Arlene Gutman\*, Tommy Harty, Keelin O'Donoghue, Richard Greene and Sara Leitao

# Perinatal mortality audits and reporting of perinatal deaths: systematic review of outcomes and barriers

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### **Abstract**

**Background:** Perinatal deaths are a devastating experience for all families and healthcare professionals involved. Audit of perinatal mortality (PNM) is essential to better understand the factors associated with perinatal death, to identify key deficiencies in healthcare provision and should be utilised to improve the quality of perinatal care. However, barriers exist to successful audit implementation and few countries have implemented national perinatal audit programs.

**Content:** We searched the PubMed, EMBASE and EBSCO host, including Medline, Academic Search Complete and CINAHL Plus databases for articles that were published from 1st January 2000. Articles evaluating perinatal mortality audits or audit implementation, identifying risk or care factors of perinatal mortality through audits, in middle and/ or high-income countries were considered for inclusion in

this review. Twenty articles met inclusion criteria. Incomplete datasets, nonstandard audit methods and classifications, and inadequate staff training were highlighted as barriers to PNM reporting and audit implementation. Failure in timely detection and management of antenatal maternal and fetal conditions and late presentation or failure to escalate care were the most common substandard care factors identified through audit. Overall, recommendations for perinatal audit focused on standardised audit tools and training of staff. Overall, the implementation of audit recommendations remains unclear.

**Summary:** This review highlights barriers to audit practices and emphasises the need for adequately trained staff to participate in regular audit that is standardised and thorough. To achieve the goal of reducing PNM, it is crucial that the audit cycle is completed with continuous reevaluation of recommended changes.

**Keywords:** neonatal death; perinatal mortality; perinatal mortality audit; stillbirth; substandard care factors.

# Introduction

Perinatal death can have significant psychological, social and even financial effects on parents and families and may also have serious implications for healthcare professionals involved [1–4]. To understand how to improve the care provided to mothers and babies and reduce these deaths, it is important to collect data surrounding these events, monitor trends over time, identify risk factors and causes of death, and use this valuable information as learning opportunities for improvement [5–7]. This can be achieved through auditing of perinatal mortality (PNM), including both stillbirths and deaths soon after delivery, referred to as neonatal deaths.

Perinatal mortality is used as one of the main indicators for the quality of care provided to mothers and infants [5, 6]. After the 2015 Millennium Development Goals identified maternal health and infant mortality as priority goals for United Nations' (UN) countries, the current Sustainable Development Goals highlighted the specific need to reduce preventable perinatal deaths, including

E-mail: arlenegutman@gmail.com

Tommy Harty, School of Medicine and Health, University College Cork, Cork, Ireland; and Cork University Hospital, Cork, Ireland Keelin O'Donoghue, Pregnancy Loss Research Group (PLRG), Department of Obstetrics and Gynaecology, University College Cork, Cork, Ireland; Cork University Maternity Hospital, Cork, Ireland; and The Irish Centre for Maternal and Child Health Research (INFANT), University College Cork, Cork, Ireland

Richard Greene, National Perinatal Epidemiology Centre, University College Cork, Cork, Ireland; Department of Obstetrics and Gynaecology, School of Medicine and Health, University College Cork, Cork, Ireland; and Cork University Maternity Hospital, Cork, Ireland Sara Leitao, National Perinatal Epidemiology Centre, University College Cork, Cork, Ireland; Department of Obstetrics and Gynaecology, School of Medicine and Health, University College Cork, Cork, Ireland; and Pregnancy Loss Research Group (PLRG), Department of Obstetrics and Gynaecology, University College Cork, Cork, Ireland

<sup>\*</sup>Corresponding author: Dr. Arlene Gutman, School of Medicine and Health, University College Cork, Cork, Ireland; and Pregnancy Loss Research Group (PLRG), Department of Obstetrics and Gynaecology, University College Cork, Cork, Ireland,

stillbirth and neonatal deaths, around the world [8]. Stillbirths in particular have a history of being underreported, unrecorded and under-researched, contributing to the higher proportions of stillbirth rates compared to neonatal deaths in high- and low-income countries [8, 9]. The U.N. has, most recently, estimated a global stillbirth rate of 13.9 stillbirths per 1,000 total births, when using the international comparison of gestational age after 28 weeks gestation, and a global neonatal death rate of 17 deaths per 1,000 live births, of neonates 0-27 days old [10, 11]. The most recent Europeristat report published in 2019, found the European stillbirth rate in 2015 was 2.7 per 1,000 total births, and the neonatal death rate (for births after 24 weeks gestation) of 1.7 neonatal deaths per 1,000 live births [12, 13]. This report includes data for indicators of maternal and newborn health in 2015 and its data collection commenced in January 2017, highlighting the challenges in obtaining timely and accurate data on such indicators. Although data has shown some reduction of perinatal mortality rates from 2010 to 2015, the differences recorded among high income countries demonstrates that there is still room for improvement [12]. The United Nations goals have brought further awareness and changes to maternal and fetal care, however further work is needed to successfully achieve these and end preventable stillbirths and neonatal deaths [8, 10, 11].

Although in the past decades 51 countries have implemented audit policies for maternal mortality and morbidity, only 17 countries have implemented similar policies for perinatal mortality and morbidity [14]. This evidences the need to develop policies and strategies across the globe to better measure PNM and analyze what could be done to reduce it. The 'Every Newborn Action Plan' (ENAP), developed by the World Health Organization (WHO), proposed the reduction of stillbirth and neonatal mortality rates to less than 12/1,000 by 2030 [15]. One of this initiative's key strategies specifically focuses on the importance of collecting audit data surrounding stillbirths and neonatal deaths [15].

Auditing allows the identification of maternal or fetal risk factors increasing the likelihood of PNM, or the monitoring of substandard care factors (SSCF) that range from adequate identification of risk factors by healthcare providers, to how the organization of a hospital may have affected the outcome of a delivery [7, 16-28]. The WHO recommends measuring specific indicators, such as perinatal and stillbirth mortality rates, and indicators of care, such as the presence of a skilled attendant at birth, or the use of antenatal corticosteroids [15, 29]. By implementing audits and utilizing them as an intervention method [30] it is possible to identify and form recommendations or action plans with the goal of improving antenatal care to reduce perinatal mortality rates [5, 7, 16, 22, 28, 31-33].

The WHO has deemed the implementation of perinatal audit and review essential to achieve goals in reducing perinatal loss [9]. Notwithstanding this, clear barriers have been identified to implementing audits and only a few countries have successfully realized national perinatal audits. It is acknowledged that the completion of perinatal audit cycles as well as the formation of recommendations and action plans based on their results, remains one of the major challenges faced in successful perinatal audit implementation [34].

This systematic review aims to explore and summarize current literature on the implementation of perinatal mortality audits in middle/high-income countries. It intends to identify factors affecting the implementation of PNM audits and the reporting of perinatal deaths. This review also plans to study the identification of risk and substandard care factors associated with perinatal outcomes through audits. Additionally, it aims to outline and identify the implementation of outcomes or measures stemming from perinatal mortality audits or reporting programs.

# Methodology

### Search strategy

For this systematic review, a search of the following electronic databases was conducted: PubMed, EMBASE and EBSCO host, including Medline, Academic Search Complete and CINAHL Plus with Full Text. This was completed by two reviewers independently, with specifically established search criteria, inclusion and exclusion criteria.

For all databases, the following search terms were used: (perinatal OR stillbirth OR neonatal OR stillborn OR intrauterine death) AND (mortality or morbidity or death) N5 (audit or surveillance or report)

The initial searches yielded a total of 16,248 articles, reduced to 13, 369 with the removal of some duplicates by the EBSCO database. These publications were subsequently screened according to their titles, generating 318 to be reviewed by abstracts. This selection process is summarized as a flow chart in Figure 1.

### Selection process and criteria

Peer-reviewed articles, with a publication date from 2000 and in English, Portuguese or Spanish were considered for inclusion in the review, according to the language abilities of reviewers. Both qualitative and quantitative research manuscripts were reviewed. Furthermore,

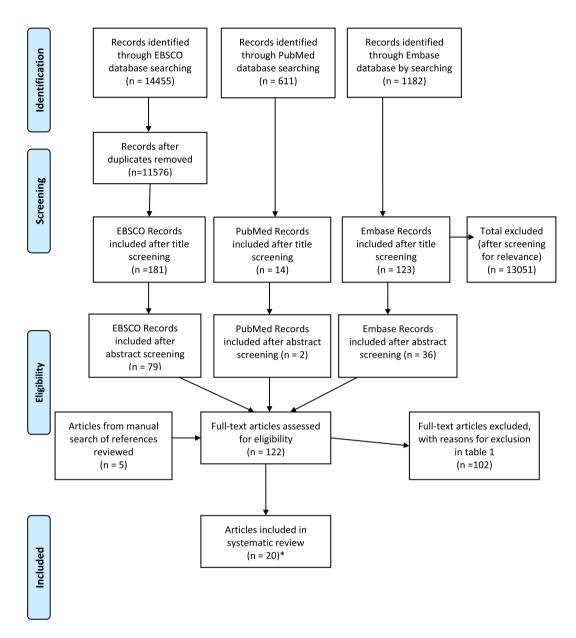


Figure 1: Flow chart of selection process.

articles evaluating perinatal mortality audits or reporting, identifying risk or care factors of perinatal mortality through audits, evaluating perinatal mortality audit implementation and focused on middle and/ or high-income countries were considered for inclusion in this systematic review. High and middle income countries were defined according to data from the World Bank [35]. Grey literature was not included nor manuscripts focusing primarily on maternal morbidity/ mortality audits or perinatal mortality audits in low-income countries or low resource settings were considered for inclusion as they are beyond the remit of this systematic review. Significant differences in maternity service provision exist between high and low income countries and the focus in reducing perinatal mortality in low resource settings also differs substantially from maternity centres in high

income countries [36]. Challenges and facilitators to perinatal audit are likely to differ greatly between these two groups and therefore discussion of perinatal audit in low income countries was considered beyond the scope of this review.

A total of 122 studies were selected for in depth, full-text review by the two reviewers. Articles found during full-text review were crossreferenced to ensure coherence in the selection process. A third reviewer supervised the review process and was available for disagreements or uncertainties related to study selection.

Full text was analyzed according to the inclusion and exclusion criteria, as well as their relevance to the objectives of this review. A manual search of these selected manuscripts was carried out to identify potentially relevant references to include, generating five

additional articles to be analyzed in full text. Only two of these references met the inclusion and exclusion criteria, along with 18 of the original 117 papers reviewed. The reasons for exclusion after full text analysis are outlined in Table 1. Following this process, total of 20 papers were selected to be included in this systematic review.

### Quality appraisal of studies

The CASP Critical Appraisal Tools for Case Control Studies and Qualitative Studies were used to assess the validity of the articles used in this systematic review [37, 38]. For cross-sectional studies, the CASP Case Control Study Checklist was applied, adapting this by removing questions 6a and b which refer specifically to questions regarding the control vs. cases group. All papers selected were considered valid, and therefore included in this review. The papers their strengths and limitations according to the appraisal tool are described in the appendices in the Critical Appraisal Table (Supplementary material, Appendix 1).

### **Data extraction**

Data from the included articles was summarized systematically. The following data was extracted from each article: Study population, Sample Size and Location; Methods including use of external reviewers, barriers recognized in audit implementation, and risk factors identified; Main outcomes relating to the objectives of this review and study limitations. This review focused on preventable or modifiable risk factors, most specifically maternal factors or factors associated with clinical care. Risk factors associated with fetal causes of death were not included in data extraction. A narrative summary was carried out and data synthesis tables (Tables 2, 3, and 4) completed to present the main characteristics and findings from the studies included.

# Results

In total, 20 papers met the inclusion criteria and were included in the analysis. However, two articles [18, 19]

referred to the same study and reported on the same data. To avoid duplication these were combined and findings of the two papers were reported as one entry (study number 15).

The main characteristics of the included studies are described in Table 1. The year of publication of the included studies ranged from 2000 to 2018. Articles originated from the Netherlands (n=6), Norway (n=1), Ireland (n=1), Italy (n=1), United Kingdom (n=1), Croatia (n=1), Brazil (n=1), Australia (n=2), New Zealand (n=1) and the United States (n=3). Five studies were qualitative in design, while the remaining 14 were quantitative. The countries from which the articles originated from is depicted in Supplemental Material, Appendix 2. The main methods involved regional [7, 16, 17, 20-23, 27, 28, 33], national [24-26, 31, 32, 39] and European [18, 19] perinatal audits, retrospective audits [16, 20-22, 26-28, 33] and descriptive audit studies [7, 16, 17, 23-25, 27, 31, 32, 39-41]. Following critical appraisal, the quality of studies was deemed to be good, overall. The quality of four studies, in total, was determined to be fair as issues were observed in the completeness of datasets [16, 25], and in the data collection methodology [22, 40]. Further detail on the quality appraisal of the studies is available in Supplementary material, Appendix 1.

Fourteen studies described factors affecting reporting of PNM [16, 18, 20, 21, 23, 24, 26, 28, 31–33, 39–41] and twelve studies reported on factors affecting the implementation of PNM audits [7, 17, 18, 20-23, 26, 28, 39-41]. Fourteen studies focused on risk factors associated with perinatal outcomes [7, 16-18, 20-28, 31] and seventeen presented information on audit recommendations and/or outcomes of implementation of a PNM audit or reporting program [7, 16, 17, 20–26, 28, 31–33, 39–41].

Table 1: Summary of papers excluded on full text review.

Papers excluded on full text review	Number of papers excluded			Total	
Reason for exclusion	EBSCO 2000-2010	EBSCO 2011-2020	PubMed	Embase	
Not within the remit of review: factors of implementation, reporting of perinatal mortality, risk factors for perinatal death, focused on perinatal audit processes and outcomes	21	15	1	14	51
Focus on low-income countries/low resource settings	3	3	0	2	8
Study design or article type: e.g. conference/meeting notes, editorials, protocols	9	8	0	13	30
Articles unavailable in English, Spanish, Portuguese	3	1	0	0	4
Duplicates	1	5	1	1	8
Total	37	32	2	30	102 <sup>a</sup>

<sup>&</sup>lt;sup>a</sup>One paper was manually extracted, outside of the database searches, and excluded due to not aligning with aims of rev.

**Table 2:** Overview of characteristics and methods of included studies.

Study number	Author, year, title	Study design, location, sample size, population	Methods	Outcome measures
1	Alderliesten et al. 2008. Design and evaluation of a perinatal audit	Perinatal audit The Netherlands n=137 All cases of fetal mortality >16 weeks gestation and neonatal deaths that occurred during Feb-Oct 1999	review to establish cause of death, Substandard Care Factors (SSCFs).  Questionnaire distributed to audit members to investigate their opinion of the audit process.  Anonymous narrative abstract	<ul> <li>Presence of SSCFs in cases of Perinatal Mortality (PM).</li> <li>Audit panel members' experiences of audit process.</li> <li>Validity of outcome of perinatal audit meetings.</li> </ul>
2	Amaral et al. 2011. A population-based surveil- lance study on severe acute maternal morbidity (near- miss) and outcomes in Campi- nas, Brazil: The Vigimoma Project.	Retrospective descriptive audit study Campinas, Brazil All cases of maternal morbidity/near-miss, maternal deaths, and perinatal deaths in Campinas from Oct to Dec 2005 (n=159 adverse perinatal events; 60 Perinatal Deaths). Total births Oct-Dec 2005 (4,491 live births)	from case records analysed. Cases collected in nine maternity services from medical and administrative records compared to defined standards, supervised by research personnel, and discussed anonymously by Municipal Committee on Maternal Mortality or Regional Health Directorate Committee. Preventability Scores assigned.	<ul> <li>Maternal Morbidity, Maternal deaths, Fetal deaths and Early Neonatal Deaths, including maternal factors, causes of death. Preventability scores for identified preventative measures.</li> </ul>
3	Dahl et al. 2000. Antenatal, neonatal and post neonatal deaths evaluated by medical audit. A population- based study in northern Nor- way – 1979–1997.	Retrospective (1976–1983) and Prospective (1983–1997) Perinatal Audit Troms County, Northern Norway n=190 (1976–1983), 282 (1984–1997) antenatal, neonatal and postnatal deaths. All antenatal, neonatal, postnatal deaths	Anonymized medical records for antenatal, neonatal and post neonatal deaths ≥20 weeks from retrospective data 1976–1983, and prospectively 1984–1997. Medical Birth Registry used to obtain total born, and birthweight (BW) and gestational age (GA) subgroups.	<ul> <li>Perinatal deaths (PNM) and rates, BW, GA, maternal risk factors, causes of death, timing of death.</li> <li>Quality of maternity care assessed in audit according to accepted standards of care.</li> </ul>
4	De Lange et al. 2008. Avoidable risk factors in peri- natal deaths: A perinatal audit in South Australia	Perinatal audit South Australia	PNM summaries from South Australian Pregnancy Outcome Unit reviewed by Maternal, Perinatal and Infant Mortality Committee.	<ul> <li>Risk factors for PNM, identified SSCFs, type of hospital where PNM occurred.</li> <li>Patterns of risk factors in cases of PNM; differences in frequency of SSCF factors be- tween differed levels of care.</li> </ul>
5	De Reu et al. 2009. The Dutch Perinatal Audit Project: a feasibility study for nationwide perinatal audit in the Netherlands	Retrospective perinatal audit n=228 All cases of PNM in three re- gions in the Netherlands in a one-year period (2003–2004)	Reporting of PNM via case report form by all professionals involved in perinatal care. Audit groups formed anonymous narratives and case documents. six audit groups classified cause of death, SSCFs and relation between the two. National Dutch perinatal database (PRN), hospital admin, checked for missed cases of PNM.	<ul> <li>Feasibility of a nationwide perinatal audit.</li> <li>Identification of SSCF and level of relation between SSCF and PNM.</li> </ul>
6	Eskes et al. 2014. Term perinatal mortality audit in the Netherlands 2010–	Perinatal audit, Population based cohort study The Netherland	Audit reviewers received training in audit process and PNM classification.	<ul> <li>Description of implementation process of Perinatal Audit (PNA).</li> </ul>

Table 2: (continued)

Study number	Author, year, title	Study design, location, sample size, population	Methods	Outcome measures
	2012: a population-based cohort study	n=943 registered PNM, n=707 audited PNM All perinatal deaths that occurred in the Netherlands during the period 2010–2012	Audit meetings were held to review cases NS identify cases of SSCF. SSCF was defined as deviation national guidelines, local protocols, or normal professional practice. Two real time databases were created to support the audit (Perinatal Audit Registry of The Netherlands (PRN-Audit) and Perinatal Audit Registry System (PARS). Audit narrative and supplemental data are provided on PRN-Audit. Audit meetings and outcomes are registered on PARS.	<ul> <li>Number of perinatal deaths, PNM meetings and numbers attending each.</li> <li>Cause of death data, presence of SSCFs and relationship to PNM.</li> </ul>
7	Flenady et al. 2010. Uptake of the PSANZ perinatal mortality audit guideline	Cross-sectional qualitative survey study Australia and New Zealand n=133 lead midwives and doctors working in birthing suites of 78 maternity hospitals with >1,000 births/year in Australia and New Zealand.	Anonymous telephone Likert style survey regarding Perinatal Society of Australia and New Zealand (PSANZ) guidelines. The lead doctor and midwife on duty at the time of the telephone call were interviewed and responses were recorded into data entry sheets.	<ul> <li>Service providers knowledge on utilisation and views of PSANZ guideline; awareness and use of guideline; practices relating to investigation and audit of perinatal deaths ac- cording to guideline; recom- mendations, barriers, and potential solutions to imple- mentation of the guideline.</li> </ul>
8	Kapurubandara et al. 2017. A perinatal review of singleton stillbirths in an Australian metropolitan tertiary centre	Retrospective case series audit Westmead Hospital, Sydney, Australia n=215 singleton stillbirths 28,109 singleton deliveries recorded at hospital (2005– 2010)	All cases of singleton still- births from hospital database between 2005 and 2010 retrospectively reviewed. Cases reviewed according to PSANZ PNM audit guidelines by team of maternal fetal medicine specialists.	<ul> <li>Cause of death, gestational age, maternal demographics, antenatal complications, postpartum maternal outcomes.</li> <li>Descriptive analysis of antenatal care, investigations, and postpartum follow up care.</li> </ul>
9	Kieltyka et al. 2012 Louisiana Implementation of the National Fetal and Infant Mortality Review (NFIMR) Pro- gram Model: Successes and Opportunities.	Commentary/Descriptive Re-	Descriptive review of the implementation of the state-wide LaFIMR and changes made from the NFIMR program guide.	<ul> <li>Differences between NFIMR recommendations and actual implementation in Louisiana.</li> </ul>
10	Kortekaas et al. 2018. Perinatal death beyond 41 weeks pregnancy: an evaluation of causes and substandard care factors as identified in perinatal audit in the Netherlands	Quantitative Descriptive Study The Netherlands n=947 term PNM 479,097 total term and post- term deliveries	Cases of term PNM (≥37 weeks) registered on Perinatal Audit Registry of Netherlands (PARS) selected for local audit. Assessed quality of care, SSCFs, cause of death with Wigglesworth classification, cause of death using ReCoDe.	<ul> <li>Term PNM stratified by gestational age at moment of death.         Classification of death using Modified ReCoDe classification.     </li> <li>SSCFs</li> </ul>
11	Lee et al. 2014. Understanding Perinatal Death: A Systematic Analysis of New York City Fetal and Neonatal Death Vital Record	Retrospective perinatal audit New York, United States n=2,665, n=1930 fetal deaths, n=735 neonatal deaths	Data of all live births, fetal and neonatal deaths provided by clinical and administrative staff in medical facilities in NYC.	<ul> <li>Demographic details, medical history and cause of death, level of completeness of fetal death records.</li> </ul>

Table 2: (continued)

Study number	Author, year, title	Study design, location, sample size, population	Methods	Outcome measures
	Data and Implications for Improvement, 2007–2011.	All third trimester fetal and neonatal deaths in New York City from 2007 to 2011	Healthcare providers classified cause of death based on WHO ICD-10 codes. Failure to meet set criteria defined fetal death registrations as incomplete. Ill-defined causes of death were defined as unspecified causes of death, or cases identified as extreme prematurity or prematurity.	<ul> <li>Impact of electronic reporting system and the revised fetal death certificate on data completeness and cause of death data.</li> </ul>
12	McNamara, O'Donoghue, and Greene 2018. Intrapartum fetal deaths and unexpected neonatal deaths in the Republic of Ireland: 2011– 2014; a descriptive study.	Descriptive Analysis of Perinatal Mortality Audit Ireland n=81 intrapartum fetal deaths, 36 unexpected neonatal deaths 282,829 total births	Data on intrapartum deaths and unexpected neonatal deaths (>34 weeks gestation or BW>2,500 g) from National Perinatal Epidemiology Centre (NPEC) PNA data from 2011 to 2014 analysed.  NPEC collects national perinatal mortality data through a standardized notification system.	<ul> <li>National intrapartum death rates, maternal and fetal fac- tors, intrapartum details, postnatal investigations and causes of death from NPEC data.</li> </ul>
13	Misra et al. 2004. The Nationwide Evaluation of Fetal and Infant Mortality Review (FIMR) Programs: Development and Implementation of Recommendations and Conduct of Essential Maternal and Child Health Services by FIMR Programs	Cross-sectional qualitative quantitative analysis of fetal and infant mortality review (FIMR) programs United States n=74 (84% total population) Total of 88 FIMR programs eligible for inclusion in study United States	Telephone interviews with FIMR program directors analysed function and output of programs.  Data on development and implementation of recommendations based on data from FIMR programs.  Quantitative analyses of differences in outcomes of various FIMR programs.	<ul> <li>Evaluation of FIMR programs to characterise their roles in improving the perinatal system of care.</li> <li>Evaluation of intermediate outcomes of FIMR programs, recommendations suggested by FIMR programs.</li> </ul>
14	Po' G, et al. 2019. A regional audit system for stillbirth: a way to better un- derstand the phenomenon	Regional Perinatal Audit Emilia-Romagna Region, Italy. n=332 stillbirths 107,528 total births (2014– 2016)	All stillbirth cases evaluated according to specifically designed diagnostic protocol in six local audits of one region. Data collection and review by Multidisciplinary team (MDT) twice a year.	<ul> <li>Maternal and fetal information, diagnostic work ups.</li> <li>WHO classification of stillbirth and ReCoDe classification for cause of death.</li> <li>Quality of Care evaluation was conducted according to the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) grade and relevant Italian Guidelines.</li> </ul>
15	Richardus et al., Differences in perinatal mortality and suboptimal care between 10 European regions: results of an international audit (2003) Suboptimal care and perinatal mortality in 10 European regions: methodology and evaluation of an international audit (2003)	cases of PNM in the regions audited between 1993 and	International audit panel with members from 12 EU countries examined PNM cases at >28 week that fall within category II, III, V, X and XI of the Nordic-Baltic Perinatal Death Classification system were analysed. Standards of care based on international guidelines/review of literature/best-practice consensus agreed by panel members. Suboptimal care defined by	portions in 10 different EU countries

Table 2: (continued)

Study number	Author, year, title	Study design, location, sample size, population	Methods	Outcome measures
16	Robertson et al. 2017. Each baby counts: National quality improvement programme to reduce intrapartum-related deaths and brain injuries in term babies	Review article of Each Baby Counts (EBC) Project, a pro- spective national perinatal audit UK n=921 All intrapartum, early neonatal deaths and infants with severe brain injury from January to December 2015	grading system adapted from CESDI123 duplicate cases included to assess intra- and inter-panel validity. Eligible babies registered and case summaries uploaded to online database. Case summaries reviewed by two EBC-trained reviewers to examine: whether information was sufficient; whether different clinical care would have resulted in different outcome.	<ul> <li>Proportion of intrapartum stillbirths, early neonatal deaths and severe brain injury</li> <li>Relation of quality of care to adverse outcome.</li> </ul>
17	Rodin et al. 2015. Perinatal Health Statistics as the Basis for Perinatal Quality Assessment in Croatia.	Retrospective Audit Study Croatia n=4,633 perinatal deaths ≥22 weeks 587,356 total births ≥22 weeks	Assessed perinatal health indicators and outcomes from perinatal hospital data collected by Croatian Institute of Public Health (CIPH) between 2001 and 2014 after the implementation of new reporting system according to WHO recommendations	<ul> <li>Perinatal outcome indicators: PNM, Fetal Mortality, Early Neonatal Mortality according to BW (&gt;500 g, &gt;1,000 g) and GA (&gt;22 weeks, &gt;28 weeks)</li> <li>Comparison of rates when definitions of PNM cases are altered.</li> </ul>
18	Van Diem et al. 2012. The implementation of unit-based perinatal mortality audit in perinatal cooperation units in the northern region of the Netherlands.	Perinatal Audit (Observational study) The Netherlands (Northern Region) n=15 perinatal cooperation units, n=112 perinatal deaths All 15 perinatal cooperation units and all their cases of PNM between Sept. 2007 and Mar. 2010. 1,026 questionnaires with Audit Participants Feedback	mented in 15 units.  Multidisciplinary core group and external confidential audit committees formed.  Cases were identified by the core committee as they occurred.	<ul> <li>Unit participation and individual staff participation in the new audit process.</li> <li>SSCFs and actions to improve care identified in the audit.</li> <li>Feedback of audit participants regarding the process</li> </ul>
19	Wolleswinkel et al. 2002. Substandard care factors in perinatal care in the Netherlands: a regional audit of perinatal deaths.	Retrospective Regional Perinatal audit The Netherlands n=332 All PNM occurring in region in the Netherlands	Cases of PNM identified through hospital and midwifery records. Expert MDT panel defined	<ul> <li>Presence of SSCF in cases of PNM; extent to which this was likely related to adverse outcome.</li> <li>Frequency of SSCF according to level of care – (midwife, obstetrician, led home birth).</li> </ul>

CESDI, Confidential Enquiry into Stillbirths and Deaths in Infancy; EBC, Each Baby Counts; FIMR, Fetal and Infant Mortality Review; LaFIMR, Louisiana Fetal and Infant Mortality Review; MDT, Multidisciplinary Team; NFIMR, National Fetal and Infant Mortality Review; NPEC, National Perinatal Epidemiology Centre; PARS, Perinatal Audit Registry of Netherlands; PNM, Perinatal Mortality; PMR, Perinatal Mortality Rate; PNA,  $Perinatal\ Audit;\ PSANZ,\ Perinatal\ Society\ of\ Australia\ and\ New\ Zealand;\ SSCF,\ Substandard\ Care\ Factors.$ 

 Table 3: Factors affecting the implementation of PNM audits and the reporting of PNMs as reported in the included studies.

Study number	Author, year, title	Factors affecting the implementation of PNM audits	Factors affecting reporting of PNMs
1	Alderliesten et al. 2008 [17]. Design and evaluation of a perinatal audit	Facilitators:  - 16/16 respondents – felt "secure discussing openly" in review.  - Barriers:  - 16/16 respondents – review was "time consuming."  - 20% audit members said they could not cooperate in future due to time.  Mean time to prepare for meeting was 4 h.  - Participant/close colleague involved in case in 26% of cases discussed.  - 3% of cases had too little information to include in the audit.  - Two reviewers unable to participate in case reviews due to personal involvement in case.	_
2	Amaral et al. 2011 [22].  A population-based surveillance study on severe acute maternal morbidity (near-miss) and outcomes in Campinas, Brazil: The Vigimoma Project.	ment in case.  Facilitators:  Benefit in regional vs. local audit to capture referred patients – 48% of patients with adverse events were referred from municipalities/supplementary systems.  University services (research) and clinicians working together on surveillance system aided in its acceptance in hospitals.  Barriers:  Time consuming process: about 30 min/case for review process: 13 four hour meetings for Municipal Committee and 7 four hour meetings for	
4	De Lange et al. 2008 [16]. Avoidable risk factors in perinatal deaths: A perinatal audit in South Australia	Regional committee.	Barriers:  - Sub-standard Care Factors (SSCF) only identified where explicitly identified in the Perinatal Mortality (PNM) summary may have underestimated presence of SSCF
5	De Reu et al. 2009 [28]. The Dutch Perinatal Audit Project: a feasibility study for nationwide peri- natal audit in the Netherlands	Barriers:  - 59 cases missing from audit (19.8%) according to LPAS (National Perinatal Audit study) due to under-reporting to the LPAS database.  - 21 cases missing according to Dutch Perinatal Registry (7.1%). In one region under-registration may be linked to lack of tertiary centre requiring out-of-region transfer. In other regions, no plausible reason identified.  - Time (average 8-h preparation) and financial burden identified as barrier to nationwide audit programme	ported by Multidisciplinary Team (MDT) assessment. Barriers:

Table 3: (continued)

Study number	Author, year, title	Factors affecting the implementation of PNM audits	Factors affecting reporting of PNMs
6	Eskes et al. 2014 [31]. Term perinatal mortality audit in the Netherlands 2010–2012: a population-based cohort study	Facilitators:  - Good attendance from all members of the MDT at Perinatal Audit (PNA) meetings. An independent chairperson at PNA meetings optimised outcomes.  - Cases reviewed by audit committee within 3–6 months minimised potential loss of details of case and contributing circumstances.	SSCF assessment. Other studies with dedicated researchers had lower rates of insufficient data.
7	Flenady et al. 2010 [41]. Uptake of the PSANZ perinatal mortality audit guideline	Facilitators:  - 19% respondents had previously received training in guideline use.  - 78% found information brochures, clinical exam, and investigation checklist useful, 82% users were satisfied with guideline overall.  Barriers:  - 90% of participants supported the need for training on guidelines,  - 79% lacked access to advice on audits and investigation of perinatal deaths.  - 77% needed more training on appraising evidence for practice.  - 45% respondents never received	Barriers:
8	Kapurubandara et al. 2017 [21]. A perinatal review of singleton stillbirths in an Australian metropolitan tertiary centre	feedback from PNM meetings.  Barriers:  Lack of maternal ethnicity data recorded in general obstetrics database.  Need for improved uptake of investigations for stillbirth according to PSANZ guidelines (e.g. universal placental exam, post-mortem uptake).	of pregnancy (TOP) should be reported.  Identified rise of stillbirth rate (OR per year=1.08, 95% CI 1.001 to 1.171, p=0.048), that was not significant when TOP was excluded (OR per year=1.03,
9	Kieltyka et al. 2012 [40]. Louisiana Implementation of the National Fetal and Infant Mortality Review (NFIMR) Program Model: Successes and Opportunities.	<ul> <li>Facilitators:         <ul> <li>Institutional Review Board, Maternal interview consent forms modeled after NFIMR.</li> <li>Updated standardized data collection forms to web-based statewide system: BASINET.</li> <li>100 active case review teams (CRT) and 25–111 community action team (CAT) members participated vs. NFIMR recommendation of 12–35 CRT and CAT members, to diversify representation at each meeting.</li> <li>CAT members involved in liaising with local and national organizations that facilitate implementation of action plans identified through auditing.</li> </ul> </li> <li>Barriers:         <ul> <li>General National guidelines required adaptations to meet state and local laws and legislation.</li> </ul> </li> </ul>	more efficiently to birth records vs. security and confidentiality.  Barriers:  NFMIR had no recommendations on how to prioritize cases when not all could be reviewed.  Vital Records Office data collection not as timely as case identification in hospitals/media obituaries. Cases sampled are only those with available data.  Staffing capacities: Louisiana FIMR (LaFIMR) prioritized reviewing specific cases (i.e. Preterm) where action is most needed, and staff had capacity to review all of these defined cases.

Table 3: (continued)

Study number	Author, year, title	Factors affecting the implementation of PNM audits	Factors affecting reporting of PNMs
11	Lee et al. 2014 [33]. Understanding Perinatal Death: A Systematic Analysis of New York City Fetal and Neonatal Death Vital Record Data and Implications for Improvement, 2007–2011.		Barriers:  - Inappropriate terminology in records suggested lack of user training.  - Unknown responses were provided for >5% of registrations for 13 of 19 items evaluated.  - Implementation of the e-reporting system led to an increase in the proportion of parameters that were reported as unknown for increased for most items.  - There was a significant difference in proportion of ill-defined causes of feta death vs. neonatal death following implementation of the e-reporting system (678) vs. FSV. p. (2000)
			tem (67% vs. 5%, p<0.0001).  - Ill-defined deaths were primarily reported as fetal death of unspecified cause (99% Fetal death records with ill-defined cause of death were significantly less likely to be incomplete (63 vs. 69%, p=0.01)
12	McNamara, O'Donoghue, and Greene	-	Facilitators:
	2018 [24].		- Inclusion of placental examination in
	Intrapartum fetal deaths and unex- pected neonatal deaths in the Republic		majority of cases (91%). Barriers:
	of Ireland: 2011–2014; a descriptive study.		<ul> <li>Differences in reporting of placenta histology among units (no stand- ardisation) to National Perinatal Epide- miology Centre.</li> </ul>
			<ul> <li>Only 60% cases had post-mortem ex- amination completed (higher for stillbirth).</li> </ul>
13	Misra et al. 2004 [32].	_	Facilitators:
	The Nationwide Evaluation of Fetal and Infant Mortality Review (FIMR) Programs: Development and Implementa-		<ul> <li>83% of directors and 58% of staf participated in training in how to use case review findings.</li> </ul>
	tion of Recommendations and Conduct of Essential Maternal and Child Health Services by FIMR Programs		<ul> <li>86% of directors and 80% staff partici- pated in training in perinatal health and/or infant mortality.</li> </ul>
	, ,		<ul> <li>Two-tier FIMR systems were more likely to report implementation of the 10 topic areas (p&lt;0.001).</li> </ul>
14	Po' G et al. 2019 [23].	Barriers:	Barriers:
	A regional audit system for stillbirth: a way to better understand the phenomenon	<ul> <li>Audit described as time consuming.</li> </ul>	<ul> <li>Disagreement of cause of death ir 16.4% of cases between local and cen- tral committees.</li> </ul>
			<ul> <li>Classification of cause of death lef- significant number of cases unexplained.</li> </ul>
			<ul> <li>Lack of specialized pathologist in perinatology resulting in heterogeneous results across local audits.</li> </ul>
			<ul> <li>Facilitator</li> </ul>
			<ul> <li>SB clinical record and complete diagnostic work-up designed for use in every Obstetrics Unit.</li> </ul>

Table 3: (continued)

Study number	Author, year, title	Factors affecting the implementation of PNM audits	Factors affecting reporting of PNMs
			<ul> <li>E-learning course for each professional (obstetricians, neonatologists and midwives) in every hospital on how to complete stillborn records and carry out diagnostic protocol.</li> </ul>
15	Richardus et al., Differences in perinatal mortality and suboptimal care between 10 European regions: results of an international audit (2003) [18] Suboptimal care and perinatal mortality in 10 European regions: methodology and evaluation of an international audit (2003) [19]	panel could not be reached.	Facilitators:  - 75% of SSCFs identified based on criteria laid out by audit panel; 25% based on consensus within subpanels.  - High level of case identification in Belgium, Finland, Norway, Scotland Denmark, England, and Sweden due to overlap between medical and civil registrations.
			Barriers:  - No association was found between completeness of data and grading of SSCF.
			<ul> <li>Differences in definition of FGR between countries.</li> <li>Lack of standardised audit criteria and methodology limit international comparison.</li> </ul>
			<ul> <li>Good consensus among panel members and subpanels (kappa coefficient 0.69 and 0.74 respectively). Reproducibility between subpanels was reasonable (kappa coefficient 0.61).</li> </ul>
16	Robertson et al. 2017 [39].	-	Facilitators:
	Each baby counts: National quality improvement programme to reduce		<ul><li>96% cases were carried out by MDT.</li><li>Barriers:</li></ul>
	intrapartum-related deaths and brain injuries in term babies		<ul> <li>34% of case reports were incomplete and had insufficient information for analysis.</li> </ul>
			<ul> <li>Only 52% of local reviewers used a specific tool/methodology to review each case including locally developed tools, National Patient Safety Authority (NPSA) intrapartum-related death pro- forma, local midwifery supervising au-</li> </ul>
17	Rodin et al. 2015 [26]. Perinatal Health Statistics as the Basis for Perinatal Quality Assessment in Croatia.	Barriers:  - Standardized definitions of cases required for international comparisons of PNM.	thority stillbirth tool.  Facilitators:  Reporting of PNM according to differing criteria (i.e. WHO criteria) altered PNM rates and emphasised specific subgroups requiring further attention (e.g. Early Neonatal Mortality highest in 22–27 gestation subgroup).
			Barriers:  - Vital data/Civil Registration systems use different definitions or do not collect PNM data to include Birth Weight and Gestational Age.

Table 3: (continued)

Study number	Author, year, title	Factors affecting the implementation of PNM audits	Factors affecting reporting of PNMs
18	Van Diem, et al. 2012 [7]. The implementation of unit-based perinatal mortality audit in perinatal cooperation units in the northern region of the Netherlands.	Facilitators:  From Audit Participants Feedback:  - 10% valued initial training, 12% valued analysing SSCFs methods the most.  - Collective non-judgemental search for SSCFs (21%), multidisciplinary team (13%), perception of safety (13%) allowing more open discussions of own care and cooperation in groups, reflection on own professional performance (5%)  Barriers:  - Limited funding  - Time-consuming process for meetings, need for motivation of caregivers to reflect on their practice.  - Frequency of meetings: 64 audit meetings held mostly outside office hours, usually twice yearly. Two larger hospitals switched to monthly and 3-monthly.	
19	Wolleswinkel et al. 2002 [20]. Substandard care factors in perinatal care in the Netherlands: a regional audit of perinatal deaths.	Barriers:  - 76 cases whose data was not available for study due to confidentiality.  - Insufficient information in 11 cases (3%).	<ul> <li>Facilitators:         <ul> <li>Half of SSCFs identified through explicit audit criteria. Half identified through implicit criteria agreed by audit panel.</li> <li>'Good' agreement between the subpanels (kappa score=0.62).</li> </ul> </li> <li>European panel assigned 2 (SSCF possibly related to case of PNM)/3 (SSCF probably related to case of PNM) scores to 46% of cases. Dutch panel 36% (sign test for paired samples, z=-1.677, p=0.094).</li> </ul>

CAT, Community Action Team; CRT, Case Review Team; FIMR, Fetal and Infant Mortality Review; MDT, Multidisciplinary Team; NFIMR, Fetal and Infant Mortality Review; PNM, perinatal mortality; PNA, perinatal audit; SSCF, substandard care factors; TOP, termination of pregnancy.

# Factors affecting the reporting of PNM in audit

### Factors affecting completeness and standardisation of data

The lack of standardised reporting criteria or clearly established definitions was mentioned in four studies [19, 21, 24, 26]. Differences in reporting, classifications and criteria used were issues raised in these studies which hampered the adequate and reliable reporting of perinatal mortalities in the context of audit. Three studies mentioned the need for a standardized tool to facilitate the process of reporting data [33, 39, 41]. One study noted that 27% of reports did not have enough information to classify the

cause of death, and that 24% of reports were incomplete at the time of data collection [26].

In a perinatal audit of intrapartum fetal deaths and unexpected neonatal deaths by McNamara et al. [24], a lack of standardisation in the reporting of placental histology was noted and a significant variation in the details of reports was observed.

Other factors that were found to affect the quality of perinatal audits include multidisciplinary input in the formulation of case summaries [28, 31, 39], staff training and capacity [7, 31, 33, 41], standardisation of audit methodology and adequate adaptation of audit procedures and guidelines to different regions or states [26, 28, 40]. One study found that clinicians needed better guidance with regards to investigating PNM (79%) and 65% of

Table 4: Risk factors identified and outcomes of perinatal audits.

Study number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
1	Alderliesten et al. 2008 [17]. Design and evaluation of a perinatal audit	Perinatal audit The Netherlands n=137 All cases of fetal mortality >16 weeks gestation and neonatal deaths that occurred during Feb-Oct 1999	Care factors:  - In 25% of cases, sub-standard care factors (SSCFs) were present.  - >16 weeks gestation - 8/137 cases, SSCFs likely contributed to PNM.  - >24 weeks - 7/88 cases, SSCFs likely contributed to Perinatal Mortality (PNM).	Recommendations:  - 86% thought audit was an important point on quality of care and recommended frequency of an audit should be max 4 times/year.  - Pathologist to be involved in audit process to determine cause of death.
8	Amaral et al. 2011 [22]. A population-based surveillance study on severe acute maternal morbidity (near-miss) and outcomes in Campinas, Brazil: The Vigimoma Project.	Retrospective descriptive audit study Campinas, Brazil All cases of maternal morbidity/nearmiss, maternal deaths, and perinatal deaths in Campinas from Oct to Dec 2005. (n=159 adverse perinatal events; 60 Perinatal Deaths).  Total births Oct-Dec 2005 (4,491 live births)	Maternal factors:  - 1/3 of stillborn, 1/6 of neonatal deaths related to maternal hypertension complications.  Care factors:  - Perinatal adverse events more frequent in public university maternity services.	Recommendations:  - Identified interventions to prevent FD/END with preventability scores (PPS):  - Avoid FD highest PPS: Educate pregnant women on prenatal warning signs (4.0 (+/11.4 SD), Improve prenatal clinical practice (3.7 ± 1.1)  - Avoid END highest PPS: Prepare team for neonatal heart surgery (5.0 ± 0), Promote prophylaxis of neonatal disease by GBS (4.0 ± 1)
m	Dahl et al. 2000 [27]. Antenatal, neonatal and post neonatal deaths evaluated by medical audit. A population-based study in northern Norway – 1979–1997.	Retrospective (1976–1983) and Prospective (1983–1997) Perinatal Audit Troms County, Northern Norway n=190 (1976–1983), 282 (1984–1997) antenatal, neonatal and postnatal deaths All antenatal, neonatal, postnatal deaths	Maternal Factors:  Non-co-habitancy: 32.8–13% (p=0.001) living single from first sub-period (1976–1983) to last sub-period (1983–1997).  Highest education level completed (p=0.001): 46.0–26.8% primary school from first to last sub-period.  50.9–37.1% High school/university from first to last subperiod.  % Smoking: 50.9–37.1% (p=0.07) in first and last subperiod.	Outcomes:  Committee review of cases led to recommendations based on scientifically proven clinical protocols. Recommended future surveillance through cross sectional studies.  Unclear whether this recommendation has been implemented into clinical practice  -

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Author, year, title r	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
De Lange et al. 2008 [16]. Avoidable risk factors in perinatal deaths: A perinatal audit in South Australia	Perinatal audit South Australia n=608 All PNM in South Australia from 2001 to 2005	Care factors:  - Sub-optimal care in 22.5% deaths, factors of non-optimal care identified in 151 occasions, by health service system (procedures and medical care not up to accepted standards) (n=124) or maternal neglect (e.g. medical advice rejected) (n=27).  - 54 deaths found to be avoidable if health service had provided optimal care, 62 cases of maternal neglect were avoidable.  Maternal factors: - Smoking (OR 2.85 (95% Cl.1.51–2.17)) - Pre-existing hypertension (AOR 1.72 (1.29–2.65)), - Pretern labour (AOR 22.05 (18.16–26.76)) - Threatened miscarriage (AOR 1.89 (1.25–14.51)) - Threatened miscarriage (AOR 1.89 (1.25–2.84)) - Threatened miscarriage (AOR 1.89 (1.25–2.84)) - Minimal antenatal care defined as <a href="mailto:antenatal visits">antenatal visits in live births or stated clearly in FDs (AOR 2.89 (2.1–4.0))  Risk Factors (RFs): - 44.4% avoidable RFs in maternal subgroup 5.1% RFs relating to access of care 9% deficiencies in antenatal care 11.2% deficiencies in antenatal care 11.2% deficiencies in professional care.</a>	Recommendations:  — Improving patient education regarding concerning symptoms in late pregnancy that could result in demise.  — Further professional education for all maternity care providers.  — Unclear whether audit recommendations are implemented into practice.

Table 4: (continued)

Study	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of imple- mentation of a PNM audit or reporting program
. 45	De Reu et al. 2009 [28]. The Dutch Perinatal Audit Project: a feasibility study for nationwide peri- natal audit in the Netherlands	Retrospective perinatal audit n=228 All cases of PNM in 3 regions in the Netherlands in a one-year period (2003– 2004)	Maternal factors:  - Tobacco use  - Obesity  - Consanguinity - Ethnicity- 41% PNM in non-Dutch mothers Care factors: - 139/239 (51%) cases had SSCFs identified Caregiver level: 32% of cases probable - Relation to cause of death Failure to transfer to tertiary care (n=3) - 25% – SSCF related to late/night shifts	Outcomes:  - Results lead the Dutch government to start a nationwide perinatal audit -creation of singular, national PNM database Although, national PNM audit not feasible for every case, local audits will assess cases of mortality within their region.
9	Eskes et al. 2014 [31].  Term perinatal mortality audit in the Netherlands 2010–2012: a populationbased cohort study	Perinatal audit, Population based cohort study The Netherland n=943 registered perinatal deaths, n=707 audited perinatal deaths. All perinatal deaths that occurred in the Netherlands during the period 2010-2012	of vith ual	Recommendations:  A total of 603 recommendations were made, based on the presence of 512 SSCF identified in 376 cases.  35% of recommendations related to organisation of care.  19% of recommendations about further use of guidelines and the development of local policies.  Further training in use of PNM classification system and investigation recommended.  Outcomes:  Some recommendations had been implemented at the time of publication, including development of a national guideline for reduced fetal maximum
~	Flenady et al. 2010 [41]. Uptake of the PSANZ perinatal mortality audit guideline	Cross-sectional qualitative survey study Australia and New Zealand n=133 lead midwives and doctors work- ing in birthing suites of 78 maternity hospitals with > 1,000 births/year in Australia and New Zealand.		Recommendations:  Recommendations:  Recommended guideline of user specific training and education.  Recommended improvements in feedback from PNM audits to ensure implementation of recommendations.  Outcomes:  Hospitals have reported successful implementation of the guideline through a dedicated Multidisciplinary Team (MDT) service

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Study number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of imple- mentation of a PNM audit or reporting program
				for PNM which incorporates clinician education and feedback.  Unclear whether the results of this study have been implemented into clinical practice.
∞	Kapurubandara et al. 2017 [21]. A perinatal review of singleton stillbirths in an Australian metropolitan tertiary centre	Retrospective case series audit Westmead Hospital, Sydney, Australia n=215 singleton stillbirths 28,109 singleton deliveries recorded at hospital (2005–2010)	Maternal factors:  - Smoking not identified as RF.  - Consanguinity identified as possible RF.  - 5% women presented late for antenatal care.  - 37% of mothers reported decreased fetal movement in week prior to Adverse Event.	Outcomes:  A formal perinatal review process was initiated in this hospital after this study (retrospective audit) was conducted.  Uptake of PSANZ guidelines for investigation of stillbirth improved after this study.
•	Kieltyka et al. 2012 [40]. Louisiana Implementation of the National Fetal and Infant Mortality Review (NFIMR) Program Model: Successes and Opportunities.	Commentary/Descriptive Review Louisiana's Fetal and Infant Mortality Review (LaFIMR) processes.	1	Outcomes:  Implemented nine unique programs in different Public Health defined regions throughout Louisiana due to variation in PNM rates in each.  Case Review Team (CRT) members reach into broader geographical areas.  Collaborations formed with local organizations that support audit activities (e.g. Healthy Start programs), with aid of Community Action Team (CAT) members.  Running under a state administrative unit allowed for identification of "outbreaks" — e.g. Cluster of anencephalies, where additional supports should be allocated e.g. in
10	Kortekaas et al. 2018 [25]. Perinatal death beyond 41 weeks pregnancy: an evaluation of causes and substandard care factors as identified in perinatal audit in the Netherlands	Quantitative Descriptive Study The Netherlands n=947 term perinatal deaths 479,097 total term and post-term deliveries	Maternal factors:  - BMI >25 (23% 37-40 + 6 weeks, 34% > 31 weeks)  Care factors:  - 178 total SSCFs in 109 cases of post-term PNM. 75 cases had at least 1 SSCF.  - No differences in number of cases with SSCFs across 2010–2012.  - 35.4% of cases, SSCFs were very likely, likely and possibly related to cause of death.	Recommendations:  Develop international standardised SSCF categories, for international data comparisons.  Obligatory basic characteristics to fill in national database and use of ICD-PNM for cause of death classification.  Post-term pregnancies require increased awareness of intrapartum asphyxia.  Improvement of proper CTG monitoring to reduce SSCF.

75% of reported recommendations had

cess of being implemented. 4% of recombeen implemented, 22% were in the pro-

mendations had not been implemented.

Over 90% of the recommendations relating

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to the following areas were implemented: SIDS, preterm labor, family planning, fetal and infant safety, and genetic risks.

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Study number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of imple- mentation of a PNM audit or reporting program
			<ul> <li>CTG evaluation and classification was most frequently reported SSCF.</li> <li>Intrapartum: asphyxia (16% in 37-40 + 6, 34% in &gt;41 weeks).</li> </ul>	<ul> <li>Unclear whether recommendations have been implemented into clinical practice.</li> </ul>
11	Lee et al. 2014 [33]. Understanding Perinatal Death: A Systematic Analysis of New York City Fetal and Neonatal Death Vital Record Data and Implications for Improvement, 2007–2011.	Retrospective perinatal audit New York, United States n=2,665, n=1,930 FDs, n=735 neonatal deaths All third trimester fetal and neonatal deaths in New York City from 2007 to 2011		Recommendations:  Recommendation of national standard FD certificate and reporting procedure to improve quality and completeness of data.  Outcomes:  Proportion of ill-defined fetal cause of FDs decreased (61% v 68%, p=0.004).
12	McNamara, O'Donoghue, and Greene 2018 [24]. Intrapartum fetal deaths and unex- pected neonatal deaths in the Republic of Ireland: 2011–2014; a descriptive study.	Descriptive Analysis of Perinatal Mortal- ity Audit Ireland n=81 intrapartum fetal deaths, 36 unex- pected neonatal deaths 282,829 total births	Maternal factors:  - 42% Overweight or obese.  - 21% smoking at booking.  - Gestational age at booking unknown in 18.8% of mothers.  - 23% booked after 16 weeks.  - 33.3% with pre-existing medical condition. Care factors:  - Failure to detect fetal growth restriction antenatally in 16/17.	Recommendations:  dentified areas of improvement in antenatal care and postmortem investigation, suggesting increased public awareness of risk factors, especially pre-conceptually.  Supported NPEC recommendation to introduce confidential enquiries in Ireland for intrapartum fetal deaths and unexpected neonatal deaths.  Unclear from this study whether this recommendation has been implemented.
13	Misra et al. 2004 [32]. The Nationwide Evaluation of Fetal and Infant Mortality Review (FIMR) Programs: Development and Implementation of Recommendations and Conduct of Essential Maternal and Child Health Services by FIMR Programs	Cross-sectional qualitative quantitative analysis of fetal and infant mortality review (FIMR) programs United States n=74 (84% total population) Total of 88 FIMR programs eligible for inclusion in study United States		Recommendations:  A total of 231 recommendations reported by survey respondents.  The five perinatal health concerns most frequently the topic of recommendations developed by the sample of FIMR were: SIDS, antenatal care, high risk women, PTL, making up 55% of reported recommendations.

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Study number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
				- For recommendations relating to high-risk women, vital or medical record issues and FIMR functions, the implementation rate was lower.  Outcomes: - 72% of directors and 54% of staff participated in training in strategies for implementing recommendations Training was associated with implementation of recommendations in the 10 identified topic areas Training of FIMR directors associated with an increase in the average number of MCH and increase in the average number of MCH.
14	Po' G, et al. 2019 [23]. A regional audit system for stillbirth: a way to better understand the phenomenon	Regional Perinatal Audit Emilia-Romagna Region, Italy. n=332 stillbirths 107,528 total births (2014–2016)	Maternal factors:  - Overweight (OR 1.42, Cl95 1.07–1.86) and Obese (OR 1.96, 1.40–2.74) mothers.  - Ethnicity: Sub-Saharan African background 3x risk (OR 2.9, 95% Cl 1.94–4.35).  Care factors:  - 14.5% cases had SSCF.  - 30.5% delayed access to care, 25% failure to diagnose/treat Diabetes Mellitus/Hypertension disorders, 16.6% FGR not detected/managed.  - According to Confidential Enquiry into	Service activities provided (p.c.0.9).  Outcomes:  Highlighted underestimation of SB cases in Birth Register vs. audit, due to overlap in classification of SB and miscarriages according to Italian law, rather than the use of WHO definition.  Identified SSCFs in multidisciplinary team review to assess quality of care.
15	Retrospective perinata Differences in perinatal mortality and (EuroNatal study) suboptimal care between 10 European n=1,619 regions: results of an international audit Regions in 10 Europea (2003) [18] Suboptimal care and perinatal mortality population of that cou in 10 European regions: methodology cases of PNM in the re and evaluation of an international audit tween 1993 and 1998.	Retrospective perinatal audit, Europe (EuroNatal study) n=1,619 Regions in 10 European countries selected that would be representative of population of that country. 60% of all cases of PNM in the regions audited between 1993 and 1998.	Stillbirth Deaths in Infancy grades – 78.7% grade 0 – no substandard care.  Maternal factors:  Most common maternal factor was related to maternal smoking (11.7%).  Care factors:  Failure to detect IUGR most common SSCF in professional care delivery (10.2%).  369 cases (23.9%) were graded as 0 (No SSCF identified).  459 cases (29.7%) were graded as 1 (SSCF identified, unlikely to contribute to PNM).	I

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Study number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
			<ul> <li>1,584 cases (37.8%) were graded as 2 (SSCF identified, might have contributed to SSCF).</li> <li>131 cases (8.5%) were graded as 3 (SSCF identified, likely to have contributed to PNM).</li> </ul>	
16	Robertson et al. 2017 [39].  Each baby counts: National quality improvement programme to reduce intrapartum-related deaths and brain injuries in term babies	Review article of Each Baby Counts (EBC) Project, a prospective national perinatal audit UK n=921 All intrapartum, early neonatal deaths and infants with severe brain injury from January to December 2015		Recommendations: Of the 150 local reviews with sufficient information: - 32 (21%) contained no actions or recommen-dations 27 (18%) contained recommendations that focused solely on individual members of staff 11 (7%) not clear if recommendations were individual or systems based 80 (53%) recommendations were systemsbased Quantitative analysis to be performed to produce in-depth reports into specific highlighted areas EBC project supporting the use of a new standardised PNM tool to aid with compre-
				hensive multidisciplinary analysis of each case. - Unclear whether recommendations have been implemented into clinical practice
17	Rodin et al. 2015 [26]. Perinatal Health Statistics as the Basis for Perinatal Quality Assessment in Croatia.	Retrospective Audit Study Croatia n=4,633 perinatal deaths ≥22 weeks 587,356 total births ≥22 weeks	Care factors: Although no specific association analysis was carried out, the study outlines the following care factors: - Antenatal visits: Mothers with ≥9 antenatal visits increased from 43% (2001) to 72.3% (2014) Ultrasound visits: Mothers with ≥4 visits increased from 63.1% (2001) to 93.4% (2014) - Caesarean Section (C/S): Proportions of C/S rising from 2001 to 2014, but Croatia's averages remain below EU averages	Outcomes:  — Audit improvement seen with use of WHO and PERISTAT reporting criteria, enabling international comparisons.

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<b>Study</b> number	Author, year, title	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
18	Van Diem et al. 2012 [7]. The implementation of unit-based perinatal mortality audit in perinatal cooperation units in the northern region of the Netherlands.	Perinatal Audit (Observational study) The Netherlands (Northern Region) n=15 perinatal cooperation units, n=112 perinatal deaths. All 15 perinatal cooperation units and all their cases of PNM between Sept. 2007 and Mar. 2010. 1,026 questionnaires with Audit Partici- pants Feedback	Care factors:  - 163 SSCFs identified.  - Use of guidelines (31%): 16% delayed, 18% incomplete use.  - Normal Practice (23%): 38% incomplete use, 32% not used without a stated reason, 16% delayed.  - Documentation (28%): 65% baseline data, 24% considerations/management.  - Communication (13%), 36% same echelon and same level, 36% different echelons, 9% towards patient.	Recommendations:  442 actions identified to improve care:  442 actions identified from questionnaires and categorized: 27% as 'medical', mostly related to guidelines and normal practice.  26% 'practice organisation', related to organization and management. 17% 'internal collaboration' relating to hand over practice. 15% 'external collaboration' resulted in day-to-day practices discussed in separate meeting.  7% other – related to peer review and professional performance reflection.  Unclear whether recommendations have been implemented into clinical practice.  Outcomes:  After these unit-based audits, audit methods were implemented in all 93 units in the Netherlands by the National Bureau for
19	Wolleswinkel et al. 2002 [20]. Substandard care factors in perinatal care in the Netherlands: a regional audit of perinatal deaths.	Retrospective Regional Perinatal audit The Netherlands n=332 All PNM occurring in region in the Netherlands	Care factors:  - 40% maternal/social (e.g. maternal smoking, no report of no fetal movements within 24 h).  - Most common SSCFs identified was smoking in pregnancy (24% of cases with 2 (possibly related to PNM)/3 (probably related to PNM)/3 (probably related to PNM) score).  - 5% related to infrastructure.  - 41% Antenatal care (e.g. IUGR detection and management, fetal monitoring, diabetes control).  - No or too late detection of IUGR (10% of cases with 2 or 3 score).  - 27% intrapartum care (e.g. intrapartum fetal monitoring, management of abnormal presentation).	Perinatal Audit, with emphasis on SSCF analysis and actions.  Recommendations:  - Efforts to be directed at encouraging smoking cessation in pregnancy.  - Unclear whether results of audit are implemented into clinical practice.

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y Author, year, title ber	Study design, location, sample size, population	Risk factors associated with perinatal out- comes identified	Recommendations and outcomes of implementation of a PNM audit or reporting program
		<ul> <li>Inadequate intrapartum fetal</li> </ul>	
		monitoring (7% cases with 2/3	
		score).	
		<ul> <li>8% neonatal care.</li> </ul>	
		<ul> <li>25% of cases (95% CI 20–30%) were given</li> </ul>	
		a 2 (one or more SSCF identified and	
		possibly related to PNM) or 3 (one or more	
		SSF identified and probably related to	
		PNM) score by the Dutch audit panel.	
		- Similar proportion of SSCF identified	
		where care led by obstetrician (26%) vs.	
		midwife (30%).	
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AOR, assisted reproductive technology; BW, birthweight; CAT, community action team; CRT, case review team; EBC, every baby counts; END, early neonatal death; FD, fetal death; FIMR, fetal and infant mortality review; IUGR, intrauterine growth restriction; IVF, In-vitro fertilization; MDT, multidisciplinary team; NFIMR, fetal and infant mortality review; PNM, perinatal mortality; PPS, preventability score; RF, risk factor; SSCF, substandard care factors. respondents to the same survey expressed that their hospitals needed better systems for collecting data and reporting PNM [41].

Additionally, three studies [18, 20, 23] reviewed the reproducibility of their results by examining consensus between subpanels of the review process in determining relation of SSCF to adverse perinatal outcome. In two of these studies, consensus was good, (kappa coefficient 0.62-0.74) [18, 20] whereas in the remaining study, there was disagreement on determining cause of death in 16.4% of cases [23].

### Factors affecting case ascertainment

The lack of linkage of medical and civil records has been mentioned as a factor affecting PNM reporting as it can allow for better and more accurate case identification. Two studies found underreporting of events through hospital systems or audit programs compared to registries or databases [26, 28]. De Reu et al. [28] specifically noted 20% of cases from the PNM database had not been reported in the audit. Kieltyka et al. [40] found that timeliness of capturing cases through civil records could affect the representation of cases being sampled in the audit process.

## Barriers to PNM audit implementation

### Time

Five studies [7, 17, 22, 23, 28] found that the time commitment associated with the audit process was obstructive to its implementation. The average time required to prepare cases for audit meetings varied between 4 and 8 h and frequent, time-consuming meetings were identified as a potential barrier to audit implementation.

### Insufficient or incomplete data

Incomplete data in cases of PNM was noted to affect data collection for audit purposes in nine studies [17, 18, 20, 21, 26, 28, 31, 33, 39]. The proportion of incomplete data were variable, ranging from 3 to 34%. Two studies [26, 28] showed that differences in data acquisition methods between civil and medical records resulted in insufficient data for perinatal audit. In one study [20], data could not be obtained from civil records due to confidentiality laws.

### Staff training

Four studies [7, 31, 32, 41] identified inadequate training in the processes of auditing as a factor which impeded their effective implementation or as a necessary factor that would improve implementation. Two studies [28, 32] showed that staff training in identifying cases of substandard care and how to implement recommendations from audit, improves outcomes in each of these domains, respectively.

### Other barriers

Other factors that were found to affect the implementation of perinatal audits include personal involvement of the clinician in cases [17], lack of consensus between audit review members in determining outcomes in cases of perinatal mortality [18], poor compliance with pre-existing audit guidelines [21] and absence of standardisation of case definition for international comparison [19, 26]. Surprisingly, only two studies positively identified funding as a barrier to implementation of a regional/national audit system [7, 28].

# Facilitators to PNM audit implementation

In a survey of perinatal mortality audit participants, 10% indicated they valued training given in the audit process, a non-judgmental environment to search for SSCFs (21%) and the multidisciplinary team approach (13%) [7]. Another study found similar results, where 100% of members felt secure discussing cases openly with other care providers [17]. Similarly, in a study by Flenady et al. [41], survey respondents valued the use of checklists and information brochures, which aided investigation and standardisation in cases of perinatal mortality.

# Recognition of risk factors associated with perinatal outcomes

In total, 12 papers identified risk factors for perinatal mortality through perinatal audit [16-18, 20-25, 27, 28, 31]. These findings are presented in Table 3. Maternal smoking during pregnancy and maternal obesity were the two most commonly identified maternal factors associated with adverse perinatal outcomes. Failure of timely detection of fetal growth restriction (FGR) and appropriate management [16, 19, 20, 23, 24], late presentation or failure of transfer to higher level of care [21, 23, 28], and failure to diagnose/

manage diabetes/hypertensive disorders in pregnancy [20, 23] were commonly identified SSCF associated with perinatal mortality. Seven of these studies analysed the relation of SSCF to perinatal mortality [17, 19, 20, 23, 25, 28, 31]. The proportion of SSCF that possibly or likely contributed to perinatal mortality was variable, ranging from 8 to 45%. Alderliesten et al. found SSCFs in 25% of PNM cases, with 8% of deaths possibly related to the SSCF in question [17]. This is comparable to findings from Kortekaas et al. who reported in 35.4% of cases of PNM, SSCFs were possibly, likely or very likely related to the death [25].

A perinatal audit in South Australia found 11.2% of SSCFs occurred due to deficiencies of professional care, and differences in the quality of perinatal care present in different types of hospitals, with country (regional) and level 1(primary care/midwifery led) hospitals having the most prevalent SSCFs [16]. De Reu et al. [28] found that in 32% of cases with SSCFs, failure to transfer to tertiary care contributed to cause of death compared to 25% of cases where the underlying cause was potentially related to night or late evening shifts. In another study in the Netherlands, the inability to follow guidelines (31% of identified SSCFs), provision of care against normal practice (23%) and inadequate communication between clinicians (13%) were the most common SSCFs [20]. Similarly, in an internal audit in the Netherlands, 35% of cases with SSCFs were associated with noncompliance or missing local protocols and 41% with deviation from normal care [31].

# Outcomes following implementation of a perinatal audit

Seventeen papers reported on the outcomes or recommendations following the implementation of perinatal audits (Table 3). Following the results of two regional audits in the Netherlands, a nationwide perinatal audit was initiated [7, 28]. This was facilitated by the creation of a perinatal mortality database, which helped with the standardisation and completeness of data collection. Similarly, following the application of an online reporting system in another regional audit by Lee et al. [33], there was an improvement in the quality of fetal death reports and a reduction in poorly defined causes of fetal death (61% vs. 68%, p=0.004). In Australia, a local perinatal review process was implemented after the results of one study in this region [21].

Overall, there is a lack of clear information on whether recommendations from perinatal audits have been implemented or not. Only five studies provided further detail on this [21, 28, 31, 32, 40]. Mishra et al. [32] analysed the proportion of recommendations implemented after the initiation of a fetal death monitoring program. They found a high rate (75%) of implementation of 231 recommendations, with a further 22% in the process of being implemented at the time of publication. Additionally, Kieltyka reported that nine public health programs were implemented in specific regions across the state of Louisiana [40].

Following an audit of 707 cases of PNM in the Netherlands, a total of 603 recommendations were made based on the identification of 512 SSCFs in 376 cases [31]. The majority of recommendations (35%) related to the organisation of care, in particular the co-operation of care between healthcare professionals in the community and in hospitals. The same audit found that over a 3-year period, the PMR decreased from 2.3/1,000 to 2/1,000 (p $\leq 0.001$ ).

### Recommendations for audit implementation

Eight studies made recommendations for improvement of the audit process and implementation of audits on either a local or national level [16, 17, 24, 25, 31, 33, 39, 41]. Audit member training was an important recommendation which was suggested by De Lange [16], Eskes [31] and Flenady [41]. This was recommended specifically in the areas of investigation and classification of perinatal mortality.

Studies also recommended multidisciplinary participation in the analyses of PNM cases, as this was found to improve the quality of case summaries and the overall audit process [17, 28, 41]. Furthermore, the implementation of a national confidential enquiry for all cases of intrapartum fetal deaths and unexpected neonatal deaths was recommended by McNamara et al. [24].

Two studies in total recommended the use of an audit tool to help with standardisation of analysis in cases of perinatal mortality [25, 39]. Both studies commented on the need for a standard case summary tool to aid in the quality and completeness of data in cases of PNM.

### Recommendations for clinical practice

Recommendations for clinical practice were made in seven studies which reflected, mostly, on the identification of risk factors and substandard care factors described in their results.

Patient or public education regarding concerning symptoms in late pregnancy [16, 22] and smoking cessation in pregnancy or other maternal risk factors [24] were the most common patient-focused recommendations made.

# **Discussion**

The current systematic review aimed to study with further depth the main challenges faced by PNM audits and facilitating factors contributing to efficient and successful PNM audit implementation. The main factors affecting the correct and reliable reporting of perinatal deaths in PNM audits were also studied. Lastly, this review intended to clearly understand the relevance and potential impact of PNM audits in identifying risk factors and recommending and (perhaps) implementing measures for improvement of quality of care. To our knowledge this is one of the first systematic reviews examining this field of Perinatal Mortality Audit with this level of detail.

The nineteen studies analysed in our review highlighted common barriers to the implementation of perinatal audits and, upon further analysis of the literature, these barriers appear to resonate with clinical audit in general. Although our review is comprehensive and includes all published literature found in the respective databases that met our inclusion criteria, it is noted that national perinatal mortality data from some countries is not included in our review, as some national reports have not been submitted to peer-reviewed journals and therefore did not meet our inclusion criteria.

# Standardisation of data collection, cause of death and case definitions

The results of this review revealed that there is a lack of consistency in the methods used to collect data on perinatal mortality and associated factors, definitions used for cases of perinatal death, and classifications of associated factors. This affects the completeness of data being collected, as seen in several studies [17, 18, 20, 21, 26, 28, 31, 33, 39]. Consequently, this impacts on the ability to use these data for identification of risk and substandard-care factors, classifying causes of death and tracking trends in perinatal mortality for improvements. Guidelines set forth by multiple national and international organizations [42–44] emphasise the importance of a structured, standardized approach to clinical audits procedures and data collection. However, our results show there are still areas where further standardization is necessary.

The use of a standardized collection system or tool has been established in several high-income countries with national perinatal audits, including the U.K., Ireland and New Zealand [45-47]. This is known to facilitate the collection of pertinent data of each reported perinatal death case, especially in high volume, fast paced environments where capturing data can be a challenge [43]. In the U.K., a validated Perinatal Mortality Review tool is also used to guide the review of perinatal death cases in a standardized manner. A report on the use of this tool stated that it has been used in the review of 88% of eligible PNM cases across England, Scotland and Wales, and over 90% of these resulted in the identification of a substandard care factor [48]. Standardization of data collection has been recommended in other mortality audit guidelines, such as the WHO's guide for paediatric mortality auditing [49].

In this review, studies identified a lack of established reporting criteria or definitions as a barrier to reporting perinatal deaths [21, 24, 26, 31, 41]. Different hospital systems, regions or countries using distinct perinatal mortality definitions hinders the comparison of perinatal mortality rates between countries. This hampers tracking trends in rates, rates across countries and learning from each other's successes [12, 34]. The WHO's definition is recommended for international comparisons, but many countries use their own definitions, with different gestational age and/or birth weight cut-offs, and differing inclusion criteria for termination of pregnancy [43]. The Lancet Stillbirth Series has emphasised that international consensus on the classification and definition of stillbirth is essential to improve care through national audits in high income countries [50].

Rodin et al.'s [26] study in this review showed how lack of data from the audit impeded the ability to classify cause of death. Lehner et al. [51] also reported that the use of a standard audit tool resulted in the identification of underlying causes of death in 168/170 stillbirth deaths originally classified as unexplained through chart review. Similarly, Allanson et al., highlighted the benefits and applicability of a standard reporting and classification system while Vergani et al. showed that applying a standard classification tool lead to a reduction of the rate of unexplained stillbirth [52, 53]. Though the global lack of quality data and poor reporting on stillbirths' cause of death is recognised and a standardised audit and classification system has been proposed [54], there is currently no international consensus on one system to apply. Although various studies have compared classification systems, establishing which would be best recommended, there is still lack of agreement and a need for a consistent system which allows for accurate comparison [52, 55, 56].

# Factors affecting the implementation of PNM audits

Lack of protected audit time, dedicated staff training, and incomplete or insufficient data were cited as the most common barriers to perinatal audit implementation in our review. Lack of resources is one of the age-old barriers to clinical audit and has been quoted extensively as a limiting factor in the development of regular, clinical audits [57-59]. Given the already burdened and time limited workload at most clinical sites, some clinicians feel that the time required to partake in audit impedes upon their clinical work, ultimately compromising patient care [60]. However, the importance of clinical audits is noted amongst clinicians as a critical identifier of suboptimal care factors and as a quality improvement strategy [30]. In Ireland, the National Perinatal Epidemiology Centre (NPEC) has often highlighted that robust clinical audit of perinatal outcomes is vital for patient care, but this requires the protected time of clinical staff [45, 61]. Improvements in this regard can be difficult to implement on an individual basis and require adjustments on either a local, regional or national level to afford healthcare workers the time to engage with clinical audits. A predetermined amount of protected hours per week for clinical trainees or dedicated research staff may help facilitate regular perinatal audits. The Healthcare Quality Improvement Partnership (HQIP) in the United Kingdom have outlined recommendations with regard to time management, to facilitate and promote regular clinical audits [42].

Four of the studies in our review identified inadequate staff training as a barrier to perinatal audit implementation [28, 31, 32]. Staff training is essential for clinical audit to ensure accurate outcomes measurement and of reliable datasets which, as part of the audit cycle, can promote systematic change. Lack of training in perinatal death classification systems amongst audit participants may lead to inaccurate identification in cause of death in these cases, subjecting audit results to potential misclassification bias. However, in two studies [28, 31], even though staff received training in audit processes and classification system, there was a considerable rate of unknown cause of perinatal death using Wigglesworth and Tulip classification systems (32% and 34.6%, respectively). This highlights the importance of training for the audit process and the relevance of adequate methods and approaches to clinician education.

Incomplete datasets were a consistent and significant finding in our results. Although, in most studies the percentage of cases with insufficient data was low, this figure was highly variable, comprising 34% of cases of PNM in one study [39]. HQIP and the National Institute for Clinical Excellence (NICE) have also highlighted the relevance of data completeness and prepared guidance to promote high quality data acquisition in clinical audits [44, 62]. Awareness of the importance for high quality data in cases of PNM is increasing, however few countries have practiced standardised auditing [63].

# Perinatal mortality audits as an important identifier of risk factors for perinatal mortality

Our analysis highlights the utility of perinatal audits in identifying risk factors for mortality and how through careful case analysis and recognition of suboptimal care factors, change can be implemented at a local, regional or national level to improve obstetric care [7, 21, 28, 33]. Although rates of perinatal deaths have fallen significantly in high-income countries in recent decades, suboptimal care still accounts for a proportion of cases and this is devastating for all parents, families and healthcare professionals involved. Failure to thoroughly examine these cases is a major deficiency in a modern healthcare setting, obstructs clinician education and may lead to recurrence of events.

There is widespread acceptance in the literature that it is essential to analyse cases of perinatal mortality to identify potentially reversible risk factors as well as preventing the recurrence of critical mistakes at both local and national system levels [14, 39, 63]. Audit and feedback have been shown to be effective in improving clinical practice and may be more effective than other quality improvement strategies particularly when the audit process is targeted at analysing practices where there is clear evidence linking processes and patient outcomes [64]. In New Zealand, following the introduction of the Perinatal and Maternal Mortality Review Committee (PMMRC) in 2007, an 11% reduction in the stillbirth rate was observed [47]. Similarly, the Netherlands achieved the greatest reduction in stillbirth rates following the implementation of the Dutch perinatal mortality audit when compared to 48 other high income countries [31, 63]. The value of national perinatal programmes has been acknowledged, however few highincome countries have implemented nationwide audit policies and fewer still routinely conduct in-depth analysis of substandard care factors, for example by confidential enquiry [34].

# Outcomes following implementation of perinatal audits

Few studies in this review commented on whether recommendations based on findings of perinatal audit have been implemented and whether the "audit loop" has been completed. Nevertheless, follow-up on audit recommendations was not a primary objective in most of the studies included. The audit cycle should always be completed by monitoring of implemented strategies and verification of their efficacy [44, 65, 66]. Qualitative analysis by Misra et al. [32] to evaluate intermediate outcomes of fetal and infant mortality review programmes, identified implementation as a critical outcome of audit, but acknowledged that this was a difficult concept to measure, given the lack of well-established measurement scales [32, 67, 68]. Closing or continuing the audit loop is an essential part of the process in order to improve clinical and professional outcomes [69, 70]. Completion of the audit process helps with clinician professional development and is an obligatory component of clinician training in many countries [64]. In a healthcare setting where professionals or services may be underperforming, PNM audits with clear targets and an action plan have been shown to produce a substantial improvement in the quality of perinatal care [71].

# **Conclusions**

This review has highlighted the barriers to successful implementation of PNM audits. While most of the studies analysed were local or regional perinatal audits, they identify changes that need to be brought about at a systematic level in order improve the quality of perinatal audit, and ultimately perinatal care. Heightened awareness of the impact of effective audit on identifying potential areas for clinical improvement is crucial and in order to promote the success and future of PNM audit, particular focus should be applied to enabling adequately trained staff to participate in regular audit that is standardised and thorough.

Finally, greater emphasis should be placed on the final and most important part of the audit process, that is closure of the perinatal audit cycle through regular assessment and re-evaluation of changes and recommendations put forward from the initial audit. Feedback from PNM audits should inform clinical governance, and recommendations from audit should be continually re-evaluated in order to achieve sustained improvement in the quality of obstetric care, achieving the ultimate goal of reducing the number of perinatal deaths.

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