff involved. Unfortunately, some deaths are inevitable (e.g. due to a fatal fetal abnormality) but others may be preventable, if significant risk factors are recognised antenatally or intrapartum. After a perinatal loss (stillbirth or neonatal death) parents commonly experience negative psychological symptoms which can persist into subsequent pregnancies.[2] Acknowledging the importance of the deceased baby as an individual and involving the bereaved parents in all aspects of the baby's care (such as washing, dressing and examinations if appropriate) can help the parents process their bereavement and plan for the future.[1,131,238]

The purpose of local child death reviews, like the ones carried out after a perinatal death (stillbirth or neonatal death) in maternity hospitals, is to gather all the information on events relevant to the death, identify contributory factors and cause of death, and to recommend changes to prevent future deaths in maternity hospitals by identifying and addressing modifiable risk factors.[130] The bereaved families should be central to the review process, treated with compassion, and offered the opportunities to be part of the review process.[130,215] A study examining parental involvement in perinatal mortality review processes in six high-income countries found procedures were not established, and only one in

twenty of the 1104 participants described a detailed approach to parental engagement in reviews.[133]

In the UK, the PARENTS 1 and PARENTS 2 studies examined how bereaved parents want to be involved in the local perinatal review process and how this can be achieved.[129,131,134,239] The PARENTS 1 study showed that bereaved parents want to be part of the perinatal review process in a way that is "open and transparent, and emphasised the need for an inclusive and positive approach to both medical and emotional aspects of care".[131,134] Many benefits of involving parents in reviews were identified, such as: the parents providing additional, relevant information to the process; helping the parents to understand events around their baby's death; and encouraging the hospital to learn lessons and change practices accordingly.[129,134] The Perinatal Mortality Review Tool (UK-PMRT) was launched in 2018 to standardise perinatal mortality reviews across the UK and to ensure bereaved parents are always involved in the review of their baby's death.[240,241] Specific material is readily available to facilitate parental engagement in reviews using the PMRT.[242]

In Ireland, bereaved parents generally have not been invited to be involved in the perinatal death review, as the current process in place does not facilitate their involvement.[243] Instead, the final results and findings are usually discussed at the parents' follow-up visit with their consultant.[3] Of note, the national Incident Management Framework published in 2018 by the Irish health service stated that families must be informed if a review is going to be carried out and should be given the opportunity to give their perspective of events.[91] However, in Ireland there is no specific guidance on involving bereaved parents in review processes specifically.

A study from 2019 showed that just over half (58%) of Irish maternity units regularly informed bereaved parents of the local perinatal death review taking place.[244] Furthermore, only 17% of Irish maternity units stated that the final review report was provided to the bereaved parents.[244] A study on ten inquiry

reports relating to perinatal deaths and pregnancy loss services in Irish maternity services stated that only 40% of the inquiries involved all of the affected families.[245]

This study aimed to learn from and with bereaved parents, how they may be appropriately involved in the local maternity hospital perinatal death review process in Ireland in a way that is beneficial to both them and the review process itself.

8.3 Methods

8.3.1 Recruitment

Bereaved parents from all regions in the Republic of Ireland were invited to participate in the study. Purposeful sampling was implemented to recruit bereaved parents in collaboration with Clinical Midwife Specialists in Bereavement Care and parent representatives working within Voluntary Organisations supporting bereaved parents. These acted as a liaison to bereaved parents who had experienced a perinatal death (stillbirth or neonatal death), informing these potential participants about the study. Inclusion criteria included parents who were over eighteen years of age, spoke fluent English, were at least six months post perinatal bereavement (stillbirth or neonatal death) and no more than six years since completion of their child's death review. Previous research with bereaved parents showed that six months after their bereavement was an acceptable timeframe for parents to be approached about research participation.[132]

Once a parent gave consent to be contacted, they were contacted by email or phone by one of the researchers with a personal invitation to participate in a semi-structured interview. Each participating parent was invited to extend the invitation to participate to their partner. Recruitment occurred between October 2020 and March 2021. Interviewing paralleled the analysis.

8.3.2 Setting

There are 19 maternity units in the Republic of Ireland, which are funded through the Department of Health.[21] The maternity units vary significantly in size and activity; between 1,000 and 8,000 babies being born per annum.[21] The majority of births (>90%) in Ireland occur in the hospital setting, under consultant-led care.[21]

8.3.3 Interviews

Semi-structured interviews were carried out at a time convenient for the parent(s). A topic guide was used with open exploratory questions to encourage a conversational flow and allow participants to express their experience, views and opinions on how, when and where parents would like to be and can be involved in the local review process into their and their baby's care (Appendix IV).

Before recruitment began, a pilot interview was carried out with a parent representative from the local pregnancy loss research group to check the topic guide for clarity. All terminology was confirmed to be sensitive to the parents' bereavement during the pilot interview. This interview was not recorded and was not included in the analysis.

All parents were offered to have interviews carried out individually or with their partner present (sometimes for support) according to their preferences. The interviews took place between November 2020 and March 2021. Due to the COVID-19 pandemic and national public health guidance, all interviews were carried out remotely using a virtual meeting platform. Specific interview protocols were established to ensure security. The interviews were semi-structured, lasted between 27 and 107 minutes (median, 58 minutes), were audio-recorded using a Dictaphone and transcribed verbatim.

8.3.4 Ethical approval

Ethical approval was received from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Ref. No. ECM 4 (d) 08/09/2020.

8.3.5 Analysis

A qualitative research design was used to identify and report patterns in the data and to describe them in rich and meaningful detail.[216] The data analysis methodology was based on the principles of reflexive thematic analysis as described by Braun and Clarke, and followed their six-phase process.[216,246] Thematic analysis was chosen as it allowed the authors to examine themes or patterns within data. We wanted to make sure to optimise the information from the parents' interviews to ensure the analysis was thorough and had depth for a wider and better understanding of the issues around the topic under study. Using thematic analysis we provide a detailed examination of the central concept (i.e. the bereaved parents' journey through their review process).

Firstly, all transcripts were anonymised, read and re-read by the first author in order to become familiarized with the data and identify initial codes. Secondly, open, systematic coding facilitated the researcher to identify codes (and quotes) related to the research objective. Six of the interviews were read and coded independently by two of the other authors (three each). The three researchers with the aid of thematic maps discussed, reviewed and grouped the initial codes to reach consensus and actively generate the main themes and related subthemes. The transcripts were then re-examined by the first author to ensure all relevant and poignant data extracts were included and fitted within the generated themes and subthemes. Two of the authors discussed, further developed and refined the themes and subthemes to generate clear definitions and names for each, as well as clarifying the overall flow of the analysis of bereaved parents' involvement in hospital reviews. Finally, these themes and subthemes were reviewed and agreed on by all authors. The four final themes are

united by a central concept (i.e. the bereaved parents' journey through their review process) and the subthemes share patterns of meaning within each theme.[246]

An audit trail of the phases of continuous analysis was kept.

8.4 Results

8.4.1 Participants

Twenty-five parents were contacted by the researcher, 20 of whom participated in 17 semi-structured interviews (Figure 8.1). In total, 16 mothers and four fathers were interviewed. Ten of their babies were stillborn and six died in the neonatal period. It was at least six months since their bereavement for all parents (median 3.5 years). There was representation from three of the four provinces in Ireland, as well as from regional and tertiary Irish maternity units.

Results are reported on the lived experiences of the parents and their views on how meaningful engagement by parents in review processes may be achieved, as well as the reasons why this is important.

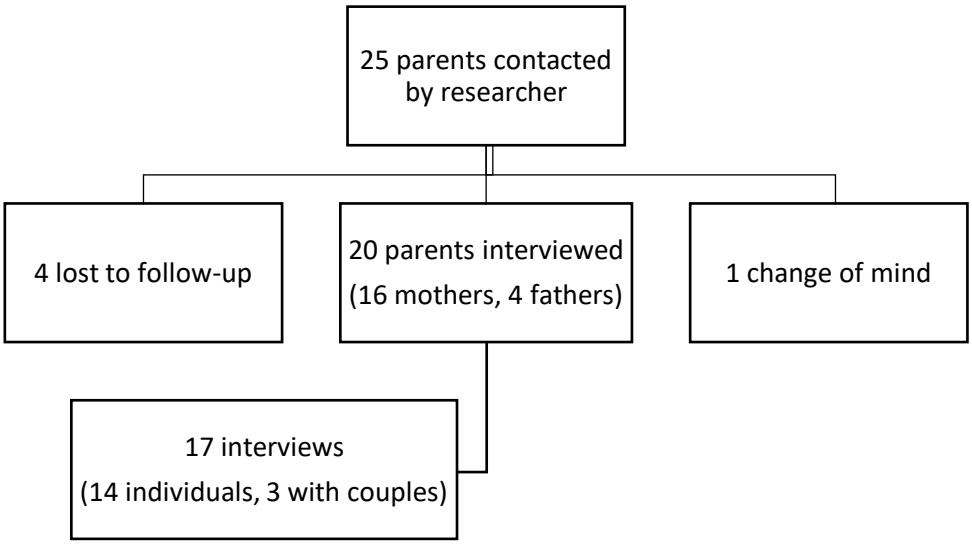

Figure 8. 1: Recruitment to interview process

8.4.2 Themes

Four overarching themes were identified from the data (Figure 8.2). The first theme 'throughout the process' contains subthemes that were important and relevant throughout the whole journey (Figure 8.2), the other three themes represented different (though at times overlapping) stages of the bereaved parents' journey through the hospital review process.

The 13 subthemes stemming from the four themes are presented in Table 8.1. Direct quotes from the interviews (indicated by '*Interview*' and the interview number) are used to highlight each theme. Short quotes are present within the main text (and subheadings); further quotes are presented in Tables 8.2 to 8.5.

Table 8. 1: Themes and subthemes identified from the interviews

Themes	**Subthemes**
Throughout process	Impact of grief on parents
	A just, compassionate culture with honesty
	Importance of communicating with parents
	Support for parents
On leaving the hospital	Information given to parents (verbal and written)
	Having a point of contact/key contact
Interaction with hospital "waiting in limbo"	The follow-up meeting for parents
	Parents providing feedback to the hospital
Review itself	Aims of reviews
	Parents' contribution to reviews
	Delivering information to parents
	Inconsistencies for parents with reviews
	Outcomes of the reviews for the hospital and the parents

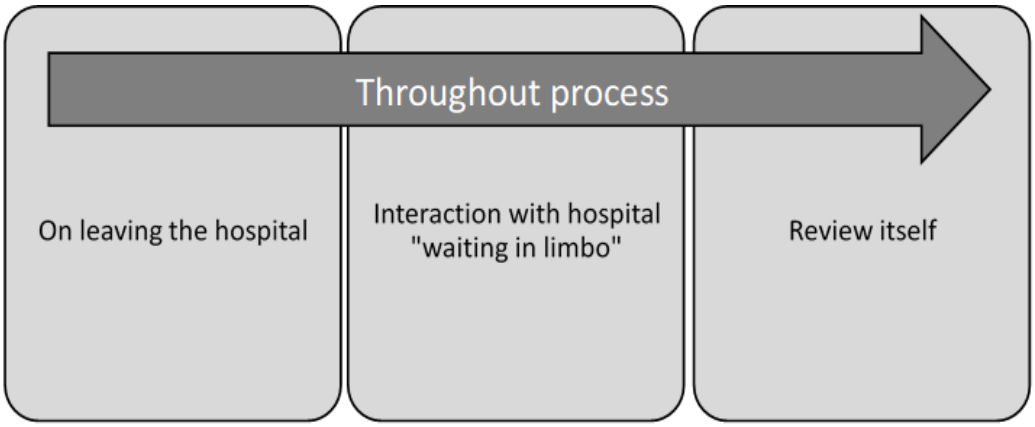

Figure 8. 2: Outline of themes in the study

The 13 subthemes stemming from the four themes are presented in Table 8.1. Direct quotes from the interviews (indicated by '*Interview*' and the interview number) are used to highlight each theme. Short quotes are present within the main text; further quotes are presented in Tables 8.2 to 8.5.

Theme 1: Throughout process "an informed approach is a fair approach"

Grief

Grief and its impact was a core experience that was mentioned by the bereaved parents. The parents expressed how **grief** has an enormous impact on them ('grief is a killer' *Interview 1*) and how it affected them both physically ('we weren't eating properly, we weren't sleeping' *Interview 11*) and mentally ('we were very raw' *Interview 3*). Some described their state of mind like a 'haze' or 'being in a dream' and 'in total shock', 'totally consumed with grief'. Grief further impacted on the way the parents were able to absorb information given to them and communicate with professionals (Table 8.2, Quotes 1 and 2). The participants felt that this needs to be taken into consideration when interacting and communicating with bereaved parents throughout the review process.

Compassionate culture

A **compassionate culture** within the hospitals and the supportive manner of professionals helped parents cope with their bereavement. The hospital culture affected how the parents were able to manage their grief and process the events around the birth and death of their baby, as well as navigate the investigations and reviews that followed (Table 8.2, Quotes 3 and 4). Parents expressed their gratitude when they met kind, supportive staff: 'they were just amazing and I can't put it in words how good they were to us' (*Interview 3)*. Whereas those parents that encountered a cold, uncaring environment described the detrimental consequences this had on them: 'I can tell you the disappointment through the whole thing was their care and like, those words. I regularly get night terrors. I relive that whole experience.' (*Interview 12)*.

Honesty and openness

Being able to ask questions and getting answers ('why did it happen' *Interview 4*) was essential to the parents (Table 8.2, Quote 5). The majority of parents expressed how important **honesty and openness** from professionals was to them from the beginning (Table 8.2, Quote 6) and throughout their bereavement journey. Those that were confronted with dishonesty or were 'kind of pushed aside' said it made them feel 'very confused', 'suspicious' and 'paranoid'. Two parents explained that they felt that openness was on the professionals' terms only (Table 8.2, Quote 7). Some felt that the current culture in the maternity services after a baby dies is to 'deny and defend' and explained that all they wanted was to 'feel safe to sit down and just say the truth' with the staff involved.

Communication with regular updates

All the parents agreed that **communication with regular updates** from professionals was extremely important throughout the review process (Table 8.2, Quote 8). However, they did feel this should be optional and adapted to each parent's needs, as some parents might prefer not to have regular contact (Table

8.2, Quote 9). A number of parents described how they had an open two-way channel of communication with staff in the hospital and could ask questions any time, an aspect they said was particularly valuable to them (Table 8.2, Quote 10). A few parents stated that they had difficulties in establishing contact with professionals, describing how they had to take the initiative, 'pursue' contact and meetings. They had to insist on being heard 'at every turn' (Table 8.2, Quote 11). One mother raised a concern about the parents that may not be adept at navigating these communication challenges: 'what about the parent that isn't willing to do that? Or doesn't even know that that's an option for them?' (*Interview 2)*.

Support

The participants also talked about their experiences of **support** throughout their bereavement journey. Some felt supported throughout this difficult time and through the hospital review process. Others mentioned how this support was lacking and how they felt they 'were forgotten' and felt like 'just another number'. Most mentioned the concept and the need of someone 'checking in' with them, especially after leaving the hospital with the abrupt change from 24 hour care to 'nothing' and feeling 'very alone' (Table 8.2, Quote 12). Those that had a bereavement midwife 'check in' really appreciated this support. A few parents mentioned how this contact should be cautious, and not be insistent or 'pushy' (Table 8.2, Quotes 13 and 14). A number of parents experienced and valued this support to include guidance through follow-up meetings and the review process (Table 8.2, Quotes 15 and 16).

Table 8. 1: Theme 1 'Throughout process'

Subtheme	Quotes
Impact of grief on parents	1. "…, when you're leaving the hospital, you're in a kind of a (pause) eh haze. …you're not able to take things in and you have questions afterwards, you know, after, you know, maybe a couple of weeks after that you you, you're kind of you have further questions that you are like, oh I should have asked that… I can't remember, you're told things as well, but you can't remember them because you're, …you're totally (pause) consumed with grief." *Interview 8*
	2. "You're going up for facts and you come away with em (pause) …kind of worry and you know you're sent down a different, a different road. Thinking I wasn't that before but now I am, you know, and that's grief and trauma too, eh grieving process, it's a very up and down road. So you need the medical side to be consistent." *Interview 2*
A just, compassionate culture with honesty	3."But even now every day if I have time, if I go to the hospital or if I am passing the hospital I always have a warm feeling about it because of the way the staff were up there. And even down to the explaining the process of what the pathologist does and the coroner was all done very naturally and there was warmth in it, there was no talking about clinical things and all that kind of stuff." *Interview 14*
	4. "…she was fantastic I have to say, I got very lucky with the lead on our review, just with her compassionate empathic approach. She was fair to all sides, …she made sure that all sides were appropriately met with fairness and justice." *Interview 13*

	5. “We had a list of questions we wanted to ask, they weren't hard, they were basic questions about my care, about the systems that failed us. We just wanted the simple answers to those. And we firmly believe if staff could engage, if there was the culture in place for this to go together… where it is protected, where we can all sit in a room, for once we could get the answers that we were looking for.” *Interview 16*
	6. “And you know, obviously if there's, if there was an issue, if they were able to tell us the truth and, and you know from the very beginning obviously that would have been better and then we could have gone away I suppose, and, and try and absorb that.” *Interview 11*
	7. “I suppose my big issue with the whole situation was the lack of information, literally we had to keep asking and asking. It was like trying to get blood from a stone. They wanted to be open and transparent but they wanted to be open and transparent if it suited them. I found the amount of information that was hidden, that was underhanded was an absolute joke.” *Interview 17*
Importance of communicating with parents	8. “So I was always kept informed. It is so important. An informed approach is a fair approach and that needs to be taken with bereaved parents… Like this is the death of a child, it is an ongoing process and all you are doing is sitting at home waiting for some sort of information. And the information that is received and the information that is given to bereaved parents, it is not enough. It is not okay to just send a one sentence email to say, yes they are still working on it.” *Interview 13*

	9. “So I suppose we wanted to know why and how, some people don't want to know that and that is entirely up to them. …all parents should be given the information whether they want to act on that information I suppose is entirely up to them, but they should definitely be given the option.” *Interview 17*
	10. "She rang a few times and then she was texting and stuff just to see how we were getting on. And I suppose, only because I kind of a good rapport built up with (name). I felt I could text her and ask her, you know, questions… And I mean, she would be great, like you'd never be, you would never be waiting long for her or anything like that.” *Interview 7*
	11. “…for me it just seemed like (pause) there hasn't been and there's still not any kind of appetite to hear my views. And like, I kind of feel like even though I've only sent a few emails, but I still kind of feel like I'm almost pestering to try to get things reviewed properly, and like our baby died! You know, I, I don't think I should be the one to have to keep following up, to try to make things be done properly… Like you know, obviously, if I wasn't trying, there'd be zero interaction. And even when I am really really trying, it's slow and it doesn't feel like that people really want to engage or listen really.” *Interview 5*
Support for parents	12. “I think the only time that I really felt I could have used more support was when I was discharged. Because you're going from a circumstance whereby you have midwives around you the whole time looking after you. You know, and you're getting fed at certain times. …you have this really good support bubble, you're wrapped in cotton wool, and

	then suddenly you're sent out to the real world and you have to stand on your own two feet and you're grieving." *Interview 4*
	13. "I think the hospital should make contact with the parents and be like, you know, look, the support is here if you need it, like, you can contact us when you're ready like… D'you know, eh would you like to talk about this? Would you, like, give them time, but also give them the option that there is always someone there to talk to. Like when they're ready." *Interview 6*
	14. "And like, she wasn't pushy. She rang all right. …But after that, then she'd text. So, like, if you didn't feel like talking, that was fine. No, she wasn't em, she wasn't pushy at all, at all. You know, you appreciated the phone call the first week because everything was so new and she was, but... Some people might be more private. I don't know. But I definitely liked (name of bereavement midwife) checking in." *Interview 7*
	15. "So we didn't really know what to expect or what to do. But in hindsight, only for our bereavement midwife at the time. She guided us through all of that. Our consultant didn't ask to meet with us." *Interview 3*
	16. "But that support *(from patient advocate)* continued all the way along throughout the years. She would always pop in every now and again and say how are things. Or if there was something I needed to ask about that I was very unsure about myself it was only a matter of picking up the phone." *Interview 13*

Theme 2: *On leaving the hospital "you're just given so much information inside in the hospital"*

Information given to parents

The first stage of parental involvement in the maternity hospital perinatal death review process began on leaving (or just before) the hospital. The parents spoke about the hospital stay after the birth being about spending time with their baby, making precious memories and their own/their partner's physical recovery. It was on leaving the hospital that they felt the **information given to parents** regarding what to expect next was 'so much' and 'there's a lot to process already', for example the funeral arrangements. Some parents described that providing written material about future meetings and review processes could help avoid this information overload. In addition, they recommended that making a follow-up call to ensure parents had received all relevant information accurately would be useful (Table 8.3, Quote 1).

The parents were very clear about what type of information was important for bereaved parents to receive as they were leaving the hospital. They felt it would be important for parents to know what happens after they leave the hospital, who will be in touch and what supports are available to them. Further, the participants thought it would be beneficial to receive clear information and timelines on follow-up visits, investigations and reviews, and the options they have regarding these (Table 8.3, Quotes 2 and 3). Seven parents suggested that, ideally, information should be provided in writing in the form of a booklet or information pack (Table 8.3, Quote 4). They said this would allow bereaved parents to process the information in their own time and 'soak things in better' during the initial period after leaving the hospital. Furthermore, the parents wanted to know what local and national support services (i.e. bereavement support, counselling,

voluntary support organisations, patient advocacy) are available to them and not to have 'go looking' for these supports (Table 8.3, Quotes 5 and 6).

Having a point of contact/key contact

Having a point of contact/key contact in the hospital (and/or a liaison for the review process) was important to the parents, to have 'a go to person, just that one link person, just one name' (Table 8.3, Quotes 7 and 8). They recommended for this contact to keep parents updated on investigations/reviews, be available to answer questions and liaise with other professionals (Table 8.3, Quote 9). The local bereavement midwife fulfilled this role for many of the parents, but this was not always made clear to them when they were leaving the hospital (Table 8.3, Quote 10). Some parents thought it was valuable to meet their key contact in person before leaving the hospital so they would 'have a face to the person' and that they would have a familiar person who would establish contact with them ('that it's not some random person that rings you after' *Interview 7*). One mother indicated that she believed that the workload was too arduous for a single individual: 'I'm not saying questions weren't answered or people weren't contacted. They were (pause), but they're counselling, they're liaising, they're contacting. That's too much for one person' (*Interview 1)*.

Table 8. 2: Theme 2 'On leaving the hospital'

Subtheme	Quotes
Information given to parents (verbal and written)	1. "…because sometimes you're just given so much information inside in the hospital. I think maybe even a follow up, a call… two or three weeks later, just to kind of nearly check in and see, 'do you want to have the follow up, do you want to have… these are the numbers available, do you want to come and have a meeting?' Here, you know, I think you're just given so much information in the hospital, sometimes you kind half forget, you know, there's so much coming at you." *Interview 8*
	2. "I think it should be arranged before you leave the hospital, just to say that this is coming down the line. The results will come back. They may show something or they may not show something. Em would you, I mean, would you like to meet with us?" *Interview 3*
	3. "There must be some two or three steps that could be, could be time-lined and person specific and explain, given to the parents on paper to go this is what the hospital will come to you with." *Interview 2*
	4. "I think there needs to be a booklet developed and that for information, that they are given to families, the coroner process, inquest, investigation, the parents' rights, advocacy support services. But it needs to explain the whole lot, even the terms of reference, as simple as that, I didn't understand enough back then and I know from listening to others that they didn't either." *Interview 15*
	5. "So I think, you know, have their doctor sit down with them the day they're being discharged and say, look, these are the, you know, supports available to you. And here are the numbers and someone will be in contact with you from these supports, you know, to know if you want to talk or when you're ready, you can reach out and talk yourself." *Interview 6*

	6. “I would have appreciated that before I left the hospital and I would have appreciated if they had already decided they were going to do a review, a hand out about what this process is. And that as parents you can contact this person at the patient advocacy service and they are there only to support you… And had we had that we would have known what to expect.” *Interview 16*
Point of contact/key contact	7. “And just to, you know, be introduced to each other and say this is your, you know, if you feel that you want to have this contact in the hospital, then, yeah, I think that's important. That's very important I think.” *Interview 11*
	8. “So I suppose like, she was kind of, like if there was anything, I'd probably go to her before somebody else, because (pause) I don't know, I suppose like, you don't really know otherwise who to contact. Em so, yeah, it is important to have a key, you know, probably a single point of contact who maybe could follow up on some things.” *Interview 5*
	9. “Em to have someone, you know, just to be able to, like a key worker or something like that, just so that you're able to talk to someone about the situation and be like, ‘OK, what's what's happening with this’ or ‘how is this gonna go’…” *Interview 6*
	10. “…I suppose, like there are the bereavement midwifes up there. Em so it's, it probably just needs to be a little clearer to the parents though, like em, who is my contact person if I want to follow up on anything that's happened?” *Interview 2*

Theme 3: Interaction with hospital "waiting in limbo"

Follow-up meeting for parents

Once the parents had left the hospital and their baby's funeral had taken place, they said they were at home 'wanting to know what happened to your child'. At this stage many felt the **follow-up meeting for parents** with the consultant would be essential to get some answers ('waiting in limbo for weeks and weeks and not knowing is terrible' *Interview 16*) and to dispel some misperceptions ('I had this tightness in my chest all along because you would feel blame, but after that meeting I felt a lot better' *Interview 10*) (Table 8.4, Quote 1). The timing for this follow-up meeting, according to the parents, needed to be flexible and suit each individual couple, though somewhere between 6 to 12 weeks after the birth was recommended (Table 8.4, Quotes 2 and 3). The parents were divided in their opinions regarding the location for the follow-up meeting, some thought it should be away from the maternity hospital, others felt going back into the maternity hospital was an opportunity to meet staff that had cared for them and their baby (Table 8.4, Quotes 4 and 5). Ultimately, the consensus was that it should be the parents' choice where they want to attend for their follow-up visit.

The conduct of this visit and the manner of the consultant can have a huge impact on the parents, either positively ('it was very reassuring' *Interview 4*) or negatively ('that meeting with that man did my mental health no good' *Interview 12*). Those that had a positive experience were grateful, especially when the meeting had been conducted according to their preferences (Table 8.4, Quote 6). In contrast, one mother described this visit as an 'opportunity missed from the hospital to keep the relationship going' (*Interview 16)*. Options regarding the follow-up visit that participants felt should be offered to parents included meeting a team of professionals rather than one individual, multiple appointments ('and leave it up

to the individual person then to choose to pursue the appointments or not' *Interview 4*) and having 'someone neutral' present (Table 8.4, Quote 7).

Provide feedback to the hospital

When asking the bereaved parents if they would have liked to **provide feedback to the hospital** on their own and their baby's care, the majority of the parents said they would have liked to, but very few were given the opportunity to do so (Table 8.4, Quote 8). Parents felt by giving feedback, both positive and negative, they would be able to give their side of events, highlight gaps and/or excellence in care and ultimately help other parents (Table 8.4, Quotes 9 and 10). Again, the consensus was that the timeframe for providing this feedback should be flexible, but around 6 to 12 weeks after the birth was deemed appropriate (Table 8.4, Quotes 11 and 12). Parents thought the invitation to provide feedback to the hospital should be both verbally and in writing, with a follow-up letter or phone-call to say 'if you want to opt in, if you want to have a chat, we're more than happy to do that' (*Interview 1)*. Many different ways of giving feedback were mentioned. Some thought writing using a questionnaire/feedback form, via email or a letter was appropriate (Table 8.4, Quote 13). Others thought verbally, over the phone or face-to face, as part of the follow-up meeting or a separate meeting, was best (Table 8.4, Quote 14). Many parents felt different options should be offered, so the bereaved parents themselves may choose how to provide feedback (Table 8.4, Quote 15).

Table 8. 3: Theme 3 'Interaction with hospital "waiting in limbo"

Subtheme	Quotes
The follow-up meeting for parents	1. "I would have liked to have had a meeting sooner after we lost (name of daughter), because as I said, like from the minute she died, I was in overdrive. …Em And I would have loved to have sat down with (name of consultant obstetrician) sooner and just been able to just converse with her about it." *Interview 4*
	2. "And it was now time to start slowly picking ourselves up a little bit. And moving forward with her. …the time was right for us. And we were ready to meet him… So I think a time frame of maybe 6 to 12 weeks, or definitely 12 weeks post, was a good time for us." *Interview 3*
	3. "Definitely, em I'm not sure if 6 weeks is long enough. I think em parents need longer, longer to try and process everything… And this just on top of having all the normal hormones that you'd have after having a baby. Em I think maybe a longer space of time before, before that discussion is maybe had. Even if it was another month added, you know." *Interview 11*
	4. "Em I felt like maybe they should have done it in another ward or another floor… it just, it was just horrible, like I was shaking, my whole body was shaking… Like, it just brought back so many memories. Maybe if they are having their meetings and stuff. Maybe they should be on a different floor or over in (name of hospital) in another room like, you know, rather than going back into the maternity hospital, where you know your baby, you had your baby there…" *Interview 9*
	5. "Well, I know she said that she felt initially coming back into (name of maternity hospital) we'll be upset you know, that she could set up something outside of the hospital… I'm so glad she set it up in the hospital because the day we went in, we met a nurse that looked after me, we met another midwife. And it really grounded us again, to say that (name of daughter) was real and that it did

	happen and we did deliver her here in the hospital. So initially put my foot inside the door, I did get upset. …But after that it was quite a safe, comfortable place and it was a safe place to go." *Interview 3*
	6. "So when I met with him, he checked with me. …So just really lovely. You know, he had offered his time. He was very respectful about me as the grieving parent. So, so he, he basically checked in saying, 'what way would you like to do this? Would you like me to, would you like to ask me questions? Would you like me to run through what happened?' He's like, 'just tell me what you need'." *Interview 2*
	7. "If you are feeling that in the moment you can, you have someone there to support you, like your partner can feel like that as well, so you kind of need someone, either a family member or someone neutral like a patient advocate or someone there with you, I would think is a good idea. We never went to a meeting in the hospital on our own, ever." *Interview 14*
Providing feedback to hospital	8. "But like you'd love them to know exactly how good their staff were, you know. Em yeah no, I suppose like there isn't really the opportunity to, to say any of that. Like when you go for, when you're getting the results even like it's, it's, it's very medical you know, you're only talking about results, future pregnancies. Like the last thing you'd be thinking about is being like, oh, 'by the way, I had a great experience, thank you'." *Interview 7*
	9. "I see that to give feedback would be great. If anything I can do to help other parents going through this and to prevent, I suppose, certain things that happened for us, not that we were met with much negativity to be honest. …Em yes, we would have loved that. Em and I suppose not just a letter but to be met, (pause) and to, to give our side of things or what we were unhappy with, or happy with… Most definitely, I think for moving forward and closure and for grieving, it would be very important on both sides, to get both sides of the story." *Interview 3*

10. “They were listening to us. Like we spoke to them for two hours… Em but kind of highlighting all of the things that we felt, you know (pause) possibly could have made a difference. And we haven't really got response on some things and, you know, kind of highlighting the things, the areas where we thought there might have been kind of gaps, em and not just for us. Like just in general, you know, like we were kinda saying, ‘look we're not experts, we're not trying to tell anybody what to do, but, this is kind of our experience’.” *Interview 5*
11. “Like maybe a couple of months down the line, not really straight after, because, you know, like especially if a mother is angry, they're going to say, ‘I hate this, I hate that’, you know what I'm saying? So, like, give it a couple of months and then, like, you know, phone them up and ask them. Or if they're meeting up with someone on the bereavement team, you know, get the person on the bereavement team to be like, ‘look were you happy with the level of care you received and your baby received at this time. And if, if not, how could we change that in the future?’…” *Interview 6*
12. “Again I would think around the 12 weeks, you know, let you process everything again, let the hormones settle down… So I think definitely let all that settle after the couple of weeks and then you would be able to speak up. And you would have time to process what has happened as well and speaking with your partner and stuff, he would have picked up things that you mightn't have picked up on.” *Interview 10*
13. “Maybe even a questionnaire or something because maybe people would be more confident to say things on a questionnaire or an email or something than they would face to face. People might shy away. I would have no problem speaking up for myself but not everybody would… There could be a comments section at the end then if people did want to put in their own little, because obviously everyone's journey was a bit different and their experience. So whether they wanted to express their anger.” *Interview 10*

	14. “I don't know how, like I suppose the, if there was a kind of a follow up meeting that it would, that would be part of that follow-up meeting, you know. Em if the bereavement midwife, whoever it is or whoever meets to go through, to meet to see if you are, you know, how you are doing, to talk to as part of that process, get feedback there, d'you know em. It, through that, that way I think would probably be a good idea.” *Interview 8*
	15. “Because, like, OK, not everybody might be used to doing emails or, you know, sometimes talking on the phone isn't, well some people might find it easier to do it on the phone, other people might do it face to face. So, yeah, I think an option. I think there should be whatever option a parent wants, really. Like I don't think it should be restricted to just, you know, contact this number between these times or something like that. I think em yeah, just an option of different ways to contact somebody would be good.” *Interview 5*

Theme 4: Review itself "a way to get answers"

Eight of the 20 parents were aware of a formal review into their care and their baby's death as it was taking place, one further mother learned of the internal review after it had been completed. The other 11 parents were not aware of any formal review taking place, either because it did not happen or because they were not told about it. However, all parents had some form of review (meaning investigations and/or meetings with professionals) to identify the cause of death for their babies and any potential contributory factors. In this section we discuss all these review processes together as for the parents the aim and desired outcomes are the same: 'to try and piece together what exactly did happen' and 'to prevent this happening to anybody else' (if possible).

Aim of reviews

For the parents the **aim of reviews** was to get answers, identify errors, prevents events recurring and possibly give them some closure (Table 8.5, Quotes 1 and 2). Unfortunately, overall the parents felt that what they experienced in the review process was not consistent with this perception (Table 8.5, Quote 3) but rather that it was done to satisfy a predetermined requirement: 'I really don't see how what's being done at the moment is in any way useful or meaningful, other than just to say that it's been done' (*Interview 5)*.

Parents' contribution to the review

This was also the case in relation to the **parents' contribution to the review** process. As one mother put it: 'I think as a parent the review process will mean very little until a parent's voice is heard a bit louder' (*Interview 14)*. All the parents agreed that their contribution to the review process was 'relevant', 'important' and 'has to be treated with credibility'. The parents' reasons for contributing to the review were 'to get the full picture', ensure all sides of events are recorded,

'the chronology', and ultimately so that lessons can be learned (Table 8.5, Quotes 4 and 5). Suggestions for involving parents appropriately included an invitation to all, ('input at the start and again before it's finalized, so that you can actually see what's been discussed' *Interview 5*) and a written statement and/or a meeting (Table 8.5, Quotes 6 and 7). The parents were clear that it should be up to the parents themselves to decide to contribute to the review or not, that 'the invite should be there anyway'. And what is offered to the parents is followed through (Table 8.5, Quote 8). Several participants felt that the current process of involving parents is protracted, one father described how 'the process was so long' and the effect this had on them (Table 8.5, Quote 9). For the parents it was essential that the information they provided was 'taken with honesty and listened to' and not 'dismissed' or 'treated as unreliable, uncredible, hearsay'. Some were asked to provide a written statement, as well as attend a meeting for an interview, at times the experience of the review meeting was described as 'traumatic', it was particularly distressing if in the end they realised their input 'had no impact, it meant nothing'.

Delivering of information to parents

The manner of **delivering information to parents** needs to be clear and compassionate. The parents requested clarity from the beginning regarding when and how results and review reports would be delivered to them. Getting results/reports without prior notice ('out of the blue' *Interview 16*) at home was described as 'disrespectful' (Table 8.5, Quotes 10 and 11). Many parents preferred receiving reports in person, with professionals facilitating the time and space to process the findings in their own time and ask questions, while also acknowledging their child as a person and their grief (Table 8.5, Quotes 12 and 13). Some parents stated that bereaved parents need to be offered input to a preliminary review report, rather being presented with the final version (Table 8.5, Quote 14). Again, the length of the review process until receiving results/reports was described as 'long' and 'very slow' by several parents ('having that hanging over you for months

is torturous' *Interview 7*), especially if there was uncertainty regarding the date of completion (Table 8.5, Quote 15). A few of the parents did not receive answers to their questions through the review process, and in some instances freedom of information requests were experienced as necessary to receive missing information (Table 8.5, Quotes 16 and 17).

Inconsistencies with reviews

The bereaved parents illustrated many **inconsistencies with reviews.** One mother felt that most parents are not made aware of reviews being started ('most people don't know that there's a hospital review happen[ing]' *Interview 5*), and two sets of parents were actually discouraged from pursuing a review (Table 8.5, Quote 18). Some of the parents explained how they were not appropriately involved in the review process ('they have to ask you these questions but they don't really want to know the answers' *Interview 17*) and what they said was not included (Table 8.5, Quote 19). It required significant effort from the parents to have to persistently contact the review team to 'be heard' and for updates ('it takes so much strength and it takes so much energy' *Interview 16*). One mother described how she felt 'shoved off, shoved off' when asking for updates. Another impact of the review process on parents was a 'burden of responsibility' and pressure to ensure recommended changes were implemented in the hospital ('we felt under enormous pressure to make sure that [em] the proper processes were put in place in the hospital to make sure that wasn't gonna happen *(sic)* to anybody else' *Interview 11*). The fear of issues recurring has led to parents feeling a sense of responsibility to ensure recommendations were progressed, solutions found and changes implemented. This added a significant level of pressure and stress to the anxiety they were already experiencing. They felt this was not fair on them and should not have been their responsibility ('we shouldn't have to do that, we have been through enough, that is not our job' *Interview 16*).

Outcomes of the reviews for the hospital and the parents

Outcomes of the reviews for the hospital and the parents differed but ultimately the one aim for both families and hospitals was to try and prevent further deaths if possible. The outcomes of the reviews for the hospital, the parents specified, should be learning and change (Table 8.5, Quote 20). However, several parents experienced their review to be a 'tick-box exercise' and felt that recommendations from the reviews were not implemented (Table 8.5, Quote 21). The parents said the review process has the potential to get answers, see positive change and to have the acknowledgment that their baby's life mattered, and therefore it can help to bring healing and closure (Table 8.5, Quotes 22 and 23). One mother summarised the potential outcomes of the review process aptly: 'it brings comfort and healing at the end of the day when it is done right, and when they are not done right you just have repetitive hurt' (*Interview 15)*.

Table 8. 4: Theme 4 'Review itself "a way to get answers"

Subtheme	Quotes
Aims of reviews	1. "As a parent I suppose you want to be your child's voice and I think the review process for a parent, as I said, is a way to get answers to something that (a) they don't understand because it is all medical, and (b) it is giving them closure." *Interview 14*
	2. "And at every single meeting we kept saying that this is about a systems failure, systemic systems failure where improvements could be made, where this was not to happen to another family. And that is what was most important." *Interview 16*
	3. "I suppose how it came across to us, was almost they were covering themselves. Unfortunately. But obviously, I know it's to assess what has taken place…" *Interview 2*
Parents' contribution to reviews	4. "Well to get our side of the story, first of all, because it was a very one sided review, they only got what the doctors and nurses involved. So there was no statement from us at all. …and, you know, for the doctors and nurses involved, em you know, obviously they're not going to try and and, em you know, say anything bad about themselves. There are, so they didn't get the full picture… I think mainly just to write down from our side of things what exactly happened and just explain exactly from our side of things." *Interview 11*
	5. "I know it's not going to be, in most cases medical information, but it's relevant… And like I was trying to (pause) kind of complement my notes as opposed to contradict them, like I was trying to give more information for it to be reviewed properly… And

	it's like, like I know most parents probably aren't doctors, but I mean, it's not just the kind of soft, emotional side of it that we can give, like a lot of the time it's actual proper information as well...” *Interview 5*
	6. “But, you know, just ask parents, like, would you like to provide any further information, you know. I don't know… giving a form would work or, you know, give people just an opportunity, at least ask them at some point, you know, would you like to give any more information? Do you have any other information that you'd like to have included in anything? *Interview 5*
	7. “…I find it easier for writing down information, personally. I know everybody wouldn't be the same, em (pause) maybe to write it down and then, you know, when they have seen that written statement or, and then maybe set up a meeting with everybody involved, then.” *Interview 11*
	8. “And then it's up to the parents, obviously, whether they decide to be part of it or not. And again, that it needs to be very clear and honest, because the parents need to know what they're getting into obviously. …So as long as the parents, whatever the parents are told they're going to be involved in, is what they're involved in. They're very clear what they're agreeing to.” *Interview 2*
	9. “It was months really trying to get all it sorted, so I think as a rule the system should be changed… because it is a traumatic time of your life and not many people want to go over this. Because every time we went over it, it was heart-breaking and it was very hard in the days afterwards we found because it is constantly on your mind. You give your account and then a few days later you weren't right really, we both found it, it was very hard.” *Interview 17*
Delivering information to parents	10. “There was no warning you will get it next week, nothing, there you go, in your in-box. So to say the least that was extremely hurtful and extremely disrespectful to a family.” *Interview 16*

11. “I think to get the results in the post, if it was me on my own, hormones raging, no baby here at home and to open a letter with the results. I think my (pause) the ground would just opened beneath me again. And it would have just added to my extra grief. The fact that (name of bereavement midwife) phoned me and said, ‘would you like to come and collect them and bring somebody with you?’ And to meet her personally and just the touch of her hand and just be able to get the results into my hand, helped. It really did help.” *Interview 3*
12. “Em so for us, initially getting our post-mortem result, we still came home with a lot of weight on our shoulders, whereas the second time round meeting with (name of consultant obstetrician), it was totally different. We came home with our bag was empty. We didn't feel that burden. So I think delivery of the information and how we're met as parents, grieving parents and that our child is acknowledged throughout the meeting.” *Interview 3*
13. “They gave it to us in the meeting. We had a patient advocate with us and that is when she kinda said, 'one second now we need the room to go through this'. If we didn't have that I don't know would we have got anywhere, would we have got half of what we needed to get out of it.” *Interview 17*
14. “But I definitely do think that if parents provide feedback, then it should be, you know, reviewed properly and noted and maybe give parents an opportunity to em review the report. And for that not to be a kind of a final report, maybe provide something to feed back into it and then finalize the report or something like that.” *Interview 5*
15. “…we had to constantly write, after three or four months, guys what stage is this at now? When it is supposed to take the 120 days, to take the length of time it took is just insane for the actual report that we got in the end.” *Interview 16*

	16. “And I will never know the answer to that. That was one thing that really upset me, I really thought that by getting a review I would have all the answers… That was the hardest part of it all I think because when you get a review as a parent you expect all your questions to be answered. Because they tell you that is what it is going to be.” *Interview 14*
	17. “So like these people, they must think that you're never going to look for freedom of information. You're never going to get all your files. You're never going to read all these emails. Like, yes, there's an awful lot of emails but, oh, my baby's dead. So I had time to read them. And as difficult as that was, I've read them.” *Interview 12*
Inconsistencies for parents with reviews	18. “You don't know what's what like, and I was asking his opinion. He basically told me 'oh reviews are not really worthwhile'. And I was like, really? Because I have a lot of unanswered questions here like, and you're here telling me this.” *Interview 12*
	19. “Em it did say patient concerns were noted, but there was no (pause) eh no detail as to what my concern were. Em or how they had been noted or how they had been reviewed at all… So, you know, I'd kind of really tried (pause) to give as much information as we could. And the only reason I was trying is because I wanted… a full review of (name of son) dying. Like, it's nothing to do with anything, it was literally just, I had information to give. I tried my best to give that information. And then even when I was kind of, you know, going out of my way to follow up and provide all the information that I could. That then was just completely ignored, you know, and it's just, it's just really annoying… I just kind of felt like we were just completely taken out of it, even though it was us and our baby who died. …it's like nobody even thought to ask us anything.” *Interview 5*
Outcomes of the review for the hospital and the parents	20. “…it wasn't like that for us in terms of, we know when staff get up that morning it wasn't their intention to not look after you, it was never their intention. They are human, they make mistakes but the biggest thing from mistakes is learning from them.” *Interview 14*

21. “But then you are looking at where these recommendations go, who is in charge of overseeing that these recommendations will be actually carried through? So it makes an absolute... What is the point in doing these investigations when they go into a drawer basically?” *Interview 16*
22. “And that was really amazing that, like, I felt like that was because of our little boy, that he inspired change and that would have been a really lovely thing to hear. I can understand how you have to be careful how you say things to parents, because there are people who sue for anything or anything. But I just thought that was very lovely to hear.” *Interview 2*
23. “And you don't want the same thing to happen to somebody else, so I think if a parent can, you know, knows themselves that they can give a bit more information and know or think at least that maybe that information might help somebody else. Or help, you know, so that another situation of the same or a similar kind of occurrence… that they might be able to stop that happening. So I think a lot of it is down to trying to (pause), do something for their baby because, like our babies have died. There's nothing really that we can do for them now. But I think for most parents, you know, you probably want to do something kind of for them so that it's not gonna happen to somebody else.” *Interview 5*

8.5 Discussion

In Ireland, bereaved parents have been infrequently included in local maternity hospitals' perinatal death review processes.[243] In this study, we learned from and with bereaved parents, how they may be appropriately involved in these reviews to aid the review process and have their views heard. From the interviews, it was apparent that meaningful parental involvement needs to be considered as a process and not a once-off meeting where report findings are divulged. Throughout this process open and clear communication between professionals and the parents is paramount, including unambiguous verbal and written information, as expressed by parents in this study and in line with previous literature.[129,131] Similarly to what has been reported in previous research, the parents in this study stated that it is essential to have a person as a key contact and support, so that they know who to contact with concerns and/or questions once they have left the hospital.[129] The bereaved parents stated that they want to give feedback to the hospital and the review process, both positive and negative, as well as receive results and reports in a supportive timely manner. The overarching expression from parents in our study was that parental inclusion in reviews needs to be flexible with realistic options available that are sensitive to parents' needs and state of mind, acknowledging their child, their role as his or her parents and their grief. This reflects the findings from earlier studies in this field.[131]

When bereaved parents are meaningfully included in maternity hospitals' perinatal death reviews, they feel their concerns are heard and their views are appreciated.[129] As expressed in our study and in line with previous research, for parents it is important to understand the circumstances and cause of death of their baby to help to process their grief and potentially plan for future pregnancies.[129,130] Further, parents in the current study explained how they can provide valuable clinical and non-clinical information to the review process, as well

as highlight good or deficient aspects of maternity and/or neonatal care. Previous literature has highlighted the importance of parental contribution to reviews and the value of such participation.[129,131,134] Collaboration between staff and bereaved parents can result in learning from events and improve services for other parents as indicated, and potentially prevent other perinatal deaths in the future.[134]

Our findings in the Irish setting mirrored many of the findings of the PARENTS 1 and PARENTS 2 studies in the UK, adding to the growing evidence of the benefits of involving bereaved families in hospitals' mortality reviews.[129,131,133,134,164,239] Like the participants in the PARENTS 2 study, our cohort of parents emphasised the importance of having a point of contact and the need for personal interaction rather than limited written correspondence.[129] Further, the concept of someone 'checking-in' was felt to be important by the participants in this study. Not having a designated person in the hospital for parents to contact with questions is an ongoing problem in some Irish maternity units.[58]

In Ireland, parents should be informed if a review into their care and their baby's death is taking place and if not, the reason for not reviewing a death. This has been stipulated in the 2018 national Incident Management Framework.[91] However, in this study parents were not consistently informed about these reviews. Further, the Incident Framework states that questions from affected persons should be considered as part of the review.[91] Despite this, many of the parents felt their queries or opinions were not considered appropriately. In the PARENTS 2 study there were mixed reactions to the feedback form developed for parents to complete after the death of their baby.[129] Similarly in our study, the parents felt there should be different options available to provide feedback to the hospital in writing or in person, depending on their preferences.

The UK-PMRT (perinatal mortality review tool) was developed and put into practice to improve the quality of local reviews by incorporating the parents' perspectives and standardising the review process.[241] Further research to

examine the potential of implementing an electronic review tool like the UK's PMRT in Ireland is warranted.

The PARENTS studies highlighted potential challenges to the engagement of bereaved parents in the reviews including the need for endorsement by local management, as well as the provision of extra human resources and supports.[134] Further, it may be difficult to balance the timing of the parental engagement to be sensitive to the parents' grief and fit with the hospital's schedule.[129] Many of the parents in this study were upset by the protracted nature of reviews in Ireland currently, with it taking many months or even years to receive post-mortem and/or review reports. A previous study by the authors showed that four of the 19 Irish maternity units released review reports more than six months after the event occurred.[244] Furthermore, recent research examining the timelines in the investigations of 122 stillbirths in Ireland reported the median time from stillbirth to the follow-up meeting with the consultant with the final report was 140 days (ranging from 54 to 579 days).[247] The current system with long delays and/or difficulties for parents to get answers and resolution, does not appear to put bereaved parents at the centre of the review process and may be contributing to delayed or complicated grief reactions of parents and families.[3,228]

Since the publication of the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death in 2016, the emphasis has been on providing sensitive and individualised bereavement care in the Irish maternity hospitals.[248] Promoting a culture of compassion and honesty is key to this.[248,249] This culture of openness and compassionate bereavement care needs to continue throughout the review process, and is not limited to the bereaved parents' stay in hospital. It is not acceptable to be unaware and insensitive to parents emotional and bereavement needs, as every interaction with a member of hospital staff has the potential to have lasting positive or negative effects.[1,3,60,228] Regular multidisciplinary, interactive education on communicating and interacting with bereaved parents for all hospital staff would help to foster a compassionate culture.[60] A workshop (called TEARDROP) has been developed and evaluated in

Ireland, and the aim is to expand this training programme nationally.[60] TEARDROP (Teaching, Excellent, pArent, peRinatal, Deaths-related, inteRactions, tO, Professionals) consist of six interactive, multidisciplinary workstations covering areas of the National Bereavement Standards to equip staff with skills to provide optimal bereavement care for parents.[60,248]

8.5.1 Practice and Policy Implications

The current study provides relevant insight and information which can have relevance to practice and the care provided to bereaved parents. Information is provided to bereaved parents on discharge from the maternity hospital after the birth/death of their baby. Seven of the parents (35%) suggested the development of an information booklet explaining the different aspects of the review process (i.e. key contact, supports available, ways to provide feedback, timelines, possible outcomes including results and reports) to complement existing information given to parents. This would be a simple intervention with a potentially large impact for parents. Further, this information booklet should clearly outline the voluntary support organisations and services available to parents.

Realistic timelines for follow-up meetings and review processes, as well as options for receiving information, results and reports should be clearly stated to parents and adhered to. Standardisation of the local perinatal death review processes at national level (based on the existing Incident Management Framework), including ways of incorporating parents' views and questions, would be helpful and alleviate discrepancies occurring in reviews and experienced by parents. The development of a review tool like the UK-PMRT and adaptation of the available associated support material [242] for the Irish setting may unify review practices further. Regular training sessions for all staff would form part of these standardised practices in Irish maternity hospitals.

A regular system of feedback is important to ensure meaningful involvement of bereaved parents in review processes is taking place, practices are sensitive to

parents' needs and to identify areas in need of further development. Parent experience surveys or a regular audit of parental involvement in maternity hospital perinatal death reviews could provide this feedback.

8.5.2 Strength and Limitations

Purposeful sampling was implemented to invite bereaved parents in this study with some potential selection bias as participants who were willing to participate in this research likely being those already engaged with maternity services and/or who had raised a previous concern about the review process to parent representatives working within Voluntary Organisations. Efforts were made to include a representative sample across Ireland and invaluable and relevant views on this matter were provided. Both individuals and couples were interviewed. Similar to other research studies [250], we found it challenging to recruit fathers to this study with only four taking part, even though the invitation to participate was extended to all partners of those that agreed to be interviewed. Due to the COVID-19 pandemic and public health guidance all interviews were carried out virtually, which facilitated geographical widespread representation of participants, but hindered the personal rapport between interviewer and interviewee.

8.5.3 Conclusions

In this study, parents clearly voiced their concerns with and desire to be included in perinatal mortality reviews. A respectful, compassionate and flexible system, tailored to the needs of parents is essential, however this is not yet consistently present for all bereaved parents in Ireland during their baby's review process. The involvement of parents in reviews needs to be carefully considered and resourced, as poorly managed engagement has the potential to cause more hurt. Causing upset and emotional harm through disrespectful or dismissive comments or practices at any stage of the review process must discontinue. Hearing parents' voices in open transparent collaboration with the hospital staff respects their baby

and their grief. It has the potential to both support their healing process and make real differences for parents and babies in the future.

Chapter 9 - Discussion

Chapter 9 – Thesis Discussion

An estimated 5.3 million perinatal deaths occur worldwide every year.[11] This includes stillbirths and neonatal deaths in both low- and high-income countries. In Ireland, 360 perinatal deaths were reported to the NPEC in 2019.[17] Each death bereaves a family and affects healthcare staff professionally and emotionally, with wider consequences on society.[1–3,6] Some perinatal deaths are inevitable but others are preventable. By recording and examining perinatal deaths, contributory and sometimes modifiable risk factors can be identified and addressed to prevent future deaths.[11,13,16]

This thesis is part of an ongoing programme of work carried out by clinical and non-clinical professionals in Ireland studying investigations and impacts of perinatal deaths on families and healthcare professionals.[1,3,6,7,10,86,125] Investigations of perinatal deaths include audits, reviews and inquiries.

There is currently a paucity of information on the methods, recommendations and impacts of these types of perinatal mortality investigations. In order to address these deficits of information, seven research studies were carried out (Table 9.1). These studies aimed to analyse the methodology of perinatal mortality inquiries and local reviews in Ireland. In addition, this research intended to identify recurrent themes in the audit and review reports' recommendations and assess their implementation. A specific aim was to advance the meaningful inclusion of bereaved parents in reviews.

Table 9. 1: Key findings of each chapter

Chapter	Title	Key findings
2	Perinatal Mortality Audits and Reviews: Past, Present and the Way Forward *(published in European Journal Obstetrics and Gynecology and Reproductive Biology)*	Lack of standardisation of perinatal mortality classifications and reviews
		Barriers to implementation of reviews (e.g. staff turnover, high clinical workload)
		Potential of electronic review tools in improving reviews
		Bereaved parents' involvement in reviews (growing evidence of benefits)
3	National perinatal mortality audits and resultant initiatives in four countries *(published in European Journal Obstetrics and Gynecology and Reproductive Biology)*	Varying methods of national audits
		Benefits of published audit reports for sharing findings
		Recurrent recommendations common to all countries (e.g. raising public awareness of perinatal mortality risk factors, detection of fetal growth restriction)
		Issues with implementing recommendations (lack of ownership, multi-agency approaches required)
4	Implementation of a national incident management framework: How does it apply to local perinatal death reviews? *(under review in Maternal Child Health Journal)*	Lack of standardisation of reviews in Ireland (review team members, timeframes, sharing of review reports)
		Bereaved parents' involvement (not consistent)
5	Irish inquiry reports relating to perinatal deaths and pregnancy loss services	Lack of standardisation of inquiry method, review team, timeframes, recommendation formation amongst others

	(published in Irish Medical Journal)	Inconsistent involvement of affected people (families and staff)
		Recurrent recommendations and lack of implementation
6	Governance of maternity services: Effects on the management of perinatal deaths and bereavement services *(published in Midwifery)*	Impact of workforce, leadership, hospital culture, risk management and work environment on maternity services
		Importance of hospital oversight, clear national documents (e.g. national guidelines) and reliable data collection on maternity services
7	Impact of bereavement care and pregnancy loss services on families: Findings and recommendations from Irish inquiry reports *(published in Midwifery)*	Hospital culture (Communication, staff demeanour) affects bereavement care positively or negatively
		Lack of involvement of families in local incident reviews
		Lack of implementation of recommendations from local reviews
8	Bereaved Parents' Involvement in Maternity Hospital Review Processes "Nobody even thought to ask us anything" *(under review in Health Expectations)*	Lack of standardisation of parental involvement in perinatal mortality reviews (no invitation or options regarding giving feedback and receiving reports)
		Detrimental effect on parents if bereavement care is lacking and they are not/not appropriately involved in reviews
		Culture to deny and defend in maternity services rather than shared learning

The interpretation of the studies carried out as part of this doctoral thesis and their implications for practice and further research are discussed under the following four themes:

1) Culture in maternity services
2) Lack of standardisation in perinatal mortality reviews
3) Implementation of review and audit recommendations
4) Collaboration between stakeholders in maternity services

These themes were recurring throughout all (or the majority) of the studies and are pertinent to the principal conclusions made in this thesis.

9.1 Culture in maternity services (Chapters 2, 4, 5, 6, 7 and 8)

9.1.1 Main findings

The culture of an organisation can be described as a collection of the attitudes, values, manners and behaviours of individuals and groups working within the organisation.[209] Historically, in Ireland the culture in maternity services was paternalistic, with healthcare professionals making care decisions for poorly informed, trusting patients and a traditional midwife (or nurse) -doctor relationship.[251] Perinatal bereavement care has also been under-appreciated.[51] Since the publication of the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death (2016) improvements have been achieved; perinatal bereavement supports within Irish maternity hospitals are being upgraded and standardised across the 19 maternity units.[51,56] However, there are ongoing concerns raised about a lack of openness between healthcare staff, patients and their families. The majority of the inquiry reports studied in Chapters 5, 6 and 7 stated that the families' voices were not heard or included after a safety incident, such as an unexpected intrapartum death.[49,50,55,58,128] Further, Chapter 7 described how open disclosure was not consistently practiced during and after the time of a pregnancy or perinatal loss. As highlighted in Chapter 8, openness and honesty after a perinatal death was essential for parents throughout their bereavement journey to process their grief and plan for future pregnancies, if

desired. The HSE updated their Open Disclosure Policy in 2019 focussing on the rights of the patients to be fully informed about their care.[120] In addition, a Patient Safety Bill (2019) will mandate open disclosure after a safety incident in the health service; this will likely become law in Ireland in the near future.[121] In the UK, Duty of Candour became statutory responsibility in 2014 stipulating all health care staff to be open and honest when an adverse incident occurs, and include a written letter to the patient (family).[252,253] These types of requirements are needed and welcomed measures towards more open and inclusive clinical care and related communication, and which will adequately consider the needs and involvement of bereaved parents in perinatal mortality review processes.

Multiple new policies and documents (including amongst others the National Maternity Strategy, the National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death, and HSE National Incident Management Framework) have been published relating to the Irish maternity services since 2016.[21,37,56,91,120] Further, many reports examining aspects of the maternity services have been published creating a document-heavy environment. Many recommendations recur through these reports and implementation has been slow, as outlined in Chapter 5. There appears to be a lack of appetite for change at both local maternity unit- and national level. Chapter 4 illustrates that local maternity hospital perinatal death reviews vary significantly and the national incident management framework has not been adapted consistently across the 19 maternity units.

A lack of leadership at local and hospital-group level, and a lack of national oversight, contributed to problems with delivering reliable perinatal bereavement care in some maternity units as discussed in Chapter 6. Management working in isolation with minimal collaboration between departments or units and a lack of awareness of the broader issues for bereaved families can result in an inconsistent approach to a compassionate culture. As stated in Chapters 7 and 8, some bereaved parents had difficulties navigating the maternity system, without knowing who to contact with specific questions or concerns and therefore

struggling to get answers. After a perinatal death has occurred, all aspects of the bereaved family's care needs, including social and mental health aspects need to be considered and managed appropriately.[56]

For staff a supportive, safety culture in maternity services means that time is protected and provided to attend essential training, both within and outside their maternity unit.[254] Chapters 5, 6 and 7 highlighted that maternity staff were not being offered or were unable to attend multi-disciplinary emergency- and bereavement care training. In addition, there was a lack of time and/or availability for professionals to take part in perinatal mortality reviews and audits; as mentioned in Chapters 4 and 6. The reasons for not participating in these important activities included workforce shortages and turnovers. In addition, minimal rewards or incentives were offered for this work and staff perceived that contributing to reviews and audits was undesirable due to the emotional burden and time commitment demanded of them (Chapters 2, 4 and 7). In the Irish maternity services there was also an ongoing lack of awareness and training as to the relevance of perinatal mortality reviews and audits to individual practice and improving safety.[90]

9.1.2 Implications for practice and policy

The voices of bereaved parents must be considered in practice and become part of routine policy. As described in Chapter 8 parents stated the importance of awareness by staff and families of impartial free advocacy services, as well as their accessibility and availability. By conveying their account of events, bereaved parents are able to identify where gaps in (continuity of) care are and can raise valuable solutions for maternity services; this resource should be seized upon by hospitals to improve care. For example, parents could be invited to speak at staff study and training days, and/or parent representatives could be invited to become members on appropriate hospital committees, such as maternity unit bereavement committees.

Appropriate and sensitive open disclosure must become part of daily practice for all healthcare professionals, this needs to be assisted by abolishing the blame culture that persists in some Irish maternity units.[120,125] There needs to be a general shift in the mentality and culture to ensure staff understand the value of open disclosure. A positive organisational culture with open communication is created by supportive leadership and effective multi-disciplinary team work with unified goals.[255] A person-centred approach, rather than a task-based environment, enhances staff commitment to and patient experience of clinical care provision.[255]

The organisational culture must also be active in translating lessons learned, recommendations and policies into routine practice. Governance structures at local and national level need to provide the time and funding to implement recommendations from reviews, audits and standard documents (such as the National Maternity Strategy and National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death) fully. In addition, staff should be facilitated to participate in perinatal mortality reviews and audits regularly. A more holistic approach to staff wellbeing and support is required around the time of their involvement in a perinatal loss and during the time of caring for bereaved parents to prevent burnout and emotional (compassion) fatigue.[6,125]

9.1.3 Further work and research

The British General Medical Council's Code of Practice stipulates for doctors 'to take part in regular reviews and audits' of their work and 'to contribute to confidential enquiries'.[252] Despite the participation of healthcare staff in local/national reviews and audits being advocated by the HSE, the Irish Medical Council and the Irish training bodies (e.g. RCPI); there appears to be a reluctance by professionals in Ireland to fulfil this requirement.[90] Further research is warranted to explore the reasons for lack of involvement by staff in local perinatal mortality reviews in Ireland; it will likely need a mixed methods approach for adequate in-depth knowledge on this. Examining the barriers and enablers to staff

engagement to promote the involvement by staff in reviews should form part of this research.

Finally, studying the awareness and understanding by staff of new national documents and standards (such as the National Maternity Strategy and the HIQA National Standards for Maternity Services)[21,37] might also help to inform the approaches needed to achieve the meaningful implementation of such valuable documents in Ireland.

9.2 Lack of standardisation in perinatal mortality reviews (Chapters 4 to 8)

9.2.1 Main findings

Chapter 4 illustrated that local perinatal mortality reviews in Ireland varied significantly regarding timeframes, membership of review teams and involvement of families (service users). Variable methods and timeframes of local maternity hospital perinatal death reviews resulted in issues for parents as highlighted in Chapter 8. Further, Chapters 4 and 8 illustrated how conflict between families and staff was created, and why some staff were deterred from participating in future reviews, due to the lack of a systematic approach and a protracted perinatal mortality review processes.

Currently, the emphasis by politicians and society in Ireland is to react to local and/or national adverse perinatal events in Irish maternity units by calling for 'a full and independent inquiry' rather than establishing reliable local investigations. The reporting of these events in the media influences public opinion, as well as accentuating the pressure on politicians and/or senior management of the HSE and/or HIQA to commission an external inquiry.[9,10] Chapters 5, 6 and 7 presented detailed analyses on high-profile inquiry reports commissioned in Ireland related to perinatal events in the maternity services. This analysis highlighted the varied methods and timeframes used for these inquiries, illustrating the absence of a standard approach in these.

The lack of standardisation of the external inquiry methodology, the development approach to recommendations and their planned implementation in Ireland means that lengthy reports are produced that continue to highlight issues in services, including maternity, but do not result in changing or ameliorating them.[124] The focus, both locally and nationally, appears to be on perinatal mortality data collection and reporting, with less emphasis on implementing perinatal death review recommendations or changing practice to address the contributory modifiable factors identified in reports. Consecutive inquiry reports into events in the Irish maternity services over a 15-year time period featured many repetitive and recurring findings as outlined in Chapters 6 and 7.

9.2.2 Implications for practice and policy

This research highlights that there is a clear need for a standardised approach to the perinatal mortality review process and the development of recommendations, with defined timelines and ownership for implementation. Further, standardised and more patient and public involvement both during adverse event reviews (such as perinatal mortality) and for developing recommendations is indicated in Ireland. The UK- PARENTS 1 and 2 studies explored and piloted the methods of bereaved parents involvement in perinatal mortality reviews.[129,131,134] The Perinatal Mortality Review Tool (PMRT), which has been in use since 2018 in the UK, mandates parental engagement in the review process.[115,256] In 2020, 3981 reviews were completed using the PMRT and 90% of bereaved parents were aware of the review taking place, with 60% making comments or raising concerns about their care e.g. poor communication.[256]

Best practice guidance is needed on perinatal mortality review methods, as well as on how to proceed with meaningful implementation of review recommendations. The Perinatal Society of Australia and New Zealand (PSANZ) has a Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death with a section dedicated to institutional perinatal mortality audit.[94] The uptake of this guideline has been studied and an educational programme, known as IMPROVE, has been rolled out to implement the use of the PSANZ guideline.[19,257] In Ireland,

an educational programme called TEARDROP has been development, and is in the process of being rolled out nationally, to advance and standardise perinatal bereavement care training for maternity staff in Ireland.[60]

In Ireland, the National Incident Management Framework should be adapted and developed further for incidents in the maternity services, which pose specific and unique pregnancy-related circumstances. Accountability of local reviews at national level is necessary and could be enhanced by using specifically designed care score cards or key performance indicators (KPI), as well as the aggregation and dissemination of learning points, especially if they are recurring. Monitoring of KPIs facilitates the tracking of adverse outcomes at local and/or national level in more detail than simply comparing rates over time. [253]

9.2.3 Further work and research

The National Perinatal Epidemiology Centre (NPEC) together with the National Women and Infants Health Programme (NWIHP) commenced the development of the Maternity Event Review Tool (MERT) in 2018.[20] The aim of MERT was to standardise local adverse intrapartum and perinatal event reviews in Ireland using this electronic tool.[20] In 2019, it was anticipated that MERT would be rolled-out across the 19 units in 2020; this has not been achieved to date. Renewed emphasis is required to achieve the standardisation of perinatal mortality reviews in Ireland. It would be useful to learn from and build on the successes of the PMRT-UK in the Irish context, adapting an electronic tool such as MERT to fit this country's characteristics and national maternity service.[106,115] Further, the data collected using the PMRT-UK and the reports produced from this data provide a wealth of information on the difficulties to implementing a national electronic review tool for the maternity services and should be utilised for the Irish setting.[106,115] Similar to results from Ireland as part of this thesis, in the UK there are some ongoing difficulties with the meaningful involvement of bereaved parents in hospital reviews into their care, as described in a recent report from Sands (Stillbirth and neonatal death charity in the UK).[258]

In addition to the local hospital-based perinatal mortality review carried out, all perinatal deaths in Ireland are referred to the district Coroner for assessment, in line with the legislation implemented in 2019.[68] Some of these deaths, where the cause of the death is uncertain, will have a post-mortem examination directed by the Coroner and may result in a Coroner's Inquest being carried out.[68] Currently, there are 34 Coroners listed in Ireland, and many will be involved with only few perinatal deaths on an annual basis. There is no standardisation around which perinatal deaths require an Inquest and which do not, which can result in similar deaths in different districts being managed differently. There is scope to investigate the feasibility of having a national perinatal (and/or paediatric) Coroner in Ireland, to standardise this aspect of care for families. At a minimum there should be standardisation of the coronial process across Ireland with predetermined timelines and pathways of communication for both parents and maternity unit staff with the relevant Coroner's office. Further, standardised approaches to perinatal post-mortem examinations and reporting by specialist perinatal pathology staff at hospital group level need to be finalised in Ireland, as recommended in the 2016 Maternity Strategy.[21,156]

9.3 Implementation of review, audit, and report recommendations (Chapters 2, 3, 5 and 8)

9.3.1 Main findings

Recommendations reviewed were made based on the key findings of perinatal mortality reviews, audits and inquiries. However, frequently, the published recommendations were not written in a standardised fashion, as explained in Chapter 5, and were recurrent in subsequent reports, as described in Chapters 3 and 5. Duplication of recommendations along recurring themes demonstrated unsuccessful implementation and probably resulted in identified issues with care persisting.

As part of national perinatal mortality audits, recommendations are written, with the ultimate aim to improve services and change care to reduce the number of deaths.[17,95,96] In Ireland, the perinatal mortality information currently being collected and analysed is not sufficient to identify truly preventable deaths.[86] A lack of completion of the audit spiral by not implementing recommendations has resulted in recurrent recommendations being made over consecutive years as highlighted in Chapter 3. In addition, Chapter 5 described how over 250 recommendations were made in ten inquiry reports, with many of the identified themes recurring over nine or more reports. Increasing healthcare workforce staffing and/or training, enhancing adverse incident management, strengthening clinical governance and undertaking comprehensive data collection were examples of these. The lack of stakeholder involvement in writing and implementing inquiry recommendations meant there was a lack of ownership over the implementation process and the inquiry process often finalised the report without defining an owner for the implementation of the recommendations.

A number of barriers and enablers of the implementation of perinatal mortality review and audit recommendations were identified from the work in this thesis. Vague, non-specific and unrealistic inquiry recommendations are more challenging to implement as highlighted in Chapter 5. In addition, this chapter described how a lack of ownership or resources inhibits inquiry recommendations being progressed. Further, without a specified timeline for delivery, recommendations are unlikely to be progressed. Chapter 2 illustrated how frequent hospital staff turnover and fear of repercussions prevented local hospital-based perinatal mortality reviews being carried out effectively in the first place. On the other hand, a well-managed regular local hospital-based perinatal mortality meeting can give rise to positive changes through constructive discussion and be educational for staff.[11]

Recommendations and solutions that are acceptable and/or desirable to frontline staff are more likely to be welcomed by staff and therefore implemented efficiently. The implementation of recommendations included in high-profile

public reports can be facilitated by political will and/or public pressure. The HSE National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were commissioned when deficiencies were highlighted in a number of inquiry reports.[50,56,128] The standards and quality of perinatal bereavement care in Ireland have improved significantly following the resourced and clinically-driven implementation of the Bereavement Standards. Chapter 2 demonstrated that a coordinated implementation plan written and administered by a team of clinical and non-clinical experts, that is funded and supported, is indispensable for progressing recommendations, especially at national level.

Chapter 8 outlined some of the effects this lack of progression of perinatal mortality review recommendations had directly on bereaved families. One main concern expressed by bereaved parents was the fear of events recurring resulting in a preventable perinatal death for another family. Some parents felt an immense pressure to ensure recommendations were progressed and solutions found, adding to the stresses they were already experiencing. Further, grief was amplified for those parents that felt the review carried out into their baby's care failed to highlight specific issues and offer tangible solutions.

9.3.2 Implications for practice and policy

This thesis supports and promotes the standardisation of an approach when making recommendations for reviews and reports using the SMART principle. This means that recommendations should be specific, measurable, achievable, realistic and time-bound.[92,253] The HSE Incident Management Framework endorses the development of SMART recommendations as part of its guidance document.[91] The PMRT (UK) reports advocate for action plans resulting from recommendations to be SMART as well as strong (to initiate system changes rather than relying on individuals to change).[115]

Further, ownership for the recommendation needs to be clearly identified; meaning the individual or department within the health service with responsibility for implementing each recommendation is identified and accountable. By

involving key stakeholders in the drafting of recommendations, it is more likely that key recommendations will be prioritised to speed up the implementation process, as we see from the work around the Bereavement Standards implementation.[51] A collaborative process between professionals in charge of governance, policy makers and frontline management would ensure that identified pressing recommendations will be progressed to ensure continuous improvement will take place for staff and patients. These professionals have different but complementary views, perspectives and experiences, which should be considered during the implementation process.

The Consolidated Framework For Implementation Research (CFIR) is an implementation science theory that considers five major factors: the intervention or change; the outer and inner settings; the individuals involved and implementation process (Figure 9.1).[259]

The intervention or change	• Intervention source (internal vs external) • Evidence and validity • Adaptability and complexity • Cost
The outer setting	• Patient needs • Peer pressure • External policies
The inner setting	• Organisational culture • Leadership • Communications • Climate (priorities, compatibility)
The individuals involved	• Knowledge and beliefs • Competency • Tenure
The implementation process	• Planning • Engagement • Execution • Evaluation

Figure 9. 1: The five domains of the CIFR[259]

Each of these factors can have a positive or negative impact on achieving the implementation of an intervention (or change). From the CIFR one can appreciate that implementing a recommended change in clinical practice needs to be considered and planned as a multifactorial process using a theoretical base.[259,260] CIFR is based on a practical and systematic approach, which promotes stakeholder engagement and incorporates an understanding of the influences of behaviours on implementation.[260] This framework has been successfully applied in maternity services internationally for perinatal educational programmes and perinatal mortality reviews.[260–262] Having a detailed and realistic implementation plan, especially for national documents such as the Irish Maternity Strategy and the HSE Bereavement Standards, is an essential step. During the implementation process it is also important to observe and address any barriers and encourage facilitators that may arise.[259,260]

9.3.3 Further work and research

Studying the awareness and understanding of key stakeholders (maternity services local and/or management, frontline staff) might help to identify the perceived and actual barriers and facilitators to assist the meaningful implementation of perinatal mortality review and audit recommendations at local and/or national level. The CIFR could be trialled to implement a recommendation identified as part of the perinatal mortality audit in Ireland. This research will need to include a broad panel of stakeholders and use a mixed methods approach to elucidate the learning from implementation. The result of this type of research may be an implementation guide or model specifically suited to the Irish maternity services.

Shared learning of successes and failures in relation to local and national recommendation progression can inspire new ways of approaching solutions. The UK's Each Baby Counts (EBC) programme (2015 to 2020) concluded that combined learning based on specific types of maternity outcomes and a focus on implementing findings 'to move from counting to action' is vital in quality improvement programmes such as EBC.[111] Having regular national study days and

online material available to share learning are two ways of promoting successful initiatives and highlighting relevant themes. The theme of the NPEC annual study day due to take place in January 2022 is "From recommendation to implementation". Findings from this thesis will be presented and disseminated at this national study day.

9.4 Collaboration between stakeholders in maternity services (Chapters 2 to 8)

9.4.1 Main findings

National collaboration between stakeholders in maternity services, such as clinicians, epidemiologists and health officials, is required to agree on definitions of stillbirths and neonatal deaths, as well as the gestational limits to be included in perinatal mortality rate calculations and the inclusion/exclusion of second trimester TOP as stated in Chapters 2 and 3.[13,27,76,77] Though issues with variations in definitions have been highlighted repeatedly[13,27,76,77] and efforts have been made by the WHO, the ICD and the ISA to align classifications[11,74,75], discrepancies still persist.

Insufficient or ineffective collaboration between stakeholders in Irish maternity services, including patients and their families, were demonstrated in five of the studies in this thesis. There is a lack of collaboration at local level between healthcare staff as highlighted in Chapter 4. The key findings and recommendations from local maternity hospital perinatal death reviews were not consistently shared between professionals across separate departments. Further, the lessons learned from local reviews are currently not shared at national level in Ireland. As highlighted in previous sections, the analysis of the ten inquiry reports revealed that many key issues and resultant recommendations were recurring and repeated in consecutive reports (as identified in Chapters 5, 6 and 7). The lack of collaboration between the inquiry commissioner, the review team and other key

stakeholders played a role in this implementation deficit. Only by forming meaningful and lasting alliances between politicians, policy-makers, national and local governance committees, frontline maternity staff, and patient and public representatives will important learning points and associated changes in care provision be introduced and maintained. Multidisciplinary team work at local level is also required to assess and address all aspects of maternity services affecting perinatal care, including pregnancy and infant loss services.

In addition, Chapter 8 described how some bereaved parents experienced an atmosphere of division during the perinatal mortality review process, with healthcare staff on one side and families on the other. Although the parents did not clarify why this was the case, they clearly stated that this culture was not acceptable to them. Parents want and need to be involved in all decision-making processes around their child's care, regardless of whether their child is living or deceased.[3,131] Sensitive and clear communication with parents around the time of the perinatal death and during the review process is key.[258]

9.4.2 Implications for practice and policy

International sharing of learning from perinatal mortality audits and reviews would benefit both high and middle-low income countries. Collective learning in addition to international reporting, as is already done by the WHO and EURO-Peristat[11,83], is required. An international body (like the WHO) or a regular international meeting, could facilitate this collaboration on learning points identified from perinatal death reviews, with a focus on implemented solutions, their successes and challenges. Further, it would contribute towards standardisation of perinatal mortality definitions and reviews.

Additionally, national sharing of learning from perinatal mortality reviews in Ireland could help to advance maternity care and prevent future adverse events. This learning can be facilitated through a national body, like NWIHP, by publishing learning notices for staff as well as the general public. Highlighting recurrent issues from different maternity units in an unbiased manner and offering solutions

at virtual or in-person study days facilitated by NWHIP or the IOG of the RCPI, would help to disseminate the knowledge.

If recommendations are provided and restricted to healthcare management, some may not progress to frontline staff, thus inhibiting the development of workable solutions in routine practice. Multidisciplinary involvement in addressing recommendations can result in lasting changes ensuing. Making SMART recommendations and considering aspects of the implementation science frameworks, such as CIFR, would increase their chance of progression and success.

Public health measures should also be considered in relation to perinatal mortality risk factors. Pre-conception health advice (starting with the education of children and young adults) regarding weight management, smoking and problems arising with advanced maternal age, is important and a still under-utilised public health measure. Misconceptions regarding risk factors for perinatal deaths are prevailing amongst the Irish public.[183]

There is growing evidence of benefits to collaboration between professionals, public representatives and/or and bereaved families.[56,131,134,139] Bereaved parents in Ireland were involved in the Bereavement Standards implementation process as part of the Parents' Forum, to ensure that bereaved parents' views were taken into consideration throughout the process.[51] The Each Baby Counts project Advisory Group and the PMRT development working group both included parents representatives.[111,256]

This collaboration is important to advance and ensure inclusion of the holistic as well as the clinical aspects of perinatal care at and around the time of pregnancy and/or infant loss, and during the perinatal mortality review process. For this collaboration to work and be effective locally, bereaved parents should be given the opportunity to provide meaningful input, their voices to be heard and have the appropriate supports and resources available to them. As part of the UK-PMRT, Parent Engagement Material for parents and staff has been developed to

facilitate meaningful involvement of parents in the perinatal mortality review process.[263]

Staff needs include specialised training and support, in managing parents needs and expectations, as well as their own mental wellbeing.[6] Creating and promoting a no-blame environment with protected time away from other clinical duties is key to a successful partnership between families, staff and management.[11]

9.4.3 Further work and research

Research is needed exploring the reasons why effective collaboration between stakeholders, such as clinicians, management and health officials, in maternity services is still lacking. Further studies on how to promote this collaboration in an adequate manner are also needed. Additionally, ethnographic research in Ireland, as has been previously carried out in the UK, could explore how the culture in Irish maternity units promotes or prohibits collaborative working and safety relating to pregnancy and infant loss services.[255]

As already mentioned the NWIHP and NPEC are developing a Maternity Event Review Tool (MERT).[20] It is now timely and relevant to explore and mandate parents' involvement in local perinatal death reviews using an electronic review tool, and build on the experiences of the UK-PMRT to achieve this collaboration successfully and in a way that benefits both the families and the review itself.[256]

9.5 Strengths and limitations

9.5.1 Strengths

This thesis aimed to analyse the methodology and structure of perinatal mortality audits, inquiries and local reviews, as well as to study recurrent themes in the audit and review reports' recommendations and assess the implementation of these recommendations. The studies in this thesis were running in parallel with a period where various strategies and standards to improve the Irish maternity services, including perinatal bereavement care, have been launched.[21,37,56] In addition, the

studies followed on from projects in the UK (PARENTS 1 and 2, PMRT[115,131,134]) to improve perinatal mortality reviews, further augmenting the relevance of this research in the Irish setting.

The impact of pregnancy loss and perinatal deaths on families was considered throughout this research, and informed each study in varying ways. The especially challenging circumstances in which parents, service users and staff were put in due to the COVID-19 pandemic has also heightened the need to promote high-quality care and best practice in perinatal bereavement care and mortality reviews. The bereaved parents' involvement in local maternity hospital perinatal mortality reviews and inquiries was central in Chapters 7 and 8, and was considered in Chapters 2, 4 and 5.

The involvement and input of relevant stakeholders was sought at different stages of the studies. Two professionals working on the perinatal mortality audit in the Netherlands (Perined) were consulted as part of Chapter 3. A parent representative from the local Pregnancy Loss Research Group (PLRG, UCC) was involved in piloting and revising the topic guide for the qualitative research piece in Chapter 8. Further, collaboration with professionals from the PLRG and the NPEC aided the development and interpretation of the research studies included in this thesis.

This thesis presents work that, to our knowledge has not been done before, compiling and summarising relevant knowledge and understanding of perinatal mortality audits and reviews at national and international level. This can advance the perinatal mortality review process in Ireland and support continuing improvement of bereavement care and perinatal mortality review practices in the country.

9.5.2 Limitations

Two limitations in this thesis were identified, the lack of available comparable data at times precluding deeper analysis, and being unable to interview stakeholders other than bereaved parents. Chapters 2 and 3 highlighted the ongoing issue of

differences in stillbirth and perinatal deaths definitions internationally. Chapter 4 showed the variations in local maternity hospital perinatal death reviews, precluding a detailed comparison of the standards of these reviews. The inquiry reports studied as part of Chapters 5, 6 and 7, though all relating to perinatal deaths and pregnancy loss services in Ireland, had diverse methods and report structures. It was possible to explore the themes of the key findings and recommendations in detail, however it was challenging to compare the methodology structures and standards of these inquiries.

The international comparison of national perinatal mortality audits and/or reviews was precluded partly by the lack of a wider publication of information on perinatal mortality programmes and tools in the English language. The language barrier and resource limitation did not allow the exploration of potential programmes which might exist in other countries (e.g. Scandinavia).

Interviews were carried out with bereaved parents to examine how they may be appropriately involved in the maternity hospital perinatal death review in ways that benefits them and the review process itself. It would also be relevant to explore the views and opinions on maternity hospital perinatal death review from other stakeholders (e.g. those who commission the reports; professionals involved in the reviews). Unfortunately, this was beyond the scope and timeline of this research thesis.

9.6 Summary

Perinatal deaths are common, affecting 360 families in Ireland in 2019 and many millions worldwide every year (an estimated 5.3 million perinatal deaths in 2015).[11,17] Each death and the standards of care received/provided around the time of birth and death has lasting effects on parents, professionals and society.[1–3,6] Key contributory factors and events are identified as part of perinatal mortality reviews to determine the cause of death and any modifiable risk factors, as well as determine preventability.[11,13,16] The culture in the maternity unit determines

how bereaved families and staff cope after an adverse event like an unexpected perinatal death. A lack of open disclosure can have negative effects on how bereaved parents process events and cope with their grief after the death of their baby. Further, the organisational culture affects how recommended changes are accepted and/or implemented. Recently many reports with multiple recommendations have been published to advance care and improve safety standards in the Irish maternity services; however, implementation thus far has been slow and incomplete. Prior to the establishment of the NWIHP in 2017, there was a lack of national oversight for the Irish maternity services. Understaffing and high staff turnover contributed to under attendance at essential emergency training and lack of involvement in perinatal mortality reviews.

Perinatal mortality reviews are currently not standardised across the 19 maternity units in Ireland. The perceived lack of reliable local investigations results in the media and/or the public demanding lengthy external inquiries. The focus is currently on collecting data and highlighting issues, and less on progressing recommendations to implement changes and prevent similar events recurring. Some recommendations are being repeated again and again. Barriers and facilitators to successful recommendation implementation were identified as part of this thesis. Many factors need to be considered when planning the progression of recommendations. Chapter 8 highlighted that the lack of implementing recommendations from local perinatal death reviews had a detrimental impact on parents. Bereaved parents want and deserve a more inclusive and collaborative environment throughout their bereavement journey. For lessons to be learned at local and national level, collaboration between hospital departments and maternity units, as well as healthcare management, policy makers and health officials, is required. Currently, these alliances are lacking.

9.7 Conclusion

The aim of this thesis was to explore the methods, systems, recommendations and bereaved parents' involvements in perinatal death reviews, inquiries and audits. A real need to standardise local perinatal mortality reviews across Irish maternity units and external inquiries into events in maternity services, was identified from the studies in this research thesis. The methodology and reporting, including the making and implementing of recommendations, should be done in a systematic manner and include all relevant stakeholders throughout the process. It ought to be possible for the implementation process to follow on from the review or inquiry process continuously and proficiently. The current reactive approach to reviews after adverse events in the maternity services, with the associated media backlash, must be amended to a proactive and open review approach, where all perinatal deaths (or a predetermined subset) get reviewed on a regular basis in a standardised fashion by a multidisciplinary team. Clinicians and policymakers in maternity services and other areas of healthcare (in Ireland and abroad) should pool their knowledge gained from systematic mortality reviews, thus learning from and with each other.

Further, while mortality reviews and reports highlight issues and contributory factors, they are in themselves not the solution, neither is simply demanding or providing increased funding or investment to services. Carefully planned initiatives or programmes, which may be complex and lengthy, are required to make changes nationally as well as locally to address the problems identified.

Tangible changes can be encouraged through programmes and/or policies which are developed at national level, followed by modification to suit each individual unit's facilities and services. For this to work the multi-disciplinary team, including management, clinical and non-clinical staff are all involved and working together to adapt these changes appropriately, thereby creating a culture for change. The strengths and weaknesses of the organisational culture and its effect on safety is

currently underappreciated in Irish maternity units, this needs to be addressed urgently.

Sharing the learning from local lessons and national perinatal mortality data needs to be further encouraged in Ireland and internationally. Compared to other countries the Irish maternity service is small with 19 maternity units, therefore it should be possible to communicate the difficulties and successes of implementing changes easily. The formation of hospital networks or groups further facilitates this. The NWIHP is in a unique position to lead the improvements. In addition, the research from this study showed that risk factors for perinatal deaths are comparable between countries, and that the knowledge gained from national improvement programmes is applicable internationally. Further international collaboration to address these risk factors in high-income countries (and worldwide) is required.

Lastly, perinatal mortality processes and the involvement of bereaved parents in perinatal death reviews need to be addressed without delay, and standardised across the 19 Irish maternity units. Suggestions to achieve this include the adaptation of the national Incident Management Framework specifically to the maternity setting, the implementation of an electronic review tool such as MERT and an assessment of the feasibility of a national perinatal (and/or paediatric) coroner for Ireland. The inclusion of parents in perinatal mortality reviews needs to be carefully considered and resourced in order for it to be beneficial to them and the review process itself. Robust supports need to be put in place to support bereaved parents, families and staff throughout this time.

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Supporting materials

Appendix I - Perinatal Post-Mortem Examinations and Placental Histology Supplementary table from Chapter 3.

Report	Year	Recommendation summary	Updates on recommendations
NPEC* Perinatal Mortality in Ireland Report	2013	A multidisciplinary approach, including perinatal pathology, is recommended in the audit of perinatal deaths at unit level	
	2013 2014 2015 2016 2017	Further research exploring factors of declining autopsy rates	
		Resourcing of regional and national perinatal pathology services to provide equal access for all deaths	This recommendation is being processed by the National Women and Infants Health Programme (from 2018)
		Inclusion of all placental histology reports for the perinatal mortality audit	Update on recommendation from previous reports: With the support of the Faculty of Pathology, the NPEC have adapted the standardised terminology in presenting the placental findings in cases of stillbirth and neonatal death (2017)
	2017	The Hospital Groups should examine the allocation of funding for the perinatal pathology service to ensure that a structured approach is taken to recruit staff in a timely manner	
MBRRACE-UK**	2013 2014	A post-mortem examination should be offered in all cases of stillbirth and neonatal death	

Perinatal Mortality Surveillance Report		For stillbirths, the placenta should always be submitted for histological examination (2014 only)	
	2015	Placental histology should be undertaken (if possible) for all stillbirths, preferably by a perinatal pathologist.	
	2016 2017	All parents should be provided with unbiased counselling for post-mortem to enable them to make an informed decision.	
		Placental histology should be undertaken for all stillbirths and if possible all anticipated neonatal deaths, preferably by a perinatal pathologist.	
Annual Report of the PMMRC***, New Zealand	2014	The Perinatal Society of Australia and New Zealand perinatal death classification (PSANZ-PDC) system be modified to allow the classification of babies dying with placental pathology	The PMMRC will apply these changes in its use of the PSANZ-PDC system beginning 2017
		The low uptake of post-mortems amongst families who experience perinatal loss should be investigated.	Update on recommendation from previous reports: The 2015 Survey of Bereaved Women looked at the information provided to women and their decisions about post-mortem examination.

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Appendix II - Summary of General Recommendations from National Perinatal Mortality Audit Reports Table from Chapter 3.

Report	Year	Recommendation summary	Updates on recommendations
NPEC* Perinatal Mortality in Ireland Report	2013	Collation of an agreed national dataset for maternity services to facilitate examination of factors influencing adverse obstetric outcomes, including perinatal mortality, ie. Through implementation of Maternal-Newborn Clinical Management System.	
	2013	The maternity hospital of delivery should be notified of any neonatal or infant death occurring in a paediatric centre/unit. A structured notification system should be developed.	
	2015, 2016	NPEC supports the Institute of Obstetrics and Gynaecology in the recommendation that anatomy ultrasound is available universally in Ireland.	As recommended by the Institute of Obstetrics and Gynaecology, second trimester fetal anomaly ultrasound scanning should be universally available for all pregnant women in Ireland (update in 2016, 2017 reports).
	2017	The NPEC Perinatal Mortality Advisory Group supports the NWIHP as they work with the Hospital Groups Chief Executive Officers to ensure that each maternity hospital/unit provides all pregnant women with access to dating and anomaly scans.	
	2017	The NPEC Perinatal Mortality Advisory Group suggests that the National Women and Infants Health Programme (NWIHP)	

		engage with the Coroner Service of Ireland regarding the clinical management of cases in order to allow timely reporting to families and hospitals of provisional information on cause of death.
MBRRACE-UK** Perinatal Mortality Surveillance Report	2013	NHS England, NHS Scotland, NHS Wales, Health and Social Care in Northern Ireland, in conjunction with professional bodies and national healthcare advisors should establish national aspirational targets for rates of stillbirths, neonatal deaths, and extended perinatal deaths against which all services can be assessed in future.
	2013, 2014, 2015	A national forum should be established by NHS England, NHS Scotland, NHS Wales, and Health and Social Care in Northern Ireland, in conjunction with professional bodies and national healthcare advisors responsible for clinical standards in relevant specialties, to agree the appropriate approach to reporting the influence on overall mortality rates of neonatal deaths and late fetal losses amongst babies born before 24 weeks' gestational age and of deaths due to congenital anomalies.
	2013, 2014, 2015,	Trusts and Health Boards with a stabilised & adjusted stillbirth, neonatal mortality or extended perinatal mortality rate that falls into the red or amber band should carry out an initial investigation of their data quality and possible

	2016, 2017	contributing local factors. Organisations should review their performance against national outcome measures with a view to understanding where improvement may be required.
	2015, 2016	Children's hospitals should continue to develop and embed systems that allow for consistent liaison with birth hospitals to facilitate the collection of maternal information.
	2016, 2017	Trust and Health Boards should use Perinatal Mortality Review Tool multidisciplinary meetings to improve the quality of cause of death coding.
	2016, 2017	Commissioning organisations should review both their crude and stabilised mortality rates alongside their high-risk population characteristics to facilitate the development of public health initiatives and to target focused interventions, such as the continued rollout of continuity of carer as recommended by Better Births, with a particular focus on women in high-risk ethnic groups and those living in areas of high deprivation.
	2017	Trusts and Health Boards should use the MBRRACE-UK real time data monitoring tool to monitor the completeness of their data. Particular emphasis should be placed on carbon monoxide monitoring and other data items feeding into national initiatives such as the Saving Babies' Lives Care Bundle version 2.

	2017	Trusts and Health Boards should work to implement fully the National Bereavement Care Pathway to ensure that all parents are offered high quality, individualised bereavement care after the loss of their baby.	
Annual Report of the PMMRC***, New Zealand	2013, 2015	As a matter of urgency, the Ministry of Health update the National Maternity Collection (MAT), including the ethnicity data as identified by the parents in the birth registration process.	The dataset has been made available to the PMMRC from 2014. The Ministry of Health has updated the MAT with ethnicity data as identified by parents during the birth registration process (sourced from Births, Deaths and Marriages) for babies born in 2016 and 2017. The Ministry expects to complete the updating of live born baby records for babies born from 2012 to 2015 by June 2018 (update from 2016 report).
	2013	That multi-disciplinary fetal surveillance training be mandatory for all clinicians involved in intrapartum care. This training includes risk assessment for mothers and babies throughout pregnancy as well as intrapartum observations.	Some DHBs reported that mandatory attendance at multi-disciplinary fetal surveillance training was required for all core staff. Other DHBs have responded that multi-disciplinary fetal surveillance training is occurring but is not compulsory.

			LMCs and obstetric staff are encouraged to attend/undertake the online programme or workshop. Other initiatives include education meetings where cardiotocograph (CTG) recordings from emergency caesareans or abnormal CTGs are reviewed as part of reflective practice, and all staff who provide intrapartum care are encouraged to undertake a 'fresh eyes' approach to CTG interpretation (update from 2014 report).
	2015	The PMMRC recommend the Ministry of Health urgently require DHBs to provide complete and accurate registration data to the MAT dataset.	
	2015	The PMMRC investigate why there has been no reduction in neonatal mortality in New Zealand.	Neonatal mortality is the focus of the special topic in 2016 report (Update from 2016 report).
	2015	The PMMRC supports the development of a national interdisciplinary clinical practice guideline on the indications and timing for induction of labour, to guide clinicians to offer induction when appropriate.	
	2016	The PMMRC recommends DHBs make available appropriate information, including appropriate counselling, for parents,	The New Zealand Newborn Clinical Network has produced a New Zealand Consensus

		families and whaˉnau about birth outcomes prior to 25 weeks' gestation to enable shared decision making and planning of active care or palliative care options.	Statement on the Care of Mother and Baby(ies) at Peri-viable Gestations, which is about to be released. This guideline standardises the care provided to mothers and babies. It includes parent information and decision aid for parents and families of babies likely to be born at 23–24 weeks' gestation.
	2016	The PMMRC recommends that DHB maternity services audit the rates of antenatal corticosteroid administration, including repeat doses when indicated, to mothers of neonates live born at less than 34 weeks' gestation, including auditing whether administration is equitable by ethnicity, DHB of residence, and maternal age.	**DHBs** – Tairāwhiti, Hawke's Bay, Auckland and Waikato DHBs have undertaken an audit of the rates of antenatal corticosteroid administration. Capital & Coast DHB has an audit in progress and Canterbury, West Coast, MidCentral and Hutt Valley DHBs all plan to audit in the 2019/20 financial year. Wairarapa DHB plans to be involved in a project auditing the use of corticosteroid administration and repeat doses through the MQSP. Taranaki DHB notes that they last audited antenatal corticosteroid administration in 2017. Northland, Hawke's Bay and Tairāwhiti DHBs have also recently updated their preterm birth guidelines

	2016	The PMMRC recommends that tertiary obstetric and neonatal intensive care units investigate and address the difference between units in survival rates amongst infants born at 23 to 26 weeks' gestation as part of their benchmarking and quality and safety initiatives.	The Newborn Clinical Network is reviewing data on survival over three years (numbers are small, so annual rates fluctuate widely). This is based on feedback from the Australia and New Zealand Neonatal Network. This review includes survival of all babies born after 22 weeks' gestation but less than 32 weeks' gestation. The review involves multidisciplinary team discussions to assess risk.
	2016	The PMMRC recommends that regulatory bodies require cultural competency training of all individuals working across all areas of the maternity and neonatal workforce. Training should address awareness of, and strategies to reduce and minimise the impact of, implicit bias and racism.	**RANZCOG** has introduced a mandatory component into the Fellowship of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists training programme. This is an online and kanohi ki te kanohi (face to face) course called 'Application of the Hui Process/Meihana Model to Clinical Practice', which is facilitated by the Māori Indigenous Health Institute (MIHI), Otago University, Christchurch. **NZCOM** – Although not a regulatory body, NZCOM has put significant focus on developing and providing continuing education in this area. Prior to the release of the PMMRC 12th annual

			report, NZCOM had initiated strategies to strengthen cultural consciousness within midwifery through the development and provision of the two new workshops for midwives nationally. The overarching aim of both workshops is to support an increased understanding and awareness of cultural consciousness within midwifery to benefit Māori and Pacifica women and whānau.
	2016	The PMMRC recommends that the Ministry of Health and DHBs have a responsibility to ensure that midwifery staffing ratios and staffing acuity tools: a. enable active observation of mothers and babies who are undertaking skin-to-skin contact in the postnatal inpatient period, b. allow for the identification of, and additional needs of, mothers who have increased risk factors for sudden unexpected death in infancy (SUDI).	**DHBs** – All DHBs have the Care Capacity Demand Management programme, which is a set of tools and processes that help DHBs better match the capacity to care with patient demand.
	2016	The PMMRC recommends that lead maternity carers (LMCs) and DHBs ensure that every baby will have access to a safe sleep place on discharge from the hospital or birthing unit, or at home, that is their own place of sleep, on their back and with no pillow. If they do not have access to a safe sleep	**RANZCOG** plans to discuss this at the upcoming Clinical Directors and Midwifery Leaders meeting. **NZCOM** has promoted the National SUDI Prevention Online Training to its members,

	place, then a wahakura or Pe¯pi-Pod®1 must be made available for the baby's use prior to discharge from hospital.	which includes the mnemonic PEPE, which stands for: • **P**lace to put the baby in their own bed: includes wahakura and Pēpi-Pods • **E**liminate smoking during pregnancy: midwives routinely refer for smoking cessation support • **P**osition baby on their back to sleep • Encourage and support mum to breastfeed. **DHBs** are contracted by the Ministry of Health to distribute about 8,500 safe sleeping devices each year, including wahakura and Pēpi-Pods, with individual DHBs deciding which are most suitable for its population. All DHBs mention education as an important factor in SUDI prevention. This includes education of health professionals and education of mothers.
2016	Maternity and primary care providers need to be aware of the increasing risk of perinatal mortality for mothers under 20 years of age in New Zealand. Inequity in perinatal	**DHBs** – Through the MQSP, every DHB has been asked to undertake and report on

		mortality for babies born to mothers under 20 years of age needs to be actively addressed.	improving care for mothers under 20 years of age in the 2018/19 work programme.
	2017	Collectively, we need to increase our understanding of the reasons for adverse outcomes in certain groups.	
	2017	The Ministry of Health should resource, support and facilitate the development of a national perinatal bereavement pathway with key stakeholders, including governmental and non-governmental organisations, to ensure high-quality, appropriate and equitable care for all.	

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Appendix III – Review tool – National report

Review tool – National Report

Version 6, Oct 2018

1. Post Mortem Practice and Procedures. Published 2005

2. HSE report into the death of TMC and son at Our Lady of Lourdes Hospital, Drogheda. Published 2008

3. National Miscarriage Misdiagnosis Review. Published 2011

4. A) HSE and B) HIQA reports into death of SH at Galway University Hospital. Published 2013

5. Review of Maternity Services at South Tipperary General Hospital. Published 2015

6. A) HSE review Midland Regional Hospital, Portlaoise Perinatal Deaths 2006 – date. Published 2014, B) HIQA report. Published 2015

7. HSE maternity clinical complaints review. Published 2017

8. HSE review Maternity Services at Portiuncula Hospital, Ballinasloe 2008 – 2014. Published 2018

Terms of reference

Objectives/Purpose	**Y/N/Partial/NA**	**Comment**
Is the purpose of the review stated clearly?		
Is the methodology explained?		
Is the methodology appropriate?		
Members of the review team	**Y/N/Partial/NA**	**Comment**
Does the report state who conducted the review?		
Please give total number of people on the review team		
Where there representatives from:		
1. RCPI Institute of O&G		

2. Obstetric consultant		
3. Midwifery (please state level e.g. director)		
4. Other medical specialist (please name)		
5. Parent/Family		
6. Support Group (please name)		
7. Organisation (please name, e.g. HIQA)		
8. External professional (state title and location please e.g. Professor O&G, University of London, UK)		
9. Other (please name)		
Does it clearly state each person's role?		
Does it clearly state each person's responsibility?		
Resources, Financial and Quality plans	**Y/N/Partial/NA**	**Comment**
Who commissioned the report?		
Who is the report presented to?		

Work structure and schedule	Y/N/Partial/NA	Comment
Is the timeframe of the review stated (i.e. length of time taken to undertake the review)?		
Is the timeframe in which the cases occurred stated (i.e. timeframe under review)?		

General content

Layout and design	Y/N/Partial/NA	Comment
How many pages long is the report?		
What is the word count?		
Do the typescript and font size used, make the document easy to read?		
Does the report have a logical flow?		
Are there clearly defined sections?		
Is there a clearly defined table of contents?		
Is the language/writing style used, easy to understand?		
Is the overall document (e.g. typescript, visual presentation, graphic design, etc.) is finished to high standard?		
Is a glossary of terms included?		
Are references included?		

(Please give number of references)		
Are the references timely (i.e. not outdated) to the review process?		
Are there any relevant references missing? (Please name the missing reference)		
How many appendices are there?		
Are the relevant documents referred to in the report presented in the appendices?		
Is the report biased towards any of the following:	**Y/N/Partial/NA**	**Comment/Example**
an individual (please specify e.g. patient, staff midwife on duty)		
a group e.g. consultant obstetricians, junior doctors		
a department/ organisation e.g. labour ward, hospital		
Is the report biased as a result of any of the following:	**Y/N/Partial/NA**	**Comment/Example**
hindsight bias (believe an event was more predictable than it was)		
outcome bias (judging a decision by its eventual outcome)		
the language used		

Background	**Y/N/Partial/NA**	**Comment**
Is there a brief summary of events leading up to the incident (chronology)?		
How many pages long is the summary of events/chronology?		
Does the summary of events/chronology avoid repetition?		
Summary	**Y/N/Partial/NA**	**Comment**
Does the report have an executive summary?		
Is the findings summary reasonably concise (e.g. 1-5 pages for Executive Summary; 1 page/400 words for Abstract)?		
Does the summary have a clear structure in relation to:		
1. Purpose, including intended audience(s)		
2. Objectives/aims		
3. Methodology		
4. Key findings and main conclusions		
5. Key causal factors and recommendations		

Overview of the Review Process

Methodology	Y/N/Partial/NA	Comment
Is there detail of how the review was conducted including reference to any review tools used?		
Were national or international guidelines used as reference? (Please specify)		
Is it clear how the reviewers reached their findings and recommendations?		
Are clear definitions of concepts (intentions) provided?		
Are clear definitions of scope (extent, opportunity) provided?		
Are clear definitions of criteria (principle, standards) provided?		
Services under review	**Y/N/Partial/NA**	**Comment**
Is there detail which hospitals/services were under review?		
Please list the hospital(s)/services under review.		
Is there detail provided in relation to the documents/records considered as part of the process?		
Please list all documents mentioned (e.g. patient records, hospital policy).		

Service user/Family involved	Y/N/Partial/NA	Comment
Was the service user/family involved in the review?		
Is there detail in relation to how the service user/family were involved in the review?		
Is there detail in relation to how the service user/family were supported in the review?		
If applicable, was the service user/family asked to comment on the chronology of events?		
Was the mismanagement and /or substandard care acknowledged to the service user/family in the report?		
Was the bereavement and/or adverse event acknowledged to the service user/family in the report?		
Was the service user/family asked for feedback after the draft report? (Please specify e.g. in writing, group discussion)		
Staff involved	**Y/N/Partial/NA**	**Comment**
Is there detail in relation to how staff were involved in the review? (Please specify if possible e.g. interview, written statement)		
Is there detail in relation to how staff were supported in the review?		

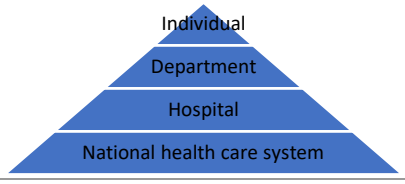
Were the staff asked for feedback after the draft report? (Please specify e.g. in writing, group discussion)		
Key findings (Where there any identified in relation to the following:)	**Y/N/Partial/NA**	**Please specify and describe (e.g. lack of communication between professionals in clinical situations, poor communication with families during and after the event)**
Service user/family (communication, personal/socioeconomic factors, language, mental/physical health)		
Task & technology factors (protocols, policies, standards, test results, decision-making aids) in particular intrapartum monitoring, risk recognition, labour/delivery/neonatal management		
Staff factors (individual, knowledge, skills, competence, physical/mental health)		
Team factors (communication verbal/written, supervision, seeking help, team structure)		
Work environmental factors (staffing levels, skill mix, workload, administrative/managerial support, equipment, resources)		
Organisational & management factors (structure, finance, leadership, policy/standards/goals, quality/safety)		

National (guidelines, acts/laws)		
Contributory factors (Where there any identified in relation to the following:)	**Y/N/Partial/NA**	**Please specify and describe (e.g. No structured staff handover)**
Service user/family (communication, personal/socioeconomic factors, language, mental/physical health)		
Task & technology factors (protocols, policies, standards, test results, decision-making aids) in particular intrapartum monitoring, risk recognition, labour/delivery/neonatal management		
Staff factors (individual, knowledge, skills, competence, physical/mental health)		
Team factors (communication verbal/written, supervision, seeking help, team structure)		
Work environmental factors (staffing levels, skill mix, workload, administrative/managerial support, equipment, resources)		
Organisational & management factors (structure, finance, leadership, policy/standards/goals, quality/safety)		
Other	**Y/N/Partial/NA**	**Comment**

Are any incidental factors/issues identified that while not impacting on this incident, highlight an area for service improvement? (Please specify in relation to patient, staff, organisation, health service)		
Were any ethical issues considered prior to/during the review? (If so, how were they reflected on?)		
Were any ethical issues encountered during the review process? (If so, how were these addressed?)		
Does the report comment on any aspects of notable/good practice? (Please give an example)		

Recommendations

Overview	Y/N/Partial/NA	Comment
Are recommendations included in the report? (Please specify number of recommendations)		
Is there a specific section dedicated to these?		
Are the recommendations linked to the contributory factors highlighted in the review?		
Is there mention of how actions/changes are necessary to ensure that the incident is unlikely to recur?		
Is there evidence that a hierarchy of controls was used to determine the		

weakest to the strongest recommendations?  		
Is the SMART principle (i.e. Specific, Measurable, Achievable, Realistic and Time-bound) applied to each recommendation?		
Do the recommendations reference existing safety initiatives (national/local standards and guidelines)?		
Does the report state that nationally applicable recommendations were identified?		
Is a timeline for the implementation of recommendations included?		
If nationally applicable recommendations were identified, how and to whom were they communicated?		
Does the report state who has responsibility for implementation of the recommendations?		
Specific recommendations	**Y/N/Partial/NA**	**Please specify and describe (e.g. Adoption of communication tool like ISBAR)**
Service user/family factors (communication, public health awareness, bereavement care)		
Task & technology factors (protocols, policies, standards, review of test results, decision-making aids)		
Staff factors (individual, knowledge/skills, competence,		

physical/mental health, education/training)		
Team factors (communication verbal/written, supervision, team structure)		
Work environmental factors (staffing levels, skill mix, workload, administrative/managerial support, equipment, resources)		
Organisational & management factors (structure, finance, leadership, policy/standards/goals, quality/safety)		
Institutional context factors (economic, external/national input)		
National (policy/standards/goals)		

Action plans

Overview	Y/N/Partial/NA	Comment
Are all recommendations linked to specific action plans?		
Does the report refer to a requirement for the report commissioner to oversee the development of an action plan to implement recommendations?		
Is a named professional responsible for developing action plans?		
Is a named professional responsible for regular review of these action plans?		

Is there a timeframe given in the implementation of action plans?		
Key performance indicators (KPI)	**Y/N/Partial/NA**	**Please specify and describe**
Are any key performance indicators described?		
Indicator Classification: (Please state if any KPIs in relation to the following were described)		
Quality and Safety		
Access to healthcare		
Governance and compliance		
Workforce		

Communication of the outcome of the review

Is the outcome of the review communicated to:	**Y/N/Partial/NA**	**Comment (Please specify how e.g. official letter, meeting)**
The service user/family		
Staff involved		
The public (i.e. official statement, not the media)		
Other services		
Is the report published?		
Where is the report published?		

Other comments:

Appendix IV – Interview guide from Chapter 8

Introduction

What do you feel is important for me to know about your family/history?

Can you tell me about the time when your baby/*baby's name* was born and the follow-up afterwards with the hospital? (Prompts: timing of investigations/follow-up)

Were you aware of any investigations or reviews going on at this time or later? (Prompts: blood test, post-mortem examination, hospital review meeting)

Review process

What do you think the review process tries to achieve? (Explain re review processes as necessary, Prompts: cause of death, answers, feedback, future)

Were you able to give feedback on your and your baby's care/*baby's name* care? (Prompts: how, when, were, to whom)

If applicable: Were you involved in any review process of your and your baby's/*baby's name* care? If yes, how?

Do you think parents would like to give feedback to the hospital? Why? Why not? (Prompts: positive, negative, changes)

Do you think parents would like be involved in the review process? (Prompts: ask questions, get answers, changes, autonomy) Do you think some parents might prefer not to be involved? Why?

What do you think is the difference for parents between giving feedback and being involved in reviews? What do you understand being involved means? (Prompts: receiving feedback back, answers to specific questions)

Where is the right place to ask parents if they want to be involved in the review process? (Prompts: in hospital, at home)

When is the right time to ask parents if they want to be involved? (Prompts: after the birth/bereavement in hospital, days/weeks later at home – time limit set by review process at 18 weeks)

How should this be communicated to parents? (Prompts: verbal/written information, letter, phone call)

Structure of parental involvement in reviews

How important is it to have a key contact for parents? Who could be an appropriate key contact? (Prompts: bereavement midwife, chaplaincy, patient support)

What would be ideal/appropriate and realistic? (Prompts: with whom, when – at what stage, where, how – feedback form/interview)

Depending on the answer to the previous question: What should be in the feedback form? (Prompts: antenatal/postnatal care, positive/negative) OR What should be discussed during the interview? (Prompts: antenatal/postnatal care, positive/negative)

What would you consider essential priorities when involving parents in the review process? (Prompt: top 3 things, time, place, people, manner)

From the parents' point of view what would be the main challenges or difficulties?

Completion

Do you have any other thoughts? Is there anything else that you think is important in the review process?

Any points you would like to go back to?

Thank you very much for taking part in this study.

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

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Helps, Ä. 2021. Study of methods, systems, recommendations and bereaved parents' involvements in perinatal death reviews, inquiries and audits. PhD Thesis, University College Cork.

Please note that Appendix V (pp. 315-316) is unavailable due to a request by the author.

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