Developing an Evidence-based, Comprehensive Model for a Facility-based Stillbirth Review Process in India: A Mixed Methods Study



Yebeen Ysabelle Boo

Kellogg College

National Perinatal Epidemiology Unit

Nuffield Department of Population Health

University of Oxford

A thesis submitted for the degree of

Doctor of Philosophy

in Population Health

Michaelmas Term, 2024

Abstract

Background: In India, the burden of stillbirth remains high. Facility-based stillbirth reviews have the potential to improve the quality of future care and reduce stillbirth incidence. However, evidence about conducting such reviews effectively at the facility level in India remains limited.

Aim: To develop an evidence-based, comprehensive model for a facility-based stillbirth review in six states in India to inform the planning, extension and scale-up of the nationwide Sentinel Stillbirth Surveillance System.

Methods: A mixed-methods approach was employed including: (1) a systematic review of types and methods of facility-based stillbirth review processes; (2) secondary analyses of existing cohort data to calculate stillbirth rates, identify risk factors for stillbirth, and explore survival probabilities of fetuses at high risk of intrapartum stillbirth by gestational age; (3) two qualitative studies to explore current stillbirth review processes in India, and identify facilitators and barriers for implementation and sustainability using the capability, opportunity, motivation and behaviour (COM-B) model.

Results: The systematic review identified facility-based stillbirth reviews implemented worldwide, and its evidence formed the basis of an initial logic model outlining components of a successful stillbirth review process. The stillbirth rate in 13 hospitals across six states in India was 22.0 per 1,000 total births. Key risk factors identified were hypertensive disorders of pregnancy, anaemia, <10th percentile birthweight for gestational age, <4 antenatal check-ups, and <100 days of antenatal iron and folic acid supplementation. Qualitative findings highlighted that despite efforts to improve data quality, pregnancy care, and review quality through stillbirth reviews, gaps remained in standardised stillbirth reporting, documentation of findings, and follow-up of recommendations. Opportunities for quality improvement included implementing key performance indicators to evaluate outcomes and the impact of the review process. Facilitators related to social opportunities included creating a blame-free environment for discussion, ensuring participation from all levels of the health system, and addressing cultural perceptions of stillbirth and post-mortem examinations. Facilitators related to physical opportunities were having clear stillbirth definitions and collecting minimum stillbirth data. Supporting healthcare professionals with targeted training and mentoring had the potential to increase capability. Reflective motivation,

specifically, the beliefs in the benefits of stillbirth reviews for both the facility and the community, was a notable factor in the willingness of healthcare professionals to implement and sustain stillbirth reviews despite system-level barriers.

Conclusion: Findings from the five research activities were triangulated into a logic model that was iteratively refined. The final model contextualised global evidence to address India's diverse health system challenges, linking inputs, activities, and outcomes while identifying facilitators, barriers and evaluation needs – critical components for implementing and sustaining stillbirth review processes. The logic model also identifies priority areas where stillbirth reviews could have the greatest impact. The model and recommendations from this study have the potential to support India's goal of reducing stillbirth rates to <10 per 1,000 total births by 2030.

Acknowledgement

I would like to thank Prof Manisha Nair, Prof Jenny Kurinczuk and Prof Monica Lakhanpaul for supervising me throughout my DPhil. I could not have completed it without your invaluable guidance and advice. My sincere appreciation goes to the collaborators of the Maternal and Perinatal Health Research Collaboration, India (MaatHRI) and the 10,056 women from six states in India who participated in the MaatHRI cohort. Without their participation, I would not have been able to do my research well.

A special thank you to my family – my mum, dad, and brother – for believing in me and for bringing laughter during overwhelming moments. To my best friend and partner, Tom McIver, thank you for always being there. I look forward to celebrating this milestone and many more with you.

A big shout out to my best friends, Kerolous, Devra, Shereen, Pawel, Gary, and Lucas, who have been so supportive. I'm looking forward to our big celebration after I click 'submit'! I also want to tell the world how amazing Dr Uchenna Gwacham-Anisiobi is. The fact that we did this together under Manisha's and Jenny's supervision made the journey a hundred times better. You truly are a fantastic friend and colleague.

I received support and encouragement from so many people, including Dr Aliki Christou, Dr Tuck Seng Cheng, Jenny Gong, Nia Roberts, and Dr Dixa Thakrar. Thank you so much for your help. I am also deeply grateful to Prof Maria Quigley and Prof Lenka Beňová for examining my thesis and for their thoughtful feedback. Thank you to the Clarendon Fund, Kellogg College, and Nuffield Department of Population Health for funding my DPhil and this important study.

Finally, and most importantly, I dedicate this thesis to women who are grieving for their baby after a stillbirth. Sadly, their babies could not experience this world and meet their loving families in person. I dedicate my research to improving maternal health in India and reducing preventable stillbirths.

Statement of contribution to work

I, Yebeen Ysabelle Boo, confirm that the work presented in this thesis is my own. I conceptualised the research, obtained the funding, accessed and cleaned the existing cohort data, gained the required ethics approvals for qualitative studies, recruited qualitative study participants, conducted all the quantitative and qualitative analyses and wrote the thesis. I am the first author of two publications (see 'list of publications' on the next page) arising from the work described in Chapters 2 and 4. Prof Manisha Nair and Prof Jenny Kurinczuk supervised the research from its inception, advising on study design, systematic review, quantitative and qualitative methodology, analyses and interpretation of results. Prof Monica Lakhanpaul provided supervision on the methodology and analyses for systematic review and qualitative studies. All supervisors provided feedback on the thesis. For the systematic review presented in Chapter 2, Dr Uchenna Gwacham-Anisiobi and Dr Dixa Thakrar independently screened 50% of abstracts and full-text reports, reviewed extracted data from the included studies and conducted the quality assessment of individual studies. Nia Roberts reviewed the search terms and search strategy. For the qualitative studies presented in Chapters 6 and 7, Dr Aliki Christou and Jenny Gong supported me as second coders and independently coded 60% of focus group discussion transcripts and meeting observation notes. Dr Aliki Christou and Prof Rachel Rowe provided valuable comments and suggestions for interpreting the results of qualitative studies.

List of publications

Peer-reviewed publications arising from thesis research

Boo YY, Gwacham-Anisiobi U, Thakrar DB, Roberts N, Kurinczuk JJ, Lakhanpaul M, Nair M. Facility-based stillbirth review processes used in different countries across the world: a systematic review. **EClinicalMedicine** 2023;59:101976. https://doi.org/10.1016/j.eclinm.2023.101976.

Boo YY, Bora AK, Chhabra S, Choudhury SS, Deka G, Kakoty S, Kumar P, Mahanta P, Minz B, Rani A, Rao S, Roy I, Solomi V C, Verma A, Zahir F, Deka R, Kurinczuk JJ, Nair M; MaatHRI collaborators. Maternal and fetal factors associated with stillbirth in singleton pregnancies in 13 hospitals across six states in India: A prospective cohort study. **Int J Gynaecol Obstet** 2024;165:462–73. https://doi.org/10.1002/ijgo.15367.

Table of Contents

Abstract 2

Acknowledgement 4

Statement of contribution to work 5

List of publications 6

Peer-reviewed publications arising from thesis research 6

Table of Contents 7

List of Figures 11

List of Tables 12

List of boxes 13

Abbreviation 14

Terminology 17

Chapter 1. Background 18

1.1 What is a stillbirth? 18

1.1.1 The challenge of stillbirth in the world 18

1.1.2 Stillbirth in India – a public health problem 20

1.2 Risk factors for stillbirth in low-and-middle-income countries (LMICs) 22

1.3 Facility-based stillbirth review 26

1.3.1 Relevant stillbirth review guidelines for India 27

1.4 Indian health system 32

1.5 Logic model 35

1.6 Aims, research questions and objectives 36

1.7 Organisation of component studies and structure of the thesis 37

Chapter 2. Systematic review of the evidence 40

2.1 Chapter introduction 40

2.2 Aim and objectives 40

2.3 Methods 40

2.3.1 Protocol and registrations 40

2.3.2 Search strategy 41

2.3.3 Inclusion and exclusion criteria 42

2.3.4 Data extraction 43

2.3.5 Quality assessment of individual studies and narrative synthesis 44

2.4 Results 45

2.4.1 Study selection 45

2.4.2 Study characteristics 47

2.4.3 Types 51

2.4.4 Aims and funding 54

2.4.5 Source of data 55

2.4.6 Definition (case assessment of stillbirth) 56

2.4.7 Data collection 59

2.4.8 Notable components 60

2.4.9 Outputs and outcomes 60

2.4.10 Facilitators and barriers to implementing a successful stillbirth review 61

2.4.11 Logic model 63

2.4.12 Quality assessment 66

2.5 Discussion 69

2.5.1 Principal findings 69

2.5.2 Discussion in light of other evidence 71

2.5.3 Strengths and limitations of the study 75

2.5.4 Conclusion 76

Chapter 3. Methods 78

3.1 Chapter introduction 78
3.2 The mixed methods research design 78
3.2.1 Dimensions of mixed methods research design 79
3.2.2 Summary of the mixed methods research design 81
3.2.3 The role of theoretical frameworks 83
3.3 Maternal and Perinatal Health Research Collaboration, India (MaatHRI) 83
3.3.1 MaatHRI prospective cohort study 85
3.3.2 Methods employed for the MaatHRI prospective cohort study 86
3.3.3 Strengths of the MaatHRI prospective cohort study 87
3.3.4 Ethics approval 87
3.4 Quantitative analysis methods 88
3.4.1 Data source 88
3.4.2 Conceptual framework 89
3.4.3 Interaction 93
3.4.4 Software 94
3.4.5 Ethics approval 94
3.4.6 Quantitative methods I: Incidence and risk factors for stillbirths in India 95
3.4.7 Quantitative methods II: risk factors for intrapartum stillbirths in India and survival probabilities of fetuses by gestational age 98
3.5 Qualitative study methods 102
3.5.1 Ethics approval 102
3.5.2 Qualitative methods I: exploring current stillbirth review processes in India 104
3.5.3 Qualitative methods II: facilitators and barriers to implementing or sustaining facility-based stillbirth reviews in India 111
3.5.4 Data analysis 116
3.5.5 Researcher reflection 124
3.5.6 Ensuring anonymity in reporting results 128

Chapter 4. Quantitative results I: incidence and risk factors for stillbirths in India 130

4.1 Chapter introduction 130
4.2 Stillbirth rate 130
4.3 Characteristics of women 131
4.4 Risk factors for overall stillbirth 137
4.4.1 Univariable analysis 137
4.4.2 Multivariable regression analysis 141
4.5 Performance of multivariable models 146
4.6 Discussion 147
4.6.1 Principal findings 147
4.6.2 Discussion in light of other evidence 148
4.6.3 Strengths and limitations 150
4.6.4 Conclusion 151

Chapter 5. Quantitative results II: risk factors for intrapartum stillbirths in India and survival probabilities of fetuses by gestational age 153

5.1 Chapter introduction 153
5.2 Intrapartum stillbirth rate 153
5.3 Characteristics of women 154
5.4 Risk factors for intrapartum stillbirth 157
5.4.1 Univariable analysis 157
5.4.2 Multivariable analysis 161
5.5 Survival probabilities of fetuses in women with complications 165
5.6 Antepartum stillbirth rate and risk factors 167
5.7 Discussion 171
5.7.1 Principal findings 171
5.7.2 Compared with risk factors for overall stillbirth 172
5.7.3 Compared with risk factors for antepartum stillbirth 172

5.7.4 Discussion in light of other evidence 173
5.7.5 Strengths and limitations 179
5.7.6 Revised logic model 181
5.7.7 Conclusion 183

Chapter 6. Qualitative results I: exploring current stillbirth review processes in India 184
6.1 Chapter introduction 184
6.2 Document analysis of stillbirth review tools and guidelines 184
6.2.1 Data collection 186
6.2.2 Stillbirth reporting 187
6.2.3 Stillbirth review guidelines 188
6.2.4 Key documents created from the Hospital B's stillbirth review 189
6.3 Structure and processes 190
6.3.1 Interlinked Theme 1: Reasons for conducting reviews 195
6.3.2 Interlinked Theme 2. Motivation for staff participation 197
6.3.3 Sequential Theme 1. Organising meetings 199
6.3.4 Sequential Theme 2. Discussion methods 203
6.3.5 Interlinked Theme 3. Atmosphere and conduct 205
6.3.6 Interlinked Theme 4. Documentation 210
6.3.7 Sequential Theme 3. Dissemination of generated learnings 210
6.3.8 Sequential Theme 4. Improving quality 214
6.4 Discussion 217
6.4.1 Principal findings 217
6.4.2 Discussion in light of other evidence 218
6.4.3 Strengths and limitations 223
6.4.4 Revised logic model 225
6.4.5 Conclusion 227

Chapter 7. Qualitative results II: facilitators and barriers to implementing or sustaining facility-based stillbirth reviews in India 228
7.1 Chapter introduction 228
7.2 Facilitators and barriers 228
7.2.1 Social opportunity 231
7.2.2 Physical opportunity 234
7.2.3 Automatic motivation 244
7.2.4 Reflective motivation 246
7.2.5 Capability 252
7.3 Actionable interventions 253
7.4 Discussion 258
7.4.1 Principal findings 258
7.4.2 Discussion in light of other evidence 259
7.4.3 Strengths and limitations 266
7.4.4 Revised logic model 268
7.4.5 Conclusion 270

Chapter 8. Discussion 271
8.1 Chapter introduction 271
8.2 What did this mixed methods study find? 271
8.2.1 Inputs 274
8.2.2 Outputs – Activities 279
8.2.3 Outputs – Generated learnings 283
8.2.4 Outcomes 285
8.3 Strengths and limitations 288
8.4 Recommendations 289
8.4.1 Policy 289
8.4.2 Indian health system 291
8.4.3 Future research 293
8.5 Conclusion 294

References 296

Appendices 314
Appendix A: Published article – Facility-based stillbirth review processes used in different countries across the world: a systematic review 314
Appendix B: Search terms used for each database 331
Appendix C: Data extraction template 334
Appendix D: Quality assessment template 340
Appendix E: Included studies and the extracted data 343
Appendix F: Consent form 370
Appendix G: Participant information sheet – for hospitals that conduct stillbirth reviews 371
Appendix H: Participant information sheet – for hospitals that do not conduct stillbirth reviews 376
Appendix I: Document analysis worksheet 381
Appendix J: Observation guide 383
Appendix K: Focus group discussions topic guide – for hospitals that conduct stillbirth reviews 386
Appendix L: Focus group discussions topic guide – for hospitals that do not conduct stillbirth reviews 388
Appendix M: Published article – Maternal and Fetal Factors Associated with Stillbirth in Singleton Pregnancies in 13 Hospitals Across Six States in India 389
Appendix N: Summary of document analysis 401

List of Figures

Figure 1-1. Health system in India: national level overview [60] 33
Figure 1-2. Organisation of the Indian health system: relationship between the national (union), state and district levels [60] 34
Figure 2-1. PRISMA flowchart of study selection 46
Figure 2-2. The geographical distribution of countries of the included studies using the World Bank income classification 2022 50
Figure 2-3. Logic model of stillbirth reviews developed from the systematic review findings 65
Figure 2-4. Summary graph of quality assessment of the included studies 69
Figure 3-1. Diagrammatic summary of the mixed methods research design used in this study 82
Figure 3-2. Organogram of MaatHRI 84
Figure 3-3. Six states of India where MaatHRI hospitals are located 85
Figure 3-4. Conceptual framework: hypothesised relationship between the structural, intermediate and proximal factors and stillbirth 93
Figure 3-5. Capability, opportunity, motivation and behaviour (COM-B) model by Michie *et al.* [195] 114
Figure 3-6. The Behaviour Change Wheel by Michie *et al.* [195] 115
Figure 3-7. An excerpt of an inductive coding during 'coding' stage of the Framework Method 122
Figure 4-1. Flow diagram of the selection of the study participants 131
Figure 4-2. Area under the receiver-operating characteristic (AUROC) curve for structural, intermediate and proximal factors 147
Figure 5-1. Flow diagram of the selection of the study participants 154
Figure 5-2. Kaplan-Meier survival curve by HDP category by gestational age 166
Figure 5-3. Kaplan-Meier survival curve by severity of anaemia by gestational age 167
Figure 5-4. Kaplan-Meier survival curve by HDP category by gestational age (antepartum stillbirth analysis) 171
Figure 5-5. First revised logic model: includes findings from the systematic review and quantitative analyses 182
Figure 6-1. Flow and interaction of stillbirth review tools and guidelines 185
Figure 6-2. Coding tree representing the themes and codes that emerged in the observation and focus group discussions 193
Figure 6-3. Second revised logic model: includes findings from the systematic review, quantitative analyses, multiple case study 226
Figure 7-1. Coding tree representing the themes and codes that emerged as facilitators and barriers 230
Figure 7-2. Final revised logic model 269
Figure 8-1. An evidence-based, comprehensive model for a facility-based stillbirth review process in six states in India 273

List of Tables

Table 1-1. Risk factors associated with stillbirth extracted from the UN IGME's literature review [33] 23
Table 2-1. General information of the included studies 47
Table 2-2. Count and percentage of studies that had the component of salient features of audit, review, and confidential enquiry by types of review process (label assigned by the study authors of included studies) 52
Table 2-3. Components of stillbirth review identified in the methods 52
Table 2-4. Definition (case assessment of stillbirth) used in the included studies 56
Table 2-5. Facilitators and barriers to implementing a successful stillbirth review 62
Table 2-6. Quality assessment of the included studies 67
Table 3-1. Characteristics of the care available in the 13 MaatHRI hospitals involved in the prospective cohort study of postpartum haemorrhage 86
Table 3-2. Availability and reason for exclusion of potential exposure variables 89
Table 3-3. Methods of assessment or measurement used to collect data and the categorisation of the exposure variables 91
Table 3-4. Frequencies of missing data of exposure variables 96
Table 3-5. Frequencies of missing data of exposure variables 100
Table 3-6. Case characteristics 107
Table 3-7. The Behaviour Change Wheel intervention function definitions [200] 116
Table 4-1. Descriptive statistics of women who had a stillbirth (antepartum and intrapartum) compared with women who had a live birth 133
Table 4-2. Unadjusted associations (univariable analysis) between exposure variables and relative risk of stillbirth 137
Table 4-3. Adjusted associations (multivariable analysis) between exposure variables and relative risk of stillbirth 142
Table 5-1. Descriptive statistics of women who had an intrapartum stillbirth compared with women who had a live birth 155
Table 5-2. Unadjusted associations (univariable analysis) between exposure variables and relative risk of intrapartum stillbirth 158
Table 5-3. Adjusted associations (multivariable analysis) between exposure variables and relative risk of intrapartum stillbirth 162
Table 5-4. Unadjusted associations (univariable analysis) between exposure variables and relative risk of antepartum stillbirth 168
Table 5-5. Adjusted associations (multivariable analysis) between exposure variables and relative risk of antepartum stillbirth 170
Table 6-1. Demographic information about focus group discussion participants 191
Table 6-2. Summary of themes or codes related to the pre-meeting phase by hospital 194
Table 6-3. Summary of themes or codes related to the during-meeting phase by hospital 202
Table 6-4. Summary of themes or codes related to the post-meeting phase by hospital 209
Table 6-5. Summary of themes or codes related to the outcomes phase by hospital 213
Table 7-1. Characteristics of hospitals that participated in the study and demographic characteristics of the focus group discussion participants 228
Table 7-2. Actionable interventions for facilitators and barriers using the Behaviour Change Wheel intervention function 254

List of boxes

Box 1-1. Stillbirth data collection systems in India 21
Box 1-2. Key terms in 'Making Every Baby Count' guidelines [54] 30
Box 1-3. Tools and forms relevant to facility-based stillbirth review provided in 'Making Every Baby Count' guidelines [54] 32
Box 2-1. Types of funding to commission stillbirth review 55
Box 2-2. Notable components of stillbirth review observed in the included studies 60
Box 3-1. File-naming system for document analysis 118

Abbreviation

ABDM: Ayushman Bharat Digital Mission

AI: Artificial Intelligence

AMB: Anaemia Mukt Bharat

aRR: Adjusted relative risks

ASHA: Accredited Social Health Activist

AUROC: Area under the receiver-operating characteristic

BMI: Body mass index

BPL: Below poverty line

CEMACH: Confidential Enquiries into Maternal and Child Health

CEMD: Confidential Enquiry into Maternal Deaths

CESDI: Confidential Enquiry into Stillbirths and Deaths in Infancy

CI: Confidence interval

CKD: Chronic kidney disease

CMACE: Centre for Maternal and Child Enquiries

CMO: Chief Medical Officer

CODAC: Causes of Death and Associated Conditions

COM-B: Capability, opportunity, motivation and behaviour

CPD: Continuous professional development

CSDH: Commission on Social Determinants of Health

CT: Computed tomography

CTG: Cardiotocography

DHS: Demographic and Health Surveys

DPhil: Doctor of Philosophy

EDD: Expected date of delivery

EMR: Electronic medical record

ENAP: Every Newborn Action Plan

FGD: Focus group discussion

FGR: Fetal growth restriction

FHS: Fetal heart sound

FOGSI: Federation of Obstetric and Gynaecological Societies of India

Hb: Haemoglobin

HCP: Healthcare professional

HDP: Hypertensive disorders of pregnancy

HIC: High-income country

HIV: Human immunodeficiency virus

ICD: International Classification of Diseases

ICMR: Indian Council of Medical Research

ID: Identification

IFA: Iron and folic acid

INAP: India Newborn Action Plan

INR: Indian Rupees

ISSHP: International Society for the Study of Hypertension in Pregnancy

IT: Information technology

IUD: Intrauterine death

LMIC: Low-and-middle-income country

LMP: Last menstrual period

MaatHRI: Maternal and perinatal Health Research collaboration, India

MPDSR: Maternal and Perinatal Death Surveillance and Review

NFHS: National Family Health Survey

NHM: National Health Mission

NST: Nonstress test

O&G: Obstetrics and gynaecology

OxTREC: Oxford Tropical Research Ethics Committee

PMRT: Perinatal Mortality Review Tool

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Q&A: Question and answer

RR: Relative risks

SDG: Sustainable Development Goals

SGA: Small for gestational age

SMART: Specific, measurable, attainable, relevant, and time-bound

SOP: Standard operating procedures

UK: United Kingdom

UN IGME: United Nations Inter-agency Group for Child Mortality Estimation

UNICEF: United Nations Children's Fund

VIF: Variance inflation factor

WBIC: World Bank income classification

WHO: World Health Organization

Terminology

I used the term 'women' throughout my thesis to refer to those who are planning to become pregnant, are pregnant, and give birth, as per my University department's practice (National Perinatal Epidemiology Unit). I used the term 'mothers' when the literature I referred to used this terminology, and I was quoting them to indicate that it was from the literature. I acknowledge that not all people who are pregnant and give birth identify as women, and it is important that evidence-based care for maternity, perinatal and postnatal health is inclusive. Likewise, the use of the word 'parents' includes anyone who has the main responsibility of caring for a baby.

Chapter 1. Background

1.1 What is a stillbirth?

Stillbirth is defined as any fetal death (a baby born with no signs of life) that occurred before birth at or beyond a pre-defined duration of gestation or birthweight [1]. The World Health Organization (WHO) recommends using 28 weeks of gestation, 1,000g of birthweight, or 35cm of crown-to-heel length for international comparisons and reporting [2], although the new International Classification of Diseases (ICD-11) defines stillbirth as a baby born following a fetal death at 154 days (22^{+0} completed weeks) or more of gestation [3]. The onset of labour is also an important factor in classifying stillbirth; if the fetal death occurred before the onset of labour and prior to birth, it is categorised as an antepartum stillbirth, whereas if the fetal death occurred after the onset of labour and prior to birth, it is an intrapartum stillbirth [4]. In this thesis, fetal death after 28 completed weeks of gestation was used as the stillbirth definition to be consistent with international reporting of stillbirth [5], as well as India's definition of stillbirth [6].

1.1.1 The challenge of stillbirth in the world

> *"The lack of attention, investment and urgency to address stillbirth has direct consequences: Progress to reduce the stillbirth rate is far too slow, and the global burden of stillbirths remains far too large" (p. 4). Excerpt from "Never Forgotten: The situation of stillbirth around the globe" [5].*

In 2021, a staggering 1.9 million babies (90% confidence interval (CI): 1.8-2.0) were stillborn, according to the United Nations Inter-agency Group for Child Mortality Estimation (UN IGME) [5]. This represents a stillbirth rate of 13.9 per 1,000 total births (90% CI: 13.3-15.1). This is criticised as a substantial underestimate of the real burden, as the definition used for this estimate was fetal death from 28 weeks of gestation and excluded stillbirths at any earlier gestational ages (22 to 27 weeks).

Unfortunately, the global burden of stillbirth is unequal, with families in sub-Saharan Africa and Southern Asia being affected the most by this tragedy. In 2021, three-quarters of all stillbirths worldwide took place in these regions [5].

Globally, 45% of all stillborn babies are estimated to have died during labour (intrapartum stillbirth), and for West and Central Africa and South Asia regions, the proportion of intrapartum stillbirth is more than 50% [5]. The stillbirth rate varies widely between countries, with the highest rate being 31.2 per 1,000 total births in Guinea-Bissau and the lowest rate being 1.6 per 1,000 total births in Japan and Monaco [5]. Women in low-income countries face an eight-fold higher risk of having a stillbirth than women in high-income countries (HICs), and in 2021, 98% of stillbirths occurred in low-and-middle-income countries (LMICs) [5].

Stillbirths have emotional implications for the families involved and negative consequences for communities [7], and especially intrapartum stillbirths are argued to be more closely related to the quality of maternity care [8]. Despite the serious impact of stillbirths and emphasising the urgency of addressing this issue, stillbirths have received inadequate attention on the global health agenda [1,9,10] and funding [11,12], particularly in comparison with maternal and child mortality. Notably, stillbirth-specific targets were conspicuously absent from the 2030 Agenda for Sustainable Development Goals (SDG) announced in 2015 [13], despite the Every Newborn Action Plan (ENAP) having set a target in 2014 to reduce stillbirth in every country and advocating for global interests in the matter [14].

One of the biggest challenges in reducing stillbirth is the lack of reliable data about stillbirths. Standardised data collection tools or standardised classification systems for recording the cause of stillbirth are unavailable in many countries, and stigma and fear of blame further exacerbate the challenges of reporting [3,5,15]. A combination of challenges – lack of reliable data to understand the whole picture of the stillbirth burden, along with a lack of interest and funding – has led to progress which has been far to slow in addressing the global burden of stillbirth. As evident in some of the testimonials from the families from the UN IGME report [5], in many cases, stillbirths are never talked

about, neither to understand the causes and risk factors, nor to generate learnings to improve care for women and babies. The bereaved families are often left behind with unanswered questions while navigating existing stigma and taboos about stillbirth from the society [9,16–21].

1.1.2 Stillbirth in India – a public health problem

In India, the scale of the problem is particularly alarming, with an estimated 286,482 stillbirths in 2021, consistently ranking as the highest absolute number of stillbirths in the world for over two decades [1,5,22]. This is despite commendable progress made in reducing stillbirth rates over the past two decades, with the rate declining from 29.8 per 1,000 total births (90% CI: 22.2-40.3) in 2000 to 12.2 per 1,000 total births (90% CI: 9.9-15.1) in 2021 [5]. Recognising stillbirths as a persistent public health challenge, India launched the India Newborn Action Plan (INAP) with the ambitious goal of reducing the stillbirth rate to less than 10 per 1,000 total births by 2030 [23].

However, for India to attain its INAP target, several challenges must be addressed, including documenting stillbirths in its data collection systems (Box 1-1). According to model estimates, Hug *et al.* [1] reported that the stillbirth rate was 13.9 per 1,000 total births in 2019. Whereas, India's Sample Registration System [24] reported a stillbirth rate of 3 per 1,000 total births in 2019, much lower than the estimates. Additionally, the estimated number of stillbirths (286,482 in 2021) was significantly higher compared with the number of stillbirths recorded as part of the Civil Registration System, which was 159,645 stillbirths in 2020 [25]. This discrepancy indicates stillbirth data in vital statistics may be underreported despite mandatory stillbirth registration in India, posing further challenges in understanding the extent of the problem.

Box 1-1. Stillbirth data collection systems in India

- Civil Registration System: A nationwide system for recording of births, deaths, and stillbirths, mandated under the Registration of Births and Deaths (Amendment) Act, 2023 [26]. It is implemented by local government registrars with oversight from state governments and the Office of the Registrar General of India.
- Sample Registration System: Established in 1970 as a population-based demographic data collection system. It operates in 8,850 sample units, covering 0.6% of the national population. It provides recording of births and deaths, with verbal post-mortem examination methods used to understand causes of death.
- Health Management Information System: A web-based monitoring system for collecting service-based health data from health facilities. It provides insights into maternal, neonatal, child, and adult health indicators at the national, district, and sub-district levels.
- National Family Health Survey (NFHS): A large-scale, demographic and health survey initiated in 1992-93, now in its sixth round (2023-24). Conducted under the Ministry of Health and Family Welfare, with coordination by the International Institute for Population Sciences. It provides district and national-level data on fertility, mortality, nutrition, and health indicators.

Ali *et al.* [27] proposed the following approach for identifying and correcting the underreporting of stillbirths and early neonatal mortality in demographic and health surveys (DHS):

- Misreporting of age at death in the first week: the number of deaths on day 7 divided by a fifth of the number of deaths on days 5 to 9 (age heaping index)
- Underreporting stillbirths or misclassification on days 0-1: Ratio of stillbirths to deaths on days 0 to 1
- Underreporting of stillbirths or misclassification: Ratio of stillbirths to the number of deaths in the first week (days 0 to 6)
- Underreporting of very early neonatal deaths: Ratio of deaths on days 0 to 1 to deaths on days 2 to 6

Using the National Family Health Survey 2019-21 (NFHS-5) [28], which is the DHS of India, Ali *et al.* [27] estimated India's stillbirth rates for 2019/21 at 11.6 to 25.7 per 1,000 total births according to the four models.

Zadey *et al.* [29] pointed out variations in stillbirth rates reported by the Indian Health Management Information System, Civil Registration System, and Sample Registration System, which are 12.25 per 1,000, 6.69 per 1,000 total births, and 3 per 1,000 total births, respectively. The authors also discussed that these stillbirth data collection systems do not provide the necessary or adequate data to use Ali *et al.*'s approach to correct the potential underreporting of stillbirths. They also note that the Civil

Registration System and Sample Registration System values for stillbirth rates are much lower than the modelled values or Health Management Information System data [30], raising questions about the feasibility of complete vital registration as a solution for LMICs.

Underreporting of stillbirth may be due to variations in the definition of stillbirth used in the country, inadequate documentation of gestation period, and categorisation of miscarriages and abortions [31]. A recent systematic review [32], including 49 reports from 46 studies conducted in 21 Indian states and Union Territories, also found that there is no standardised definition of stillbirth used within India nor a consistent classification system for the causes of stillbirth.

1.2 Risk factors for stillbirth in low-and-middle-income countries (LMICs)

A literature review [33] examined risk factors and determinants for stillbirth in LMICs and created a conceptual framework for stillbirth by synthesising 23 studies to improve understanding of the pathways to stillbirth. Table 1-1 describes the risk factors associated with stillbirth reported in this literature review.

Table 1-1. Risk factors associated with stillbirth extracted from the UN IGME's literature review [33]

	Level of association (terminology used in the literature review)			
Domain	**Definite**	**Probable**	**Possible**	**Insignificant**
Social determinants	• Rural residence • Unregistered paternal country of origin in local women • Unregistered paternal country of origin in migrant women • Sexual assault • High temperature exposure for a whole trimester or longer	• Physical assault • Assault with intimate partner violence • Unplanned out-of-hospital birth • Maternal Aboriginal status • Maternal Black ethnicity • Maternal migration status	• PM 2.5 pollution exposure • Foreign paternal country of origin • High temperature exposure in the week before childbirth • Indoor air pollution • Low level of occupation/social class • No formal maternal education • Deprived neighbourhoods • Exposure to water disinfectant by-products	• Other ambient air pollution exposure
Behavioural	• Maternal supine sleeping position	• Illicit drug use • Alcohol use during pregnancy • Tobacco chewing • Maternal smoking • Maternal marijuana use • Daily daytime naps	• Any maternal alcohol use diagnosis • Maternal caffeine consumption	• Heavy lifting
Obstetric	• Previous pre-eclampsia • Previous/recurrent stillbirth	• Interpregnancy interval <6 months • Interpregnancy interval between 60 and 100 months • Previous preterm birth • Gravidity >5 • Previous small for gestational age infant	• Previous caesarean section	
Index pregnancy	• Grade 3 macrosomia • Velamentous cord insertion • Cord prolapse • True cord knot	• Gestational diabetes • Malaria P. falciparum present peripherally at delivery • Breech presentation	• Obstetric cholestasis • Nulliparity • Hypothyroidism in first trimester	• Antepartum bleeding of unknown origin

	Level of association (terminology used in the literature review)			
Domain	**Definite**	**Probable**	**Possible**	**Insignificant**
Index pregnancy (continued)	• Reduced fetal movement • Uterine rupture • Obstructed labour • Uncomplicated multiple pregnancy • Co-twin intrauterine demise • Fetal growth restriction • Pre-eclampsia • Placenta accrete • Congenital anomalies • Parvovirus-19 +fetal hydrops • Gestational syphilis	• Placenta previa • Long sleep duration during pregnancy • Multiple loops of nuchal cord • Preterm birth • Placental abruption • Prolonged pregnancy (42 weeks of gestation)	• Grade 2 macrosomia • Male sex of fetus • Obstructive sleep apnoea during pregnancy • Restless leg syndrome during pregnancy • Short sleep duration during pregnancy • Small for gestational age infant • In-vitro fertilisation	• Subjective sleep disordered breathing • Cord around the neck
Medical	• Celiac disease • Human cytomegalovirus • Group B Streptococcal infections • Influenza • Dengue virus infection • Pre-gestational diabetes • Systemic lupus erythematous • Reflux nephropathy • Sickle cell disease • Systemic infections/sepsis	• Advanced maternal age (>35 years) • Hepatitis E • Pre-gestational hypertension • Depression • Anaemia • Consanguinity • Pre-pregnancy obesity • Maternal human immunodeficiency virus (HIV) infection • Congenital anomalies of the kidneys and urinary tracts • Coronavirus disease • Human papillomavirus • Chlamydia • Hyperthyroidism • Diabetic nephropathy • Herpes simplex virus	• Polycystic ovary syndrome • Epilepsy • Glomerular chronic kidney disease • Tubulointerstitial chronic kidney disease • Female genital mutilation • Underweight pre-pregnancy • Severe mental illness • Endometriosis • Overweight pre-pregnancy	• Primary Sjögren's syndrome • Vitamin D deficiency • Asthma

In India, various types of studies, including population surveillance [34,35], case series [36], cross-sectional [37] and case-control studies [38], have explored risk factors or spatial patterns influencing stillbirths in India however, these studies adopted study designs susceptible to bias or were primarily descriptive in nature.

Understanding intrapartum stillbirth in India remains a significant research gap, despite its potential to highlight areas for improving pregnancy care. When a literature search[1] was conducted to identify the proportion and risk factors for facility-based intrapartum stillbirth in India, only two single-centre studies were found as studies that described the proportion of facility-based intrapartum stillbirth out of total stillbirths [39,40]. In the past, several studies have pointed out difficulties in abstracting types of stillbirth (antepartum or intrapartum) in the study population for analysis due to lack of or no data on the timing of fetal death [34,37,41]. The WHO recommends that the health system record a standard minimum perinatal dataset, which includes the timing (antepartum and intrapartum) of stillbirths [5].

Furthermore, only one study reported risk factors for intrapartum stillbirth, a cohort study at a rural development trust hospital in Bathalapalli, Andhra Pradesh [40]. This cohort study analysed 8,906 births using the data compiled from perinatal mortality meetings (April 2017 to December 2018) and found that 21.0% of facility-based stillbirths were intrapartum (22/105). The study also identified preterm birth and low birthweight (<2,500g) as statistically significant risk factors. However, the findings were limited by the single-centre design and the absence of adjustments for potential confounders, as only univariable analysis was performed.

[1] MEDLINE (OvidSP) [1946-January 6, 2024], EMBASE (OvidSP) [1974-January 6, 2024], and Global Health (OvidSP) [1973–2023 Week 52] were searched from their inception of the databases until 6 January 2024 using MESH terms encompassing "Stillbirth*", "Intrapartum", "Fresh", "Risk Factors", and "India" with Boolean operators.

1.3 Facility-based stillbirth review

The fundamental aim of a stillbirth review is to "support objective, robust and standardised review to provide answers for bereaved parents about why their baby died" [42] and to "ensure local and national learning to improve care and ultimately prevent future deaths" [42]. Stillbirth review at the facility level is especially critical, as it provides opportunities to review the incidence rate, causes and risk factors for stillbirths, as well as identify any issues related to the quality of pregnancy and childbirth care at the hospital. The identified risk factors for stillbirth and issues with quality of care can then be used to inform the implementation of evidence-based interventions for reducing facility-based stillbirth in the future. For example, stillbirth reviews were started in the United Kingdom (UK) as part of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) in 1992, which was an expansion of the already established and long-running Confidential Enquiry into Maternal Deaths (CEMD) [43]. The rationale for the establishment of stillbirth reviews as part of the perinatal mortality reviews in the UK was to identify ways to prevent stillbirths and reduce stillbirth rates in the country.

However, evidence about the effectiveness of stillbirth reviews, specifically whether they improve pregnancy care and reduce stillbirths, is limited. A Cochrane review by Willcox *et al.* [44] found two cluster-randomised trials which assessed death reviews at health facilities – the QUARITE intervention in West Africa [45], which focused on promoting maternity death reviews to address maternal mortality, and the OPERA intervention in France [46], which focused on perinatal mortality and morbidity. The review concluded that the QURITE intervention, which focused on maternal mortality review, "probably made no difference to the number of stillbirths," and for the OPERA intervention, "do not know what the effect was on stillbirths or on the number of mothers or older babies and children who died because the study did not measure this". Willcox *et al.* [44] further emphasised that for death reviews to be effective in reducing mortality, they should be implemented as part of an intervention package that considers the training of healthcare professionals (HCPs), annual updates of the review process, and supervision and mentorship from external facilitators.

While existing literature offers some insights into the effectiveness of mortality reviews, only one study in the systematic review [44] has explored how these reviews function in the context of perinatal mortality. Furthermore, historical systematic reviews focused on the broad topic of death review, often combining maternal and perinatal reviews together, or broad level of review, and inclusion criteria accepted studies that were conducting surveillance only and did not investigate the quality of care [44,47–51]. This gap in the literature necessitated an in-depth systematic review focusing exclusively on stillbirth review processes, as discussed in Chapter 2.

1.3.1 Relevant stillbirth review guidelines for India

Two key guidelines (one national and one international) were identified as relevant stillbirth review guidelines for India. The national guidelines for stillbirth review, operational guidelines for establishing the Sentinel Stillbirth Surveillance System[2] [6], was developed by the WHO Country Office for India for India's Ministry of Health and Family Welfare in June 2016. The international guidelines, Making Every Baby Count: audit and review of stillbirths and neonatal deaths [52], was published by the WHO in the same year.

1.3.1.1 India's operational guidelines

In India, following the INAP aiming to reduce the stillbirth rate to <10 per 1,000 total births by 2030, the National Health Mission of the Ministry of Health and Family Welfare released the operational guidelines for establishing the Sentinel Stillbirth Surveillance System in 2016 [6]. The scope of this guidelines was to provide standard guidance to operationalise sentinel stillbirth surveillance at medical colleges, large district hospitals, and institutions.

[2] Stillbirth review in India

The guidelines defines stillbirth as "fetal death weighing at least 1,000g, or with a gestational age of 28 completed weeks or greater, or a crown-heel length of 35cm or more", and it designates the Head of the Department of Obstetrics and Gynaecology as the focal point (nodal officer) responsible for all surveillance-related activities using this stillbirth definition. The guidelines also states that other job roles, including obstetricians and gynaecologists, paediatricians, resident doctors, medical officers, nurses, and pathologists, should also be involved and trained in the standard operating procedures. As part of the job responsibilities, a designated paediatrician will examine and confirm the stillbirth diagnosis while the pathologist will conduct the post-mortem examinations, according to the guidelines.

For data collection, the guidelines includes a proforma (in Annexure 2) for stillbirth review. It is recommended that this proforma be filled out through standard history taking and examination of both the woman and the baby by obstetricians, resident doctors, or nurses. The proforma incorporates the modified Causes of Death and Associated Conditions (CODAC) classification [53], which the nodal officer should use when assigning the cause of stillbirth after receiving complete documentation of the woman and baby. If the cause remains uncertain, the guidelines advises having discussions with the family to help identify the cause.

When it comes to managing data, the guidelines recommends that a data manager maintains records of all stillbirths and their information in a separate register at the medical college or hospital. It also suggests that data is managed electronically to enable faster reporting. Furthermore, the guidelines explains that surveillance activities within a state will be under the overall guidance of the State Child Health Nodal Officer. It outlines the State Child Health Nodal Officer's responsibilities, including facilitating the establishment of surveillance at sentinel centres, ensuring the team is trained, and ensuring reports are submitted on time. They are also responsible for identifying new sentinel sites, acting as a link between sentinel centres, the National Nodal Centre, and the Ministry of Health and Family Welfare, and ensuring regular reporting of stillbirths under Health Management Information System monthly format Section 4.1.2.

At the national level, there is also oversight by the National Nodal Centre, which provides leadership and technical guidance to ensure uniform, high-quality implementation of sentinel surveillance. As stated in the guidelines, this centre is responsible for conducting staff training at sentinel health facilities and medical colleges, reviewing and analysing reports, mentoring and supporting centres enrolled in the surveillance system, and monitoring the progress and quality of stillbirth surveillance. The National Nodal Centre is also responsible for providing recommendations to the Ministry of Health and Family Welfare for improving implementation and scaling the surveillance system across the country.

Additionally, the guidelines provides advice on how to approach a family to seek consent for stillbirth post-mortem examinations and topics to discuss during this conversation. This includes discussing the value of post-mortem examinations, issues related to retained fetal tissues, the possibility that a cause may not be found, any costs associated, the appearance of the baby following post-mortem examinations, the likely timeframe for results to become available, and arrangements for communicating the findings.

However, the operational guidelines focuses solely on surveillance activities such as defining stillbirths, data collection, and reporting, without providing specific guidance on conducting stillbirth reviews. Therefore, these guidelines should be considered alongside the WHO's Making Every Baby Count guidelines [52], which offers detailed guidance on conducting reviews and emphasise learning from each case to inform actionable solutions rather than merely reporting numbers. Recent recommendations by the Federation of Obstetric and Gynaecological Societies of India (FOGSI) [54], issued in August 2024, also highlight the importance of stillbirth reviews and provide a stillbirth review audit form. FOGSI suggests that such reviews can be used to learn from past stillbirths, improve care systems, and strengthen vital statistics systems to achieve better outcomes.

1.3.1.2 The World Health Organization (WHO)'s Making Every Baby Count

The WHO's Making Every Baby Count: Audit and Review of Stillbirths and Neonatal Deaths [52] was developed to encourage countries to implement perinatal mortality reviews to identify their underlying

causes and prevent future occurrences. The guidelines states that the objectives of the review of stillbirths and neonatal deaths are:

- To understand the burden of stillbirths and neonatal deaths by capturing trends over time for all births and deaths
- To generate information about causes of death and modifiable factors by examining individual deaths in detail and using the information to guide action to prevent similar deaths in the future
- To provide accountability for results and compel decision-makers to give the problem of stillbirths and neonatal deaths due attention and response

For establishing a facility-based stillbirth review, the guidelines advises establishing a review committee that includes diverse representatives linked to existing maternal death surveillance processes and mobilising minimal resources, such as meeting space, stationery or software, and staff training. There are sections on how the committee should decide on an approach for reviews, which may include reviewing a subset of cases, focusing on specific causes, or prioritising preventable deaths. For data collection and select cases to review, the guidelines recommends having at least two designated staff to lead the activities. Box 1-2 describes the key terms defined in the guidelines.

Box 1-2. Key terms in 'Making Every Baby Count' guidelines [52]

- Mortality audit and death review are interchangeable terms for clinical practices focused on reviewing deaths to improve outcomes
- A stillbirth is defined for international comparison as fetal death with weight ≥1,000g, gestation ≥28 weeks, or body length ≥35cm, although ICD-10[3] uses ≥500g, ≥22 weeks, or ≥25cm
- A modifiable factor refers to circumstances that might have prevented a death if different actions were taken, emphasising improvement rather than blame

[3] The ICD-11, released after the guidelines was established, defines stillbirth as the birth of a baby following fetal death at 154 days (22^{+0} completed weeks) or more of gestation. If gestational age information is unavailable, a birth weight of ≥500 g can be used as a proxy to classify a stillbirth.

The guidelines introduces a six-step review cycle:

1. Identifying cases for review: recording all births, stillbirths, and neonatal deaths, ensuring the capture of the minimum set of perinatal indicators, and deciding which deaths (all or a subset) to collect more information for a detailed review
2. Collecting information: empowering designated staff to gather standardised data from patient files promptly after death
3. Analysing information: identifying system problems contributing to deaths, with data analysis focusing on trends in rates, causes of death, geographic location and modifiable factors
4. Recommending solutions: developing specific, measurable, attainable, relevant, and time-bound (commonly called SMART) solutions for identified problems, considering priorities on burden and feasibility, whether the solution will be ongoing or one-off
5. Implementing solutions: taking immediate, medium-term, or long-term actions to prevent stillbirths and neonatal deaths, using successes to advocate for and spur further action
6. Evaluating both process and outcomes and refining as needed: looking back at what worked and what did not in order to ensure that future recommendations are informed by the collected data and lead to action

The guidelines emphasises the importance of ensuring confidentiality and legal protection for review participants while actively engaging HCPs, review programme managers, administrators and community liaisons. It also provides practical tools and forms to support the review process, as listed in Box 1-3 and further supplementary materials were released in 2021 to support implementation [55]. When reporting findings, the guidelines advises keeping reports concise, constructive, and focused on improvement rather than blame, and include data trends, case studies, and follow-up actions.

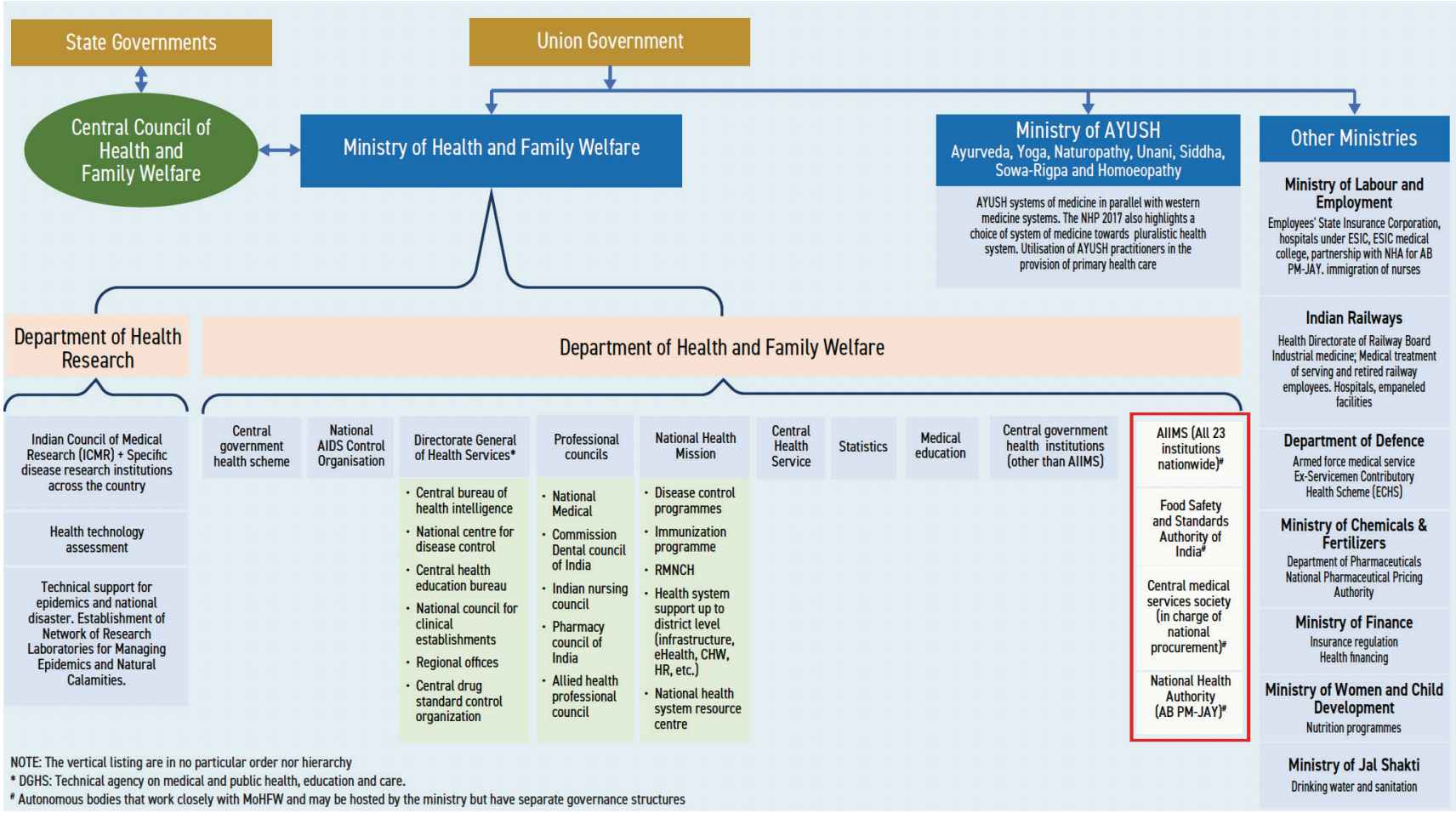
Box 1-3. Tools and forms relevant to facility-based stillbirth review provided in 'Making Every Baby Count' guidelines [52]

- Annex 1: Stillbirth and neonatal death case review form
- Annex 2: Births and deaths summary form
- Annex 3: Minimum set of perinatal indicators to collect for all births and perinatal deaths
- Annex 4: Approaches for classifying modifiable factors
- Annex 5: Setting up a mortality audit steering committee
- Annex 6: Sample audit meeting code of practice declaration
- Annex 7: Sample calculations for reporting
- Annex 8: Stillbirth and neonatal mortality audit – meeting minutes and action items form
- Annex 9: Steps for establishing a mortality audit for stillbirths and neonatal deaths

1.4 Indian health system

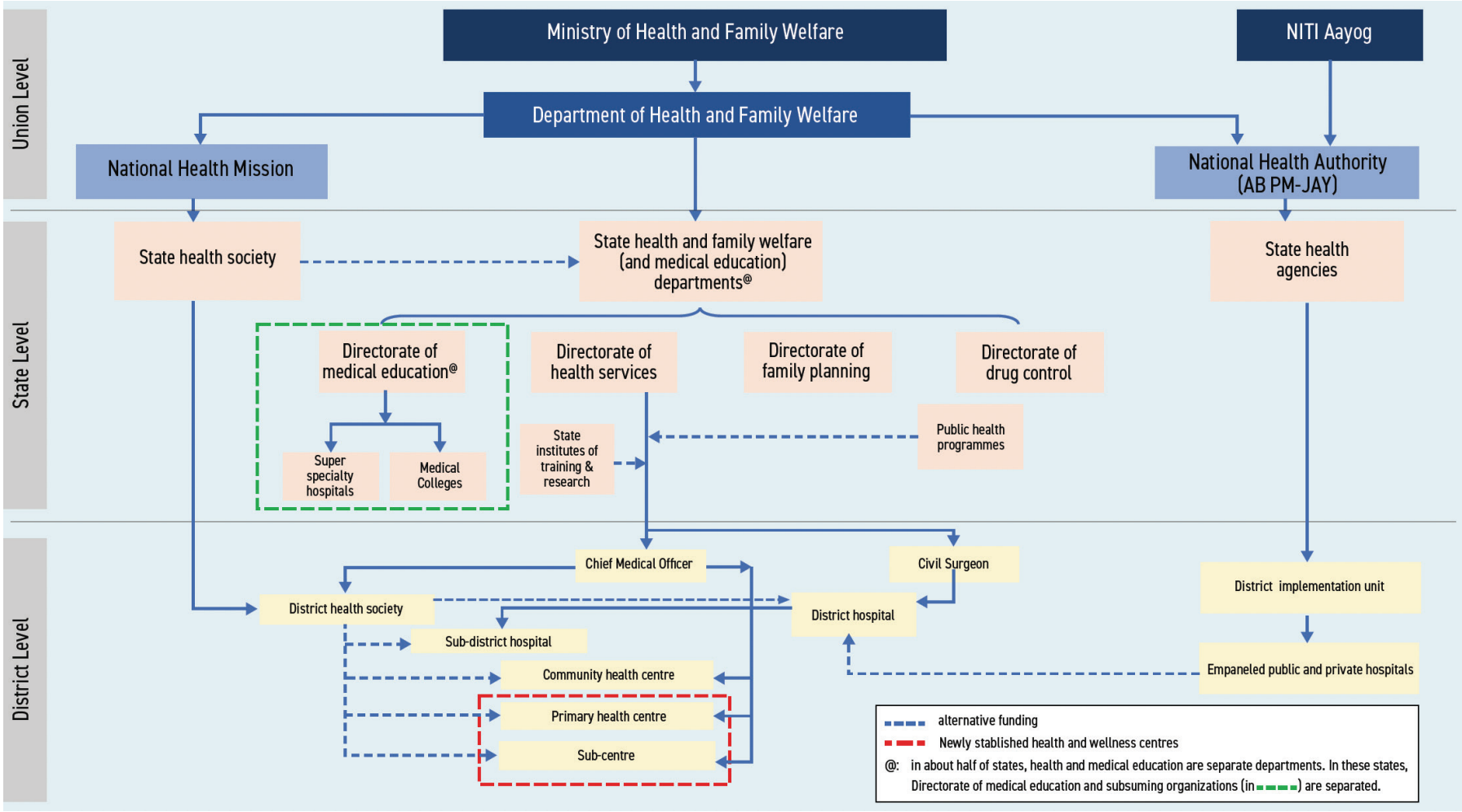
India has a federal structure of governance with national and state jurisdiction over polices (Figure 1-1). Under the Indian Constitution, health is a state responsibility, and each state is required to provide free universal access to health care services [56,57]. The Indian health system operates with each state managing its own health facilities, while the Central Government oversees policymaking, planning, funding, and coordination of national health programmes to ensure equitable health service coverage and consistent performance across states [57,58]. India has a mixed health system, and there are both public and private service providers. The public sector health services follow a three-tier structure. Primary health centres and sub-centres deliver primary care, and secondary care is delivered by community health centres, sub-district (Taluka) hospitals and district hospitals. Medical colleges and super specialty hospitals are tertiary health facilities in India. In addition, private healthcare in India ranges from corporate hospitals to outpatient clinics and mission hospitals that offer secondary or tertiary care at low or no cost [58]. As seen in Figure 1-2, the funding stream for facilities up to the district level is the Chief Medical Officer's responsibility, with the Central Government contributing funds through the National Health Mission. Medical colleges and super specialty hospitals receive funding support directly from the state health departments [58].

Figure 1-1. Health system in India: national level overview [58]



Copyright statement: this diagram is distributed under the terms of the Creative Commons Attribution Non- Commercial Share Alike 3.0 IGO licence (CC BY-NC-SA. 3.0 IGO. https://creativecommons.org/ licenses/by-nc-sa/3.0/igo/) by © World Health Organization 2022 (on behalf of the Asia Pacific Observatory on Health Systems and Policies). This diagram is 'Figure 2.1 Health in India, roles and functions of key players at the national level' in the book written by Selvaraj *et al.* [58].

Figure 1-2. Organisation of the Indian health system: relationship between the national (union), state and district levels [58]



Copyright statement: this diagram is distributed under the terms of the Creative Commons Attribution Non- Commercial Share Alike 3.0 IGO licence (CC BY-NC-SA. 3.0 IGO. https://creativecommons.org/ licenses/by-nc-sa/3.0/igo/) by © World Health Organization 2022 (on behalf of the Asia Pacific Observatory on Health Systems and Policies). This diagram is 'Figure 2.2 Organization of health: relationships between the Union, state and district levels' in the book written by Selvaraj *et al.* [58].

When it comes to stillbirth review, it is the National Health Mission of the Department of Health and Family Welfare that is responsible for such initiative, and they produced the operational guidelines for establishing the Sentinel Stillbirth Surveillance System in India [6]. This initiative is governed and financed jointly by the central and state governments. Given that states are independently responsible for the delivery of healthcare in India, in the study reported here, there were some assumptions made about variations in service delivery models, the types of routine health records collected and reported to higher authorities (state and national levels) for the purpose of stillbirth reporting.

1.5 Logic model

A logic model maps out how an intervention can work, starting from the perspective of the situation and priorities. It summarises what inputs and outputs are required to implement an intervention while enabling consideration of the assumption and external factors. The model also identifies anticipated outcomes and impact, often categorised into short-, medium- and long-term.

Since the logic model template by Taylor-Powell *et al.* [59] is designed for programme development, this template allows researchers to elaborate on how the activity itself becomes an output as well as gives opportunities to observe other secondary outputs that could occur from conducting a stillbirth review (activities). While the training material of this logic model template denotes 'participation' as secondary outputs with a description of "who must be reached for the short-term outcomes to be achieved?", this template was adapted to evidence 'generated learnings' of the stillbirth reviews as the secondary outputs. This adaptation aligns more closely with the development of a stillbirth review process, as generated learnings are an important secondary output for achieving outcomes in this context. Additionally, assumptions and external factors were documented by analysing the facilitators and barriers that influence implementation or sustainability.

1.6 Aims, research questions and objectives

The overarching aim of the research reported in this thesis was to develop an evidence-based, comprehensive model for a facility-based stillbirth review process in six states in India to inform the planning, extension and scale-up of the nationwide Sentinel Stillbirth Surveillance System.

However, due to limited evidence about stillbirth review processes and with no systematic review available on this topic, the first objective was:

Objective 1. To systematically review all types and methods of facility-based stillbirth review processes used in different countries across the world, in both HICs and LMICs

Then, based on the systematic review findings (Objective 1), three research questions linking back to this thesis's overarching aim were identified, and the four objectives (Objectives 2-5) in this mixed methods study were refined. Three research questions were as follows:

- What is the incidence of stillbirth and its associated risk factors within the Indian population, and how does this contribute to understanding the need for implementing a stillbirth review process that is adapted and contextualised for the diverse settings in India?
- What are the key components and methodologies utilised in facility-based stillbirth review processes in India?
- What are the knowledge gaps and perceptions among Indian HCPs regarding facility-based stillbirth review, and what are the facilitators and barriers to its implementation and sustainability?

To explore the first research question, "What is the incidence of stillbirth and its associated risk factors within the Indian population, and how does this contribute to understanding the need for implementing a stillbirth review process that is adapted and contextualised for the diverse settings in India?", following objectives were included for the thesis:

Objective 2. To investigate the incidence of and risk factors for stillbirth in an Indian population

Objective 3. To identify risk factors for intrapartum stillbirth and examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age

For the second and third research questions, "What are the key components and methodologies utilised in facility-based stillbirth review processes in India?" and "What are the knowledge gaps and perceptions among Indian HCPs regarding facility-based stillbirth review, and what are the facilitators and barriers to its implementation and sustainability?", following objectives were included:

Objective 4. To explore and compare the structure and processes of facility-based stillbirth reviews in secondary and tertiary hospitals in India

Objective 5. To identify facilitators and barriers to implementing or sustaining facility-based stillbirth reviews as reported by Indian HCPs

1.7 Organisation of component studies and structure of the thesis

Chapter 1 – Background – provides the background information, including the burden of stillbirth in the world and in India, risk factors for stillbirth, facility-based stillbirth review processes, logic model and the aim, research questions and objectives of the thesis. The final section describes the thesis's structure while summarising the contents of each chapter and how chapters link together.

Chapter 2 – Systematic review of the evidence – presents the systematic review of all types and methods of facility-based stillbirth review processes used in different countries across the world, in both HICs and LMICs. It addresses Objective 1 of the thesis and also bridges the knowledge gap in the literature since there was no evidence of a systematic review that critically appraised and synthesised the methods used for the facility-based stillbirth review process across the world in detail at the time of this review. This systematic review was published in eClinicalMedicine in 2023 [60].

Chapter 3 – Methods – describes why the mixed methods research design was chosen to address the aim and objectives of the thesis, linking back to the research questions generated from the synthesised evidence of the systematic review (Chapter 2). A summary diagram in this chapter shows that this mixed methods study was convergent parallel in design, which means the quantitative and qualitative components of the research were performed independently, and their results were triangulated to address the overarching aim of the thesis. This chapter also introduces the Maternal and Perinatal Health Research Collaboration, India (MaatHRI), a research platform that was the data source (MaatHRI hospital-based cohort) for the quantitative secondary analyses (Chapters 4 and 5) and supported the recruitment of hospitals and focus group discussion (FGD) participants for the primary data collection for the qualitative studies (Chapters 6 and 7). In addition, this chapter introduces and justifies the analytical methods adopted for the quantitative component and the study methods used for the qualitative component.

Chapter 4 – Quantitative results I: incidence and risk factors for stillbirths in India – describes the findings of the exploratory quantitative analysis investigating the incidence of and risk factors for overall stillbirth in singleton pregnancies in 13 hospitals across six states in India. This chapter addresses Objective 2 of the thesis and was published in the International Journal of Gynecology & Obstetrics in 2024 [61]. The findings of this chapter also guided the methods used in Chapter 5 to support addressing Objective 3 of the thesis.

Chapter 5 – Quantitative results II: risk factors for intrapartum stillbirths in India and survival probabilities of fetuses by gestational age – presents the results of further quantitative analysis to identify the risk factors for intrapartum stillbirth in singletons and examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age. This chapter addresses Objective 3 of the thesis.

Chapter 6 – Qualitative results I: exploring current stillbirth review processes in India – addresses Objective 4 of the thesis and describes the facility-based stillbirth review processes in three Indian

hospitals using a multiple case study approach (document analysis, observation and FGDs). The findings highlight both the similarities and differences among the hospitals in various aspects: the types of data collected, stillbirth reporting processes, the guidelines used for stillbirth reviews, and the key document outputs generated from the review. Additionally, it examines the reasons for conducting stillbirth reviews, staff motivation for participation, the organisation and atmosphere of the meetings, how stillbirths are discussed, and the dissemination of the learnings generated. Finally, the chapter explores how hospitals utilise these reviews to improve the quality of data, care, and the overall review process.

Chapter 7 – Qualitative results II: facilitators and barriers to implementing or sustaining facility-based stillbirth reviews in India – presents the facilitators and barriers to implementing or sustaining facility-based stillbirth reviews as reported by Indian HCPs using the capability, opportunity, motivation and behaviour (COM-B) model. It addresses Objective 5 of the thesis and identifies actionable interventions that could improve the implementation or sustainability of stillbirth reviews in India using the Behaviour Change Wheel intervention functions.

Chapter 8 – Discussion – provides an overarching discussion that triangulates the findings from Chapters 2 to 7. Using the evidence synthesised or generated in the previous chapters, the final revised logic model and sets of recommendations were developed to improve a facility-based stillbirth review process, which is adapted and contextualised for the diverse settings in India. Therefore, this chapter addresses the overarching aim of the thesis and provides recommendations for policy, Indian health systems, and future research while reflecting on the strengths and limitations of the overall research.

Chapter 2. Systematic review of the evidence

2.1 Chapter introduction

This chapter presents the systematic review in which all types and methods of facility-based stillbirth review processes used in different countries across the world, in both high-income countries (HICs) and low-and-middle-income countries (LMICs), were reviewed and critically analysed. It addresses Objective 1 of the thesis and also bridges the knowledge gap in the literature since there was no evidence of a systematic review that critically appraised and synthesised the methods used for the facility-based stillbirth review process across the world in detail at the time of this review. This chapter was published in eClinicalMedicine as an article titled 'Facility-based stillbirth review processes used in different countries across the world: a systematic review' [60]. A copy of this article is presented in Appendix A.

2.2 Aim and objectives

The aim of the research presented in this chapter was to systematically review all types and methods of facility-based stillbirth review processes used in different countries across the world, in both HICs and LMICs. The primary objective was to examine how stillbirth reviews in facility settings are being conducted worldwide and to identify the outcomes of implementing the reviews. The secondary objective was to identify facilitators and barriers influencing the implementation of the facility-based stillbirth review processes from the included studies.

2.3 Methods

2.3.1 Protocol and registrations

The protocol for this systematic review was developed and was registered before any stage of the systematic review was completed. The Unique Identification number of PROSPERO is

CRD42022304239 [62]. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was followed to report the findings [63].

2.3.2 Search strategy

The following electronic bibliographic databases were searched: MEDLINE (OvidSP) [1946 to January 11, 2023], EMBASE (OvidSP) [1974 to January 11, 2023], World Health Organization (WHO) Global Index Medicus (globalindexmedicus.net), Global Health (OvidSP) [1973 to 2022 Week 52] and CINAHL (EBSCOHost) [1982 to January 11, 2023]. For unpublished or grey literature, the WHO databases (who.int), Google Scholar (scholar.google.com) and ProQuest Dissertations & Theses Global (proquest.com) were searched, as well as hand-searching the reference lists of included studies. MESH terms encompassing "*Clinical Audit", "*Perinatal Mortality", "Pregnancy Complications", and "Stillbirth" were used with Boolean operators. The search dates were from the inception of the databases to 10 December 2021 and were updated every month to identify any further studies for inclusion. The final search was conducted on 11 January 2023, and the references were imported into Covidence software [64].

The searches employed sensitive, topic-based strategies designed for each database, and used terms related to or describing "stillbirth review" (Appendix B). When developing search terms related to or describing "stillbirth review", Willcox *et al.*'s Cochrane review [44] search terms were used as a guide since this Cochrane review's search terms were relevant to the topic of perinatal mortality review. Once the search terms and strategy were developed by me, they were reviewed by an experienced Life Sciences information librarian and the second reviewer for the Willcox *et al.*'s Cochrane review [44].

The sensitivity and reliability of the search terms were examined by conducting an initial search to observe if the terms captured all of the important studies identified during the preliminary literature review prior to commencing the systematic review. The inclusion and exclusion criteria were applied to

5% of the papers identified during the initial pilot search to ensure that the current strategy was sufficiently robust to classify the studies appropriately.

The screening was conducted as a two-stage process. Firstly, all titles and abstracts were screened based on inclusion and exclusion criteria, followed by a full-text screening. Both stages were carried out independently by three reviewers; I reviewed all the articles, and two other reviewers reviewed 50% each. In both stages, if there was a disagreement, the three reviewers worked to resolve it by consensus, and if it was not resolved after the consensus meeting, a senior supervisor was consulted. Cohen's kappa was used to calculate the level of agreement among reviewers. Any excluded articles during the full-text screening were issued with a valid reason conforming to the inclusion and exclusion criteria, and the results of the searches and reviews were recorded using the PRISMA guidelines [63].

2.3.3 Inclusion and exclusion criteria

The systematic review included studies that used a facility-based review process or a review tool to investigate stillbirths (antepartum or intrapartum) and explained the methods used. This means any stillbirth review process in a facility-based setting, whether as a subgroup of perinatal mortality review or a standalone process to investigate stillbirths, and any other type of review processes such as audit, review or meeting, confidential enquiries or any combination of these were eligible for inclusion. A stillbirth review is more extensive than stillbirth surveillance and investigates the quality of care, attempts to identify avoidable stillbirth (resulting from suboptimal care) or modifiable factors in addition to the identification of a stillbirth, and details of the pregnancy and birth. Therefore, the systematic review excluded studies that reviewed maternal or neonatal deaths only without any inclusion of stillbirths, had no details of the methods used for the stillbirth review process or only reviewed stillbirths that occurred outside a facility setting. Studies that conducted stillbirth surveillance only and did not investigate the quality of care, avoidable stillbirth (resulting from suboptimal care) or modifiable factors were also excluded. There were no language or geographical restrictions, and all types of studies were considered except systematic reviews, case reports and editorials.

2.3.4 Data extraction

A data extraction template was created before beginning the extraction process. The template had four main sections:

1. General information
2. Facility-based stillbirth review process
3. Outputs and outcomes
4. Facilitators and barriers to implementation of the stillbirth review

In the template, specific questions and examples were provided to guide the reviewers in extracting relevant information for each section (Appendix C). Data from the included studies imported directly into Covidence software by me, and two other reviewers independently reviewed this information.

2.3.4.1 Type of review process

When extracting the type of review process of each included study, the label assigned by the study authors was prioritised over the methodological characteristics of their stillbirth review process. For example, if the authors of an included study referred to their review process as an 'audit', it was categorised as an 'audit' even if it exhibited features typical of a 'confidential enquiry'.

Subsequently, the type of review process (label assigned by the study authors) was critically appraised by comparing the described methods of the review process against standard guidance. This standard guidance was informed by an integrative literature review conducted by Helps et al. [65], which outlines the usual characteristics of perinatal audits, local reviews and confidential enquiries:

- Audit: (i) data collection, (ii) case assessment of stillbirth, (iii) implementation of changes based on outputs, and (iv) re-evaluation

- Review: (i) a collaboration between different specialities in obstetrics, midwifery, neonatology and pathology, i.e. a multidisciplinary team, (ii) examine reasons for suboptimal care or avoidable factors, and (iii) dissemination of key findings and learning points to all relevant clinical staff
- Confidential inquiry: all the aspects of a review but is distinguished by cases being identified via 'an anonymous review' process [65] – different from the usual standards of anonymity where reviewers receive case notes with no prior knowledge or links and, therefore, can offer a fresh pair of critical but fair eyes

2.3.5 Quality assessment of individual studies and narrative synthesis

Several tools for risk of bias assessment and different types of frameworks for narrative synthesis were considered and piloted before finalising the most applicable methods to appraise the included studies. It was then decided that the quality assessment of individual studies would be conducted independently by myself and the other two reviewers using an adapted version of the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews: Checklist for Case Series [66] (Appendix D).

The adapted Checklist for Case Series in this systematic review included nine of the ten questions from the original checklist in the quality assessment template, with four response options: Yes, No, Unclear, and Not Applicable. One question – the fifth question in the checklist, "Did the case series have complete inclusion of participants?" – was excluded because, after reviewing the checklist's guidance, it was deemed irrelevant. This exclusion is due to the nature of stillbirth reviews not being similar to case series, as some stillbirth reviews purposely select vulnerable groups that have a higher risk of stillbirths.

Using the existing template developed by Taylor-Powell *et al.* [59], a theoretical logic model was developed *de novo* to present a narrative synthesis of the findings of all studies included in the review in a usable format. In the context of this systematic review, conducting a stillbirth review itself (activities) became an output, while there were also secondary outputs that resulted from conducting a stillbirth review. Therefore, the logic model built for this systematic review had two outputs: activities and

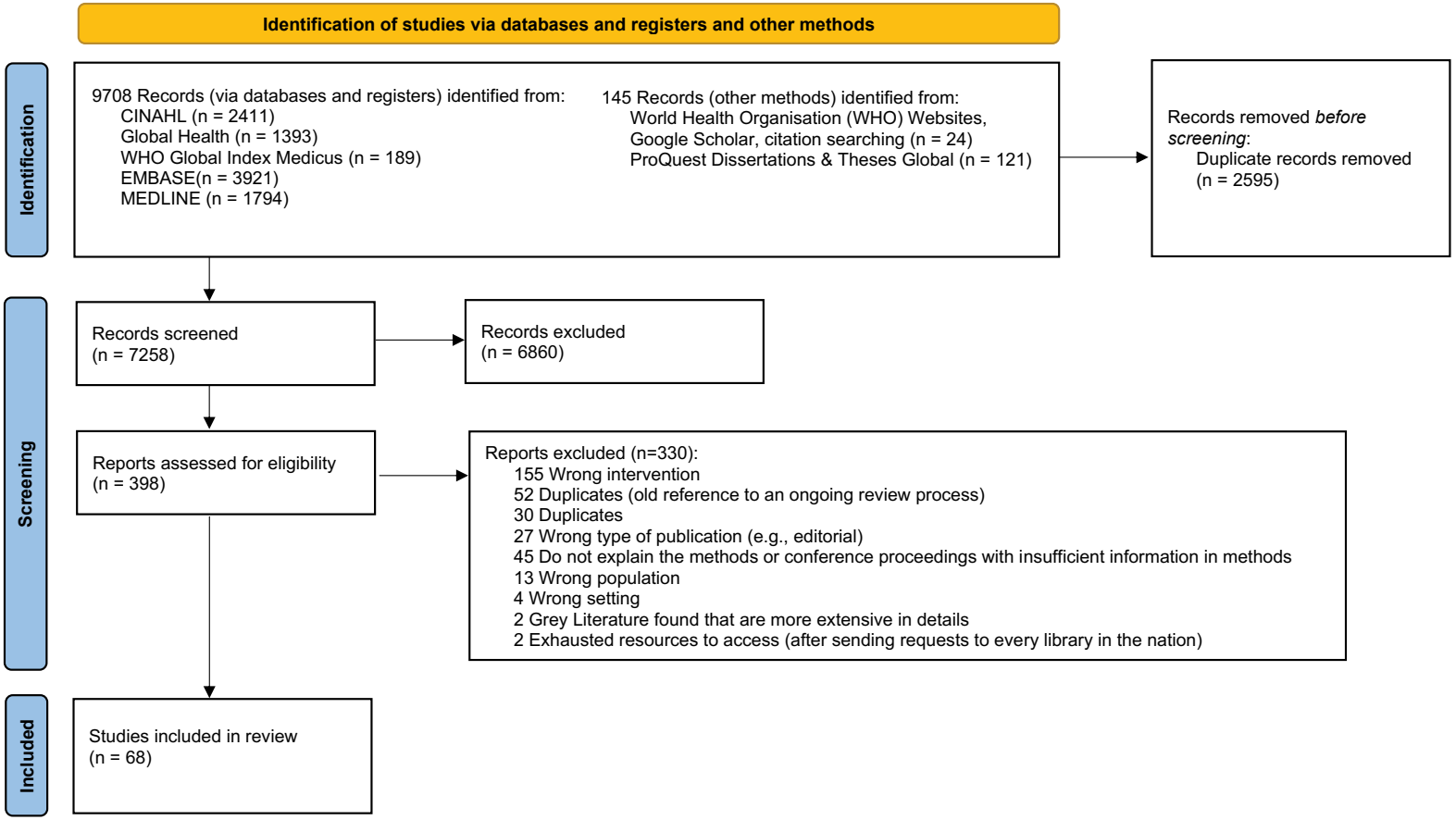
generated learnings. The logic model was finalised when a consensus was reached between co-reviewers and supervisors via multiple iterations following several group discussions.

2.4 Results

2.4.1 Study selection

The study searches identified 9,708 records from databases and registers. One hundred forty-five records were identified additionally via other methods such as grey literature search or hand searching the reference lists of included studies. After removing duplicate records, 7,258 titles and abstracts were eligible for the first stage of screening. After excluding 6,860 records (which did not meet the inclusion criteria), 398 full texts were screened in the second stage. After completing the full-text screening, a total of 68 studies met the inclusion criteria and were finally included in the systematic review (Figure 2-1). If there were studies that used the same methods and reports were produced annually, the most recent report was included. The year of publication listed in the tables may differ from the reference, as it reflects the date the article was first published online rather than when it appeared in print. The inter-rater reliability comparing the percent agreement between reviewers during the title and abstract screening was 0.8 (Cohen's Kappa statistics=0.11), and full-text screening was 0.9 (Cohen's Kappa statistics=0.35).

Figure 2-1. PRISMA flowchart of study selection



PRISMA 2020 flow diagram for new systematic reviews, which included searches of databases, registers and other sources [63]. Copyright statement: this PRISMA 2020 flow diagram is distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

2.4.2 Study characteristics

Table 2-1 summarises the general information of the 68 included studies – (i) country, (ii) its income category as per the World Bank income classification (WBIC), (iii) time period, and (iv) the level at which the facility-based stillbirth reviews were conducted. The table is organised by WBIC category and then alphabetically by country name.

Table 2-1. General information of the included studies

First author, publication year	Country	Level of review	Time period
High-income countries			
Flenady, 2021 [67]	Australia	D	1 Jan 2018-1 Dec 2018
Richardus, 2003 [68]	Belgium; Denmark; Finland; Greece; Netherlands; Norway; Spain; United Kingdom	I	1993-1998
Andersen, 1991 [69]	Denmark	D	1985-1986
Westergaard, 1997 [70]	Denmark; Sweden	I	1991
Sauvegrain, 2020 [71]	France	D	1 Jan-31 Dec 2014
de Caunes, 1990 [72]	Guadeloupe*	N	Nov 1983-Dec 1985
Furst, 1989 [73]	Israel	L	Oct 1987-Feb 1988
D'Aloja, 2021 [74]	Italy	L; D; N	1 Jul 2017-30 Jun 2019
Alderliesten, 2008 [75]	Netherlands	D	1999
Dekker, 2003 [76]	Netherlands	L	1986-1995
Eskes, 1993 [77]	Netherlands	L	1969-1983
van Diem, 2010 [78]	Netherlands	O^	Nov 2004-May 2005
van Diem, 2012 [79]	Netherlands	D	Sep 2007-Mar 2010
Wolleswinkel-van den Bosch, 2002 [80]	Netherlands	D	1996-1997
Eskes, 2014 [81]	Netherlands	N	2010-ongoing‡
PMMRC, 2021 [82]	New Zealand	N	2007-ongoing‡
Berge, 1991 [83]	Norway	L	1976-89
Bjellmo, 2019 [84]	Norway	N	1999-2015
Fossen, 1999 [85]	Norway	D	1989-1997
Han, 2018 [86]	Singapore	L	Jan 2004-Dec 2008
De la Puente, 2002 [87]	Spain	L	1997-1998
Miranda, 1996 [88]	Spain	L	1979-1992
Eksmyr, 1986 [89]	Sweden	D	1973-1978
Essén, 2002 [90]	Sweden	N	1990-1996
Sterpu, 2020 [91]	Sweden	D	2017
Chepkin, 2019 [42]	United Kingdom	L	Feb 2018-ongoing‡
Cross-Sudworth, 2015 [92]	United Kingdom	L	2008
Draper, 2017 [93]	United Kingdom	N	Nov 2016-May 2017
Hundley, 2001 [94]	United Kingdom	D	Not stated (re-review of the review that was conducted during the

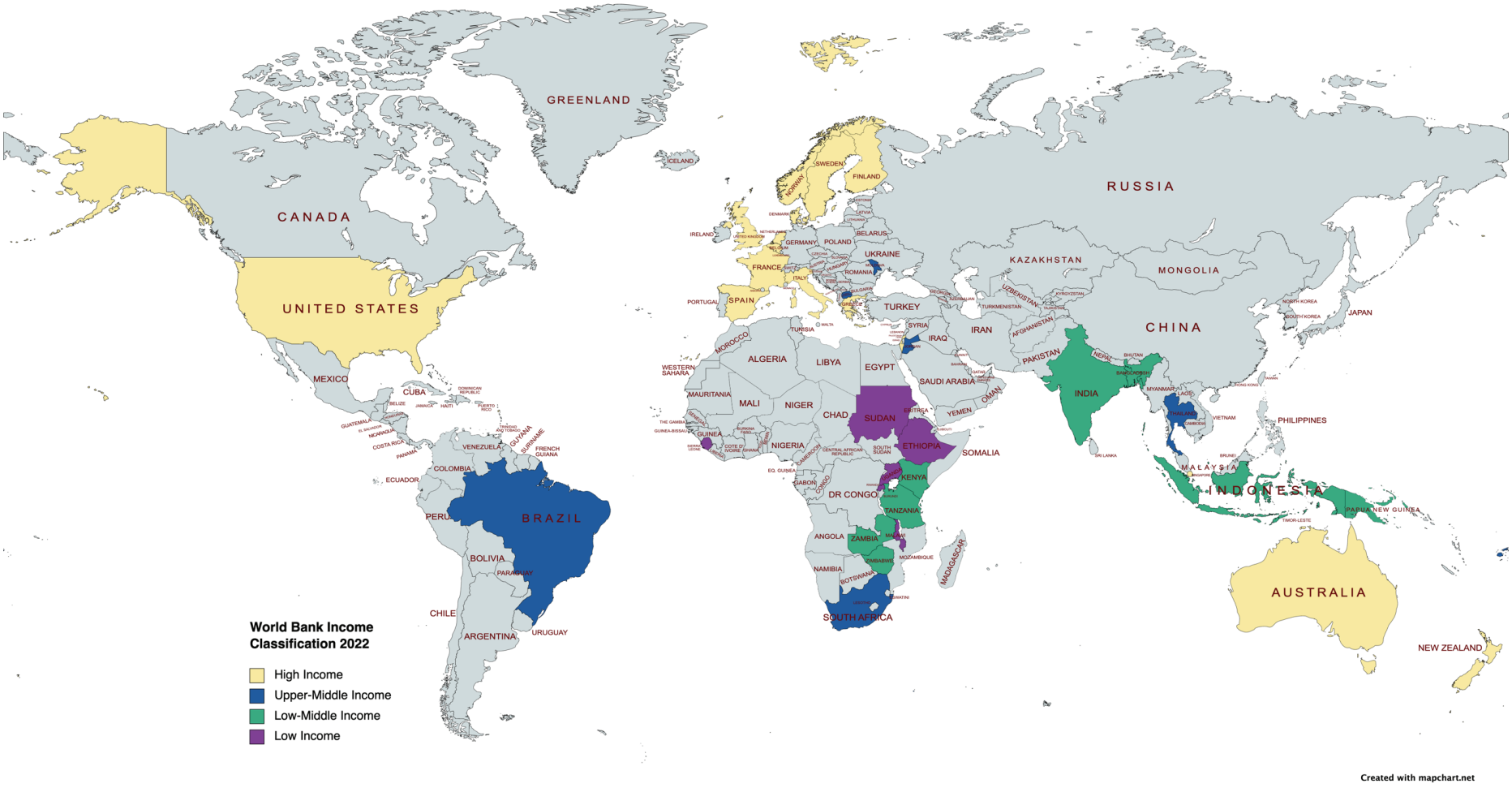
First author, publication year	Country	Level of review	Time period
			Aberdeen Trial in 1992-1993)
Maternal and Child Health Research Consortium, 1999 [95]	United Kingdom	N	The Confidential Enquiry into Stillbirth and Deaths in Infancy (CESDI) from 1993-2002; the Confidential Enquiries into Maternal and Child Health (CEMACH) from 2003-2008; Centre for Maternal and Child Enquiries (CMACE) from 2009-2011
Mersey Region Working Party on Perinatal Mortality, 1982 [96]	United Kingdom	D	1979
Tan, 1999 [97]	United Kingdom	D	1991
Tang, 2011 [98]	United Kingdom	L	2004-2009
Bausch, 1996 [99]	United States	D	1992
Harper, 1977 [100]	United States	D	1973
Kieltyka, 2012 [101]	United States	D	2001-unknown§
Moawad, 1990 [102]	United States	D	1983-1987
The National Center for Fatality Review and Prevention, 2021 [103]	United States	N	Late 1980s-ongoing‡
Vallejo, 1991 [104]	United States	D	1988
Upper-middle income countries			
Amaral, 2011 [105]	Brazil	D	Oct-Dec 2005
Raman, 2015 [106]	Fiji	L	2011-12
Alyahya, 2021 [107]	Jordan	L	1 Aug 2019-1 Feb 2020
Stratulat, 2014 [108]	Moldova	N	2006-2010
Copenhagen: WHO Regional Office for Europe, 2020 [109]	North Macedonia	N	2019
Govender, 2017 [110]	South Africa	L	1 Apr 2014-31 Mar 2015
Pattinson, 1995 [111]	South Africa	D	Aug 1991-Jul 1992
Rhoda, 2014 [112]	South Africa	N	From the early 1990s, but was not a truly national programme until 2012.
Ward, 1995 [113]	South Africa	L	1 Jan 1991-31 Dec 1992
Wilkinson, 1997 [114]	South Africa	D	May 1991-Dec 1995
Mo-suwan, 2009 [115]	Thailand	D	15 Oct 2000-19 Mar 2002
Low-income and low-middle-income countries			
Demise, 2015 [116]	Ethiopia	L	Jun-Nov 2012
Musafili, 2017 [117]	Rwanda	L	Jul 2012-May 2013
El Amin, 2002 [118]	Sudan	L	May-Aug 2000
Kirabira, 2020 [119]	Uganda	L	2008-unknown§
Biswas, 2015 [120]	Bangladesh	D	2010-2011
Bhatt, 1989 [121]	India	L	1965-unknown§
Sharma, 2022 [122]	India	L	Dec 2018-Nov 2019
Supratikto, 2002 [123]	Indonesia	D	1994-unknown§
Bandali, 2019 [124]	Kenya	O+	2014-unknown§
Omwodo, 2020 [125]	Kenya	L	1 May 2017-31 Aug 2018
Aminu, 2017 [126]	Kenya; Malawi; Sierra Leone; Zimbabwe	L	Jan-Sep 2015

First author, publication year	Country	Level of review	Time period
Vallely, 2020 [127]	Papua New Guinea	D	Jul 2017-Jan 2020
Hinderaker, 2003 [128]	Tanzania	D	Not stated
Maaløe, 2016 [129]	Tanzania	L	1 Oct 2014-31 Jan 2015
Mbaruku, 2009 [130]	Tanzania	L	Jul 2002-Jul 2004
Mdoe, 2022 [131]	Tanzania	L	Jan 2019-May 2020
Wilkins, 2015 [132]	Timor-Leste	L	Nov 2009-Dec 2010
Kasengele, 2017 [133]	Zambia	L	2012-2014

L: local or hospital(s), D: district or state, N: national, I: international, O: other
* Guadeloupe was included as a high-income country as it is a French overseas region.
O+ Implemented nationally. However, this paper focuses on Bungoma country as it is the only country in Kenya that has reviewed more than 50% of perinatal deaths in 2017.
O^ Included three regions, therefore, between D and N levels.
‡ The review process was ongoing at the time of data extraction.
§ It is unknown whether the review process has continued.

The 68 studies were from 39 countries (Figure 2-2). When categorising the countries using the WBIC 2022, 39 studies were from 17 HICs, and 29 were from 22 LMICs [134]. There was variation among the studies in the level of review or time period, regardless of the WBIC category.

Figure 2-2. The geographical distribution of countries of the included studies using the World Bank income classification 2022



This map was created for free at MapChart.net. This work is licensed under a Creative Commons Attribution-ShareAlike 4.0 International License.

The level of review was categorised based on the place or the region where the review was conducted. The review process may have involved national guidelines or tools, but if the review described in the study was conducted at a regional level, it was considered a regional-level review. However, if the study conducted its review in different facilities or regions in more than one country, the study was considered an international review.

Twenty-seven studies were stillbirth reviews conducted at a local[4] or hospital level [42,73,76,77,83,86–88,92,98,106,107,110,113,116–119,121,122,125,126,129–133], 25 were conducted at a district or state level [67,69,71,75,79,80,85,89,91,94,96,97,99–102,104,105,111,114,115,120,123,127,128], 11 were conducted at a national level [72,81,82,84,90,93,95,103,108,109,112], and two were conducted at an international level [68,70]. Three studies could not be categorised [74,78,124]. One study, while it was conducted at a national level, focused on a county called Bungoma since it was the only county in the country (Kenya) that had reviewed more than 50% of stillbirths in 2017, whereas other counties had a very low review rate [124]. Another study was conducted at all three levels (district, state, and national), as their process was a three-tiered system [74]. Lastly, one study was a feasibility study to understand if the audit could be performed at a national level and involved three regions in a country [78].

2.4.3 Types

There were three types of review process (label assigned by the study authors of included studies) – audit, review, and confidential enquiry. Although some studies may have used the words 'audit' and 'review' interchangeably, they have not explicitly stated that they used the term interchangeably in their studies. Table 2-2 presents the comparison of the types of review (label assigned by the study authors) against the salient features of the audit, review, and confidential enquiry described by Helps *et al.* [65].

[4] Not in the entire district

Table 2-2. Count and percentage of studies that had the component of salient features of audit, review, and confidential enquiry by types of review process (label assigned by the study authors of included studies)

Salient features of the audit, review, and confidential enquiry as described by Helps *et al.* [65]	Types of stillbirth review process (label assigned by the study authors of included studies)		
	Audit (N=41)	**Review (N=28)**	**Confidential enquiry (N=14)**
Audit component 1: Data collection	39 (95%)	28 (100%)	14 (100%)
Audit component 2: Case assessment of stillbirth	33 (81%)	24 (86%)	13 (93%)
Audit component 3: Implementation of changes based on outputs	12 (29%)	9 (32%)	3 (21%)
Audit component 4: Re-evaluation (i.e., a continuous cycle)	11 (27%)	10 (36%)	3 (21%)
Review component 1: A collaboration between different specialities in obstetrics, midwifery, and pathology (i.e., the multidisciplinary team)	23 (56%)	21 (75%)	13 (93%)
Review component 2: Examine reasons (what, when, who) for suboptimal care or avoidable factors	33 (81%)	22 (79%)	12 (86%)
Review component 3: Dissemination of key findings and learning points to all relevant clinical staff	13 (32%)	11 (39%)	5 (36%)
Confidential enquiry: Anonymous, in addition to the above three components of a review process	5 (12%)	12 (43%)	11 (79%)

Out of 41 studies that labelled their review process as an 'audit', 95% of the studies included the component of data collection, while re-evaluation (i.e., a continuous cycle) was only presented in 27% of the studies. Many, however, also had components of a review and confidential enquiry (Table 2-2 and Table 2-3). Twenty-eight studies that labelled their review process as a 'review' or 'confidential enquiry' also showed similar patterns; not all studies contained the salient features of the review or confidential enquiry.

Table 2-3. Components of stillbirth review identified in the methods

First author and year	A 1	A 2	A 3	A 4	R 1	R 2	R 3	C
Reported type: Audit								
Alderliesten, 2008 [75]	✓	✓	X	X	✓	✓	✓	✓
Alyahya, 2021 [107]	✓	✓	✓	✓	✓	✓	✓	X
Aminu, 2017 [126]	✓	✓	✓	X	✓	✓	X	✓
Berge, 1991 [83]	✓	✓	X	X	X	X	X	X
Bhatt, 1989 [121]	✓	X	X	X	X	✓	✓	X
Bjellmo, 2019 [84]	✓	✓	X	X	X	X	X	X
Copenhagen: WHO Regional Office for Europe, 2020 [109]	✓	✓	X	X	✓	✓	X	X
de Caunes, 1990 [72]	✓	✓	X	X	X	X	✓	X
Demise, 2015 [116]	✓	✓	✓	✓	✓	✓	✓	X

First author and year	A 1	A 2	A 3	A 4	R 1	R 2	R 3	C
Eksmyr, 1986 [89]	✓	X	X	X	✓	✓	X	X
El Amin, 2002 [118]	✓	✓	X	X	✓	✓	X	X
Eskes, 1993 [77]	X	✓	X	X	✓	✓	X	X
Eskes, 2014 [81]	✓	✓	✓	✓	✓	✓	✓	X
Essén, 2002 [90]	✓	✓	X	X	X	✓	X	X
Flenady, 2021 [67]	✓	✓	✓	✓	✓	✓	✓	X
Fossen, 1999 [85]	✓	X	X	X	X	✓	✓	X
Furst, 1989 [73]	✓	✓	X	X	X	✓	X	X
Govender, 2017[110]	✓	X	✓	X	X	✓	X	X
Han, 2018 [86]	✓	✓	X	X	X	✓	X	✓
Kasengele, 2017 [133]	✓	✓	✓	✓	X	X	✓	X
Kirabira, 2020 [119]	✓	✓	✓	✓	✓	✓	✓	X
Maaløe, 2016 [129]	✓	✓	X	X	X	X	X	X
Mbaruku, 2009 [130]	✓	✓	X	X	✓	✓	X	X
Mdoe, 2022 [131]	✓	✓	✓	✓	✓	✓	✓	X
Miranda, 1996 [88]	✓	X	X	X	✓	✓	X	X
Moawad, 1990 [102]	✓	✓	X	X	✓	✓	X	X
Musafili, 2017 [117]	✓	✓	X	X	✓	✓	X	X
Omwodo, 2020 [125]	✓	✓	X	X	✓	X	X	X
Pattinson, 1995 [111]	X	✓	✓	X	X	✓	X	X
Raman, 2015 [106]	✓	X	X	✓	X	✓	X	X
Sauvegrain, 2020 [71]	✓	✓	X	X	X	✓	X	X
Sterpu, 2020 [91]	✓	✓	X	X	✓	✓	X	X
Supratikto, 2002 [123]	✓	✓	✓	✓	✓	✓	X	X
Vallely, 2020 [127]	✓	X	X	X	X	✓	X	X
van Diem, 2010 [78]	✓	✓	X	X	✓	X	X	X
van Diem, 2012 [79]	✓	X	✓	X	✓	✓	✓	X
Ward, 1995 [113]	✓	✓	X	✓	X	✓	X	X
Westergaard, 1997 [70]	✓	✓	X	X	X	✓	X	✓
Wilkinson, 1997 [114]	✓	✓	X	X	X	X	X	X
Wolleswinkel-van den Bosch, 2002 [80]	✓	✓	X	X	✓	✓	X	X
D'Aloja, 2021* [74]	✓	✓	X	✓	✓	✓	✓	✓
Reported type: Review								
Bandali, 2019 [124]	✓	✓	✓	✓	✓	✓	✓	X
Bausch, 1996 [99]	✓	X	X	X	X	X	X	X
Biswas, 2015 [120]	✓	✓	✓	✓	✓	✓	X	X
Chepkin, 2019 [42]	✓	✓	✓	✓	✓	✓	✓	X
Harper, 1977 [100]	✓	✓	X	X	✓	✓	X	X
Hinderaker, 2003 [128]	✓	✓	X	X	X	✓	X	X
Hundley, 2001 [94]	✓	X	X	X	X	✓	X	X
Kieltyka, 2012 [101]	✓	X	✓	✓	✓	X	X	✓
Mo-suwan, 2009 [115]	✓	✓	X	X	X	X	X	X
PMMRC, 2021 [82]	✓	✓	✓	✓	✓	✓	✓	X
Rhoda, 2014 [112]	✓	✓	X	✓	✓	X	✓	X

First author and year	A 1	A 2	A 3	A 4	R 1	R 2	R 3	C
Sharma, 2022 [122]	✓	✓	X	X	X	✓	✓	X
The National Center for Fatality Review and Prevention, 2021 [103]	✓	✓	✓	✓	✓	✓	✓	X
Wilkins, 2015 [132]	✓	✓	X	X	X	✓	X	X
Reported type: Confidential inquiry								
Amaral, 2011 [105]	✓	✓	✓	✓	✓	✓	X	✓
Andersen, 1991 [69]	✓	✓	X	X	✓	✓	X	✓
Cross-Sudworth, 2015 [92]	✓	✓	X	X	✓	✓	✓	✓
De la Puente, 2002 [87]	✓	✓	✓	X	✓	✓	X	X
Dekker, 2003 [76]	✓	✓	X	X	✓	X	X	X
Draper, 2017 [93]	✓	✓	X	X	✓	✓	✓	✓
Maternal and Child Health Research Consortium, 1999 [95]	✓	✓	✓	✓	✓	✓	✓	✓
Mersey Region Working Party on Perinatal Mortality, 1982 [96]	✓	✓	X	X	✓	✓	X	✓
Richardus, 2003 [68]	✓	✓	X	X	✓	✓	X	✓
Stratulat, 2014 [108]	✓	X	X	X	✓	X	✓	X
Tan, 1999 [97]	✓	✓	X	X	✓	✓	X	✓
Tang, 2011 [98]	✓	✓	X	X	✓	✓	X	✓
Vallejo, 1991 [104]	✓	✓	X	X	X	✓	X	✓
D'Aloja, 2021* [74]	✓	✓	X	✓	✓	✓	✓	✓

A1: Data collection, A2: Case assessment of stillbirth, A3: Implementation of changes based on outputs, A4: Re-evaluation (i.e. a continuous cycle), R1: A collaboration between different specialities in obstetrics, midwifery, and pathology (i.e. the multidisciplinary team), R2: Examine reasons for suboptimal care or avoidable factors, R3: Dissemination of key findings and learning points to all relevant clinical staff, C: Anonymous review

* D'Aloja, 2021 was described as both an audit and confidential inquiry by the authors.

2.4.4 Aims and funding

The included studies had one or more of the following aims for conducting a stillbirth review:

- To prevent stillbirth, to improve all aspects of care by making adequate and informed recommendations guided by clear local, national or international criteria or practices [42,72,74,82,93,96,100,103,108,109,112–114,121,122,126,131,133]
- To analyse causes of stillbirth or any suboptimal care during the pregnancy [42,67,68,72,73,76–81,83,85–89,93–100,102,104,107,110,111,115,116,118,123–132]
- To evaluate the current review process or tool implemented and what the facilitators and barriers were [75,89,91,101,105,106,110,119,120]

- To compare if there were differences in stillbirth rate between groups of pregnant women that occurred due to systematic differences in the quality of care [69–71,84,90,92]

Types of funding used for conducting stillbirth reviews are described in Box 2-1.

Box 2-1. Types of funding to commission stillbirth review

- For 29 out of 68 studies (43%), the following funders were solely responsible for commissioning the review process:
  - Government agencies (15 studies [42,71,74,75,81,82,87,89,91–93,95,96,130,133])
  - Non-governmental organisations (9 studies [76,77,79,80,108,119,124,126,131])
  - Universities or professional associations (2 studies [83,104])
  - Research grants (3 studies [67,68,127])
- Fifteen studies [69,72,84,90,100,103,105,107,115,117,118,120,123,128,129] out of 68 received funding from two or more organisations (22%)
- Twenty-four out of the 68 studies (35%) received no funding or did not list any funding information for the stillbirth review process [70,73,78,85,86,88,94,97–99,101,102,106,109–114,116,121,122,125,132]

2.4.5 Source of data

Routine data was used as at least one of the data sources to identify eligible stillbirths for review in 44 out of 68 included studies (65%) [67–69,73,76,79–91,95,99–105,107,109,112,114,116,118–122,124,126,127,129–133]. Routine data included birth or death registries, hospital records, social care organisations' records, and obstetric records. Four studies (6%) used interviews with care providers as a supplementary source of data, in addition to routine records, to identify stillbirths for review [79,87,120,130].

Sixteen studies (24%) implemented a specific data identification system to build a stillbirth database only for the purposes of the review or to enable the review to be started [42,71,72,74,75,81,82,93–96,110,115,123,124,128]. For example, they requested care providers to fill in a form within a reasonable time after the stillbirth in the facility and report through an online surveillance system or via phone call and fax to notify the review team to enable a review to be started [42,74,75,95,96,123,124].

Some studies used an existing specific database that was not built for the purpose of the stillbirth review only but to support research on how to reduce stillbirth. For example, a study utilised a prospective cohort of antenatal attendees' data to identify stillbirth within the cohort for review [115]. Twelve studies (18%) did not state the data sources they used [77,111,97,70,97,106,117,92,125,108,113,78]. Appendix E explains the detailed lists of sources of data used for each study.

2.4.6 Definition (case assessment of stillbirth)

There is no universally accepted definition of stillbirth, and the definition tends to vary between countries and within countries [4]. This was an issue also observed in the included studies. Out of the 68 studies, 21 did not list any definition of stillbirth used for case assessment, 29 studies used only one criterion (either gestational age or birthweight) to define stillbirths for case assessment, and three studies used three criteria (gestational age, birthweight, and crown-heel length) (Table 2-4).

Table 2-4. Definition (case assessment of stillbirth) used in the included studies

First author and year	Country[$]	Age of gestation (weeks)	Birthweight (g)	Crown-heel Length (cm)
High-income countries				
Flenady, 2021 [67]	Australia	≥34[+]	-	-
Richardus, 2003 [68]	Belgium; Denmark; Finland; Greece; Netherlands; Norway; Spain; United Kingdom	≥28	-	-
Andersen, 1991 [69]	Denmark	≥28	-	-
Westergaard, 1997 [70]	Denmark; Sweden	>28[*]	-	-
Sauvegrain, 2020 [71]	France	≥22	-	-
de Caunes, 1990 [72]	Guadeloupe	≥22	-	-
Furst, 1989 [73]	Israel	-	-	-
D'Aloja, 2021 [74]	Italy	≥28	-	-
Alderliesten, 2008 [75]	Netherlands	-	-	-
Dekker, 2003 [76]	Netherlands	>24	≥500	-
Eskes, 1993 [77]	Netherlands	-	>500	-
van Diem, 2010 [78]	Netherlands	-	-	-

First author and year	Country[$]	Age of gestation (weeks)	Birthweight (g)	Crown-heel Length (cm)
van Diem, 2012 [79]	Netherlands	>22	>500	≥25
Wolleswinkel-van den Bosch, 2002 [80]	Netherlands	≥24	-	-
Eskes, 2014 [81]	Netherlands	≥37[+]	-	-
PMMRC, 2021 [82]	New Zealand	≥20	≥400	
Berge, 1991 [83]	Norway	≥24	-	-
Bjellmo, 2019 [84]	Norway	-	-	-
Fossen, 1999 [85]	Norway	≥22	-	-
Han, 2018 [86]	Singapore	≥28	≥500	-
De la Puente, 2002 [87]	Spain	≥22	>500	-
Miranda, 1996 [88]	Spain	-	≥1,000	-
Eksmyr, 1986 [89]	Sweden	-	-	-
Essén, 2002 [90]	Sweden	-	-	-
Sterpu, 2020 [91]	Sweden	≥22+0	-	-
Chepkin, 2019 [42]	United Kingdom	≥22+0	>500	-
Cross-Sudworth, 2015 [92]	United Kingdom	≥24	-	-
Draper, 2017 [93]	United Kingdom	≥37[*‡]	-	-
Hundley, 2001 [94]	United Kingdom	-	-	-
Maternal and Child Health Research Consortium, 1999 [95]	United Kingdom	>24	-	-
Mersey Region Working Party on Perinatal Mortality, 1982 [96]	United Kingdom	-	-	-
Tan, 1999 [97]	United Kingdom	-	≥2,500[&]	
Tang, 2011 [98]	United Kingdom	-	-	-
Bausch, 1996 [99]	United States	-	-	-
Harper, 1977 [100]	United States	-	-	-
Kieltyka, 2012 [101]	United States	≥24	-	-
Moawad, 1990 [102]	United States	-	≥501	-
The National Center for Fatality Review and Prevention, 2021 [103]	United States	-	-	-
Vallejo, 1991 [104]	United States	≥20	≥500	-
Low-and-middle-income countries				
Biswas, 2015 [120]	Bangladesh	-	-	-
Amaral, 2011 [105]	Brazil	-	≥500	-
Demise, 2015 [116]	Ethiopia	≥28	≥1,000	-
Raman, 2015 [106]	Fiji	-	-	-
Bhatt, 1989 [121]	India	-	-	-
Sharma, 2022 [122]	India	≥28	≥1,000	-
Supratikto, 2002 [123]	Indonesia	-	-	-
Alyahya, 2021 [107]	Jordan	≥24	-	-

First author and year	Country[$]	Age of gestation (weeks)	Birthweight (g)	Crown-heel Length (cm)
Bandali, 2019 [124]	Kenya	-	-	-
Omwodo, 2020 [125]	Kenya	≥22	≥500	-
Aminu, 2017 [126]	Kenya; Malawi; Sierra Leone; Zimbabwe	≥28	≥1,000	≥35
Stratulat, 2014 [108]	Moldova	>37[§]	≥2,500[§]	-
Copenhagen: WHO Regional Office for Europe, 2020 [109]	North Macedonia	≥22	≥500	-
Vallely, 2020 [127]	Papua New Guinea	-	-	-
Musafili, 2017 [117]	Rwanda	≥22	≥500	-
Govender, 2017 [110]	South Africa	-	≥500	-
Pattinson, 1995 [111]	South Africa	-	>1,000	-
Rhoda, 2014 [112]	South Africa	-	-	-
Ward, 1995 [113]	South Africa	>28	≥1,000	-
Wilkinson, 1997 [114]	South Africa	-	-	-
El Amin, 2002 [118]	Sudan	-	≥500	-
Hinderaker, 2003 [128]	Tanzania	≥28	-	-
Maaløe, 2016 [129]	Tanzania	-	≥1,000	-
Mbaruku, 2009 [130]	Tanzania	-	≥2,000[*]	-
Mdoe, 2022 [131]	Tanzania	≥28	-	-
Mo-suwan, 2009 [115]	Thailand	≥28-40	-	-
Wilkins, 2015 [132]	Timor-Leste	≥22	≥500	-
Kirabira, 2020 [119]	Uganda	≥28	≥1,000	≥35
Kasengele, 2017 [133]	Zambia	-	-	-

[*] Intrapartum stillbirth only
[‡] Singleton at term only
[§] Stillbirths at term without intrauterine growth restriction only
[+] Late gestational stillbirth only
[&] Stillbirth most likely to be influenced by obstetric care and management

Sometimes, case assessment was limited to particular interests as the review may focus on one aspect of stillbirth; for example, two studies [70,130] focused solely on intrapartum stillbirth, two studies [67,81] on late gestational stillbirth, and one study [97] included only stillbirths with a birthweight above 2,500g considering these as most likely to be "influenced by obstetric care and management". Draper *et al.* [93] focused on term, singleton, and intrapartum stillbirths, and Stratulat *et al.* [108] focused on term stillbirths without intrauterine growth restriction, using a birthweight of 2,500g as a proxy.

Excluding seven studies that focused on a particular type of stillbirth, the minimum gestational age reported ranged from 20 to 28 weeks, the minimum birthweight ranged from 400g to 1,000g, and the

minimum crown-heel length ranged from 25cm to 35cm. When stratified by a country's income classification, studies conducted in LMICs had narrower ranges for the lower limits: a gestational age of 22 to 28 weeks, a birthweight of 500g to 1,000g, and a crown-heel length of 35cm. Compared to studies conducted in HICs, those in LMICs reported higher minimum thresholds, with gestational age higher by two weeks, birthweight higher by 100g, and crown-heel length higher by 10cm.

In addition, six studies [70,74,93,95,125,133] used additional definitions to classify antepartum and intrapartum stillbirths; all six studies used the 'onset of labour' or 'onset of care in labour' as a criterion to differentiate the two types of stillbirths.

2.4.7 Data collection

Abstracting or directly reviewing data from already available data (e.g. hospital notes, social care data, death registry, theatre records) was the most common method of gathering data to facilitate a stillbirth review. This means there was no interview with staff or parents, and no further information was sought other than utilising the routine data. A total of 36 out of 68 studies (53%) used this method [95,93,109,104,94,133,127,102,69,113,70,88,87,76,112,129,86,100,89,99,85,80,90,118,75,78,105,79,101,132,110,124,84,91,131,81]. Twenty-six studies (38%) [42,67,68,71–74,82,92,96,98,103,106,107,114–117,119–123,126,128,130], on the other hand, collected additional data for the purpose of the review; for example, by conducting interviews with women, healthcare providers, and family members, by requesting contextual background information about the facilities and women, and by carrying out additional tests (e.g. macroscopically examining placenta and cords) that would otherwise not be done. Six studies (9%) did not state how they collected data to facilitate the stillbirth review process [77,83,97,108,111,125]. Appendix E provides a detailed review of data collection methods used for each study.

2.4.8 Notable components

In addition to the components listed in Table 2-2, there were other notable components of stillbirth review that were observed in some of the included studies (Box 2-2).

Box 2-2. Notable components of stillbirth review observed in the included studies

- Reviewers being trained in the review process [112,119,132]
- Data needed for the review being delivered to the reviewers prior to the review process to help with their preparation [69,75,93,109,118]
- Structured forms or checklists to fill in during the review [42,74,75,81,94,106–110,123–126,129,131]
    - **VERSUS** discussion-oriented process [121]
- No review meetings (chart review only) [79,83,86,98,103,106,126,131]
    - **VERSUS** two-stage review process
- Individual judgement (case review), then a collective judgement after a panel discussion to reach a consensus [68,75,76,84,91,104,108,112,118,128,132]
    - **VERSUS** review meetings only [72,81]
- Cause of death recorded using well-known classifications or selected contributory factors from a framework [71–76,78,81,82,95,96,100,102,104,110,111,113,115–117,119,122,125]
- Grading of suboptimal care using an established grading system (e.g. the Confidential Enquiry into Stillbirth and Deaths in Infancy (CESDI) grading) [42,67,75,76,79,81,87,92,93,104,106,108,110,117,118,122,123,126,128,132,133]
- External reviews being conducted for quality assurance [72,75,84,103,118]
- Creating action plans and follow-up plans [42,72–74,81,91,94,97,102,105,107,118,120,124,131,133]
- Assessing if the death was avoidable, if there was suboptimal care, usually using a grading system or criteria [42,69,70,72,74,77–79,82–84,86–90,92,93,95,96,99,100,102,104,110,112,115–117,119,122,124,128,130,132,133]
- Evaluation against criteria or guidelines [42,81,84,93,101,112,115,129,133]
    - **VERSUS** evaluation against personal knowledge, experience, and culture [113,118,129]
- Having separate administrative staff or a Chair to facilitate reviews [81,92,93,127]
- Lead presenter presents the allocated case [67,91,93,102,115,117,118,128,133]
- Findings distributed in multiple languages [118]
- Grade or comment on the quality of clinical notes [112,119,132]

2.4.9 Outputs and outcomes

All included studies produced outputs (data or information) resulting from the stillbirth review. The themes identified were:

- Risk, protective and modifiable risk factors for stillbirth (maternal, fetal, and obstetric)
- Trends in stillbirth (e.g. changes in stillbirth rate)

- Counts or proportion of causes of stillbirth (cause of death)
- Details and grading of suboptimal care (what, when, who)
- Proportion of stillbirths where post-mortem examinations were conducted
- Recommendation of actions to be implemented to reduce future stillbirths
- Quality of case notes (record-keeping)

Not all reviews led to an outcome. Identified in 14 studies, the following short-term and medium-term outcomes were observed:

- Providing cost-effective ways of increasing mothers' awareness of stillbirth risk factors and level of knowledge about recognising the need to seek care [107]
- Improving referral pathways and record keeping to streamline the quality management process of providing optimal care [42,82,107,110,116,120,124]
- Increasing and improving clinical tests available and medical resources or capacity such as equipment, and available healthcare professionals (HCPs) within the department within the facilities [42,82,87,95,107,108,111,116,119,122,124,133]
- Providing training to HCPs to increase their knowledge and medical skills [82,95,107,111,116,124]

None of the studies reported any long-term outcomes or impact on reducing the number of stillbirths.

2.4.10 Facilitators and barriers to implementing a successful stillbirth review

Facilitators and barriers to successfully implementing a stillbirth review were identified from 14 included studies [42,82,87,95,107,108,110,111,116,119,120,122,124,133] (Table 2-5), and they were categorised into three main themes: resources, expertise, and commitment. These three themes were connected in the sense that the facilities with greater commitment (e.g. leadership buy-in) were more willing to provide resources (e.g. funds, training, administrative staff) to implement and strengthen their stillbirth review process. This further encouraged staff to be more committed to the ethos and aims of the review process. With adequate training provided (resources), staff gained confidence in communication skills, which

enabled them to build trust with women, as well as focus on a blame-free culture when conducting the reviews. Adequate resources also helped to engage experts from different specialities to create a multidisciplinary panel.

Table 2-5. Facilitators and barriers to implementing a successful stillbirth review

Themes	Facilitators (number of studies reporting)	Barriers (number of studies reporting)
Resources • Facilitators (N=22) • Barriers (N=21)	• Administrative staff and supporting researchers dedicated to the stillbirth review (N=3) • Training in conducting stillbirth review (N=3) • Availability of neutral chairs in the meetings to reduce the risk of bias (consistent review methods) and create a safe environment for panels to discuss stillbirths (N=2) • Data collection and stillbirth review tools or frameworks (N=6) • Adequate data available (N=2) • Funding (N=6)	• Poor or missing post-mortem examination data (N=3) • Amount of time spent in gathering data from multiple sources and inconsistencies in data between multiple sources (N=5) • Inadequate capacity and resources (human resources, no tools or frameworks to collect data, conduct reviews, or summarise the results of the reviews) (N=7) • Changes in guidelines since the stillbirth occurred (N=1) • Lack of training in collecting data or conducting reviews (N=2) • Language barriers between the women or families and the HCPs to collect necessary data (N=1) • Limited funds for conducting reviews and implementing the action points from the review results (N=2)
Expertise • Facilitators (N=13) • Barriers (N=11)	• Multidisciplinary review teams or panels (N=6) • External reviewers as part of the multidisciplinary review teams (N=2) • Supervision from the senior members of the review team (N=3) • Trust between facility staff and women or families to collect data required (N=2)	• Inconsistencies of grading or identification of suboptimal care between reviewers (N=2) • Poor record keeping to document events adequately (N=7) • Emotional involvement of the panel in the stillbirths (N=1) • Lack of confidentiality leading to pressure on certain departments or job titles of HCPs (N=1)
Commitment • Facilitators (N=16) • Barriers (N=7)	• Equal opportunities to participate regardless of the level of seniority or job titles in the panel (N=2) • Anonymous, blame-free, no-fault review environment (N=6) • Strong commitment of the public care or research sectors and participation of the private health care sectors by sharing common	• Perceived differences in status between representatives of different HCPs in the review panel (e.g. midwives versus senior obstetricians) (N=1) • Lack of leadership buy-in (N=2) • Lack of motivation of the HCPs to reflect their care (N=2) • The volume of stillbirths when this is large in number (N=2)

Themes	Facilitators (number of studies reporting)	Barriers (number of studies reporting)
	aims of reducing stillbirth and improving care (N=5) • Number of stillbirths (smaller the size, easier to review all cases) (N=1) • Leadership buy-in (N=2)	

2.4.11 Logic model

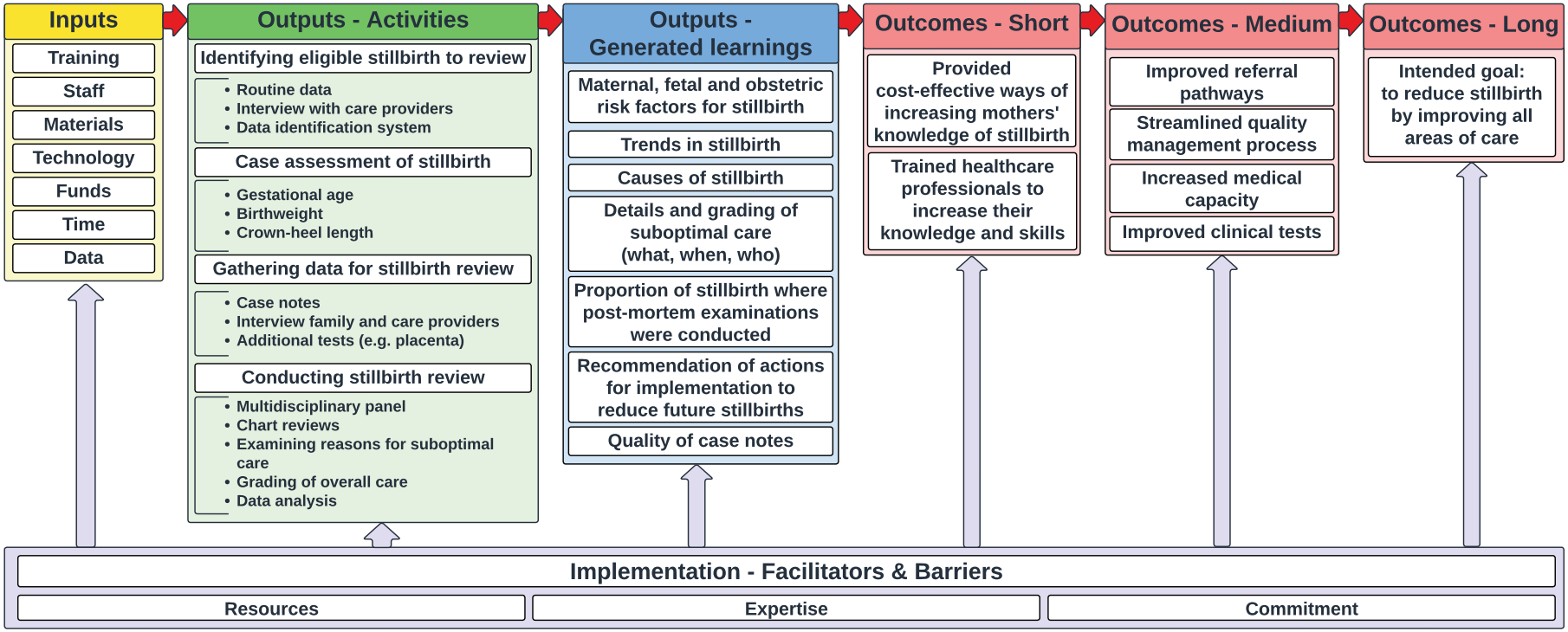
A logic model was developed after carrying out the narrative synthesis of the included studies. Figure 2-3 maps out how a facility-based stillbirth review can work effectively, beginning with inputs and activities (primary outputs) that generate learnings (secondary outputs) and ultimately lead to short-, medium-, and long-term outcomes. However, the relationship between inputs, outputs, outcomes, and impact must be understood within the context of the facilitators and barriers to implementing a successful stillbirth review. For example, while the "proportion of stillbirth where post-mortem examinations were conducted" was not an output or generated learning from the review directly aimed at reducing stillbirth, this was included in the logic model because poor or missing post-mortem examination data was identified as a barrier in conducting stillbirth reviews in some studies [74,126] (see Table 2-5). Post-mortem examinations and placental histology are important examinations to help identify the cause of stillbirth [135–137].

The model also highlights the importance of staff commitment and the availability of resources (e.g. tools and guidelines) as facilitators for conducting stillbirth reviews. When staff are equipped with these resources, the quality of collected data can improve, making it more likely that adequate quality data is available for thorough reviews. As mentioned above, an important barrier identified was the poor or missing post-mortem examination data was an important barrier identified. While staff training could improve data quality, engaging parents will be necessary to obtain consent for post-mortem examinations. Engaging with parents in the review process will also enable staff to collect more robust socio-demographic data and provide an opportunity for parents to share additional relevant information pertinent to the review. Furthermore, this engagement can create a pathway for parents to stay connected

with the review process and find out why their baby died after the review process is concluded. However, these activities require dedicated time for interviewing families and specific training in respectful bereavement care, which were identified as inputs in the logic model.

As illustrated in the logic model, the generated learnings (secondary outputs) have the potential to lead to various outcomes. Short-term outcomes included the provision of new training programmes for staff, and medium-term outcomes included improved referral pathways to improve the quality of care in the facilities. However, none of the included studies reported any direct evidence of achieving long-term outcomes or impacts on reducing stillbirths. Long-term outcomes or impacts may take longer to materialise, and even when achieved, it could be difficult to attribute them solely or directly to the review process alone.

Figure 2-3. Logic model of stillbirth reviews developed from the systematic review findings



2.4.12 Quality assessment

Quality assessment of the included studies is visualised in Table 2-6 and Figure 2-4. As seen in Figure 2-4, almost all included studies (97%) had clear criteria for inclusion in the review. The exceptions were a study from India by Bhatt [121] and an Indonesian study by Supratikto *et al.* [123], which only explained the inclusion criteria for maternal deaths occurring in a facility setting.

In order to measure stillbirth in a standard and reliable way for all cases included, the review should use a consistent definition of stillbirth applicable to all cases or consistent experts' assessment methods. This was seen in 71% of the included studies but could not be determined for 25%. Additionally, three studies did not measure stillbirth in a standard and reliable way for all cases [73,100,106].

Most of the studies (85%) were able to demonstrate which source of data they used for identification of the stillbirth, and 82% of the studies had consecutive inclusion of stillbirths to reduce selection bias. At a minimum, the stillbirth review should collect some important demographic characteristics of the women who had a stillbirth to compare against well-known risk factors for stillbirth. However, 46% of the included studies did not include information such as the age of the woman, parity, gestational age at birth, pregnancy complications and the number of antenatal visits during pregnancy.

While all included studies in this systematic review stated that their stillbirth review process evaluated the quality of care or avoidable factors, 35% of the included studies did not discuss the details of suboptimal care. In addition, these studies did not explain when the risk factors could have been avoided in relation to the pregnancy period (e.g. antenatal, labour and delivery) and who could have addressed these factors (e.g. obstetric staff, social care staff, mothers). It is important to consider what can be improved in the facility setting to prevent any future stillbirth since this was one of the main aims of conducting a stillbirth review.

While all studies may have identified the weakness in their facilities and made recommendations, most of the studies (79%) did not describe whether they actioned any recommendations as a result of the review outcomes. Lastly, 90% of the studies reported the information of the presenting sites or clinics, and 96% used appropriate statistical analysis methods to analyse their data.

Table 2-6. Quality assessment of the included studies

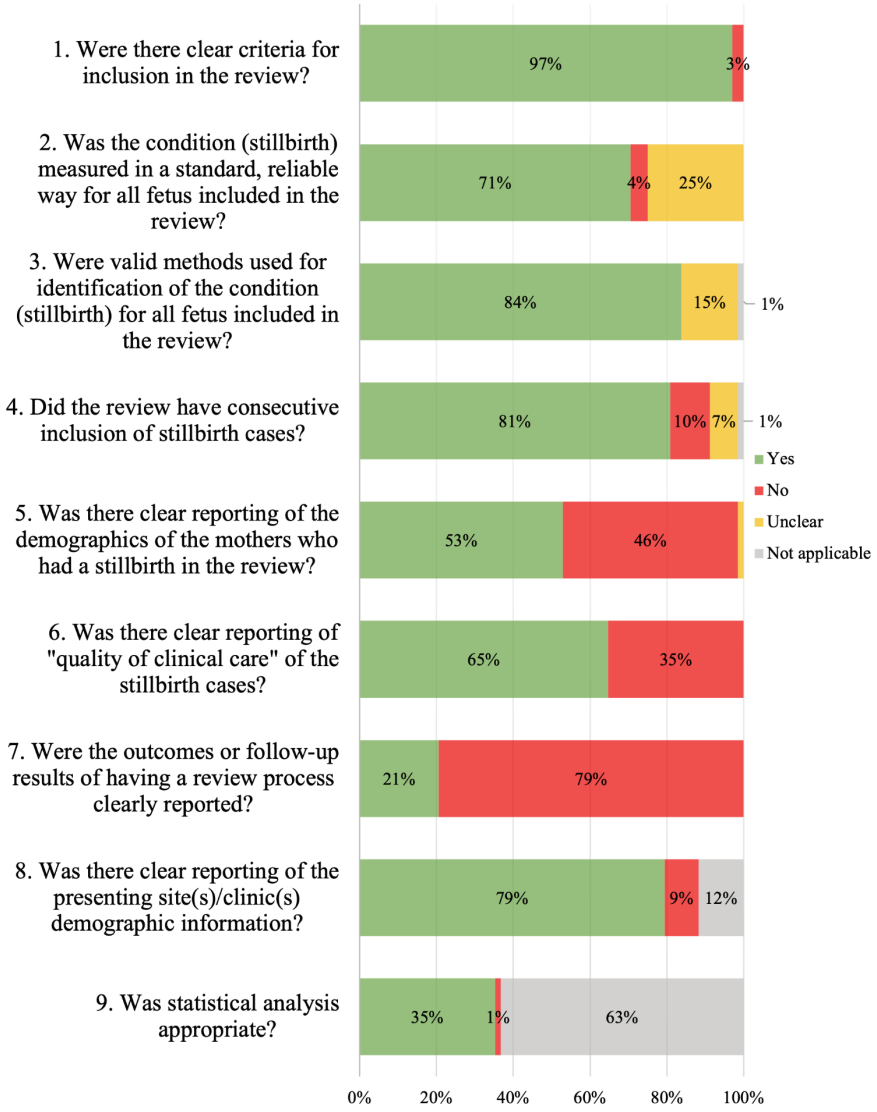
	Quality assessment criteria								
First author and year	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Alderliesten, 2008 [75]	Y	U	U	Y	Y	N	Y	Y	NA
Alyahya, 2021 [107]	Y	Y	Y	Y	N	Y	Y	Y	NA
Amaral, 2011 [105]	Y	Y	Y	Y	Y	Y	N	Y	NA
Aminu, 2017 [126]	Y	Y	Y	Y	Y	Y	N	Y	NA
Andersen, 1991 [69]	Y	Y	Y	Y	N	Y	N	Y	Y
Bandali, 2019 [124]	Y	U	Y	N	N	N	Y	Y	NA
Bausch, 1996 [99]	Y	Y	U	Y	N	N	N	N	NA
Berge, 1991 [83]	Y	U	Y	Y	N	N	N	Y	Y
Bhatt, 1989 [121]	N	U	Y	U	N	N	N	Y	NA
Biswas, 2015 [120]	Y	U	U	U	N	N	Y	Y	NA
Bjellmo, 2019 [84]	Y	Y	Y	Y	Y	N	N	N	Y
Chepkin, 2019 [42]	Y	Y	Y	N	Y	Y	N	Y	NA
Copenhagen: WHO Regional Office for Europe, 2020 [109]	Y	Y	Y	Y	Y	N	N	NA	Y
Cross-Sudworth, 2015 [92]	Y	Y	Y	Y	Y	Y	N	Y	NA
D'Aloja, 2021 [74]	Y	Y	Y	N	N	N	N	Y	NA
de Caunes, 1990 [72]	Y	Y	Y	Y	N	N	N	N	NA
De la Puente, 2002 [87]	Y	Y	Y	Y	N	Y	Y	NA	NA
Dekker, 2003 [76]	Y	Y	Y	Y	Y	Y	N	Y	NA
Demise, 2015 [116]	Y	Y	Y	Y	Y	Y	Y	Y	NA
Draper, 2017 [93]	Y	Y	Y	Y	Y	Y	N	Y	Y
Eksmyr, 1986 [89]	Y	U	Y	Y	N	Y	N	Y	NA
El Amin, 2002 [118]	Y	Y	Y	N	Y	Y	N	Y	Y
Eskes, 1993 [77]	Y	Y	U	Y	N	Y	N	Y	NA
Eskes, 2014 [81]	Y	Y	Y	Y	U	Y	N	Y	Y
Essén, 2002 [90]	Y	U	Y	Y	Y	Y	N	NA	Y
Flenady, 2021 [67]	Y	Y	Y	Y	Y	Y	N	N	Y
Fossen, 1999 [85]	Y	U	Y	Y	N	Y	N	Y	NA
Furst, 1989 [73]	Y	N	Y	Y	N	N	N	Y	NA
Govender, 2017 [110]	Y	Y	Y	Y	Y	Y	Y	Y	NA
Han, 2018 [86]	Y	Y	Y	Y	Y	Y	N	Y	NA
Harper, 1977 [100]	Y	N	Y	Y	Y	Y	N	NA	Y
Hinderaker, 2003 [128]	Y	Y	Y	Y	Y	Y	N	Y	Y
Hundley, 2001 [94]	Y	U	NA	NA	Y	Y	N	Y	NA
Kasengele, 2017 [133]	Y	Y	Y	Y	N	N	Y	Y	NA
Kieltyka, 2012 [101]	Y	Y	Y	N	N	N	N	Y	NA
Kirabira, 2020 [119]	Y	Y	Y	N	Y	Y	Y	Y	Y
Maaløe, 2016 [129]	Y	Y	Y	Y	Y	N	N	Y	Y
Maternal and Child Health Research Consortium, 1999 [95]	Y	Y	U	N	Y	Y	Y	Y	NA
Mbaruku, 2009 [130]	Y	Y	Y	Y	N	Y	N	Y	N

	Quality assessment criteria								
First author and year	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Mdoe, 2022 [131]	Y	Y	Y	Y	Y	Y	N	Y	NA
Mersey Region Working Party on Perinatal Mortality, 1982 [96]	Y	U	U	Y	N	Y	N	Y	NA
Miranda, 1996 [88]	Y	Y	Y	Y	N	Y	N	Y	NA
Mo-suwan, 2009 [115]	Y	Y	Y	Y	Y	N	N	Y	Y
Moawad, 1990 [102]	Y	Y	Y	Y	N	Y	N	Y	NA
Musafili, 2017 [117]	Y	Y	Y	Y	Y	Y	N	Y	NA
Omwodo, 2020 [125]	Y	Y	Y	Y	Y	N	N	Y	NA
Pattinson, 1995 [111]	Y	Y	U	U	N	Y	Y	N	NA
PMMRC, 2021 [82]	Y	Y	Y	Y	Y	Y	N	N	Y
Raman, 2015 [106]	Y	N	U	Y	Y	Y	N	Y	Y
Rhoda, 2014 [112]	Y	U	Y	Y	N	N	N	NA	NA
Richardus, 2003 [68]	Y	Y	Y	Y	N	N	N	Y	Y
Sauvegrain, 2020 [71]	Y	Y	Y	Y	Y	N	N	Y	Y
Sharma, 2022 [122]	Y	Y	Y	Y	Y	Y	Y	Y	NA
Sterpu, 2020 [91]	Y	Y	Y	Y	Y	Y	N	Y	Y
Stratulat, 2014 [108]	Y	U	U	Y	N	N	Y	NA	NA
Supratikto, 2002 [123]	N	U	Y	U	N	N	N	Y	NA
Tan, 1999 [97]	Y	Y	Y	Y	Y	Y	N	Y	NA
Tang, 2011 [98]	Y	U	U	Y	N	Y	N	Y	Y
The National Center for Fatality Review and Prevention, 2021 [103]	Y	U	Y	U	N	N	N	Y	NA
Vallejo, 1991 [104]	Y	Y	Y	Y	Y	Y	N	Y	NA
Vallely, 2020 [127]	Y	Y	Y	Y	Y	Y	N	Y	NA
van Diem, 2010 [78]	Y	U	Y	Y	N	N	N	NA	Y
van Diem, 2012 [79]	Y	Y	Y	Y	Y	Y	Y	Y	NA
Ward, 1995 [113]	Y	Y	Y	Y	N	Y	N	Y	Y
Westergaard, 1997 [70]	Y	Y	Y	Y	Y	Y	N	NA	Y
Wilkins, 2015 [132]	Y	Y	Y	Y	Y	Y	N	Y	NA
Wilkinson, 1997 [114]	Y	U	Y	Y	N	N	N	Y	NA
Wolleswinkel-van den Bosch, 2002 [80]	Y	Y	Y	Y	N	Y	N	Y	Y

1. Were there clear criteria for inclusion in the review?
2. Was the condition (stillbirth) measured in a standard, reliable way for all fetus included in the review?
3. Were valid methods used for identification of the condition (stillbirth) for all fetus included in the review?
4. Did the review have consecutive inclusion of stillbirth cases?
5. Was there clear reporting of the demographics of the women who had a stillbirth in the review?
6. Was there clear reporting of "quality of clinical care" of the stillbirth cases?
7. Were the outcomes or follow-up results of having a review process clearly reported?
8. Was there clear reporting of the presenting site(s) or clinic(s) demographic information?
9. Was statistical analysis appropriate?

Y: Yes, N: No, U: Unknown, NA: Not applicable

Figure 2-4. Summary graph of quality assessment of the included studies



Out of the 68 included studies, each green bar states the proportion of studies that fulfilled the respective risk of bias question; red states those that did not; yellow states those that were unclear; and grey states those that were not applicable.

2.5 Discussion

2.5.1 Principal findings

This systematic review identified different types and methods of facility-based stillbirth review processes around the world, and a logic model was built from the extracted evidence to describe what a successful

stillbirth review process could look like. The search identified 68 studies that described the methods used to conduct a facility-based stillbirth review from 39 countries (17 HICs and 22 LMICs).

According to identified studies, stillbirth reviews were conducted at various levels (district, state, and national), and three types of stillbirth reviews were identified (audit, review, and confidential enquiry). However, there was a mismatch between the type of review process reported (label assigned by the study authors) and the actual salient features of each review type according to the standard guidance. Stillbirth reviews from many countries had agreed that the aim of the stillbirth reviews was to prevent stillbirth and to improve all aspects of care by making adequate and informed recommendations guided by clear local, national or international criteria or practices. In terms of data sources for identifying stillbirths for the review, routine data was the most popular method. Some studies additionally conducted interviews with care providers, and many studies implemented a specific data identification system to build a stillbirth database only for the purposes of the review.

Case assessment using the stillbirth definition was used in 48 out of 68 studies. However, there was variation among the studies in the inclusion of these characteristics and the ranges included, regardless of the type of country involved. All stillbirth review processes identified in this study generated outputs that can lead to outcomes. The generated learnings from the stillbirth review processes informed the action plans and allowed facilities to consider where the changes should happen to improve the quality of care in the facilities, enabling positive short-term and medium-term outcomes. Short-term and medium-term outcomes were reported in 14 studies, but the long-term outcome (impact) of the review process on reducing stillbirth, which is more difficult to establish, was not reported in any study. Furthermore, facilitators and barriers identified from 14 studies focused on three main themes: resources, expertise, and commitment.

2.5.2 Discussion in light of other evidence

The stillbirth review process was not standardised in many countries at a local or national level, despite the known value of such review programmes in reducing stillbirth rates over time and identifying gaps in care [138]. While it is important to have a standard process across all regions in a country, this might be only possible in a small country like the United Kingdom (UK), where there is not much variation in the healthcare system and healthcare provision across the regions. In other words, standardisation might not be possible in large countries with variable systems, such as the United States, India, and others, which do not have a standard care provision system for all health facilities.

This was evident in the United States's national stillbirth review process, the Fetal Infant Mortality Review Program, as guidelines existed at the national level, yet different states were implementing the stillbirth reviews using different methods that uniquely work for each state [101,103]. This was in contrast to the programme that exists in the UK, where the confidential enquiries and review methods employ standardised tools that can be used in any region in order to facilitate standardised national monitoring [42,82,93].

It was observed, however, that even with a national programme in place, without a robust environment to implement the programme, the uptake of stillbirth review can be very low in areas that do not have adequate resources and support. For example, in Kenya, despite perinatal death being added as a component to the National Maternal Death, Surveillance and Response in Kenya in 2016, Bungoma was the only county that reviewed more than 50% of the deaths. This study reported that the technical and training support from UKAID was the main reason why the programme could be successfully implemented and strengthened in this county, compared to others that did not receive this type of support [124].

There was a lack of application of core principles of an audit process within studies that labelled their review processes as an 'audit'. For instance, many 'audit' studies [70–75,77,78,80,83–86,88–

91,102,106,109,113,114,117,118,121,125,127,129,130] lacked implementation of changes based on outputs and failed to ensure a continuous audit cycle of re-evaluation. Reporting on how changes are made by making adjustments in clinical practices based on stillbirth review outputs can be challenging, as it can be a gradual and time-consuming process that requires both service-level and policy-level support, and many other processes and findings may be involved beyond reviews. However, there is a need for clear guidelines on how to measure the impact of such changes. The continuous audit cycle of re-evaluation can also be challenging due to the cost (time and financial) associated with conducting a stillbirth review. In particular, compromises to clinical care could be counterproductive if HCPs are required to spend clinical time participating in the review meetings without providing additional resources to pay for this time [44].

For the studies that labelled their stillbirth review process as 'reviews', dissemination of key findings and learning points to relevant staff were not observed in many. The dissemination of information should be carried out in a way that activates knowledge translation within the hospitals or units, which then forms part of the knowledge-to-action cycle and can support promoting sustainable changes that improve clinical practices [139]. Therefore, it is crucial for the process to enable effective dissemination of learning points in the future and promote them through training platforms that are already available in their facilities [140].

While the United States Department of Veterans Affairs Root Cause Analysis Tool states that training and dissemination are weak means of changing either behaviour or outcomes, many studies from LMICs found that these types of actions are effective ways to change clinical practices to reduce suboptimal care in health facilities [141]. This may be due to differences in health systems or provider knowledge and practices between HICs and LMICs. For example, some LMICs may not usually have the facilities or practices in place to conduct training for the HCPs or disseminate generated information from the reviews about why a baby died to the wider stakeholders. Therefore, when training and dissemination activities in the LMICs happen, it may have more impact on quality of care improvements than HICs.

The results of this systematic review also revealed that a stillbirth review process could be an amalgamation of different types rather than being confined to the salient features that are thought to be desirable for a specific type, and different processes will most definitively comprise a variable mix of audit, review and confidential enquiry components. It is important to recognise that implementing a stillbirth review in a facility-based setting is a 'test and learn' process, and if the desired components of a stillbirth review are missing, it does not mean that the review methods are ineffective. As seen in early maternal mortality reviews in Ireland, the UK and the United States, from the 1920s to 1940s, the processes initially did not examine the standard of care; however, this was later revised, and more structured approaches to maternal mortality reviews were established [65]. Understanding that stillbirth review is relatively new compared to maternal mortality reviews, stillbirth review processes are likely to adapt and improve over time. Different countries, districts, and hospitals will have different stillbirth review processes to optimise their resources and contextualise their healthcare system, as well as cultural and social norms.

The definition used to assess stillbirth varied greatly between studies, and this study found that a universal definition of stillbirth is needed to facilitate a meaningful comparison of stillbirth rates between regions and to correctly identify risk, protective, and modifiable risk factors for stillbirth, even in HICs [142]. This challenge has also been discussed extensively in a previous systematic review by Aminu *et al.* [143] and in the 2023 report by the United Nations Inter-agency Group for Child Mortality Estimation (UN IGME) [5].

Moreover, this study found that the minimum gestational age, birthweight, and crown-heel length ranges used in defining stillbirth were lower in HICs than the minimums used in LMICs. This could be because LMICs prefer to use the WHO definition of stillbirth for international comparison and reporting [2]. The WHO's rationale for moderating the definition of stillbirth cut-off for international comparison to 1,000g or more at birth, or ≥28 completed weeks of gestation, or attainment of at least 35cm crown-heel length could be due to ensuring comparability between countries; many LMICs may not capture late fetal deaths accurately, or data is limited [144,145]. In addition, in countries where neonatal intensive

care units are limited, babies below the gestational age of 28 weeks may not be viable when delivered prematurely, whereas, in HICs, these facilities are often available, and lower gestational age babies can survive with adequate neonatal care and treatment [146].

There were unique components of stillbirth review in some studies that showed positive effects on achieving their aims, which can be considered to be utilised in future designs of stillbirth review. Some studies stated that training staff about the review process before they participate were crucial since effective training not only reduced measurement errors from between-reviewer variations but also allowed panel members to prioritise the guiding principles for stillbirth reviews, for example, focusing on improvements to health systems and not individuals (blame-free policy) [75,107].

Sharing review-related data a few weeks prior to the review meeting was another effective way to promote the review meetings. Also, this practice helped the panels stay focused on the agenda without feeling unprepared or rushed because they would not have had enough time to absorb the information in the clinical notes if they did not have the data beforehand. Furthermore, allowing panels to study the stillbirth before the meetings allowed them to understand each case fully and helped them gain confidence in participating during the discussion. This may also create a system where there is a lead presenter to present an allocated case in each session to open up the discussion more naturally during the review meeting.

Some facilities had structured forms or checklists that guided the stillbirth review process, while some only conducted the review via discussion with the panel. Nonetheless, having well-known classifications to assess the cause of death or a framework to select contributory factors could increase the consistency between the reviewers and the extent to which consensus is reached. Although, it is important to note that current classification systems are imperfect. Aminu *et al.* [143] noted that there are over 35 classification systems for stillbirth, and none of them were adopted globally. Some studies also argued that even the widely known classification systems, such as the Extended Wigglesworth and Amended Aberdeen systems, are considered limited in classifying stillbirth [143,147].

Since creating action plans and follow-up plans are important steps to implement changes based on stillbirth review outputs, having a clear reporting of suboptimal care (what, when, who), grading suboptimal care using an established grading system (e.g. Confidential Enquiry into Stillbirth and Deaths in Infancy (CESDI) [95]) and assessing if the identified suboptimal care factors contributed to stillbirth could equip review panels to select and justify appropriate action plans effectively.

Also, having separate administrative staff or a Chair to facilitate reviews was identified as a facilitator of implementing successful stillbirth reviews. Having support staff solely responsible for implementing and carrying out the stillbirth review process could be effective in reducing the workload of clinical staff, increasing the motivation of panel members, and increasing consistency of review quality between review meetings. Furthermore, as poor or inadequate data quality was identified as one of the barriers to implementation, an opportunity for review panels to grade or comment on the quality of clinical notes could increase awareness among the HCPs of the importance of accurate and detailed record-keeping.

2.5.3 Strengths and limitations of the study

The strength of this systematic review is that it was one of the first studies to critically appraise and synthesise the methods used for facility-based stillbirth review processes across the world in detail. It used a robust methodology, including having several independent reviewers for screening, extracting and conducting quality assessment. Since there were high levels of heterogeneity between included studies due to the nature of the aim of this systematic review (methodological characteristics, clinical heterogeneity, diversity in the populations from different regions and countries), several tools for risk of bias assessment and different types of frameworks for narrative synthesis were considered and piloted before finalising the most applicable methods to appraise the included studies.

While using a logic model for narrative synthesis was deemed most appropriate for this study, a logic model represents a linear model of how processes should work. Since the sequence of implementing a

stillbirth review in the real world is not linear, and assumptions are often not met, the logic model proposed in this study should be interpreted with flexibility when designing a stillbirth review process in the real world. Moreover, the proposed logic model assumed its applicability across all settings and countries. However, in practice, employing the same process can lead to different outcomes in varying contexts. Therefore, users of this model need to critically appraise and, if necessary, adapt the logic model by considering their specific contextual settings and understanding the complexities involved in implementing a stillbirth review within their environment.

In addition, studies reporting on the stillbirth review process may not always reach mainstream sources of literature, and despite efforts made to retrieve studies by searching published, unpublished, or grey literature, the systematic review might not have identified every possible method used for facility-based stillbirth review processes.

Finally, this study compared different types of reviews using Helps et al.'s [65] interpretation of the desired components of audits, reviews, and confidential enquiries as a standard guidance. However, Helps *et al.* [65] focused on the types and evolution of audits and reviews in HICs alone when deriving the desired components. Considering this study looks at stillbirth review processes in both HICs and LMICs, there were limitations to using Helps *et al.*'s [65] interpretation of salient features for different types of review processes because their method may not fully reflect LMICs' health systems, which may differ from HIC's systems for standard care provision.

2.5.4 Conclusion

This systematic review identified different types and methods of facility-based stillbirth review processes implemented around the world, and a logic model was built from the extracted evidence to describe what a successful stillbirth review process might encompass. Therefore, the logic model developed from the findings of this comprehensive review could be used as a guide or be contextually adapted by health facilities to improve their stillbirth review process. Moreover, this systematic review raises important

questions about what the gold standard stillbirth review process is, how this can be achieved, and whether a global consensus can be reached. Since most stillbirths (98%) occur in LMICs, there is an urgent need to introduce standardised stillbirth review processes in more LMICs while considering the facilitators and barriers, resources required, training and support needs. The logic model developed from this review is the first step in trying to achieve a global standard for stillbirth review, though its utility and usability need to be assessed, and a consensus about its use as a global standard for stillbirth review needs to be reached.

Chapter 3. Methods

3.1 Chapter introduction

The chapter describes why the mixed methods research design was chosen to address the aim and objectives of the thesis, linking back to the research questions generated from the synthesised evidence of the systematic review (Chapter 2). A summary diagram in this chapter shows that this mixed methods study was convergent parallel in design, which means the quantitative and qualitative components of the research were performed independently, and their results were triangulated to address the overarching aim of the thesis. This chapter also introduces the Maternal and Perinatal Health Research Collaboration, India (MaatHRI), a research platform that was the data source (MaatHRI hospital-based cohort) for the quantitative secondary analyses (Chapters 4 and 5) and supported the recruitment of hospitals and focus group discussion (FGD) participants for the primary data collection for the qualitative studies (Chapters 6 and 7). In addition, this chapter introduces and justifies the analytical methods adopted for the quantitative component and the study methods used for the qualitative component.

3.2 The mixed methods research design

The mixed methods research design was chosen to address the aim and objectives of the thesis, linking back to the three research questions informed by the synthesised evidence of the systematic review and research objectives (see 1.6 in Chapter 1). Throughout this thesis, the mixed methods research design was defined as the following, referring to Johnson *et al.*'s [148] definition of mixed methods research:

> *"Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e. g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration" (p. 123).*

The adoption of a mixed methods research design for this study was underpinned by the 'methodological' pragmatism stance. Pragmatism, as put by Johnson *et al.* [149], "takes an explicitly value-oriented approach to research" and focuses on addressing a complex social problem. Methodological pragmatism, therefore, posits that the research questions should have the greatest importance and that the research design should be the most optimal to address them, whether taking a qualitative, quantitative, or mixed approach [149–151]. Thus, in order to apply appropriate methods to answer the research questions (see 1.6 in Chapter 1), this mixed-method study included different components of both quantitative and qualitative study designs.

3.2.1 Dimensions of mixed methods research design

When designing mixed methods research, it is important to understand and carefully consider the following seven major dimensions of the mixed methods research design approach in order to maximise knowledge and validity [152]:

1. Purpose
2. Theoretical drive
3. Timing (simultaneity and dependency)
4. Point of integration
5. Typological versus interactive design approaches
6. Planned versus emergent design
7. Design complexity

Using Bryman's classification [153], the purpose of this mixed methods study can be defined as 'triangulation', with elements of 'completeness' and 'different research questions'. 'Triangulation' was the main purpose of this mixed methods study because I sought convergence, corroboration, or correspondence of results from different methods at the point of interpretation. However, this was not the only purpose of using a mixed methods research design. The aim was also to provide 'completeness' by providing rich evidence across all aspects of implementing and sustaining a facility-based stillbirth

review process in six states in India. Additionally, using both qualitative and quantitative designs appropriately addressed distinct research questions, which meant the study purpose also included addressing 'different research questions'.

Johnson *et al.* explained [148] three theoretical drives that can be used in a mixed methods research design: qualitative dominant, quantitative dominant, or equal-status. The approach used here can be defined as an equal-status mixed methods research design having equal priorities of both quantitative and qualitative components.

Additionally, the timing of the two components can be defined as concurrent and independent since each component was conducted simultaneously and was not influenced by the results of the other component. Using the notation of Morse [154], this study can be illustrated as 'QUAN + QUAL'. Furthermore, because quantitative and qualitative components were performed independently, and their results were triangulated only at the point of interpretation to address the overarching aim of the thesis, it is a 'convergent parallel' design.

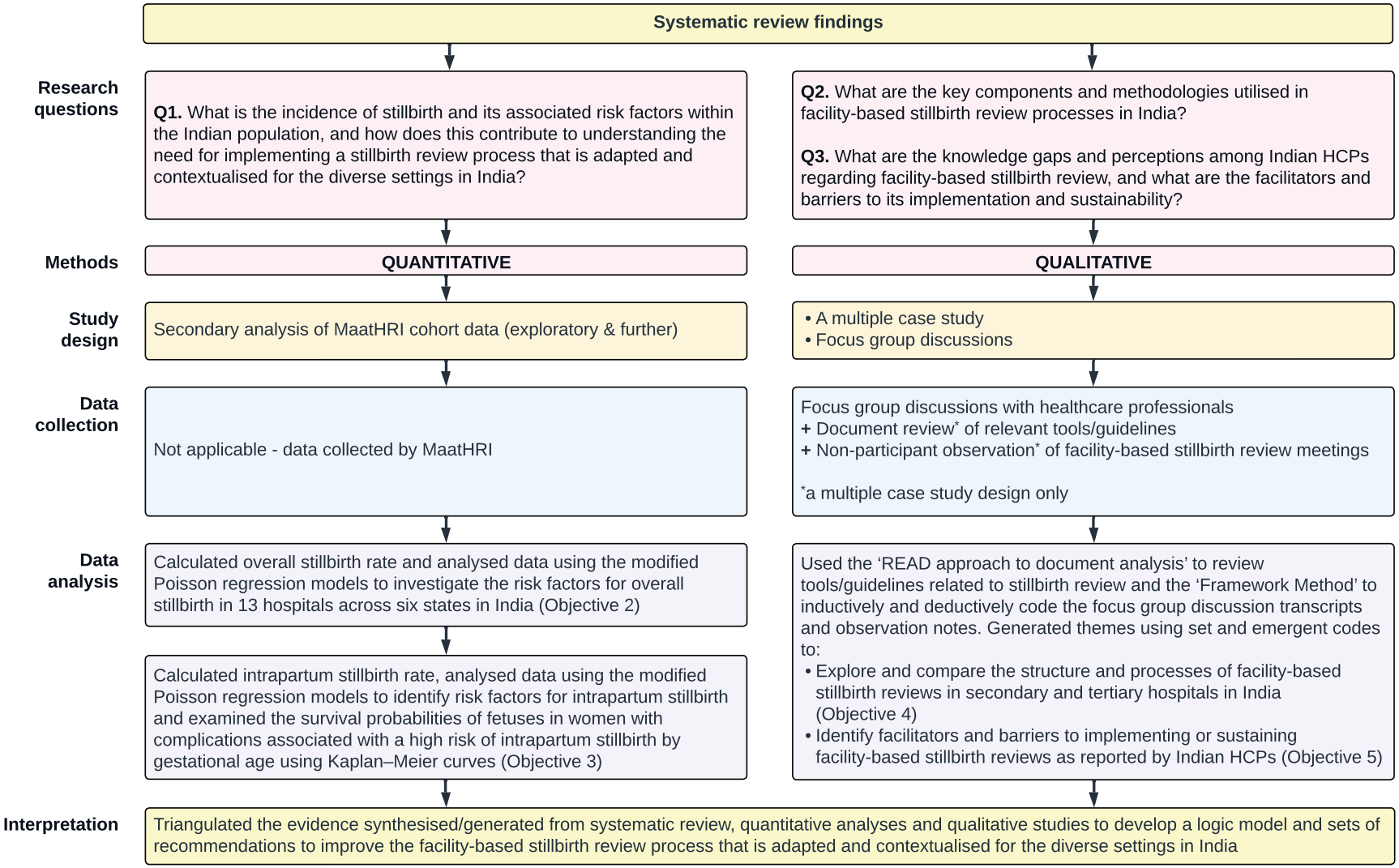
I chose to use a typological design approach rather than an interactive approach, using Loomis and Maxwell's definition [155]. This is because the objectives of this study were straightforward, and once the purposes, theoretical drive, timing and point of integration of this mixed methods study were decided, the typology became very clear. This meant this study's research design was also fully specified at the planning stage of the thesis and was thus a 'planned design'.

Finally, the design complexity can be defined as a 'simple design' using Teddlie and Tashakkori's definition [156] since it did not have multiple levels of realities (it used only facility-level data in six states in India) and had only one point of integration.

3.2.2 Summary of the mixed methods research design

The diagram below summarises that this mixed methods study was convergent parallel in design, with equal priorities given to both quantitative and qualitative components (Figure 3-1). In addition, it describes how each component was performed independently, and their results were triangulated at the point of the interpretation to address the overarching aim of the thesis. The diagram also clarifies that each component was selected for its appropriateness in addressing the research questions formulated from the systematic review findings, stemming from the methodological pragmatism stance.

Figure 3-1. Diagrammatic summary of the mixed methods research design used in this study



HCP: healthcare professional, MaatHRI: Maternal and Perinatal Health Research Collaboration, India, READ: Ready materials, Extract data, Analyse data, Distil

3.2.3 The role of theoretical frameworks

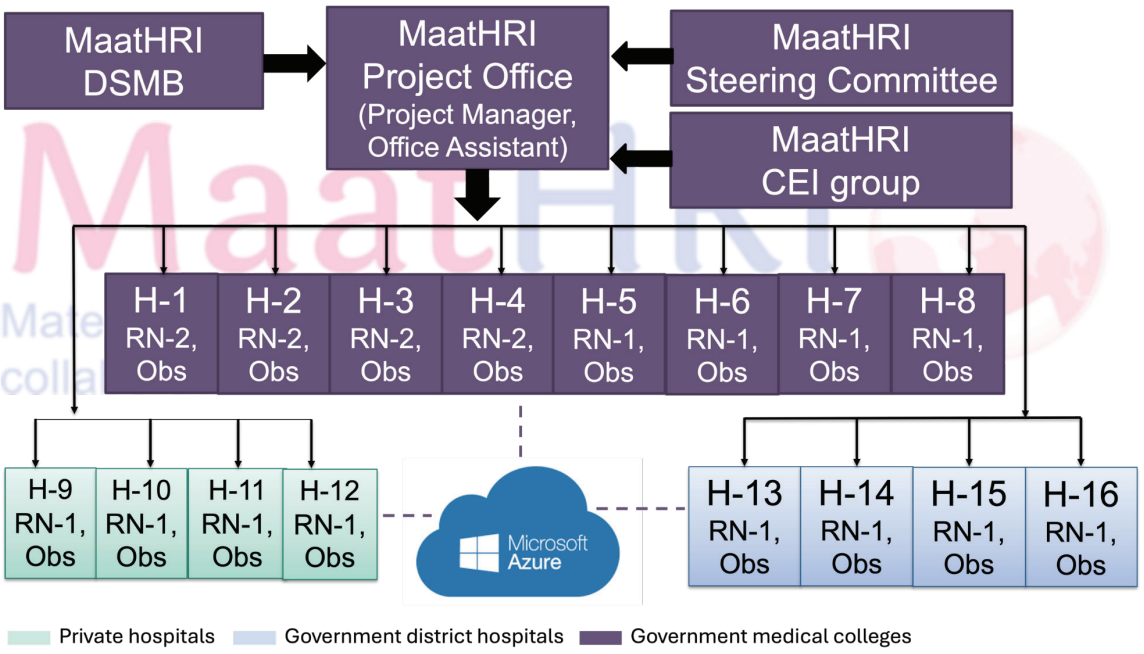
Three theoretical frameworks underpinned this research: the logic model built from the systematic review findings, the conceptual model describing the hierarchical inter-relation of structural, intermediate, and proximal factors associated with stillbirth, and the capability, opportunity, motivation and behaviour (COM-B) model and the Behaviour Change Wheel.

Both the quantitative and qualitative components drew on the logic model developed from the synthesis of the systematic review evidence. The details of this logic model can be found in 2.4.11 in Chapter 2. This initial logic model was further revised after triangulation of the evidence from both the quantitative and qualitative research to develop an evidence-based comprehensive facility-based stillbirth review process for the diverse settings in India.

3.3 Maternal and Perinatal Health Research Collaboration, India (MaatHRI)

MaatHRI is a United Kingdom (UK)-India collaborative research platform for maternal and perinatal health research established in September 2018 that aims to conduct research and translate new scientific discoveries to improve care for mothers and children [157]. As shown in Figure 3-2, its large multidisciplinary team comprises research staff, clinicians, members of the public, and academics from India and the UK.

Figure 3-2. Organogram of MaatHRI

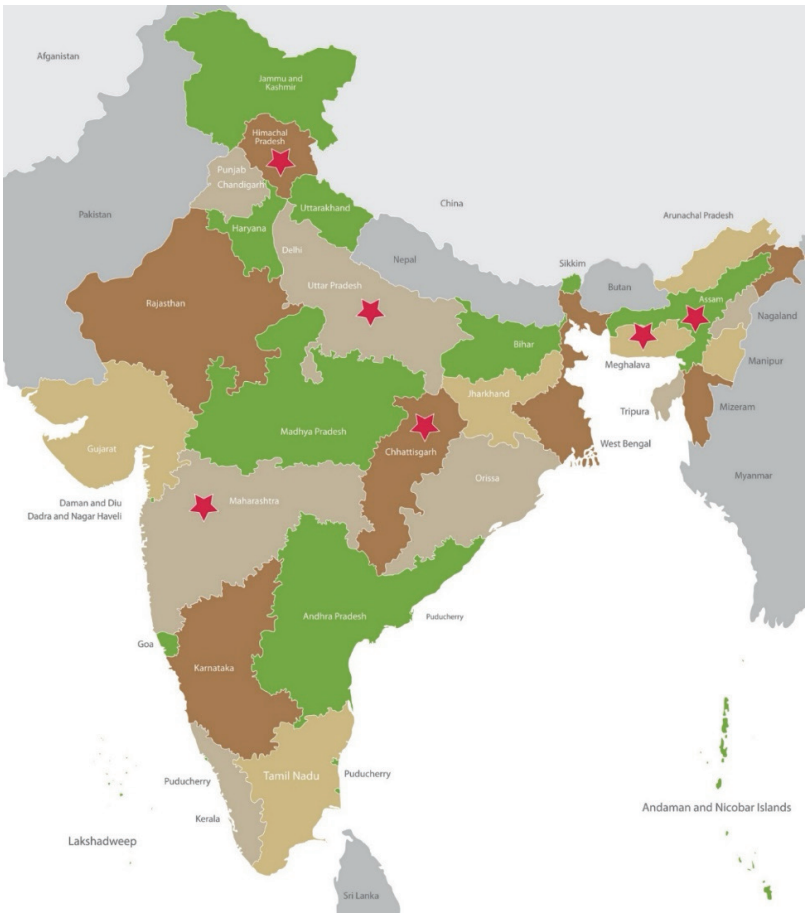


Adapted with permission from the MaatHRI Principal Investigator M Nair.
DSMB stands for Data Safety and Monitoring Board, CEI stands for Community Engagement and Involvement, H stands for Hospitals, RN stands for Research Nurse, and Obs stands for Obstetrician.

MaatHRI has three roles as a research platform [157]: (i) to routinely collect data about the prevalence of known and emerging pregnancy complications; (ii) to conduct large hospital-based epidemiological studies to generate evidence to improve clinical management and outcomes for pregnant women; and (iii) to develop research capacity and skills in MaatHRI hospitals. MaatHRI has 16 collaborating hospitals in six states in India (Assam, Meghalaya, Maharashtra, Uttar Pradesh, Himachal Pradesh and Chhattisgarh) (Figure 3-3), and these hospitals were included in the network based on two criteria:

1. Willingness of the hospital to participate in large research collaboration
2. A high burden of maternal and perinatal deaths in the population covered by the hospital

Figure 3-3. Six states of India where MaatHRI hospitals are located



Reprinted with permission from the MaatHRI Principal Investigator M Nair.
Star (★) indicates the states where MaatHRI hospitals are located.

For this mixed-methods study, MaatHRI provided the data for the secondary analyses (MaatHRI hospital-based cohort) for the quantitative components of the study and supported the recruitment of hospitals and FGD participants for the primary data collection in the qualitative studies.

3.3.1 MaatHRI prospective cohort study

Out of 16 MaatHRI hospitals, 13 hospitals (nine medical colleges, four community hospitals) participated in a prospective cohort study, data from which were used in this thesis [157]. This cohort study was designed to investigate the risk of postpartum haemorrhage among pregnant women with anaemia who undergo induction or augmentation of labour [158–160]. The included hospitals have

adequate facilities for providing maternal and newborn care, and Table 3-1 describes the characteristics of the MaatHRI hospitals participating in this prospective cohort study.

Table 3-1. Characteristics of the care available in the 13 MaatHRI hospitals involved in the prospective cohort study of postpartum haemorrhage

Maternal care functions	N (%)
Skilled staff available 24 hours	13 (100.0)
Access to operating theatre	13 (100.0)
Functioning ambulance available	13 (100.0)
Electricity always available	13 (100.0)
Reliable access to clean water	13 (100.0)
Infection control	13 (100.0)
Partograph use	13 (100.0)
Cardiotocography (CTG) monitors	11 (84.6)
Hand-held dopplers	11 (84.6)
Emergency carts	13 (100.0)
Functional blood bank	12 (92.3)
Anaesthetic care (by technicians or anaesthetists)	13 (100.0)
Fridge for storage of drugs	13 (100.0)
Neonatal Intensive Care Unit	12 (92.3)
Removal of retained products of conception	13 (100.0)
Parenteral oxytocin	13 (100.0)
Parenteral magnesium sulphate	13 (100.0)
Manual removal of placenta	12 (92.3)
Parenteral antibiotics	13 (100.0)

3.3.2 Methods employed for the MaatHRI prospective cohort study

In this cohort study, pregnant women from 28 weeks of gestation, aged 18 years or older and planning a vaginal birth at one of the 13 hospitals were recruited from October 2018 to September 2023. Women were excluded if they were unwilling to provide informed consent or were planning a caesarean section at the time of recruitment. Out of 10,064 women approached at the 13 MaatHRI study hospitals, 99.9% of women (N=10,056) consented to participate, and their baseline information, including sociodemographic characteristics, previous and current pregnancy problems, medical comorbidities and other pregnancy characteristics, were collected by the research nurses. Haemoglobin concentration in the third trimester was measured by collecting, processing, and analysing women's blood samples at the time of recruitment or using their most recent routine haemoglobin record if blood analysis was not feasible or if their blood samples were haemolysed. The participants were then followed up during labour, childbirth and up to 48 hours postpartum. Further information about the methods employed for the

MaatHRI prospective cohort, including recruitment, data collection, and quality assurance, is available in the published MaatHRI methodology paper [157,160].

3.3.3 Strengths of the MaatHRI prospective cohort study

The major strengths of the study were that it adopted an advanced standardisation method to collect data and blood parameters, real-time monitoring of data and participant safety, and secure data transfer protocols. To reduce bias in data measurement, MaatHRI's electronic data collection forms had checks and validations to flag logical errors for quality assurance, with the MaatHRI Project Manager monitoring data entry on a day-to-day basis and any errors identified were rectified immediately by the research nurses.

In addition, to minimise reporting bias, a pseudonymised laboratory model was used, which meant a standard test requisition form for blood analysis only included the participant identification (ID), age and barcode. Data stored in the cloud were encrypted and password protected, with each hospital only able to access its own data. Also, any identifiable information was collected for follow-up but could only be viewed, not downloaded, by authorised staff. For blood sample analysis, standardised procedures were used, with Dr Lal Pathlabs, MaatHRI laboratory partner, providing infrastructure and blood collection kits to all study hospitals.

3.3.4 Ethics approval

Ethics approval for the MaatHRI cohort study was provided by the institutional review boards of each coordinating Indian institution, namely: Srimanta Sankaradeva University of Health Sciences, Guwahati, Assam; Makunda Christian Leprosy and General Hospital, Assam; Nazareth Hospital, Shillong, Meghalaya; Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra; Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh; Dr Rajendra Prasad Government Medical College Kangra at Tanda, Himachal Pradesh; and Sewa Bhawan Hospital Society, Chhattisgarh. It also

received approval from the Government of India's Health Ministry's Screening Committee, the Indian Council of Medical Research, New Delhi and from the Oxford Tropical Research Ethics Committee (OxTREC), University of Oxford, UK. Written informed consent was obtained from all participants prior to data and blood sample collection.

3.4 Quantitative analysis methods

As indicated in Figure 3-1, the quantitative component of the mixed method study involved two quantitative secondary analyses of data to address the following objectives of the thesis:

- Objective 2: To investigate the incidence of and risk factors for stillbirth in an Indian population
- Objective 3: To identify risk factors for intrapartum stillbirth and examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age

3.4.1 Data source

The anonymised dataset of the MaatHRI postpartum haemorrhage cohort study was used to address the two objectives in my secondary analyses. I was not involved in the design, conduct, or data collection of the cohort study, nor did I collect any additional data. The dataset was downloaded from the MaatHRI data platform by MaatHRI staff, and then I carried out extensive cleaning by cross-referencing tick box data entries with any free texts within them to ensure consistency and accuracy. I also carried out cross-referencing between similar data items, including gestational age, which was reported in more than one area of the data collection form. As these were secondary analyses, the sample size was fixed and not determined through a power calculation tailored to my specific research objectives or statistical analyses.

3.4.2 Conceptual framework

A conceptual framework was developed to provide guidance for the statistical analysis and to specifically ensure that the analysis accounted for the effects of structural and intermediate factors [161]. The following steps were used for this development:

1. A list of potential exposure variables was compiled based on their clinical relevance or whether they were found to be significant risk factors for stillbirth in the literature [34–38,162–164]. Then, the availability and data quality of these variables were assessed. Table 3-2 summarises the identified variables, their availability in the dataset, and the reasons for exclusion where applicable.

Table 3-2. Availability and reason for exclusion of potential exposure variables

Potential exposure variables	Availability in the dataset	Reason for exclusion
Urban/rural	✓	-
Marital status	✓	Low variability in the data – the majority of participants were married (>99.9%)
Women's education level	✓	-
Religion	✓	-
Below poverty line (BPL) status	✓	-
Smoking status	✓	-
Tobacco consumption	✓	-
Alcohol consumption	✓	Low variability in the data – the majority of participants never consumed alcohol (>98.4%)
Chewing betel nuts	✓	-
Women's age	✓	-
Parity	✓	-
Stillbirth/miscarriage history	✓	-
History of caesarean sections	✓	-
Pre-existing haemoglobinopathy	✓	Small number of participants with the condition (<1.6%) – merged into composite variable 'Pre-existing medical problems'
Pre-existing cardiac problems	✓	Small number of participants with the condition (<0.1%) – merged into composite variable 'Pre-existing medical problems'
Pre-existing diabetes	✓	Small number of participants with the condition (<0.3%) – merged into composite variable 'Pre-existing medical problems'

Potential exposure variables	Availability in the dataset	Reason for exclusion
Pre-existing mental health problems	X	Free text data was considered, but no information was recorded on this topic
Pre-existing thyroid problems	X	Free text data was considered, but there was a small number of participants with the condition (<0.2%) – merged into composite variable 'Pre-existing medical problems'
Body mass index (BMI) category for South Asian	✓	-
Number of antenatal check-ups	✓	-
Duration of iron and folic acid (IFA) supplementation	✓	-
Severity of anaemia	✓	-
Gestational diabetes	✓	Small number of participants with the condition (<0.1%)
Placental problems	✓	Small number of participants with the condition (<0.6%)
Infections	X	Free text data was considered, but recording was inconsistent, with very few entries and no information on how the diagnosis was made
Sepsis	✓	Small number of participants with the condition (<0.1%)
Antepartum haemorrhage	✓	Small number of participants with the condition (<0.1%)
Hypertensive disorders of pregnancy (HDP)	✓	-
Fetal growth restriction (FGR)	X	Free text data was considered, but recording was inconsistent, with very few entries and no information on how the diagnosis was made
Inter-institutional referral	X	Free text data was considered, but no information was recorded on this topic
Use of partograph	X	Free text data was considered, but no information was recorded on this topic
Gestational age at birth	✓	-
Fetal sex	✓	-
Birthweight for gestational age	✓	-

2. Exposure variables that were available in the dataset, had sufficient data quality, and numbers were included in the final set of exposure variables. They were then grouped into socioeconomic, behavioural, biodemographic, pregnancy, and fetal characteristics. Table 3-3 describes the methods of assessment or measurement used to collect data and the categorisation of each variable.

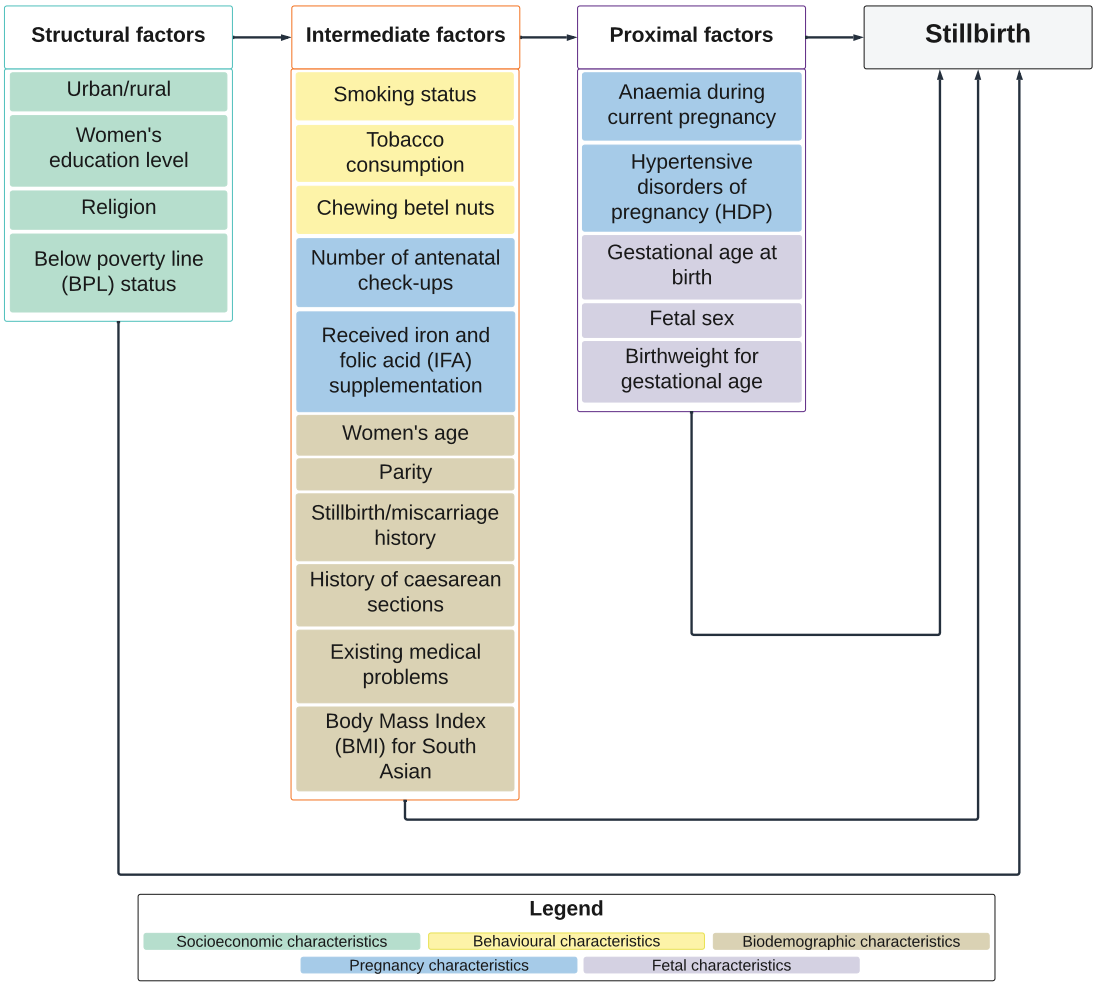
Table 3-3. Methods of assessment or measurement used to collect data and the categorisation of the exposure variables

Socioeconomic characteristics	
Urban/rural	Area of residence self-reported at the baseline assessment: *urban/suburban*, and *rural*.
Women's education level	Woman's education level self-reported at the time of baseline assessment: *tertiary or above (beyond 12th class)*, *up to secondary school (6-12th class)*, *up to primary school (5th class)*, and *illiterate*. The category *illiterate* was only selected during the baseline assessment if the woman could not read or write.
Religion	Religion at the time of baseline assessment: *Hindu*, and *Muslim and others*.
Below poverty line (BPL) status	BPL status self-reported at the time of baseline assessment: *no*, *unknown*, and *yes*. The Planning Commission of India defines BPL households as households (average five family members) with a per capita consumption expenditure of Indian Rupees (INR) 816.00 on a monthly basis in rural areas and an expenditure of INR 1,000.00 in urban areas using the Tendulkar methodology [165].
Women's behavioural characteristics	
Smoking status	Smoking status self-reported at the time of baseline assessment: *never*, and *ever* (before or during pregnancy).
Tobacco consumption	Tobacco consumption (chewing) self-reported at the time of baseline assessment: *never*, *before pregnancy*, and *during pregnancy*.
Chewing betel nuts	Smoking status self-reported at the time of baseline assessment: *never*, *before pregnancy*, and *during pregnancy*.
Women's biodemographic characteristics	
Women's age	Derived from the date of birth or, if unknown, age verbally confirmed by the woman recorded during the baseline assessment: *<20 years, 20-24 years, 25-29 years, 30-34 years*, and *>34 years*.
Parity	Parity derived from the antenatal history: *nulliparous*, *para 1-2*, and *para 3 or more*.
Stillbirth/miscarriage history	Stillbirth/miscarriage history derived from clinical notes of last pregnancy or previous obstetrics problem: *no*, *never pregnant*, and *yes*. Coded as *Never pregnant* if a woman was 'first-time pregnant' at the time of baseline assessment.
History of caesarean sections	History of caesarean sections derived from clinical notes of last pregnancy or previous obstetrics problem: *no*, *never pregnant*, and *yes*. Coded as *never pregnant* if a woman was 'first-time pregnant' at the time of baseline assessment.
Pre-existing medical problems	Any pre-existing medical problems derived from clinical notes: *No*, and *Yes*.
Body mass index (BMI) category for South Asian	BMI derived from clinical notes and categorised using BMI category for South Asian [166]: *<18.5, 18.5-22.9, 23-24.9*, and *≥25*.
Pregnancy-related characteristics	
Number of antenatal check-ups	Number of antenatal check-ups received until the time of baseline assessment derived from the antenatal history: *4 or more*, *2-3*, and *0-1*. Introduced in 2002, the World Health Organization (WHO)'s Focused Antenatal Care model recommends pregnant women receive at least four comprehensive antenatal check-ups [167]. While this has changed to eight check-ups in 2016 [168], there were not enough women who received eight check-ups in the dataset to use this cut-off category. Also, the number of women receiving one check-up was small and therefore, had to be group together with those who received no antenatal check-up.

Duration of iron and folic acid (IFA) supplementation	Duration of IFA supplementation received until the time of baseline assessment derived from the antenatal history: *180 days or more, 100-179 days, fewer than 100 days*, and *none*. These categories are in line with the Anaemia Mukt Bharat (AMB) guidelines where pregnant women are recommended to receive prophylactic supplementation of one IFA tablet with 60 mg of elemental iron and 500 microgram of folic acid, every day for 180 days from the second trimester onwards [169].
Severity of anaemia	Haemoglobin (Hb) concentration in the third trimester was measured by collecting, processing and analysing women's blood samples at the time of recruitment or by using their most recent routine haemoglobin record: *no anaemia (Hb ≥11 g/dL)*, *mild (Hb 10–10.9 g/dL)*, *moderate (Hb 7–9.9 g/dL)*, and *severe (Hb <7 g/dL)*. Levels of severity of anaemia were defined using the WHO definition for haemoglobin cut-offs [170].
Hypertensive disorders of pregnancy (HDP)	If women were diagnosed with any HDP problems during the current pregnancy according to clinical notes, or identified as reasons for obstetric interventions (e.g. induction) in free texts: *no*, *other HDP* and *pre-eclampsia/eclampsia*. *Other HDP* was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia defined by the International Society for the Study of Hypertension in Pregnancy (ISSHP) [171].
Fetal characteristics	
Gestational age at birth	Gestational age at birth was derived from actual date of birth and expected date of delivery (EDD): *Preterm (28^{+0} to 36^{+6} weeks), Early term (37^{+0} to 38^{+6} weeks), Full term (39^{+0} to 40^{+6} weeks)*, *and Late/post term (≥41^{+0} weeks)*.
Fetal sex	Sex of the fetus: *male,* and *female*.
Birthweight for gestational age	Birthweight for gestational age, gender-specific z-scores and centiles were generated using the INTERGROWTH-21st tool [172]: *<10^{th} percentile*, *10^{th} to 90^{th} percentile*, and *>90^{th} percentile*.

3. Exposure variables were categorised as structural, intermediate and proximal factors informed by the World Health Organization (WHO)'s Commission on Social Determinants of Health (CSDH) conceptual framework [173]
4. The complex hierarchical inter-relationships between these factors and stillbirth were visualised (Figure 3-4)

Figure 3-4. Conceptual framework: hypothesised relationship between the structural, intermediate and proximal factors and stillbirth



3.4.3 Interaction

The following interactions were identified *a priori* as these were deemed plausible from the literature:

- Women's education level and below poverty level (BPL) status: Studies suggest that some poorer households are excluded from the BPL status due to errors in inclusion and exclusion criteria, political influence and corruption in India [174–176]; it was theorised that systematic barriers might exist, making it challenging for women with lower levels of education to obtain or apply for BPL status
- Women's education and any of the factors related to behavioural characteristics (smoking status, tobacco consumption, chewing betel nut): Goyal *et al.* [177] observed that smokeless tobacco

and dual usage were highest among uneducated women, and smoked tobacco was highest among women educated up to secondary school

- Age and any of the factors related to behavioural characteristics (smoking status, tobacco consumption, chewing betel nut): According to Lal *et al.* [178], Indian women younger than 30 years were more likely to be past or current smokers
- BPL status and any of the factors related to behavioural characteristics (smoking status, tobacco consumption, chewing betel nut): Goyal *et al.* [177] found Indian women from the poorest quintile (first quintile) had the highest prevalence of smokeless tobacco consumption, while the fourth quintile showed maximum usage of smoked tobacco or were dual users
- Residence and any of the factors related to behavioural characteristics (smoking status, tobacco consumption, chewing betel nut): Gupta *et al.* [179] found that the odds of using tobacco were significantly higher in rural areas and urban slum localities in Haryana, India, however, the residence data recorded in the dataset does not differentiate between urban/suburban residences and urban slums

3.4.4 Software

All analyses were performed using R version 4.2.2 and RStudio 2023.03.0+386 [180].

3.4.5 Ethics approval

The secondary analyses involved de-identified data, and specific ethics approval was not required.

3.4.6 Quantitative methods I: Incidence and risk factors for stillbirths in India

3.4.6.1 Sample selection

All singleton pregnancies where the outcome of the fetus was available were included in this analysis. Women with multiple pregnancies and those with missing fetal outcomes, such as due to loss to follow-up were excluded.

3.4.6.2 Outcome variable

The outcome variable was stillbirth, defined as any fetal death that occurred from 28 completed weeks of gestation [5]. To understand the subtypes of stillbirth, these were categorised into antepartum (before the onset of labour) and intrapartum (during the course of labour and birth) stillbirths. Since there was no specific variable which reported the vital status of the fetus at the onset of labour, stillbirth subtype information was derived from the free text data related to the reasons or indications for caesarean section, induction and augmentation of labour and details of maternal complications and fetal complications. This involved carefully reviewing free text data for any mention of skin maceration, fetal heart rate on admission, or other relevant clinical details, for example, intrauterine death (IUD), to determine whether the stillbirth was antepartum or intrapartum.

3.4.6.3 Missing data

Frequencies of missing data for exposure variables are described in Table 3-4. While there was missing information for some exposure variables, the proportion of missingness was very small: almost all the exposure variables had less than 0.4% missing data, and even the variables with the highest proportion of missing information (which were body mass index (BMI) and smoking status) had less than 4% missing. Therefore, the missing data were presumed to be missing at random, and a complete case analysis was conducted.

Table 3-4. Frequencies of missing data of exposure variables

Variables	N (%)
Urban/rural	0 (0.0)
Women's education level	33 (0.3)
Religion	0 (0.0)
Below poverty line (BPL) status	0 (0.0)
Smoking status	367 (3.7)
Tobacco consumption	0 (0.0)
Chewing betel nuts	0 (0.0)
Number of antenatal check-ups	0 (0.0)
Duration of iron and folic acid (IFA) supplementation	0 (0.0)
Women's age	0 (0.0)
Parity	0 (0.0)
Stillbirth/miscarriage history	15 (0.2)
History of caesarean sections	24 (0.2)
Pre-existing medical problems	1 (<0.1)
Body mass index (BMI) category for South Asian	387 (3.9)
Severity of anaemia	0 (0.0)
Hypertensive disorders of pregnancy (HDP)	0 (0.0)
Gestational age at birth	1 (<0.1)
Fetal sex	0 (0.0)
Birthweight for gestational age	34 (0.3)

3.4.6.4 Descriptive statistics

Frequency distributions for categorical exposure variables and the median and interquartile range for continuous exposure variables were compared between stillbirths (overall, antepartum, and intrapartum) and live births. Maternal and fetal characteristics between overall stillbirths and live births were compared using a t-test for normally distributed continuous variables, a non-parametric Wilcoxon rank sum test for not normally distributed continuous variables, or Pearson's chi-squared test for categorical variables.

3.4.6.5 Overall stillbirth rate and confidence interval (CI)

The overall stillbirth rate and a 95% confidence interval (CI) per 1,000 total births were calculated using the stillbirths and live births recorded in the cohort study. The 95% CI was calculated using Ulm's method [181], which provides exact confidence limits by using the relationship between the Poisson and chi-squared distributions.

3.4.6.6 Statistical analysis

Univariable analysis using modified Poisson regression was conducted to assess unadjusted associations between each exposure variable and the outcome. Then, multivariable modified Poisson regression models were built to explore adjusted associations. Only variables that were associated with the outcome in the univariable analysis at a p-value of <0.05 overall or within the subgroups were included in the regression models using a hierarchical approach informed by the conceptual framework (Figure 3-4), starting with the structural factors (model 1), followed by intermediate factors (model 2), and proximal factors (model 3).

Modified Poisson regression was selected over logistic regression to estimate relative risks, which provide a more interpretable measure of association in cohort studies. Odds ratios from logistic regression are often misinterpreted as relative risks in cohort studies and tend to overestimate the true relative risk [182,183]. Log-binomial regression was considered as an alternative but was not used due to its potential convergence issues. Additionally, modified Poisson regression has been shown to provide more reliable and unbiased estimates of relative risks, particularly under model misspecification [184].

In accordance with the MaatHRI's agreement with collaborators, any measures of variation between hospitals were not reported to prevent the attribution of blame and misinterpretation, as variations in stillbirth rates are largely due to differences in caseloads. Some MaatHRI hospitals are tertiary referral centres, which manage a higher proportion of high-risk pregnancies and cater to larger populations than other hospitals.

Since the choice of hospital was influenced by the similar factors driving the risk of stillbirth resulting in higher stillbirth rates in tertiary hospitals, including hospital as a fixed effect in the regression models would not appropriately adjust for these differences. Instead, it could potentially introduce bias by adjusting for a collider in the hypothesised relationship between risk factors, hospital, and the outcome

between risk factors, hospital and the outcome. Therefore, hospital was not included as a fixed effect in the regression models.

The plausible interactions identified *a priori* were tested in the multivariable analysis if the variables were included in the multivariable models and the p-value was <0.05. Multicollinearity was tested using the variance inflation factor (VIF). Variables with a value of VIF five or more were not included in the same model. All associations were reported as relative risks (RRs) or adjusted RRs (aRRs) with 95% CIs and p-values. A two-tailed p-value <0.05 was considered to be statistically significant.

While Victora *et al.* [161] suggested assessing the effects of structural factors before adjusting for intermediate and proximal factors (model 1), the results of the fully adjusted model (model 3) were emphasised in the interpretation. This approach was chosen to align with the overarching aim of the thesis, where findings from the quantitative analyses were intended to support the activity of prioritising which stillbirths to review. By presenting all three models using a hierarchical approach informed by the conceptual framework, it was also possible to observe how relative risks of structural factors changed as intermediate and proximal factors were sequentially included, providing insight into how the effects of structural factors on stillbirth risk may be mediated through potentially modifiable intermediate and proximal factors.

3.4.6.7 Area under the receiver-operating characteristic (AUROC) curve

Model discrimination was assessed using the area under the receiver-operating characteristic (AUROC) curves.

3.4.7 Quantitative methods II: risk factors for intrapartum stillbirths in India and survival probabilities of fetuses by gestational age

The methods for further analysis of the same data set were guided by the findings of the exploratory quantitative analysis (results from overall stillbirth analysis summarised in Chapter 4). There was a high

proportion of intrapartum stillbirth (78%), and a certain period of gestational age at birth was a significant risk factor for overall stillbirth. While the analysis was conducted for both subgroups of stillbirth (antepartum and intrapartum), this further analysis (Chapter 5) focused on intrapartum stillbirth since the risk factors for intrapartum stillbirths were more likely to be relevant for a facility-based stillbirth review in terms of management and care at an appropriate time (gestational age) and quality.

3.4.7.1 Sample selection for intrapartum stillbirth analysis

All singleton pregnancies where the outcome of the fetus was available and known to be an intrapartum stillbirth were included in this analysis. Women with multiple pregnancies, those with missing fetal outcomes or gestational age and women who had an antepartum stillbirth were excluded.

3.4.7.2 Outcome variable

The outcome variable was intrapartum stillbirth, defined as any fetal death that occurred from 28 completed weeks of gestation after the onset of labour [5]. While the diagnosis of intrapartum stillbirth ideally requires confirmation of fetal heart rate at labour onset, the WHO guidelines indicate that skin appearance (absence of maceration) can serve as a proxy where fetal heart monitoring is unavailable or when labour begins before arrival at a health facility. Given the lack of specific data on fetal status at labour onset, details about stillbirth subtypes were again inferred from the free-text data related to the reasons or indications for caesarean section, induction and augmentation of labour and details of maternal complications and fetal complications. For example, free-text data were reviewed for mentions of skin maceration, fetal heart rate on admission, or IUD to classify stillbirths as antepartum or intrapartum.

3.4.7.3 Missing data

Similar to the exploratory quantitative analysis (described in the above section 3.4.6.3), the proportion of missingness was very small (Table 3-5) and not likely to be influenced by the outcome of interest.

Therefore, the missing data were assumed to be missing at random, and a complete case analysis was conducted.

Table 3-5. Frequencies of missing data of exposure variables

Variables	N (%)
Urban/rural	0 (0.0)
Women's education level	33 (0.3)
Religion	0 (0.0)
Below poverty line (BPL) status	0 (0.0)
Smoking status	364 (3.7)
Tobacco consumption	0 (0.0)
Chewing betel nuts	0 (0.0)
Number of antenatal check-ups	0 (0.0)
Duration of iron and folic acid (IFA) supplementation	0 (0.0)
Women's age	0 (0.0)
Parity	0 (0.0)
Stillbirth/miscarriage history	15 (0.2)
History of caesarean sections	24 (0.2)
Pre-existing medical problems	1 (<0.1)
Body mass index (BMI) category for South Asian	386 (3.9)
Severity of anaemia	0 (0.0)
Hypertensive disorders of pregnancy (HDP)	0 (0.0)
Gestational age at birth	0 (0.0)
Fetal sex	0 (0.0)
Birthweight for gestational age	34 (0.3)

3.4.7.4 Descriptive statistics

Frequency distributions for categorical exposure variables and the median and interquartile range for continuous exposure variables were compared between intrapartum stillbirths and live births. Maternal and fetal characteristics between intrapartum stillbirths and live births were compared using a t-test for normally distributed continuous variables, a non-parametric Wilcoxon rank sum test for not normally distributed continuous variables, or Pearson's chi-squared test for categorical variables.

3.4.7.5 Intrapartum stillbirth rate and confidence interval

The intrapartum stillbirth rate and 95% CI per 1,000 total births were calculated using the intrapartum stillbirths and live births recorded in the cohort study (excluding antepartum stillbirths). The 95% CI was calculated using Ulm's method [181], also described in 3.4.6.5.

3.4.7.6 Statistical analysis

The same method (modified Poisson regression) and modelling approach used in the overall stillbirth analysis (see 3.4.6.6) was first applied to identify the risk factors for intrapartum stillbirth. When building the modified Poisson regression models, multicollinearity was tested using the VIF, and variables with a value of VIF of five or more were not included in the same model.

Significant risk factors, specifically complications potentially modifiable by clinical interventions were then identified from the modified Poisson regression results and selected for time-to-event analysis. This analysis aimed to explore how intrapartum stillbirth risks associated with these conditions evolved throughout pregnancy (while censoring for preterm live births), with a particular focus on the timing of intrapartum stillbirth as per gestational age. To achieve this, the Kaplan-Meier survival curves were estimated to examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age.

This time-to-event analysis using Kaplan-Meier survival curves complemented the results from the modified Poisson regression models, which provided relative risks to identify intrapartum stillbirth risk factors. While the relative risks offered a snapshot of the overall likelihood of an intrapartum stillbirth occurring by the end of pregnancy (cumulative risk), it did not provide information on the specific gestational age at which intrapartum stillbirths occurred. Given that interventions for certain complications, such as preeclampsia, can involve induction of labour before term or early term rather than expectant management, it was important to investigate whether interventions at specific gestational ages for high-risk conditions could reduce the risk of intrapartum stillbirth. Therefore, Kaplan-Meier survival curves were used to graphically visualise how survival probabilities of fetuses evolved throughout pregnancy for women with complications. Preterm live births were censored at birth when plotting the Kaplan-Meier survival curves as recommended for stillbirth analysis [185–187].

All associations were reported as relative risks (RRs) or adjusted RRs (aRRs) for the results of the modified Poisson regression with 95% CIs and p-values. A two-tailed p-value <0.05 was considered to be statistically significant.

3.4.7.7 Antepartum stillbirth analysis

For the antepartum stillbirth analysis, the same methods employed in the intrapartum analysis were used but with antepartum stillbirth as the outcome variable. The sample selection hence excluded intrapartum stillbirths instead of antepartum stillbirths. Modified Poisson regression models and time-to-event analysis using Kaplan-Meier survival curves were employed. This analysis was conducted to explore potential differences in risk factors for antepartum stillbirths compared with risk factors for intrapartum stillbirths.

3.5 Qualitative study methods

As shown in Figure 3-1, the qualitative component of the mixed method study involved two study designs: a multiple case study and FGDs. The multiple case study design addressed Objective 4 and the FGD study design addressed Objective 5 of the thesis:

- Objective 4: To explore and compare the structure and processes of facility-based stillbirth reviews in secondary and tertiary hospitals in India
- Objective 5: To identify facilitators and barriers to implementing or sustaining facility-based stillbirth reviews as reported by Indian healthcare professionals (HCPs)

3.5.1 Ethics approval

Ethics approval was sought and received from OxTREC, University of Oxford, UK (OxTREC reference: 539-23). An ethics approval waiver was also received from the local collaborators from each participating hospital. The collaborators reviewed the research proposal and confirmed that, following the Indian Council of Medical Research (ICMR) ethical guidelines, ethics approval was not required. Written

informed consent was obtained from all FGD participants using the consent form in Appendix F. The study was deemed to be of minimal risk to participants.

It was important that any ethical issues were identified and mitigated prior to the study. I identified that it could be inconvenient and unethical for FGD participants to give 1-2 hours of their professional time at the hospital to participate in the study, especially if they were participating in two FGDs (FGDs component of the multiple case study and the other qualitative study in this thesis – facilitators and barriers study – that used FGD study design). Not considering this issue meant I would be asking for prolonged access to their professional time on one or more occasions without any compensation. Therefore, I prioritised participants' availability in terms of minimal impact on their professional duties while scheduling the FGDs, and I also chose specific questions that are relevant to my research objectives, which were not anticipated to exceed the 90 minutes allocated. I also identified that participants may find talking about stillbirths upsetting, especially if they or a loved one has had a stillbirth. Therefore, I undertook specific training to understand how to respond if the participant looked distressed or emotional during the FGDs. Also, before the FGD began, it was made clear that FGD participants would be free to ask the researcher to pause or stop the FGD at any time as per the distress policy written in the participant information sheet (Appendix G and H).

Cultural considerations were one of the main ethical issues identified with respect to this study. I attempted to mitigate these issues with the following measures:

- Differences in cultural background between facilitator and participants: I chose to use FGD design rather than a 1:1 interview design for two reasons. First, a stillbirth review itself involves a group discussion, and FGDs closely mirror this dynamic, which I wanted to explore and compare. Second, because I had a different cultural background compared to the participants (positionality as a researcher is described in section 3.5.5.2), I believed that FGDs can also tap into a natural discussion, social or group norms and public (rather than personal) accounts as participants work in the same field (obstetrics) and may feel familiar with talking about stillbirth prevention [188–190], making FGDs an appropriate format despite cultural differences. This

choice was also informed by Guest *et al.*'s [188] study, which found that personal and sensitive disclosures were more likely to occur in FGDs than in 1:1 interviews. The authors noted that one factor could be the data collector's demographics – a White woman – while the participants were typically older African American men. They suggested that participants might have felt more comfortable revealing personal and sensitive information in a group setting among individuals with similar cultural backgrounds, compared with a more intimate 1:1 context with an interviewer of a different gender and cultural background [188].

- Communication, including using local language: There was a notetaker at each FGD who provided support with communication if needed. I was informed during the planning stage that English is the spoken language preferred by all clinicians and hospital or programme managers who would be approached to participate in the FGDs and the panel of stillbirth review meetings where I was going to conduct non-participant observation.

In addition to the participant information sheet, an arrangement was made so that the MaatHRI Project Manager and collaborators were available to answer any research-related questions, including about participants' rights, and to provide local support for any interested participants.

3.5.2 Qualitative methods I: exploring current stillbirth review processes in India

3.5.2.1 The multiple case study design

A case study's central tenet is to explore an event or phenomenon in depth in its natural context [191]. For the purpose of this study, Stake's [192] definition of a case study was used:

> *"A case study is both the process of learning about the case and the product of our learning" (p.237).*

As identified in the literature (Chapter 2), stillbirth review processes vary in approach and scope even within the same country, and these variations are natural since different contexts exist in which the

process is being implemented and sustained. Therefore, to explore and compare the structure and processes for facility-based stillbirth reviews in secondary and tertiary hospitals in India, the study design had to facilitate an in-depth and exploratory approach which also allows potentially unexpected themes and topics to emerge, as well as themes and topics that were hypothesised to emerge according to the evidence synthesised from the literature (see 2.4.11 in Chapter 2). The case study design employing multiple data sources (document analysis, non-participant observation and FGDs) enabled an in-depth understanding of each case (in this instance, a particular hospital delivering maternity care and conducting stillbirth reviews) and the semi-structured methods and inductive nature of the data analysis allowed for capturing information about more explanatory 'how', 'what' and 'why' questions.

The multiple case study approach involves learning about more than one case, either simultaneously or sequentially, to generate a broader understanding of a particular process [191]. It also supports understanding the differences and similarities between cases and what factors influence these differences and similarities. As it was important that different structures and processes of facility-based stillbirth reviews in different hospitals were all recognised and studied in depth so different ways of workings were appropriate and, a decision was made to employ a multiple case study rather than a single case study approach.

3.5.2.2 Defining the case

In this study, a case was defined as a secondary or tertiary Indian hospital currently conducting stillbirth reviews, which is referred to as the unit of analysis (the case) to explore the 'research problem' [193]. Simons [193] also explains that it is useful to consider the boundaries of the case when defining it, for example, people, policies, and histories that extend beyond physical location. Therefore, the boundaries of the case in this instance were established as follows:

- People: any HCP or staff associated with any of the activities of stillbirth review
- Process: tools or guidelines, activities involved, as well as history and motivations of those who participate in the stillbirth review process

- Structure: job roles involved in the process, how the discussions are facilitated in the meeting, meeting atmosphere or conduct

3.5.2.3 Sampling of hospitals

A purposive and convenience sampling method was used for the multiple case study design. First, all MaatHRI hospitals were approached with information about the aim and objectives of the study. Second, hospitals were sampled using two inclusion criteria:

- Currently conducting stillbirth review (purposive)
- Feasible for an observer to attend the review meeting (convenience)

The number of cases is carefully selected in multiple case studies [191]. Initially, four hospitals indicated their interest in participating in the case study, explaining they were currently conducting stillbirth reviews and that it was feasible for an observer to attend the review meeting; two hospitals were from the same state, and two hospitals were from two other states. However, even before further thought was given to understanding how each case would be different geographically and culturally and would affect the process practised in real-life settings [193], it was found that one of these hospitals did not conduct stillbirth reviews. Instead, it conducts a neonatal mortality review. Therefore, it was concluded that all three hospitals that met the inclusion criteria of sampling of hospitals and volunteered would be included, and each of these hospitals would become a case in the multiple case study. From here on, I will refer to these hospitals as Hospital A, B, and C instead of Case A, B, and C.

As described in Table 3-6, without imposing any additional criteria for case selection, each hospital included in this study was found to be unique. The diverse characteristics of each hospital enabled an understanding of how stillbirth reviews are performed in each hospital type and what challenges each may face due to the different levels of stillbirth burden and staff capacity. Also, in Hospital A, in particular, the stillbirth review process started in 1977, and variations in case characteristics allowed comparison with newer review processes (Hospital B and C).

Table 3-6. Case characteristics

	Case		
	Hospital A	**Hospital B**	**Hospital C**
Hospital type	Tertiary – government	Secondary – government	Tertiary – private
Annual births (2022)	8,344	1,664	2,096
Stillbirth rate per 1,000 total births (2022)	16.5	16.8	2.0
Number of doctors in obstetrics and gynaecology (2022/2023)	20	6	14
Number of obstetrics and gynaecology nurses (2022/2023)	42	8	11
Year stillbirth review started	1977	2023	2019 (stopped during Covid-19 and restarted in 2022)
Frequency of stillbirth review meetings	Weekly	Monthly	Every two weeks

3.5.2.4 Data sources and collection

Since the aim of adopting a case study approach is to develop a thorough understanding of the case, the case study approach usually employs multiple data sources. An underlying assumption is that if diverse data sources are used [194], it allows researchers to develop a holistic picture of the event or process. This study's multiple case study used three of the most common data sources employed in case studies [192,193]: document analysis, observation and FGDs.

For the document analysis, documents relating to stillbirth review, such as tools or guidelines, were requested from each hospital. Prior to this, formal permission to review the documents from each hospital was sought and the document analysis worksheet (Appendix I) was given to each hospital, so both the researcher and the hospital could proactively go through the list together. This practice ensured that relevant and reasonably accessible documents were provided for the case study. This process started as soon as the hospital sampling process was completed, so if needed, any physical copies could be given when the researcher visited during the fieldwork and added to the list of documents.

For the observation element, I sought formal permission to observe the stillbirth review meetings from each hospital before I attended the meeting as a non-participant observer. I asked how often each hospital conducts its stillbirth review, then planned my fieldwork accordingly so I was able to observe all three hospitals' stillbirth review meetings. The fieldwork was conducted in August 2023, and observations were conducted between the 3-9 August 2023.

There were several reasons for selecting the non-participant observation method. Firstly, I was not part of any of the hospitals or an HCP in any setting, but a Doctor of Philosophy (DPhil) student interested in this topic. This means I had limited access to the stillbirth review meetings and certainly had no opportunity or skills to engage in participant observation as a panel member. By being a non-participant observer, I was able to take a neutral position within the setting and record what I observed without interacting directly with the review panel.

Second, I was not interested in my subjective experiences during the meeting *per se*, and the research focus was purely on the structure and process of stillbirth review meetings of each hospital. It was important that I was able to explore all dimensions of the event, including panel composition, space and materials used in the meeting, attendance, and panel member's behaviours, interactions between panel members, and the atmosphere and conduct of the meeting. To do this, I used an observation guide as a helpful aid when attending the stillbirth review meetings as a non-participant observer (Appendix J), although it was used as a flexible framework and not as a rigid checklist. To remind myself, I made a note at the top of the guide that I was to observe the meeting holistically, capturing important details and nuances. Rather than focusing on ticking off items from a list, I endeavoured to engage in active listening and to carefully observe the process.

To document my observations, I made free-text notes. This means I was writing in my own words and using descriptive language to convey my observations accurately. As soon as the observation concluded, I also took some time for personal reflection. These reflections involved capturing my thoughts and impressions about the meeting on paper.

The non-participant observation was overt in nature, which meant the panel members (study subjects) knew I was observing their meeting. This was to ensure I was transparent about my study to the review panel when explaining my attendance at their stillbirth review meeting. However, the limitation of this method is that it can affect how participants act in front of the observer, and thus the meeting being observed does not necessarily reflect true real-life practices [195]. Therefore, when I entered the meeting space, I introduced myself as an observer–researcher to all participants in the meeting using truthful, concise, and understandable local terms intended to avoid alarm or cause offence. For example, I was clear to the participants that I am a postgraduate student (not a government official) who wants to learn about how stillbirth reviews are being conducted in India. I also acknowledged the sensitivity of the topic and assured the participants that my intention in this study was to contribute positively to the field. I also talked about what will happen to the data, how it will be stored and how I will protect the confidentiality of what participants have said (which were also written down in the participant information sheet). For each hospital, I asked the review panel where they prefer me to sit. I mentioned that I could sit in a corner or at the side of the table to minimise disturbance and also to ensure I had a clear view of the meeting. I sought to be flexible wherever I could to reduce any discomfort that was associated with observation.

FGDs were conducted to explore the stillbirth review process with HCPs and staff involved in stillbirth reviews, especially areas that cannot be observed from the meeting or need further explanation to understand why certain structures or processes are used. It was a conscious decision to use FGDs rather than a 1:1 interview as one of the data sources in this study because the stillbirth review itself involves a group discussion, and FGDs were thought to closely resemble a stillbirth review process, which I wanted to explore and compare. So, it was also a tool to compare what was observed with what was discussed in the FGD. In addition, the culture within the hospital can play an important role when discussing stillbirth prevention or any activities related to it (including stillbirth review) and knowing I am a non-Indian, non-medic researcher, it was important that differences in culture and societal norms between the participants and me were addressed, and it was concluded that FGDs would be the most appropriate

approach to do so. Further reflection on my positionality and how it influenced being a non-participant observer and a facilitator of FGDs are discussed in sections 3.5.5.2 and 3.5.5.3.

For the recruitment of FGD participants, all members of the stillbirth review panel were invited to participate and were provided with information about the study's aim and objectives through the participant information sheet sent four weeks before the fieldwork. The information was also verbally communicated during previous MaatHRI meetings and immediately after the meeting observation. From those individuals who indicated their interests, those who were willing and available when the FGD was conducted were invited to participate. FGDs were planned to be carried out on the same day after the non-participant observation of the review meeting. However, for one hospital, that was not possible, and the FGD had to be carried out online in October 2023.

In total, 20 FGD participants were included in the multiple case study, with one FGD per hospital, each including 6 to 8 participants. The three hospitals in the multiple case study also agreed to participate in a second qualitative study (facilitators and barriers study, see 3.5.3) that used the FGD study design, and participants in the FGD component of the multiple case study also agreed to participate in the other study. As described in 3.5.1, it was thought to be inconvenient and inappropriate for FGD participants to give more than 90 minutes of their professional time at the hospital to participate in the study on more than one occasion, so this issue was mitigated by facilitating the FGD to address the aims of both studies. Therefore, the FGD topic guide (Appendix K) included questions to meet both study objectives. For the multiple case study's objectives, the topic guide focused on perceptions of stillbirth review, how the meetings are organised, how the cases are selected and discussed, and how generated learning from the reviews is used.

3.5.3 Qualitative methods II: facilitators and barriers to implementing or sustaining facility-based stillbirth reviews in India

3.5.3.1 Focus group discussion study design

Similar to the rationale of using FGDs rather than 1:1 interviews in the multiple case study, FGDs were used to address the aim of this study as FGDs produce insights and data from the interaction between participants. The aim of this study was to understand HCPs' knowledge and perceptions of stillbirth reviews and FGDs were chosen as the methodology because they allow for the exploration of participants' attitudes, feelings, beliefs, experiences, and reactions in a way that may not be possible through other methods such as 1:1 interviews [188–190]. It was anticipated that these attitudes, feelings, and beliefs would be more likely to emerge through the social dynamics and interaction inherent in a focus group setting.

However, similar to 1:1 interviews, any discussion-focused qualitative method can have barriers to active and easy interaction [196]. To mitigate these potential barriers, I undertook an introduction to qualitative research methods training a few weeks before conducting and facilitating the FGDs. As mentioned above, reflections on the positionality and being a facilitator of the FGDs are discussed in 3.5.5.2 and 3.5.5.3.

3.5.3.2 Sampling of participants

The hospital staff involved in obstetric care or the stillbirth review process at MaatHRI hospitals were informed about the study's aim and objectives through the participant information sheet, shared four weeks before the fieldwork, and via verbal communication during earlier MaatHRI meetings. It was important for this study to have an equal number of FGDs with participants from hospitals that do not currently conduct stillbirth reviews, as well as with participants from hospitals that currently do so. This was done to ensure that any common and different themes between the two groups could be identified and also to achieve maximum variation of experiences.

Purposive sampling was used to select participants for the FGDs from those who were interested in participating. For hospitals with established stillbirth review processes, panel members were prioritised, while for hospitals without such processes, key stakeholders who would be responsible for establishing and conducting stillbirth reviews were prioritised. Those who did not consent to participate or were unavailable during the scheduled FGDs were excluded. The MaatHRI Project Manager and collaborators were key to recruitment of participants.

3.5.3.3 Data collection

One FGD per hospital with a total of eight FGDs were conducted between August and October 2023. Three of these FGDs were conducted online, while five were conducted face-to-face. Two of the online FGDs were planned to be conducted virtually due to safety concerns in the area that prevented me from travelling alone. Additionally, one FGD was originally planned to be conducted in person, but this was not possible on the day, so an online FGD was conducted at a later date.

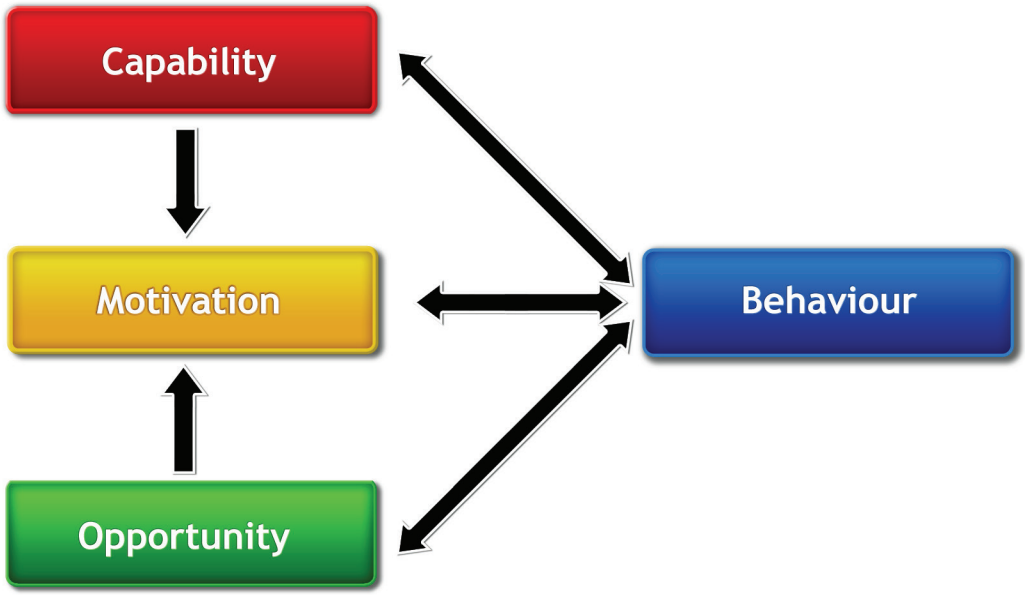
An FGD topic guide was developed and used to help facilitate the discussions. The guide included in Appendix K was used for FGDs in hospitals that currently conduct stillbirth reviews, and the guide in Appendix L was used for hospitals that do not conduct stillbirth reviews. As described above, the FGD topic guide for hospitals that currently conduct stillbirth reviews (Appendix K) featured additional targeted questions for this qualitative study in addition to the FGD questions for the multiple case study in order to consolidate two FGDs into a single session. This consolidation aimed to minimise the number of FGDs required for participants eligible for both qualitative studies involved in this thesis (a total of two qualitative studies). The specific focus of the topic guide in addressing the study's objectives centred on exploring facilitators and barriers to the implementation or sustainability of stillbirth reviews within the context of India.

3.5.3.4 Capability, opportunity, motivation and behaviour (COM-B) model and the Behaviour Change Wheel

The stillbirth review itself is essentially a tool for hospitals to obtain information about where care, which, had it been different, may have resulted in a different outcome for the baby, and to build recommendations for actions for implementation to improve care in the future and thus reduce the risk of future stillbirths. It serves as a potent tool for quality improvement, empowering HCPs to assess their hospital's care quality and monitor changes over time [197]. However, there could be difficulties in identifying eligible stillbirths to review because there might be inadequate data sources, inconsistent definitions of stillbirth, or HCPs may not have information about which patient group to focus on in each meeting or gathering data for the review because case notes or any additional information gathered postpartum are inadequate to conduct a robust review. In addition, the stillbirth review meeting itself might have challenges because not all required job roles are represented by the panel members or staff are not interested in participating; the panel members may not understand how to examine the quality of care, reasons for suboptimal care or analyse the data to convert information collected into meaningful learnings.

Implementing stillbirth reviews in hospitals requires a system-wide change addressing facilitators and barriers to implementing or sustaining stillbirth reviews at all levels (community, HCPs, facility and policy). Willcox *et al.*'s [51] systematic review of qualitative studies that documented stakeholders' experiences of implementing Maternal and Perinatal Death Surveillance and Review (MPDSR) in low-and-middle-income countries (LMICs) utilised the COM-B model (Figure 3-5) to understand the determinants of behaviours influencing MPDSR implementation in LMICs and the Behaviour Change Wheel (Figure 3-6) to plan interventions to improve its implementation [198,199].

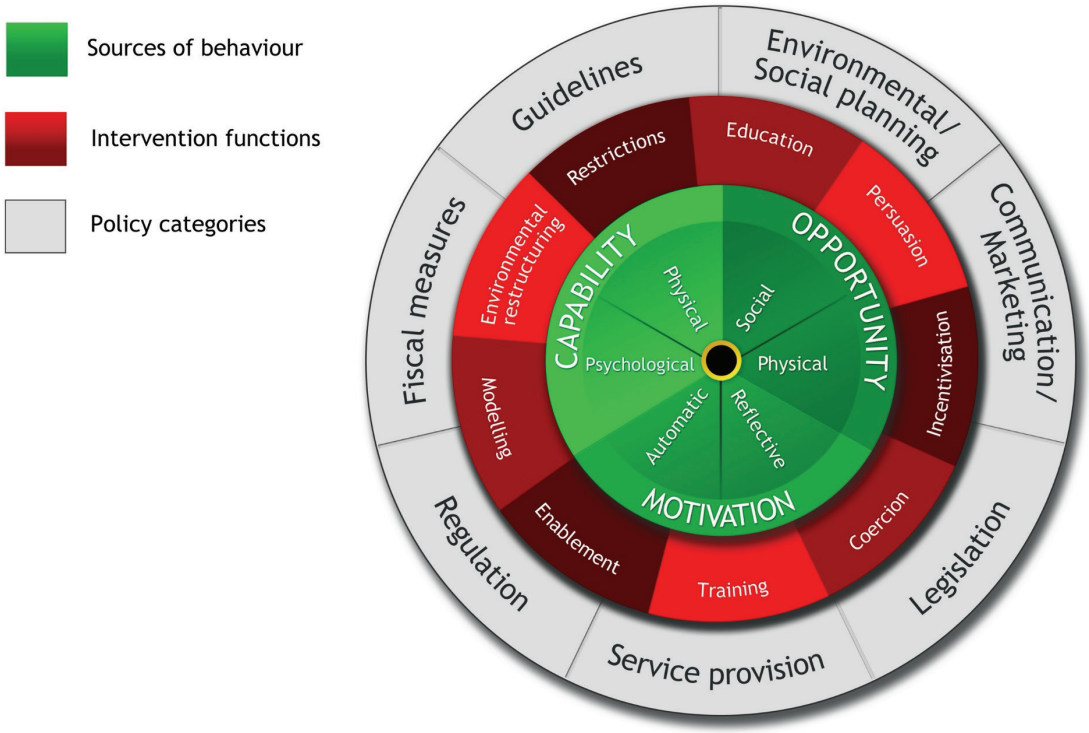
Figure 3-5. Capability, opportunity, motivation and behaviour (COM-B) model by Michie *et al.* [198]



Copyright statement: this diagram is distributed under the terms of the Creative Commons CC BY license, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Similarly, this study utilised the COM-B model to identify facilitators and barriers to implementing and sustaining facility-based stillbirth reviews in India, and the Behaviour Change Wheel to identify actionable interventions by linking these facilitators and barriers to the Behaviour Change Wheel intervention functions.

Figure 3-6. The Behaviour Change Wheel by Michie *et al.* [198]



Copyright statement: this diagram is distributed under the terms of the Creative Commons CC BY license, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

The definitions for the COM-B domains used in this study were adapted from Willcox *et al.*'s [51] systematic review of qualitative studies, along with the original definition used for broader policy research by Michie *et al.* [198,199].

- Capabilities: the knowledge and skills required at the community, facility, and policy levels to implement and sustain stillbirth reviews in hospitals.
- Opportunities: all external factors (physical and social) at the community, facility, and policy levels needed to implement and sustain stillbirth reviews in the hospitals. This domain was sub-categorised into physical opportunities and social opportunities.
    - Physical: environmental context and resources such as time, data, location and resources used in stillbirth reviews
    - Social: social influences such as cultural norms and social cues within the hospital or wider Indian context

- Motivation: all factors that energise or influence the internal processes at the community, facility, and policy levels to implement and sustain stillbirth reviews in their hospitals. This domain was sub-categorised into automatic motivation and reflective motivation.
    - Automatic: habitual processes and emotional responses such as desires, impulses and inhibitions
    - Reflective: conscious, analytical decision-making such as making plans and evaluating things that have already happened

Table 3-7 outlines the definitions for the Behaviour Change Wheel intervention functions referred to in this study, which were taken from Michie *et al.* [200].

Table 3-7. The Behaviour Change Wheel intervention function definitions [200]

Intervention function	**Definition**
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means or reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)

Copyright statement: Permission is granted for tables to be reproduced from the book [200] provided that the source is properly acknowledged. This table is extracted from: Michie S, Atkins L, West R. (2014) The Behaviour Change Wheel: A Guide to Designing Interventions. London: Silverback Publishing. www.behaviourchangewheel.com.

3.5.4 Data analysis

For the multiple case study, three types of data sources were collected: documents related to the stillbirth review process (including tools and guidelines), notes from observations of stillbirth review meetings, and recordings of FGDs. As Crowe *et al.* [191] noted, "making sense and offering a coherent

interpretation of the typically disparate sources of data is far from straightforward" when conducting a multiple case study. This challenge was also evident in my study, where providing an in-depth understanding of each case and exploring differences and similarities between cases required a tailored analytical approach to integrate findings across the three data sources. Initially, the Framework Method [201] was selected for all three data sources. However, it became apparent that document analysis required a different approach than that used for observation and FGD data. Therefore, document analysis was conducted using the READ approach [202], which was more better suited for examining documents, while the Framework Method was applied to both observation notes and FGD transcripts. In multiple case study research, synthesising and coherently interpreting diverse data sources is complex, and there is no standard format for the analysis process. This flexibility allowed me to adopt a pragmatic approach, selecting the most appropriate methods to integrate data sources effectively. For the facilitators and barriers study, where only FGD data was collected, the Framework Method was employed using an analytical framework specific to this study, separate from the framework used for the multiple case study.

3.5.4.1 Document analysis: the READ approach

The READ approach is a systematic method for conducting document analysis in health policy studies at any level (global, national, local) [202]. It consists of four steps:

1. Ready your materials
2. Extract data
3. Analyse data
4. Distil your findings

The READ approach to document analysis was selected to analyse documents relating to stillbirth review (such as tools or guidelines) in the multiple case study because it was envisioned that while facility-based stillbirth review process guidelines exists at the national level in India [6], each hospital would adopt a unique process that is aligned to their aim and objectives of the stillbirth review, available resources in

their hospital and the burden of stillbirth in the population they care for. Therefore, since the READ approach can be adapted to accommodate many types of research questions and can be used in any level of setting, it was an appropriate method for document analysis for the multiple case study. In addition, the READ approach was the only specific guidance that provides systematic, step-by-step procedures to help researchers analyse documents with rigour [202].

For the first step, 'ready your materials', the READ approach explains, "researchers must set parameters in terms of the nature and number of documents they plan to analyse, based on the research question" [202]. Hence, the document analysis worksheet (Appendix I) was used as a tool to ensure relevant documents were sent to me in a reasonable timeframe. Also, this worksheet helped track and follow up on missing documents with each hospital easily. Most hospitals sent the documents as scanned hard copies or digital copies, and these digital files were then renamed using the file-naming system for the documents. Box 3-1 below shows an example of how a file was renamed using the agreed file-naming system.

Box 3-1. File-naming system for document analysis

Hospital ID: B
Document number: 7
Document name: Labour room register
Date: No date

File name: B.7.LabourRoomRegister_Nd

The second step, 'extract data', involves extracting relevant data from each document, ranging from basic data such as document title, author, and date to conceptual data such as the type of stillbirth data collected (if the document is a proforma for stillbirth data collection), the definition of stillbirth used (in the case of stillbirth review guidelines), the intended audience of the document, any critical points raised (in the case of meeting minutes), and summary of key document analysis findings significant to the research objectives. For this step, as advised by Dalglish *et al.* [202], I used an Excel spreadsheet with each row representing a document and each column representing a category of information to extract. The extraction process started by reading and highlighting relevant data for each category of data extraction, while noting down any questions as 'memos' so I could review the document again in detail

to find any new information I may have missed initially. I also utilised Indian government websites (both national and state levels) to verify if any of the documents originated from these sources, as some of the documents were the forms used for vital statistics reporting in India.

During the third step, 'analyse data,' I examined the similarities and differences in documents across three hospitals. I identified which hospitals had documents unique to their hospital (e.g. local guidelines for stillbirth review), which documents were used to report stillbirths for the purpose of Civil Registration System, and which document types were only available at certain hospital and why the other hospitals did not have these document types. This step also involved categorising documents into those that exist due to the stillbirth review process and those that exist regardless of the stillbirth review process because they are for routine health records or for the purpose of Civil Registration System.

The last step, 'distil your findings,' allowed me to refine and summarise the most significant findings from within and between the documents I reviewed. The outputs from this step formed part of my results chapter of the multiple case study (Chapter 6).

3.5.4.2 The Framework Method

To analyse the FGD transcripts and observation notes, I followed Gale et al.'s [201] guide to the Framework Method:

1. Transcription
2. Familiarisation with the interview
3. Coding
4. Developing a working analytical framework
5. Applying the analytical framework
6. Charting data into the framework matrix
7. Interpreting the data

The Framework Method is a qualitative analysis approach that is part of thematic or content analysis. It can be applied inductively, deductively, or using a combined approach. It enables researchers to identify similarities and differences in data, which are then used to understand the relationships and draw descriptive or explanatory conclusions around identified themes. The method was developed by Ritchie and Spencer [203,204] in the late 1980s for large-scale policy research, although it has been widely used in other fields including health research. Three studies also used this method of qualitative analysis to understand the implementation of facility-based death reviews in LMICs [205–207]. The Framework Method's distinctive feature is a matrix output with rows (cases), columns (codes), and cells of summarised data. By adopting the matrix output, the Framework Method enables researchers to systematically reduce and analyse data by case and code.

In the first stage, 'transcription', an approved third-party transcription company was contracted to transcribe the eight FGD recordings. The transcripts were produced using the 'intelligent verbatim' method, which captures the full content of the FGD recordings while omitting filler words such as 'ums' and 'ers' and acknowledgements such as 'mm-hm', unless they indicate hesitation or a response to a direct question. Stuttered, short, or restarted sentences were excluded unless their omission would obscure the meaning, whereas basic non-verbal cues, such as [pause] and [laughs], were included.

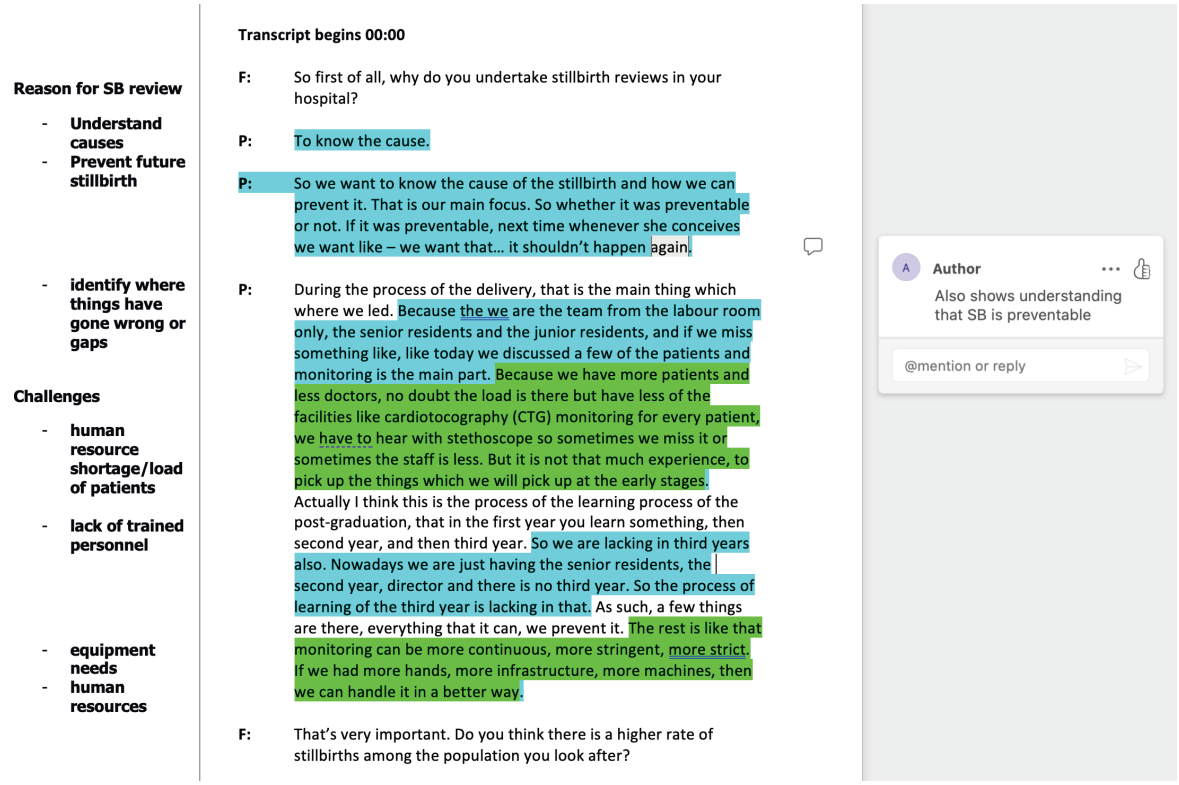
Once the transcripts were returned, I reviewed them for errors by comparing them with the original FGD recordings. Any errors identified were corrected, and names or acronyms were either spelt out or redacted using square brackets (e.g. '[name]'). Participants were also asked to review the transcripts for errors and provide tracked changes. Out of the eight hospitals, one requested minor changes, while the others reported no corrections.

In the second stage, 'familiarisation with the interview,' I thoroughly read and re-read each transcript and listened to the recordings to become familiar with the data. Two additional coders supported me; although they did not have access to the recordings to maintain confidentiality (as the recordings could contain identifiable voices), they familiarised themselves with the transcripts by reading them multiple

times, as well as reading the observation notes. Both coders have experience in maternal health research and have previously analysed qualitative data. This process was also carried out for the analysis of the observation notes, as for the multiple case study, observation notes were created from non-participant observation of stillbirth review meetings, and these data were also analysed using the Framework Method. During this stage, we highlighted important sentences and discussed them regularly as a coding team. This stage also provided an opportunity to review existing frameworks or theories that could be used for developing the matrix in later stages.

In the third stage, 'coding', three FGD transcripts and three sets of observation notes were independently coded by three coders using an inductive approach. We each highlighted segments of text and assigned codes to describe the content in the left-hand margin. Any memos or reflections were recorded using the comment function in the document. For example, as shown in the excerpt (Figure 3-7), a coder assigned the code 'reason for stillbirth review – understand causes' to segments where participants discussed why they conduct stillbirth reviews in their hospital and that is 'to know the cause'. The coder also noted in the comments that the segment 'it shouldn't happen again' suggests that participants have an understanding that stillbirths are preventable.

Figure 3-7. An excerpt of an inductive coding during 'coding' stage of the Framework Method



In the fourth stage, 'developing a working analytical framework', after three coders had each inductively coded the same three transcripts and observation notes, we met to discuss the codes we had assigned to each segment of the text. Since the three FGD transcripts included data for both the FGD components of the multiple case study and the facilitators and barriers study, discussions were held separately for each study. The first discussion focused on codes related to the structure and processes of facility-based stillbirth reviews, while the second addressed facilitators and barriers to implementing or sustaining these reviews. During the discussion about the structure and processes, codes from the observation notes were also included, as these notes were part of the multiple case study only. Where there were discrepancies in how the codes were assigned between coders, discussions helped the coders determine which terms best captured the meaning of the data and reach a consensus on the label of the code. Following these discussions, the coders developed an analytical framework based on the agreed codes.

In the fifth stage, 'applying the analytical framework', the analytical framework was applied to code the remaining FGD transcripts (five out of eight) and to review the three previously coded FGDs. NVivo

version 14 [208], a computer-assisted qualitative data analysis software, was used for this process. NVivo facilitated faster digital coding and allowed for the merging of coding files from different coders at the end of the process.

When applying the analytical framework, any new codes that emerged that did not fit the existing framework were assigned new codes, following the same process used in the 'coding' stage but with the support of NVivo. These new codes were reviewed to determine whether they could be merged with similar existing codes in the framework or retained as new codes. Conceptually related codes were then grouped into themes. The logic model from the systematic review and the COM-B model served as theoretical frameworks to develop themes from these codes. Thus, while codes were identified inductively, themes were also identified deductively using these theoretical frameworks. The final analytical framework comprised 35 codes clustered into eight themes for the multiple case study and 40 codes clustered into five themes for the facilitators and barriers study.

In the sixth stage, 'charting data into the framework matrix', I summarised the data into a matrix for each theme or code using Microsoft Excel. For the multiple case study, the matrix had one column per hospital and one row per code. For the facilitators and barriers study, the matrix was organised with one column per group (those conducting stillbirth reviews versus those not conducting them) and one row per code.

In the final stage, 'interpreting the data', I sought to move beyond the descriptive data to understand its implications within the hospital(s) and the broader Indian context. This involved consulting relevant literature to explain the observed phenomena and identify areas needing improvement. For the facilitators and barriers study, actionable interventions were also identified using the Behaviour Change Wheel.

3.5.5 Researcher reflection

3.5.5.1 Recruiting hospitals and participants

Despite being a student and conducting this study independently, which could have made it challenging to gain access to hospitals and HCPs, I was able to successfully connect with and obtain consent from many hospitals and their HCPs to participate in my qualitative studies. This was possible, largely due to the pre-existing collaboration (more information about MaatHRI collaboration is in 3.3) that was in place within my department, and specifically because my primary supervisor is the Principal Investigator of this multi-centre collaboration.

Reflecting on what I did well to gain access and recruit hospitals and participants, I believe the most important thing that worked well was that I employed a systematic approach to recruitment. During the first year of DPhil, I conducted a systematic review, which was desk-based work, and it meant I was not in a rush to conduct any fieldwork until this stage was completed. While I did not have clear objectives on which activities I would carry out for this thesis until the systematic review was completed and research questions were refined based on the results, I knew that MaatHRI would be used as a research platform for this study. I attended several MaatHRI events, which provided opportunities for formal and informal conversations about my interests in stillbirth, and I slowly built rapport with the collaborators who then spoke to me about their hospitals. Since stillbirth can be a sensitive topic with lingering stigma and blame, these conversations were a great way to open up opportunities for future participation in my studies.

However, recruiting FGD participants posed further challenges nevertheless, and while the MaatHRI collaborators were more informed and connected about the topic, wider hospital staff were generally not so engaged with MaatHRI, and this caused several questions to arise. Some participants also expressed sudden doubts just before the FGD started because they were afraid that the FGD would find faults in their clinical practice.

To deal with this, it was incredibly helpful to have local MaatHRI collaborators and the Project Manager to support me; they agreed to provide local support for any interested participants, including answering any research-related questions and helping with the recruitment process. Also, when there were participants who were unsure on the day whether to proceed, MaatHRI collaborators and the Project Manager both helped participants feel comfortable by confirming that this study was not an audit or a fault-finding activity.

3.5.5.2 Positionality

India was the very first country in which I conducted fieldwork during my undergraduate studies, and this was a very impactful and positive experience for me, so naturally, I subsequently looked for further research opportunities in India. While these experiences did not directly influence my choice of DPhil topic, my personal history had an undeniable role in shaping my priorities, beliefs, and perspectives as a researcher conducting this study, as well as the pragmatic approach I wanted to adopt when collecting and analysing qualitative data. I also wanted my study to be contextualised to the setting where its outcomes would be applied since I was already a committed believer in the concept that a process or intervention could not work without such contextualisation.

I am not an Indian. In fact, I am from South Korea, not Britain, which is where my University is located. I come from a different culture and environment than the participants, and I do not speak any languages spoken in India other than English. The only shared position between the participants and I was that we were all there to improve the quality of maternity care and to reduce stillbirths in India.

So, when I was analysing the data, it simply did not make sense to me to solely use my subjective views of what counts as 'facilitators' or 'barriers' to implementing or sustaining the stillbirth review. This meant I approached this study with a more objective mindset of what participants reported as being of the utmost importance. This is partially because I felt that I would never really comprehend the burden of

stillbirth in India as fully as an Indian HCP, and some people might argue that what I previously read in the literature and how my own knowledge was formed are somewhat biased.

I am also not an HCP and have never experienced what it means to look after patients and have direct contact with families who have suffered a loss due to stillbirth. I have attended several conferences where parents, some of whom were researchers, shared their experiences, and HCPs shared what it means to be involved in such a tragedy, but in the end, these are not my first-hand experiences, and I will never fully know how such loss feels. This could have been a significant barrier to building trust, and I felt this during some of the FGDs. Some participants, rightfully so, pointed out that I would not understand the pressure a lot of Indian HCPs are under regarding families' physical violence towards them when being informed about stillbirth and the challenges of bringing up the topic of post-mortem examinations compared with the UK setting.

3.5.5.3 Being a facilitator in focus group discussions

Reflecting on my experiences as a facilitator in FGDs and as a foreign researcher, I wish I had more time to build a greater rapport with the potential participants before the FGDs took place. Unfortunately, due to the limitations of my DPhil timeline and funding, I did not have a chance to build trust with the potential participants of the FGD before I travelled to India. While I never once felt unwelcomed by the participants, I thought that my position made some participants feel hesitant to share their very honest opinions with me. Perhaps that was why engaging all participants was often challenging at the start of the FGD. During several sessions, I observed that nurses and junior staff (e.g. postgraduate students, resident doctors) tended to contribute less, particularly at the beginning of the FGD. This may be due to existing hierarchies in the hospital and their reluctance to share thoughts in front of senior staff, as well as with me. However, this did not lead me to doubt my decision to conduct FGDs instead of 1:1 interviews. I believe that they might not have engaged with me at all if the discussion had not been held in a group setting. I noticed that some participants who initially did not contribute opened up in

the latter half of the FGD and gained the confidence to express their opinions, as they realised that everyone else had been contributing honestly.

I also felt that, at times, since the topic of the FGDs is very sensitive, the conversation around stillbirth and post-mortem examination consent sometimes led to discomfort among participants. This led to discussions occasionally veering off-topic; for example, participants started focusing on specific job roles' responsibility for stillbirth, and I had to carefully steer the discussion back to the main aim of the FGD. I felt uneasy when this happened, and I started to feel researcher fatigue during the FGD. I was upset that one of the participants was being blamed for issues related to antenatal care provision and late referrals during the FGD I organised and facilitated. As it was my first time in this situation, I did not know how to manage it in the best way. I sought help from my supervisor and colleagues after this incident. Reflecting back, I believe this event made me stronger. I learned a lot from it, and especially because it happened early on in my fieldwork, it motivated me to practice how to facilitate future FGDs to stay neutral and respectful and complete my planned work effectively. This process also taught me how to manage conflicts in a discussion setting.

One of the cultural challenges I had to navigate was the culture of more than one person talking at the same time. I first noticed this when the recording quality of one of the FGDs was poor because participants were talking over each other, affecting clarity. I soon learned from the Project Manager who was accompanying me to hospitals that this is a common practice in Indian culture and is not considered a negative thing. However, for the sake of recording quality and the need for transcriptions, I started employing clear instructions to participants at the start of the FGD about not speaking when someone else was speaking. This not only improved the quality of the recordings but also encouraged respectful listening among participants.

Despite these challenges, there were also moments of success. In some FGDs, participants were highly motivated and contributed actively, and I think it was because, as more FGDs were completed, I became better at probing at the right time and encouraging responses without making participants feel pressured.

This was the moment when I learned that being an outsider is not always going to be a barrier to facilitating FGDs because skills can be learned. I also realised that I could always work on building rapport with the participants through my voice, facial expressions, and respectful reactions, even if I had no prior interactions with them. The experiences I had as a facilitator certainly taught me that, with open-mindedness and respectful listening, I could overcome initial barriers and connect deeply with people, leading to truly impactful and heartfelt discussions.

3.5.6 Ensuring anonymity in reporting results

Protecting the anonymity of MaatHRI hospitals and participants who took part in my qualitative research while still conveying detailed and accurate accounts of observations and discussions from the FGDs has been one of my top priorities when reporting results. Since MaatHRI is a well-known research collaboration with a searchable online presence, careful decisions were made not to disclose the names of the states where the hospitals are located or include participant details that could allow someone familiar with MaatHRI hospitals and staff to identify the source of a quote. This was especially important for me because of my position as a researcher and how poorly thought-through reporting of results of sensitive topics such as stillbirth could affect the research-subject relationship and damage future research with MaatHRI collaboration as well as new DPhil students who wish to conduct similar types of studies [209–211].

I found Ellis's reflection [209] on returning to the community where she conducted ethnographic studies during her undergraduate degree to be particularly useful in considering my approach. In her article, she discusses how her published book on her undergraduate ethnographic research caused community members to feel betrayed and humiliated. Participants and their neighbours identified themselves in the content, and they felt exposed by Ellis's interpretations of sensitive topics such as jokes, birth control, sex, and other personal matters.

From her reflection, I learned that in order to report my results responsibly, I should start by being honest with the participants about the purpose of my qualitative studies and that the findings will be used for my thesis and potentially for further academic journal publications or social media. I am glad that, by following the usual rigorous research process for this type of research, I had a process of dealing with this from the recruitment stage. This started with providing a comprehensive participant information sheet about the purpose of my study before participants signed up, and also reminding the participants during the fieldwork how the data would be used and that they do not have any obligations to continue participating even if the FGD has started.

Ellis also advised in her reflection [209], when appropriate, that participants should be asked to read what has been written, challenge interpretations about sensitive information, and researchers should agree with participants on whether to include such content in the publication. Therefore, I organised validation and dissemination workshops (18 October 2024) with MaatHRI collaborators from the hospitals that participated in my study to review my approach to reporting results and gather their comments on how I interpreted what I observed in the meetings and what I heard during the FGDs. All MaatHRI collaborators were also given a chance to read the results and examine the discussion I had written. During this process, I checked with them to ensure that the details I wrote about hospital characteristics and FGD participants' demographic information were sufficient for readers to understand the context of the hospitals (e.g. burden of stillbirth, organisational structure) while also protecting the anonymity of the hospitals and participants.

Chapter 4. Quantitative results I: incidence and risk factors for stillbirths in India

4.1 Chapter introduction

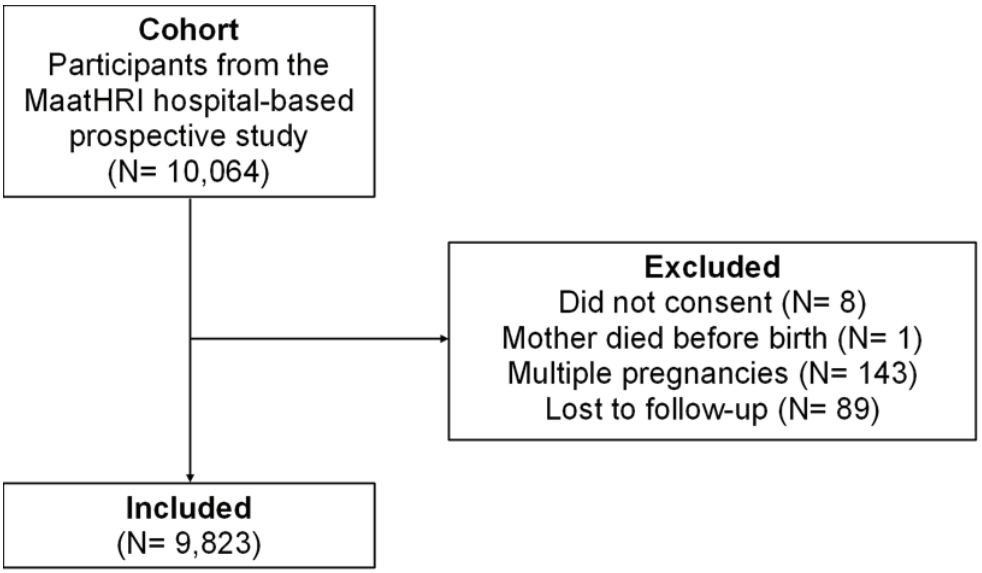
This chapter describes the findings of the exploratory quantitative analysis investigating the incidence of and risk factors for overall stillbirth in singleton pregnancies in 13 hospitals across six states in India. This was a secondary analysis of the data from the Maternal and perinatal Health Research collaboration, India (MaatHRI) prospective cohort study. This chapter addresses Objective 2 of the thesis. The findings of this chapter also guided the methods used in Chapter 5 to support addressing Objective 3 of the thesis.

This chapter was published in the International Journal of Gynecology & Obstetrics as an article titled 'Maternal and Fetal Factors Associated with Stillbirth in Singleton Pregnancies in 13 Hospitals Across Six States in India' [61]. A copy of this article is included in Appendix M.

4.2 Stillbirth rate

After excluding women who did not consent (N=8), who died before giving birth (N=1), had multiple pregnancies (N=143) and were lost to follow-up (N=89), a total of 9,823 women with singleton pregnancies were eligible for inclusion in the analysis (Figure 4-1).

Figure 4-1. Flow diagram of the selection of the study participants



There were 216 stillbirths (48 antepartum and 168 intrapartum) in the study population, representing a stillbirth rate of 22.0 per 1,000 total births (95% confidence interval (CI): 19.2-25.1). Of these 22.2% were antepartum and 77.8% were intrapartum stillbirths.

4.3 Characteristics of women

Women who had any type of stillbirth were different from women who had live births in terms of a number of factors, as described in Table 4-1. In terms of socioeconomic characteristics, the stillbirth group had lower levels of education than the live birth group, but the two groups were similar in other areas of socioeconomic characteristics – area of residence, religion, and below poverty line (BPL) status. For lifestyle characteristics, there was no significant difference in the proportion of women who reported currently practising an unhealthy lifestyle, such as smoking, consuming tobacco or chewing betel nuts, between the live birth group and the stillbirth group. Women in the stillbirth group were, on average, older and had higher parity, and a higher proportion of the women had a stillbirth/miscarriage history than the live births group. A history of caesarean sections, pre-existing medical problems, body mass index (BMI) were similar between the two groups.

When comparing pregnancy characteristics between the two groups, the women in the stillbirth group received fewer antenatal check-ups and were less likely to take iron and folic acid (IFA) supplements, and when they took IFA supplementation, it was for a shorter duration[5]. In addition, a higher proportion of women who experienced a stillbirth had anaemia and/or hypertensive disorders of pregnancy (HDP). A comparison of fetal characteristics revealed that the stillbirth group were born at an earlier gestational age, had a significantly higher proportion of preterm births, and had lower birthweight for gestational age percentiles. The fetal sex proportions between the two groups were similar.

[5] The iron and folic acid (IFA) supplementation duration was measured at the baseline of the cohort study when all women were in their third trimester. As per Indian guidelines, IFA supplementation is recommended for 180 days starting from the second trimester, meaning that preterm birth would not have resulted in a shorter duration of supplementation.

Table 4-1. Descriptive statistics of women who had a stillbirth (antepartum and intrapartum) compared with women who had a live birth

Variable/Level	Antepartum stillbirths (N=48)	Intrapartum stillbirths (N=168)	Overall stillbirths (N=216)	Live births (N=9,607)	P-value[a]
Structural factors					
Urban/rural					0.248
Urban/suburban	9 (18.8%)	29 (17.3%)	38 (17.6%)	1,419 (14.8%)	
Rural	39 (81.3%)	139 (82.7%)	178 (82.4%)	8,188 (85.2%)	
Women's education level					**<0.001**
Tertiary or above (beyond 12th class)	9 (18.8%)	18 (10.7%)	27 (12.5%)	1,628 (16.9%)	
Up to secondary school (6-12th class)	17 (35.4%)	73 (43.5%)	90 (41.7%)	5,070 (52.8%)	
Up to primary school (5th class)	13 (27.1%)	41 (24.4%)	54 (25.0%)	2,002 (20.8%)	
Illiterate	9 (18.8%)	36 (21.4%)	45 (20.8%)	874 (9.1%)	
Missing	0 (0%)	0 (0%)	0 (0%)	33 (0.3%)	
Religion					0.794
Hindu	38 (79.2%)	119 (70.8%)	157 (72.7%)	7,059 (73.5%)	
Muslim and others	10 (20.8%)	49 (29.2%)	59 (27.3%)	2,548 (26.5%)	
Below poverty line (BPL) status					0.058
No	14 (29.2%)	45 (26.8%)	59 (27.3%)	3,195 (33.3%)	
Unknown	10 (20.8%)	21 (12.5%)	31 (14.4%)	1,594 (16.6%)	
Yes	24 (50.0%)	102 (60.7%)	126 (58.3%)	4,818 (50.2%)	
Intermediate factors					
Smoking status					0.237
Never	27 (56.3%)	116 (69.0%)	143 (66.2%)	6,185 (64.4%)	
Ever	18 (37.5%)	41 (24.4%)	59 (27.3%)	3,069 (31.9%)	
Missing	3 (6.3%)	11 (6.5%)	14 (6.5%)	353 (3.7%)	
Tobacco consumption					0.183
Never	42 (87.5%)	155 (92.3%)	197 (91.2%)	9,007 (93.8%)	
Before pregnancy	0 (0%)	5 (3.0%)	5 (2.3%)	110 (1.1%)	
During pregnancy	6 (12.5%)	8 (4.8%)	14 (6.5%)	490 (5.1%)	
Chewing betel nuts					0.459
Never	28 (58.3%)	120 (71.4%)	148 (68.5%)	6,328 (65.9%)	
Before pregnancy	1 (2.1%)	6 (3.6%)	7 (3.2%)	235 (2.4%)	
During pregnancy	19 (39.6%)	42 (25.0%)	61 (28.2%)	3,044 (31.7%)	
Number of antenatal check-ups					**<0.001**

Variable/Level	Antepartum stillbirths (N=48)	Intrapartum stillbirths (N=168)	Overall stillbirths (N=216)	Live births (N=9,607)	P-value[a]
Median [Q1,Q3]	3.00 [2.75,4.00]	3.00 [2.00,3.00]	3.00 [2.00,4.00]	3.00 [3.00,4.00]	
Number of antenatal check-ups					**<0.001**
4 or more	16 (33.3%)	39 (23.2%)	55 (25.5%)	4,199 (43.7%)	
2-3	27 (56.3%)	104 (61.9%)	131 (60.6%)	4,624 (48.1%)	
0-1	5 (10.4%)	25 (14.9%)	30 (13.9%)	784 (8.2%)	
Duration of iron and folic acid (IFA) supplementation					**<0.001**
Median [Q1,Q3]	60.0 [37.5,90.0]	90.0 [30.0,100]	90.0 [30.0,100]	100 [90.0,150]	
Duration of iron and folic acid (IFA) supplementation					**<0.001**
180 days or more	2 (4.2%)	11 (6.5%)	13 (6.0%)	1,484 (15.4%)	
100-179 days	5 (10.4%)	42 (25.0%)	47 (21.8%)	4,195 (43.7%)	
Fewer than 100 days	36 (75.0%)	90 (53.6%)	126 (58.3%)	3,578 (37.2%)	
None	5 (10.4%)	25 (14.9%)	30 (13.9%)	350 (3.6%)	
Women's age (years)					**<0.001**
Median [Q1,Q3]	25.0 [21.0,29.0]	26.0 [22.0,29.3]	25.5 [22.0,29.0]	24.0 [21.0,28.0]	
Women's age					**<0.001**
<20 years	4 (8.3%)	11 (6.5%)	15 (6.9%)	852 (8.9%)	
20-24 years	19 (39.6%)	59 (35.1%)	78 (36.1%)	4,090 (42.6%)	
25-29 years	16 (33.3%)	56 (33.3%)	72 (33.3%)	3,167 (33.0%)	
30-34 years	6 (12.5%)	25 (14.9%)	31 (14.4%)	1,139 (11.9%)	
>34 years	3 (6.3%)	17 (10.1%)	20 (9.3%)	359 (3.7%)	
Parity (N)					0.152
Median [Q1,Q3]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]	
Parity					**0.004**
Nulliparous	27 (56.3%)	111 (66.1%)	138 (63.9%)	6,429 (66.9%)	
Para 1-2	18 (37.5%)	41 (24.4%)	59 (27.3%)	2,779 (28.9%)	
Para 3 or more	3 (6.3%)	16 (9.5%)	19 (8.8%)	399 (4.2%)	
Stillbirth/miscarriage history					**0.001**
No	11 (22.9%)	46 (27.4%)	57 (26.4%)	2,810 (29.2%)	
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6,250 (65.1%)	
Yes	10 (20.8%)	15 (8.9%)	25 (11.6%)	533 (5.5%)	
Missing	0 (0%)	1 (0.6%)	1 (0.5%)	14 (0.1%)	
History of caesarean sections					0.505
No	17 (35.4%)	55 (32.7%)	72 (33.3%)	2,846 (29.6%)	

Variable/Level	Antepartum stillbirths (N=48)	Intrapartum stillbirths (N=168)	Overall stillbirths (N=216)	Live births (N=9,607)	P-value[a]
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6,250 (65.1%)	
Yes	4 (8.3%)	7 (4.2%)	11 (5.1%)	487 (5.1%)	
Missing	0 (0%)	0 (0%)	0 (0%)	24 (0.2%)	
Pre-existing medical problems					0.955
No	45 (93.8%)	164 (97.6%)	209 (96.8%)	9,288 (96.7%)	
Yes	3 (6.3%)	4 (2.4%)	7 (3.2%)	318 (3.3%)	
Missing	0 (0%)	0 (0%)	0 (0%)	1 (0.0%)	
BMI category for South Asian					0.480
<18.5	7 (14.6%)	49 (29.2%)	56 (25.9%)	2,487 (25.9%)	
18.5-22.9	30 (62.5%)	78 (46.4%)	108 (50.0%)	5,297 (55.1%)	
23-24.9	8 (16.7%)	17 (10.1%)	25 (11.6%)	892 (9.3%)	
≥25	2 (4.2%)	8 (4.8%)	10 (4.6%)	561 (5.8%)	
Missing	1 (2.1%)	16 (9.5%)	17 (7.9%)	370 (3.9%)	
Proximal factors					
Severity of anaemia					**<0.001**
No anaemia (Hb ≥11 g/dL)	3 (6.3%)	13 (7.7%)	16 (7.4%)	1,463 (15.2%)	
Mild (Hb 10-10.9 g/dL)	7 (14.6%)	20 (11.9%)	27 (12.5%)	1,169 (12.2%)	
Moderate (Hb 7-9.9 g/dL)	28 (58.3%)	77 (45.8%)	105 (48.6%)	5,845 (60.8%)	
Severe (Hb <7 g/dL)	10 (20.8%)	58 (34.5%)	68 (31.5%)	1,130 (11.8%)	
Hypertensive disorders of pregnancy (HDP)					**0.002**
No	42 (87.5%)	145 (86.3%)	187 (86.6%)	8,777 (91.4%)	
Other HDP[b]	3 (6.3%)	17 (10.1%)	20 (9.3%)	697 (7.3%)	
Pre-eclampsia/eclampsia	3 (6.3%)	6 (3.6%)	9 (4.2%)	133 (1.4%)	
Gestational age at birth (weeks)					**<0.001**
Median [Q1,Q3]	35.0 [33.0,38.0]	37.0 [34.8,39.0]	37.0 [34.0,39.0]	39.0 [38.0,40.0]	
Gestational age at birth					**<0.001**
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	30 (62.5%)	66 (39.3%)	96 (44.4%)	1,401 (14.6%)	
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	8 (16.7%)	35 (20.8%)	43 (19.9%)	2,484 (25.9%)	
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	9 (18.8%)	60 (35.7%)	69 (31.9%)	5,452 (56.8%)	
Late/post term (≥$41^{0/7}$ weeks)	1 (2.1%)	6 (3.6%)	7 (3.2%)	270 (2.8%)	
Missing	0 (0%)	1 (0.6%)	1 (0.5%)	0 (0%)	
Fetal sex					0.969
Male	27 (56.3%)	87 (51.8%)	114 (52.8%)	5,083 (52.9%)	

Variable/Level	Antepartum stillbirths (N=48)	Intrapartum stillbirths (N=168)	Overall stillbirths (N=216)	Live births (N=9,607)	P-value[a]
Female	21 (43.8%)	81 (48.2%)	102 (47.2%)	4,524 (47.1%)	
Birthweight for gestational age (percentile)					**<0.001**
Median [Q1,Q3]	25.9 [0.398,69.2]	4.01 [0.120,29.6]	6.83 [0.143,39.2]	13.6 [2.92,36.0]	
Birthweight for gestational age					**0.021**
<10th percentile	19 (39.6%)	93 (55.4%)	112 (51.9%)	4,146 (43.2%)	
10th to 90th percentile	24 (50.0%)	69 (41.1%)	93 (43.1%)	5,075 (52.8%)	
>90th percentile	5 (10.4%)	4 (2.4%)	9 (4.2%)	354 (3.7%)	
Missing	0 (0%)	2 (1.2%)	2 (0.9%)	32 (0.3%)	

Hb: haemoglobin, BMI: body mass index

[a] Nonparametric statistical test for continuous variables and Pearson's chi-squared test for categorical variables.

[b] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

4.4 Risk factors for overall stillbirth

4.4.1 Univariable analysis

Table 4-2 describes the results of the univariable analysis, which are the unadjusted associations between each exposure variable and the outcome stillbirth of any type.

Table 4-2. Unadjusted associations (univariable analysis) between exposure variables and relative risk of stillbirth

Variable/Level	Univariable analysis	
	RR (95% CI)	**P-value**
Structural factors		
Urban/rural		
Urban/suburban	1 (Ref)	-
Rural	0.82 (0.58-1.17)	0.255
Women's education level		
Tertiary or above (beyond 12th class)	1 (Ref)	-
Up to secondary school (6-12th class)	1.07 (0.71-1.67)	0.761
Up to primary school (5th class)	**1.61 (1.02-2.59)**	**0.043**
Illiterate	**3.00 (1.88-4.89)**	**<0.001**
Religion		
Hindu	1 (Ref)	-
Muslim and others	1.04 (0.77-1.39)	0.796
Below poverty line (BPL) status		
No	1 (Ref)	-
Unknown	1.05 (0.67-1.61)	0.819
Yes	**1.41 (1.04-1.93)**	**0.031**
Intermediate factors		
Smoking status		
Never	1 (Ref)	-
Ever	0.83 (0.61-1.12)	0.243
Tobacco consumption		
Never	1 (Ref)	-
Before pregnancy	2.03 (0.72-4.43)	0.118
During pregnancy	1.30 (0.72-2.15)	0.346
Chewing betel nuts		
Never	1 (Ref)	-
Before pregnancy	1.27 (0.54-2.50)	0.542
During pregnancy	0.86 (0.63-1.15)	0.320
Number of antenatal check-ups		
4 or more	1 (Ref)	-
2-3	**2.13 (1.56-2.94)**	**<0.001**
0-1	**2.85 (1.81-4.41)**	**<0.001**
Duration of iron and folic acid (IFA) supplementation		
180 days or more	1 (Ref)	-
100-179 days	1.28 (0.71-2.46)	0.437
Fewer than 100 days	**3.92 (2.30-7.28)**	**<0.001**
None	**9.09 (4.85-18.04)**	**<0.001**

Variable/Level	Univariable analysis	
	RR (95% CI)	**P-value**
Women's age		
<20 years	1 (Ref)	-
20-24 years	1.08 (0.64-1.95)	0.781
25-29 years	1.28 (0.76-2.33)	0.377
30-34 years	1.53 (0.84-2.92)	0.175
>34 years	**3.05 (1.57-6.06)**	**0.001**
Parity		
Nulliparous	1.01 (0.75-1.38)	0.945
Para 1-2	1 (Ref)	-
Para 3 or more	**2.19 (1.27-3.59)**	**0.003**
Stillbirth/miscarriage history		
No	1 (Ref)	-
Never pregnant	1.05 (0.77-1.44)	0.767
Yes	**2.25 (1.38-3.56)**	**<0.001**
History of caesarean sections		
No	1 (Ref)	-
Never pregnant	0.84 (0.64-1.13)	0.248
Yes	0.90 (0.45-1.62)	0.732
Pre-existing medical problems		
No	1 (Ref)	-
Yes	0.98 (0.42-1.92)	0.955
BMI category for South Asian		
<18.5	1.10 (0.79-1.51)	0.555
18.5-22.9	1 (Ref)	-
23-24.9	1.36 (0.86-2.07)	0.162
≥25	0.88 (0.43-1.59)	0.690
Proximal factors		
Severity of anaemia		
No anaemia (Hb ≥11 g/dL)	1 (Ref)	-
Mild (Hb 10-10.9 g/dL)	**2.09 (1.14-3.96)**	**0.020**
Moderate (Hb 7-9.9 g/dL)	1.63 (0.99-2.87)	0.068
Severe (Hb <7 g/dL)	**5.25 (3.13-9.36)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)		
No	1 (Ref)	-
Other HDP[a]	1.34 (0.82-2.07)	0.217
Pre-eclampsia/eclampsia	**3.04 (1.44-5.58)**	**0.001**
Gestational age at birth		
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	**5.13 (3.77-7.01)**	**<0.001**
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	1.36 (0.92-1.98)	0.112
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	1 (Ref)	-
Late/post term (≥$41^{0/7}$ weeks)	2.02 (0.84-4.10)	0.076
Fetal sex		
Male	1 (Ref)	-
Female	1.01 (0.77-1.31)	0.970
Birthweight for gestational age		
<10^{th} percentile	**1.46 (1.11-1.93)**	**0.007**
10^{th} to 90^{th} percentile	1 (Ref)	-
>90^{th} percentile	1.38 (0.65-2.58)	0.359

Hb: Haemoglobin, RR: relative risk, CI: confidence interval, BMI: body mass index
[a] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

In the univariable analysis, two structural factors showed a statistically significant association with stillbirth: women's education level and BPL status. Urban/rural and religion were not statistically significant risk factors for stillbirth. Compared with women with a tertiary or above level of education, women with up to primary school level education had 1.61 times (95% CI: 1.02-2.59) higher risk of stillbirth and women who cannot read or write (illiterate) had a three times higher risk (95% CI: 1.88-4.89). Women with up to secondary school level had a higher risk of stillbirth by 1.07 times (95% CI: 0.71-1.67), which was not statistically significant. Women with BPL status also had a higher risk of stillbirth (relative risk (RR): 1.41, 95% CI: 1.04-1.93) compared with women without. Women with unknown BPL status also had a marginally higher risk of stillbirth (RR: 1.05, 95% CI: 0.67-1.61), but the association was not statistically significant.

The number of antenatal check-ups was a strong intermediate factor associated with stillbirth: women who only had 2-3 check-ups had 2.13 times increased risk of stillbirth (95% CI: 1.56-2.94), and the risk was even higher for women who had 0-1 check-up (RR: 2.85, 95% CI: 1.81-4.41). Duration of IFA supplementation was another significant intermediate factor associated with stillbirth. Those who had fewer than 100 days of IFA supplementation had an almost four-fold increase in the risk of stillbirth (RR: 3.92, 95% CI: 2.30-7.28) than women who had IFA for 180 days or more. The risk was even greater in those who took no IFA supplementation (RR: 9.09, 95% CI: 4.85-18.04), a nine-fold increase in risk. While those who only had IFA for 100-179 days also had a higher risk of stillbirth (RR: 1.28, 95% CI: 0.71-2.46) than those who had IFA for 180 days or more, this latter result was not statistically significant in contrast to the results relating to IFA above.

Advanced maternal age, especially those older than 34 years, had a higher and statistically significant risk of stillbirth compared with women <20 years of age (RR 3.05, 95% CI: 1.57-6.06). Initially, the reference group for calculating relative risk in this exposure variable was women aged 20–24 years, as teenage pregnancies (<20 years age group) were expected to have a higher risk of stillbirth compared to those aged 20–24 years. However, a U-shaped association was not observed, so the reference group was changed to women <20 years of age. Other age groups also had higher risk (compared with the <20

years age group), but the risk was not statistically significant. Women with high parity (para 3 or more) were found to have a higher risk of stillbirth than para 1-2 women (RR: 2.19, 95% CI: 1.27-3.59), as well as women with stillbirth/miscarriage history (RR: 2.25, 95% CI: 1.38-3.56). A history of caesarean sections reduced the risk of stillbirth by 10%, although this result was not significant (RR: 0.90, 95% CI: 0.45-1.62).

The severity of anaemia was a significant proximal risk factor for stillbirth. Compared with women with no anaemia, women who had mild anaemia had a 2.09 times higher risk of stillbirth (95% CI: 1.14-3.96). While the relative risk was not significantly higher for those in the moderate anaemia category (RR: 1.63, 95% CI: 0.99-2.87), it was found that women with severe anaemia had more than five-fold increased risk of stillbirth than women with no anaemia (RR: 5.25, 95% CI: 3.13-9.36). Women with pre-eclampsia/eclampsia also had a high risk of stillbirth compared with women with no HDP, and the risk was over three-fold greater (RR: 3.04, 95% CI: 1.44-5.58). Other HDP conditions (such as chronic hypertension or gestational hypertension) had a 1.34-fold higher risk of stillbirth, but this was not statistically significant (95% CI: 0.82-2.07).

Preterm birth was associated with a five-fold higher risk of stillbirth (RR: 5.13, 95% CI: 3.77-7.01). A higher risk was also observed for early-term birth (RR: 1.36, 95% CI: 0.92-1.98) and late/post-term birth (RR: 2.02, 95% CI: 0.84-4.10), although the latter two were not statistically significant. Less than 10th percentile birthweight for gestational age was another significant proximal risk factor for stillbirth with a 1.46 higher risk of stillbirth compared with 10th to 90th percentile birthweight for gestational age babies (95% CI: 1.11-1.93). The risk was also higher among babies with >90th percentile birthweight for gestational age, but it was not statistically significant (RR: 1.38, 95% CI: 0.65-2.58). Lastly, fetal sex was not a risk factor for stillbirth.

4.4.2 Multivariable regression analysis

The results of the multivariable analysis using a hierarchical approach, starting with the structural factors (model 1), followed by intermediate factors (model 2), and proximal factors (model 3), are shown in Table 4-3. The following variables were excluded in the multivariable regression models due to lack of significant association in the univariable analysis results: urban/rural (area of residence), religion, smoking status, tobacco consumption, chewing betel nuts, history of caesarean sections, pre-existing medical problems, BMI category and fetal sex. Additionally, parity and stillbirth/miscarriage history showed high collinearity when included together, so they were not included in the same model. Further details are provided in the sections below.

Table 4-3. Adjusted associations (multivariable analysis) between exposure variables and relative risk of stillbirth

Variable/Level	Model 1: Adjusted for structural factors		Model 2: Adjusted for structural & intermediate factors		Model 3: Adjusted for structural, intermediate & proximal factors	
	aRR (95% CI)	**P-value**	**aRR (95% CI)**	**P-value**	**aRR (95% CI)**	**P-value**
Structural factors						
Women's education level						
Tertiary or above (beyond 12th class)	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Up to secondary school (6-12th class)	1.05 (0.69-1.65)	0.816	1.16 (0.76-1.84)	0.499	1.10 (0.72-1.74)	0.680
Up to primary school (5th class)	1.48 (0.93-2.40)	0.102	1.31 (0.81-2.17)	0.286	1.08 (0.66-1.81)	0.753
Illiterate	**2.95 (1.84-4.83)**	**<0.001**	**2.60 (1.59-4.33)**	**<0.001**	**2.11 (1.29-3.53)**	**0.003**
Below poverty line (BPL) status						
No	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Unknown	1.13 (0.72-1.75)	0.574	0.94 (0.60-1.45)	0.788	0.90 (0.57-1.40)	0.652
Yes	1.36 (0.99-1.88)	0.058	0.80 (0.57-1.13)	0.205	0.73 (0.52-1.03)	0.067
Intermediate factors						
Number of antenatal check-ups						
4 or more			1 (Ref)	-	1 (Ref)	-
2-3			**1.61 (1.15-2.29)**	**0.006**	**1.65 (1.17-2.34)**	**0.004**
0-1			1.45 (0.89-2.33)	0.129	1.40 (0.86-2.25)	0.171
Duration of iron and folic acid (IFA) supplementation						
180 days or more			1 (Ref)	-	1 (Ref)	-
100-179 days			1.44 (0.79-2.81)	0.252	1.92 (1.00-3.92)	0.060
Fewer than 100 days			**3.92 (2.26-7.42)**	**<0.001**	**4.82 (2.62-9.56)**	**<0.001**
None			**8.29 (4.30-16.83)**	**<0.001**	**9.01 (4.45-19.13)**	**<0.001**
Women's age						
<20 years			1 (Ref)	-	1 (Ref)	-
20-24 years			1.09 (0.64-1.97)	0.772	1.12 (0.66-2.03)	0.699
25-29 years			1.33 (0.77-2.44)	0.331	1.31 (0.75-2.42)	0.363
30-34 years			1.56 (0.83-3.04)	0.179	1.56 (0.83-3.06)	0.178
>34 years			**2.41 (1.17-5.04)**	**0.018**	**2.39 (1.16-5.00)**	**0.018**
Parity[a]						
Nulliparous			1.10 (0.79-1.54)	0.582	1.08 (0.77-1.51)	0.670

Variable/Level	Model 1: Adjusted for structural factors		Model 2: Adjusted for structural & intermediate factors		Model 3: Adjusted for structural, intermediate & proximal factors	
	aRR (95% CI)	**P-value**	**aRR (95% CI)**	**P-value**	**aRR (95% CI)**	**P-value**
Para 1-2			1 (Ref)	-	1 (Ref)	-
Para 3 or more			1.14 (0.63-1.97)	0.649	1.26 (0.70-2.17)	0.418
Stillbirth/miscarriage history[a]						
No			1 (Ref)	-	1 (Ref)	-
Never pregnant			1.27 (0.90-1.80)	0.182	1.28 (0.91-1.82)	0.159
Yes			**2.29 (1.40-3.64)**	**0.001**	**2.15 (1.30-3.45)**	**0.002**
Proximal factors						
Severity of anaemia						
No anaemia (Hb ≥11 g/dL)					1 (Ref)	-
Mild (Hb 10-10.9 g/dL)					**1.88 (1.02-3.58)**	**0.045**
Moderate (Hb 7-9.9 g/dL)					1.25 (0.75-2.20)	0.418
Severe (Hb <7 g/dL)					**2.95 (1.72-5.34)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						
No					1 (Ref)	-
Other HDP[b]					**2.08 (1.21-3.38)**	**0.005**
Pre-eclampsia/eclampsia					**2.69 (1.27-5.01)**	**0.004**
Gestational age at birth[c]						
Preterm (28^{+0} to 36^{+6} weeks)					**3.98 (2.88-5.52)**	**<0.001**
Early term (37^{+0} to 38^{+6} weeks)					**1.49 (1.00-2.20)**	**0.046**
Full term (39^{+0} to 40^{+6} weeks)					1 (Ref)	-
Late/post term (≥41^{+0} weeks)					1.86 (0.77-3.78)	0.121
Birthweight for gestational age[c]						
<10^{th} percentile					**1.42 (1.07-1.88)**	**0.015**
10 to 90^{th} percentile					1 (Ref)	-
>90^{th} percentile					0.91 (0.43-1.73)	0.799

Hb: haemoglobin, aRR: adjusted relative risk, CI: confidence interval

[a] Due to the high collinearity between parity and stillbirth/miscarriage history, these variables were not included in the same model together.

[b] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

[c] Birthweight for gestational age was calculated using gestational age at birth, therefore, these variables were not included in the same model together.

4.4.2.1 Structural factors

Once BPL status was adjusted for (model 1), the risk of stillbirth among women with up to primary school education compared with women who had tertiary or above education was no longer statistically significant. However, the risk of stillbirth among women who cannot read or write (illiterate) compared with women who had tertiary or above education was still significant even after full adjustment (model 3), with a 2.11-fold increased risk of stillbirth (95% CI: 1.29-3.53). Living below the poverty line was no longer a significant risk factor for stillbirth after women's education level was adjusted for (model 1). There was no interaction between women's education level and BPL status.

4.4.2.2 Intermediate factors

The following intermediate factors were included in the multivariable analysis (Model 2 and 3): number of antenatal check-ups, duration of IFA supplementation, women's age, parity, and stillbirth/miscarriage history. However, due to the high collinearity between parity (variance inflation factor (VIF): 14.58) and stillbirth/miscarriage history (VIF: 12.80), these variables were not included in the same model together.

Women who received 2-3 check-ups had an increased risk of stillbirth of 1.61 (95% CI: 1.15-2.29) compared with women who received four or more check-ups. This result was statistically significant after full adjustment (Model 3), and the relative risk did not materially change (adjusted relative risk (aRR): 1.65, 95% CI: 1.17-2.34). The risk of stillbirth associated with only receiving 0-1 antenatal check-up was elevated but no longer statistically significant following adjustment for the other factors (aRR: 1.45, 95% CI: 0.89-2.33).

After full adjustment (Model 3), the risk of stillbirth among women who received fewer than 100 days of IFA supplementation remained high (aRR: 4.82, 95% CI: 2.62-9.56) compared with those who received supplementation for at least 180 days. This risk was even higher among those who received no IFA supplementation, with a relative risk of 9.01 (95% CI: 4.45-19.13) after full adjustment. The relative risk was elevated but only marginally statistically significant for those who had 100-179 days of IFA

supplementation (aRR: 1.92, 95% CI: 1.00-3.92), and there was confirmed evidence of a linear trend with increasing IFA supplementation duration (p-value: <0.001).

Women's age group >34 years compared with age group <20 years continued to be a significant intermediate risk factor for stillbirth, with the relative risk being 2.39 (95% CI: 1.16-5.00) after full adjustment of other factors. When women's age was included in the model as a continuous variable, there was a 5% increase in risk for every one-year increase in age after full adjustment (aRR: 1.05, 95% CI: 1.02-1.08). The test for trend with a p-value of 0.009 also confirmed a linear trend with increasing age.

4.4.2.3 Proximal factors

The following proximal factors were included in the multivariable analysis (Model 3): severity of anaemia, HDP, gestational age at birth and birthweight for gestational age. Of note, by definition, birthweight for gestational age was calculated using gestational age at birth, so these variables were not included in the same model.

It was found that women who had mild anaemia compared with no anaemia had an almost two-fold higher risk of stillbirth (aRR: 1.88, 95% CI: 1.02-3.58). Also, the fully adjusted relative risk for women with severe anaemia remained almost three-fold higher compared with women who did not have anaemia (aRR: 2.95, 95% CI: 1.72-5.34). This was despite IFA supplementation (which did not correlate with the severity of anaemia) having been adjusted for. In contrast, the adjusted relative risk for moderate anaemia was elevated but remained non-significant (aRR: 1.25, 95% CI: 0.75-2.20).

The risk of stillbirth among women with HDP other than pre-eclampsia and eclampsia remained statistically significant after full adjustment. This group had more than a two-fold higher risk of stillbirth than women who did not have HDP (aRR: 2.08, 95% CI: 1.21-3.38). In addition, the risk was 2.69 times higher for women who had pre-eclampsia/eclampsia (95% CI: 1.27-5.01).

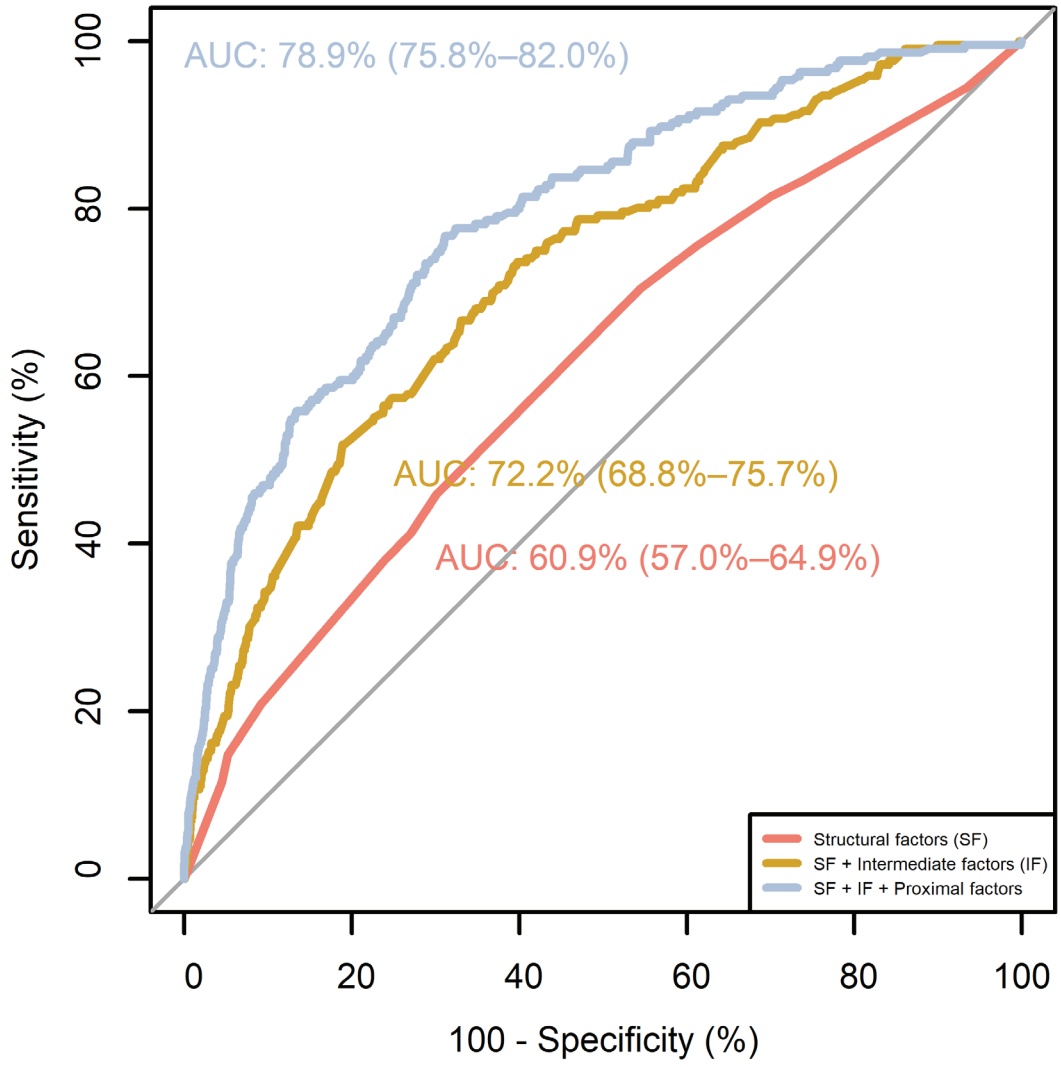
The risk of stillbirth among preterm births compared with full-term births remained high, with a relative risk of 3.98 (95% CI: 2.88-5.52). Early-term birth was also a significant risk factor once other factors were adjusted for and were associated with a 1.49 times higher risk of stillbirth (95% CI: 1.00-2.20) than full-term births.

Lastly, babies with birthweight <10th percentile for gestational age had a 1.42 times higher risk of stillbirth (95% CI: 1.07-1.88) compared with babies with birthweight between the 10th to 90th percentile for gestational age. Although not statistically significant, babies with birthweight >90th percentile for gestational age had a 9% lower risk of stillbirth than babies with birthweight 10-90th percentile for gestational age (aRR: 0.91, 95% CI: 0.43-1.73).

4.5 Performance of multivariable models

Figure 4-2 shows the area under the receiver-operating characteristic (AUROC) curve for model 1 (adjusting for structural factors only), model 2 (adjusting for structural and intermediate factors) and model 3 (fully adjusted including proximal factors). Together, the structural and intermediate factors discriminated between stillbirth and live birth for 72.2% (95% CI: 68.8%-75.7%) of the risk of stillbirth. With the addition of the proximal factors, this increased to 78.9% (95% CI: 75.8%-82.0%).

Figure 4-2. Area under the receiver-operating characteristic (AUROC) curve for structural, intermediate and proximal factors



4.6 Discussion

4.6.1 Principal findings

This exploratory quantitative analysis investigating the incidence of and risk factors for overall stillbirth in 13 hospitals across six states in India showed that the stillbirth rate in 13 hospitals across six states in India was 22.0 per 1,000 total births (95% CI: 19.2-25.1) and 77.8% of all stillbirths occurred intrapartum.

After adjusting for relevant structural, intermediate and proximal risk factors, women's illiteracy (not being able to read or write) was a significant structural risk factor. Significant immediate risk factors were receiving only 2-3 antenatal check-ups rather than the recommended four, receiving IFA supplementation for fewer than 100 days or receiving no IFA supplementation at all, women's age >34 years and having a history of stillbirth or miscarriage. The statistically significant proximal risk factors were having mild or severe anaemia, experiencing any type of HDP, preterm or early-term birth, and birthweight <10th percentile for gestational age.

4.6.2 Discussion in light of other evidence

The stillbirth rate of 22.0 per 1,000 total births in the study population was substantially higher than the 2021 estimate for India's overall stillbirth rate of 12.2 per 1,000 total births [5], despite the fact that these births occurred in a facility setting and did not include home births or planned caesarean sections before the third trimester. This could be because nine out of 13 MaatHRI hospitals (69.2%) where the study population was recruited from medical colleges, which typically serve a higher proportion of high-risk women compared with community hospitals. It is also possible that the estimate for India overall could be a consequence of undercounting, as identified by Zadey *et al.* [29] and that the estimate from the study reported here is a more realistic estimate.

Also, more than 77% of the stillbirths in this study were intrapartum, compared with 45% globally and 51% in the South Asia region (estimated proportions of intrapartum stillbirth) [5]. Intrapartum stillbirths are considered to be more closely related to the quality of maternity care than antepartum stillbirths [8] and thus, this study's findings demonstrate the need for implementing a stillbirth review process that is adapted and contextualised for the diverse settings in India [60].

Altijani *et al.* [37] found women's illiteracy as a significant stillbirth risk factor, which was also true in this study. As highlighted by Souza *et al.* [212], improving access to high-quality maternity care, which enables better management of medical conditions and pregnancy complications, has the potential to modify or

counterbalance the risk of adverse maternal health outcomes associated with socioeconomic inequalities, such as those related to women's low education levels and low-income status. Importantly, this study demonstrated that several of the major risk factors for stillbirth are potentially modifiable. For instance, ensuring that women receive at least four antenatal check-ups and take IFA supplementation during pregnancy were identified as interventions that could potentially significantly reduce the risk of stillbirth in India. Complications such as having anaemia in the third trimester and HDP were also identified as major risk factors that greatly increased the risk of stillbirth, consistent with findings from other studies [213–217]. These complications are potentially amenable to management interventions.

However, this study also demonstrated that while several major risk factors for stillbirth are potentially modifiable, addressing these factors alone may not lead to a substantial reduction in overall stillbirth rates. The AUROC results showed that structural factors had a strong ability to discriminate between stillbirths and live births, contributing significantly to the model's predictive power (60.9%). In contrast, intermediate and proximal factors, including those with high relative risks, added only 18.0% to the model's discriminatory ability. This suggests that while interventions targeting these modifiable risk factors are essential and likely to improve maternal and fetal health outcomes, their impact on overall stillbirth rates may be limited unless structural factors are also addressed.

There are multiple other causes of anaemia in India, including iron deficiency anaemia, and interventions to address anaemia should be tailored to the types of anaemia [218]. Despite routine iron supplementation being available at no cost to women [169], overall, 84.9% of the cohort had anaemia (haemoglobin <11 g/dL), and 12.2% had severe anaemia (haemoglobin <7 g/dL). Furthermore, even after adjusting for the effects of IFA supplementation, anaemia remained a significant risk factor for stillbirth, and this was especially critical for women with severe anaemia who experienced almost a three-fold increased risk of stillbirth compared with women without anaemia. This suggests that low haemoglobin levels may not necessarily translate into iron deficiency anaemia, and addressing anaemia (especially severe anaemia) with iron supplementation alone may not be effective in addressing this important risk factor for stillbirth in India. The absence of collinearity between the duration of IFA

supplementation and the severity of anaemia also supports this interpretation. Therefore, understanding the underlying causes of anaemia is crucial to developing targeted treatment strategies. The complex, multifactorial relationship between iron supplementation and anaemia and risk of stillbirth supports MaatHRI's recent study findings, which emphasised the importance of using iron biomarkers and not relying solely on haemoglobin measurement to facilitate tailored prevention, control, and treatment activities for managing anaemia during pregnancy [218].

Further analysis should be conducted to explore early-term birth (37^{+0} to 38^{+6} weeks) and birthweight below the 10^{th} percentile for gestational age as risk factors for stillbirth, particularly for intrapartum stillbirth, as the risks may differ from that associated with antepartum stillbirth. While the association between preterm birth and stillbirth is relatively well established [34,37,145,219], research on the risk of intrapartum stillbirth associated with early-term birth is limited. Smith [220] suggests that there was a 2.2 times increased risk of intrapartum stillbirth at 37 weeks of gestation compared with 38 weeks in the Scottish population between 1985 and 1996. In contrast, Trudell *et al.* [221] recommended early-term birth for small for gestational age (SGA) pregnancies to minimise the risk of stillbirth, based on findings from a perinatal database (recruited between 1990 and 2009) in the United States. However, further evidence is needed to determine whether these findings can be applied to the Indian population.

4.6.3 Strengths and limitations

The main strength of this study is that it employed a large prospective design, allowing examination of the relationship between maternal and fetal factors associated with stillbirth. The prospective cohort study design, in combination with appropriate statistical analysis methods, allowed an assessment of the relative risks of factors associated with stillbirth in India. Rigorous and standardised methodologies were utilised to minimise bias and improve the validity and reliability of the findings, including adopting a hierarchical approach to adjust for confounders where data were available, checking for VIF to prevent high multicollinearity in the model and assessing model discrimination using AUROC curves.

However, there are several limitations to consider. This study is a secondary analysis of cohort data originally collected to investigate risk factors for postpartum haemorrhage rather than stillbirth. As a result, there were limitations in the available variables that could be used, and the sample size was fixed and not calculated specifically to address the objectives of this analysis. Hence, certain variables identified as stillbirth risk factors were not studied, contributing to the potential for residual confounding in the results. The AUROC analysis demonstrated that while structural, intermediate, and proximal factors collectively provided a strong ability to discriminate between stillbirth and live birth outcomes (78.9%), more than 20% of the discriminatory capacity remained unexplained, suggesting the possibility of residual confounding and unidentified risk factors not captured in this study.

Additionally, since the original focus was on postpartum haemorrhage, the exclusion criteria for recruitment were women who were planning to undergo a caesarean section at the time of recruitment; therefore, this is likely to have introduced selection bias. According to a study that analysed characteristics of the caesarean section using the National Family Health Survey 2019-21 (NFHS-5) data for 230,870 Indian women, the odds of opting for elective caesarean were higher among women with higher wealth status, women who identified as Christian and those with lower parity [222]. It is also important to consider that a planned caesarean is often recommended for certain circumstances to protect the woman and baby's health [223], for example, when the baby is in the breech position, if the woman has placenta praevia or has certain infections (e.g. human immunodeficiency virus, genital herpes). Reflecting on multiple factors that are associated with planned caesarean and whether medically indicated or not [224], there may be a higher or lower risk of stillbirth among this subgroup. Therefore, there is a need for cautious interpretation before extending the study's findings to this particular subgroup.

4.6.4 Conclusion

The findings of this study emphasised the significance of addressing modifiable factors to reduce the risk of stillbirths in India and how improving access to high-quality antenatal care and improving the

management of complications, including the availability of emergency obstetric care for women with preeclampsia/eclampsia, are vital steps toward achieving a reduction in overall stillbirth in India. However, addressing structural risk factors is equally important, as these factors substantially contribute to stillbirth risk. The study also highlighted the importance of understanding the underlying causes of anaemia to develop targeted treatment strategies, recognising the complex, multifactorial relationship between iron supplementation and anaemia.

The findings from this chapter guided the objectives for further quantitative analysis reported in Chapter 5. The second quantitative analysis focused on gaining a deeper understanding of intrapartum risk factors for stillbirth and how there might be differences in risk factors between the two stillbirth subgroups (antepartum and intrapartum). Also, to examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age.

Chapter 5. Quantitative results II: risk factors for intrapartum stillbirths in India and survival probabilities of fetuses by gestational age

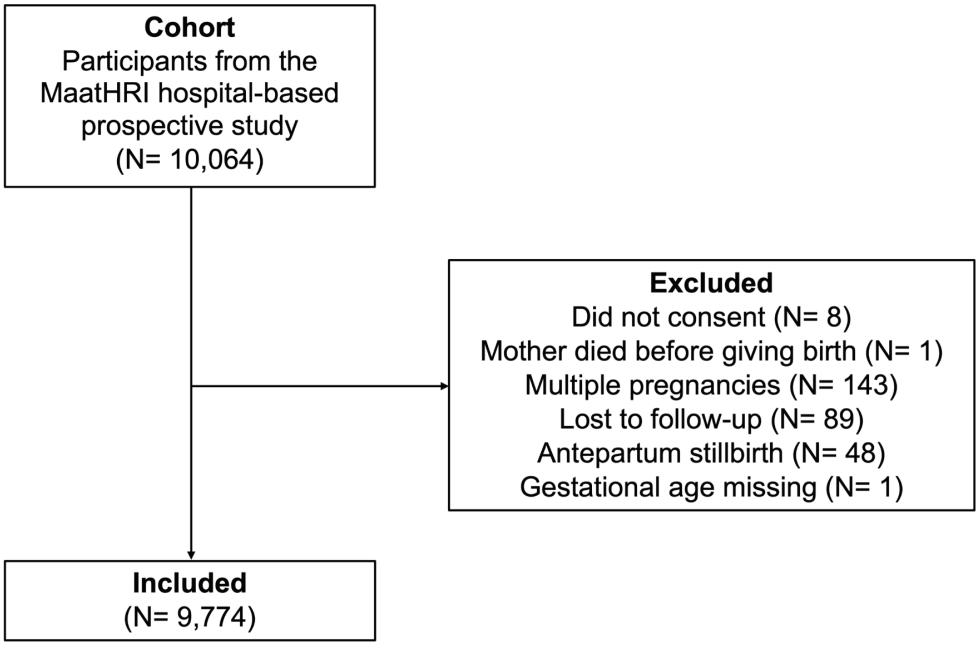
5.1 Chapter introduction

This chapter presents the results of further quantitative analysis to identify the risk factors for intrapartum stillbirth in singletons and examine the survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age. This was a secondary analysis of the data from the Maternal and perinatal Health Research collaboration, India (MaatHRI) prospective cohort study. This chapter addresses Objective 3 of the thesis.

5.2 Intrapartum stillbirth rate

After excluding women who did not consent (N=8), who died before giving birth (N=1), had multiple pregnancies (N=143), were lost to follow-up (N=89), had antepartum stillbirth (N=48) and had missing gestational age (N=1), a total of 9,774 women were eligible for inclusion in the analysis (Figure 5-1).

Figure 5-1. Flow diagram of the selection of the study participants



A total of 167 pregnancies resulted in intrapartum stillbirths, and 9,607 were live births, representing an intrapartum stillbirth rate of 17.1 per 1,000 total births (95% confidence interval (CI): 14.6-19.9).

5.3 Characteristics of women

Women who had intrapartum stillbirths were different from women who had live births in several characteristics, as described in

Table 5-1. Regarding socioeconomic characteristics, a higher proportion of women in the intrapartum stillbirth group were illiterate than in the live birth group. Also, there was a high proportion of women with below poverty line (BPL) status in the intrapartum stillbirth group. The two groups were similar with respect to other socioeconomic characteristics: area of residence and religion. For lifestyle characteristics, the proportions of women who reported smoking, consuming tobacco or chewing betel nut were similar in the two groups. Women in the intrapartum stillbirth group were, on average, older and had higher parity but were not significantly different in terms of stillbirth/miscarriage history, history of caesarean section, pre-existing medical problems or body mass index (BMI).

When comparing pregnancy characteristics between the two groups, the intrapartum stillbirth group received fewer antenatal check-ups. Additionally, fewer women in the intrapartum stillbirth group took iron and folic acid (IFA) supplementation and when they did, they took it for a shorter duration[6]. Also, anaemia and hypertensive disorders of pregnancy (HDP) were more prevalent in the intrapartum stillbirth group. While a higher proportion of women had preterm birth in the intrapartum stillbirth group, a higher proportion of women in the live birth group had an early-term birth. Fetal sex proportions between the two groups were similar. In addition, birthweight for gestation age was, on average, much lower in intrapartum stillbirth group, with a median percentile of 3.98 compared with live birth's median percentile of 13.6. Overall, 55.7% in the intrapartum stillbirth group had babies born at <10th percentile birthweight for gestational age compared with 43.2% in the live birth group.

Table 5-1. Descriptive statistics of women who had an intrapartum stillbirth compared with women who had a live birth

Variable/Level	Intrapartum stillbirths (N=167)	Live births (N=9,607)	P-value[a]
Structural factors			
Urban/rural			0.349
Urban/suburban	29 (17.4%)	1,419 (14.8%)	
Rural	138 (82.6%)	8,188 (85.2%)	
Women's education level			**<0.001**
Tertiary or above (beyond 12th class)	18 (10.8%)	1,628 (16.9%)	
Up to secondary school (6-12th class)	72 (43.1%)	5,070 (52.8%)	
Up to primary school (5th class)	41 (24.6%)	2,002 (20.8%)	
Illiterate	36 (21.6%)	874 (9.1%)	
Missing	0 (0%)	33 (0.3%)	
Religion			0.520
Hindu	119 (71.3%)	7,059 (73.5%)	
Muslim and others	48 (28.7%)	2,548 (26.5%)	
Below poverty line (BPL) status			**0.029**
No	45 (26.9%)	3,195 (33.3%)	
Unknown	21 (12.6%)	1,594 (16.6%)	
Yes	101 (60.5%)	4,818 (50.2%)	
Intermediate factors			
Smoking status			0.070
Never	115 (68.9%)	6,185 (64.4%)	
Ever	41 (24.6%)	3,069 (31.9%)	

[6] The iron and folic acid (IFA) supplementation duration was measured at the baseline of the cohort study when all women were in their third trimester. As per Indian guidelines, IFA supplementation is recommended for 180 days starting from the second trimester, meaning that preterm birth would not have resulted in a shorter duration of supplementation.

Variable/Level	Intrapartum stillbirths (N=167)	Live births (N=9,607)	P-value[a]
Missing	11 (6.6%)	353 (3.7%)	
Tobacco consumption			0.089
Never	154 (92.2%)	9,007 (93.8%)	
Before pregnancy	5 (3.0%)	110 (1.1%)	
During pregnancy	8 (4.8%)	490 (5.1%)	
Chewing betel nuts			0.148
Never	119 (71.3%)	6,328 (65.9%)	
Before pregnancy	6 (3.6%)	235 (2.4%)	
During pregnancy	42 (25.1%)	3,044 (31.7%)	
Number of antenatal check-ups			**<0.001**
Median [Q1,Q3]	3.00 [2.00,3.00]	3.00 [3.00,4.00]	
Number of antenatal check-ups			**<0.001**
4 or more	39 (23.4%)	4,199 (43.7%)	
2-3	103 (61.7%)	4,624 (48.1%)	
0-1	25 (15.0%)	784 (8.2%)	
Duration of iron and folic acid (IFA) supplementation (days)			**<0.001**
Median [Q1,Q3]	90.0 [30.0,100]	100 [90.0,150]	
Duration of iron and folic acid (IFA) supplementation			**<0.001**
180 days or more	11 (6.6%)	1,484 (15.4%)	
100-179 days	41 (24.6%)	4,195 (43.7%)	
Fewer than 100 days	90 (53.9%)	3,578 (37.2%)	
None	25 (15.0%)	350 (3.6%)	
Women's age (years)			**<0.001**
Median [Q1,Q3]	26.0 [22.0,29.5]	24.0 [21.0,28.0]	
Women's age			**<0.001**
<20 years	11 (6.6%)	852 (8.9%)	
20-24 years	58 (34.7%)	4,090 (42.6%)	
25-29 years	56 (33.5%)	3,167 (33.0%)	
30-34 years	25 (15.0%)	1,139 (11.9%)	
>34 years	17 (10.2%)	359 (3.7%)	
Parity			0.461
Median [Q1,Q3]	0 [0,1.00]	0 [0,1.00]	
Parity			**0.002**
Nulliparous	110 (65.9%)	6,429 (66.9%)	
Para 1-2	41 (24.6%)	2,779 (28.9%)	
Para 3 or more	16 (9.6%)	399 (4.2%)	
Stillbirth/miscarriage history			0.274
No	46 (27.5%)	2,810 (29.2%)	
Never pregnant	106 (63.5%)	6,250 (65.1%)	
Yes	14 (8.4%)	533 (5.5%)	
Missing	1 (0.6%)	14 (0.1%)	
History of caesarean sections			0.699
No	54 (32.3%)	2,846 (29.6%)	
Never pregnant	106 (63.5%)	6,250 (65.1%)	
Yes	7 (4.2%)	487 (5.1%)	
Missing	0 (0%)	24 (0.2%)	
Pre-existing medical problems			0.511
No	163 (97.6%)	9,288 (96.7%)	
Yes	4 (2.4%)	318 (3.3%)	
Missing	0 (0%)	1 (0.0%)	
BMI category for South Asian			0.352
<18.5	49 (29.3%)	2,487 (25.9%)	

Variable/Level	Intrapartum stillbirths (N=167)	Live births (N=9,607)	P-value[a]
18.5-22.9	77 (46.1%)	5,297 (55.1%)	
23-24.9	17 (10.2%)	892 (9.3%)	
≥25	8 (4.8%)	561 (5.8%)	
Missing	16 (9.6%)	370 (3.9%)	
Proximal factors			
Severity of anaemia			**<0.001**
No anaemia (Hb ≥11 g/dL)	12 (7.2%)	1,463 (15.2%)	
Mild (Hb 10-10.9 g/dL)	20 (12.0%)	1,169 (12.2%)	
Moderate (Hb 7-9.9 g/dL)	77 (46.1%)	5,845 (60.8%)	
Severe (Hb <7 g/dL)	58 (34.7%)	1,130 (11.8%)	
Hypertensive disorders of pregnancy (HDP)			**0.018**
No	144 (86.2%)	8,777 (91.4%)	
Other HDP[b]	17 (10.2%)	697 (7.3%)	
Pre-eclampsia/eclampsia	6 (3.6%)	133 (1.4%)	
Gestational age at birth (weeks)			**<0.001**
Median [Q1,Q3]	37.0 [35.0,39.0]	39.0 [38.0,40.0]	
Gestational age at birth			**<0.001**
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	66 (39.5%)	1,401 (14.6%)	
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	35 (21.0%)	2,484 (25.9%)	
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	60 (35.9%)	5,452 (56.8%)	
Late/post term (≥$41^{0/7}$ weeks)	6 (3.6%)	270 (2.8%)	
Fetal sex			0.835
Male	87 (52.1%)	5,083 (52.9%)	
Female	80 (47.9%)	4,524 (47.1%)	
Birthweight for gestational age (percentile)			**<0.001**
Median [Q1,Q3]	3.98 [0.120,28.4]	13.6 [2.92,36.0]	
Birthweight for gestational age			**0.003**
<10^{th} percentile	93 (55.7%)	4,146 (43.2%)	
10 to 90^{th} percentile	68 (40.7%)	5,075 (52.8%)	
>90^{th} percentile	4 (2.4%)	354 (3.7%)	
Missing	2 (1.2%)	32 (0.3%)	

Hb: haemoglobin, BMI: body mass index

[a] Nonparametric statistical test for continuous variables and Pearson's chi-squared test for categorical variables.

[b] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

5.4 Risk factors for intrapartum stillbirth

5.4.1 Univariable analysis

Unadjusted associations between exposure variables and intrapartum stillbirth are presented in Table 5-2.

Table 5-2. Unadjusted associations (univariable analysis) between exposure variables and relative risk of intrapartum stillbirth

Variable/Level	Univariable analysis	
	RR (95% CI)	**P-value**
Structural factors		
Urban/rural		
Urban/suburban	1 (Ref)	-
Rural	0.83 (0.56-1.26)	0.354
Women's education level		
Tertiary or above (beyond 12th class)	1 (Ref)	-
Up to secondary school (6-12th class)	1.28 (0.78-2.21)	0.348
Up to primary school (5th class)	**1.84 (1.07-3.27)**	**0.032**
Illiterate	**3.62 (2.08-6.51)**	**<0.001**
Religion		
Hindu	1 (Ref)	-
Muslim and others	1.12 (0.79-1.55)	0.523
Below poverty line (BPL) status		
No	1 (Ref)	-
Unknown	0.94 (0.55-1.55)	0.803
Yes	**1.48 (1.05-2.12)**	**0.029**
Intermediate factors		
Smoking status		
Never	1 (Ref)	-
Ever	0.72 (0.50-1.02)	0.074
Tobacco consumption		
Never	1 (Ref)	-
Before pregnancy	**2.59 (0.92-5.66)**	**0.037**
During pregnancy	0.96 (0.43-1.82)	0.900
Chewing betel nuts		
Never	1 (Ref)	-
Before pregnancy	1.35 (0.53-2.80)	0.475
During pregnancy	0.74 (0.51-1.04)	0.090
Number of antenatal check-ups		
4 or more	1 (Ref)	-
2-3	**2.37 (1.65-3.46)**	**<0.001**
0-1	**3.36 (2.01-5.51)**	**<0.001**
Duration of iron and folic acid (IFA) supplementation		
180 days or more	1 (Ref)	-
100-179 days	1.32 (0.70-2.69)	0.419
Fewer than 100 days	**3.33 (1.87-6.61)**	**<0.001**
None	**9.06 (4.57-19.18)**	**<0.001**
Women's age		
<20 years	1 (Ref)	-
20-24 years	1.10 (0.60-2.21)	0.778
25-29 years	1.36 (0.74-2.75)	0.348
30-34 years	1.69 (0.85-3.57)	0.149
>34 years	**3.55 (1.68-7.80)**	**0.001**
Parity		
Nulliparous	1.16 (0.82-1.67)	0.425
Para 1-2	1 (Ref)	-
Para 3 or more	**2.65 (1.45-4.63)**	**<0.001**
Stillbirth/miscarriage history		
No	1 (Ref)	-
Never pregnant	1.04 (0.74-1.48)	0.844

Variable/Level	Univariable analysis	
	RR (95% CI)	**P-value**
Yes	1.59 (0.84-2.81)	0.129
History of caesarean sections		
No	1 (Ref)	-
Never pregnant	0.90 (0.65-1.25)	0.510
Yes	0.76 (0.32-1.56)	0.497
Pre-existing medical problems		
No	1 (Ref)	-
Yes	0.72 (0.22-1.70)	0.517
BMI category for South Asian		
<18.5	1.35 (0.94-1.92)	0.102
18.5-22.9	1 (Ref)	-
23-24.9	1.31 (0.75-2.15)	0.320
≥25	0.98 (0.44-1.91)	0.959
Proximal factors		
Severity of anaemia		
No anaemia (Hb ≥11 g/dL)	1 (Ref)	-
Mild (Hb 10-10.9 g/dL)	**2.07 (1.02-4.36)**	**0.047**
Moderate (Hb 7-9.9 g/dL)	1.60 (0.91-3.09)	0.131
Severe (Hb <7 g/dL)	**6.00 (3.34-11.73)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)		
No	1 (Ref)	-
Other HDP[a]	1.48 (0.86-2.37)	0.130
Pre-eclampsia/eclampsia	**2.67 (1.05-5.53)**	**0.018**
Gestational age at birth		
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	**4.13 (2.91-5.87)**	**<0.001**
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	1.28 (0.83-1.92)	0.251
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	1 (Ref)	-
Late/post term (≥$41^{0/7}$ weeks)	2.00 (0.77-4.26)	0.106
Fetal sex		
Male	1 (Ref)	-
Female	1.03 (0.76-1.40)	0.836
Birthweight for gestational age		
<10^{th} percentile	**1.66 (1.22-2.28)**	**0.002**
10^{th} to 90^{th} percentile	1 (Ref)	-
>90^{th} percentile	0.85 (0.26-2.04)	0.744

Hb: haemoglobin, RR: relative risk, CI: confidence interval, BMI: body mass index
[a] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

The univariable analysis demonstrated that women's education level and BPL status were statistically significant structural risk factors. Women who cannot read or write (illiterate) had a 3.62 times higher risk of intrapartum stillbirth (95% CI: 2.08-6.51) than women with a tertiary or higher level of education. Also, women with up to primary school level of education had a 1.84 times higher risk of intrapartum stillbirth (95% CI: 1.07-3.27). Women with BPL status had a 1.48 times higher risk of intrapartum stillbirth compared to women without BPL status (95% CI: 1.05-2.12).

Women who chewed tobacco before pregnancy had a 2.59 times higher risk of intrapartum stillbirth (95% CI: 0.92-5.66). Other intermediate factors related to an unhealthy lifestyle (smoking status, chewing betel nuts) were not statistically significant risk factors for intrapartum stillbirth. Women who attended 2-3 antenatal check-ups had 2.37 times (95% CI: 1.65-3.46) higher risk of intrapartum stillbirth compared with those who attended four or more check-ups. The risk was even higher among women who had 0-1 check-up (relative risk (RR): 3.36, 95% CI: 2.01-5.51). Women who did not take any IFA supplementation had more than nine times higher risk of intrapartum stillbirth (RR: 9.06, 95% CI: 4.57-19.18) compared with women who received IFA supplementation for 180 days or more. Receiving IFA supplementation for fewer than 100 days also increased the risk by more than three-fold (RR: 3.33, 95% CI: 1.87-6.61). Women aged >34 years had an increased risk of intrapartum stillbirth by 3.55 times (95% CI: 1.68-7.80) compared with the age group <20 years. Relative risks for other age groups were not significantly different from the comparison group (<20 years).

In addition, women with higher parity (para 3 or more) had an increased risk of intrapartum stillbirth than women who were para 1-2 (RR: 2.65, 95% CI: 1.45-4.63). Nulliparous women also had a higher risk (RR: 1.16, 95% CI: 0.82-1.67), but this was not statistically significant. Stillbirth/miscarriage history, history of caesarean sections and pre-existing medical problems and BMI category were not significant intermediate risk factors for intrapartum stillbirth.

For proximal factors, the severity of anaemia, HDP, gestational age at birth and birthweight for gestational age were statistically significant risk factors. Women with mild anaemia had more than a two-fold increased risk of intrapartum stillbirth (RR: 2.07, 95% CI: 1.02-4.36) compared with women without anaemia, and women with severe anaemia had a six-fold increased risk of intrapartum stillbirth (95% CI: 3.34-11.73). Women with moderate anaemia also had a higher risk of stillbirth (RR: 1.60, 95% CI: 0.91-3.09), but this was not statistically significant. Having pre-eclampsia/eclampsia increased the risk of intrapartum stillbirth by 2.67 times (95% CI: 1.05-5.53) compared with women who did not have any HDP. Other types of HDP (such as chronic hypertension or gestational hypertension) also had an

increased risk of intrapartum stillbirth (RR: 1.48, 95% CI: 0.86-2.37), but the association was not statistically significant.

Preterm birth had a more than a four-fold increased risk of intrapartum stillbirth compared with full-term birth (RR: 4.13, 95% CI 2.91-5.87). Early-term and late/post-term births were also associated with an increased risk, but the relative risks were not statistically significant. Furthermore, babies born at <10th percentile birthweight for gestational age had a 1.66 times higher risk of intrapartum stillbirth (95% CI: 1.22-2.28) compared with babies born between the 10th to 90th percentile birthweight for gestational age.

5.4.2 Multivariable analysis

Using the hierarchical approach starting from structural factors (Model 1), variables that had p-values <0.05 overall or within the subgroups in the univariable analysis were included in the multivariable models (Table 5-3).

Table 5-3. Adjusted associations (multivariable analysis) between exposure variables and relative risk of intrapartum stillbirth

Variable/Level	Model 1: Adjusted for structural factors		Model 2: Adjusted for structural & intermediate factors		Model 3: Adjusted for structural, intermediate & proximal factors	
	aRR (95% CI)	**P-value**	**aRR (95% CI)**	**P-value**	**aRR (95% CI)**	**P-value**
Structural factors						
Women's education level						
Tertiary or above (beyond 12th class)	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Up to secondary school (6-12th class)	1.25 (0.76-2.16)	0.399	1.35 (0.81-2.35)	0.269	1.26 (0.76-2.20)	0.391
Up to primary school (5th class)	1.65 (0.95-2.95)	0.083	1.35 (0.76-2.49)	0.314	1.06 (0.59-1.97)	0.839
Illiterate	**3.49 (2.01-6.31)**	**<0.001**	**3.01 (1.69-5.54)**	**<0.001**	**2.37 (1.33-4.38)**	**0.004**
Below poverty line (BPL) status						
No	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Unknown	1.02 (0.60-1.70)	0.932	0.81 (0.47-1.35)	0.435	0.77 (0.45-1.30)	0.344
Yes	**1.44 (1.01-2.08)**	**0.048**	0.91 (0.62-1.35)	0.624	0.81 (0.55-1.20)	0.281
Intermediate factors						
Tobacco consumption						
Never			1 (Ref)	-	1 (Ref)	-
Before pregnancy			1.42 (0.50-3.18)	0.445	1.29 (0.45-2.91)	0.583
During pregnancy			0.58 (0.26-1.12)	0.140	0.62 (0.27-1.20)	0.192
Number of antenatal check-ups						
4 or more			1 (Ref)	-	1 (Ref)	-
2-3			**1.84 (1.24-2.77)**	**0.003**	**1.90 (1.27-2.87)**	**0.002**
0-1			1.68 (0.96-2.88)	0.065	1.60 (0.91-2.76)	0.097
Duration of iron and folic acid (IFA) supplementation						
180 days or more			1 (Ref)	-	1 (Ref)	-
100-179 days			1.47 (0.77-3.04)	0.269	**2.12 (1.04-4.67)**	**0.049**
Fewer than 100 days			**3.02 (1.65-6.11)**	**<0.001**	**4.03 (2.05-8.66)**	**<0.001**
None			**7.79 (3.80-16.97)**	**<0.001**	**9.10 (4.15-21.05)**	**<0.001**
Women's age						
<20 years			1 (Ref)	-	1 (Ref)	-
20-24 years			1.14 (0.62-2.31)	0.685	1.21 (0.66-2.46)	0.559

Variable/Level	Model 1: Adjusted for structural factors		Model 2: Adjusted for structural & intermediate factors		Model 3: Adjusted for structural, intermediate & proximal factors	
	aRR (95% CI)	**P-value**	**aRR (95% CI)**	**P-value**	**aRR (95% CI)**	**P-value**
25-29 years			1.55 (0.83-3.17)	0.194	1.56 (0.83-3.21)	0.193
30-34 years			1.93 (0.94-4.19)	0.081	1.97 (0.96-4.28)	0.074
>34 years			**3.13 (1.39-7.28)**	**0.007**	**3.17 (1.41-7.36)**	**0.006**
Parity						
Nulliparous			1.29 (0.88-1.92)	0.203	1.28 (0.87-1.91)	0.226
Para 1-2			1 (Ref)	-	1 (Ref)	-
Para 3 or more			1.31 (0.68-2.41)	0.406	1.47 (0.76-2.70)	0.234
Proximal factors						
Severity of anaemia						
No anaemia (Hb ≥11 g/dL)					1 (Ref)	-
Mild (Hb 10-10.9 g/dL)					1.87 (0.93-3.95)	0.087
Moderate (Hb 7-9.9 g/dL)					1.24 (0.70-2.41)	0.493
Severe (Hb <7 g/dL)					**3.33 (1.82-6.63)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						
No					1 (Ref)	-
Other HDP[a]					**2.48 (1.36-4.25)**	**0.002**
Pre-eclampsia/eclampsia					**2.54 (0.99-5.35)**	**0.023**
Gestational age at birth[b]						
Preterm (28^{+0} to 36^{+6} weeks)					**3.25 (2.26-4.69)**	**<0.001**
Early term (37^{+0} to 38^{+6} weeks)					1.45 (0.94-2.22)	0.087
Full term (39^{+0} to 40^{+6} weeks)					1 (Ref)	-
Late/post term (≥41^{+0} weeks)					1.80 (0.69-3.86	0.172
Birthweight for gestational age[b]						
<10^{th} percentile					**1.57 (1.14-2.17)**	**0.006**
10 to 90^{th} percentile					1 (Ref)	-
>90^{th} percentile					0.55 (0.16-1.33)	0.243

Hb: haemoglobin, Other HDP: chronic hypertension or gestational hypertension

[a] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

[b] Birthweight for gestational age was calculated using gestational age at birth, therefore, these variables were not included in the same model together.

Not being able to read or write (illiteracy) remained a significant structural risk factor for intrapartum stillbirth after full adjustment. Compared with women with tertiary or above education level, this group had a 2.37 times higher risk of intrapartum stillbirth (95% CI: 1.33-4.38). In contrast, BPL status was no longer a significant risk factor once intermediate factors were adjusted for (adjusted relative risk (aRR): 0.91, 95% CI: 0.62-1.35). There were no interactions between women's education level and BPL status, women's education level and tobacco consumption, age and tobacco consumption, and BPL status and tobacco consumption.

After full adjustment for intermediate factors, women who received 2-3 antenatal check-ups had a 1.90 times higher risk of intrapartum stillbirth compared with those who attended four or more visits (95% CI: 1.27-2.87). The risk of intrapartum stillbirth for women who received 0-1 antenatal check-up was elevated but no longer statistically significant after intermediate factors were adjusted for (aRR: 1.68, 95% CI: 0.96-2.88). Similarly, tobacco consumption before pregnancy was no longer significant once intermediate factors were adjusted for (aRR: 1.42, 95% CI: 0.50-3.18).

The duration of IFA supplementation continued to remain a significant risk factor for intrapartum stillbirth after full adjustment. Women who did not take any IFA supplementation had a 9.10 times higher risk of intrapartum stillbirth (95% CI: 4.15-21.05) compared with women who took IFA supplementation for 180 days or more. In addition, women who received IFA supplementation for fewer than 100 days had a four-fold increased risk (aRR: 4.03, 95% CI: 2.05-8.66). There was confirmed evidence of a linear trend with increasing IFA supplementation duration (p-value: <0.001).

Women aged 34 years or older had a 3.17 times higher risk of intrapartum stillbirth compared with women aged <20 years (95% CI: 1.41-7.36). In comparison, other age groups did not have a statistically significant higher risk of stillbirth compared with <20 years age group, although risks were elevated. The test for trend with a p-value of 0.002 confirmed a linear trend with increasing age. Having higher parity, para 3 or more, was no longer a significant risk factor once other intermediate factors were accounted for (aRR: 1.31, 95% CI: 0.68-2.41).

Significant proximal risk factors associated with intrapartum stillbirth included severe anaemia, any type of HDP, preterm birth and <10th percentile birthweight for gestational age. While mild and moderate anaemia were not statistically significant risk factors once other factors were adjusted for, severe anaemia remained a significant risk factor for intrapartum stillbirth. After full adjustment, women with severe anaemia had a 3.33 times higher risk of intrapartum stillbirth compared with those women without anaemia (95% CI: 1.82-6.63). Women with pre-eclampsia/eclampsia had an adjusted relative risk of 2.54 (95% CI: 0.99-5.35) when compared with women who did not have any type of HDP, while those with other types of HDP had an adjusted relative risk of 2.48 (95% CI: 1.36-4.25).

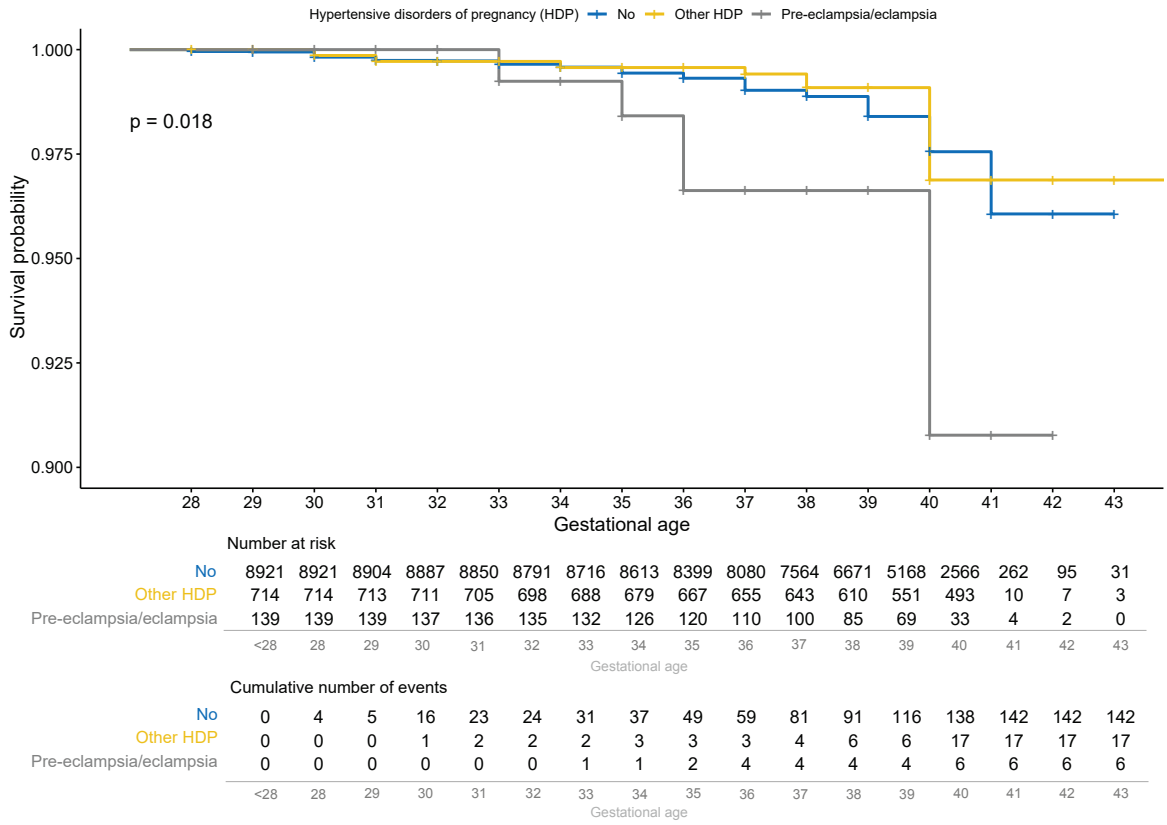
Preterm birth remained a significant proximal risk factor after full adjustment of all other factors. Compared with full-term birth, women with babies born preterm had a 3.25 times higher risk of intrapartum stillbirth (95% CI: 2.26-4.69). Early-term or late/post-term birth did not significantly increase the risk of intrapartum stillbirth. Babies born at less than the 10th percentile birthweight for gestational age was another significant proximal risk factor: compared with babies born between the 10th to 90th percentile birthweight for gestational age, this group had a 1.57 times higher risk of intrapartum stillbirth (95% CI: 1.14-2.17). However, babies born over the 90th percentile birthweight for gestational age did not have a significantly increased risk of intrapartum stillbirth.

5.5 Survival probabilities of fetuses in women with complications

Severe anaemia and HDP conditions were complications associated with a high risk of intrapartum stillbirth, according to the modified Poisson regression results. Therefore, they were selected for time-to-event analysis to explore how intrapartum stillbirth risks associated with these conditions evolved throughout pregnancy, with a particular focus on the timing of intrapartum stillbirth. When survival probabilities of fetuses by gestational age in women with HDP were compared with women without HDP (Figure 5-2), the Kaplan-Meier survival curve showed similar survival probabilities between HDP categories until the 34 weeks of gestation. Beyond this point, the survival probabilities of the fetuses for

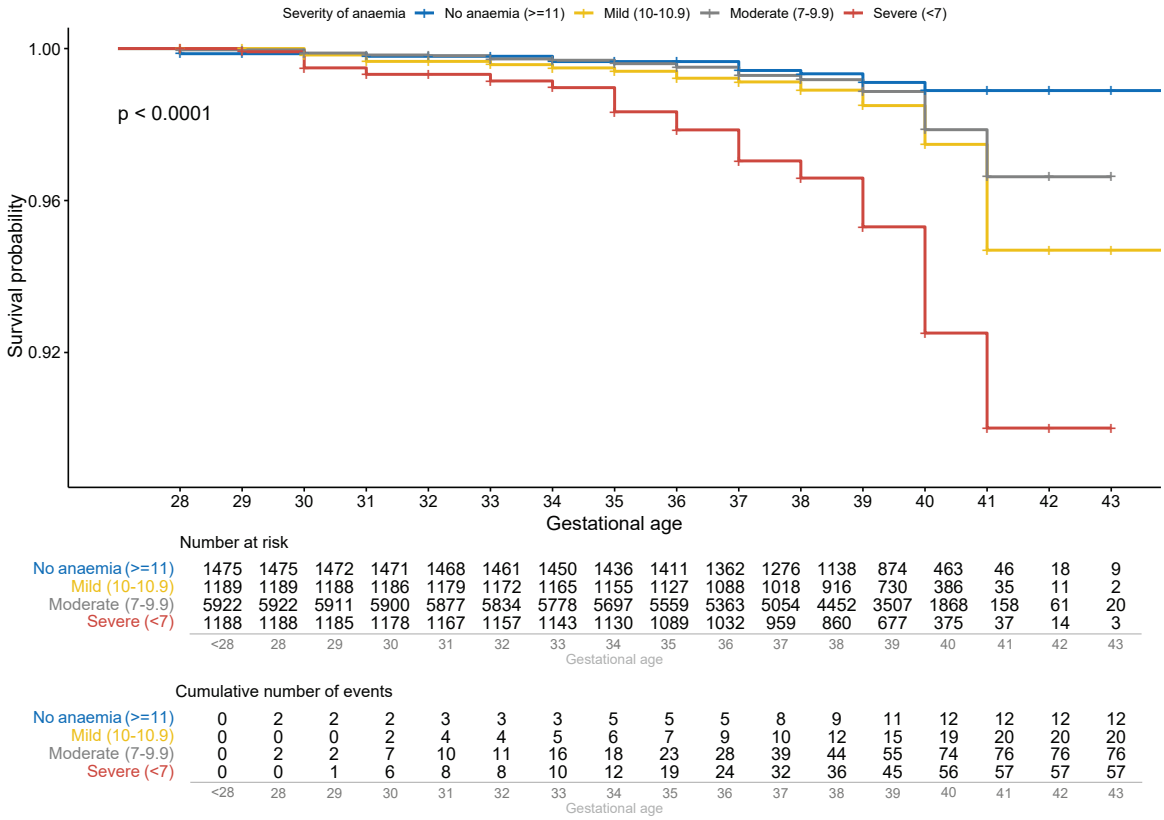
women with pre-eclampsia/eclampsia declined substantially compared with those without HDP or with other HDP conditions such as chronic hypertension or gestational hypertension (p-value: 0.018).

Figure 5-2. Kaplan-Meier survival curve by HDP category by gestational age



Whereas the survival probabilities for fetuses of women with severe anaemia during the third trimester started to decrease from as early as the 30 weeks of gestation compared with women with mild/moderate anaemia or no anaemia (p-value: <0.0001) (Figure 5-3). The survival probabilities for this group continued to decline as the gestational age increased.

Figure 5-3. Kaplan-Meier survival curve by severity of anaemia by gestational age



5.6 Antepartum stillbirth rate and risk factors

There were 48 antepartum stillbirths and 9,607 live births, representing an antepartum stillbirth rate of 4.9 per 1,000 total births (95% CI: 3.7-6.6). Additional analysis investigating risk factors for antepartum stillbirth found the following risk factors as statistically significant at univariable analysis using the modified Poisson regression model (Table 5-4):

- Intermediate factors: Duration of IFA supplementation, stillbirth/miscarriage history
- Proximal factors: severity of anaemia, HDP, gestational age at birth, birthweight for gestational age

Table 5-4. Unadjusted associations (univariable analysis) between exposure variables and relative risk of antepartum stillbirth

	Univariable analysis	
	RR (95% CI)	**P-value**
Structural factors		
Urban/rural		
Urban/suburban	1 (Ref)	-
Rural	0.75 (0.38-1.66)	0.441
Women's education level		
Tertiary or above (beyond 12th class)	1 (Ref)	-
Up to secondary school (6-12th class)	0.61 (0.28-1.43)	0.227
Up to primary school (5th class)	1.17 (0.51-2.84)	0.712
Illiterate	1.85 (0.72-4.75)	0.190
Religion		
Hindu	1 (Ref)	-
Muslim and others	0.73 (0.34-1.41)	0.376
Below poverty line (BPL) status		
No	1 (Ref)	-
Unknown	1.43 (0.62-3.19)	0.389
Yes	1.14 (0.60-2.25)	0.704
Intermediate factors		
Smoking status		
Never	1 (Ref)	-
Ever	1.34 (0.73-2.42)	0.334
Tobacco consumption		
Never	1 (Ref)	-
Ever	2.13 (0.81-4.64)	0.083
Chewing betel nuts		
Never	1 (Ref)	-
Before pregnancy	0.96 (0.04-4.50)	0.970
During pregnancy	1.41 (0.77-2.50)	0.250
Number of antenatal check-ups		
4 or more	1 (Ref)	-
2-3	1.53 (0.83-2.90)	0.178
0-1	1.67 (0.55-4.26)	0.317
Duration of iron and folic acid (IFA) supplementation		
180 days or more	1 (Ref)	-
100-179 days	0.88 (0.19-6.18)	0.883
Fewer than 100 days	**7.40 (2.26-45.55)**	**0.006**
None	**10.46 (2.26-73.07)**	**0.005**
Women's age		
<20	1 (Ref)	-
20-24	0.99 (0.37-3.41)	0.985
25-29	1.08 (0.39-3.76)	0.896
30-34	1.12 (0.32-4.39)	0.859
>34	1.77 (0.35-8.05)	0.453
Parity		
Nulliparous	0.65 (0.36-1.20)	0.157
Para 1-2	1 (Ref)	-
Para 3 or more	1.16 (0.27-3.43)	0.812
Stillbirth/miscarriage history		
No	1 (Ref)	-
Never pregnant	1.10 (0.56-2.32)	0.784
Yes	**4.72 (1.97-11.20)**	**<0.001**

	Univariable analysis	
	RR (95% CI)	**P-value**
History of caesarean sections		
No	1 (Ref)	-
Never pregnant	0.72 (0.40-1.35)	0.298
Yes	1.37 (0.39-3.71)	0.569
Existing medical problems		
No	1 (Ref)	-
Yes	1.94 (0.47-5.30)	0.267
BMI category for South Asian		
<18.5	0.50 (0.20-1.07)	0.097
18.5-22.9	1 (Ref)	-
23-24.9	1.58 (0.67-3.28)	0.251
≥25	0.63 (0.10-2.09)	0.528
Proximal factors		
Severity of anaemia		
No anaemia (Hb ≥11 g/dL)	1 (Ref)	-
Mild (Hb 10-10.9 g/dL)	2.91 (0.81-13.50)	0.122
Moderate (Hb 7-9.9 g/dL)	2.33 (0.83-9.74)	0.164
Severe (Hb <7 g/dL)	**4.29 (1.31-19.12)**	**0.027**
Hypertensive disorders of pregnancy (HDP)		
No	1 (Ref)	-
Other HDP[a]	0.90 (0.22-2.47)	0.860
Pre-eclampsia/eclampsia	**4.63 (1.12-12.71)**	**0.010**
Gestational age at birth		
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	**12.72 (6.29-28.45)**	**<0.001**
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	1.95 (0.73-5.09)	0.170
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	1 (Ref)	-
Late/post term (≥$41^{0/7}$ weeks)	2.24 (0.12-11.91)	0.445
Fetal sex		
Male	1 (Ref)	-
Female	0.87 (0.49-1.54)	0.645
Birthweight for gestational age		
<10^{th} percentile	0.97 (0.52-1.76)	0.919
10^{th} to 90^{th} percentile	1 (Ref)	-
>90^{th} percentile	**2.96 (1.00-7.14)**	**0.027**

Hb: Haemoglobin, RR: relative risk, CI: confidence interval, BMI: body mass index
[a] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

As seen in Table 5-5, the results of the multivariable modified Poisson regression showed that after adjusting for risk factors that were significant in the univariable analysis, antepartum stillbirth was significantly associated with fewer than 100 days of IFA supplementation (aRR: 7.34, 95% CI: 2.12-46.55), having no IFA supplementation (aRR: 8.26, 95% CI: 1.70-59.63), history of stillbirth or miscarriage (aRR: 4.58, 95% CI: 1.90-10.95), pre-eclampsia/eclampsia (aRR: 3.53, 95% CI: 0.85-9.85), and preterm birth (aRR: 9.25, 95% CI: 4.50-20.97). After adjusting for other factors, anaemia was not significantly associated with antepartum stillbirth, although the adjusted relative risks suggested a high risk across all severity categories of anaemia. Similarly, while not statistically significant after adjustment,

babies born with a birthweight greater than the 90th percentile for gestational age had a higher risk of antepartum stillbirth (aRR: 2.29, 95% CI: 0.76–5.60) compared to those born within the 10th to 90th percentile range.

Table 5-5. Adjusted associations (multivariable analysis) between exposure variables and relative risk of antepartum stillbirth

Variable/Level	Model 1: Adjusted for intermediate factors		Model 2: Adjusted for intermediate & proximal factors	
	aRR (95% CI)	**P-value**	**aRR (95% CI)**	**P-value**
Intermediate factors				
Duration of iron and folic acid (IFA) supplementation				
180 days or more	1 (Ref)	-	1 (Ref)	-
100-179 days	0.88 (0.19-6.14)	0.878	0.93 (0.19-6.66)	0.931
Fewer than 100 days	**7.42 (2.27-45.67)**	**0.006**	**7.34 (2.12-46.55)**	**0.008**
None	**9.28 (1.99-64.91)**	**0.008**	**8.26 (1.70-59.63)**	**0.014**
Stillbirth/miscarriage history				
No	1 (Ref)	-	1 (Ref)	-
Never pregnant	1.03 (0.52-2.16)	0.940	1.01 (0.51-2.14)	0.972
Yes	**4.37 (1.82-10.37)**	**0.001**	**4.58 (1.90-10.95)**	**0.001**
Proximal factors				
Severity of anaemia				
No anaemia (Hb ≥11 g/dL)			1 (Ref)	-
Mild (Hb 10-10.9 g/dL)			2.48 (0.69-11.55)	0.189
Moderate (Hb 7-9.9 g/dL)			1.52 (0.53-6.38)	0.497
Severe (Hb <7 g/dL)			2.15 (0.65-9.69)	0.250
Hypertensive disorders of pregnancy (HDP)				
No			1 (Ref)	-
Other HDP[a]			1.35 (0.32-3.87)	0.630
Pre-eclampsia/eclampsia			**3.53 (0.85-9.85)**	**0.037**
Gestational age at birth[b]				
Preterm (28^{+0} to 36^{+6} weeks)			**9.25 (4.50-20.97)**	**<0.001**
Early term (37^{+0} to 38^{+6} weeks)			1.89 (0.70-4.97)	0.195
Full term (39^{+0} to 40^{+6} weeks)			1 (Ref)	-
Late/post term (≥41^{+0} weeks)			1.98 (0.11-10.61)	0.516
Birthweight for gestational age[b]				
<10th percentile			1.02 (0.55-1.86)	0.960
10 to 90th percentile			1 (Ref)	-
>90th percentile			2.29 (0.76-5.60)	0.097

Hb: haemoglobin, Other HDP: chronic hypertension or gestational hypertension

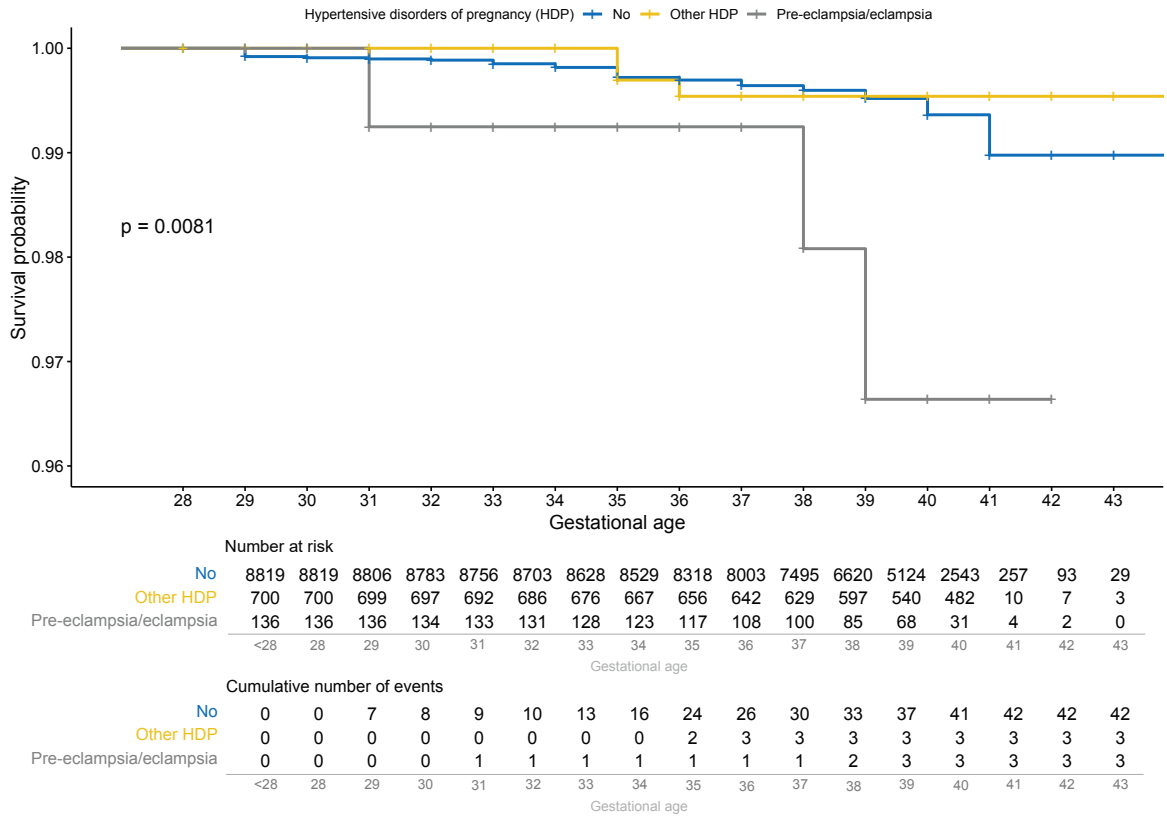
[a] Other HDP was defined as chronic hypertension or gestational hypertension or any other HDP other than pre-eclampsia or eclampsia.

[b] Birthweight for gestational age was calculated using gestational age at birth, therefore, these variables were not included in the same model together.

Moreover, the Kaplan-Meier survival curve of survival by HDP category by gestational age (Figure 5-4) showed that the survival probabilities of the fetuses among women with pre-eclampsia/eclampsia started

to decline around 31 weeks of gestation and very rapidly declined again from 38 weeks of gestation, when compared with those without HDP or with other HDP conditions such as chronic hypertension or gestational hypertension (p-value: 0.0081).

Figure 5-4. Kaplan-Meier survival curve by HDP category by gestational age (antepartum stillbirth analysis)



5.7 Discussion

5.7.1 Principal findings

The intrapartum stillbirth rate for this Indian population of pregnant women recruited from 13 hospitals across six states was 17.1 per 1,000 total births (95% CI: 14.6-19.9). Notably, illiteracy among women had a significant association with intrapartum stillbirth, with illiterate women having more than double the risk compared with women with tertiary education or higher. Intermediate factors such as fewer than four antenatal check-ups, none or fewer than 100 days of IFA supplementation, and age >34 years also

increased the risk of intrapartum stillbirth. Additionally, severe anaemia, HDP conditions, preterm birth and being <10th percentile birthweight for gestational age substantially increased the risk of intrapartum stillbirth. Survival probability analysis by gestational age indicated distinct patterns between different HDP types and anaemia severity, with survival probabilities for fetuses of women with pre-eclampsia/eclampsia and severe anaemia starting to decrease at earlier gestational age than other HDP types or anaemia severity.

5.7.2 Compared with risk factors for overall stillbirth

The risk factors which were statistically significant for overall stillbirth, after adjusting for relevant structural, intermediate and proximal risk factors, were women's illiteracy (not being able to read or write), receiving 2-3 antenatal check-ups, taking IFA supplementation for fewer than 100 days or not taking IFA supplementation at all, women's age group >34 years and having a history of stillbirth or miscarriage. Additionally, having mild or severe anaemia, experiencing any type of HDP, preterm or early term birth and birthweight <10th percentile for gestational age were significant proximal risk factors. Therefore, the risk factors for intrapartum stillbirth closely mirrored the risk factors for overall stillbirth in this cohort, most likely because intrapartum stillbirths accounted for a large proportion (77.8%) of overall stillbirths (Chapter 4).

5.7.3 Compared with risk factors for antepartum stillbirth

Antepartum stillbirth was significantly associated with inadequate IFA supplementation (fewer than 100 days or none), a history of stillbirth or miscarriage, pre-eclampsia/eclampsia, and preterm birth. In addition, survival probabilities of the fetuses among women with pre-eclampsia/eclampsia started to decline around 31 weeks of gestation and very rapidly declined again from 38 weeks of gestation when compared with those without HDP or with other HDP conditions such as chronic hypertension or gestational hypertension. The shape of survival probabilities between HDP categories depicted in the

Kaplan-Meier survival curve for antepartum stillbirth analysis was similar to the curves for intrapartum stillbirth.

Due to the small number of antepartum stillbirths in this cohort (N=48), there is likely to have been insufficient power to detect statistically significant associations between antepartum stillbirth and other factors. So, it is important to note that the comparison between the two subtypes may not be entirely reliable, although it is informative. For non-significant risk factors, confidence intervals were carefully assessed to understand the practical meaning of a finding [225].

Relative risks from the antepartum stillbirth analysis were similar in magnitude and direction to the results of the intrapartum stillbirth analysis for illiteracy, inadequate antenatal check-ups, age >34 years, severe anaemia and other types of HDP (such as chronic hypertension or gestational hypertension), although the 95% confidence intervals were wider. This indicates that these factors impact fetal survival regardless of the timing of stillbirth (before or after the onset of labour). However, some differences between antepartum and intrapartum stillbirth risk factors were also observed, athough with caution, due to potential limitations in statistical power. For example, a history of stillbirth or miscarriage was a significant risk factor for antepartum stillbirth but not for intrapartum stillbirth. Additionally, babies born at a birthweight greater than the 90th percentile for gestational age had a higher risk of antepartum stillbirth (aRR: 2.29, 95% CI: 0.76-5.60) compared to those born between the 10th to 90th percentile, while this same group had a lower risk of intrapartum stillbirth than babies born in the 10th to 90th percentile range. This finding suggests the need for further research to investigate whether excessive fetal growth may contribute to compromised survival in utero.

5.7.4 Discussion in light of other evidence

While understanding risk factors specific to intrapartum stillbirth can contribute meaningfully to shaping the policy focus regarding the quality of intrapartum care, research into facility-based intrapartum stillbirth in India is scarce, hindering efforts to address this issue effectively. For example, a literature

search[7] identified only one study [40] that reported the proportion and risk factors for facility-based intrapartum stillbirth in India. This cohort study conducted at a rural development trust hospital in Bathalapalli, Andhra Pradesh [40], where 8,906 births were analysed, found only 21.0% of facility-based stillbirths were intrapartum (22 intrapartum stillbirths out of 105 overall stillbirths), and preterm birth and low birthweight (<2,500g) were identified as statistically significant risk factors. However, the study's reliance on data from a single hospital and with no statistical adjustment for potential confounders limit the strength of its findings. Compared with the evidence from the single-centre cohort study, which had lower than average (45%) proportion of intrapartum stillbirths for a low-and-middle-income country (LMIC) setting [5], this study found that the number of intrapartum stillbirths in MaatHRI's multi-centre prospective cohort study was much higher (N=167) with a high intrapartum stillbirth rate (17.1 per 1,000 total births) compared with the antepartum stillbirth rate of 4.9 per 1,000 total births. This could be because nine of the 13 MaatHRI hospitals (69.2%) were medical colleges, where they usually serve a higher proportion of high-risk women, whereas the previous study was based in a secondary rural hospital.

The higher risk of intrapartum stillbirth among illiterate women in this study aligns with other epidemiological studies in LMICs that link lower maternal education with higher intrapartum stillbirth risk [219,226,227]. However, these studies did not specifically categorise illiteracy within women's education levels. Since other education levels, including 'Up to primary school,' were not significantly associated with increased intrapartum stillbirth risk in this study, future research should not combine literacy and formal education levels when trying to understanding the role of maternal education and reading and writing ability in maternal health outcomes. Literacy itself may provide distinct benefits in preventing intrapartum stillbirth [228], even if women do not have any formal education, for example, by enabling healthcare-seeking behaviours [229,230].

[7] MEDLINE (OvidSP) [1946-January 6, 2024], EMBASE (OvidSP) [1974-January 6, 2024], and Global Health (OvidSP) [1973–2023 Week 52] were searched from their inception of databases until 6 January 2024 using MESH terms encompassing "Stillbirth*", "Intrapartum", "Fresh", "Risk Factors", and "India" with Boolean operators.

In 2016, the World Health Organization (WHO) increased the recommended number of antenatal check-ups for pregnant women from four to eight [168]. This change was based on evidence indicating that more frequent antenatal check-ups are associated with a reduced likelihood of stillbirths, as they provide more opportunities to detect and manage potential medical and obstetric complications. The WHO reported that eight or more check-ups could reduce perinatal deaths by up to 8 per 1,000 total births compared with four visits [168]. However, in this study cohort, only 2.1% of the women received eight or more antenatal check-ups (N=209), making it unfeasible to analyse this group separately. In fact, only 43.3% of the cohort population received four or more check-ups. Although in this study, a linear relationship between the number of antenatal check-ups and the risk of intrapartum stillbirth was not observed. Thus, improving access to high-quality antenatal care and ensuring pregnant women receive the target number of high-quality antenatal check-ups remain important strategies for reducing intrapartum stillbirth in India and improving other aspects of care.

According to Khanam *et al.*'s systematic review [231], compliance rates of IFA supplementation among pregnant women in India ranged from 12.0% to 91.3%, and the following factors were found to affect compliance: knowledge of IFA supplementation and anaemia, the timing of antenatal care registration and the number of check-ups, socioeconomic status, women's education level, type of family, women's age, and individual reasons such as forgetfulness or associated side effects including abdominal pain, nausea, and constipation. In this study, 15.3% of the cohort reported taking IFA supplementation for 180 days or more and 58.6% for 100 days or more. Women who did not take IFA or took IFA for fewer than 100 days had a significantly higher risk of intrapartum stillbirth. To prevent intrapartum stillbirth, it is crucial to address IFA intake by ensuring pregnant women receive adequate supplementation. Khanam *et al.* [231] suggest that improving IFA supplementation compliance rates in India requires nutritional counselling, health education from healthcare professionals (HCPs), and family support for pregnant women. By implementing these measures, it may be possible to enhance IFA intake and reduce the risk of intrapartum stillbirth.

This study found that women aged over 34 years have a threefold increased risk of intrapartum stillbirth compared with women <20 years of age, and there was a statistically significant linear trend between increasing age and intrapartum stillbirth even after adjustment for other risk factors. The results were similar to Salihu *et al.*'s retrospective cohort study [232], which found a linear increase in the risk for both antepartum and intrapartum stillbirth with increasing maternal age, based on maternity data from Missouri, United States. Although the mechanisms by which advanced maternal age increases the risk of intrapartum stillbirth remain unclear, a large Scottish retrospective cohort study found women aged ≥40 at term had an increased rate of intrapartum stillbirth due to intrapartum anoxia compared with age group 25-34 years [233]. Additionally, an emerging study by Lean *et al.* [234] found evidence of reduced placental efficiency and altered placental function in women ≥35 years of age, with placental adaptations observed even in normal pregnancies. Intrapartum stillbirth is also often linked to fetal distress and obstructed labour, highlighting the importance of access to high-quality obstetric care during the intrapartum period [235].

The study reported here demonstrated that the fetal survival probability in the intrapartum period remained similar across HDP categories until the 34 weeks of gestation, after which the fetal survival probabilities for women with pre-eclampsia/eclampsia declined rapidly. For antepartum stillbirth, survival probabilities of the fetuses among women with pre-eclampsia/eclampsia started to decline around the 31 weeks of gestation and very rapidly declined again from 38 weeks of gestation, when compared with those without HDP or with other HDP conditions, such as chronic hypertension or gestational hypertension. While this study lacked consistent data on when pre-eclampsia/eclampsia was diagnosed or developed, which may influence these observed trends, planned childbirth before term may offer benefits to women with pre-eclampsia/eclampsia in India. This finding is consistent with the outcomes of the CRADLE-4 trial [236], a multicentre randomised controlled trial which assessed the safety of planned birth between 34^{+0} and 36^{+6} weeks of gestation for women with pre-eclampsia in LMICs. This trial emphasised that planned childbirth before term can significantly reduce severe maternal hypertension and risk of stillbirth and indicated that clinicians in LMICs can safely offer it. The CRADLE-4 trial included 565 women across five sites in Zambia and four sites in India. However, in

India, the trial was restricted to four referral sites in urban areas of Karnataka, involving only 156 women. Given Karnataka has relatively good health facilities [237], whether planned childbirth before term poses a similar level of safety and efficacy to women and fetuses in other states warrants further investigation. This is particularly important as the data reported here indicates that preterm birth is associated with a higher risk of intrapartum stillbirth compared with full-term birth. In an individual participant data meta-analysis comparing planned birth to expectant management in pre-eclampsia women, Beardmore-Gray *et al.* [238] found that planned birth from 34 weeks of gestation significantly reduced adverse maternal outcomes and the number of infants born small for gestational age (SGA) (both $<3^{rd}$ and $<10^{th}$ percentile). However, the authors also noted that the risk of composite perinatal outcome (short-term neonatal respiratory morbidity) increased, and there is a balance of risks to consider when considering planned birth. Therefore, additional evidence is needed to support the decision-making process for both clinicians and women regarding the timing of intervention.

Severe anaemia in the third trimester significantly affected fetal survival during the intrapartum period, with a pronounced decrease in survival probability as early as 30 weeks of gestation and a three-fold higher risk of intrapartum stillbirth compared to women with no anaemia. Severe anaemia was not a statistically significant risk factor for antepartum stillbirth after full adjustment, but the risk was still more than two-fold higher in this group than in women with no anaemia, which should not be ignored. Throughout pregnancy, the fetus relies on maternal iron stores, dietary iron absorption, and turnover of maternal erythrocytes for its iron supply [239], and the heightened demand for iron during pregnancy, necessary for both woman and fetus, often disrupts the body's iron balance, especially if the pregnancy has commenced with insufficient iron reserves [240]. This prompts consideration of whether prevention and management of anaemia before the third trimester could be the sole intervention available for preventing both antepartum and intrapartum stillbirth, as anaemia is likely to compromise fetal growth and development, which increases stillbirth risk. Additionally, severe anaemia may exacerbate fetal stress during labour, further raising the risk of intrapartum stillbirth in cases where the fetus is already compromised.

The proportion of women with an underweight BMI category in this cohort was more than a quarter (25.9%), and some studies reported that having a BMI lower than 18.5 is associated with anaemia [241–243]. However, BMI was not significantly associated with antepartum and intrapartum stillbirth in this study. Also, this study investigated the risk of anaemia by adjusting for IFA supplementation. Therefore, while preventing anaemia may involve general nutrition to ensure adequate weight gain during pregnancy, targeted approaches are also likely to be necessary. When considering strategies to prevent severe anaemia in the third trimester, there is an urgent need for tailored prevention and management of anaemia in pregnant women in India, as factors beyond dietary deficiencies of iron may also contribute to low haemoglobin levels during pregnancy [218].

There was also a very high percentage of babies with less than 10th percentile birthweight for gestational age in this cohort since almost half of the babies were in this category (43.4%). However, it was not possible to distinguish if the babies with less than 10th percentile birthweight for gestational age were SGA with fetal growth restriction (FGR) or without FGR in this cohort. This group (<10th percentile birthweight for gestational age), however, was found to be at higher risk of intrapartum stillbirth than the 10th to 90th percentile group. Melamed *et al.* defined FGR as the failure of the fetus to meet its growth potential due to a pathological factor, although they also recommended that SGA definition may be used as a proxy for FGR in low-resource settings [244]. To improve the detection of FGR, utilisation of umbilical artery Doppler in combination with cardiotocography/nonstress test (CTG/NST) in the early period of pregnancy could be beneficial [244,245]. Also, symphysis-fundal height has been suggested as a simple and inexpensive tool that can be used as the primary screening strategy for FGR in low-risk pregnancies in low-resource settings. Once the severity of FGR is confirmed, the timing of birth can be determined according to local, national or international guidelines [244–246], thereby potentially reducing the risk of intrapartum stillbirth. However, the timing of birth should be carefully assessed, especially when considering preterm birth, given the logistical constraints in LMICs related to the care of very premature infants and the safety of such interventions, which is yet to be confirmed in the Indian context.

5.7.5 Strengths and limitations

As already discussed in the overall stillbirth analysis in Chapter 4, the main strength of this study is that it employed a large prospective design from 13 hospitals across six states in India, which used robust, rigorous, and standardised methodologies in data collection to understand the risk factors for intrapartum stillbirth in the Indian population. The study findings are potentially generalisable to the wider Indian population with similar characteristics to the MaatHRI cohort because the socioeconomic, behavioural, bio-demographic and pregnancy characteristics of women in the MaatHRI cohort are diverse.

Furthermore, in contrast to another cohort study that solely utilised univariable analysis to explore potential risk factors for intrapartum stillbirth in India [40], this study employed advanced statistical methods to examine independent associations of stillbirth risk factors with intrapartum stillbirth in India and compared this with risk factors for antepartum stillbirths. Modified Poisson regression models were employed to estimate the relative risks of risk factors for intrapartum stillbirth while adjusting for confounding factors. The time-to-event analysis employing Kaplan-Meier survival curve was used to understand survival probabilities of fetuses in women with complications associated with a high risk of intrapartum stillbirth by gestational age. The multivariable modified Poisson regression models also used the hierarchical approach, informed by the WHO's Commission on Social Determinants of Health (CSDH) conceptual framework [173], when adjusting for confounding factors so the significance of the impact of structural and intermediate factors for intrapartum stillbirth risk was not overlooked.

Finally, to adequately classify antepartum and intrapartum stillbirths, with the latter known to be more closely related to various measures of obstetric care than antepartum stillbirths [8], I did not just rely on the reported stillbirth outcome collected by research nurses. I manually cross-referenced all free-text variables within the cohort data to categorise the subtypes accurately. However, while the data cleaning process adopted every possible method to categorise the stillbirth subtypes, some women may have arrived at the hospital after the onset of labour, and some intrapartum stillbirths could have been

misclassified as antepartum stillbirths, and these stillbirths may have been instead included in the antepartum analysis. In the past, several studies have also pointed out difficulties in abstracting types of stillbirth (antepartum/intrapartum) in study populations for analysis due to a lack of data about the timing of fetal death [34,37,41].

One of the limitations of this study, also discussed in the overall stillbirth analysis in Chapter 4, reflects on the cohort's original research focus, which was not on stillbirth. The cohort was originally designed to investigate the risk factors for postpartum haemorrhage, and one of the exclusion criteria of this study participants was participants who planned caesarean at the time of recruitment. Since factors associated with planned caesarean may be either medically indicated or elective [222–224], the risk of intrapartum stillbirth could vary within this subgroup, meaning that the findings of this study may not fully apply to them.

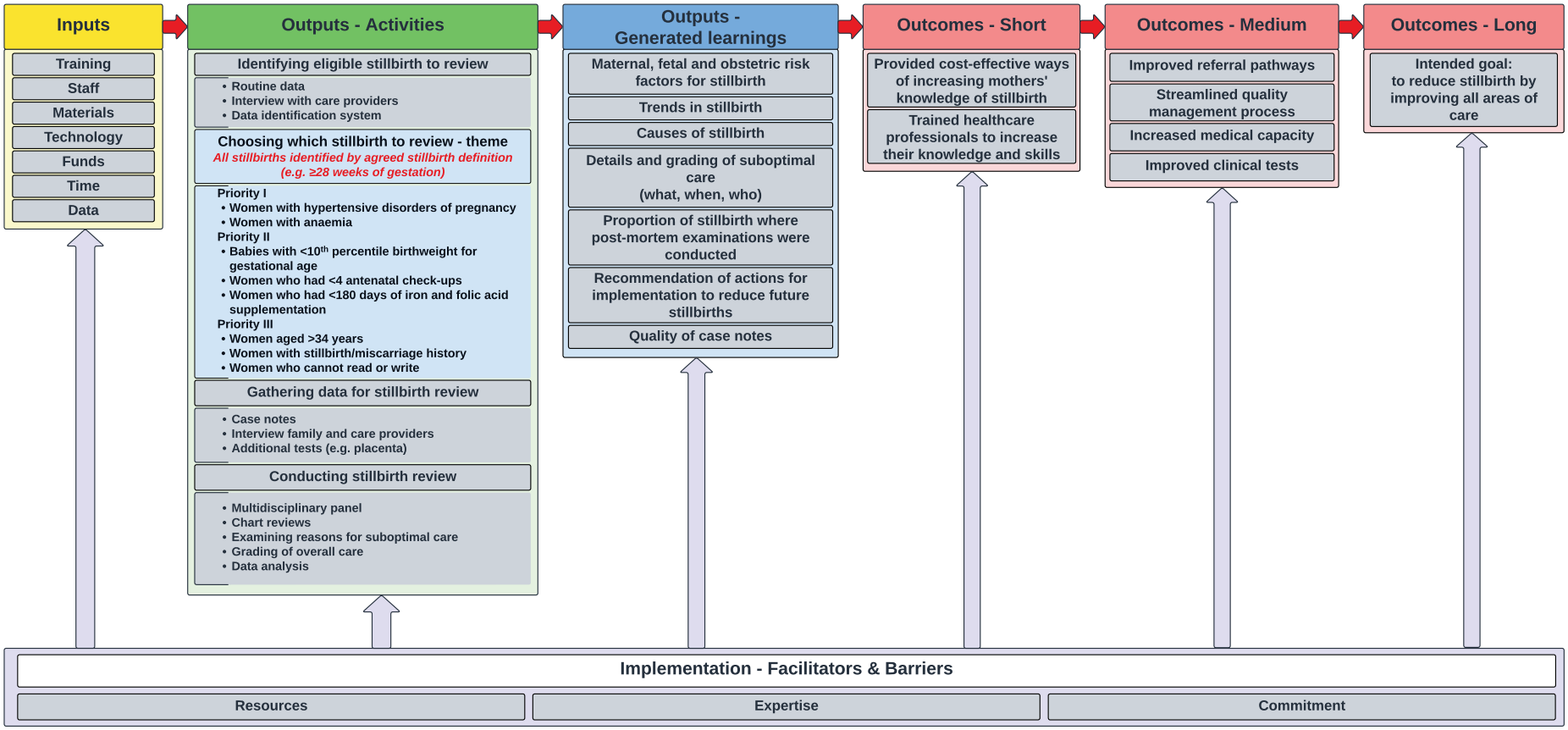
Additionally, while the MaatHRI cohort included in this analysis was diverse, it did not fully represent the entire Indian population. The hospitals included in the study are primarily located in specific regions, and did not capture the full spectrum of healthcare settings nor community settings, cultural practices, and socioeconomic statuses present across all of India. This limitation affects the generalisability of the findings to populations outside the study regions and women with substantially different characteristics from those of the MaatHRI cohort or those giving birth in non-facility-based settings.

Finally, this study was unable to include all variables relevant to intrapartum stillbirth in the analysis. For instance, mental health history, despite its recognised importance in understanding stillbirth risk [247], was not available within the MaatHRI cohort dataset. The omission of key variables associated with stillbirth could not be addressed, which is a common limitation in secondary analysis studies utilising data collected for different primary objectives. Therefore, residual confounding factors are likely to exist in this study, and other risk factors may have been missed.

5.7.6 Revised logic model

An initial logic model was developed by synthesising evidence from the systematic review (Figure 2-3), which is detailed in Section 2.4.11 in Chapter 2. This initial logic model has been revised to incorporate empirical findings from the two quantitative analyses (as seen in Figure 5-5), particularly to support the activity of "choosing which stillbirth to review" within the stillbirth review process. As highlighted in the systematic review (indicated in red italic font), all stillbirths can be reviewed within a hospital, provided they meet the agreed definition of stillbirth. However, if a hospital lacks the capacity or time to review every stillbirth, prioritising stillbirths based on specific themes can be helpful. This approach of selecting a 'theme' for each stillbirth review aligns with the WHO guidelines [52]. The order of priorities listed in the revised logic model was derived from the findings of the quantitative analyses and considers how likely the clinicians in the hospital could modify the risks, starting with modifiable risk factors in the proximal factors, then the risk factors associated with antenatal care and finally, structural factors or intermediate factors that cannot be easily changed in the context of facility-based care. The logic model is discussed in detail in Chapter 8.

Figure 5-5. First revised logic model: includes findings from the systematic review and quantitative analyses



Legend key Grey box: Findings from the systematic review Blue box: Findings from the quantitative analyses *Red italic font*: Evidence overlapping with the systematic review findings

5.7.7 Conclusion

Existing evidence suggests that the risk of intrapartum stillbirth has a closer correlation with the quality of obstetric care than for antepartum stillbirths. However, this study found that the risk factors for intrapartum stillbirth were not very different from antepartum stillbirth, and policies addressing the overall stillbirth burden could have an impact on all stillbirths in India. Given that facility-based interventions are better suited to address proximal risk factors, while most structural and intermediate risk factors require community-based interventions and government policy, collaborative efforts across multidisciplinary sectors are essential to improve access to high-quality antenatal care and manage complications effectively.

It was also observed that while planned childbirth before term may offer benefits for women with pre-eclampsia/eclampsia in India, further evidence must be generated to assess its safety and feasibility across different healthcare settings. Nevertheless, the study findings emphasise the importance of accurately recording gestational age at birth and reviewing the timing of interventions offered to women, especially for women with pre-eclampsia/eclampsia and severe anaemia.

In addition, future studies must seek to understand how severe anaemia during pregnancy may affect fetal survival during the intrapartum period, noting a pronounced decrease in survival probability as early as from the 30 weeks of gestation, and how we can adopt a multisectoral approach to evaluate interventions for preventing and managing anaemia (especially severe anaemia) in India and their impact on reducing intrapartum stillbirths.

Lastly, wherever possible, utilising umbilical artery Doppler in early pregnancy to differentiate between FGR and SGA fetuses is recommended. Once placental involvement is confirmed, the timing of birth can be determined according to appropriate guidelines based on the stages of fetal deterioration, potentially reducing the risk of intrapartum stillbirth.

Chapter 6. Qualitative results I: exploring current stillbirth review processes in India

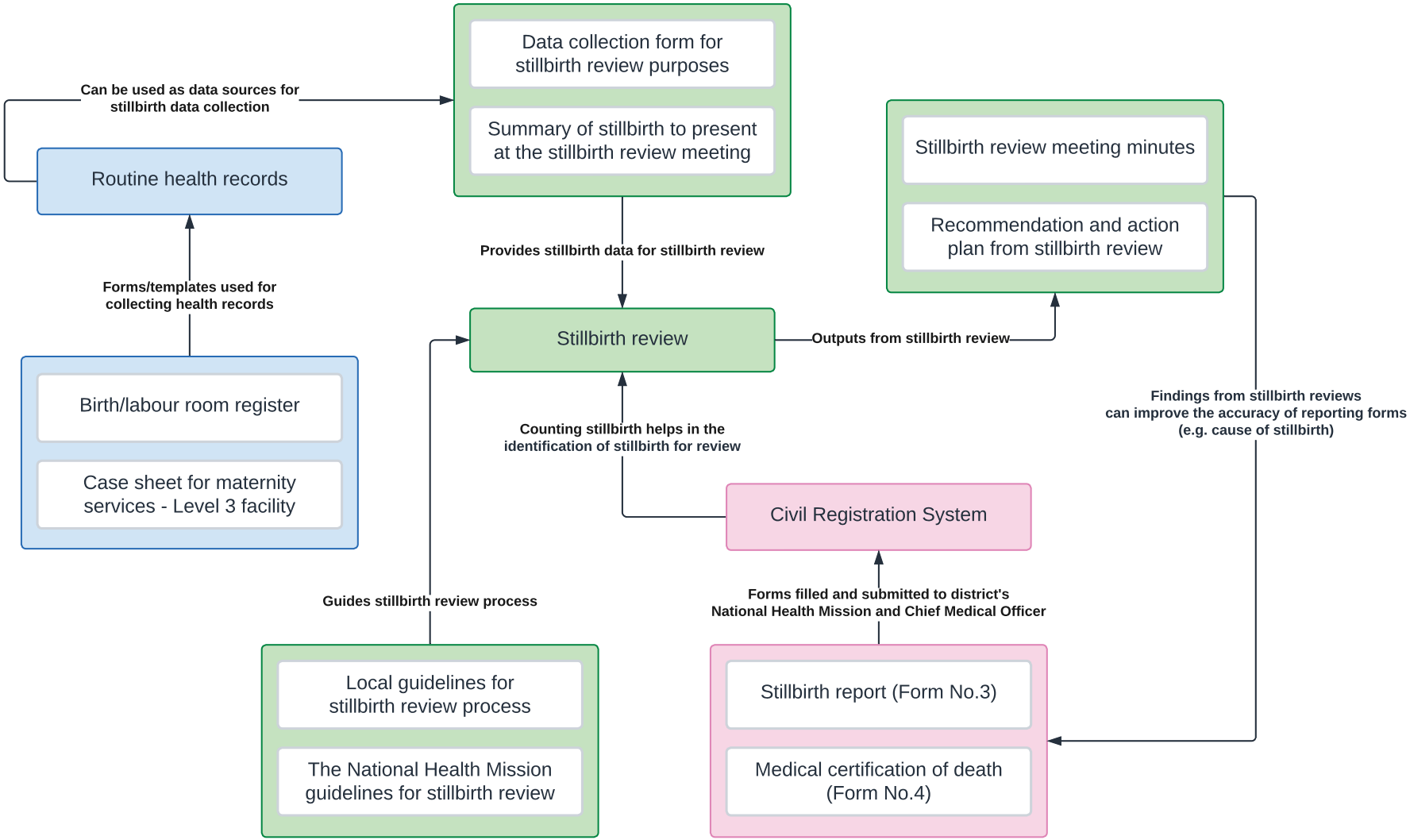
6.1 Chapter introduction

This chapter addresses Objective 4 of the thesis and describes the facility-based stillbirth review processes in three Indian hospitals using a multiple case study approach (document analysis, observation and focus group discussions (FGDs)). The findings highlight both the similarities and differences among the hospitals in various aspects: the types of data collected, stillbirth reporting processes, the guidelines used for stillbirth reviews, and the key document outputs generated from the review. Additionally, it examines the reasons for conducting stillbirth reviews, staff motivation for participation, the organisation and atmosphere of the meetings, how stillbirths are discussed, and the dissemination of the learnings generated. Finally, the chapter explores how hospitals utilise these reviews to improve the quality of data, care, and the overall review process.

6.2 Document analysis of stillbirth review tools and guidelines

A total of 15 documents that are relevant tools or guidelines for facility-based stillbirth review were analysed across three hospitals (A, B and C). Most of these documents were proformas (N=5), while others included registers (N=2), reports (N=2), memoranda (N=3), meeting minutes (N=1) and guidelines (N=2). Figure 6-1 below visualises the flow and interaction of reviewed documents, summarising how they directly or indirectly support or result from the stillbirth review process. Also, a detailed summary of each document analysed is available in Appendix N.

Figure 6-1. Flow and interaction of stillbirth review tools and guidelines



6.2.1 Data collection

6.2.1.1 Routine health records

As part of the routine health records, Hospitals A and C employed structured registers in their obstetrics and gynaecology (O&G) departments, which were the Government of India labour room register of the 'DAKSHATA Implementation Package' – a strategic initiative by the National Health Mission to strengthen the quality of intrapartum and immediate postpartum care. The hospitals utilised these registers to collect routine health records from all women admitted.

Upon document analysis, these registers were found to be effective tools for enabling hospitals to collect comprehensive data about women's socio-demographic circumstances, obstetric history, complications, and outcomes. The registers included data categories aligned with the World Health Organization (WHO) recommendations for essential birth data collection [52] and provided free-text areas for each category. It was found that if information were correctly noted in these registers, they would ensure critical data related to women's care was systematically gathered and recorded and would be expected to be used as part of the stillbirth review process, such as when gathering data for the purpose of stillbirth reviews.

Similar to the other two hospitals, Hospital B used a proforma for routine health records called 'Case sheet for maternity services – L3 facility: Admission form'. This proforma was found to be the first two pages of the Government of India case sheet for the 'DAKSHATA Implementation Package'. It was very similar to the 'Labour room register' that Hospitals A and C used but only had options for ticking boxes rather than having a free-text style for record-keeping, which is the only option in the 'Labour room register'.

6.2.1.2 Data for the stillbirth review

Hospital A used a proforma specifically for collecting stillbirth data for the purpose of stillbirth review, the 'Data of stillbirth cases' form. This document had headings for data items collected for the stillbirth

review as rows, with each column representing a case number (for each stillbirth). The document was reported to be intended for the person gathering data for the stillbirth review. This type of form was not used in the other hospitals.

6.2.2 Stillbirth reporting

6.2.2.1 Civil Registration System

Hospitals A and C made use of the 'Stillbirth report' proforma (also called Form No.3) to report stillbirths to higher authorities as part of India's Civil Registration System. This proforma required an informant (a healthcare professional (HCP), if a stillbirth occurred in a facility setting) to provide legal and statistical information about each stillbirth before getting the form signed by the government Registrar of Births and Deaths.

According to Hospital C's reporting flowchart of stillbirth reports (a four-step process for reporting stillbirths to higher authority as part of the Civil Registration System), the process involved talking to the woman to gather information for the stillbirth report, using the delivery register to complete the report, rechecking the details for accuracy, and sending the completed report to the government Registrar at local Chief Medical Officer's office within 21 days following the death. Subsequently, the flowchart stated that stillbirth reports were also sent to the municipal office, although the timeline for this submission was not specified.

Once the stillbirth report was sent to the National Health Mission or Chief Medical Officer by the hospital, it was expected that the stillbirth report would be added to the state and national stillbirth register as part of the registration of births and deaths as defined in the Registration of Births and Deaths (Amendment) Act, 2023 [26].

6.2.2.2 Other stillbirth reporting process

In contrast to Hospitals A and C, Hospital B did not follow the same standardised reporting process using a 'stillbirth report' proforma. According to email correspondence from Hospital B, this hospital reported that they are not required by the National Health Mission or the state government to send the stillbirth statistics using the 'Stillbirth report' proforma (Form No.3), although they send integrated reports that include various types of surveillance data, including the number and type of stillbirths, to district and state government authorities.

At the validation meeting I held after the document analysis, hospitals confirmed that stillbirth reports are sent to the National Health Mission and Chief Medical Officer, and depending on the hospital type, the reporting process differed. For tertiary government hospitals, they sent the completed 'Stillbirth report' proforma directly to the National Health Mission and Chief Medical Officer, whereas for secondary hospitals or tertiary private hospitals, reports (either using the 'Stillbirth report' proforma or other reporting methods) were sent to the Chief Medical Officer's office. Then, the National Health Mission project manager in the office sent the reports to their organisation.

6.2.3 Stillbirth review guidelines

Hospital B was the only hospital among the three hospitals that had established local guidelines for their stillbirth review process in their hospital. Their local guidelines provided information on how to employ a structured approach to reviewing stillbirths, with clear objectives and defined roles for the review panel members. The guidelines listed the primary objectives of Hospital B's stillbirth review process, which were: (i) to examine the incidence of stillbirths and perinatal deaths, (ii) to determine the causes of stillbirth, (iii) to evaluate contributing factors to stillbirth, and (iv) to conduct root cause analyses of stillbirth. Also, Hospital B's guidelines provided clear definitions of stillbirth and subtypes of stillbirth to be used by the review panel members.

According to the guidelines, the stillbirth review schedule in this hospital was set for the first Saturday of the month following each death, and the review panel comprised the superintendent (Chair), an obstetrician-gynecologist (nodal person), a paediatrician, in-charge nurses from various departments, and a nursing administrator. It also explained that the stillbirth review process should start with prompt notification and documentation of stillbirths, followed by comprehensive review of medical records, and then detailed discussions of each stillbirth during the review meeting. The guidelines also emphasised that the review panel is responsible for making actionable recommendations and assigning these recommendations to specific responsible individuals with clear timelines for implementation. In addition to the local guidelines, Hospital B reported that they also adhere to the national guidelines created by the National Health Mission (Operational Guidelines for Establishing Sentinel Stillbirth Surveillance System) [6].

6.2.4 Key documents created from the Hospital B's stillbirth review

Three documents were created from Hospital B's monthly stillbirth review: 'Report of stillbirth', 'Monthly audit meeting minutes', and the 'Recommendation and action plan adopted by stillbirth review panel'.

The 'Report of stillbirth' contained information about the number of births and stillbirths for the month and information about each stillbirth. The following information was available for each stillbirth in this report: the woman's date of admission, date and time of birth, the woman's gravida and parity, problems identified at admission, gestational age, birth weight, and any relevant medical or obstetric history. Hospital B reported that stillbirth data within this report was what was presented to the panel during the stillbirth review meeting.

The 'Monthly audit meeting minutes' contained the record of what was discussed during the meeting: the stillbirth statistics of the month (total births, stillbirths, and neonatal deaths), names and signatures

of the attendees, details of any issues with care identified during the review and action points to address these gaps in care.

The 'Recommendation and action plan generated by the stillbirth review panel' outlined the specific recommendations made by the review panel based on their stillbirth review for that month. Each recommendation was accompanied by the name of the responsible person and a timeline for implementation.

6.3 Structure and processes

In this multiple case study, two of the hospitals (Hospitals A and C) that participated were tertiary hospitals with postgraduate students, while Hospital B was a secondary hospital that did not have any postgraduate students. In the context of medical education in India, these postgraduate students are medical doctors who have completed their undergraduate medical education (Bachelor of Medicine and Bachelor of Surgery degree), are pursuing further training in a specific speciality and are involved in providing clinical care. In some Indian hospitals, these postgraduate students are called junior residents, which was the case for Hospital A. Hospital A also had senior residents who had completed their postgraduate training. In Hospital C, there were only residents who were postgraduate students. For consistency, in this chapter, any junior residents in Hospital A or residents in Hospital C were referred to as 'postgraduate students'. Table 6-1 describes the demographic information about FGD participants. Some hospitals had review panels with more diverse demographic characteristics than others due to their specific stillbirth review setup. For instance, in Hospital A, there were no nurses or administrative staff participating in the stillbirth review panel, whereas in Hospital B, these job roles were part of the panel. However, in Hospital C, although there were no nurses or administrative staff involved in the stillbirth reviews, nurses were invited to the FGD because the head of O&G felt it was appropriate and valuable to have their opinions. However, it is important to note that no one who was a postgraduate student was invited to FGD of Hospital C, even though they were part of the review panel in that hospital. The reason stated for this was that these postgraduate students were busy with other work and could not attend the meeting due to staff shortage. Also, all FGD participants were female for Hospital A, even

though there was a male review panel member. The reason for this was that the male consultant doctor in O&G who was also a review panel member felt that he was too senior to attend the FGD and felt his being in the space would cause postgraduate students to feel less comfortable expressing their opinions.

Table 6-1. Demographic information about focus group discussion participants

	Hospital A (N=8)	Hospital B (N=6)	Hospital C (N=6)
Job role			
Consultant doctor – obstetrics & gynaecology	1	1	3
Postgraduate student – obstetrics & gynaecology	7	0	0
Administration/superintendent	0	1	0
Nurse manager	0	1	2
Staff nurse	0	3	1
Gender			
Female	8	5	6
Male	0	1	0
Age group			
Under 30	4	1	5
30-49	4	3	0
Over 50	0	2	1
Duration of involvement in the stillbirth review process			
Less than 1 year	2	6	0
1-3 years	5	0	1
More than 3 years	1	0	5

The framework analysis of data from observation notes and the discussion during the FGDs identified four 'sequential' themes corresponding to distinct phases of the facility-based stillbirth review process in three hospitals in India: pre-meeting (organising meetings), during the meeting (discussion methods), post-meeting (dissemination of generated learnings), and the outcomes of the meeting (improving quality). For the last phase, the 'improving quality' theme, the term 'quality' was assigned to assess whether the outcomes of the meeting seemed appropriate and were reflective of what a good quality stillbirth review process should look like because none of the hospitals discussed how the review process had any impact on reducing stillbirth in their hospitals nor have they been measuring quality improvement activities implemented following reviews to evaluate if their quality of care and review processes have been improving. Additionally, four 'interlinked' themes connected to these 'sequential' themes were identified: reasons for conducting reviews, motivation for participation, atmosphere and conduct, and documentation. These 'interlinked' themes were recognised as serving as key enablers and influencers across phases within the stillbirth review process. The coding tree diagram (Figure 6-2),

which summarises the themes and codes from the framework analysis of the observation notes and transcripts from the FGDs with HCPs involved in the stillbirth review process, visualises the interconnectedness of these 'sequential' and 'interlinked' themes within the overall structure, processes, and outcomes of the stillbirth reviews. Tables 6-2 to 6-5 summarise the themes and codes for each phase of the stillbirth review process by hospital.

Figure 6-2. Coding tree representing the themes and codes that emerged in the observation and focus group discussions

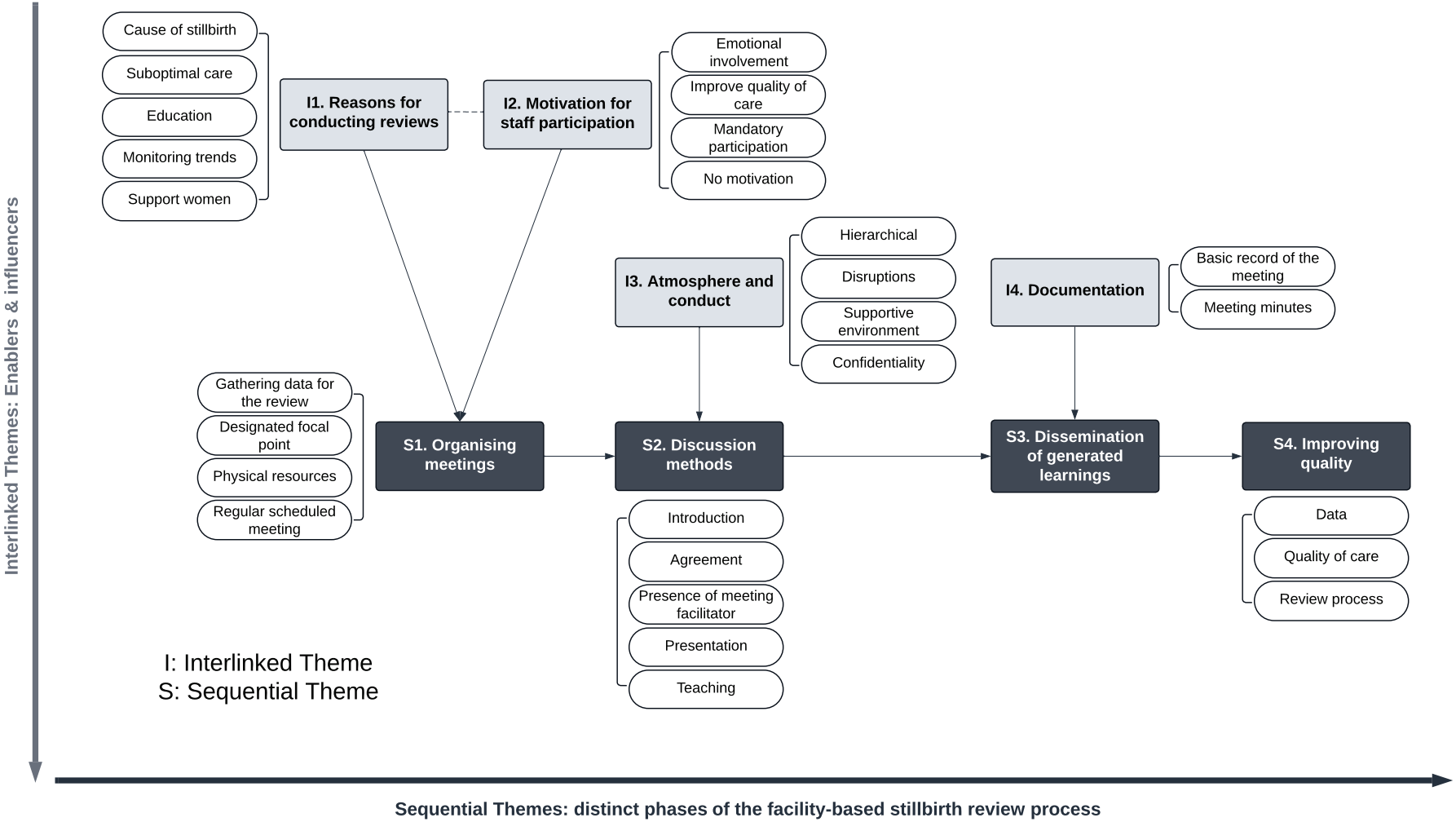


Table 6-2. Summary of themes or codes related to the pre-meeting phase by hospital

Theme/code	Hospital A	Hospital B	Hospital C
Reasons for conducting reviews	• To find out the cause of stillbirth • To find any suboptimal care • For postgraduate students to learn • To communicate review findings to women	• To find out the cause of stillbirth • To find any suboptimal care • To monitor trends of stillbirth	• To find out the cause of stillbirth • To find any suboptimal care • For postgraduate students to learn • To communicate review findings to women
Motivation for participation	• To improve quality of care • Mandatory for postgraduate students	• Emotional involvement with the stillbirth • No motivation	• To improve quality of care
Gathering data for the review	• Duty doctor prepares case summary, reviewed by senior resident	• Consultant records details within 48 hours using a proforma	• Questionnaire used to document details from admission to discharge
Designated focal point	• Presence of a designated focal person for organising review meetings	• Presence of a designated focal person for organising review meetings	• Responsibility assigned to the teaching department based on academic calendar
Space where stillbirth review meeting takes place	• Obstetrics and gynaecology (O&G) department hallway • Lecture theatre setup with rows of chairs, stand, and screen projector	• Superintendent's office • Setup with chairs at a table at the back of the office	• Conference hall • Quiet space with a round table for panel members
Case notes (before/during the meeting)	• No case notes or materials during the meeting • Information presented via slides	• Chair brings case notes • Nurses have notepads	• Non-anonymised case notes on table, referred to during discussions
Regular scheduled meeting	• There is a roster for which postgraduate student is presenting at the meeting • If there is no stillbirth in a particular week, then the meeting will occur the week after • All postgraduate students present in their three-year residency programme	• The first Saturday of a month	• Important cases of stillbirth (along with other maternal and neonatal mortality or near misses) are selected for the weekly Wednesday discussion • Depending on the academic calendar (scheduled for two tutorials per week), one tutorial of the week is kept for discussing cases, such as stillbirth and neonatal death reviews

6.3.1 Interlinked Theme 1: Reasons for conducting reviews

6.3.1.1 Cause of stillbirth and suboptimal care contributing to the occurrence

All hospitals reported that their primary reason for conducting stillbirth reviews was to ascertain the cause of stillbirth and any suboptimal care factors that contributed to the occurrence. The hospitals agreed that when suboptimal care factors are identified as contributing to a potentially preventable stillbirth, they can review these factors to discuss which appropriate measures to implement for the improvement of future care provision.

> *"We basically conduct the stillbirth review to find out the cause of the stillbirth, so that in future it will give a better outcome, if there's some factors which are preventable, then we can work on it." (Consultant O&G, Hospital C)*

They recognised that stillbirth reviews are valuable tools for first identifying gaps in care and determining what could have been done differently in 'individual' women, which then builds on for the 'system' change; this process enables hospitals to apply insights from individual women to improve the overall quality of care for all women.

> *"Whether it was preventable or not. If it was preventable, next time whenever she conceives, we want like – we want that… it shouldn't happen again." (Postgraduate student O&G, Hospital A)*

Hospital B emphasised that in order to reduce stillbirths in their hospital, they must consider which changes to make in the health facility or in the community to address suboptimal care and that the implementation of action points would not happen without actually conducting stillbirth reviews to deep dive on details of suboptimal care, what, when and who.

> *"It's to know how to prevent it, or should be there any change of policy, or in the facility, or in the community, so that the [stillbirth] number is decreasing." (Consultant O&G, Hospital B)*

6.3.1.2 Stillbirth reviews as an educational tool for postgraduate students

The educational benefits of stillbirth reviews were also highlighted as the reason for conducting stillbirth reviews in the cases of tertiary hospitals that have teaching responsibility for postgraduate students (Hospitals A and C). The consultants explained that the postgraduate students were involved in the reviews to improve their professional learning by understanding why and how a stillbirth occurred and to learn about how the review process works so that they can present or lead discussions in the future.

> *"Because we have postgraduate students in the department who are learning, this sort of review will also help them. This is the part of the postgraduate curriculum. They should also attend these meetings and get to know how these things are conducted, and how they can also improve upon." (Consultant O&G, Hospital C)*

6.3.1.3 Monitoring trends in stillbirth rates

While not mentioned in Hospitals A and C, Hospital B specifically mentioned monitoring trends in stillbirth rates as one of their reasons for conducting stillbirth reviews. Hospital B emphasised the importance of tracking the rate of stillbirths to: (i) assess the effectiveness of stillbirth reviews in reducing the number of stillbirths over time, and (ii) ensure all stillbirths were counted, which can aid in identifying stillbirths for review.

> *"And at the same time, whether our rate of stillbirth has been decreasing or increasing, or the rate has to be determined. [Pause] That is another reason of the objective." (Superintendent, Hospital B)*

6.3.1.4 Supporting women by communicating findings and addressing their concerns

Finally, hospitals mentioned that they conduct stillbirth reviews to communicate review findings with women who had stillbirths, address their concerns, and provide support for their future pregnancies. Hospitals A and C emphasised the need to provide women with information about why their stillbirths occurred so that they could better understand the circumstances surrounding their stillbirths. However,

it was noted that Hospital C's approach tended to focus on the 'mistakes made' by women who had stillbirths, which could be perceived as blaming rather than supporting them.

> *"Once we have the action plan, we can at least advise the patient in the future not to make the same mistake so that she can come for an early antenatal checkup. So once she's booked with us, and when she comes to regular antenatal checkups, if she cannot come to the tertiary hospital like us, if she goes into the primary health centre, then the high risk factors can be detected, and then the cause can be prevented." (Consultant O&G, Hospital C)*

6.3.2 Interlinked Theme 2. Motivation for staff participation

6.3.2.1 Emotional involvement with the stillbirth

In Hospital B, emotional involvement was identified as a key motivation for attendance at stillbirth review meetings. A conversation between a nurse manager and a consultant highlighted their mutual dedication to addressing the emotional aspects of stillbirth and encouraging each other to actively follow up on these stillbirths at the review meeting.

> *"Consultant O&G: Actually, where that's a tragic incident no? so people start practically-*
>
> *Nurse manager: Yeah, we are practically involving with them, so we are facing their problem.*
>
> *Consultant O&G: They are self-motivated to come and follow up these things." (Conversation between Consultant O&G and Nurse Manager, Hospital B)*

6.3.2.2 Improving the quality of care

Improving the quality of care was another identified motivator across the two hospitals. In Hospital A, a postgraduate student highlighted the importance of addressing 'mistakes' made at the facility level to improve the quality of care.

"All these mistakes, it's all like where action has to be actually taken and where we can improve ourselves." (Postgraduate student O&G, Hospital A)

Similarly, in Hospital C, the goal of the meetings was articulated as an effort to improve women's care by discussing past events and potential preventive measures.

The goal or objectives of the meeting was explained as 'we want to improve the care of the patients by discussing what happened, what could have happened'. (Observation notes, Hospital C)

6.3.2.3 Mandatory participation for postgraduate students

Mandatory participation was mentioned in Hospital A, where a consultant acknowledged the requirement for postgraduate students to attend these meetings for their learning experience. The consultant informed that all postgraduate students also have to present at the meeting during their three years of training, and the review meeting rota reflects this curriculum requirements. This also meant that the consultants who have teaching responsibilities were also required to attend the meetings.

"[laughs] Well, the postgraduate students, they have to come. Because it's for their learning." (Consultant O&G, Hospital A)

6.3.2.4 No motivation

For Hospital B, a superintendent expressed 'no motivation' for attending the meetings and suggested that participation is more a matter of obligation as part of their job role than interest. Similar to Hospital A, where consultants would naturally attend the meetings due to their teaching responsibilities, Hospital B also had responsibilities to attend the review meetings because their job roles were required in the review panel according to the local stillbirth review guidelines this hospital follows.

"I don't think there's any motivation for it! [laughs] We only come for the meeting." (Superintendent, Hospital B)

6.3.3 Sequential Theme 1. Organising meetings

6.3.3.1 Gathering stillbirth data for the review

In all three hospitals, the process of gathering data for stillbirth reviews followed a structured approach with some variations. In Hospital A, the responsibility for data collection was delegated systematically. A postgraduate student compiled a summary of the incident, which was then reviewed by a senior resident before being forwarded to the designated officer in the hospital, who sent the stillbirth report to the Chief Medical Officer of the district office.

> *"The junior resident [postgraduate student] prepares a summary of how it happened, from initial point to the end point. And then the summary will be made. It will be checked by the senior resident and then it will be handed over to the concerned person who is sending the report every day to the Chief Medical Officer (CMO) office." (Postgraduate student O&G, Hospital A)*

Hospital B employed a similar systematic approach: the care provider initiated the stillbirth notification, and then the responsible person collected additional data using the stillbirth review proforma within 48 hours of the stillbirth notification for the review meeting.

> *"[Once there is a stillbirth, it is reported by] the service provider. It may be a doctor, it may be a sister [nurse], and then it comes to me. I'm the only person on this audit report. So within 48 hours I came to them with the proformas, a recording of them then, it's a very brief recording done, and after when the patient has been discharged we review that ticket." (Consultant O&G, Hospital B)*

In Hospital C, a standardised questionnaire was utilised to gather data for the stillbirth review, which required information from the time of admission of the woman to discharge.

> *"Once the stillbirth has been notified, we've come to know there is a stillbirth, we have a file where we have a questionnaire as per the hospital, where we find out the causes, and the questionnaire, for example, what time the admission was done, what time she delivered, was she a booked case or an unbooked case? If she was an unbooked case, where were her previous antenatal checkups, any ultrasound, any other investigations were done previously, and whether she came late in latent labour or active*

labour, or whether she came with a history of loss of fetal movement when she comes to us, and whether we found out with an ultrasound that she's already had a stillbirth, or an intrauterine death." (Consultant O&G, Hospital C)

6.3.3.2 Designated focal point for organising review meetings

The designated focal point for organising the meetings varied among the hospitals. For Hospitals A and B, there was a designated officer who was responsible for organising the stillbirth reviews.

"I'm the nodal officer. I look after the stillbirth review and make the roaster." (Consultant O&G, Hospital A)

Whereas in Hospital C, there was no focal point (individual) for organising the stillbirth review, and the responsibility was on the teaching department (group).

"The meeting is organised by the department... I wouldn't say every week because we don't have that many stillbirths that we need to discuss every week. So depending on the calendar, our academic calendar, we have twice a week academics, so once a week we keep for these sorts of cases, like stillbirth review, neonatal reviews. So, accordingly we see whichever cases are there, then we build according to our own calendar, we fix up the meeting." (Consultant O&G, Hospital C)

6.3.3.3 Physical resources used during the meeting

The physical resources used during the meetings also differed across the hospitals. In Hospital A, meetings were held in a lecture hall style, with chairs arranged in rows. There was a projector and a podium for presentations. In Hospitals B and C, the meetings were conducted like a round table discussion, with participants seated facing each other around a central desk. However, the seating arrangement in Hospital C differed from that of Hospital B. In Hospital C, consultants sat on one side of the table, while postgraduate students were positioned 1–2 metres away, on the opposite side, separated from the senior staff. In Hospital B, by comparison, the panel was seated in a mixed arrangement, which appeared more collegiate.

The availability and use of clinical notes during meetings varied across hospitals. In Hospital A, participants reported that they do not have access to materials such as PowerPoint slides presented during the meeting or clinical notes about the stillbirth before the meeting. Instead, they relied on information presented on the day.

> *"Facilitator: Is there information or a slide deck perhaps you would share before the meeting?*
>
> *Consultant O&G: No.*
>
> *Postgraduate student O&G 1: No.*
>
> *Postgraduate student O&G 2: No.*
>
> *Postgraduate student O&G 3: No, not before the meeting. Only the people who were involved in that case were [shared with the information]. They must be known to them." (Conversation between Facilitator and participants, Hospital A)*

Hospital B also reported no prior access to clinical notes; however, the observation of the meeting noted that clinical notes (non-anonymised) were available at the desk during the meeting for panel members to refer back to and this practice was also observed in Hospital C.

> *Resources such as case notes are presented on the table, and everyone refers to the case notes when discussing each stillbirth. (Observation notes, Hospital C)*

6.3.3.4 Regular scheduled meeting

All hospitals employed regular scheduling and structured rotation of responsibilities when organising review meetings. It was particularly emphasised in Hospital A, where a formal roster system was reported as a tool to ensure continuous engagement and learning from the postgraduate students.

> *"We have a roster for that and all the junior residents [postgraduate students] turn by turn, there's a roster made for each week… So turn by turn, all the postgraduate students will be presenting in their three-year course." (Consultant O&G, Hospital A)*

Table 6-3. Summary of themes or codes related to the during-meeting phase by hospital

Theme/code	Hospital A	Hospital B	Hospital C
Introduction	• No aim and objectives explained • No mention of minutes/action points from the last meeting	• Aim and objectives explained • No mention of minutes/action points from the last meeting	• Aim and objectives explained • No mention of minutes/action points from the last meeting
Reaching agreement	• No consensus • Senior staff give feedback to junior staff	• Consensus among panel members	• Clinical guidelines referenced for decisions
Presence of meeting facilitator	• None identified	• Yes	• Senior staff rotate as facilitators
Presentation	• Postgraduate student presents using slides	• Facilitator reads summaries to panel	• Postgraduate student verbally presents stillbirth details (main doctor who cared for the woman)
Teaching	• Question and answer (Q&A) format • Senior staff question presenting postgraduate students	• Not applicable (non-teaching hospital)	• Teaching focuses on preparing postgraduates for exams, for example, clinical manoeuvres
Seating plan	• Postgraduates in front rows • Senior staff in the back rows	• Round table, no fixed seating	• Consultants on one side • Postgraduates seated 1–2 metres away from the table, opposite senior staff
Interaction between panel members	• Postgraduates did not engage • Senior staff and senior residents dominated discussion	• All members contributed • The superintendent (Chair) was most outspoken	• Senior staff discussed and communicated outcomes to postgraduates
Disruptions	• Senior staff took phone calls • Late arrivals (3 attendees)	• None identified	• None identified
Confidentiality	• No explicit discussion of healthcare professional (HCP) names	• No explicit discussion of HCP names	• Consultants directly asked postgraduates to identify responsible HCPs and summarise care

6.3.4 Sequential Theme 2. Discussion methods

6.3.4.1 Introduction at the start of the review meeting

There was no introduction observed at the start of the stillbirth review meeting for Hospital A; however, Hospitals B and C outlined the meeting's goal as part of the introduction. Hospital B provided the most detailed introduction regarding the purpose of the stillbirth review and the meeting attendees at the start of the meeting, led by the meeting facilitator (O&G consultant), compared to other hospitals. However, there was no mention of minutes or action points from the previous meetings for any hospital.

> *Before the meeting started, a brief introduction of each member attending the stillbirth review meeting was given by the meeting facilitator who is a consultant doctor in the hospital's obstetrics and gynaecology department…There was no mention of minutes/action points from the last meeting. The aim and objectives of the meeting were explained as 'to investigate if the stillbirth could have been prevented' and 'create action points' from the learnings. (Observation notes, Hospital B)*

6.3.4.2 Reaching an agreement

When differences in opinions arose, hospitals took different approaches to reaching an agreement. Hospital B took a consensus-led approach where the panel's discussion naturally led to joint decisions without the direct involvement of the meeting facilitator or the superintendent (Chair). It was observed that there was a participatory decision-making process, aided by the meeting's clear agenda and structure. This approach was not noticed in Hospitals A and C, where the decision-making process was more of a learning experience for the postgraduate students.

> *When there were differences in opinions, it looked like the discussion within the panel naturally led to an agreement without the direct involvement of the meeting facilitator or the Chair, and the decision was made jointly. (Observation notes, Hospital B)*

On the other hand, Hospital C followed a guideline-led approach, referencing specific protocols of obstetric practices during the discussion. For instance, the protocol for managing preterm breech births

by performing caesarean sections was mentioned when suboptimal care was identified in a preterm, breech stillborn baby. This practice was not explicitly noted in the discussions of Hospitals A and B.

> *Protocols of obstetric practices are mentioned, such as 'in our hospital, when there is a preterm, breech baby, caesarean is performed'. (Observation notes, Hospital C)*

6.3.4.3 The presence of a meeting facilitator

The presence and role of the meeting facilitator varied across the hospitals. In Hospital B, the meeting facilitator summarised each stillbirth to the review panel and frequently asked clarifying questions to ensure a comprehensive discussion. In contrast, the meeting facilitator's role in Hospital C was less consistent, with different senior staff occasionally taking the position. There was no meeting facilitator in Hospital A, though consultants initiated the discussions by asking questions to the presenter after a postgraduate student gave a presentation about stillbirth. The presenter was expected to answer the questions.

> *One of the senior staff members seems to be the Chair of the meeting, although it was noted that other senior staff members will act as the Chair from time to time. (Observation notes, Hospital C)*

6.3.4.4 Presentation of each stillbirth

In Hospital B, the chair's role was expanded to include presenting each stillbirth in the meeting. The Chair verbally presented each stillbirth's data, and the rest of the panel members asked a series of questions to confirm details. Similarly, in Hospital C, a postgraduate student verbally presented the summary of a stillbirth case (including demographic and clinical details) before a question and answer session was initiated by the consultants.

On the other hand, a postgraduate student at Hospital A used a screen projector and a slide deck to present each stillbirth. The slide deck contained information such as the women's demographic details, the time they were examined upon arrival at the hospital, their past obstetric and menstrual history,

ultrasonography findings, and the outcome of the baby and woman. Compared to the other two hospitals, Hospital A provided the most detailed information about each stillbirth during the review meeting.

> *Obstetric history was very detailed and included information such as about their marriage, how many years it took them to conceive their first or any subsequent child, and what the outcomes were. Ultrasonography findings and outcomes included information such as if there were any complications found and what kind of efforts were made for the baby after being born. Autopsy/pathology results were not discussed in any of the cases, although it was noted that in all cases, parents did not want to have an autopsy. (Observation notes, Hospital A)*

6.3.4.5 Teaching opportunities for postgraduate students

In Hospital C, the stillbirth review process also functioned as a teaching opportunity for postgraduate students. During discussions, postgraduate students were required to stand and respond to questions posed by consultants. This approach appeared to be designed to prepare postgraduate students for upcoming exams since some questions emphasised clinical manoeuvres for particular obstetric complications. When the postgraduate student did not know the answer, the consultant said the postgraduate student 'must know this manoeuvre' because this type of question will be asked in the exam.

> *It was an interview style of discussion, where questions must be answered when asked by the senior staff...Perhaps, because the resident doctors are postgraduate students who need to pass upcoming exams, the senior staff seems to ask them questions about certain methods or manoeuvres to use for particular obstetric complications. (Observation notes, Hospital C)*

6.3.5 Interlinked Theme 3. Atmosphere and conduct

6.3.5.1 Hierarchical

The hierarchical nature and disciplinary tone of the senior doctors at the meetings were evident, especially at Hospitals A and C, where the stillbirth reviews were conducted as part of the postgraduate

students' education. While the postgraduate students at Hospital A did not perceive the disciplinary aspects of the meetings as 'supportive', they understood them as important for their learning.

> *"Facilitator: Do you think everyone supports each other in the meeting?*
>
> *Consultant O&G: Yeah.*
>
> *[laughter from Postgraduate students O&G]*
>
> *Facilitator: I'm seeing some smiles.*
>
> *Several Postgraduate students O&G: Maybe!*
>
> *Postgraduate student O&G: Some people might think it is very strict. I mean it is not fault finding, like [Name] said, but you should know that you have done something wrong, or by mistake it has happened, either in the monitoring or because of some other thing. But for that thing, sometimes it's the strictness or little of disciplines needed for that. But otherwise they don't just make a scapegoat, but you should know that there was something wrong.*
>
> *Consultant O&G: But senior have to teach them. So they have to be firm with the postgraduate students. Teachers, they have to be firm. They might have to scold them. But that is okay."*
> *(Conversation between Postgraduate student O&G and Consultant O&G, Hospital A)*

The seating arrangements at Hospital A resembled a hierarchy within the O&G department, as noted in the observation notes. During the meeting, the front two rows were occupied by postgraduate students, then two middle rows behind the postgraduate students were empty, and then senior residents occupied the seats after the empty rows. The senior staff (head of department, professors/associate professors/consultants) all sat in the last row.

> *There seemed to be a layout how the participants sit in this meeting space, front two rows were occupied by postgraduate students, two middle rows after where postgraduate students sat were empty, then senior residents occupied the seats after the empty rows. Senior staff (head of department, professors/associate professors) all sat in the last row.*
> *(Observation notes, Hospital A)*

Similar arrangements were observed at Hospital C, where consultants sat on one side and postgraduate students on the other.

Senior staff (Consultant O&G) are sitting on one side of the table, and postgraduate students are sitting one metre away from the desk and on the other side...The space between the table and the chair for the postgraduate students seems to be for postgraduate students to stand up when questions are being asked. It was an interview style of discussion, where questions must be answered when asked by the senior staff. (Observation notes, Hospital C)

6.3.5.2 Disruptions

Disruptions were notably present in Hospital A, which appeared to affect the flow and focus of the meeting. The source of disruptions was mainly due to people coming in and out of the meeting during the first 20 minutes.

Within 10-15 minutes since the meeting started, one of the senior staff's phones had rung and this person left briefly to take the phone call. Three more postgraduate students joined to sit at the front. A few minutes later, one last person joined, and the person seemed to be a senior resident as she sat with them. (Observation notes, Hospital A)

In contrast, no significant disruptions were observed in Hospitals B and C, and there was a more controlled and formal meeting environment in these settings.

6.3.5.3 Supportive environment

All panel members of Hospital B were actively engaged to participate in the meeting discussion and showed a higher level of involvement compared with Hospitals A and C. Observations indicated that members were confident in asking questions whenever doubts arose about the topics under discussion. Although the superintendent was the most vocal member, likely due to their seniority and years of experience compared to other members, during the FGD, panel members expressed that there was equal participation across the panel. The supportive environment was evident as members explained that they contributed by giving their expert opinions relevant to their clinical areas during the meeting; for instance, delivery room nurses provided insights about labour ward procedures and the women's responses to

situations that arise in the ward, while consultants offered additional perspectives about potential clinical interventions and improvements.

> *"Superintendent: We give our opinions, like what we can do for the next, for better, to prevent stillbirths. We are giving out all our opinions and the delivery room sister [nurse] then she can explain what happens in the labour room.*
>
> *Nurse manager: Yes, because we can explain how a person with a condition can react in the labour ward and how we can help them." (Conversation between Superintendent and Nurse Manager, Hospital B)*

6.3.5.4 Confidentiality of the healthcare professional (HCP) involved in the care of a woman who had a stillbirth

In the context of Hospital C, consultants directly asked postgraduate students which person was in charge of the woman's care and to summarise the details of the stillbirth. This practice exposed the identity of the HCP involved.

> *The meeting discussed cases by first asking who was in charge and asking the person who was in charge of the woman's care (case) to summarise the details. (Observation notes, Hospital C)*

Table 6-4. Summary of themes or codes related to the post-meeting phase by hospital

Theme/code	Hospital A	Hospital B	Hospital C
Documentation of meeting	• Date, attendees, and signatures recorded • No minutes taken (meeting mainly for teaching purposes)	• Date, attendees, and signatures recorded • Facilitator and superintendent (Chair) signed notes with action points, which are read out to the panel, assigning responsibilities	• Date, attendees, and signatures recorded • No minutes taken
Dissemination of generated learnings	• Shared verbally with colleagues, excluding nurses	• Responsible person for the action point comes into the hospital so the panel can follow up with the action points • Primarily verbal communication	• Action plans verbally communicated to postgraduate students by senior staff during the meeting

6.3.6 Interlinked Theme 4. Documentation

6.3.6.1 Basic record of the meeting

In Hospitals A and C, documentation from the meeting was minimal and seemed to be limited to obtaining signatures from senior staff and postgraduate students post-meeting, which appeared more akin to a sign-off for a training activity rather than a formal record of the discussion and recommendations for actions. The practice of recording meeting minutes varied, with Hospital A explicitly stating the absence of written minutes was due to the educational nature of the meetings.

> *"We don't write minutes of the meeting because it is merely for the teaching purposes, as I told you." (Consultant O&G, Hospital A)*

6.3.6.2 Meeting minutes

In contrast, Hospital B demonstrated a more structured approach to documenting the meeting. After the meeting, the Chair and the superintendent signed notes that contained the action points from the meeting. These signed documents were then read out to the panel, and the Chair ensured that all notes were agreed by the panel present and individual responsibilities were clearly communicated. Additionally, all panel members signed a register book to officially document their participation at the meeting.

> *After the meeting, the Chair and the superintendent signed the notes which seem to be the document that contains the action points from the meeting. Once this document was countersigned, the Chair read out the agreed and signed action points to the panel with individual responsible for each action point. In addition, all panel members signed a register book stating that the stillbirth review meeting has taken place on what date with which members in attendance. (Observation notes, Hospital B)*

6.3.7 Sequential Theme 3. Dissemination of generated learnings

The dissemination method of generated learnings from the stillbirth review meetings varied across the hospitals. In Hospital A, the dissemination activities were largely verbal and informal. Postgraduate

students mentioned that discussions occurred among themselves and colleagues but did not typically include nurses.

> *"Facilitator: Do you communicate the learnings within the hospital? So, outside of the meeting, do you perhaps share it?*
>
> *All: Yes, we do.*
>
> *Postgraduate student O&G: In terms of learning, we discuss. Not with the nurses, we discuss with each other and our colleagues." (Conversation between Facilitator and participants, Hospital A)*

However, the need for more structured protocols and standard operating procedures (SOPs) to guide postgraduate students was recognised.

> *"One thing I must say, like she said, it is only verbal [dissemination of learnings]. There I think that our institute is lacking... Yes, the standard operating procedures (SOPs) should be there to guide the junior residents [postgraduate students], the senior residents, given the capability, because if you have a difference of opinion, everyone is treating the patient she's been treating for so many years. She must have seen the problems of the patient, and she must have said that this should be event, this should be done. So that is the only thing, the protocol, the standard operating procedures (SOPs) should be there of a particular institute because everyone is giving us the guidelines [on how to treat the women]. As such, we cannot follow it blindly, because we have constraints in the infrastructure and the human resource, so we have to modify according to the postgraduate student. That is the only thing, like she said, that's only verbal. There we can go for it." (Postgraduate student O&G, Hospital A)*

The postgraduate student explained that clinical guidelines, derived from the learning generated from stillbirth reviews in the form of SOPs, would provide clarity on the processes to follow and help prevent similar lapses in care. As the postgraduate student pointed out, there were often different approaches shared by consultants with varied experiences, which can lead to contradictory advice. The postgraduate student also expressed that these guidelines should be adapted to the local resources available and updated regularly.

In Hospital B, the process of disseminating recommendations was more structured. A specific individual responsible for the action point (agreed at the meeting) will regularly meet with the panel to discuss the action points and timeline of implementation. According to observation notes, Hospital B was also the only hospital that had written down the action points from the meeting.

> *"Actually after the review process we have somebody come in and so we can follow up our recommendation and we can go for an action plan like that." (Consultant O&G, Hospital B)*

Additionally, communication of learnings to wider stakeholders (outside of the review panel) who are responsible for providing care for women within the community and facility settings involved direct conversation rather than written notes in Hospital B.

> *"Facilitator: Do you give out any of the notes to them? Or do you talk to them?*
>
> *Nurse manager: We mainly talk to them." (Conversation between Facilitator and Nurse manager, Hospital B)*

In Hospital C, action plans were communicated verbally during the meeting. Consultants provided immediate feedback and instructions to postgraduate students. Similar to Hospital A, Hospital C did not document these instructions, and it was unclear how the findings from the stillbirth review would be archived or documented for new staff in the future to prevent similar lapses in care.

> *Action plans were communicated verbally during the meeting to the postgraduate students by the senior staff. For example, individual changes required were fed back to the postgraduate students - '[this method] should be used', 'you should call a senior for such case'. (Observation notes, Hospital C)*

Table 6-5. Summary of themes or codes related to the outcomes phase by hospital

Theme/code	Hospital A	Hospital B	Hospital C
Data quality	• Active discussion on data accuracy during the review meeting	• Data cross-referenced with labour register before finalising action points	• Focus on improving documentation quality, emphasised in doctor training
Quality of care	• Applied generated learning from reviews to enhance vigilance and care for pregnant women	• Signed notes and action points reflect commitment to improving care	• Focus on corrective and preventive actions from review findings
Quality of stillbirth review process	• Improvements noted due to increased manpower • Reviews conducted since 1977	• Not discussed	• Not discussed

6.3.8 Sequential Theme 4. Improving quality

6.3.8.1 Data

The review process was used as a tool to improve data quality and record-keeping practices in the hospitals. During the stillbirth review meeting, Hospital A addressed any data discrepancies or missing information by actively pointing out the accuracy and completeness of the data presented (in the slide deck) or asking presenters to re-check the details with the staff involved.

> *There were some questions around if the data presented in the slide deck was correct. (Observation notes, Hospital A)*

During the meeting at Hospital B, the panel noted that one of the stillbirths had limited information in the summary report regarding whether the woman was known as a high-risk pregnancy at the time of admission. This led the nurse manager to request the labour register to be checked via a call to verify the details, and the data were double-checked before finalising the action points.

> *One of the deaths had limited information on if the mother was known as having a high-risk pregnancy at the time of the admission, so the nurse manager called someone to bring down the register book of the case in question. The nurse manager called out the case details for identification, and at the end of the meeting, this fact was double-checked before finalising the action point. (Observation notes, Hospital B)*

A consultant from Hospital C emphasised the importance of improving the quality of documentation as part of the review process for effective review and learning, and noted that it is a key focus in the training of doctors at the hospital.

> *"So, those documentation I think is very important from the time of admission, until the process of labour is completed. Plus at the time of birth, what was the condition of the baby. So, we always stress that to our doctors, 'Please do your documentation correctly,' which will help us in reviewing where we have gone wrong. If there is no documentation then we cannot review anything because every time everybody will not be present at that point. It is the two or three persons who are present during the*

time of labour, that is the document she will take for discussion." (Consultant O&G, Hospital C)

6.3.8.2 Quality of care

The quality of care improvements stemming from the stillbirth review meetings were evident in the discussions in Hospital A. Postgraduate students acknowledged that the learnings generated from stillbirth reviews are applied to future clinical care, such as being 'more vigilant' in similar medical or obstetric complications and overall women's care.

> *"Postgraduate student O&G 1: Obviously if some stillbirth has occurred in my duty I'll know the cause. Whatever I've missed, I knew in the review. Next time if same patient comes to my labour room then I'll be more vigilant towards it. I'll know that this will happen, at this point, I know the facts about it. I knew I missed this part and I will not miss this time. We learn from it.*
>
> *Postgraduate student O&G 2: I learn something new every day." (Conversation between Postgraduate students, Hospital A)*

An example provided by a postgraduate student highlighted the application of learnings to monitor the use of oxytocin during labour, which was the recommendation from the previous stillbirth review meeting.

> *"Facilitator: I know you said you verbally discuss about action points, can you give any example of how this was done, any experience in the past that you can give me as an example?*
>
> *Postgraduate student O&G: We can monitor the oxytocin we are using for augmentation of labour, like how much drop it is going, whether the patient is getting hyperstimulated or not, and senior doctor on duty or the junior residents [postgraduate students], and then they can monitor the patient, whether the monitoring is done regularly by the junior residents [postgraduate students] or not." (Conversation between Facilitator and Postgraduate student, Hospital A)*

In Hospital B, the focus on quality of care was also evident through structured follow-ups on action points. The signed notes and agreed action points indicated a commitment to improving care based on

the review outcomes. In addition, Hospital C emphasised corrective measures and preventive actions based on findings from the review process.

> *"Rightly as Doctor said, whatever we find in the file, or whether from the date of admission, or from whenever she comes from the outpatient department, whatever we missed, we do it correctly. I want to stress one more point. As we had said before, if our patient was a booked patient then we can correct her and we can take timely intervention. So, as earlier we mentioned that in our hospital whatever we can do, we try to do the corrective measures and the preventive action." (Consultant O&G, Hospital C)*

6.3.8.3 Review process

Lastly, Hospital A emphasised that they have been conducting stillbirth review meetings since 1977 and that having a long history of review process improved the quality of the stillbirth reviews over time by learning and optimising their processes. A consultant explained that the quality improvements in their review process were mainly due to increased manpower who can support the process, including data collection.

> *"Facilitator: I know some of you have been here in this hospital for a long time, some of you are fairly new, but in terms of process, do you think it's changed or evolved as the years go?*
>
> *Consultant O&G: I think so. Because previously we would just, I did my postgraduate from this college, so there were just two postgraduates at that time, so very less manpower was there. So obviously we now have lots of manpower, so definitely quality has improved a lot, definitely" (Conversation between Facilitator and Consultant, Hospital A)*

However, even for Hospital A, which has a long history of review process, no quality improvement has been measured for their stillbirth review process, for example, by using key performance indicators. Also, across three hospitals, there was a lack of discussion related to whether the review process has been contributing to reducing stillbirths, and it was difficult to understand if there were any evaluation plans were in place to understand the outcomes and impact of the stillbirth review process in any of the hospitals.

6.4 Discussion

6.4.1 Principal findings

The document analysis from this multiple case study found that all hospitals employed standard forms to collect routine health data, with one hospital additionally using a specific stillbirth review proforma to collect stillbirth data. Hospitals also reported stillbirths to the higher authorities, Chief Medical Officer and the National Health Mission, though only tertiary hospitals were reported to use the 'Stillbirth report' proforma required for the Civil Registration System. Stillbirth review guidelines was not adopted by two of the three hospitals, although one hospital, which had local guidelines for their stillbirth review process, reported that they also adhere to the national guidelines created by the National Health Mission. This particular hospital was also the only hospital that created written documents from the stillbirth review, such as monthly reports, meeting minutes and a list of action points.

The framework analysis of the observation notes and FGDs revealed that the reasons for conducting stillbirth reviews were similar across the three hospitals. These reasons included the desire to determine the cause of stillbirth, assess whether the stillbirth was preventable, and identify any instances of suboptimal care that may have contributed to preventable stillbirths. Hospitals reported that they had conducted their reviews due to the motivation of wanting to improve the quality of care in their hospital and emotional involvement. However, in two hospitals, there was less intrinsic motivation for some review panel members, as attendance was either mandatory or part of their professional responsibilities.

All hospitals began their review process by gathering stillbirth data. Each hospital held regularly scheduled meetings for stillbirth reviews, with dates and times fixed well in advance to ensure that all participants were informed. The logistical aspects of organising stillbirth review meetings, such as compiling the list of attendees and making arrangements for clinical duties while the panel attends the meeting, were carried out by a designated focal person. There were variations in how stillbirths were discussed, the atmosphere and conduct during the meetings and the documentation produced. All

hospitals reported that their stillbirth review process improved the quality of care and data quality, with one hospital that had a long history of stillbirth review process reporting their process also improved the review quality over time, although this was not measured through quality improvement indicators.

6.4.2 Discussion in light of other evidence

All three hospitals had standard forms (registers or case sheets) for collecting routine health records. These forms were comprehensive and allowed hospitals to capture women's socio-demographic information, obstetric history, complications, and outcomes for both women and babies. While one hospital also had a separate data collection form for the purpose of stillbirth review, all hospitals used routine health records as their main data source for gathering data for stillbirth reviews. This was similar to the systematic review findings (Chapter 2), which found abstracting or directly reviewing data from already available sources as the most common method of gathering information for stillbirth reviews [95,93,109,104,94,133,127,102,69,113,70,88,87,76,112,129,86,100,89,99,85,80,90,118,75,78,105,79,101,132,110,124,84,91,131,81]. It was envisaged that if these routine health records are completed as intended and stored securely, data can be found and extracted effectively for stillbirth review purposes when there is a stillbirth. In practice, however, the accuracy, completeness, and storage of these forms may be inadequate. Several studies noted that poor record-keeping skills exist at the facility level, and missing records make it very difficult for death reviews to be carried out [120,124,248–251].

For the three hospitals in this study, there were measures to correct data discrepancies and fill in missing information during their stillbirth review meetings. This was recognised as one of the positive outcomes of the stillbirth review process, as it not only improved data quality through an audit of existing records but also prompted further staff training on improving record-keeping practices. The systematic review also identified "providing training to HCPs to increase their knowledge and medical skills [82,95,107,111,116,124]" as a short-term outcome of the stillbirth review process. In low-and-middle-income countries (LMICs), identifying the staff's training needs and providing this training were found as effective ways to change clinical practices to reduce suboptimal care in health facilities [51,60,252].

This study also found that only tertiary hospitals submitted the 'Stillbirth report' proforma (also called Form No.3) required for the Civil Registration System, and the secondary hospital was not required to report their stillbirth using this form but via an integrated report of different mortality data. This was despite the Civil Registration System mandates that all stillbirths be documented using Form No.3 and signed by the government Registrar of Births and Deaths, regardless of whether they occurred in a health facility or a community setting [26]. In addition, while all hospitals confirmed reporting their stillbirth statistics to higher authorities, the reporting process varied by hospital type. For example, secondary and tertiary private hospitals submitted stillbirth reports (using the 'Stillbirth Report' proforma or other methods) only to the Chief Medical Officer's office. The National Health Mission project manager in the Chief Medical Officer's office then forwarded these reports to the National Health Mission. This highlights a gap in standardised stillbirth reporting practices across different levels of health facilities, which could lead to inconsistencies in the stillbirth data reported at the national level. As Zadey *et al.* [29] pointed out, there are already huge variations in stillbirth rates between different data sources for stillbirth rate calculation; stillbirth rates calculated using Civil Registration System were much lower (6.69 per 1,000 total births) than the modelled values using the National Family Health Survey 2019-21 (NFHS-5), 11.6 to 25.7 per 1,000 total births [27,28], or Indian Health Management Information System data 12.25 per 1,000 total births [30].

Out of the three hospitals that participated in this study, only one reported that it had adopted both local and national guidelines. It was also the only hospital that produced written documents (monthly report, meeting minutes, and actionable points) beyond basic records. Other hospitals only recorded signatures from senior staff and postgraduate students after the meeting. This was similar to the systematic review findings (Chapter 2), where dissemination of key findings and learning points to relevant staff was observed in only 39% of studies that labelled their stillbirth review processes as 'reviews'. Kinney *et al.* [253] noted that having meeting minutes and recommendations are markers of progress for 'evidence of practice' because documentation provides evidence that regular meetings take place and enables reflection on their quality [48]. This particular hospital's approach to documenting review findings

proved instrumental in effectively disseminating learning and initiating the implementation of action points. Specifically, this approach (1) ensured that findings from each review were thoroughly recorded and accessible for future reference; (2) provided a record for staff who may not have attended the meetings but are involved in women's care; (3) enabled new staff joining the hospital to review past findings and avoid repeating similar suboptimal care practices; and (4) increased accountability by ensuring that recommendations were implemented within agreed timelines.

The importance of assigning responsibility and having a system for following up on recommendations has been highlighted as a key facilitator for sustaining stillbirth reviews at the facility level, and documenting meeting minutes and assigning actions in writing was recognised as an effective way to improve accountability for recommendations [253]. If the two hospitals that currently do not produce written minutes adopted this approach, it would likely streamline the implementation of action points and provide consistent clinical guidance. Indeed, an FGD participant from one of these hospitals suggested that documenting review findings and creating clinical guidelines could resolve issues related to contradictory advice from staff on managing complex cases [120,124,252–256]. The WHO guidelines includes a meeting minutes and action items form that hospitals may consider using to support this process [52].

The varied factors motivating staff participation across hospitals highlighted the complexity of sustaining an effective stillbirth review process in India. While emotional involvement and a commitment to improving the quality of care emerged as key motivators, mandatory attendance and expectations tied to professional roles were also important factors for staff participation. This suggests that there is a need for a balanced approach that combines both intrinsic and extrinsic motivators. Such an approach can ensure that all staff recognise the importance of their contributions; active participation is linked to supporting women and babies but also meeting the expectations tied to their professional roles. In cases where individual staff lack motivation due to a lack of direct clinical responsibility or personal experience with stillbirth, a system-wide approach, including mandatory attendance for specific roles, may effectively drive the review process forward. Mandatory attendance has already been identified as an enabler for

implementing the culture of accountability, learning and improvement for the review process in LMICs [49].

For the two hospitals with teaching responsibilities for postgraduate students, using stillbirth reviews as an educational tool was specifically highlighted. This emphasis on review as a tool to educate postgraduate students was consistent with findings from another stillbirth review process in India [121]. However, this practice also reinforced a hierarchical and disciplinary tone among senior doctors during the meetings. While postgraduate students viewed this disciplinary approach as a valuable part of their learning experience, they also noted that it did not necessarily constitute a 'supportive' environment during the review meeting. Fear of disciplinary measures has been identified as a significant barrier to improving the quality of the death review process, as panel members may hesitate to reveal gaps in their clinical care [49,51,248,257,258]. Evidence from the literature suggests addressing this challenge by separating the review process from disciplinary actions [251] and implementing a "no name, no blame" policy [52,259]. Additionally, adapting the teaching aspects of the stillbirth review to focus on overall learning rather than specific individual performance could improve the review process. This would involve framing educational aspects of reviews as opportunities for systemic learning rather than scrutinising individual mistakes or lack of knowledge, thus promoting a more open and supportive environment where both postgraduate students and consultants can contribute equally to discussions on stillbirth.

There was a clear assigned responsibility within the three hospitals for activities associated with organising review meetings. A designated focal point existed at each hospital to make sure stillbirth data was gathered for the purpose of the stillbirth reviews and to ensure meetings took place at regularly scheduled times. Having a designated focal person and regularly scheduled meetings were thought to be tangible and immediate indicators of organisational commitment to conducting and sustaining the stillbirth review process [49]. Also, regularly scheduled meetings across all hospitals further demonstrated that stillbirth reviews were integrated into their routine practice [253].

Despite having a clear structure for assigned roles, none of the hospitals provided pre-reading materials to the review panel before the meetings. Previous studies indicate that distributing necessary data to panel members ahead of time helps with preparation and enables meaningful engagement during the review process [69,75,93,109,118]. Therefore, hospitals might benefit from adopting a practice where summaries of stillbirth and any additional testing or investigation data are circulated prior to the meetings.

Several studies emphasised that incorporating follow-up and monitoring mechanisms for recommendations will automatically increase the motivation of the review panel [51,248]. However, action points [124,251,260] from previous meetings were not discussed in any of the hospitals. Therefore, hospitals may benefit from allocating a portion of their meeting time, preferably during the introduction, to address these action points. An effective introduction may also minimise disruptions, reinforce adherence to the meeting's code of conduct (such as a blame-free policy), and maintain focus on the primary objectives of the review [261,262].

The lack of discussion on whether the review process has contributed to reducing stillbirths highlighted an opportunity to assess quality improvement by implementing key performance indicators to evaluate outcomes and the impact of the stillbirth review process in India. These indicators could focus on data collection quality, the review process itself, and the effectiveness of generated action points, along with the interlinked themes identified in this study as enablers and influencers. The WHO [55] describes the purpose of the monitoring review process as to: (i) document the implementation of the process and any recommendations suggested by the review panel, and (ii) deliver improvements to the quality of care provided. Examples of process evaluation indicators could include the number of stillbirths identified and reviewed, the proportion of stillbirths where care issues were identified as relevant to the outcome, and the proportion of reviews that identified recommendations and action points. For outcome/impact evaluation indicators, the proportion of recommendations implemented, tracking of the number of overall, antepartum and intrapartum stillbirths, and tracking of the number of stillbirths by cause can be used to understand if the trends in facility-level stillbirth rates have been decreasing over time. Additionally, indicators could assess of proportion of routine health records that were deemed

incomplete to be used in the stillbirth review data collection. The WHO [55] emphasises the importance of quality improvement monitoring systems, recommending their use to evaluate whether stillbirth review processes are improving the quality of care and outcomes while also identifying areas requiring further improvement, and assessing whether the stillbirth review process has contributed to a sustained reduction in stillbirth rates over time.

6.4.3 Strengths and limitations

One of the strengths of this study was its use of a case study approach that incorporated multiple data sources. The qualitative data were collected by conducting document analysis, non-participant observations, and FGDs, and this meant the processes and structures of stillbirth reviews within each hospital were explored from various perspectives. Observations captured the interactions and dynamics of the meetings, while FGDs provided deeper insights into participants' experiences and perceptions. Document analysis further contributed by evidencing the guidelines followed, resources available, and outputs generated, which cannot be assessed in real-time due to the time required to compile such documents. In addition, the methodological triangulation of data from these multiple data sources increased the reliability and depth of the study findings, as it allowed for a comparative analysis between observed practices, reported discussions, and documented evidence.

Another strength of this study was the variation between the hospitals recruited, as they were located in different regions of India and represented different hospital types (tertiary and secondary, government and private). This meant that the study's findings could potentially apply to other Indian hospitals with similar characteristics. Furthermore, the purposive sampling method ensured that the hospitals selected for the study were relevant to the objective. Having clear definitions and boundaries for each case, encompassing people, processes, and structures involved in stillbirth reviews, also contributed to the methodological rigour of the multiple case study design.

This study also had some limitations. The reliance on non-participant observation meant that the presence of the observer could have influenced participants' behaviour, potentially altering how meetings were conducted. To mitigate the observer effect, it is generally recommended to build rapport with participants and make them feel at ease [263]. However, due to constraints associated with a DPhil study, such as limited funds and time, only one meeting per hospital was observed, which restricted the ability to assess or fully mitigate the observer effect. There were efforts made to minimise any observer effect, for example, before the meeting started, I (the observer) clearly introduced myself as a postgraduate student researcher and asked for preferences on where I should sit.

Additionally, there were limitations related to the FGD. For one hospital, the FGD could not be conducted on the same day as the observation due to constraints on staff time, which was a key aspect of how fieldwork was planned and executed for the other two hospitals, resulting in this hospital's FGD being held online two months later. This delay and the use of an online platform may have affected the depth and quality of the discussions compared to the face-to-face FGDs conducted at the other hospitals. The online format may have also influenced the dynamics and richness of the interactions during the FGDs. Jones *et al.*'s [264] literature review of studies comparing face-to-face and online FGDs highlighted that online FGDs often elicit shorter, less detailed responses, and sometimes resemble question-and-answer sessions [265–267]. However, Jones *et al.* [264] also noted that, where time and resources are limited, or when online sessions are more feasible, online FGDs can be a suitable alternative. Importantly, in this study, the online FGD generated similar themes to those of the face-to-face FGDs.

Furthermore, one hospital was unable to include postgraduate students in the FGD despite their involvement in the review panels due to difficulties in arranging coverage for their clinical duties. This exclusion likely resulted in a partial perspective on the stillbirth review process, particularly in understanding how more junior staff (compared to consultants) contribute to and experience the review meetings within the hierarchical structure of the hospital.

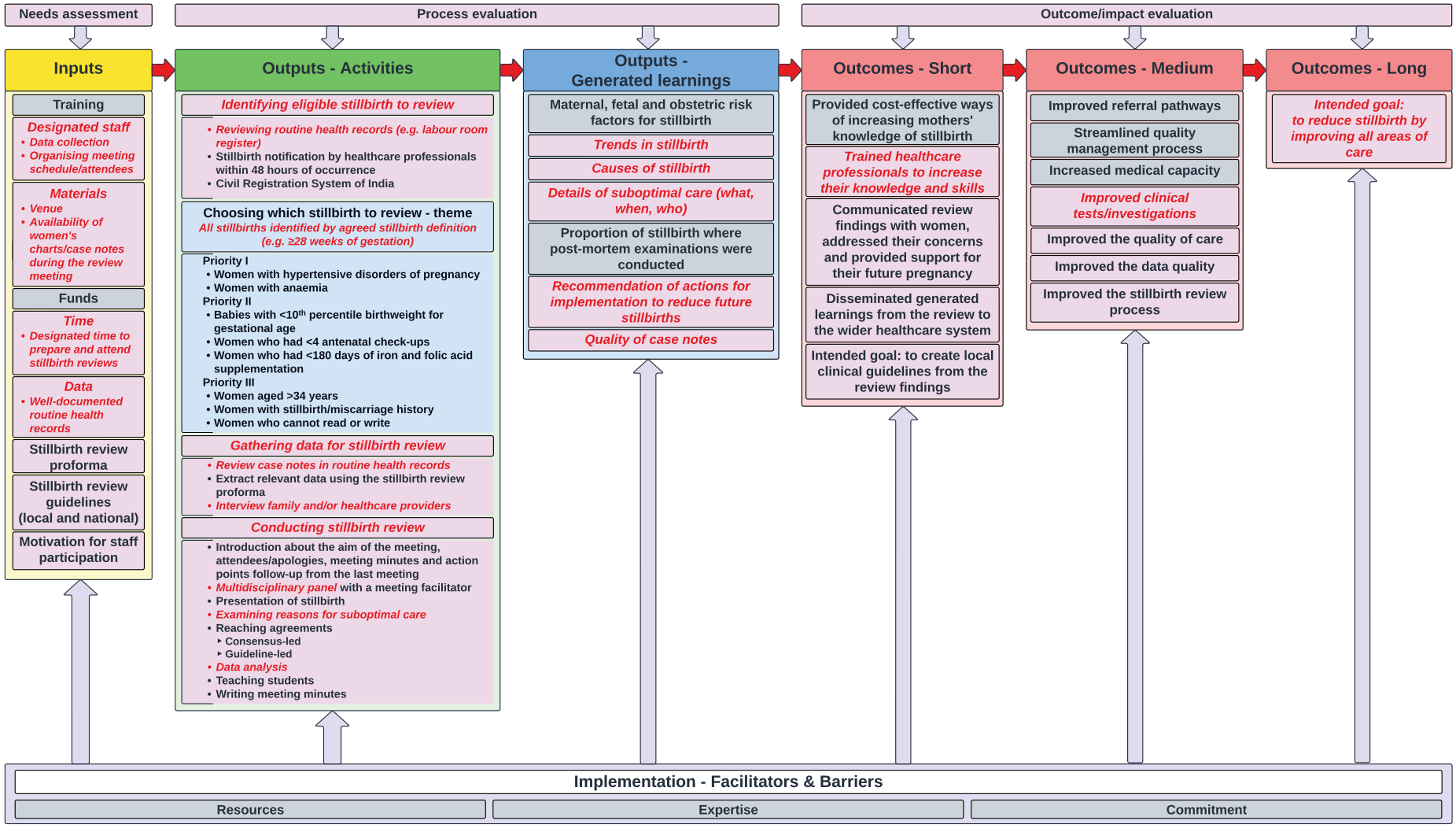
Another limitation was related to the purposive sampling method. While this approach ensured that hospitals relevant to the study's objectives were included, it also meant that the findings may not be generalisable to all Indian hospitals outside of the sampled cases within the Maternal and perinatal Health Research collaboration, India (MaatHRI) platform. The selected hospitals, although varied, may not have fully represented the range of stillbirth review processes across different settings in India or other countries.

Finally, the study's reliance on document analysis to understand guidelines, resources, and outputs was limited by the availability and completeness of documents provided by the hospitals. Some documents might have been missing or not given despite multiple attempts to source them – before, during and after fieldwork – which could have affected the comprehensiveness of the evidence regarding the guidelines followed and the resources used in the stillbirth review process. Although in this study, all hospitals confirmed that they did not possess certain types of documents listed in the document analysis worksheet used to guide document requests and I felt satisfied I have obtained every document fitting my criteria. Additionally, I was able to get clarification on any questions I had about the data flow of different documents during the validation meeting.

6.4.4 Revised logic model

The logic model which was updated in 5.7.6 (Chapter 5) by adding the findings from the quantitative analyses is further updated in Figure 6-3 to include the empirical findings from the multiple case study. The findings from the multiple case study are represented in pink boxes in the revised logic model. Additionally, there are some overlaps in evidence with the findings extracted from the systematic review, as indicated in red italic font. The logic model is discussed in detail in Chapter 8.

Figure 6-3. Second revised logic model: includes findings from the systematic review, quantitative analyses, multiple case study



6.4.5 Conclusion

The multiple case study provided important insights into the current stillbirth review processes adopted in three different hospitals in India. The use of a case study approach incorporating document analysis, non-participant observations, and FGDs enabled a comprehensive exploration of the processes and structures involved in stillbirth reviews in India. The findings emphasised the importance of routine health records and standard forms in stillbirth data collection and different discussion methods that exist for how the stillbirth review process was set up and organised in each hospital. This includes the presence of a meeting facilitator, having teaching responsibility of postgraduate students, atmosphere and conduct during the meeting. The study also found that while hospitals have made efforts to improve data quality and review processes, gaps remain in standardised reporting of stillbirth, documentation of the review process and following up on recommendations and action plans. Also, the opportunity to assess quality improvement by implementing key performance indicators to evaluate outcomes and the impact of the stillbirth review process in India is as yet unfulfilled.

The findings indicate that hospitals with established documentation practices, such as producing written reports and meeting minutes, may be better positioned to implement action points and improve the review process. Moreover, the adoption of local and national guidelines and the use of systematic documentation of stillbirth could contribute to further improving stillbirth reviews.

The study also highlighted the challenges associated with non-participant observation and FGDs, including potential observer effects and limitations related to online FGDs and the exclusion of certain review panel members in the FGD. For future studies, the researcher should observe multiple meetings at each hospital to mitigate observer effects and ensure that all relevant participants are included in FGDs, ideally conducted face-to-face and as close as possible to the observation date.

Chapter 7. Qualitative results II: facilitators and barriers to implementing or sustaining facility-based stillbirth reviews in India

7.1 Chapter introduction

This chapter presents the findings from the analysis of facilitators and barriers to implementing or sustaining facility-based stillbirth reviews as reported by Indian healthcare professionals (HCPs) using the capability, opportunity, motivation and behaviour (COM-B) model. It addresses Objective 5 of the thesis and identifies actionable interventions that could improve the implementation or sustainability of stillbirth reviews in India using the Behaviour Change Wheel intervention functions.

7.2 Facilitators and barriers

The framework analysis of data from the focus group discussions (FGDs) identified facilitators and barriers that influence the implementation or sustainability of stillbirth reviews across eight hospitals. These findings were categorised under COM-B domains at the community, facility, and policy levels. The characteristics of hospitals participating in the FGDs and the demographic characteristics of FGD participants are described in Table 7-1.

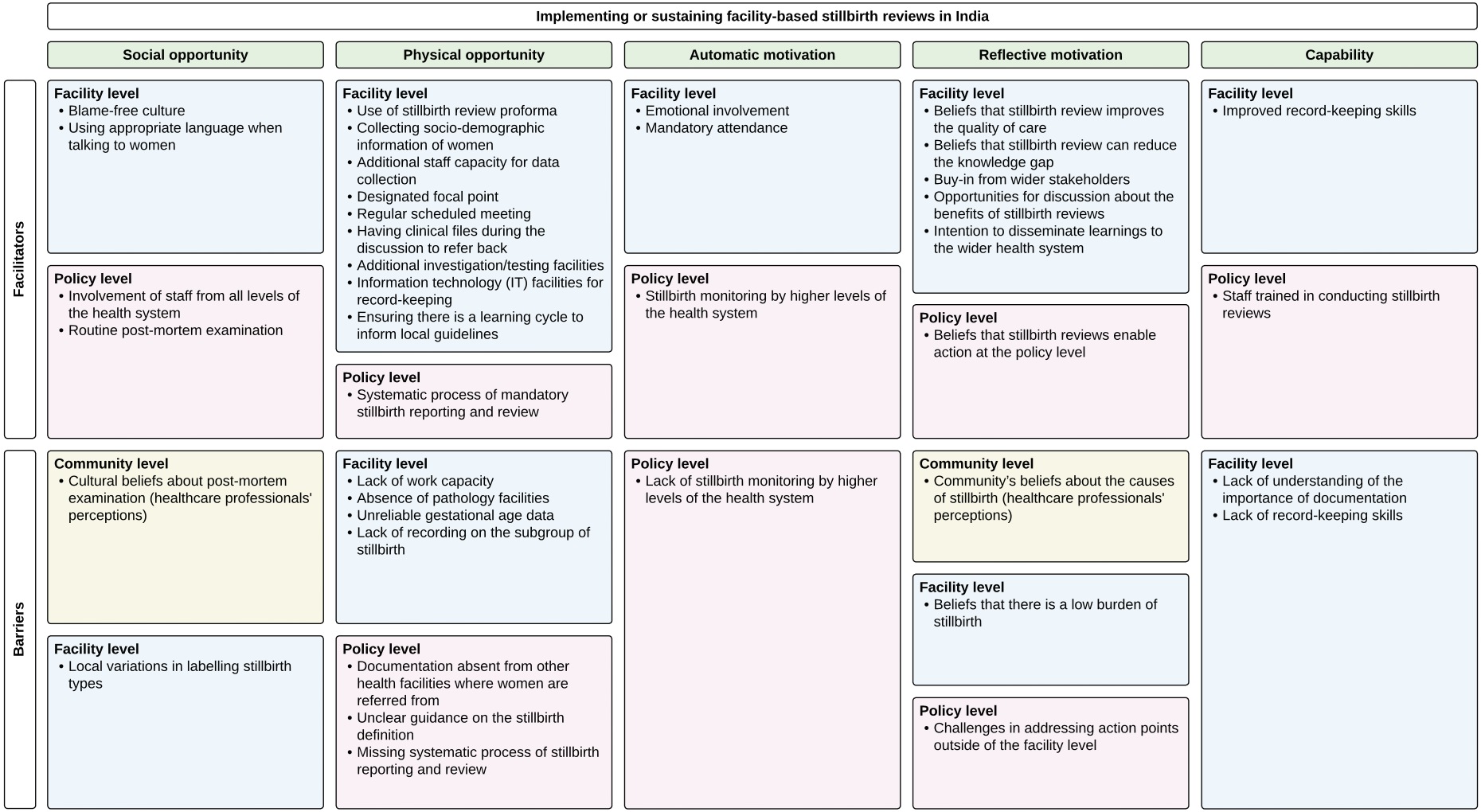
Table 7-1. Characteristics of hospitals that participated in the study and demographic characteristics of the focus group discussion participants

	Stillbirth review hospitals (N=3)	**No stillbirth review hospitals (N=5)**
Hospital type		
Tertiary - government	1	4
Tertiary - private	1	1
Secondary - government	1	0
Focus group discussion participants (N)	20	40
Method of discussion		
Online	1	2
In person	2	3
Job role		
Consultant doctor – obstetrics & gynaecology	5	8

	Stillbirth review hospitals (N=3)	No stillbirth review hospitals (N=5)
Senior resident – obstetrics & gynaecology	0	2
Postgraduate student – obstetrics & gynaecology	7	1
Consultant doctor – paediatrics	0	6
Consultant doctor – community health	0	1
Consultant doctor – pathology	0	1
Administration/superintendent	1	2
Nurse manager	3	5
Staff nurse	4	11
National Health Mission Community Health Officer	0	3
Gender		
Female	19	25
Male	1	15
Age group		
Under 30 years	10	9
30-49 years	7	23
Over 50 years	3	8

Figure 7-1 represents the coding tree diagram that summarises the themes and codes from the framework analysis. Throughout this chapter, hospitals that currently conduct stillbirth reviews were labelled as 'Review hospitals', and hospitals that do not conduct stillbirth reviews were labelled as 'Non-review hospitals'. For ease of presentation, statements and perspectives shared by participants have been attributed to their respective hospitals, representing the collective voices of the individuals within them.

Figure 7-1. Coding tree representing the themes and codes that emerged as facilitators and barriers



7.2.1 Social opportunity

7.2.1.1 Opportunities to participate without fear of blame

Fostering a blame-free culture at the facility level was reported as a facilitator for enabling constructive discussions during stillbirth reviews. One hospital from the Non-review group noted that stillbirth reviews should be viewed as opportunities for systemic learning and improvement rather than as fault-finding exercises targeting individual staff involved in the stillbirth.

> *"And the review process should be – it should never be a fault-finding one. This is wrong. It should not be. It should be constructive so that we can save the next baby. This should be our – it's not that, oh, I have done. oh, you have done this wrong, so I will accuse her next time. This time, you have done... So this – it's never a fault-finding thing. It has to be a healthy one." (Non-review.2 Hospital)*

This hospital also noted that using appropriate language when speaking with parents about stillbirth is important for collecting additional information that can aid the review process. The hospital emphasised that collecting information in a non-accusatory manner helps reduce social pressure in doctor-patient interactions, as 'scolding' language may lead patients to withhold important information.

> *"How we get the information from the parents or maybe the mother... yes, that can only be done if you do not accuse them. If you are scolding, then they will try to hide. Why didn't you come to the hospital? You should have come in at the right time. Then they will try to hide. So many factors are there. It should not be intimidating or accusing certain things." (Non-review.2 Hospital)*

7.2.1.2 Opportunities for staff from all levels of the health system to participate

Two hospitals recognised that involving staff from all levels of the health system in stillbirth reviews, beyond just doctors, improves the quality of the review process. A Review hospital noted that including a broad range of job roles, such as administrative staff and nurses, can improve learning across the hospital because different perspectives are considered during the discussion.

"Basically we are not involving so much the administrative staff, nor the sister staff... I really feel it would be better if we could involve other people also [in the stillbirth review], but at the present moment it is just the whole department with the doctors and the junior staff. We conduct the review." (Review.3 Hospital)

One hospital from the Non-review group noted that involving community health workers who provided antenatal care in the sub-district where women reside can provide a more complete picture of the factors contributing to stillbirths. The hospital noted that this approach is particularly valuable compared to relying solely on notes from antenatal care and referred to the current process used in maternal mortality meetings, which currently includes inviting sub-district community health workers.

"Labour room staff, the obstetricians along with the neonatologist who are attending to our delivery. We can involve all the person. But only one part is we need those who have provided her [women's] antenatal care. So we can include those person also. To get a complete review, and that is the way we are doing in maternal mortality... Suppose she [sub-centre health worker] is working in a sub-centre facility. And stillbirth occurred in her [sub-centre health worker's] jurisdiction. In that particular month, she [sub-centre health worker] attends. If [stillbirth] doesn't happen, she [sub-centre health worker] does not attend." (Non-review.2 Hospital)

7.2.1.3 Navigating cultural challenges in obtaining consent for post-mortem examinations

Cultural beliefs surrounding post-mortem examinations were identified as a barrier, with hospitals noting that the absence of these results hinders the accurate identification of stillbirth causes. A Review hospital reported that obtaining consent for post-mortem examinations is particularly challenging due to prevailing cultural beliefs in India, often upheld by family members such as grandparents. The hospital felt that this challenge would persist despite the presence of government regulations or designated post-mortem units.

"We don't have a system of any post-mortem for the fetus... So, many causes of stillbirth or intrauterine demise, and we might not have an answer. We might bracket them into unexplained causes like we couldn't find any maternal cause, and we don't have any

system of how we can evaluate whether the fetus had some congenital anomalies or, unless by ultrasound, if we detect some gross congenital anomalies which are incompatible with life... But many times, the ultrasound might be absolutely normal, but there might be some inherent problem in the fetus... In our setup, it will be very difficult because of the cultural belief that's also important in this part; they will not allow, even if the government brings a rule or we have a post-mortem unit, we will not get consent from the parents to do a post-mortem. I think this part of the place where we are it will be very difficult to get consent for post-mortem... The grandmother especially rather than the parents [laughs], who will disagree to the examination." (Review.3 Hospital)

However, one hospital from the Non-review group believed government authorities could support implementing routine post-mortem examinations with an opt-out option to address this challenge, similar to the routine human immunodeficiency virus (HIV) screening programme in their hospital.

"Yes, I think the resources that we need is if we have a kind of hospital authority making it routine autopsy for all stillbirths. That is going to help us. If it becomes a routine, say it's always routine. Say opt – say it's always routine. Just opt-out. Somebody says I'm not ready; otherwise, it's a routine. It's like human immunodeficiency virus (HIV) screening, you know, opt-out. Yes, so that is the best method, I would say." (Non-review.1 Hospital)

7.2.1.4 Understanding local variations in labelling stillbirth types

While two out of eight hospitals (1/3 Review hospitals and 1/5 Non-review hospitals) used terms such as 'antepartum' and 'old' to label stillbirths that occur before the onset of labour, the remaining six hospitals called this subtype of stillbirth as 'intrauterine deaths (IUDs)'.

"Participant: Only intrapartum deaths are considered a stillbirth.

Facilitator: So, only intrapartum death is considered a stillbirth, and how do you define intrapartum death?

Participant: Once a person is in labour." (Non-review.5 Hospital)

It was unclear whether these hospitals exclude antepartum stillbirths from their stillbirth statistics due to local variations in labelling this subtype of stillbirth. However, two hospitals specifically pointed out

during the FGDs that only intrapartum stillbirths are classified as 'stillbirths' at their hospitals. The implications of this variation of definitions in the stillbirth statistics or perceptions regarding antepartum stillbirth were not explored further.

> *"Actually, for us, we consider intrauterine deaths (IUDs) and stillbirth a different way. Like intrauterine death (IUD), we consider if it's 28 weeks above, then supposedly there is no fetal heart sound (FHS), or there is nothing like, if a patient comes with a complaint of less fetal movement, we find out if there is an absence of fetal heart sound (FHS). Then we consider after a scan or a proper scan, we diagnose there is an intrauterine fetal demise. So, we take it as an intrauterine death (IUD). Whereas for a stillbirth, we consider, during the process of delivery, if the fetal heart sound (FHS) was still present during the process of delivery, so if the child comes out - what to say - there was no response, or there is an absence of heart rate so to say, so we take those as stillbirths....Yeah, intrapartum, something which has occurred earlier than labour, it is intrauterine demise. And the process, which is taken during the process of labour, if it's intrapartum, then we consider label it a stillbirth." (Review.3 Hospital)*

7.2.2 Physical opportunity

7.2.2.1 Using standard proforma to collect stillbirth data

Two hospitals from the Non-review group highlighted the need for a standard proforma for stillbirth reviews to facilitate systematic data collection. One hospital mentioned that proper formatting and record-keeping are challenges, and having a proforma would help standardise the collection of data and aid in the review process. They noted that a proforma would simplify record-keeping and facilitate organising stillbirth review meetings.

> *"We are good at working but keeping records becomes an issue. So we do not have, probably we should, if we have improper formatting, how to put the records for a stillbirth. What are the things to be noted? And if we have that kind of a proforma or something, then probably it will be good for us to find out the cause and also keep a record and then we can do the review meeting like the way we do our maternity… Pre-filled proforma would be easier for us." (Non-review.1 Hospital)*

Both hospitals referenced the use of proformas in maternal mortality reviews as an example to follow in stillbirth review process.

> *"If it is like whatever we have in maternal death review. We have a standard form. We have to fill up certain findings so that we make it uniform and that we are getting a certain amount of the same information. We do not miss anything. Proforma. We have a standard proforma to be filled up." (Non-review.2 Hospital)*

One hospital that currently employs a proforma for its stillbirth review reported that it helps gather consistent information about stillbirths, such as admission details, time of birth, and whether the case was booked or unbooked. However, this hospital highlighted that it is still important to have clinical files available during review meetings in case details are missed on the proforma.

> *"We have a file where we have a questionnaire as per the hospital, where we find out the causes, and the questionnaire, for example, what time the admission was done, what time she delivered, was she a booked case or an unbooked case?... During the discussion actually, we should have the patient's file with us, the patient's clinical file from when she was admitted; it should be with us. And all the clinical notes from page 1 to the last page with all investigations report we have to review that." (Review.3 Hospital)*

7.2.2.2 Minimum stillbirth data required for reviews

One hospital from the Non-review group emphasised the importance of collecting socio-demographic information as part of stillbirth data. They suggested that every woman admitted to the labour room should undergo a social survey to gather this type of information, which is often missing and difficult to follow up once a woman is discharged.

> *"Every patient or every mother who is admitted in labour room should have a social survey." (Non-review.4 Hospital)*

Collecting data on types of stillbirth was another area that hospitals wanted to improve in their stillbirth data collection since there is currently a lack of recording of such information.

"It's quite hard to collect the [stillbirth] data. We just take the numbers." (Non-review.1 Hospital)

"There's a delivery register so there we make an entry whether live or dead, live or stillbirth." (Non-review.2 Hospital)

One major barrier reported in gathering the minimum data required for stillbirth reviews is the frequent absence of documentation from previous health facilities where women are referred from. This issue was reported to affect both Review and Non-review hospitals. Two of the Review hospitals reported that not having clinical notes from previous hospitals during the women's pregnancy hinders the process of action planning.

"From other periphery hospitals' records we are not getting. Without this information, we cannot comment direction. We cannot get that or discuss." (Review.2 Hospital)

As one Review hospital noted, despite challenges from absent documentation, they aim to "try to find" any available data for their review, recognising that even a minimal set of stillbirth data can significantly inform and improve the care provided to women.

"Those cases which have already come with a stillbirth from outside, in those cases it's a little bit difficult to get into the very minute details because we won't have so much data. But whatever data we have, accordingly, we try to find it." (Review.3 Hospital)

Non-review hospitals also identified this barrier, particularly regarding the lack of recorded fetal heart rates, making it challenging to determine if the stillbirth occurred before or during labour.

"Similarly, where she's undergoing [care in] a particular hospital, then the documentation is not there... Many of the time, we see that the fetal heart rate is not written. We are not very sure whether it is a case of intrauterine fetal death, the time of occurring or on the way during transportation. Without accurate documentation of what happened throughout the pregnancy, it will be impossible to know what the state of the fetus was and when the death exactly occurred. Was it during the delay of transferring, or was it at the hospital? You will not know." (Non-review.2 Hospital)

One Non-review hospital stated that conducting a stillbirth review was virtually impossible due to the lack of information about the active labour phase and delays in transfer. This challenge not only significantly limited their ability to review stillbirths but also led to frustration within the system.

> *“Maybe [we can discuss stillbirth]. But we would not have done it very elaborately because it is not like we were monitoring the labour throughout. We would have never monitored the person. So most of the time, it is the last thing they come, and we try to save the mother. They [other facilities] would have not even monitored from their active phase. It is not that we don’t want to help… We will not be able to [conduct a review], because it is difficult for us to get all the information about the patient. It’s a major thing which is something to think about and take action." (Non-review.4 Hospital)*

7.2.2.3 Availability of Information technology (IT) facilities for record-keeping

Two hospitals from the Review group identified Information technology (IT) facilities as a key facilitator for improving record-keeping. They noted that managing records on paper is prone to loss and often results in incomplete data during stillbirth reviews.

> *"Software documentation should be there, yes. The very main issue in our government hospitals is that documentation is not proper because this type of computer is not there. But without this thing, people loose documents." (Review.2 Hospital)*

Another Review hospital highlighted the benefits of their electronic medical record (EMR) system in managing data efficiently and reducing the risk of losing important information.

> *"Actually, in our hospital, documentation and data managing is very good. We have an electronic medical record (EMR) system from the obstetrics department; all the data is collected and saved. In the labour room, we have registers for stillbirths, normal deliveries, and caesarean sections, so our data is very well-kept actually. So, I think in our hospital, this is up to the mark now; we don’t have any problem regarding managing data. So that is my point that in that aspect we don’t have any problem." (Review.3 Hospital)*

In contrast, Non-review hospitals did not identify the availability of IT facilities as a facilitator. Instead, they were more focused on ensuring minimum stillbirth data is collected using standard proformas to facilitate a comprehensive data collection process.

7.2.2.4 Unclear guidance on the stillbirth definition

One Non-review hospital reported that unclear guidance on the definition of stillbirth results in inadequate attention and prioritisation of the stillbirth burden. The hospital pointed out that lack of clarity in the definition of stillbirth meant that there is confusion about whether obstetricians should be responsible for reviewing and addressing preventable stillbirths or whether stillbirths should be included in their neonatal mortality review process.

> *"Well, stillbirth actually we don't give much importance… because first of all, the definition isn't clear. Those which should be considered a stillbirth or which should be considered as intrauterine death. So many of them overlap… These are deaths which are really causing problems because these stillbirth babies, they are not accounted by the obstetricians nor Indian neonatal mortality [review process]." (Non-review.3 Hospital)*

Another Non-review hospital echoed these concerns, highlighting the negative outcome of the ambiguous definition of stillbirth and subgroups of stillbirth. One of the points raised is that if the gestational age cut-off was from 24 weeks of gestation, the number of stillbirths may be very high. This hospital noted that a clear definition set by the Indian government should be available so it can be employed by the hospital for the purpose of stillbirth review and selection of stillbirths. Also, this hospital noted that if they were to start the stillbirth review, the definition of stillbirth is the first thing they will clarify.

> *"World Health Organization (WHO) is still saying that it is after the age of maturity. That is 28 weeks. Now, there are certain issues like 24 to 28. So those things have to be very specific; otherwise, sometimes, we might have a lot of cases. We don't know. Till now, sometimes it might be like 24…between 24 to 28 if the cases are there where we can see the fetus fully formed, but then whether to call them stillbirth? I mean intrauterine death (IUD), or to call them abortus. So those factors are also there. If we go for a formal*

review, then we will definitely define it. Whatever time, we will be taking 28 or 24. Personally, I prefer this 24. Okay. But it is what – what is a particular stance of the government of India, that is our importance. Whatever government decides – they say we take 28, we take 28." (Non-review.2 Hospital)

7.2.2.5 Systematic process of mandatory stillbirth reporting and review

All three Review hospitals emphasised the importance of a systematic process for stillbirth reporting and review. They explained this approach ensures that all stillbirths are counted and reviewed thoroughly.

"It may be a doctor, it may be a sister [nurse], and then it comes to me. I'm the only person on this audit report. So within 48 hours I came to them with the proformas, a recording of them then, it's a very brief recording done, and after when the patient has been discharged we review that ticket" (Review.2 Hospital)

The hospitals also reported that the government-mandated reporting processes support this systematic approach by requiring hospitals to report stillbirth statistics monthly. They explained this mandatory obligation ensures that all stillbirths are counted and considered as potential stillbirths for review.

"The junior resident prepares a summary of how it happened, from the initial point to the endpoint. And then, the summary will be made. It will be checked by the senior resident, and then it will be handed over to the concerned person who is sending the report every day to the Chief Medical Officer (CMO) office… No stillbirth is missed. The guy who's in the office checks everything with the staff nurses' register, and we report it. And that is complied data in the office." (Review.1 Hospital)

A Non-review hospital, which also reports monthly stillbirth statistics, indicated that the reporting requirement at the policy level could be integrated into their approach of identifying eligible stillbirth to review, as the two are closely linked. For instance, they emphasised the importance of knowing the number of stillbirths that occurred each month and identifying which stillbirth should be prioritised for review during their meetings.

"We have to at least send the regular information to the government [about a number of stillbirths]. So every day, the data goes like how many deliveries we have. So what are the numbers

of preterms or you know, like what would they be? So all the goes to the government every day at the end of the month also, we see how many are [stillbirth] there like that." (Non-review.4 Hospital)

Another Non-review hospital described an ideal process for stillbirth review, which involves prompt notification of stillbirth that occurred in the hospital, immediate registration for reporting purposes and conducting regular stillbirth reviews from registered stillbirths.

"I think the process will be like recording, then immediately registering them, and then have a monthly or two-monthly review of the cases." (Non-review.2 Hospital)

7.2.2.6 Challenges in high workload

Some hospitals (two from the Review group and one from the Non-review group) highlighted challenges related to a lack of work capacity impacting their ability to organise and conduct stillbirth reviews. For instance, some hospitals struggle with record-keeping due to the high demands on their staff involved in direct clinical care for patients, and sometimes, this leads to incomplete or missing routine health records, which are often sources of data for stillbirth reviews.

"No, I am saying that record keeping can sometimes become difficult because we have to do delivery also, no? So sometimes record keeping becomes difficult for us. That's why some records may be lacking, won't be there." (Review.2 Hospital)

Two hospitals, one from the Review group and one from the Non-review group, emphasised that appointing additional staff could help with the burden associated with stillbirth data collection.

"Extra manpower could help us with the data collection." (Non-review.1 Hospital)

However, hospitals understood that this may not be possible without funding and resources, and that they will still attempt to review stillbirths thoroughly with existing data.

"Unless we have a team, which can individually go to their home and get the output from the medical and the primary health

centres. But you have to do whatever you can with the data you have if you can." (Non-review.4 Hospital)

Additionally, hospitals pointed out that the need for extra staff time to attend meetings can be problematic, as this is time-consuming and often conflicts with the high workload associated with clinical care.

"Because they are involved with the actual service delivery, so review person, they have to come and the human resources cultures there. Time-consuming also, the human resources problem is there" (Review.2 Hospital)

"Basically, we are not involving so much the administrative staff, nor the sister staff…because we are a busy hospital, there is very little time to work on to get everybody together at the same time, to conduct a process." (Review.3 Hospital)

A Non-review hospital interested in implementing a stillbirth review process noted that they are very 'overworked' and unable to address logistical challenges in organising stillbirth review meetings. They believe that these aspects of work should be managed by higher levels of the health system, rather than being the hospital's responsibility.

"For logistics [of organising meetings] I think the authority can do, we can't do anything because we, all of us, are so overworked. We are very much. We have lots and lots of patients." (Non-review.1 Hospital)

7.2.2.7 Scheduling stillbirth review meetings

All three hospitals in the Review group agreed that having a regularly scheduled meeting for stillbirth reviews is an important facilitator. It allows staff to be aware of the meetings in advance and enables them to arrange their schedules accordingly. One hospital highlighted that having a specific day each month for the stillbirth review improves attendance.

"And if a particular day of the month is scheduled for a review meeting, then I think it will be better. Then one that day, we can keep more staff, so that's how they can come for the meeting." (Review.2 Hospital)

Another Review hospital emphasised the value of a fixed calendar for organising meeting schedules.

> *"I think the calendar should be fixed for everything. If you're giving some advice to those who are not doing it [Non-review hospitals], you should have your regular calendar that this is the day we will do a stillbirth review, and this is the day we will discuss neonatal deaths, this is the day… So if you have a calendar, then this whole week you are prepared with the cases, this week, this number of cases is to be put up for discussion. But definitely the maintenance of a regular calendar, sometimes we miss out from our side also, but definitely making a regular calendar will surely help in the long run." (Review.3 Hospital)*

Additionally, a Review hospital noted that having a designated focal point is crucial for ensuring the review process is integrated into daily practice.

> *"So having a set day, review meeting embedded in the practice. And we have a nodal officer, so the nodal officer is there, so it is my responsibility, I have to look for this, I have to look after the stillbirth if this happens, I make sure that there is a stillbirth review." (Review.1 Hospital)*

7.2.2.8 Additional investigation/testing facilities to improve the completeness of stillbirth data

One Review hospital reported a lack of facilities for conducting post-mortem examinations, additional investigations or testing, such as pathology laboratories, which are necessary for understanding the causes of stillbirth. This limitation was identified as a barrier related to resource availability.

> *"We don't have a system of any post-mortem for the fetus… maybe in higher centres they will, and they will evaluate the fetus, do the post-mortem of the fetus, take specimens. Also, placental biopsy and histopathology of the placenta, which we are not doing routinely, and for the fetal side also, we will not be allowed to do that here. We don't have a system of doing a post-mortem." (Review.3 Hospital)*

In contrast, a Non-review hospital highlighted that the presence of a pathology department enables them to perform additional investigations, including fetal post-mortem examination, to determine the causes

of stillbirth. This demonstrated that having resources for additional testing is valuable for data completeness of each stillbirth and understanding the cause of stillbirth.

> *"We are not collecting any data but investigating the patient if we have stillbirth issues. We do investigate, and we do some special tests for the patient to find out particular causes in them. At present, a study is being undertaken by our postgraduate student. An autopsy of stillbirths." (Non-review.1 Hospital)*

7.2.2.9 Using a reliable method to determine accurate gestational age

One Non-review hospital identified unreliable gestational age data as a barrier to stillbirth review, noting that calculating gestational age by the last menstrual period (LMP) is often unreliable. While sonography, which is required for accurately determining gestational age, was recognised as a potential facilitator, the hospital reported that some women may not have an ultrasound examination.

> *"I think another issue is like this last menstrual period (LMP). I mean, this dating of pregnancy by their history is also very, very – not very reliable. There are some who don't even remember the last menstruation period date so it's very difficult for us to detect [the gestational age]. The majority group do not go for sonography." (Non-review.2 Hospital)*

7.2.2.10 Ensuring there is a learning cycle to inform local guidelines

One Review hospital emphasised that review findings should be documented and inform formal local clinical guidelines rather than being communicated solely through verbal discussions, a finding also discussed in 6.3.7 (Chapter 6). This hospital noted that currently, they only share insights from stillbirth reviews verbally, and it often leads to varied clinical practices based on individual experiences rather than evidence-based guidelines. This variability in treatment approaches was identified as a challenge, as it may result in inconsistent care. The hospital recognised that incorporating learnings from stillbirth reviews into formal local clinical guidelines would ensure a consistent approach to similar cases, and it would also record any instances of suboptimal care for future reference, benefiting new and rotating staff who join the hospital and participate in the stillbirth review panel.

"One thing I must say, like she said, it is only verbal [dissemination of learnings]. There I think that our institute is lacking... Yes, the standard operating procedures (SOPs) should be there… because if you have a difference of opinion, everyone is treating the patient she's been treating for so many years. She must have seen the problems of the patient, and she must have said that this should be event, this should be done. So that is the only thing, the protocol, the standard operating procedures (SOPs) should be there of a particular institute because everyone is giving us the guidelines [on how to treat the women]." (Review.1 Hospital)

7.2.3 Automatic motivation

7.2.3.1 Emotional involvement

A Review hospital described that the emotional impact of stillbirths on HCPs motivates their participation in stillbirth reviews, a finding also discussed in 6.3.2.1 (Chapter 6). This hospital described that the tragedy of stillbirth often leads the staff to be emotionally involved with the family and feel a strong personal commitment to actively engage in reviews.

"Actually, where that's a tragic incident, no?... They are self-motivated to come and follow up these things." (Review.2 Hospital)

7.2.3.2 Mandatory attendance to stillbirth reviews

Mandatory attendance emerged as an automatic motivator for certain job roles within hospitals to participate in stillbirth reviews, another finding also discussed in 6.3.2.3 (Chapter 6). At a Review hospital, for example, postgraduate students who are medical doctors pursuing advanced training in a specific specialty were required to attend stillbirth reviews. The hospital explained that these students' attendance is tracked as part of their internal assessments, making their participation mandatory.

"We have students who are bound to attend, their attendance is marked, and their internal assessment is based on that, so the choice of not attending is not there! [laughs]" (Review.1 Hospital)

7.2.3.3 Stillbirth monitoring by higher levels of the health system

Stillbirth monitoring by higher levels of the health system was described as a facilitator that stems from reinforcement, which promotes hospitals to carry out their own stillbirth reviews to improve their stillbirth reporting to the higher levels of the health system. A review hospital described how stillbirth data collected locally is reported to the National Health Mission and they use this information to conduct their own analysis of aggregated data to identify common causes of stillbirth and delays in care at the national level. For this mandatory process, the hospital emphasised that they must report all stillbirths and incorporate insights from facility-based reviews into the reports submitted to the National Health Mission.

> *"Participant: That data will be compiled at the national level, and then the protocols and the guidelines which we get from the National Health Mission (NHM), that is from that data. Where the delays have happened, what is the most common cause of stillbirth. But they used to extract that data from there, the stillbirth reviews from here go in there.*
>
> *Facilitator: So, National Health Mission (NHM) will use the data that you've sent to their own review panel?*
>
> *Participant: Yes. You have to report all the stillbirths." (Review.1 Hospital)*

However, a Non-review hospital noted that where there is a lack of stillbirth monitoring at higher levels, stillbirths are often unaccounted for by both obstetricians and paediatricians, and reviews would not be initiated by either department in the hospital. This lack of monitoring at higher levels of the health system creates a barrier to conducting stillbirth reviews in India, as there are no incentives or negative consequences for hospitals if they do not report, review, or analyse stillbirths that occur during their care.

> *"So these [stilbirths] are the, you know, the deaths of the babies which are going unmonitored, and it's really a big issue for us to see why there's that many. Because we [obstetricians] are not taking accountability, the neonatologist or the paediatricians are not taking accountability of the stillbirth." (Non-review.3 Hospital)*

7.2.4 Reflective motivation

7.2.4.1 Beliefs that stillbirth reviews enable action

A review hospital discussed knowing that a stillbirth review improves the quality of future care is a facilitator to sustaining stillbirth reviews. This hospital explained that recommendations from the stillbirth reviews are taken on board by the staff in their obstetrics and gynaecology (O&G) department, and they observe positive changes in practices and infrastructure afterwards. For instance, they described how there are improved monitoring protocols in their labour ward following a recent stillbirth review, which identified a stillbirth occurred due to inadequate monitoring of fetal heart rate during the active phase of labour.

> *"There was one case when monitoring was not properly done, and there was an intrauterine death (IUD). So I'm sure today in the ward that they will strictly monitor, and from now they will be monitoring every hour hour...I think they take inputs from us, from everyone involved in the labour room team and, based on those inputs, if there are some changes made in terms of infrastructure or the staff or duty roster." (Review.1 Hospital)*

Three hospitals from the Non-review group also mentioned the beliefs that reviewing stillbirths helps identify suboptimal practice in both antenatal and intrapartum care is a key reason for their intention to implement stillbirth reviews in their hospitals.

> *"We'll find out what are the lapses in our management, particularly antenatal management, intrapartum management, so that we know our…what are the difficulties? How much time did we take to deliver? Was there any delay? So all these unsolved things, which I think, further improve our management, intrapartum management." (Non-review.1 Hospital)*

They believed that conducting reviews of stillbirths would help in understanding delays in care, such as the timing of referrals and caesarean sections, and in addressing these by implementing actions identified from the reviews.

> *"Make sure we haven't missed. Suppose we fail to refer at the right time, or we fail to do a caesarean section at the right time, then we should review why this delay occurs... At the same time, we should discuss ways and means how we can remove those factors. So that next time, your next stillborn can be avoided." (Non-review.2 Hospital)*

Furthermore, some hospitals anticipated that stillbirth reviews would drive policy level actions. For instance, hospitals believed that findings from reviews could influence policymakers in considering which interventions they should prioritise and fund to reduce the burden of stillbirth.

> *"Local government staff will then [once stillbirth review findings are disseminated] be ready to put more attention on stillbirth prevention." (Non-review.4 Hospital)*

Hospitals also saw the learnings generated from stillbirth reviews as resources to advocate for policy changes. They believed that highlighting deficiencies in hospital resources or staff skills, such as lacking equipment or the ability to use available equipment, at local and national levels through dissemination of learnings could prompt policymakers to address these barriers.

> *"Suppose you monitor the high-risk fetus, which needs computed tomography (CT) scans. Suppose some hospitals is not having that computed tomography (CT) scans, so that will come into the discussion. Then, in that way, we can formally say, this machine is not available, so there are some of the high-risk fetus that cannot be monitored properly. This way, we can understand the problem and inform and impress higher policymakers. We know we can take it to the higher grounds. They [policymakers] should know what is happening and where. What is the outcome of the review? Because they're policymakers, they will decide what should be done." (Non-review.2 Hospital)*

However, two hospitals (one Review and one Non-review) reported challenges in addressing action points beyond the facility level, which can demotivate staff due to a perceived lack of impact outside the hospital. A review hospital noted the difficulties in increasing the number of antenatal check-ups for unbooked women, which was an area of intervention identified from the review. They noted that despite efforts that have been made to advise women at discharge to return for their regular check-ups, because

effective intervention often requires community-level support, which is beyond the hospital's control, it has been difficult to address the identified action points.

> *"The only problem we have is with the unbooked cases, because we don't get to do the corrective intervention and preventive action. Many times at discharge, I will tell them, 'Please, for your next pregnancy, come here, come for your regular checkups.' But by the time they go home and then they are into their… maybe we have not been able to convince them as such that they should come back to us, or maybe the circumstances where they are, it is difficult for them to come for regular antenatal checkups with us." (Review.3 Hospital)*

Similarly, a Non-review hospital highlighted challenges in motivating community health workers to facilitate timely referrals due to the lack of incentives they can provide. Additionally, they noted that any community-level interventions require approval from district authorities, which adds another layer of complexity.

> *"Yeah, basically, one of the things which are not in our hand is the primary care because, for every intervention, we need to get permission from the district authority... We are trying to have a network with Accredited Social Health Activist (ASHA) workers, but because we can't give them any incentive, they are not going to bring those sick patients to us. You know, early referral. That is what we want them to do. At least come early so that intervention will be timely. So, the governmental barrier is there, so if that has been taken care of, probably the outcome will improve." (Non-review.4 Hospital)*

7.2.4.2 Beliefs that there is a low burden of stillbirth

A review hospital reported that they review all stillbirths because they believe that there is a low burden of stillbirth in the population of the catchment area covered by the hospital. This perceived low burden of stillbirth, regardless of whether this was really true in comparison to other regions of India, was seen as a facilitator because this hospital remained positive about being capable of reviewing all stillbirths and feeling motivated to conduct thorough reviews for every stillbirth to improve their current practice.

> *"Facilitator: And do you find it quite challenging, or is it actually not a problem at all to review all cases?*

Participant: We don't have many stillbirths, so it's not a problem for us." (Review.2 Hospital)

7.2.4.3 Community's beliefs about the causes of stillbirth (perceived by healthcare professionals (HCPs))

A Review hospital expressed their concerns regarding working together with the community to gather further socio-demographic data about pregnant women, seeking post-mortem examination consents and community interventions due to the community's beliefs about the causes of stillbirth. They explained the community holds strong cultural beliefs that stillbirths are due to spiritual doing, and this perspective often leads them to be reluctant to pursue further investigations or interventions. For example, seeking consent for post-mortem examinations was often challenging as many families were opposed, viewing such requests as conflicting with their beliefs. This challenge was identified as a demotivating factor for sustaining the stillbirth review process, as hospitals felt they might have to act against community beliefs when investigating the underlying causes of stillbirths and implementing preventive measures.

"The problem is that in our culture, if there are any stillbirths or even, for example, it was a sudden intrauterine death (IUD), it's their religious belief that it's God's doing, so they just accept it like that… So that is one hurdle, so for us to go further ahead and find out the cause, especially the genetic and the chromosomal causes, it will be quite difficult." (Review.3 Hospital)

7.2.4.4 Beliefs that stillbirth review can reduce the knowledge gap

Hospitals' beliefs that stillbirth reviews can reduce the knowledge gap at both the facility level and within the wider health system were reported as important facilitators that increase motivation among HCPs to conduct stillbirth reviews. One Non-review hospital highlighted that staff will be motivated to participate because the evidence presented from stillbirth reviews will provide meaningful feedback to doctors and increase overall awareness of common issues related to causes of stillbirth.

"And if you know the facts, you can give feedback to the doctors who are working. Whoever comes for review will be coming to know that these things are happening in particular hospitals. So

everybody will be aware of this. Increase our knowledge also. A stillbirth review, any review, definitely will help increase our knowledge and that way, it will be better. It will motivate us." (Non-review.2 Hospital)

A review hospital already recognised the benefits of stillbirth reviews in generating knowledge. They described how stillbirth reviews expand knowledge beyond the immediate team involved in the case to the broader hospital system and how staff subsequently apply this knowledge in their future roles even after they move on to a new hospital.

"Most of the stillbirths, the unusual ones or the ones which were a little bit controversial, we remember. We remember all those cases vividly. They also remind us that shouldn't happen. It [today's meeting] was like in three years this is the first time we saw that kind of case. So because of such meetings and reviews, the team which was involved and other people came to know the team that handled the case. And these people once they finish their postgraduate, will go to the periphery hospitals. So all of this knowledge they can apply there also. It's for their learning. If they encounter such kinds of patients, they can apply this knowledge. It's lifelong learning." (Review.1 Hospital)

A Non-review hospital also noted that one of the goals of stillbirth reviews should be to disseminate the generated knowledge to the wider health system. They felt having this intention could directly motivate the hospital, as it enables them to share insights and findings that were previously difficult to substantiate or highlight due to a lack of available data.

"After getting information, then we need to go and talk to our teams. Not only talking here. The place we are talking to should be from all the information we are discussing. That's the main benefit. That's the only way we can extend [the review findings] to the beneficiaries or to the clinicians or to the community. That will be very beneficial for others." (Non-review.2 Hospital)

7.2.4.5 Buy-in from wider stakeholders

Acknowledging that different professional roles and identities have parts to play in stillbirth reviews, both Review and Non-review hospitals noted that gaining buy-in from wider stakeholders is essential

for the stillbirth review panel within the hospital to initiate the implementation of stillbirth reviews and sustain the ongoing practice.

> *"There should be new enhancement also from the higher stakeholders, so we are getting more buy-in from more people in this organisation." (Review.2 Hospital)*
>
> *"We definitely need time and expect people to help." (Non-review.4 Hospital)*

In particular, a Non-review hospital pointed out that getting buy-in from diverse departments at the facility level, such as pathology and forensic medicine, is a priority. They acknowledged that this can be challenging, as not everyone may be receptive to the idea of a stillbirth review process, and overcoming resistance would be a significant challenge.

> *"Pathway required from the pathology department, forensic department, all of the departments. I think the biggest challenge will be that, because some people, they don't like that. Most of them. Most of the people are opposed to it." (Non-review.1 Hospital)*

Moreover, another Non-review hospital emphasised the necessity of engaging not just medical staff but also community health workers and women in the stillbirth review process. However, they emphasised that this would not be possible without buy-in from the higher levels of authority.

> *"Buy-in from the authority...bringing mothers and Accredited Social Health Activist (ASHA) workers in the process." (Non-review.5 Hospital)*

7.2.4.6 Opportunities for discussion about the benefits of stillbirth reviews

At the end of the FGD, a Non-review hospital highlighted that FGD was an important 'sensitisation' exercise to think about the stillbirth review process and that the discussion from the FGD boosted their motivation to implement stillbirth reviews within their hospital. Prior to the FGD, the hospital had recognised the importance of conducting these reviews but had struggled to initiate the process due to

various constraints. The hospital felt that simply discussing the benefits of stillbirth reviews could be a valuable tool for improving motivation at the facility level.

> *"I just want to tell you – this was a good sensitisation procedure what you have come and told us about. This [facility-based stillbirth review] has to be done. It's a very good way of sensitising us that we can put this in our plate of review meetings, if possible. We know we're overworked but still then it's a good sensitisation because we are actually, we are in the process of trying, but till now we couldn't do, we couldn't do it" (Non-review.1 Hospital)*

7.2.5 Capability

7.2.5.1 Record-keeping skills and understanding the importance of documentation

Two hospitals (a review hospital and a Non-review hospital) emphasised the importance of training postgraduate students in record-keeping skills, noting that this is a mandatory responsibility for doctors rather than an optional task. The hospital explained that providing record-keeping training is an important facilitator for stillbirth reviews because the training can improve the completeness of routine health records, which is essential for accurately filling out stillbirth review proforma.

> *"And we keep on stressing the point, the juniors, every discussion we have, we stress the point to them that documentation, documentation, documentation, because in this area of medical-legal issues, if you don't have proper documentation, you're not going anywhere. So, we stress to our junior residents that documentation is a part of your learning process; even if you don't want to do it, you will have to do it. Like you have to do it." (Review.3 Hospital)*

7.2.5.2 Staff trained in how to conduct effective stillbirth reviews

Finally, a Non-review hospital recognised that staff must be trained before implementing stillbirth reviews. They pointed out that if the staff are not trained, they may not be able to identify relevant causes or suboptimal care factors associated with stillbirth or lead meaningful discussions to develop appropriate recommendations of actions for implementation to reduce future stillbirths.

"The person who will be leading the review, he or she should be trained. That is another important issue because unless he's trained, then he may not be able to review or may not be able to review or lead that discussion on the review process. Training is an important part." (Non-review.2 Hospital)

7.3 Actionable interventions

Table 7-2 presents actionable interventions designed to upscale facilitators and address barriers reported by Indian HCPs. These interventions are mapped from the COM-B model and the Behaviour Change Wheel intervention functions, offering targeted and theory-based strategies to improve social and physical opportunities, automatic and reflective motivation, and capability that influence the implementation and sustainability of facility-based stillbirth reviews. For instance, within the social opportunity domain, 'opportunities to participate without fear of blame' is suggested to be addressed through interventions such as regular workshops to emphasise the purpose of stillbirth reviews as a tool for learning and improvement rather than blame. Additionally, the presence of a neutral meeting facilitator is recommended to ensure meeting principles, such as a blame-free culture, are communicated and upheld during review meetings.

Table 7-2. Actionable interventions for facilitators and barriers using the Behaviour Change Wheel intervention function

COM-B domain	Facilitator/barrier reported by Indian HCPs	Actionable interventions identified using the Behaviour Change Wheel intervention function
Social opportunity	• Opportunities to participate without fear of blame • Opportunities for staff from all levels of the health system to participate • Navigating cultural challenges in obtaining consent for post-mortem examinations • Understanding local variations in labelling stillbirth types	<u>Education</u> • Increase the HCPs' and community's knowledge about what post-mortem examination entails (e.g. different types of post-mortem examinations) • Organise regular workshops that emphasise the learning purpose of stillbirth reviews, helping all levels of the health system to understand that the goal is to improve the quality of care rather than blame or discipline individuals <u>Enablement</u> • Have a neutral meeting facilitator who will communicate and enforce meeting principles during the stillbirth review meeting • Have open communication with the HCPs on which labels are most appropriate to categorise different types of stillbirth ensuring they align with accepted international definitions and discuss potential positive or negative implications for having local variations • Invite staff from different levels of the health system to the stillbirth review meeting if they are involved in women's care <u>Environmental restructuring</u> • Create terms of reference for review panel that includes purpose of the review, authority of the panel, panel membership, duties and responsibilities of the panel, and details of the procedural issues (e.g. frequency of meetings, quorum, completion and distribution of meeting minutes and action points timeline) • Ask current and potential participants (including those who collect data) to sign a code of conduct 'charter' pledging their commitment to providing a safe environment for all panel members and the community and incorporate this 'charter' into the local stillbirth review guidelines • Develop national guidelines for labelling and defining stillbirth types while ensuring consistency with national or international definitions <u>Modelling</u> • Encourage senior staff (e.g. consultants, superintendent) to demonstrate a blame-free, supportive culture where review discussion focuses on system-level issues and not on individual performance <u>Persuasion</u> • Develop culturally sensitive communication materials (e.g. pamphlets and videos) that address common concerns about post-mortem examinations, emphasising the benefits of system change to improve the quality of care in women

COM-B domain	Facilitator/barrier reported by Indian HCPs	Actionable interventions identified using the Behaviour Change Wheel intervention function
		• Include testimonials or examples of how stillbirth reviews have led to positive changes in the system (e.g. improvements in monitoring protocols or infrastructure) <u>Restriction</u> • Explore with the community whether an opt-out consent system for post-mortem examinations could work in the Indian context <u>Training</u> • Provide opportunities where the HCPs can practice how to communicate with the family about obtaining consent for post-mortem examinations • Provide training for the HCPs on national and international definitions of stillbirth and how these can be applied to ensure consistency in stillbirth reporting • Provide training for pathologists on minimally invasive post-mortem techniques and imaging, allowing parents the option to choose different levels of post-mortem examination rather than being limited to a complete post-mortem (the traditional method involving surgical incisions)
Physical opportunity	• Using standard proforma to collect stillbirth data • Minimum stillbirth data required for reviews • Availability of IT facilities for record-keeping • Unclear guidance on the stillbirth definition • Systematic process of mandatory stillbirth reporting and review • Challenges in high workload • Scheduling stillbirth review meetings	<u>Education</u> • Increase the community's knowledge about what ultrasound entails <u>Enablement</u> • Create protected time for staff to focus on stillbirth reviews without competing with other work demands • Designate a team for documenting and formalising stillbirth review findings into local clinical guidelines and other action points • Establish partnerships between hospitals with different investigation and testing facilities, creating a referral and transfer system that allows hospitals without these resources to access them as needed • Provide additional resources such as extra staff to assist with data collection and organising review meetings <u>Environmental restructuring</u> • Clearly define and assign specific job roles within the hospital to be accountable for counting and reporting stillbirths • Develop a standard proforma for the local use from the existing national or international guidelines that would help with data collection for stillbirth review • Develop and disseminate clear, standardised definition of stillbirth to be documented in local and national clinical guidelines, including criteria for different subgroups of stillbirth to ensure consistency across different levels of health system • Ensure hospitals are equipped with the necessary ultrasound equipment

COM-B domain	Facilitator/barrier reported by Indian HCPs	Actionable interventions identified using the Behaviour Change Wheel intervention function
	• Additional investigation/testing facilities to improve the completeness of stillbirth data • Using a reliable method to determine accurate gestational age • Ensuring there is a learning cycle to inform local guidelines	• Establish a standardised referral and information-sharing system between different levels of health facilities that ensures the transfer of clinical documentation when women are referred • Develop protocols that prompt the use of sonography in all women, and especially in cases where gestational age is uncertain • Include sections of socio-demographic and clinical data that must be filled in as part of the referral form when referring women to higher level of health facilities • Introduce or enhance facilities' IT facilities (access to reliable computers, internet and software) to support the implementation of an EMR system • Introduce or strengthen the stillbirth reporting requirements at the policy level by mandating timely notification (e.g. within 48 hours) of stillbirths to designated staff • Invest in building or upgrading investigation or testing facilities within hospitals, such as pathology labs or access to advanced diagnostic equipment • Prompt the HCPs to ask for minimum socio-demographic information and fetal heart rate upon admission with a reminder at the top of the labour room register <u>Training</u> • Provide hands-on training to the HCPs on how to use sonography to determine accurate gestational age
Automatic motivation	• Emotional involvement • Mandatory attendance to stillbirth reviews • Stillbirth monitoring by higher levels of the health system	<u>Environmental restructuring</u> • Implement a hospital policy that requires mandatory attendance of minimum job roles at stillbirth reviews <u>Incentivisation</u> • Provide recognition to hospitals that consistently meet stillbirth reporting requirements and demonstrate improvements in stillbirth monitoring and review processes, as part of wider health system monitoring efforts in India <u>Persuasion</u> • Share case studies and personal testimonials from HCPs who turned emotional challenges from stillbirths into contributing to making positive changes in quality of care through participation in stillbirth reviews
Reflective motivation	• Beliefs that stillbirth reviews enable action • Beliefs that there is a low burden of stillbirth • Community's beliefs about the causes of	<u>Education</u> • Develop culturally sensitive education materials to address community beliefs about the causes of stillbirth • Provide regular stillbirth data reports comparing the hospital's stillbirth rates to regional and national averages, emphasising that even a low burden is significant in the community and that each stillbirth review contributes to improving maternal and fetal outcomes

COM-B domain	Facilitator/barrier reported by Indian HCPs	Actionable interventions identified using the Behaviour Change Wheel intervention function
	stillbirth (perceived by HCPs) • Beliefs that stillbirth review can reduce the knowledge gap • Buy-in from wider stakeholders • Opportunities for discussion about the benefits of stillbirth reviews	• Provide targeted training sessions or workshops to key stakeholders resistant to the stillbirth review process, focusing on the importance of the review, clarifying their roles, and demonstrating how their participation improves maternal and fetal outcomes <u>Enablement</u> • Create continuous learning opportunities where HCPs can share knowledge gained from stillbirth reviews with their colleagues and wider health system • Work with traditional health workers, religious or community leaders to help shift community's perceptions around stillbirth, encouraging community support for stillbirth reviews and participation in data collection <u>Environmental restructuring</u> • Establish a multidisciplinary working group that includes representatives from key stakeholder groups across the community, facility, and government (e.g. pathologists, community health workers, obstetricians, nurses, policymakers) <u>Persuasion</u> • Conduct regular peer-led discussion sessions where experienced HCPs share their successes and how they navigated challenges during stillbirth reviews • Generate quantitative and qualitative evidence (evaluation) showing how actions taken as a result of stillbirth reviews have led to measurable improvements in pregnancy care
Capability	• Record-keeping skills • Understanding the importance of documentation • Staff trained in how to conduct effective stillbirth reviews	<u>Enablement</u> • Provide ongoing support and mentorship programmes where senior staff mentor students and nurses on effective documentation practices <u>Environmental restructuring</u> • Implement regular audits of data quality for routine health records and stillbirth documentation <u>Training</u> • Develop and deliver specialised training programmes on how to conduct effective stillbirth reviews, including identifying causes of stillbirth, identifying suboptimal care, conducting data analysis and leading discussions to create recommendations of actions • Develop and deliver specialised training programmes on how to organise stillbirth reviews, including identifying eligible stillbirths for review, selecting which stillbirth to prioritise, and gathering the necessary data • Implement mandatory training sessions that focus on improving record-keeping skills
HCP: healthcare professionals, EMR: electronic medical records, IT: information technology		

7.4 Discussion

7.4.1 Principal findings

This study examined the facilitators and barriers affecting the implementation or sustainability of facility-based stillbirth reviews in India, drawing from what Indian HCPs discussed during the FGDs. Utilising the COM-B model, these factors were explored across multiple levels of the healthcare system – community, facility, and policy levels. Facilitators and barriers related to physical opportunity were the most frequently reported, with a strong emphasis on the need for resources and infrastructure for stillbirth data collection and reporting, as well as improvements in the quality of care. Actionable interventions to address these factors included the standardisation of stillbirth data collection, improving IT infrastructure, and clearly defining and assigning specific job roles within the hospital to be accountable for counting and reporting stillbirths. The study also identified the need for a supportive, blame-free culture and improved engagement across different levels of the health system to improve social opportunities. To address these needs it would be important to implement regular educational workshops to emphasise the constructive nature of stillbirth reviews, fostering a supportive review culture through senior staff's proactive demonstration (modelling), and developing culturally sensitive communication strategies to address community concerns about post-mortem examinations.

Regarding automatic and reflective motivation, the study recommended creating incentives for staff participation in stillbirth reviews and sharing case studies that demonstrate how stillbirth reviews led to tangible improvements in pregnancy care. Additionally, understanding the community's beliefs about stillbirth and working with traditional health workers, religious or community leaders to help shift the community's perceptions around stillbirth was suggested as a means to garner the community's support for the review process. For improving capability, actionable interventions include mandatory training programmes for effective documentation and review processes, along with ongoing support and mentorship to improve record-keeping skills and review practices.

7.4.2 Discussion in light of other evidence

The results of this study echoed several findings in Willcox *et al.*'s systematic review of qualitative studies, which looked at determinants of behaviours influencing the implementation of maternal and perinatal death surveillance and response (MPDSR) in low-and-middle-income countries (LMICs) [51]. Both this study and Willcox *et al.* [51] found that physical and social opportunities depend on adequate resources (human resources, standard proforma, stillbirth data), regularly scheduled meetings, and opportunities for all levels of the health system to participate in a blame-free environment.

Opportunities to participate without fear of blame should be supported with the 'education' intervention function of the Behaviour Change Wheel to prevent the leadership team from misinterpreting stillbirth reviews as a tool for disciplining staff. The literature [248,251] and findings from the multiple case study (Chapter 6) indicated that despite the intended goal of stillbirth reviews being to improve the quality of care, the process could be misconstrued when intertwined with other objectives, such as teaching responsibilities.

The significance of employing blame-free language and attitudes should also extend beyond the internal dynamics between staff at the facility level; it should be adopted for interactions with women, family members, and the community [17,18]. In addition, engaging with traditional health workers, religious or community leaders to shift perceptions around stillbirth could foster community engagement in stillbirth reviews and encourage women to participate in interviews with HCPs for data collection [268,269]. Given that extended family members and fathers often influence decisions in India's cultural context [17], culturally sensitive communication strategies addressing the community's common concerns about stillbirth should target a broader audience, not just women [19,20].

Findings also highlighted that the use of 'scolding' language towards women following a stillbirth can discourage them from providing crucial information about their pregnancy. This reluctance can not only impede the collection of necessary data to understand the causes of stillbirth and identify suboptimal

care factors, but it can also create greater mistrust between the health system and women. Such mistrust may result in women avoiding healthcare services in future pregnancies, either due to fear of being mistreated or a lack of confidence in the system. This can, in turn, exacerbate health inequalities in maternal and fetal outcomes. Atkins *et al.* [16] found that 25.4% of parents did not find their care after stillbirth respectful, and parents from middle-income countries were less likely to report respectful care compared with high-income countries (HICs). Without urgent efforts to eliminate the disrespectful treatment of parents and raise awareness about stigma, bias, and disrespect around stillbirth, bereaved women and families may face mistreatment under the guise of 'data collection' for stillbirth reviews. The International Stillbirth Alliance's Parent Voices Initiative advocacy toolkit [18] includes training modules for HCPs, covering topics such as the definition of stillbirth, its impact on parents, and the support that health facilities can provide. The toolkit also offers approaches for respectful communication with parents following a stillbirth, along with a checklist for HCPs on how to support parents. This checklist includes suggestions such as asking if parents would like to see and hold their baby, providing opportunities to create memories, and addressing stigma by offering information about stillbirth, postnatal care, and grief. This toolkit is specifically designed for HCPs in India and is a valuable resource for addressing education and enablement needs, targeting both social opportunities and reflective motivation.

One of the actionable interventions that can be adopted is having a code of conduct 'charter' pledging the staff's commitment to providing a safe environment for all panel members and the community and incorporating this 'charter' into the local stillbirth review guidelines. This method has been described as an effective strategy to implement a blame-free culture extending to both HCPs and women [49,206,270,271]. The World Health Organization (WHO) guidelines includes a sample meeting code of practice that could serve as a useful reference for developing a 'charter' [52,55]. Establishing a respectful inquiry culture would also naturally open opportunities for wider and more willing participation from all levels of the health system and the community.

The study also identified several interventions to address cultural and procedural barriers to obtaining consent for post-mortem examinations. The need to increase knowledge about post-mortem examinations was highlighted in this study based on a systematic review identifying factors affecting the uptake of post-mortem examination, including concerns about invasiveness, organ retention, and cultural sensitivities [272]. Supporting HCPs and the community in understanding more about the nature and benefits of post-mortem examinations may help demystify the procedure and alleviate apprehensions. This aligns with findings from Lewis *et al.*'s systematic review [272], which emphasised the importance of clear and compassionate communication and the provision of educational materials tailored to the needs of bereaved families [273,274]. Additionally, employing 'community champions' (also known as community health workers, ambassadors, or peer workers) has been effective in navigating cultural challenges to obtaining consent for post-mortem examinations and improving healthcare utilisation among seldom-heard populations [275–277].

One hospital suggested that exploring an opt-out consent system for post-mortem examinations could help address some barriers observed in the Indian context, similar to the opt-out practice used for HIV testing in their hospital. However, such a policy may conflict with the primary psychological barrier that parents face, which is the desire to 'protect' their baby from perceived unnecessary harm [278–280]. Furthermore, there is currently no literature specifically examining opt-out consent systems for post-mortem examinations. Thus, future community-based research is needed to assess whether an opt-out consent system could be effectively implemented for post-mortem examinations within the Indian context.

In addition, Stock *et al.* [281] found that the relocation of perinatal pathology services to the same site as the obstetric unit led to an increase in post-mortem examination rates. This improvement was attributed to the improved availability of specialist perinatal pathologists, allowing for more timely post-mortem examinations to be conducted locally. This study also found that not having pathology labs or access to advanced diagnostic equipment were barriers to conducting post-mortem examinations, and therefore, the government should consider investing in building or upgrading investigation and testing facilities

within hospitals. Recognising that such interventions can take years to implement or may be challenging for smaller hospitals, there should also be support for establishing partnerships between hospitals with varying levels of diagnostic capabilities. Creating a referral and transfer system would enable hospitals without these resources to access the necessary facilities as needed. Also, training pathologists in minimally invasive post-mortem techniques and imaging needs to be prioritised since this would also allow parents the choice of less invasive examination options rather than limiting them to a complete post-mortem (the traditional method involving surgical incisions) [274].

Developing culturally sensitive communication materials, such as pamphlets and videos, could address specific concerns related to post-mortem examinations in diverse communities. These materials should reflect local cultural norms and values, as identified in a qualitative study in Delhi, where bereaved families expressed concerns about their child's disfigurement and wondered what the benefits of the procedure were [282]. Moreover, providing communication training to HCPs can improve their communication skills and confidence in discussing post-mortem examinations with families. The literature supports this approach, highlighting that training and support for staff improve their ability to guide and support bereaved parents and provide respectful care [16,21,283,284].

This study found that there are local variations in labelling stillbirth types, especially around antepartum stillbirths since two hospitals reported that they do not label them as 'stillbirths'. According to United Nations Children's Fund (UNICEF), stillbirth misclassifications can arise from deliberate actions, such as attempts to avoid blame or additional administrative burdens, or inadvertent errors due to unclear guidance on stillbirth definitions [285]. However, this study's scope did not include investigating why there were local variations in labelling stillbirth types and if this has led to misclassifications.

Since local variations in labelling stillbirth types may have mixed implications, there should be open communication with the HCPs about which labels they think are most appropriate to categorise different types of stillbirths and discuss any potential positive or negative implications for having local variations. For instance, adopting different labels might increase community acceptance in areas where the term

'stillbirth' is culturally sensitive or stigmatised. On the other hand, excluding antepartum stillbirths from the 'stillbirth' category could undermine the perceived importance of these stillbirths among HCPs, as they may view them as less relevant due to the absence of direct care involvement. Nevertheless, this study emphasised the importance of having clear guidance on the stillbirth definition, which has been highlighted by many researchers in this field [5,15,60,143,286,287]. Additionally, introducing or strengthening stillbirth reporting requirements at the policy level – such as mandating timely notification (e.g. within 48 hours) of stillbirths – will ensure counting and reporting of all stillbirths, regardless of local labelling variations.

Improving the minimum stillbirth data required for reviews can be achieved through a multifaceted approach. First, several hospitals discussed difficulties in getting information from lower-level health facilities where women were receiving care before being referred to their hospitals, and data around antenatal care (which the lower-level health facilities were providing) were often missing from the stillbirth review. To address this, there should be standardised referral and information-sharing systems between different levels of health facilities so data collected during the antenatal period are transferred and stored at the hospital where women give birth. Additionally, involving lower-level health facilities or community health workers in the stillbirth review process could help address gaps in documentation by enabling them to directly contribute the data they collected during antenatal care.

Second, the use of standard proforma for collecting stillbirth data was suggested as a facilitator for many hospitals in this study. The WHO's 'Minimum set of perinatal indicators' form [52,55] and India's national stillbirth guidelines 'Stillbirth review proforma' [6] would offer a strong foundation for hospitals aiming to standardise their data collection processes. Implementing these proformas should be accompanied by adequate training and ongoing support, including mentorship programmes where senior staff guide students and nurses in effective documentation practices. Additionally, conducting regular audits of data quality for both routine health records and stillbirth documentation could supplement the 'training' and 'enablement' aspects of the Behaviour Change Wheel intervention functions, ensuring a continuous improvement cycle in data quality and completeness.

Third, an adequate data storage system should be in place so that all routine health records can be kept safely; not least, this is needed to provide high-quality care, and when data is needed for the stillbirth reviews, it can be pulled out efficiently [51]. Hospitals identified needing adequate IT facilities that enable EMR, which will facilitate their current record-keeping practice. India's Ayushman Bharat Digital Mission (ABDM), launched in September 2021, may provide a valuable opportunity for health facilities to explore support for EMR implementation [288]. As part of a central sector scheme, ABDM provides funding to state governments for human resources, capacity building, and information, education, and communication activities to facilitate its rollout across all states in India [289]. By leveraging ABDM, health facilities may be better positioned to overcome the financial and operational barriers associated with EMR implementation. However, as McKernan *et al.* emphasised, the development of EMR will require strong commitment and leadership from the clinical community to be patient-focused throughout its development and implementation [290].

Lastly, resources should be available to support improving the quality of fetal heart rate monitoring and gestational age assessment data. As discussed above, this study identified frequent gaps in documentation from referring health facilities, particularly regarding the recording of fetal heart rates prior to transfer. The absence of this information makes it challenging to ascertain whether a stillbirth occurred before or during labour. To address this, it is essential to ensure that referring facilities routinely check and record fetal heart rates and include this information when transferring women to higher-level health facilities. This requires adequate training, availability of equipment, and accountability systems to ensure fetal heart rates are recorded promptly upon a woman's arrival at any facility, regardless of the onset of labour [291].

When fetal heart rate information is unavailable, determining the timing of stillbirth in relation to the onset of labour remains complex unless there are clear indications of prolonged fetal demise (e.g. macerated stillbirth). Furthermore, defining the onset of labour itself can be challenging, as there is no global consensus on its definition [292]. In the United Kingdom (UK), the onset of 'care' in labour is

used to determine the timing of stillbirth [293], and this approach may offer a standardised framework for categorising stillbirths of unknown timing in other settings.

This study also identified the use of LMP as an unreliable method for determining gestational age – a common challenge in LMICs identified in the literature [3,15,168,294–296]. To address this, Blencowe *et al.* [3] recommended improving antenatal care to ensure women receive at least one ultrasound, as per the WHO guidelines [168], and also utilising Artificial Intelligence (AI) to improve the accuracy of ultrasound-based gestational age assessments [297], particularly in settings where trained sonographers are limited or when ultrasound is performed in later in pregnancy and accurate dating of gestational age can be more challenging.

All three hospitals in the Review group identified that having a regularly scheduled meeting for stillbirth reviews is an important facilitator. However, for hospitals to have such system-level inputs embedded in their clinical practice, significant human resources are required to be committed. For example, additional resources such as extra staff to assist with data collection or organising review meetings and creating protected time for staff to focus on stillbirth reviews without competing with other clinical work demands. The findings from the multiple case study (Chapter 6) found that while some senior staff (e.g. consultants) only participate in the review meetings, the majority of staff are frequently responsible for logistical tasks, including data collection. Since many hospitals in this study talked about the challenges of high workloads preventing them from record-keeping, organising and conducting stillbirth reviews, adequate funding and resources should be provided at the policy level to support hospitals in tackling the logistical challenges of conducting stillbirth reviews.

Staff trained in conducting effective stillbirth reviews was identified as an important capability required for an effective stillbirth review process. This training should address factors that increase motivation, such as the belief that stillbirth reviews enable actions and help reduce knowledge gaps. It should also be tailored to specific roles [51]; for example, staff not directly interacting with patients may need additional support to understand the purpose and benefits of stillbirth reviews. Peer-led discussion

sessions, where experienced HCPs share their successes and how they navigated challenges during stillbirth reviews, could be a simple yet effective way to gain broader buy-in from all stakeholders, including community leaders.

When stillbirth reviews are conducted well, the findings have the capacity to reduce stillbirth rates and other adverse maternal and fetal outcomes by improving all areas of care for all women. In a way, it is a positive cycle because the belief that reviews can lower the burden of stillbirth has the potential to motivate staff to improve the quality of the stillbirth reviews. To embed a culture of accountability in implementing recommendations and drive learning and improvement in the review process, initiatives such as mandatory attendance [49] and developing written documents based on review findings [253] may also be necessary.

7.4.3 Strengths and limitations

This study recruited FGD participants from hospitals with and without current stillbirth review processes so that a wide range of experiences and viewpoints about facilitators and barriers to implementing or sustaining facility-based stillbirth reviews could be captured. This was a major strength of the study, as hospitals with established stillbirth review processes offered insights into the enablers and challenges of ongoing reviews, while hospitals without such processes highlighted issues related to developing and implementing these programmes from the ground up and any barriers they foresaw.

The study also identified several common concerns across both groups, providing a more generalisable picture of the situation in India regarding facility-based stillbirth reviews. Although facility-based stillbirth reviews have been an National Health Mission initiative since 2016, many hospitals have not utilised or acknowledged the existing national guidelines. This study highlighted areas for actionable interventions, providing valuable insights into the community, facility and policy level support needed to help hospitals implement national and international initiatives. By employing the COM-B model and the Behaviour Change Wheel intervention functions, the study also utilised a theoretical foundation for

systematically identifying factors related to opportunity, motivation, and capability and for designing targeted interventions, thereby adding rigour to the study's recommendations.

One limitation of this study was the potential for selection bias, as the recruitment of FGD participants depended on individuals who chose to engage and could take time off from their clinical duties. For instance, one FGD did not include any postgraduate students, despite their involvement in the review panel, due to difficulties arranging coverage for their clinical responsibilities. This meant that the perspectives of less engaged or more junior staff members might be underrepresented in this study, and it did not include viewpoints from all staff and levels of the health system.

Additionally, this study may contain social desirability bias if FGD participants provided responses they believe are expected or acceptable rather than their true opinions. Stillbirth is always a difficult topic to discuss, and fear of blame may have existed among the participants during the FGD. I have tried to mitigate this potential bias by acknowledging the sensitivity of the topic and assured the participants that my intention in this study was to contribute positively to the field before the FGD started.

The three hospitals' FGDs that could not be conducted face-to-face due to safety-related or logistical constraints may not have produced rich data in comparison to face-to-face FGDs. As mentioned previously, the literature highlights that online FGDs often elicit shorter, less detailed responses and sometimes resemble question-and-answer sessions [265–267]. However, it is also important to note that it would not have been possible to include these three hospitals in this study without having the option of conducting FGD using online platforms. By adopting this approach, the study was able to minimise selection bias and ensure broader representation.

Moreover, the variability in how stillbirth reviews are perceived across different hospitals could limit the generalisability of the study's findings. Hospitals operate under diverse conditions with varying levels of resources, expertise, and commitment, which can influence their opinions related to stillbirth reviews.

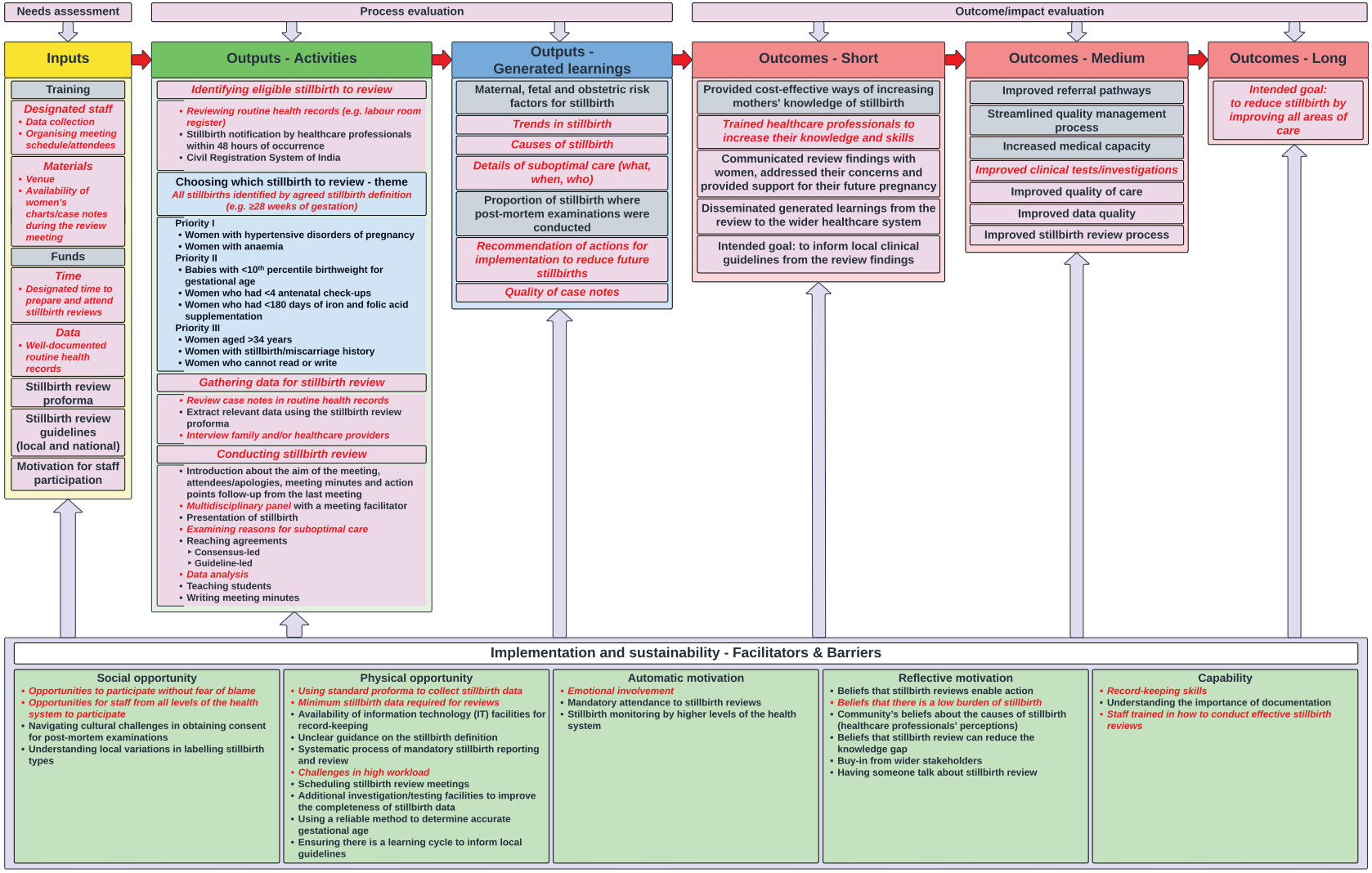
The study's limited sample size, though informative, might not fully reflect the experiences of all health facilities in India, particularly those in different regions or with different operational contexts.

Finally, despite the importance of understanding how local variations in labelling stillbirth types might affect stillbirth statistics or perceptions regarding particular subtypes of stillbirth, this aspect was not explored further. This limitation stemmed partly from the scope of the study, which did not explicitly focus on this issue, and partly from my hesitation to probe deeper when hospitals disclosed this information. At the time, I felt uncertain about probing deeper when hospitals disclosed this information, as I was concerned that further questioning might be perceived as challenging their practices. Additionally, the topic guide for the FGDs was designed to align with the study's objectives and did not include prompts to explore this matter. Hence, it limited the depth of insights gained on this critical issue. In future studies, I would aim to address such challenges by preparing strategies to navigate sensitive discussions, ensuring that important topics can be explored while maintaining trust and respect with participants.

7.4.4 Revised logic model

Figure 7-2 presents the final stage of logic model revisions since it includes findings from all studies included in this thesis (systematic review, quantitative analyses, qualitative studies). This final revised logic model will be discussed in detail in the final discussion chapter (Chapter 8) – Discussion.

Figure 7-2. Final revised logic model



7.4.5 Conclusion

The facilitators and barriers study revealed that the implementation and sustainability of facility-based stillbirth reviews in India can be improved by creating a blame-free environment, ensuring participation from all levels of the health system, and addressing cultural challenges related to perceptions of stillbirth and post-mortem examinations. Facilitators related to physical opportunities, such as having clear stillbirth definitions and collecting minimum stillbirth data, should be supported with targeted training and mentoring to improve HCPs' capability to utilise these resources effectively. At the policy level, addressing high workload challenges through adequate funding and resources and establishing a monitoring system for stillbirth reviews and reporting would help hospitals embed a culture of accountability, implement recommendations from stillbirth reviews, and drive improvements in the review process. Additionally, reflective motivation – specifically, the beliefs in the benefits of stillbirth reviews for both the facility and the community – was identified as a significant factor in why HCPs would implement and sustain stillbirth reviews despite barriers related to social and physical opportunities.

Chapter 8. Discussion

8.1 Chapter introduction

This chapter provides an overarching discussion that triangulates the findings from Chapters 2 to 7. Using the evidence synthesised or generated in the previous chapters, the final revised logic model and sets of recommendations were developed to improve a facility-based stillbirth review process, which is adapted and contextualised for the diverse settings in India. Therefore, this chapter addresses the overarching aim of the thesis and provides recommendations for policy, Indian health systems, and future research while reflecting on the strengths and limitations of the overall study.

8.2 What did this mixed methods study find?

The overarching aim of this study was to develop an evidence-based, comprehensive model for a facility-based stillbirth review process in six states in India to inform the planning, extension and scale-up of the nationwide Sentinel Stillbirth Surveillance System[8]. It achieved this by triangulating the results from five research activities, each aligned with the study's five specific objectives, within a logic model. The logic model outlines the interconnected layers of a facility-based stillbirth review process in India, from inputs to long-term outcomes, while also identifying key facilitators and barriers to its implementation and sustainability within the Indian health system.

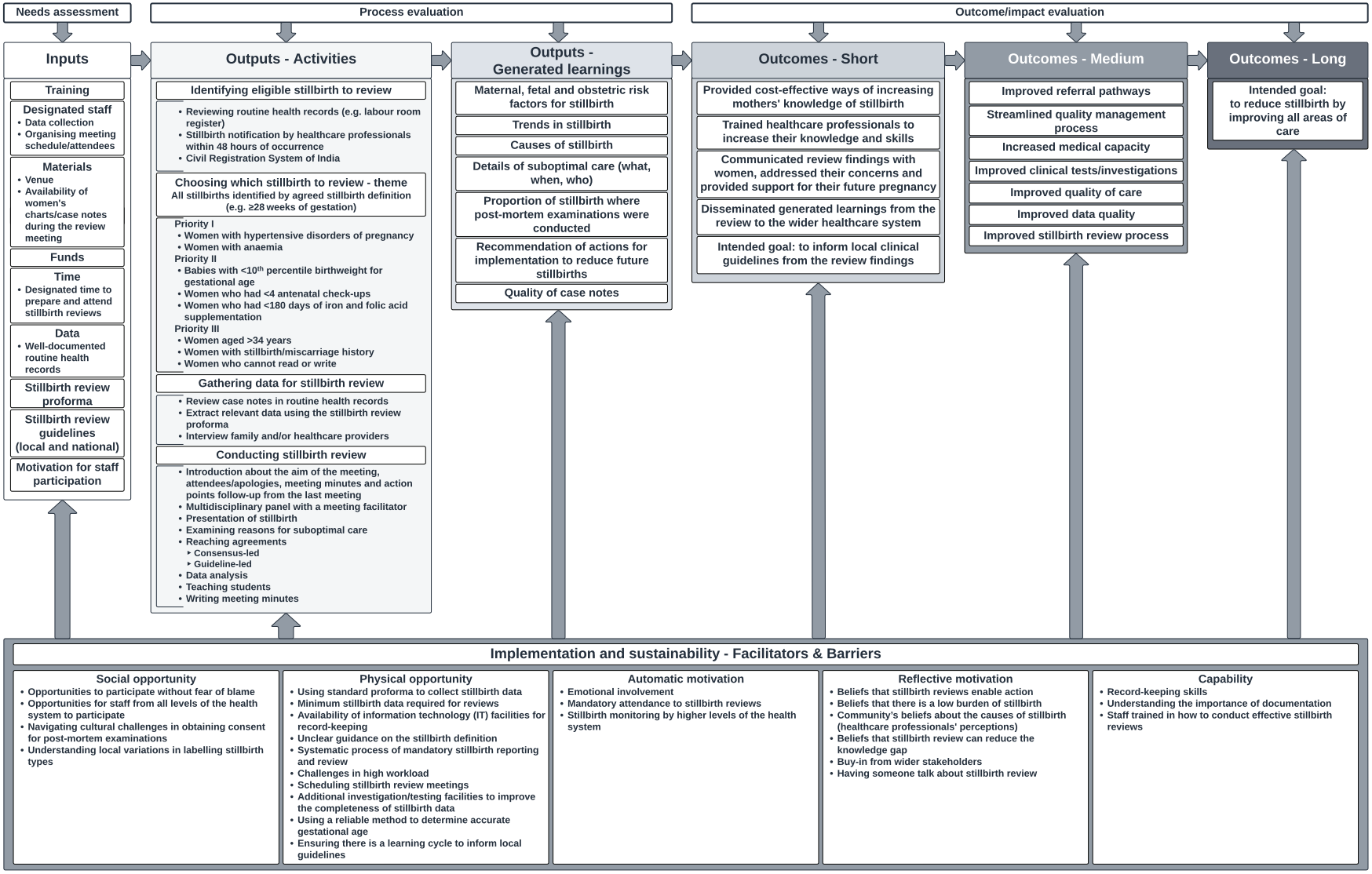
To demonstrate the step-by-step triangulation process of results, the logic model underwent three iterations from the initial model created based on the systematic review findings – which synthesised the global data on stillbirth review processes – to contextualise it for the diverse settings in India by incorporating evidence generated from the empirical studies.

[8] Stillbirth review in India

- Initial logic model (Figure 2-3) was created as part of the systematic review's narrative synthesis of 68 eligible studies. It summarised the inputs required for conducting stillbirth review process activities, the activities involved in the review process, and the learnings generated from stillbirth reviews (Chapter 2)
- First revised logic model (Figure 5-5) incorporated the findings from two quantitative analyses, which identified stillbirth rates, maternal risk factors, and fetal risk factors for overall, intrapartum, and antepartum stillbirth in singleton pregnancies within an Indian population from 13 hospitals across six states (Chapters 4 & 5)
- Second revised logic model (Figure 6-3) included the findings from the multiple case study (first qualitative study), which explored current facility-based stillbirth review processes in three Indian hospitals (Chapter 6)
- Final revised logic model (Figure 7-2) integrated the findings from the second qualitative study, which identified facilitators and barriers influencing the implementation or sustainability of stillbirth reviews across eight hospitals using the capability, opportunity, motivation and behaviour (COM-B) model (Chapter 7)

Below, I discuss the specifics of each component within the logic model while highlighting how facilitators and barriers identified at multiple levels, community, facility, and policy, have influenced all aspects of the model, from inputs to outcomes. Figure 8-1 presents the final logic model for the study: an evidence-based, comprehensive model for a facility-based stillbirth review process in six states in India.

Figure 8-1. An evidence-based, comprehensive model for a facility-based stillbirth review process in six states in India



8.2.1 Inputs

The 'Inputs' section of the logic model emphasises the foundational elements required for stillbirth review activities to happen. While nearly all components identified through the systematic review were reflected in the practices of Indian hospitals, exceptions were the absence of structured 'Training' and allocated 'Funds'. Based on the empirical findings presented in this study, three new components were introduced in the Indian context: 'Stillbirth review proforma', 'Stillbirth review guidelines' and 'Motivation for staff participation'.

It was not explicitly investigated why the stillbirth review processes in Indian hospitals did not include training activities on how to conduct effective reviews, unlike evidence from other countries' processes [75,81,107]. However, in the qualitative studies, several hospitals reported challenges related to high workloads, which were highlighted as factors preventing staff from organising and conducting stillbirth reviews. Therefore, it is likely that when administrative burdens are high and staff shortages persist, allocating time for training becomes even more difficult. Furthermore, if hospitals do not fully recognise the benefits of training, it may not be prioritised. For instance, training was identified as a facilitator by a Non-review hospital (a hospital that does not conduct stillbirth reviews) in the facilitators and barriers study, but it was not mentioned by any of the hospitals that conducted a review (Review hospitals).

Both national and the World Health Organization (WHO) stillbirth review guidelines recommends mobilising minimal resources, including staff training [6,52]. However, at the system level, particularly in low-and-middle-income country (LMIC) settings, several key barriers likely hinder the development and implementation of training activities. These include a lack of funding, inadequate infrastructure, and a shortage of qualified personnel to coordinate and manage continuous professional development (CPD) programmes, which are further exacerbated by limited support from the government and professional healthcare bodies [298–304]. Given that funding was also identified as a missing component for implementing and sustaining stillbirth reviews in the Indian context, it is likely that hospitals also lack the resources to cover the costs of training activities.

In Indian hospitals undertaking reviews, staff roles in the stillbirth review process were largely clearly defined, with a designated focal point responsible for data collection and organising meeting schedules and attendees. For data collection, having this structured approach allowed hospital staff to know exactly whom to contact in the event of a stillbirth and what data would be required for the designated staff to gather. For organising meeting schedules and attendees, having designated staff made scheduling review meetings easier because they announced the meeting date well in advance in their calendar (usually at the same time of day each week), and the designated staff ensured that the appropriate panel members were invited to attend. Additionally, having a responsible person for data collection strengthened the stillbirth surveillance system as the designated staff member took the initiative to verify data across multiple sources, ensuring all stillbirths were accurately recorded and reported to higher levels of the health system and the National Health Mission. Several studies highlighted that having a designated focal person in a facility is a key enabler for the effective implementation of stillbirth reviews [49,112,120,205,271]. Improving the completeness of vital registration is a key priority for the Indian government [305,306], and having a systematic stillbirth reporting process can ensure that all stillbirths are accounted for and automatically referred for discussion during the reviews. This creates a positive interaction between surveillance activities and review processes, improving both systems.

The availability of venues in Indian hospitals, such as conference rooms, ensured that stillbirth review meetings took place in a controlled, private environment and minimised disruptions by limiting access to only panel members. According to the WHO guidelines [52], having dedicated meeting spaces is another recommended minimal resource when establishing a stillbirth review process. Given the sensitive nature of stillbirth reviews, where discussions may involve identifying healthcare professionals (HCPs) involved in women's care, ensuring confidentiality can be met by establishing a designated venue to maintain this privacy and allowing sensitive discussions to occur without the risk of external intrusion.

Moreover, a set venue and a regular meeting schedule have been identified as important facilitators for stillbirth reviews because all staff were aware of the timing and location of meetings, making the process

more streamlined and less prone to delays or misunderstandings. Consistency in scheduling and venue was also mentioned as an enabler for improved attendance rate because HCPs could plan their other clinical responsibilities around the review and be supported by the senior staff. Regularly scheduled meetings are recognised as tangible inputs towards stillbirth review implementation in other studies [49,205,271].

The multiple case study found that staff involved in the stillbirth review process had designated time to attend the review meetings but lacked time to prepare for the reviews. Preparation for reviews involves a series of activities (which are detailed in the 'Outputs – Activities' section of the logic model), and without senior leadership's buy-in to provide designated time to do so, it can be difficult for staff to complete these tasks thoroughly [50]. Preparation often includes gathering necessary data, reviewing case notes, coordinating with other departments, and ensuring that all required panel members are available. If time is not allocated for these critical tasks, the quality of the review process can be compromised, affecting the overall effectiveness of stillbirth reviews. Furthermore, the lack of time for preparation may also result in panel members feeling overwhelmed or unprepared and not feeling confident in actively participating in the discussion. Hence, a commitment to ensuring designated time is allocated for both preparation and attendance is required [51,55,205].

Having women's charts and case notes readily available during the reviews can be useful if hospitals are extracting stillbirth data from these data sources for completing stillbirth review proforma. This is because discussion during reviews sometimes requires further details beyond the summary information provided in the completed stillbirth review proforma. Also, in some Indian hospitals, stillbirth reviews were used as a tool to check the data quality of case notes. Therefore, having the complete records of women accessible in the meeting room allows panel members to double-check facts easily, without delays caused by searching for data sources outside of the venue. However, it is also important to consider anonymising case notes when possible. In one hospital's review meeting, the confidentiality of the HCP involved in the care of a woman who experienced a stillbirth was compromised when they were specifically called upon to present their experiences. Given that this study identified the need for a

supportive, blame-free culture and improved engagement across different levels of the health system to address social opportunities, anonymising case notes can help mitigate the fear of blame and potential repercussions against individuals, even when external parties within the health system attend the review meetings [51,260,307,308]. Nevertheless, the anonymisation process can be time-consuming and needs to be meticulous; therefore, innovative methods to streamline the anonymisation process, such as automated redaction tools assisted by Artificial Intelligence (AI) and machine learning, should be explored to assess their feasibility [309].

There was no evidence that Indian hospitals received specific funding for stillbirth review activities. Since the National Health Mission is responsible for leading the stillbirth review initiative in India, its initiatives would typically be financed jointly by the central and state governments [58]. In this structure, tertiary government hospitals, such as medical colleges, would receive funding support directly from the state health department. For secondary hospitals, it would be the responsibility of the district's Chief Medical Officer to allocate and distribute funding accordingly. If there were dedicated funding for stillbirth review activities, it could significantly support various aspects of the process. Indian hospitals, for example, could hire additional staff responsible for stillbirth data collection, provide necessary training, and enhance infrastructure such as testing facilities and information technology (IT) systems for record-keeping. Funding could also enable the development of culturally sensitive communication materials to address community concerns around post-mortem examinations and beliefs about the causes of stillbirth. These improvements are directly linked to ensuring that minimum data requirements for stillbirth reviews are met. Many hospitals reported difficulties in obtaining information from lower-level health facilities, where women received antenatal care before being referred to higher-level hospitals. Without additional staff to collect this data from lower-level facilities, it becomes extremely challenging for hospitals to conduct effective reviews of the whole pathway to care. Also, since collecting complete stillbirth data often involves additional investigations such as post-mortem examinations and interviews with family or HCPs, staff need to be trained to have respectful conversations with parents to obtain information and consent for additional investigations.

Local guidelines, as seen in one hospital, can provide structured protocols covering who should attend, when and where the meetings should take place, and the confidentiality measures required to protect the integrity of the review process. The implementation of local guidelines helps clarify participant responsibilities and ensures that all involved, whether panel members or those responsible for scheduling, understand their roles [49,50,310]. In certain hospitals, attendance for stillbirth reviews was mandatory, which emerged as an automatic motivator [49]. Additionally, the emphasis on 'mandatory responsibility' surrounding record-keeping was directly linked to the completeness of routine health records, as well as the requirement to report stillbirth statistics monthly as part of government-mandated processes regarding the identification of stillbirth (all stillbirths are counted and considered for review) [311].

Despite the existence of national stillbirth review guidelines [6], which includes the definition of stillbirth and a suggested proforma for data collection, several hospitals expressed confusion over the definition of stillbirth and the need for a standard proforma for data collection. Most of the hospitals were unaware of the existing national guidelines, which are mechanisms recognised as driving a dysfunctional mortality review process [50,312,313]. Hospitals noted that unclear guidance on the stillbirth definition led to inconsistencies in identifying and resulted in no specific job roles in the hospital feeling accountable for reducing them. One hospital reported that this issue caused both obstetricians and paediatricians to overlook stillbirths, resulting in reviews not being initiated in either department. To address this, it may be necessary to review and revise the current national guidelines, drawing from international best practices. The revised guidelines has the potential to lead to clear and standardised definitions of stillbirth, as well as structured responsibilities and reporting requirements that can be adopted consistently across the Indian states.

Given the importance of establishing a systematic process for mandatory stillbirth reporting and review within both local and national frameworks identified in this study, it is also essential that local guidelines align closely with national guidelines. This alignment will not only increase the consistency and reliability of the reviews conducted – improving both the quality of regular meetings within individual hospitals and the quality of meetings across different hospitals – but also provide more integrated findings for

addressing stillbirths across various healthcare settings from a policymaker's perspective. Ultimately, the synergy between local and national guidelines, along with training programmes and standardised data collection practices, can lead to improved outcomes in stillbirth prevention and the quality of pregnancy care across India.

8.2.2 Outputs – Activities

Overall, the stillbirth review activities conducted in Indian hospitals were largely aligned with those identified in the systematic review evidence. The activities typically follow a logical sequence: first, stillbirths must be identified within the hospital; second, a review is conducted to determine whether the identified stillbirths meet the hospital's defined review criteria. Following this, further data collection and extraction are required to prepare for the review. Finally, the review itself takes place, during which the panel discusses the stillbirths, analyses the data, identifies areas of care that, had they been different, might have resulted in a different outcome for the baby, and agrees on actionable solutions to improve care.

Identifying eligible stillbirths for review was primarily facilitated by a designated staff member who took the initiative to verify data from multiple sources, mainly routine health records and HCP notifications within 48 hours. Some hospitals synergised their mandatory stillbirth reporting process with the Civil Registration System, using this opportunity to identify all stillbirths that occurred within their hospital as potential stillbirths for review.

However, a key difference between the systematic review evidence and the empirical findings lies in the second step of the stillbirth review activities. In the systematic review, this step was referred to as the 'Case assessment of stillbirth' which primarily involves evaluating whether a stillbirth meets the panel's agreed definition (hence why the initial logic model in Figure 2-3 refers to this). This typically includes criteria such as gestational age, birthweight, or crown-heel length to assess stillbirths based on established definitions. The empirical evidence from the quantitative analyses, however, highlighted potential

challenges in reviewing all stillbirths using the definition in the national stillbirth review guidelines – fetal death weighing at least 1,000g, or with a gestational age of 28 completed weeks, or a crown-heel length of 35cm or more. Due to India's high stillbirth rate, some hospitals may consider prioritising theme-based stillbirths for review based on significant risk factors or subtypes associated with the quality of care. Thus, it became more appropriate to reframe this step as 'choosing which stillbirth to review – theme.'

This approach of selecting a 'theme' for each stillbirth review aligns with the WHO guidelines [52], which recommends that review panels adopt a focused approach, whether by reviewing a subset of stillbirths, focusing on specific causes, or prioritising preventable deaths. Similarly, seven studies identified from the systematic review followed a similar approach; their stillbirth reviews focused on particular themes of stillbirth [67,70,81,93,97,108,130]. Nonetheless, some hospitals may opt to review all stillbirths that meet the agreed definition. For instance, one hospital in the facilitators and barriers study reported that they feel the burden of stillbirths is low enough to review every stillbirth despite the actual number of stillbirths being contrary to this perception. Therefore, the model reflects that one possible theme for Indian hospitals when 'choosing which stillbirth to review' is 'all stillbirths identified by the agreed stillbirth definition'.

If Indian hospitals decide to prioritise reviews by specific themes, the logic model suggests three priority areas based on findings from the quantitative analyses. The logic model's order of priorities considers areas where stillbirth reviews can have the most impact in reducing stillbirth by improving all areas of care, starting with modifiable risk factors in the proximal factors, then the risk factors associated with antenatal care, and finally, structural factors or intermediate factors that cannot be changed by facility-based care. These structural and intermediate factors, however, require a different approach for stillbirth prevention, which falls under the responsibility of government-led initiatives, such as addressing socioeconomic inequalities, improving accessibility to healthcare services, and improving community-level antenatal care.

The order of priorities was derived from the findings of the quantitative analyses and, therefore, supports evidence-based decision-making. However, as discussed in the results of the quantitative analyses, there is still limited evidence on which interventions are most effective for managing complications in Indian settings or how existing international clinical evidence should be adapted for local contexts. For instance, while studies like the CRADLE-4 trial demonstrate the safety of planned childbirth before term between 34^{+0} and 36^{+6} weeks of gestation in cases of pre-eclampsia in LMICs [237], their applicability to Indian health settings with a high burden of maternal and perinatal deaths remains uncertain, particularly in rural or resource-constrained environments. Similarly, the high proportion of babies with less than the 10^{th} percentile birthweight for gestational age in the sample population of the quantitative analyses found the importance of differentiating between small for gestational age (SGA) and fetal growth restriction (FGR), which may have implications for the timing or mode of delivery. Therefore, continuous efforts are needed to strengthen clinical evidence that hospitals can use as guidelines to assess their care and determine if stillbirths could have been prevented. This requires greater investment in research tailored to the Indian context, with a focus on validating and implementing evidence-based interventions that address modifiable factors, optimise antenatal care, and manage complications effectively. Additionally, stillbirth reviews should integrate these findings into actionable recommendations to ensure that action points for improving the quality of care are systematically implemented and evaluated.

While stillbirths can be identified from existing data sources without advanced data collection (first activity), conducting a review meeting necessitates gathering in-depth data, such as extracting information from case notes using a stillbirth review proforma and interviewing family or HCPs to obtain further data that may be unavailable in the case notes. Several hospitals indicated that missing data in case notes presented significant challenges, especially when a woman was referred from lower-level health facilities, where antenatal care information was not transferred along with her referral to the hospital. A key example of missing data in case notes that created difficulties in stillbirth reviews was the absence of fetal heart rate information. This gap in information made it challenging for hospitals to determine whether a stillbirth was antepartum or intrapartum, but reviews still proceeded despite the uncertainty. While further investigation is needed to understand how these uncertainties around the

timing of stillbirths affected the review process, the quantitative analyses found higher rates of intrapartum stillbirths in the cohort population. This raised the question of whether hospitals might have classified stillbirths that should have been categorised as antepartum stillbirths as intrapartum stillbirths due to the lack of clarity around fetal heart rate detection before labour had started. One hospital noted the need to utilise human resources to access stillbirth data from lower-level health facilities, emphasising that despite the administrative burden associated with sourcing stillbirth data, gathering minimum sets of stillbirth data where women received care prior to referral is valuable for informing and improving the quality of care provided at their hospital and improving the data available for stillbirth reviews.

Additionally, when conducting interviews with families to obtain further information that may not be available in the case notes, it is pivotal to approach these discussions with empathy and respect. The use of 'scolding' or punitive language towards women who have experienced a stillbirth can significantly discourage them from talking about their pregnancy and any information that they are afraid of sharing in case of judgment [16–18,314]. A woman who has just lost her child will be experiencing profound grief, and subjecting her to interrogative or accusatory language rather than providing bereavement care can further exacerbate her trauma [19]. This emphasises the importance of fostering a blame-free culture, which should extend to both HCPs and families during stillbirth reviews [17,18,51,52,257,259]. While stillbirth remains a topic that is often not openly discussed in this setting, promising research has emerged over the past decade, including the development of a toolkit that provide guidance on respectful communication with parents following a stillbirth [16–19,314]. The toolkit also includes checklists for HCPs, providing actionable steps to support bereaved families effectively [18].

The final activity, conducting stillbirth reviews, was found to have a diverse practice among hospitals. This diversity stemmed from differences in responsibilities, such as teaching commitments, and variations in resources, including clinical guidelines. Additionally, the level of formality in conducting reviews was influenced by the panel composition and the stated purpose of the meetings. For example, one hospital noted that they did not document meeting minutes because the primary focus of the review was to teach postgraduate students.

Despite these variations, several examples of good practices emerged that could be implemented more widely. One notable practice was producing written documents of review findings that extended beyond basic records. Documenting review findings proved essential for disseminating learning and initiating the implementation of action points [253]. This approach ensured that findings were thoroughly recorded for future reference, provided a record for staff who may not have attended the meetings, enabled new staff to review past findings to avoid repeating suboptimal care practices, and increased accountability by ensuring that recommendations were implemented within agreed timelines.

Another beneficial practice used by some hospitals was adapting the educational components of the stillbirth review to focus on system-level learning rather than individual mistakes or knowledge gaps. This involved framing educational aspects as opportunities for collective learning, thereby promoting a more open and supportive environment where all panel members, including postgraduate students and consultants, can contribute equally to discussions and thus learning about stillbirth.

8.2.3 Outputs – Generated learnings

The generated learnings from stillbirth reviews will largely depend on the specific areas that hospitals choose to focus on during their review processes. By default, all stillbirth reviews should aim to identify the causes of stillbirth and the suboptimal care contributing to these occurrences. Moreover, these reviews should produce actionable, preferably system-level, recommendations to reduce future stillbirths [52,55,141]. The WHO recommends the use of root cause analysis to identify gaps in care that led to or contributed to stillbirths and to develop action points [52]. In this study, generating learnings from the review process was consistently observed as a core component of stillbirth reviews in Indian hospitals. Beyond these primary areas of focus, some hospitals also identified additional insights indirectly linked to the review process, such as the importance of assessing the quality of data in routine health records and tracking trends in stillbirth rates over time.

However, the empirical findings from this study also revealed significant gaps in generating new learnings related to identifying recurring issues with care associated with stillbirth. In the United Kingdom (UK), for example, the Perinatal Mortality Review Tool (PMRT) has the capacity to produce summary reports that identify themes and patterns in suboptimal care across multiple reviews conducted over a specific period [315]. While this is not a statistical analysis, it allows recurring issues to become evident, highlighting areas that require system-level improvements. Adopting a similar approach in India has the potential to enable hospitals to quantify (e.g. count) and track common problems with care without requiring advanced analytical capacity. Therefore, further research could focus on developing user-friendly tools tailored to Indian hospital settings to facilitate basic analysis and summary report generation. Similar to the PMRT, such tools could enable hospitals to examine their own data, identify recurring suboptimal care factors, and generate actionable recommendations that are both 'Specific, Measurable, Achievable, Relevant, and Time-bound' (commonly called SMART) [55,315] and 'strong' [141,316]. Kurinczuk *et al.* [316] describe 'strong' actions as those that "implement system changes to eliminate reliance on individuals to make correct decisions. These actions involve standardised and permanent physical or digital designs that reduce human error and are sometimes referred to as forcing actions."

Furthermore, in contrast to the systematic review evidence, none of the Indian hospitals in this study reported the proportion of stillbirths for which post-mortem examinations were conducted. This lack of reporting likely stems from the very few post-mortem examinations that actually took place or hospitals' lack of capacity to 'count' them. Hospitals faced significant challenges in obtaining consent for these examinations, as many families were reluctant to agree, often due to cultural beliefs. Additionally, some hospitals lacked the necessary facilities to conduct post-mortem examinations. Measuring the proportion of stillbirths with post-mortem examinations is only meaningful if a baseline number of such examinations are conducted, particularly as hospitals strive to improve uptake. To improve the situation surrounding post-mortem examinations, both social and physical opportunities need to be addressed. Increasing knowledge among HCPs and the community about post-mortem examinations, along with developing culturally sensitive communication materials, could demystify the

process and encourage community acceptance [272]. Additionally, implementing training for HCPs on communication skills [273,274] and providing pathologists with training on minimally invasive techniques [274], along with establishing partnerships between hospitals for resource sharing [281,317], would improve the capacity to conduct post-mortem examinations effectively and ethically.

8.2.4 Outcomes

The implementation of stillbirth review processes has led to several short- and medium-term outcomes in Indian hospitals undertaking reviews. One hospital also planned to achieve further outcomes by informing the development of or expansion of local clinical guidelines from the stillbirth review findings. However, this study highlighted a major lack of systematic evaluation regarding the effectiveness of stillbirth review processes in India and worldwide. Although the Indian hospitals included in this study have generated action points, no quality improvement measurements have been established through key performance indicators to assess the impact of these reviews on improving care and reducing stillbirths.

While incorporating key performance indicators is essential for tracking progress and improvements in a stillbirth review process, it is important to maintain an appropriate focus. Only emphasising indicators risks diverting attention from the actual quality of the reviews conducted. Additionally, excessive monitoring of too many indicators may lead to inefficiencies and take away valuable time and resources from the staff and the hospital. Recognising these concerns, the following selected indicators are proposed, aligned with recommendations from the WHO guidelines [55]:

- Inputs
    - Availability of committed funds for stillbirth review activities
    - Availability of local stillbirth review guidelines
    - Availability of full-time equivalent of designated staff for stillbirth review data collection and organising meetings
    - Availability of designated preparation and attendance time for staff involved in stillbirth reviews

    - Number of staff trained in the stillbirth review process
    - Proportion of reviews conducted in an appropriate venue
    - Proportion of reviews where women's charts or case notes were available during the meeting
    - Proportion of routine health records that were deemed incomplete or inadequate for use in stillbirth reviews
- Outputs
    - Number of stillbirths identified
    - Number of stillbirths planned for review
        - Proportion of planned reviews where stillbirth review proforma was used to gather data
        - Proportion of planned reviews that involved interviews with family or healthcare providers to gather further data
    - Number of stillbirths reviewed
        - Proportion of stillbirths where a cause was identified
        - Proportion of stillbirths where issues during pre-conception and antenatal care were identified as relevant to the outcome, e.g. inadequate assessment of fetal growth using sonography, management of significant medical/surgical/social problems, inadequate investigation/management of reduced fetal movements
        - Proportion of stillbirths where issues during labour and birth were identified as relevant to the outcome, e.g. fetal monitoring in labour, staffing issues, assessment of maternal risk status, maternal and fetal monitoring in labour
    - Number of review meetings conducted
        - Proportion of reviews with specific job role present, e.g. obstetricians, nurses, administration support, superintendent, community health workers, other external members
        - Proportion of reviews that identified 'Specific, Measurable, Achievable, Relevant, and Time-bound' (commonly called SMART) recommendations

        - Proportion of reviews that identified 'strong[9]' recommendations
        - Proportion of reviews where meeting minutes and action points were written
- Short-term and medium-term outcomes
    - Proportion of recommendations implemented
    - Details of recommendations implemented
- Long-term outcomes or Impact
    - Tracking of the number of overall, antepartum and intrapartum stillbirths (monthly/quarterly/annually)
    - Tracking of the number of stillbirths by cause (monthly/quarterly/annually)

The absence of evaluations creates uncertainty about the effectiveness of the review processes in lowering stillbirth rates. Furthermore, documenting evidence around effectiveness is essential for advocating for increased support from funders to sustain or expand stillbirth reviews in India. Incorporating evaluation needs was, therefore, a critical consideration in the development of the logic model. As indicated in the top boxes of the model, which feature arrows pointing toward each component, the logic model proposes appropriate evaluation types for inputs, outputs, and outcomes. A needs assessment for inputs can help hospitals identify the resources required to effectively conduct stillbirth review activities. Additionally, process evaluations focusing on outputs (activities and generated learnings) can facilitate continuous improvement by identifying what works and what does not work during the implementation period. Finally, conducting outcome and impact evaluations will provide valuable insights into how the action points derived from the reviews contribute to measurable improvements in the quality of care for all women and, ultimately it is hoped, to the prevention of future stillbirths and a reduction in the stillbirth rate.

[9] The strength of an action describes how well the action would eliminate human error [141,316]. Strong actions are system changes which remove the reliance on individuals to choose the correct action. They use standardisation and permanent physical or digital designs to eliminate human error and are sometimes referred to as 'forcing' actions.

8.3 Strengths and limitations

A major strength of this study is that it triangulated results from five different research activities, which strengthened the evidence and provided a comprehensive understanding of the gaps that exist in stillbirth review processes, both in the literature and in real-world practice in India. Without conducting a mixed-methods study, I would not have been able to incorporate multiple perspectives. For example, had I only focused on stillbirth rates and risk factors, I would not have discovered the challenges HCPs in India face in determining accurate gestational age or in categorising stillbirths due to missing fetal heart rate data. I believe the use of the logic model effectively tied everything together through a series of iterations, clearly outlining the critical components required to implement and sustain a stillbirth review process.

While similar models, such as the WHO's 'mortality audit cycle' [52], are important, they typically focus on limited components of the process, often omitting essential inputs and the expected outcomes of the activities. In contrast, my logic model offers a broader view, addressing the full spectrum of stillbirth review activities, inputs, and outcomes, which is especially critical for countries without established quality improvement processes in their health systems. Kinney *et al.*'s [49,257] framework for promoting a positive implementation culture for Maternal and Perinatal Death Surveillance and Review (MPDSR) is also informative for understanding facilitators and barriers. However, it does not delve deeply into the activities of the process or include aspects related to outcomes and evaluation. Thus, previous models have tended to focus on fragmented aspects of the process, rather than presenting a holistic picture.

Given that my study focuses on India across six states, I believe the evidence generated will contribute to the revision of India's national stillbirth review guidelines and increase attention to the importance of implementing and sustaining stillbirth reviews as part of India's India Newborn Action Plan (INAP) goal of reducing stillbirth rates to <10 per 1,000 total births by 2030. However, due to time and funding constraints typical of doctoral research, the number of hospitals included in my study may limit the generalisability of my findings within and beyond the Indian context of six states. There may be regional variations in practices, and some local context-specific challenges may not have been captured in this

study. Additionally, healthcare practices in India can differ significantly between urban and rural settings, as well as between private and public hospitals [318].

Furthermore, the logic model I developed is inherently linear and suggests a straightforward progression of programme implementation from inputs to outcomes. However, in the real world, the process of stillbirth reviews is more complex, with numerous external factors (e.g. cultural barriers, resource availability, and political influences) affecting the activities and outcomes. While the logic model provides a useful framework, it may not fully capture the intricate, non-linear relationships and iterative nature of the practice and learnings that emerge in the real world. That said, the model does acknowledge this limitation of linearity and incorporates further considerations, such as facilitators and barriers and the evaluation needs for each component, which are required to continuously improve and adapt the process as it matures.

8.4 Recommendations

8.4.1 Policy

A key recommendation for the National Health Mission is to review and revise the current national guidelines for facility-based stillbirth reviews in India, incorporating international best practices that can be useful for the Indian setting. These revisions should not only outline the structure, responsibilities, and reporting requirements but also establish a clear, standardised approach to stillbirth definitions and reviews that can be adopted consistently across states. Additionally, it is important to improve the current stillbirth review tools and proformas available in the guidelines by testing their usability and ensuring they are distributed effectively so hospitals are aware of them and can implement them in their hospitals. This would standardise data collection, ensure consistency in review processes across hospitals and align all facilities within the health system to adhere to consistent definitions for stillbirth.

State policies should also consider making stillbirth reviews a mandatory practice in secondary and tertiary hospitals [311]. This could include policies that mandate the review of specific themes, such as priority areas identified to have the greatest impact on improving care and reducing stillbirths. Additionally, policies should enable primary health centres and community health workers to be actively involved in the review process, particularly if the reviews are hosted by secondary or tertiary hospitals. This has the potential to create opportunities for staff at all levels of the health system to participate. In addition, national policies should promote a blame-free culture during stillbirth reviews by implementing improved legal protections for HCPs and health facilities [308,309,311]. For instance, the maternal death review statute in New Jersey, United States, explicitly guarantees legal protections that shield panel members from legal and disciplinary proceedings based on information presented during the review [319]. Kenya has also introduced the Maternal, Newborn, and Child Health Bill, 2023, which supports the safeguarding of healthcare providers acting in good faith to improve the quality of maternal, newborn, and child health [309,320]. This would allow reviews to focus on system-level improvements rather than individual fault-finding and would encourage a more open and constructive environment for HCPs to engage in.

Another recommendation for the National Health Mission and state policies is to recognise the value of collaborative efforts between facility-based and community-based interventions in improving care and reducing stillbirths. Given that facility-based interventions are better suited to address proximal risk factors (such as pre-eclampsia/eclampsia and severe anaemia), while most structural and intermediate risk factors require community-based interventions (such as access to antenatal care and iron and folic acid (IFA) supplementation), state policies should enable collaboration across systems. This would involve ensuring that hospitals work closely with community health workers and other community-based organisations and making it easier for hospitals to initiate such collaborative actions once they identify these action points through stillbirth reviews. A governance structure should be in place at the state level to oversee activities, but the process of obtaining approval from the state government should be streamlined to ensure that hospitals are not overburdened with lengthy or bureaucratic procedures.

8.4.2 Indian health system

An important recommendation for the Indian health system is the implementation of training programmes for HCPs on the full scope of stillbirth reviews, which should include data collection, analysis, and reporting. The programme must also specifically address how to conduct blame-free, constructive reviews, fostering open dialogue and continuous learning. The training should be designed to navigate the cultural sensitivities around post-mortem examinations and support HCPs in providing respectful care to bereaved parents.

Stillbirth reviews should also be integrated into India's nationwide Sentinel Stillbirth Surveillance System, or Civil Registration System. This way, all stillbirths will be counted as part of the systematic process of mandatory stillbirth reporting and considered for review. Additionally, tracking the trends in stillbirths and their causes over time through these surveillance systems will provide valuable evidence of the effectiveness of the review process and help drive future policy decisions.

At the facility level, local stillbirth review guidelines should be created and implemented which are aligned with the national guidelines. The local guidelines should deal with the local process and clearly detail the frequency of stillbirth review meetings, the roles required for participation, and the step-by-step process for conducting the reviews. It is essential that these guidelines emphasise the importance of forming multidisciplinary review panels, which should include obstetricians, nurses, community health workers, pathologists and administrative staff to ensure diverse perspectives are incorporated into discussions and receive buy-in from all relevant stakeholders. Facilities should also allocate separate funds for review activities, such as investing in designated staff responsible for collecting data, organising reviews, and improving record-keeping. This approach would ensure that stillbirth reviews are not reliant on already overstretched operational budgets or clinical staff capacity.

Furthermore, when implementing a stillbirth review, all health facilities within the health system should establish a system of accountability to ensure that responsibilities are carried out by each stakeholder

when agreed at the meeting and recommendations made during reviews are followed up and addressed in subsequent reviews. Additionally, mechanisms for learning and feedback should be created, where the outcomes of reviews and lessons learned are shared with key stakeholders across the whole health system and inform the development of or revision of local clinical guidelines.

To facilitate this process, documentation of review activities through written meeting minutes and action points should be prioritised. These written records will provide a reference for staff who may not have attended the meetings but are involved in women's care and will also enable new staff joining the hospital to review past findings and avoid repeating similar suboptimal care practices. In the long term, however, these records should form the basis for creating 'strong' actions that result in system changes to reduce reliance on individuals to review and act on meeting minutes. Strong actions involve standardisation and the implementation of permanent physical or digital designs, often referred to as 'forcing' actions, which eliminate human error. By evolving from written records to integrated system-level solutions, such as automated prompts or decision-support tools embedded in digital patient management systems, health facilities can ensure that recommendations from stillbirth reviews are consistently and effectively implemented.

Finally, all health facilities, including primary health centres, should collect stillbirth data and ensure the timely transfer of these data to the hospital responsible for conducting the review. A robust data record-keeping and transfer system should be established across hospitals, so the missing data does not prevent reviews from being conducted. The stillbirth data should particularly focus on accurate recording of gestational age at birth and fetal heart rate at labour onset. This study highlighted the importance of making informed decisions about the timing of clinical interventions when complications arise, such as pre-eclampsia/eclampsia and severe anaemia, to reduce the risk of stillbirth. Without high-quality stillbirth data, assessing whether clinical interventions occurred at the appropriate time and whether any suboptimal care factors contributed to the outcome would be difficult. In addition, while ensuring the completeness of the minimum stillbirth data proposed by the WHO is an important starting point [52,55], it should also be acknowledged that having access to partial data alone may not provide sufficient

information about the care provided to women. To effectively evaluate the quality of care, access to a complete set of case notes should be considered as the next step once the collection and transfer of minimum stillbirth data are consistently practised.

8.4.3 Future research

Future research should focus on evaluating the impact of stillbirth reviews on improving care and reducing stillbirth rates in India. Although stillbirth reviews are conducted in some Indian hospitals, this study found no data demonstrating their effectiveness in reducing stillbirths. Future studies should adopt both quantitative and qualitative approaches to assess the impact of stillbirth reviews on reducing stillbirths, improving the quality of care, ensuring accurate recording of stillbirth data, and generating and implementing actionable recommendations. Additionally, research should explore effective strategies for engaging wider stakeholders, including staff from other departments who should be part of the panel (e.g. pathologists, nurses, community health workers) in the review process.

Future research is also needed to better understand the postnatal and bereavement care provided to women who have experienced a stillbirth. These studies should explore their experiences regarding bereavement care and how HCPs communicated with them about what happened to their baby. Moreover, research should explore the cultural barriers around the uptake of post-mortem examinations and investigate how options of minimally invasive post-mortem techniques and imaging can increase consent.

The quantitative analyses in this study observed that planned preterm induction or caesarean section may offer benefits for women with pre-eclampsia/eclampsia in preventing stillbirth in India [236]. However, further studies are needed to assess the safety, feasibility, and optimal timing of such interventions across diverse settings in India. Therefore, future research should focus on assessing both maternal and neonatal outcomes of planned preterm births for women with these conditions in high-risk settings within India.

To improve differentiation between SGA and FGR, future research should prioritise validating cost-effective tools for detecting FGR in resource-constrained settings, such as combining umbilical artery Doppler with cardiotocography/nonstress test (CTG/NST) or using symphysis-fundal height as a primary screening tool in low-risk pregnancies [244,245]. Improving data on gestational age should also employ a similar approach; research should evaluate strategies for ensuring at least one antenatal ultrasound per the WHO guidelines [168] and investigate the potential of AI to enhance ultrasound-based gestational age estimation [297], especially in settings with limited sonography expertise or late-pregnancy scans.

Another area for future research is the effect of severe anaemia during pregnancy on fetal survival. The study showed that the probability of survival of a fetus decreased from the 30 weeks of gestation for pregnancies complicated by severe anaemia. Future studies should explore the physiological mechanisms by which severe anaemia affects fetal survival during pregnancy to develop a multisectoral approach to addressing anaemia management. Research should also explore how community-based health services can complement facility-based care in managing anaemia.

8.5 Conclusion

This thesis synthesised findings from five research activities to present a logic model and evidence-based recommendations for improving the facility-based stillbirth review process in India. The iterative refinement of the logic model demonstrates how global evidence from the systematic review can be effectively contextualised through a series of empirical studies adopting a mixed-methods research design to address the diverse challenges and opportunities within India's health system. By linking inputs, activities, and outcomes, the model highlights the interconnected components required for effective implementation and sustainability of a stillbirth review process in India while identifying key facilitators and barriers at multiple levels – community, facility, and policy – and evaluation needs for continuous improvement and adaptation.

The findings emphasise the importance of a collaborative and systematic approach to stillbirth reviews, integrating different perspectives and achieving joint action and accountability across health facilities, community health workers, and government stakeholders. However, this approach requires wider stakeholders' commitment to addressing important gaps in the current review process, such as training needs, funding, and the standardisation of processes. Furthermore, policy alignment through national and local guidelines is essential to improving systematic stillbirth reporting and review systems, ensuring that stillbirth data are accurately recorded, and promoting a supportive, blame-free culture among facility staff, community members, and women.

References

[1] Hug L, You D, Blencowe H, Mishra A, Wang Z, Fix MJ, et al. Global, regional, and national estimates and trends in stillbirths from 2000 to 2019: a systematic assessment. Lancet 2021;398:772–85. https://doi.org/10.1016/S0140-6736(21)01112-0.

[2] World Health Organization. Neonatal and perinatal mortality: country, regional and global estimates. Geneva: World Health Organization; 2006.

[3] Blencowe H, Hug L, Moller A-B, You D, Moran AC. Definitions, terminology and standards for reporting of births and deaths in the perinatal period: International Classification of Diseases (ICD-11). Int J Gynaecol Obstet 2024. https://doi.org/10.1002/ijgo.15794.

[4] Tavares Da Silva F, Gonik B, McMillan M, Keech C, Dellicour S, Bhange S, et al. Stillbirth: Case definition and guidelines for data collection, analysis, and presentation of maternal immunization safety data. Vaccine 2016;34:6057–68. https://doi.org/10.1016/j.vaccine.2016.03.044.

[5] United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). Never Forgotten: The situation of stillbirth around the globe. New York: United Nations Children's Fund; 2023.

[6] Child Health Division Ministry of Health & Family Welfare Government of India. Operational Guidelines for Establishing Sentinel Stillbirth Surveillance System. New Delhi: Ministry of Health and Family Welfare; 2016.

[7] Heazell AEP, Siassakos D, Blencowe H, Burden C, Bhutta ZA, Cacciatore J, et al. Stillbirths: economic and psychosocial consequences. Lancet 2016;387:604–16. https://doi.org/10.1016/S0140-6736(15)00836-3.

[8] Goldenberg RL, McClure EM, Bann CM. The relationship of intrapartum and antepartum stillbirth rates to measures of obstetric care in developed and developing countries. Acta Obstet Gynecol Scand 2007;86:1303–9. https://doi.org/10.1080/00016340701644876.

[9] de Bernis L, Kinney MV, Stones W, Ten Hoope-Bender P, Vivio D, Leisher SH, et al. Stillbirths: ending preventable deaths by 2030. Lancet 2016;387:703–16. https://doi.org/10.1016/S0140-6736(15)00954-X.

[10] Sachs J, Kroll C, Lafortune G, Fuller G, Woelm F. From crisis to sustainable development: the SDGs as roadmap to 2030 and beyond: includes the SDG index and dashboards. Cambridge New York Port Melbourne New Delhi Singapore: Cambridge University Press; 2022.

[11] Agravat P, Loucaides EM, Kumar MB, Howells A, García AM, Sebina I, et al. Research funding for newborn health and stillbirths, 2011-20: a systematic analysis of levels and trends. Lancet Glob Health 2023;11:e1794–804. https://doi.org/10.1016/S2214-109X(23)00379-0.

[12] Kumar MB, Bath D, Binyaruka P, Novignon J, Lawn JE, Pitt C. Donor aid mentioning newborns and stillbirths, 2002-19: an analysis of levels, trends, and equity. Lancet Glob Health 2023;11:e1785–93. https://doi.org/10.1016/S2214-109X(23)00378-9.

[13] United Nations. Transforming our World: The 2030 Agenda for Sustainable Development. 2015.

[14] World Health Organization. Every newborn: an action plan to end preventable deaths. Geneva: World Health Organization; 2014.

[15] Patterson JK, Aziz A, Bauserman MS, McClure EM, Goldenberg RL, Bose CL. Challenges in classification and assignment of causes of stillbirths in low- and lower middle-income countries. Semin Perinatol 2019;43:308–14. https://doi.org/10.1053/j.semperi.2019.03.021.

[16] Atkins B, Blencowe H, Boyle FM, Sacks E, Horey D, Flenady V. Is care of stillborn babies and their parents respectful? Results from an international online survey. BJOG 2022;129:1731–9. https://doi.org/10.1111/1471-0528.17138.

[17] Majumder M, Kumar GA, Ali SB, George S, Dora SP, Akbar Md, et al. Socio-cultural practices and experience of mothers' post stillbirth and newborn death: a population-based perspective from India. BMC Pregnancy Childbirth 2024;24:778. https://doi.org/10.1186/s12884-024-06906-0.

[18] The International Stillbirth Alliance, Stillbirth Advocacy Working Group, Public Health Foundation of India Gurugram, The London School of Hygiene & Tropical Medicine, Post Graduate Institute of Medical Education and Research Chandigarh. Raising Parent Voices Advocacy Toolkit: India Healthcare Providers Version. 2022.
[19] Das MK, Arora NK, Gaikwad H, Chellani H, Debata P, Rasaily R, et al. Grief reaction and psychosocial impacts of child death and stillbirth on bereaved North Indian parents: A qualitative study. PLoS ONE 2021;16:e0240270. https://doi.org/10.1371/journal.pone.0240270.
[20] Ayebare E, Lavender T, Mweteise J, Nabisere A, Nendela A, Mukhwana R, et al. The impact of cultural beliefs and practices on parents' experiences of bereavement following stillbirth: a qualitative study in Uganda and Kenya. BMC Pregnancy Childbirth 2021;21:443. https://doi.org/10.1186/s12884-021-03912-4.
[21] Ellis A, Chebsey C, Storey C, Bradley S, Jackson S, Flenady V, et al. Systematic review to understand and improve care after stillbirth: a review of parents' and healthcare professionals' experiences. BMC Pregnancy Childbirth 2016;16:16. https://doi.org/10.1186/s12884-016-0806-2.
[22] Comfort H, McHugh TA, Schumacher AE, Harris A, May EA, Paulson KR, et al. Global, regional, and national stillbirths at 20 weeks' gestation or longer in 204 countries and territories, 1990–2021: findings from the Global Burden of Disease Study 2021. The Lancet 2024;404:1955–88. https://doi.org/10.1016/S0140-6736(24)01925-1.
[23] Ministry of Health & Family Welfare Government of India. Indian Newborn Action Plan. 2014.
[24] Office of the Registrar General & Census Commissioner India (ORGI). Sample Registration System (SRS) statistical report 2019. Registrar General of India New Delhi; 2022.
[25] Office of the Registrar General I. Vital statistics of India based on the civil registration system 2020. New Delhi: Ministry of Home Affairs, Government of India; 2022.
[26] Government of India. The Registration of Births and Deaths (Amendment) Act, 2023. New Delhi: Ministry of Law and Justice; 2023.
[27] Ali MM, Bellizzi S, Boerma T. Measuring stillbirth and perinatal mortality rates through household surveys: a population-based analysis using an integrated approach to data quality assessment and adjustment with 157 surveys from 53 countries. Lancet Glob Health 2023;11:e854–61. https://doi.org/10.1016/S2214-109X(23)00125-0.
[28] International Institute for Population Sciences (IIPS), ICF. National family health survey (NFHS-5), 2019-2021: India. Mumbai: International Institute for Population Sciences (IIPS); 2022.
[29] Zadey S, Dubey S, Wadhwani V. Data considerations in measuring stillbirths in India. Lancet Reg Health Southeast Asia 2023;19:100282. https://doi.org/10.1016/j.lansea.2023.100282.
[30] National Data and Analytics Platform. Health Management Information System (HMIS): Performance of Key Health Management Information System (HMIS) Indicators across District (2017-18 to 2019-20). National Data and Analytics Platform; 2022.
[31] Dandona R, George S, Majumder M, Akbar M, Kumar GA. Stillbirth undercount in the sample registration system and national family health survey, India. Bulletin of the World Health Organization 2023;101:191.
[32] Sharma B, Lahariya C, Majella MG, Upadhyay A, Yadav S, Raina A, et al. Burden, Differentials and Causes of Stillbirths in India: A Systematic Review and Meta Analysis. Indian J Pediatr 2023;90:54–62. https://doi.org/10.1007/s12098-023-04749-9.
[33] United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). Stillbirth in Low- and Middle-Income Countries: A conceptual framework. New York: UNICEF; 2022.
[34] Newtonraj A, Kaur M, Gupta M, Kumar R. Level, causes, and risk factors of stillbirth: a population-based case control study from Chandigarh, India. BMC Pregnancy Childbirth 2017;17:371. https://doi.org/10.1186/s12884-017-1557-4.
[35] Sharma B, Raina A, Kumar V, Mohanty P, Sharma M, Gupta A. Counting stillbirth in a community - To understand the burden. Clinical Epidemiology and Global Health 2022;14:100977. https://doi.org/10.1016/j.cegh.2022.100977.

[36] Goldenberg RL, Saleem S, Goudar SS, Silver RM, Tikmani SS, Guruprasad G, et al. Preventable stillbirths in India and Pakistan: a prospective, observational study. BJOG 2021;128:1762–73. https://doi.org/10.1111/1471-0528.16820.
[37] Altijani N, Carson C, Choudhury SS, Rani A, Sarma UC, Knight M, et al. Stillbirth among women in nine states in India: rate and risk factors in study of 886,505 women from the annual health survey. BMJ Open 2018;8:e022583. https://doi.org/10.1136/bmjopen-2018-022583.
[38] Neogi SB, Negandhi P, Chopra S, Das AM, Zodpey S, Gupta RK, et al. Risk Factors for Stillbirth: Findings from a Population-Based Case-Control Study, Haryana, India. Paediatr Perinat Epidemiol 2016;30:56–66. https://doi.org/10.1111/ppe.12246.
[39] Malewar SS, More V, Dwivedi J. Analysis of Perinatal Mortality in a Tertiary Care Hospital in India: A Retrospective Observational Study. Journal of South Asian Federation of Obstetrics and Gynaecology 2022;14:502–4. https://doi.org/10.5005/jp-journals-10006-2111.
[40] Torre Monmany N, Astete JA, Ramaiah D, Suchitra J, Krauel X, Fillol M, et al. Extended Perinatal Mortality Audit in a Rural Hospital in India. Am J Perinatol 2023;40:375–86. https://doi.org/10.1055/s-0041-1727220.
[41] Purbey A, Nambiar A, Roy Choudhury D, Vennam T, Balani K, Agnihotri SB. Stillbirth rates and its spatial patterns in India: an exploration of HMIS data. Lancet Reg Health Southeast Asia 2023;9:100116. https://doi.org/10.1016/j.lansea.2022.100116.
[42] Chepkin S, Prince S, Johnston T, Boby T, Neves M, Smith P, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: First Annual Report. Oxford: National Perinatal Epidemiology Unit; 2019.
[43] Kurinczuk JJ, Draper ES, Field DJ, Bevan C, Brocklehurst P, Gray R, et al. Experiences with maternal and perinatal death reviews in the UK--the MBRRACE-UK programme. BJOG 2014;121 Suppl 4:41–6. https://doi.org/10.1111/1471-0528.12820.
[44] Willcox ML, Price J, Scott S, Nicholson BD, Stuart B, Roberts NW, et al. Death audits and reviews for reducing maternal, perinatal and child mortality. Cochrane Database Syst Rev 2020;3:CD012982. https://doi.org/10.1002/14651858.CD012982.pub2.
[45] Dumont A, Fournier P, Abrahamowicz M, Traoré M, Haddad S, Fraser WD, et al. Quality of care, risk management, and technology in obstetrics to reduce hospital-based maternal mortality in Senegal and Mali (QUARITE): a cluster-randomised trial. Lancet 2013;382:146–57. https://doi.org/10.1016/S0140-6736(13)60593-0.
[46] Dupont C, Winer N, Rabilloud M, Touzet S, Branger B, Lansac J, et al. Multifaceted intervention to improve obstetric practices: The OPERA cluster-randomized controlled trial. Eur J Obstet Gynecol Reprod Biol 2017;215:206–12. https://doi.org/10.1016/j.ejogrb.2017.06.026.
[47] Pattinson R, Kerber K, Waiswa P, Day LT, Mussell F, Asiruddin SK, et al. Perinatal mortality audit: counting, accountability, and overcoming challenges in scaling up in low- and middle-income countries. Int J Gynaecol Obstet 2009;107 Suppl 1:S113-121, S121-122. https://doi.org/10.1016/j.ijgo.2009.07.011.
[48] Kerber KJ, Mathai M, Lewis G, Flenady V, Erwich JJHM, Segun T, et al. Counting every stillbirth and neonatal death through mortality audit to improve quality of care for every pregnant woman and her baby. BMC Pregnancy Childbirth 2015;15 Suppl 2:S9. https://doi.org/10.1186/1471-2393-15-S2-S9.
[49] Kinney MV, Walugembe DR, Wanduru P, Waiswa P, George A. Maternal and perinatal death surveillance and response in low- and middle-income countries: a scoping review of implementation factors. Health Policy Plan 2021;36:955–73. https://doi.org/10.1093/heapol/czab011.
[50] Willcox ML, Okello IA, Maidwell-Smith A, Tura AK, van den Akker T, Knight M. Maternal and perinatal death surveillance and response: a systematic review of qualitative studies. Bulletin of the World Health Organization 2023;101:62.
[51] Willcox ML, Okello IA, Maidwell-Smith A, Tura AK, Van Den Akker T, Knight M, et al. Determinants of behaviors influencing implementation of maternal and perinatal death surveillance and response in low- and middle-income countries: A systematic review of qualitative studies. Intl J Gynecology & Obste 2024;165:586–600. https://doi.org/10.1002/ijgo.15132.

[52] World Health Organization. Making every baby count: audit and review of stillbirths and neonatal deaths. Geneva: World Health Organization; 2016.
[53] Frøen JF, Pinar H, Flenady V, Bahrin S, Charles A, Chauke L, et al. Causes of death and associated conditions (Codac): a utilitarian approach to the classification of perinatal deaths. BMC Pregnancy Childbirth 2009;9:22. https://doi.org/10.1186/1471-2393-9-22.
[54] Ramamurthy Pal S and FM, Pandey K. FOGSI & ICOG Good Clinical Practice Recommendations: Prevention and Management of Stillbirths. Mumbai: The Federation of Obstetric and Gynaecological Societies of India; 2024.
[55] World Health Organization. Maternal and Perinatal Death Surveillance and Response: Materials to Support Implementation. 1st ed. Geneva: World Health Organization; 2021.
[56] Chokshi M, Patil B, Khanna R, Neogi SB, Sharma J, Paul VK, et al. Health systems in India. J Perinatol 2016;36:S9–12. https://doi.org/10.1038/jp.2016.184.
[57] Gupta I. International Health Care System Profiles: India. The Commonwealth Fund 2020. https://www.commonwealthfund.org/international-health-policy-center/countries/india (accessed January 24, 2024).
[58] Selvaraj S, Karan A, Srivastava S, Bhan N, Mukhopadhyay I. India health system review. New Delhi: World Health Organization, Regional Office for South-East Asia on behalf of the Asia Pacific Observatory on Health Systems and Policies; 2022.
[59] Taylor-Powell E, Henert E. Developing a Logic Model Teaching and Training Guide. University of Wisconsin, Extension Cooperative Extension; 2008.
[60] Boo YY, Gwacham-Anisiobi U, Thakrar DB, Roberts N, Kurinczuk JJ, Lakhanpaul M, et al. Facility-based stillbirth review processes used in different countries across the world: a systematic review. EClinicalMedicine 2023;59:101976. https://doi.org/10.1016/j.eclinm.2023.101976.
[61] Boo YY, Bora AK, Chhabra S, Choudhury SS, Deka G, Kakoty S, et al. Maternal and fetal factors associated with stillbirth in singleton pregnancies in 13 hospitals across six states in India: A prospective cohort study. Int J Gynaecol Obstet 2024;165:462–73. https://doi.org/10.1002/ijgo.15367.
[62] Boo YY, Gwacham-Anisiobi U, Thakrar DB, Roberts N, Kurinczuk JJ, Lakhanpaul M, et al. A systematic review of facility-based stillbirth review processes used in different countries across the world. PROSPERO: International Prospective Register of Systematic Reviews 2022. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022304239 (accessed February 11, 2022).
[63] Page MJ, Moher D, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. PRISMA 2020 explanation and elaboration: updated guidance and exemplars for reporting systematic reviews. BMJ 2021;372:n160. https://doi.org/10.1136/bmj.n160.
[64] Veritas Health Innovation. Covidence systematic review software 2022.
[65] Helps A, 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;250:24–30. https://doi.org/10.1016/j.ejogrb.2020.04.054.
[66] Munn Z, Barker TH, Moola S, Tufanaru C, Stern C, McArthur A, et al. Methodological quality of case series studies: an introduction to the JBI critical appraisal tool. JBI Evid Synth 2020;18:2127–33. https://doi.org/10.11124/JBISRIR-D-19-00099.
[67] Flenady V, Kettle I, Laporte J, Birthisel D, Hardiman L, Matsika A, et al. Making every birth count: Outcomes of a perinatal mortality audit program. Aust N Z J Obstet Gynaecol 2021;61:540–7. https://doi.org/10.1111/ajo.13325.
[68] Richardus JH, Graafmans WC, Bergsjø P, Lloyd DJ, Bakketeig LS, Bannon EM, et al. Suboptimal care and perinatal mortality in ten European regions: methodology and evaluation of an international audit. J Matern Fetal Neonatal Med 2003;14:267–76. https://doi.org/10.1080/jmf.14.4.267.276.
[69] Andersen KV, Lange AP, Helweg-Larsen K. A Perinatal Audit of Stillbirths in Three Danish Counties. Scandinavian Journal of Social Medicine 1991;19:127–33. https://doi.org/10.1177/140349489101900208.
[70] Westergaard HB, Langhoff-Roos J, Larsen S, Borch-Christensen H, Lindmark G. Intrapartum death of nonmalformed fetuses in Denmark and Sweden in 1991. A perinatal audit. Acta Obstet Gynecol Scand 1997;76:959–63. https://doi.org/10.3109/00016349709034909.

[71] Sauvegrain P, Carayol M, Piedvache A, Guéry E, Bréart G, Bucourt M, et al. Understanding high rates of stillbirth and neonatal death in a disadvantaged, high-migrant district in France: A perinatal audit. Acta Obstet Gynecol Scand 2020;99:1163–73. https://doi.org/10.1111/aogs.13838.
[72] de Caunes F, Alexander GR, Berchel C, Guengant JP, Papiernik E. The Guadeloupean perinatal mortality audit: process, results, and implications. Am J Prev Med 1990;6:339–45.
[73] Furst AL, Shamba E. Methodological issues associated with an audit of stillbirth in a family medicine practice in Israel. Fam Pract 1989;6:177–81. https://doi.org/10.1093/fampra/6.3.177.
[74] D'Aloja P, Salvatore MA, Sampaolo L, Privitera MG, Donati S, Perinatal Mortality Surveillance System Working Group. A nationwide surveillance system to reduce perinatal death cases in Italy: implementing a population-based pilot project. E&P 2021;45:343–52. https://doi.org/10.19191/EP21.5.A002.097.
[75] Alderliesten ME, Stronks K, Bonsel GJ, Smit BJ, van Campen MMJ, van Lith JMM, et al. Design and evaluation of a regional perinatal audit. Eur J Obstet Gynecol Reprod Biol 2008;137:141–5. https://doi.org/10.1016/j.ejogrb.2007.06.002.
[76] Dekker CJ, Springer MP, Kanhai HHH. Perinatal mortality in a region where obstetric primary care is provided by the general practitioner: An audit. Huisarts en Wetenschap 2003;46:191–5.
[77] Eskes M, van Alten D, Treffers PE. The Wormerveer study; perinatal mortality and non-optimal management in a practice of independent midwives. Eur J Obstet Gynecol Reprod Biol 1993;51:91–5. https://doi.org/10.1016/0028-2243(93)90019-9.
[78] van Diem M, De Reu P, Eskes M, Brouwers H, Holleboom C, Slagter-Roukema T, et al. National perinatal audit, a feasible initiative for the Netherlands!? A validation study. Acta Obstet Gynecol Scand 2010;89:1168–73. https://doi.org/10.3109/00016349.2010.500468.
[79] van Diem MT, Timmer A, Bergman KA, Bouman K, van Egmond N, Stant DA, et al. The implementation of unit-based perinatal mortality audit in perinatal cooperation units in the northern region of the Netherlands. BMC Health Serv Res 2012;12:195. https://doi.org/10.1186/1472-6963-12-195.
[80] Wolleswinkel-van den Bosch JH, Vredevoogd CB, Borkent-Polet M, van Eyck J, Fetter WPF, Lagro-Janssen TLM, et al. Substandard factors in perinatal care in The Netherlands: a regional audit of perinatal deaths. Acta Obstet Gynecol Scand 2002;81:17–24. https://doi.org/10.1034/j.1600-0412.2002.810104.x.
[81] Eskes M, Waelput AJM, Erwich JJHM, Brouwers HAA, Ravelli ACJ, Achterberg PW, et al. Term perinatal mortality audit in the Netherlands 2010–2012: a population-based cohort study. BMJ Open 2014;4:e005652. https://doi.org/10.1136/bmjopen-2014-005652.
[82] PMMRC. Fourteenth Annual Report of the Perinatal and Maternal Mortality Review Committee | Te Pūrongo ā-Tau Tekau mā Whā o te Komiti Arotake Mate Pēpi, Mate Whaea Hoki: Reporting mortality and morbidity 2018 | Te tuku pūrongo mō te mate me te whakamate 2018. Wellington: Health Quality & Safety Commission.; 2021.
[83] Berge LN, Rasmussen S, Dahl LB. Evaluation of fetal and neonatal mortality at the University Hospital of Tromsø, Norway, from 1976 to 1989. Acta Obstet Gynecol Scand 1991;70:275–82. https://doi.org/10.3109/00016349109007872.
[84] Bjellmo S, Hjelle S, Krebs L, Magnussen E, Vik T. Adherence to guidelines and suboptimal practice in term breech delivery with perinatal death- a population-based case-control study in Norway. BMC Pregnancy Childbirth 2019;19:330. https://doi.org/10.1186/s12884-019-2464-7.
[85] Fossen D, Silberg IE. [Perinatal deaths in the county of Ostfold 1989-97]. Tidsskr Nor Laegeforen 1999;119:1272–5.
[86] Han JY, Huang EY, Tan KH. Targeted patient education-A critical step toward reducing stillbirth rates. Perinatology 2018;19:41–9.
[87] De La Puente ML, Martí A, Pascual E, Prat N, Piqué P, Codina R, et al. Análisis de la mortalidad perinatal en el Bages (Barcelona). Revista de Calidad Asistencial 2002;17:106–10. https://doi.org/10.1016/S1134-282X(02)77486-1.
[88] Miranda JA, Herruzo AJ, Mozas J, Calderón MA, Agüera J, Biel E, et al. Influence of obstetric and perinatal care on perinatal mortality. Eur J Obstet Gynecol Reprod Biol 1996;67:103–7. https://doi.org/10.1016/0301-2115(96)02434-7.

[89] Eksmyr R, Larssen KE, Bakketeig LS, Bergsjø P, Finne P, Laurini R, et al. Perinatal mortality in a Swedish county 1973-1978. Time trends revealed by perinatal audit. Acta Paediatr Scand 1986;75:17–23. https://doi.org/10.1111/j.1651-2227.1986.tb10151.x.
[90] Essén B, Bödker B, Sjöberg NO, Langhoff-Roos J, Greisen G, Gudmundsson S, et al. Are some perinatal deaths in immigrant groups linked to suboptimal perinatal care services? BJOG 2002;109:677–82.
[91] Sterpu I, Bolk J, Perers Öberg S, Hulthén Varli I, Wiberg Itzel E. Could a multidisciplinary regional audit identify avoidable factors and delays that contribute to stillbirths? A retrospective cohort study. BMC Pregnancy Childbirth 2020;20:700. https://doi.org/10.1186/s12884-020-03402-z.
[92] Cross-Sudworth F, Williams M, Gardosi J. Perinatal deaths of migrant mothers: Adverse outcomes from unrecognised risks and substandard care factors. British Journal of Midwifery 2015;23:734–40. https://doi.org/10.12968/bjom.2015.23.10.734.
[93] Draper ES, Kurinczuk JJ, Kenyon S, on behalf of MBRRACE-UK. MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester; 2017.
[94] Hundley V. Determining success in the provision of maternity care. PhD. University of Aberdeen (United Kingdom), 2001.
[95] Maternal and Child Health Research Consortium. Confidential Enquiry into Stillbirths and Deaths in Infancy: 6th annual report. London: Maternal and Child Health Research Consortium; 1999.
[96] Mersey Region Working Party on Perinatal Mortality. Confidential inquiry into perinatal deaths in the Mersey region. Lancet (London, England) 1982;1:491–4.
[97] Tan KH, Wyldes MP, Settatree R, Mitchell T. Confidential regional enquiry into mature stillbirths and neonatal deaths--a multi-disciplinary peer panel perspective of the perinatal care of 238 deaths. Singapore Med J 1999;40:251–5.
[98] Tang A-W, Sabir N, Comber K, Liebling R, Pollard J, Roberts D. A pro forma and review process for the assessment of standards of care in stillbirths: Assessment of standards of care in stillbirths. BJOG: An International Journal of Obstetrics & Gynaecology 2011;118:1661–4. https://doi.org/10.1111/j.1471-0528.2011.03094.x.
[99] Bausch LC, Smith CV. A focused review of fetal deaths in Nebraska in 1992. The Nebraska Medical Journal 1996;81:120–1.
[100] Harper RG, Sokal MM, Sokal S, Mastrota VF, Davis JG. The high-risk perinatal registry. A systematic approach for reducing perinatal mortality. Obstet Gynecol 1977;50:264–8.
[101] Kieltyka L, Craig M, Goodman DA, Wise R. Louisiana implementation of the National Fetal and Infant Mortality Review (NFIMR) program model: successes and opportunities. Matern Child Health J 2012;16 Suppl 2:353–9. https://doi.org/10.1007/s10995-012-1186-5.
[102] Moawad AH, Lee KS, Fisher DE, Ferguson R, Phillippe M. A model for the prospective analysis of perinatal deaths in a perinatal network. American Journal of Obstetrics and Gynecology 1990;162:15–22. https://doi.org/10.1016/0002-9378(90)90811-K.
[103] The National Center for Fatality Review and Prevention. Fetal and Infant Mortality Review Manual: A Guide for Communities. Okemos: National Center for Fatality Review and Prevention; 2021.
[104] Vallejo BC. Confidential inquiry into perinatal mortality in the Lower Rio Grande Valley, 1988. Doctor of Public Health. The University of Texas School of Public Health, 1991.
[105] Amaral E, Souza JP, Surita F, Luz AG, Sousa MH, Cecatti JG, et al. A population-based surveillance study on severe acute maternal morbidity (near-miss) and adverse perinatal outcomes in Campinas, Brazil: The Vigimoma Project. BMC Pregnancy Childbirth 2011;11:9. https://doi.org/10.1186/1471-2393-11-9.
[106] Raman S, Iljadica A, Gyaneshwar R, Taito R, Fong J. Improving maternal and child health systems in Fiji through a perinatal mortality audit. International Journal of Gynecology & Obstetrics 2015;129:165–8. https://doi.org/10.1016/j.ijgo.2014.11.010.
[107] Alyahya MS, Khader YS, Al-Sheyab NA, Shattnawi KK, Altal OF, Batieha A. Modifiable Factors and Delays Associated with Neonatal Deaths and Stillbirths in Jordan: Findings from

Facility-Based Neonatal Death and Stillbirth Audits. Am J Perinatol 2023;40:731–40. https://doi.org/10.1055/s-0041-1730434.
[108] Stratulat P, Curteanu A, Caraus T, Petrov V, Gardosi J. The experience of the implementation of perinatal audit in Moldova. BJOG 2014;121 Suppl 4:167–71. https://doi.org/10.1111/1471-0528.12996.
[109] Copenhagen: WHO Regional Office For Europe. Perinatal mortality audit: North Macedonia 2019. World Health Organization; 2020.
[110] Govender I. Auditing stillbirths at Lower Umfolozi War Memorial Regional Hospital: A 12-month review. S Afr Med J 2017;107:1121–6. https://doi.org/10.7196/SAMJ.2017.v107i12.12491.
[111] Pattinson RC, Makin JD, Shaw A, Delport SD. The value of incorporating avoidable factors into perinatal audits. S Afr Med J 1995;85:145–7.
[112] Rhoda NR, Greenfield D, Muller M, Prinsloo R, Pattinson RC, Kauchali S, et al. Experiences with perinatal death reviews in South Africa--the Perinatal Problem Identification Programme: scaling up from programme to province to country. BJOG 2014;121 Suppl 4:160–6. https://doi.org/10.1111/1471-0528.12997.
[113] Ward HR, Howarth GR, Jennings OJ, Pattinson RC. Audit incorporating avoidability and appropriate intervention can significantly decrease perinatal mortality. S Afr Med J 1995;85:147–50.
[114] Wilkinson D. Reducing perinatal mortality in developing countries. Health Policy Plan 1997;12:161–5. https://doi.org/10.1093/heapol/12.2.161.
[115] Mo-suwan L, Isaranurug S, Chanvitan P, Techasena W, Sutra S, Supakunpinyo C, et al. Perinatal death pattern in the four districts of Thailand: findings from the Prospective Cohort Study of Thai Children (PCTC). J Med Assoc Thai 2009;92:660–6.
[116] Demise A, Gebrehiwot Y, Worku B, Spector JM. Prospective Audit of Avoidable Factors in Institutional Stillbirths and Early Neonatal Deaths at Tikur Anbessa Hospital in Addis Ababa, Ethiopia. Afr J Reprod Health 2015;19:78–86.
[117] Musafili A, Persson L-Å, Baribwira C, Påfs J, Mulindwa PA, Essén B. Case review of perinatal deaths at hospitals in Kigali, Rwanda: perinatal audit with application of a three-delays analysis. BMC Pregnancy Childbirth 2017;17:85. https://doi.org/10.1186/s12884-017-1269-9.
[118] El Amin S, Langhoff-Roos J, Bødker B, Bakr AA, Ashmeig AL, Ibrahim SA, et al. Introducing qualitative perinatal audit in a tertiary hospital in Sudan. Health Policy Plan 2002;17:296–303. https://doi.org/10.1093/heapol/17.3.296.
[119] Kirabira VN, Aminu M, Dewez JE, Byaruhanga R, Okong P, van den Broek N. Prospective study to explore changes in quality of care and perinatal outcomes after implementation of perinatal death audit in Uganda. BMJ Open 2020;10:e027504. https://doi.org/10.1136/bmjopen-2018-027504.
[120] Biswas A, Rahman F, Eriksson C, Halim A, Dalal K. Facility Death Review of Maternal and Neonatal Deaths in Bangladesh. PLoS One 2015;10:e0141902. https://doi.org/10.1371/journal.pone.0141902.
[121] Bhatt RV. Professional responsibility in maternity care: role of medical audit. Int J Gynaecol Obstet 1989;30:47–50. https://doi.org/10.1016/0020-7292(89)90214-2.
[122] Sharma B, Aggarwal N, Suri V, Siwatch S, Kakkar N, Venkataseshan S. Facility-based stillbirth surveillance review and response: an initiative towards reducing stillbirths in a tertiary care hospital of India. J Perinat Med 2022;50:722–8. https://doi.org/10.1515/jpm-2021-0440.
[123] Supratikto G, Wirth ME, Achadi E, Cohen S, Ronsmans C. A district-based audit of the causes and circumstances of maternal deaths in South Kalimantan, Indonesia. Bull World Health Organ 2002;80:228–34.
[124] Bandali S, Thomas C, Wamalwa P, Mahendra S, Kaimenyi P, Warfa O, et al. Strengthening the "P" in Maternal and Perinatal Death Surveillance and Response in Bungoma county, Kenya: implications for scale-up. BMC Health Serv Res 2019;19:611. https://doi.org/10.1186/s12913-019-4431-4.
[125] Omwodo K. A qualitative perinatal audit at a rural health facility in Eldoret, Kenya. Int J Community Med Public Health 2020;7:449. https://doi.org/10.18203/2394-6040.ijcmph20200413.

[126] Aminu M. Cause of and Factors Contributing to Stillbirth in Sub-Saharan Africa. PhD. The University of Liverpool (United Kingdom), 2017.
[127] Vallely LM, Smith R, Bolnga JW, Babona D, Riddell MA, Mengi A, et al. Perinatal death audit and classification of stillbirths in two provinces in Papua New Guinea: A retrospective analysis. Int J Gynaecol Obstet 2021;153:160–8. https://doi.org/10.1002/ijgo.13431.
[128] Hinderaker SG, Olsen BE, Bergsjø PB, Gasheka P, Lie RT, Havnen J, et al. Avoidable stillbirths and neonatal deaths in rural Tanzania. BJOG 2003;110:616–23.
[129] Maaløe N, Housseine N, Bygbjerg IC, Meguid T, Khamis RS, Mohamed AG, et al. Stillbirths and quality of care during labour at the low resource referral hospital of Zanzibar: a case-control study. BMC Pregnancy Childbirth 2016;16:351. https://doi.org/10.1186/s12884-016-1142-2.
[130] Mbaruku G, van Roosmalen J, Kimondo I, Bilango F, Bergström S. Perinatal audit using the 3-delays model in western Tanzania. Int J Gynaecol Obstet 2009;106:85–8. https://doi.org/10.1016/j.ijgo.2009.04.008.
[131] Mdoe P, Katengu S, Guga G, Daudi V, Kiligo IE, Gidabayda J, et al. Perinatal mortality audit in a rural referral hospital in Tanzania to inform future interventions: A descriptive study. PLoS One 2022;17:e0264904. https://doi.org/10.1371/journal.pone.0264904.
[132] Wilkins A, Earnest J, Mccarthy EA, Shub A. A retrospective review of stillbirths at the national hospital in Timor-Leste. Aust NZ J Obst Gynaeco 2015;55:331–6. https://doi.org/10.1111/ajo.12337.
[133] Kasengele CT, Mowa R, Katai C, Kunda S, Ng'ambi M, Porteous C, et al. Factors contributing to intrapartum stillbirth: a criteria-based audit to support midwifery practice in Zambia. African Journal of Midwifery and Women's Health 2017;11:67–71. https://doi.org/10.12968/ajmw.2017.11.2.67.
[134] The World Bank. World Bank Country and Lending Groups. The World Bank 2022. https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups (accessed May 22, 2022).
[135] Miller ES, Minturn L, Linn R, Weese-Mayer DE, Ernst LM. Stillbirth evaluation: a stepwise assessment of placental pathology and autopsy. Am J Obstet Gynecol 2016;214:115.e1-6. https://doi.org/10.1016/j.ajog.2015.08.049.
[136] Ptacek I, Sebire NJ, Man JA, Brownbill P, Heazell AEP. Systematic review of placental pathology reported in association with stillbirth. Placenta 2014;35:552–62. https://doi.org/10.1016/j.placenta.2014.05.011.
[137] Scalise C, Cordasco F, Sacco MA, Ricci P, Aquila I. The Importance of Post-Mortem Investigations in Stillbirths: Case Studies and a Review of the Literature. Int J Environ Res Public Health 2022;19:8817. https://doi.org/10.3390/ijerph19148817.
[138] Flenady V, Wojcieszek AM, Middleton P, Ellwood D, Erwich JJ, Coory M, et al. Stillbirths: recall to action in high-income countries. Lancet 2016;387:691–702. https://doi.org/10.1016/S0140-6736(15)01020-X.
[139] Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns 2008;73:526–35. https://doi.org/10.1016/j.pec.2008.07.018.
[140] Curtis K, Fry M, Shaban RZ, Considine J. Translating research findings to clinical nursing practice. J Clin Nurs 2017;26:862–72. https://doi.org/10.1111/jocn.13586.
[141] US Department of Veterans Affairs. Root Cause Analysis Tools. VA National Center for Patient Safety; 2016.
[142] Flenady V, Middleton P, Smith GC, Duke W, Erwich JJ, Khong TY, et al. Stillbirths: the way forward in high-income countries. Lancet 2011;377:1703–17. https://doi.org/10.1016/S0140-6736(11)60064-0.
[143] Aminu M, Unkels R, Mdegela M, Utz B, Adaji S, van den Broek N. Causes of and factors associated with stillbirth in low- and middle-income countries: a systematic literature review. BJOG 2014;121 Suppl 4:141–53. https://doi.org/10.1111/1471-0528.12995.
[144] Lawn JE, Yakoob MY, Haws RA, Soomro T, Darmstadt GL, Bhutta ZA. 3.2 million stillbirths: epidemiology and overview of the evidence review. BMC Pregnancy Childbirth 2009;9:S2. https://doi.org/10.1186/1471-2393-9-S1-S2.

[145] Lawn JE, Gravett MG, Nunes TM, Rubens CE, Stanton C, GAPPS Review Group. Global report on preterm birth and stillbirth (1 of 7): definitions, description of the burden and opportunities to improve data. BMC Pregnancy Childbirth 2010;10 Suppl 1:S1. https://doi.org/10.1186/1471-2393-10-S1-S1.
[146] Yasmin S, Osrin D, Paul E, Costello A. Neonatal mortality of low-birth-weight infants in Bangladesh. Bull World Health Organ 2001;79:608–14.
[147] Flenady V, Frøen JF, Pinar H, Torabi R, Saastad E, Guyon G, et al. An evaluation of classification systems for stillbirth. BMC Pregnancy Childbirth 2009;9:24. https://doi.org/10.1186/1471-2393-9-24.
[148] Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a Definition of Mixed Methods Research. Journal of Mixed Methods Research 2007;1:112–33. https://doi.org/10.1177/1558689806298224.
[149] Johnson RB, Onwuegbuzie AJ. Mixed Methods Research: A Research Paradigm Whose Time Has Come. Educational Researcher 2004;33:14–26.
[150] Foster C. Methodological pragmatism in educational research: from qualitative-quantitative to exploratory-confirmatory distinctions. International Journal of Research & Method in Education 2024;47:4–19. https://doi.org/10.1080/1743727X.2023.2210063.
[151] Tashakkori A, Teddlie C. Mixed methodology: combining qualitative and quantitative approaches. Nachdr. Thousand Oaks: Sage Publ; 2008.
[152] Schoonenboom J, Johnson RB. How to Construct a Mixed Methods Research Design. Kolner Z Soz Sozpsychol 2017;69:107–31. https://doi.org/10.1007/s11577-017-0454-1.
[153] Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative Research 2006;6:97–113. https://doi.org/10.1177/1468794106058877.
[154] Morse JM. Approaches to qualitative-quantitative methodological triangulation. Nurs Res 1991;40:120–3.
[155] Loomis D, Maxwell J. Mixed methods design: An alternative approach. Handbook of Mixed Methods in Social & Behavioral Research, Sage Publications, Thousand Oaks 2003.
[156] Teddlie C, Tashakkori A. Foundations of mixed methods research: integrating quantitative and qualitative approaches in the social and behavioral sciences. illustrated, reprint ed. Los Angeles: SAGE Publ; 2010.
[157] Nair M, Bezbaruah B, Bora AK, Bora K, Chhabra S, Choudhury SS, et al. Maternal and perinatal Health Research Collaboration, India (MaatHRI): methodology for establishing a hospital-based research platform in a low and middle income country setting. F1000Res 2020;9:683. https://doi.org/10.12688/f1000research.24923.3.
[158] Cheng TS, Zahir F, Carolin SV, Verma A, Rao S, Choudhury SS, et al. Risk factors for labour induction and augmentation: a multicentre prospective cohort study in India. Lancet Reg Health Southeast Asia 2024;25:100417. https://doi.org/10.1016/j.lansea.2024.100417.
[159] Nair M, Chhabra S, Choudhury SS, Deka D, Deka G, Kakoty SD, et al. Relationship between anaemia, coagulation parameters during pregnancy and postpartum haemorrhage at childbirth: a prospective cohort study. BMJ Open 2021;11:e050815. https://doi.org/10.1136/bmjopen-2021-050815.
[160] Cheng TS, Zahir F, Solomi C, Verma A, Rao S, Choudhury SS, et al. Does induction or augmentation of labor increase the risk of postpartum hemorrhage in pregnant women with anemia? A multicenter prospective cohort study in India. Int J Gynaecol Obstet 2024. https://doi.org/10.1002/ijgo.16008.
[161] Victora CG, Huttly SR, Fuchs SC, Olinto MT. The role of conceptual frameworks in epidemiological analysis: a hierarchical approach. Int J Epidemiol 1997;26:224–7. https://doi.org/10.1093/ije/26.1.224.
[162] Mbah AK, Alio AP, Marty PJ, Bruder K, Whiteman VE, Salihu HM. Pre-eclampsia in the first pregnancy and subsequent risk of stillbirth in black and white gravidas. Eur J Obstet Gynecol Reprod Biol 2010;149:165–9. https://doi.org/10.1016/j.ejogrb.2009.12.035.
[163] Gardosi J, Madurasinghe V, Williams M, Malik A, Francis A. Maternal and fetal risk factors for stillbirth: population based study. BMJ 2013;346:f108. https://doi.org/10.1136/bmj.f108.
[164] Haruyama R, Gilmour S, Ota E, Abe SK, Rahman MM, Nomura S, et al. Causes and risk factors for singleton stillbirth in Japan: Analysis of a nationwide perinatal database, 2013-2014. Sci Rep 2018;8:4117. https://doi.org/10.1038/s41598-018-22546-9.

[165] Planning Commission (Government of India). Press Note on Poverty Estimates, 2011-12. 2013.
[166] Misra A, Chowbey P, Makkar BM, Vikram NK, Wasir JS, Chadha D, et al. Consensus statement for diagnosis of obesity, abdominal obesity and the metabolic syndrome for Asian Indians and recommendations for physical activity, medical and surgical management. J Assoc Physicians India 2009;57:163–70.
[167] World Health Organization. WHO antenatal care randomized trial : manual for the implementation of the new model. Ensayo Clínico Aleatorizado de Control Prenatal de La OMS : Manual Para La Puesta En Práctica Del Nuevo Modelo de Control Prenatal 2002.
[168] World Health Organization. WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organization; 2016.
[169] National Health Mission. Anemia Mukt Bharat: Poshan Abhiyaan. PM's Overarching Scheme for Holistic Nourishment 2023. https://anemiamuktbharat.info/ (accessed September 18, 2023).
[170] World Health Organization. Haemoglobin concentrations for the diagnosis of anaemia and assessment of severity. Geneva: World Health Organization; 2011.
[171] Magee LA, Brown MA, Hall DR, Gupte S, Hennessy A, Karumanchi SA, et al. The 2021 International Society for the Study of Hypertension in Pregnancy classification, diagnosis & management recommendations for international practice. Pregnancy Hypertens 2022;27:148–69. https://doi.org/10.1016/j.preghy.2021.09.008.
[172] Villar J, Ismail LC, Victora CG, Ohuma EO, Bertino E, Altman DG, et al. International standards for newborn weight, length, and head circumference by gestational age and sex: the Newborn Cross-Sectional Study of the INTERGROWTH-21st Project. The Lancet 2014;384:857–68. https://doi.org/10.1016/S0140-6736(14)60932-6.
[173] World Health Organization. A conceptual framework for action on the social determinants of health 2010:76.
[174] Alkire S, Seth S. Selecting a Targeting Method to Identify BPL Households in India. Soc Indic Res 2013;112:417–46. https://doi.org/10.1007/s11205-013-0254-6.
[175] Drèze J, Khera R. The BPL Census and a Possible Alternative. Economic and Political Weekly 2010;45:54–63.
[176] Ram F, Mohanty SK, Ram U. Understanding the Distribution of BPL Cards: All-India and Selected States. Economic and Political Weekly 2009;44:66–71.
[177] Goyal LD, Verma M, Garg P, Bhatt G. Variations in the patterns of tobacco usage among indian females - findings from the global adult tobacco survey India. BMC Womens Health 2022;22:442. https://doi.org/10.1186/s12905-022-02014-3.
[178] Lal P, Aghi M, Sharma D, Pandey A. Age of initiation of cigarette smoking and quit attempts among young women in India - evidence from Global Adult Tobacco Survey 2009 and 2017. Tob Induc Dis 2018;16. https://doi.org/10.18332/tid/84333.
[179] Gupta V, Yadav K, Anand K. Patterns of tobacco use across rural, urban, and urban-slum populations in a north Indian community. Indian J Community Med 2010;35:245–51. https://doi.org/10.4103/0970-0218.66877.
[180] RStudio Team. RStudio: Integrated Development for R 2023.
[181] Ulm K. A simple method to calculate the confidence interval of a standardized mortality ratio (SMR). Am J Epidemiol 1990;131:373–5. https://doi.org/10.1093/oxfordjournals.aje.a115507.
[182] Zou G. A Modified Poisson Regression Approach to Prospective Studies with Binary Data. American Journal of Epidemiology 2004;159:702–6. https://doi.org/10.1093/aje/kwh090.
[183] Knol MJ, Le Cessie S, Algra A, Vandenbroucke JP, Groenwold RHH. Overestimation of risk ratios by odds ratios in trials and cohort studies: alternatives to logistic regression. CMAJ 2012;184:895–9. https://doi.org/10.1503/cmaj.101715.
[184] Chen W, Qian L, Shi J, Franklin M. Comparing performance between log-binomial and robust Poisson regression models for estimating risk ratios under model misspecification. BMC Med Res Methodol 2018;18:63. https://doi.org/10.1186/s12874-018-0519-5.
[185] Hirst JE, Villar J, Victora CG, Papageorghiou AT, Finkton D, Barros FC, et al. The antepartum stillbirth syndrome: risk factors and pregnancy conditions identified from the INTERGROWTH-21st Project. BJOG 2018;125:1145–53. https://doi.org/10.1111/1471-0528.14463.

[186] Platt RW. A Proportional Hazards Model with Time-dependent Covariates and Time-varying Effects for Analysis of Fetal and Infant Death. American Journal of Epidemiology 2004;160:199–206. https://doi.org/10.1093/aje/kwh201.
[187] Smith GCS. Estimating risks of perinatal death. Am J Obstet Gynecol 2005;192:17–22. https://doi.org/10.1016/j.ajog.2004.08.014.
[188] Guest G, Namey E, Taylor J, Eley N, McKenna K. Comparing focus groups and individual interviews: findings from a randomized study. International Journal of Social Research Methodology 2017;20:693–708. https://doi.org/10.1080/13645579.2017.1281601.
[189] Kitzinger J. Qualitative Research: Introducing focus groups. BMJ 1995;311:299–302. https://doi.org/10.1136/bmj.311.7000.299.
[190] Tausch AP, Menold N. Methodological Aspects of Focus Groups in Health Research: Results of Qualitative Interviews With Focus Group Moderators. Glob Qual Nurs Res 2016;3:2333393616630466. https://doi.org/10.1177/2333393616630466.
[191] Crowe S, Cresswell K, Robertson A, Huby G, Avery A, Sheikh A. The case study approach. BMC Med Res Methodol 2011;11:100. https://doi.org/10.1186/1471-2288-11-100.
[192] Stake RE. The art of case study research. Thousand Oaks, CA, US: Sage Publications, Inc; 1995.
[193] Simons H. Case study research in practice. Los Angeles: Sage; 2009.
[194] Pinnock H, Huby G, Powell A, Kielmann T, Price D, Williams S, et al. The process of planning, development and implementation of a General Practitioner with a Special Interest service in Primary Care Organisations in England and Wales: a comparative prospective case study. Report for the National Co-Ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO) 2008.
[195] Williams JP. Non-participant observation. In: Given LM, editor. The Sage encyclopedia of qualitative research methods, Los Angeles, Calif: Sage Publications; 2008.
[196] Morgan D. Focus Groups as Qualitative Research. 2455 Teller Road, Thousand Oaks California 91320 United States of America: SAGE Publications, Inc.; 1997. https://doi.org/10.4135/9781412984287.
[197] Willcox M. Confidential enquiry into child deaths in two contrasting settings in Africa. PhD. University of Oxford, 2016.
[198] Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011;6:42. https://doi.org/10.1186/1748-5908-6-42.
[199] Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). Health Technol Assess 2015;19:1–188. https://doi.org/10.3310/hta19990.
[200] Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. London: Silverback Publishing; 2014.
[201] Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013;13:117. https://doi.org/10.1186/1471-2288-13-117.
[202] Dalglish SL, Khalid H, McMahon SA. Document analysis in health policy research: the READ approach. Health Policy and Planning 2021;35:1424–31. https://doi.org/10.1093/heapol/czaa064.
[203] Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. The Qualitative Researcher's Companion, 2455 Teller Road, Thousand Oaks California 91320 United States of America: SAGE Publications, Inc.; 2002, p. 305–29. https://doi.org/10.4135/9781412986274.n12.
[204] Ritchie J, Lewis J, McNaughton Nicholls C, Ormston R, editors. Qualitative research practice: a guide for social science students and researchers. Second edition. Los Angeles: Sage; 2014.
[205] Belizán M, Bergh A-M, Cilliers C, Pattinson RC, Voce A, the Synergy Group. Stages of change: A qualitative study on the implementation of a perinatal audit programme in South Africa. BMC Health Serv Res 2011;11:243. https://doi.org/10.1186/1472-6963-11-243.

[206] Congo B, Sanon D, Millogo T, Ouedraogo CM, Yaméogo WME, Meda ZC, et al. Inadequate programming, insufficient communication and non-compliance with the basic principles of maternal death audits in health districts in Burkina Faso: a qualitative study. Reprod Health 2017;14:121. https://doi.org/10.1186/s12978-017-0379-1.
[207] Hofman JJ, Mohammed H. Experiences with facility-based maternal death reviews in northern Nigeria. Int J Gynaecol Obstet 2014;126:111–4. https://doi.org/10.1016/j.ijgo.2014.02.014.
[208] Lumivero. NVivo 2023.
[209] Ellis C. Emotional and ethical quagmires in returning to the field. Journal of Contemporary Ethnography 1995;24:68–98. https://doi.org/10.1177/089124195024001003.
[210] Sieber J, Tolich M. Planning Ethically Responsible Research. 2455 Teller Road, Thousand Oaks California 91320 United States: SAGE Publications, Inc.; 2013. https://doi.org/10.4135/9781506335162.
[211] Tolich M. Internal Confidentiality: When Confidentiality Assurances Fail Relational Informants. Qualitative Sociology 2004;27:101–6. https://doi.org/10.1023/B:QUAS.0000015546.20441.4a.
[212] Souza JP, Day LT, Rezende-Gomes AC, Zhang J, Mori R, Baguiya A, et al. A global analysis of the determinants of maternal health and transitions in maternal mortality. The Lancet Global Health 2024;12:e306–16. https://doi.org/10.1016/S2214-109X(23)00468-0.
[213] Basta M, Hanif K, Zafar S, Khabazeh A, Amin F, Sharif Khan S, et al. Impact of Hypertensive Disorders of Pregnancy on Stillbirth and Other Perinatal Outcomes: A Multi-Center Retrospective Study. Cureus 2022;14:e22788. https://doi.org/10.7759/cureus.22788.
[214] Nair M, Choudhury MK, Choudhury SS, Kakoty SD, Sarma UC, Webster P, et al. Association between maternal anaemia and pregnancy outcomes: a cohort study in Assam, India. BMJ Glob Health 2016;1:e000026. https://doi.org/10.1136/bmjgh-2015-000026.
[215] Nair M, Churchill D, Robinson S, Nelson-Piercy C, Stanworth SJ, Knight M. Association between maternal haemoglobin and stillbirth: a cohort study among a multi-ethnic population in England. Br J Haematol 2017;179:829–37. https://doi.org/10.1111/bjh.14961.
[216] Vogel JP, Souza JP, Mori R, Morisaki N, Lumbiganon P, Laopaiboon M, et al. Maternal complications and perinatal mortality: findings of the World Health Organization Multicountry Survey on Maternal and Newborn Health. BJOG 2014;121 Suppl 1:76–88. https://doi.org/10.1111/1471-0528.12633.
[217] Ngoc NTN, Merialdi M, Abdel-Aleem H, Carroli G, Purwar M, Zavaleta N, et al. Causes of stillbirths and early neonatal deaths: data from 7993 pregnancies in six developing countries. Bull World Health Organ 2006;84:699–705. https://doi.org/10.2471/blt.05.027300.
[218] Nair M, Choudhury SS, Rani A, Solomi C, Kakoty SD, Medhi R, et al. The complex relationship between iron status and anemia in pregnant and postpartum women in India: Analysis of two Indian study cohorts of uncomplicated pregnancies. Am J Hematol 2023;98:1721–31. https://doi.org/10.1002/ajh.27059.
[219] Kc A, Wrammert J, Ewald U, Clark RB, Gautam J, Baral G, et al. Incidence of intrapartum stillbirth and associated risk factors in tertiary care setting of Nepal: a case-control study. Reprod Health 2016;13:103. https://doi.org/10.1186/s12978-016-0226-9.
[220] Smith GC. Life-table analysis of the risk of perinatal death at term and post term in singleton pregnancies. Am J Obstet Gynecol 2001;184:489–96. https://doi.org/10.1067/mob.2001.109735.
[221] Trudell AS, Cahill AG, Tuuli MG, Macones GA, Odibo AO. Risk of stillbirth after 37 weeks in pregnancies complicated by small-for-gestational-age fetuses. Am J Obstet Gynecol 2013;208:376.e1-7. https://doi.org/10.1016/j.ajog.2013.02.030.
[222] Pandey AK, Raushan MR, Gautam D, Neogi SB. Alarming Trends of Cesarean Section—Time to Rethink: Evidence From a Large-Scale Cross-sectional Sample Survey in India. J Med Internet Res 2023;25:e41892. https://doi.org/10.2196/41892.
[223] Betran AP, Ye J, Moller A-B, Souza JP, Zhang J. Trends and projections of caesarean section rates: global and regional estimates. BMJ Glob Health 2021;6:e005671. https://doi.org/10.1136/bmjgh-2021-005671.
[224] Boerma T, Ronsmans C, Melesse DY, Barros AJD, Barros FC, Juan L, et al. Global epidemiology of use of and disparities in caesarean sections. Lancet 2018;392:1341–8. https://doi.org/10.1016/S0140-6736(18)31928-7.

[225] Dziak JJ, Dierker LC, Abar B. The Interpretation of Statistical Power after the Data have been Gathered. Curr Psychol 2020;39:870–7. https://doi.org/10.1007/s12144-018-0018-1.
[226] Milton R, Modibbo F, Gillespie D, Alkali FI, Mukaddas AS, Kassim A, et al. Incidence and sociodemographic, living environment and maternal health associations with stillbirth in a tertiary healthcare setting in Kano, Northern Nigeria. BMC Pregnancy Childbirth 2022;22:692. https://doi.org/10.1186/s12884-022-04971-x.
[227] Komboigo BE, Zamane H, Coulibaly A, Sib SR, Thiombiano M, Thieba B. Factors associated with intrapartum stillbirth in a tertiary teaching hospital in Burkina Faso. Front Glob Womens Health 2023;4:1038817. https://doi.org/10.3389/fgwh.2023.1038817.
[228] Dewalt DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP. Literacy and health outcomes: a systematic review of the literature. J Gen Intern Med 2004;19:1228–39. https://doi.org/10.1111/j.1525-1497.2004.40153.x.
[229] Gokhale MK, Rao SS, Garole VR. Infant mortality in India: use of maternal and child health services in relation to literacy status. J Health Popul Nutr 2002;20:138–47.
[230] Lam Y, Broaddus ET, Surkan PJ. Literacy and healthcare-seeking among women with low educational attainment: analysis of cross-sectional data from the 2011 Nepal Demographic and Health Survey. Int J Equity Health 2013;12:95. https://doi.org/10.1186/1475-9276-12-95.
[231] Khanam A, Vohra K, Achary Mg T, Ranjith A, Bharti H, Ghosh R, et al. A Systematic review of factors affecting compliance toward oral iron-folic acid supplementation among pregnant women in India. Indian J Community Health 2022;34:456–63. https://doi.org/10.47203/IJCH.2022.v34i04.002.
[232] Salihu HM, Wilson RE, Alio AP, Kirby RS. Advanced maternal age and risk of antepartum and intrapartum stillbirth. J of Obstet and Gynaecol 2008;34:843–50. https://doi.org/10.1111/j.1447-0756.2008.00855.x.
[233] Pasupathy D, Wood AM, Pell JP, Fleming M, Smith GCS. Advanced maternal age and the risk of perinatal death due to intrapartum anoxia at term. Journal of Epidemiology & Community Health 2011;65:241–5. https://doi.org/10.1136/jech.2009.097170.
[234] Lean SC, Heazell AEP, Dilworth MR, Mills TA, Jones RL. Placental Dysfunction Underlies Increased Risk of Fetal Growth Restriction and Stillbirth in Advanced Maternal Age Women. Sci Rep 2017;7:9677. https://doi.org/10.1038/s41598-017-09814-w.
[235] Kramer MS, Liu S, Luo Z, Yuan H, Platt RW, Joseph KS. Analysis of Perinatal Mortality and Its Components: Time for a Change? American Journal of Epidemiology 2002;156:493–7. https://doi.org/10.1093/aje/kwf077.
[236] Beardmore-Gray A, Vousden N, Seed PT, Vwalika B, Chinkoyo S, Sichone V, et al. Planned delivery or expectant management for late preterm pre-eclampsia in low-income and middle-income countries (CRADLE-4): a multicentre, open-label, randomised controlled trial. Lancet 2023;402:386–96. https://doi.org/10.1016/S0140-6736(23)00688-8.
[237] Countdown to 2030. Country Equity Profiles - India. Country Equity Profiles 2023. https://www.countdown2030.org/equity-profiles (accessed February 21, 2024).
[238] Beardmore-Gray A, Seed PT, Fleminger J, Zwertbroek E, Bernardes T, Mol BW, et al. Planned delivery or expectant management in preeclampsia: an individual participant data meta-analysis. Am J Obstet Gynecol 2022;227:218-230.e8. https://doi.org/10.1016/j.ajog.2022.04.034.
[239] Wu G, Bazer FW, Cudd TA, Meininger CJ, Spencer TE. Maternal nutrition and fetal development. J Nutr 2004;134:2169–72. https://doi.org/10.1093/jn/134.9.2169.
[240] Alwan NA, Hamamy H. Maternal Iron Status in Pregnancy and Long-Term Health Outcomes in the Offspring. J Pediatr Genet 2015;4:111–23. https://doi.org/10.1055/s-0035-1556742.
[241] Eltayeb R, Binsaleh NK, Alsaif G, Ali RM, Alyahyawi AR, Adam I. Hemoglobin Levels, Anemia, and Their Associations with Body Mass Index among Pregnant Women in Hail Maternity Hospital, Saudi Arabia: A Cross-Sectional Study. Nutrients 2023;15:3508. https://doi.org/10.3390/nu15163508.
[242] Mocking M, Savitri AI, Uiterwaal CSPM, Amelia D, Antwi E, Baharuddin M, et al. Does body mass index early in pregnancy influence the risk of maternal anaemia? An observational study in Indonesian and Ghanaian women. BMC Public Health 2018;18:873. https://doi.org/10.1186/s12889-018-5704-2.
[243] Patel A, Prakash AA, Das PK, Gupta S, Pusdekar YV, Hibberd PL. Maternal anemia and underweight as determinants of pregnancy outcomes: cohort study in eastern rural

Maharashtra, India. BMJ Open 2018;8:e021623. https://doi.org/10.1136/bmjopen-2018-021623.
[244] Melamed N, Baschat A, Yinon Y, Athanasiadis A, Mecacci F, Figueras F, et al. FIGO (international Federation of Gynecology and obstetrics) initiative on fetal growth: best practice advice for screening, diagnosis, and management of fetal growth restriction. Int J Gynaecol Obstet 2021;152 Suppl 1:3–57. https://doi.org/10.1002/ijgo.13522.
[245] Figueras F, Gratacos E. An integrated approach to fetal growth restriction. Best Practice & Research Clinical Obstetrics & Gynaecology 2017;38:48–58. https://doi.org/10.1016/j.bpobgyn.2016.10.006.
[246] Gandhi A, Ganatra A, Sharma KA. FOGSI GCPR on Fetal Growth Restriction. Mumbai: The Federation of Obstetric and Gynaecological Societies of India (FOGSI); 2021.
[247] Adane AA, Bailey HD, Morgan VA, Galbally M, Farrant BM, Marriott R, et al. The impact of maternal prenatal mental health disorders on stillbirth and infant mortality: a systematic review and meta-analysis. Arch Womens Ment Health 2021;24:543–55. https://doi.org/10.1007/s00737-020-01099-9.
[248] Kongnyuy EJ, van den Broek N. The difficulties of conducting maternal death reviews in Malawi. BMC Pregnancy Childbirth 2008;8:42. https://doi.org/10.1186/1471-2393-8-42.
[249] Combs Thorsen V, Sundby J, Meguid T, Malata A. Easier said than done!: methodological challenges with conducting maternal death review research in Malawi. BMC Med Res Methodol 2014;14:29. https://doi.org/10.1186/1471-2288-14-29.
[250] Afayo V. Maternal death surveillance and response, barriers and facilitators in Arua Regional Referral Hospital 2018.
[251] Muvuka B. Uncovering the stories behind the numbers : a case study of maternal death surveillance and response in Goma, Democratic Republic of Congo. PhD. University of Louisville, 2019.
[252] Tayebwa E, Sayinzoga F, Umunyana J, Thapa K, Ajayi E, Kim Y-M, et al. Assessing Implementation of Maternal and Perinatal Death Surveillance and Response in Rwanda. IJERPH 2020;17:4376. https://doi.org/10.3390/ijerph17124376.
[253] Kinney MV, Ajayi G, De Graft-Johnson J, Hill K, Khadka N, Om'Iniabohs A, et al. "It might be a statistic to me, but every death matters.": An assessment of facility-level maternal and perinatal death surveillance and response systems in four sub-Saharan African countries. PLoS ONE 2020;15:e0243722. https://doi.org/10.1371/journal.pone.0243722.
[254] Nyamtema AS, Urassa DP, Pembe AB, Kisanga F, van Roosmalen J. Factors for change in maternal and perinatal audit systems in Dar es Salaam hospitals, Tanzania. BMC Pregnancy Childbirth 2010;10:29. https://doi.org/10.1186/1471-2393-10-29.
[255] Ayele B, Gebretnsae H, Hadgu T, Negash D, G/Silassie F, Alemu T, et al. Maternal and perinatal death surveillance and response in Ethiopia: Achievements, challenges and prospects. PLoS One 2019;14:e0223540. https://doi.org/10.1371/journal.pone.0223540.
[256] Mukinda FK, George A, Van Belle S, Schneider H. Practice of death surveillance and response for maternal, newborn and child health: a framework and application to a South African health district. BMJ Open 2021;11:e043783. https://doi.org/10.1136/bmjopen-2020-043783.
[257] Kinney M, Day L, Palestra F, Biswas A, Jackson D, Roos N, et al. Overcoming blame culture: key strategies to catalyse maternal and perinatal death surveillance and response. BJOG 2022;129:839–44. https://doi.org/10.1111/1471-0528.16989.
[258] Muffler N, Trabelssi MEH, De Brouwere V. Scaling up clinical audits of obstetric cases in Morocco. Trop Med Int Health 2007;12:1248–57. https://doi.org/10.1111/j.1365-3156.2007.01911.x.
[259] Jepkosgei J, Nzinga J, Adam MB, English M. Exploring healthcare workers' perceptions on the use of morbidity and mortality audits as an avenue for learning and care improvement in Kenyan hospitals' newborn units. BMC Health Serv Res 2022;22:172. https://doi.org/10.1186/s12913-022-07572-8.
[260] Armstrong CE, Lange IL, Magoma M, Ferla C, Filippi V, Ronsmans C. Strengths and weaknesses in the implementation of maternal and perinatal death reviews in Tanzania: perceptions, processes and practice. Trop Med Int Health 2014;19:1087–95. https://doi.org/10.1111/tmi.12353.

[261] De Kok B, Imamura M, Kanguru L, Owolabi O, Okonofua F, Hussein J. Achieving accountability through maternal death reviews in Nigeria: a process analysis. Health Policy and Planning 2017;32:1083–91. https://doi.org/10.1093/heapol/czx012.
[262] Bakker W, Van Den Akker T, Mwagomba B, Khukulu R, Van Elteren M, Van Roosmalen J. Health workers' perceptions of obstetric critical incident audit in Thyolo District, Malawi. Tropical Med Int Health 2011;16:1243–50. https://doi.org/10.1111/j.1365-3156.2011.02832.x.
[263] Oswald D, Sherratt F, Smith S. Handling the Hawthorne effect: The challenges surrounding a participant observer. Review of Social Studies 2014;1:53–73.
[264] Jones JE, Jones LL, Calvert MJ, Damery SL, Mathers JM. A Literature Review of Studies that Have Compared the Use of Face-To-Face and Online Focus Groups. International Journal of Qualitative Methods 2022;21:16094069221142406. https://doi.org/10.1177/16094069221142406.
[265] Abrams KM, Wang Z, Song YJ, Galindo-Gonzalez S. Data Richness Trade-Offs Between Face-to-Face, Online Audiovisual, and Online Text-Only Focus Groups. Social Science Computer Review 2015;33:80–96. https://doi.org/10.1177/0894439313519733.
[266] Brüggen E, Willems P. A Critical Comparison of Offline Focus Groups, Online Focus Groups and E-Delphi. International Journal of Market Research 2009;51:1–15. https://doi.org/10.1177/147078530905100301.
[267] Schneider SJ, Kerwin J, Frechtling J, Vivari BA. Characteristics of the Discussion in Online and Face-to-Face Focus Groups. Social Science Computer Review 2002;20:31–42. https://doi.org/10.1177/089443930202000104.
[268] Russell N, Tappis H, Mwanga JP, Black B, Thapa K, Handzel E, et al. Implementation of maternal and perinatal death surveillance and response (MPDSR) in humanitarian settings: insights and experiences of humanitarian health practitioners and global technical expert meeting attendees. Confl Health 2022;16:23. https://doi.org/10.1186/s13031-022-00440-6.
[269] Marston C, Renedo A, McGowan CR, Portela A. Effects of community participation on improving uptake of skilled care for maternal and newborn health: a systematic review. PLoS One 2013;8:e55012. https://doi.org/10.1371/journal.pone.0055012.
[270] Richard F, Ouédraogo C, Zongo V, Ouattara F, Zongo S, Gruénais ME, et al. The difficulty of questioning clinical practice: experience of facility-based case reviews in Ouagadougou, Burkina Faso. BJOG 2009;116:38–44. https://doi.org/10.1111/j.1471-0528.2008.01741.x.
[271] Maternal and Child Survival Program (MCSP). Assessment of Maternal and Perinatal Death Surveillance and Response Implementation in Zimbabwe. Maternal and Child Survival Program: Harare, Zimbabwe 2017.
[272] Lewis C, Hill M, Arthurs OJ, Hutchinson C, Chitty LS, Sebire NJ. Factors affecting uptake of postmortem examination in the prenatal, perinatal and paediatric setting. BJOG 2018;125:172–81. https://doi.org/10.1111/1471-0528.14600.
[273] Aiyelaagbe E, Scott RE, Holmes V, Lane E, Heazell AEP. Assessing the quality of bereavement care after perinatal death: development and piloting of a questionnaire to assess parents' experiences. Journal of Obstetrics and Gynaecology 2017;37:931–6. https://doi.org/10.1080/01443615.2017.1316710.
[274] Ben-Sasi K, Chitty LS, Franck LS, Thayyil S, Judge-Kronis L, Taylor AM, et al. Acceptability of a minimally invasive perinatal/paediatric autopsy: healthcare professionals' views and implications for practice. Prenatal Diagnosis 2013;33:307–12. https://doi.org/10.1002/pd.4077.
[275] Hussain F, Gurley E, Blevins J, Kone A, Al Masud A, Mulla AS, et al. Identifying and utilizing community champions and resource persons to increase MITS acceptance in Bangladesh. 69th ASTMH Annual Meeting 2020, Toronto: American Society of Tropical Medicine and Hygiene; 2020.
[276] Lofters A, Prakash V, Devotta K, Vahabi M. The potential benefits of "community champions" in the healthcare system. Healthc Manage Forum 2023;36:382–7. https://doi.org/10.1177/08404704231179911.
[277] Shields-Zeeman L, Pathare S, Walters BH, Kapadia-Kundu N, Joag K. Promoting wellbeing and improving access to mental health care through community champions in rural India: the Atmiyata intervention approach. Int J Ment Health Syst 2017;11:6. https://doi.org/10.1186/s13033-016-0113-3.

[278] Horey D, Flenady V, Conway L, McLeod E, Yee Khong T. Decision influences and aftermath: parents, stillbirth and autopsy. Health Expect 2014;17:534–44. https://doi.org/10.1111/j.1369-7625.2012.00782.x.
[279] Meaney S, Gallagher S, Lutomski JE, O'Donoghue K. Parental decision making around perinatal autopsy: a qualitative investigation. Health Expect 2015;18:3160–71. https://doi.org/10.1111/hex.12305.
[280] Snowdon C, Elbourne DR, Garcia J. Perinatal pathology in the context of a clinical trial: a review of the literature. Arch Dis Child Fetal Neonatal Ed 2004;89:F200-203. https://doi.org/10.1136/adc.2002.012740.
[281] Stock SJ, Goldsmith L, Evans MJ, Laing IA. Interventions to improve rates of post-mortem examination after stillbirth. Eur J Obstet Gynecol Reprod Biol 2010;153:148–50. https://doi.org/10.1016/j.ejogrb.2010.07.022.
[282] Das MK, Arora NK, Debata P, Chellani H, Rasaily R, Gaikwad H, et al. Why parents agree or disagree for minimally invasive tissue sampling (MITS) to identify causes of death in under-five children and stillbirth in North India: a qualitative study. BMC Pediatr 2021;21:513. https://doi.org/10.1186/s12887-021-02993-6.
[283] Downe S, Kingdon C, Kennedy R, Norwell H, McLaughlin M-J, Heazell AEP. Post-mortem examination after stillbirth: views of UK-based practitioners. Eur J Obstet Gynecol Reprod Biol 2012;162:33–7. https://doi.org/10.1016/j.ejogrb.2012.02.002.
[284] Siassakos D, Jackson S, Gleeson K, Chebsey C, Ellis A, Storey C, et al. All bereaved parents are entitled to good care after stillbirth: a mixed-methods multicentre study (INSIGHT). BJOG 2018;125:160–70. https://doi.org/10.1111/1471-0528.14765.
[285] UNICEF. Stillbirth Definition and Data Quality Assessment for Health Management Information Systems (HMIS). New York: UNICEF 2022.
[286] Lawn JE, Blencowe H, Pattinson R, Cousens S, Kumar R, Ibiebele I, et al. Stillbirths: Where? When? Why? How to make the data count? Lancet 2011;377:1448–63. https://doi.org/10.1016/S0140-6736(10)62187-3.
[287] Reinebrant HE, Leisher SH, Coory M, Henry S, Wojcieszek AM, Gardener G, et al. Making stillbirths visible: a systematic review of globally reported causes of stillbirth. BJOG 2018;125:212–24. https://doi.org/10.1111/1471-0528.14971.
[288] Mishra US, Yadav S, Joe W. The Ayushman Bharat Digital Mission of India: An Assessment. Health Systems & Reform 2024;10:2392290. https://doi.org/10.1080/23288604.2024.2392290.
[289] Press Information Bureau Government of India. Ministry of Health and Family Welfare: Update on expansion of Ayushman Bharat Digital Mission. Press Information Bureau Government of India 2023. https://pib.gov.in/PressReleseDetailm.aspx?PRID=1985424&reg=3&lang=1 (accessed December 9, 2024).
[290] McKernan J, Greene PRA, Robson DM, O'Donoghue DK. Electronic Medical Records in Obstetric and Perinatal Care. GLOWM 2021. https://doi.org/10.3843/GLOWM.412413.
[291] Plotkin M, George J, Bundala F, Tibaijuka G, Njonge L, Lemwayi R, et al. Scale-Up of Doppler to Improve Intrapartum Fetal Heart Rate Monitoring in Tanzania: A Qualitative Assessment of National and Regional/District Level Implementation Factors. IJERPH 2020;17:1931. https://doi.org/10.3390/ijerph17061931.
[292] Hanley GE, Munro S, Greyson D, Gross MM, Hundley V, Spiby H, et al. Diagnosing onset of labor: a systematic review of definitions in the research literature. BMC Pregnancy Childbirth 2016;16:71. https://doi.org/10.1186/s12884-016-0857-4.
[293] Smith LK, Van Blankenstein E, Fox G, Seaton SE, Martínez-Jiménez M, Petrou S, et al. Effect of national guidance on survival for babies born at 22 weeks' gestation in England and Wales: population based cohort study. Bmjmed 2023;2:e000579. https://doi.org/10.1136/bmjmed-2023-000579.
[294] Deputy NP, Nguyen PH, Pham H, Nguyen S, Neufeld L, Martorell R, et al. Validity of gestational age estimates by last menstrual period and neonatal examination compared to ultrasound in Vietnam. BMC Pregnancy Childbirth 2017;17:25. https://doi.org/10.1186/s12884-016-1192-5.

[295] Macaulay S, Buchmann EJ, Dunger DB, Norris SA. Reliability and validity of last menstrual period for gestational age estimation in a low-to-middle-income setting. J Obstet Gynaecol Res 2019;45:217–25. https://doi.org/10.1111/jog.13801.
[296] Unger H, Thriemer K, Ley B, Tinto H, Traoré M, Valea I, et al. The assessment of gestational age: a comparison of different methods from a malaria pregnancy cohort in sub-Saharan Africa. BMC Pregnancy Childbirth 2019;19:12. https://doi.org/10.1186/s12884-018-2128-z.
[297] Ambroise Grandjean G, Oster J, Dap M, Morel O, Hossu G. Artificial intelligence and fetal ultrasound biometry: Challenges and perspectives. Diagnostic and Interventional Imaging 2023;104:200–1. https://doi.org/10.1016/j.diii.2023.01.008.
[298] Chekijian S, Yedigaryan K, Bazarchyan A, Yaghjyan G, Sargsyan S. Continuing Medical Education and Continuing Professional Development in the Republic of Armenia: The Evolution of Legislative and Regulatory Frameworks Post Transition. J Eur CME 2020;10:1853338. https://doi.org/10.1080/21614083.2020.1853338.
[299] Chilomo C, Mondiwa M, Wasili R. Strengthening professional development in Malawi. African Journal of Midwifery and Women's Health 2014;8:10–2. https://doi.org/10.12968/ajmw.2014.8.1.10.
[300] Dunleavy K, Chevan J, Sander AP, Gasherebuka JD, Mann M. Application of a contextual instructional framework in a continuing professional development training program for physiotherapists in Rwanda. Disability and Rehabilitation 2018;40:1600–8. https://doi.org/10.1080/09638288.2017.1300692.
[301] Human Resources for Health in 2030 (HRH2030) consortium. Factors Influencing CPD Effectiveness and Practices in the Healthcare Sector in Jordan. Amman: USAID Jordan; 2018.
[302] Merry L, Castiglione SA, Rouleau G, Létourneau D, Larue C, Deschênes M-F, et al. Continuing professional development (CPD) system development, implementation, evaluation and sustainability for healthcare professionals in low- and lower-middle-income countries: a rapid scoping review. BMC Med Educ 2023;23:498. https://doi.org/10.1186/s12909-023-04427-6.
[303] Moetsana-Poka F, Lebaka M, McCarthy CF. Developing a Continuing Professional Development Program to Improve Nursing Practice in Lesotho. Afr J Midwifery Womens Health 2014;8:10–3. https://doi.org/10.12968/ajmw.2014.8.Sup2.10.
[304] Msibi GS, Mkhonta NR, Nkwanyana NR, Mamba B, Khumalo GT. Establishing a national programme for continuing professional development of nurses and midwives in Swaziland. African Journal of Midwifery and Women's Health 2014;8:14–6. https://doi.org/10.12968/ajmw.2014.8.Sup2.14.
[305] Rao C, Gupta M. The civil registration system is a potentially viable data source for reliable subnational mortality measurement in India. BMJ Glob Health 2020;5:e002586. https://doi.org/10.1136/bmjgh-2020-002586.
[306] Gupta M, Rao C, Lakshmi PVM, Prinja S, Kumar R. Estimating mortality using data from civil registration: a cross-sectional study in India. Bull World Health Organ 2016;94:10–21. https://doi.org/10.2471/BLT.15.153585.
[307] Abouchadi S, Belghiti Alaoui A, Meski FZ, De Brouwere V. Implementing a maternal mortality surveillance system in Morocco – challenges and opportunities. Tropical Med Int Health 2013;18:357–65. https://doi.org/10.1111/tmi.12053.
[308] Kidanemariam MB, Miljeteig I, Moland KM, Melberg A. Legal issues in the implementation of Maternal Death Surveillance and Response: a scoping review. Health Policy and Planning 2024;39:985–99. https://doi.org/10.1093/heapol/czae071.
[309] Smith H, Ameh C, Godia P, Maua J, Bartilol K, Amoth P, et al. Implementing Maternal Death Surveillance and Response in Kenya: Incremental Progress and Lessons Learned. Glob Health Sci Pract 2017;5:345–54. https://doi.org/10.9745/GHSP-D-17-00130.
[310] Agaro C, Beyeza-Kashesya J, Waiswa P, Sekandi JN, Tusiime S, Anguzu R, et al. The conduct of maternal and perinatal death reviews in Oyam District, Uganda: a descriptive cross-sectional study. BMC Women's Health 2016;16:38. https://doi.org/10.1186/s12905-016-0315-5.
[311] Ngwena CG, Kismödi E, Palestra F, Stahlhofer M, Mohan K. Legislation strengthening Maternal and Perinatal Death Surveillance and Response systems. Intl J Gynecology & Obste 2024;166:1367–72. https://doi.org/10.1002/ijgo.15764.
[312] Cahyanti RD, Widyawati W, Hakimi M. "Sharp downward, blunt upward": district maternal death audits' challenges to formulate evidence-based recommendations in Indonesia - a

qualitative study. BMC Pregnancy Childbirth 2021;21:730. https://doi.org/10.1186/s12884-021-04212-7.
[313] Said A, Sirili N, Massawe S, Pembe AB, Hanson C, Malqvist M. Mismatched ambition, execution and outcomes: implementing maternal death surveillance and response system in Mtwara region, Tanzania. BMJ Glob Health 2021;6:e005040. https://doi.org/10.1136/bmjgh-2021-005040.
[314] Roberts LR, Anderson BA, Lee JW, Montgomery SB. Grief and Women: Stillbirth in the Social Context of India. Int J Childbirth 2012;2:187–98. https://doi.org/10.1891/2156-5287.2.3.187.
[315] Kurinczuk JJ, Smith P, Bevan C, Brigante L, Burden C, Draper ES, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool. Fifth Annual Report – Technical Paper. Oxford: National Perinatal Epidemiology Unit; 2023.
[316] Kurinczuk JJ, Smith P, Bevan C, Brigante L, Burden C, Draper ES, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Review Tool: Fifth Annual Report. Oxford: National Perinatal Epidemiology Unit; 2023.
[317] NHS England. Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services 2023.
[318] Kumar A. The Transformation of The Indian Healthcare System. Cureus 2023;15:e39079. https://doi.org/10.7759/cureus.39079.
[319] New Jersey Statutes. New Jersey Maternal and Infant Health Innovation Center Act. 2023.
[320] Republic of Kenya. The Maternal, Newborn And Child Health Bill, 2023. 2023.

Appendices

Appendix A: Published article – Facility-based stillbirth review processes used in different countries across the world: a systematic review

Facility-based stillbirth review processes used in different countries across the world: a systematic review

Yebeen Ysabelle Boo,[a,*] Uchenna Gwacham-Anisiobi,[a] Dixa B. Thakrar,[b] Nia Roberts,[c] Jennifer J. Kurinczuk,[a] Monica Lakhanpaul,[d] and Manisha Nair[a]

[a]National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom
[b]Cancer Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom
[c]Bodleian Health Care Libraries, University of Oxford, Oxford, United Kingdom
[d]UCL Great Ormond Street Institute of Child Health, Faculty of Population Health Sciences, University College London, London, United Kingdom

eClinicalMedicine 2023;59: 101976
Published Online 27 April 2023
https://doi.org/10.1016/j.eclinm.2023.101976

Summary

Background Facility-based stillbirth review provides opportunities to estimate incidence, evaluate causes and risk factors for stillbirths, and identify any issues related to the quality of pregnancy and childbirth care which require improvement. Our aim was to systematically review all types and methods of facility-based stillbirth review processes used in different countries across the world, to examine how stillbirth reviews in facility settings are being conducted worldwide and to identify the outcomes of implementing the reviews. Moreover, to identify facilitators and barriers influencing the implementation of the identified facility-based stillbirth reviews processes by conducting subgroup analyses.

Methods A systematic review of published literature was conducted by searching MEDLINE (OvidSP) [1946-present], EMBASE (OvidSP) [1974-present], WHO Global Index Medicus (globalindexmedicus.net), Global Health (OvidSP) [1973–2022 Week 8] and CINAHL (EBSCOHost) [1982-present] from their inception until 11 January, 2023. For unpublished or grey literature, the WHO databases, Google Scholar and ProQuest Dissertations & Theses Global were searched, as well as hand searching the reference lists of included studies. MESH terms encompassing "*Clinical Audit", "*Perinatal Mortality", "Pregnancy Complications", and "Stillbirth" were used with Boolean operators. Studies that used a facility-based review process or any approach to evaluate care prior to stillbirth, and explained the methods used were included. Reviews and editorials were excluded. Three authors (YYB, UGA, and DBT) independently screened and extracted data, and assessed the risk of bias using an adapted JBI's Checklist for Case Series. A logic model was used to inform the narrative synthesis. The review protocol was registered with PROSPERO, CRD42022304239.

Findings A total of 68 studies from 17 high-income (HICs) and 22 low-and-middle-income countries (LMICs) met the inclusion criteria from a total of 7258 identified records. These were stillbirth reviews conducted at different levels: district, state, national, and international. Three types were identified: audit, review, and confidential enquiry, but not all desired components were included in most processes, which led to a mismatch between the description of the type and the actual method used. Routine data from hospital records was the most common data source for identifying stillbirths, and case assessment was based on stillbirth definition in 48 out of 68 studies. Hospital notes were the most common source of information about care received and causes/risk factors for stillbirth. Short-term and medium-term outcomes were reported in 14 studies, but impact of the review process on reducing stillbirth, which is more difficult to establish, was not reported in any study. Facilitators and barriers in implementing a successful stillbirth review process identified from 14 studies focused on three main themes: resources, expertise, and commitment.

Interpretation This systematic review's findings identified that there is a need for clear guidelines on how to measure the impact of implementation of changes based on outputs of stillbirth reviews and methods to enable effective dissemination of learning points in the future and promoting them through training platforms. In addition, there is a need to develop and adopt a universal definition of stillbirth to facilitate meaningful comparison of stillbirth rates between regions. The key limitation of this review is that while using a logic model for narrative synthesis was deemed most appropriate for this study, sequence of implementing a stillbirth review in the real world is not linear,

*Corresponding author. National Perinatal Epidemiology Unit (NPEU), Nuffield Department of Population Health, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF, United Kingdom.
E-mail address: yebeen.boo@ndph.ox.ac.uk (Y.Y. Boo).

and assumptions are often not met. Therefore, the logic model proposed in this study should be interpreted with flexibility when designing a stillbirth review process. The generated learnings from the stillbirth review processes inform the action plans and allow facilities to consider where the changes should happen to improve the quality of care in the facilities, enabling positive short-term and medium-term outcomes.

Funding Kellogg College, University of Oxford, Clarendon Fund, University of Oxford, Nuffield Department of Population Health, University of Oxford and Medical Research Council (MRC).

Copyright © 2023 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Keywords: Stillbirth; Perinatal mortality; Mortality audit; Logic model; Systematic review

Research in context

Evidence before this study

Stillbirth review at the facility level is especially critical, as it provides opportunities to review the incidence rate, causes and risk factors for stillbirths, as well as identify any issues related to the quality of pregnancy and childbirth care at the hospital. The risk factors and quality of care gaps identified may inform the implementation of evidence-based interventions for reducing facility-based stillbirth in the future. However, we could find no evidence of a systematic review that critically appraised and synthesised the methods used for facility-based stillbirth review process across the world, in detail, to date when following databases were searched from their inception until 11 January, 2023: MEDLINE (OvidSP) [1946-present], EMBASE (OvidSP) [1974-present], WHO Global Index Medicus (globalindexmedicus.net), Global Health (OvidSP) [1973–2022 Week 8] and CINAHL (EBSCOHost) [1982-present]. We also could not find any unpublished or grey literature that met our inclusion criteria from the World Health Organization (WHO) databases, Google Scholar and ProQuest Dissertations & Theses Global. The inclusion criteria for our search was any systematic reviews that reviewed all types and methods of facility-based stillbirth review processes used in different countries across the world and any systematic reviews that only reviewed types and methods of facility-based stillbirth review processes used in particular country settings or certain income levels only were excluded. MESH terms encompassing "*Clinical Audit", "*Perinatal Mortality", "Pregnancy Complications", and "Stillbirth" were used with Boolean operators for our search and there were no language or geographical restrictions.

Added value of this study

This systematic review is the first that we know of, to systematically review all types and methods of facility-based stillbirth review processes used in different countries across the world. It uses a robust methodology by including independent reviewers for screening, extracting and quality assessment. The systematic review demonstrated that stillbirth review processes are not standardised in many countries at a local/national level, despite their known importance in identifying gaps in care. However, we found that the learnings from the stillbirth review processes were able to inform action plans and allowed facilities to consider where the changes should be made to improve the quality of care in the facilities, thus enabling positive short-term and medium-term outcomes. Additionally, we identified facilitators and barriers influencing the implementation of the identified facility-based stillbirth review processes from the included studies.

Implications of all the available evidence

This systematic review identified different types and methods of facility-based stillbirth review processes implemented around the world and a logic model was built from the extracted evidence to describe what a successful stillbirth review process might encompass. The logic model could be used as a guide or contextually adapted by health facilities to improve their stillbirth review process. Since most stillbirths (98%) occur in low-and-middle-income countries (LMICs), there is an urgent need to introduce standardised stillbirth review processes in more LMICs, while considering the facilitators and barriers, resources required, training and support needs.

Introduction

Stillbirth reviews were started in the United Kingdom (UK) as part of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) in 1992, which was an expansion of the already established and long running Confidential Enquiry into Maternal Deaths (CEMD).[1] A stillbirth is a baby born with no signs of life after a given threshold, usually related to the gestational age or birthweight. The rationale for the establishment of stillbirth reviews in the UK was to identify ways to prevent stillbirths and reduce stillbirth rates in the country. In 2016, the World Health Organization (WHO) released a guide: Making Every Baby Count: Audit and review of stillbirths and neonatal deaths, to encourage countries to implement stillbirth reviews to identify underlying reasons why stillbirths occurred

and what can be learnt to prevent stillbirths in the future.[2]

The fundamental aim of a stillbirth review is to "support objective, robust and standardised review to provide answers for bereaved parents about why their baby died"[3] and to "ensure local and national learning to improve care and ultimately prevent future deaths."[3] Stillbirth review at the facility level is especially critical, as it provides opportunities to review the incidence rate, causes and risk factors for stillbirths, as well as identify any issues related to the quality of pregnancy and childbirth care at the hospital. The identified risk factors and issues with quality of care can then be used to inform the implementation of evidence-based interventions for reducing facility-based stillbirth in the future. However, we could find no evidence of a systematic review that critically appraised and synthesised the methods used for facility-based stillbirth review process across the world, in detail, to date.

Our aim was to systematically review all types and methods of facility-based stillbirth review processes used in different countries across the world, both high-income countries (HICs) and low-and-middle-income countries (LMICs). The primary objective was to examine how stillbirth reviews in facility settings are being conducted worldwide and to identify the outcomes of implementing the reviews. The secondary objective was to identify facilitators and barriers influencing the implementation of the identified facility-based stillbirth reviews processes by conducting subgroup analyses.

Methods

Search strategy and selection criteria

The protocol for this systematic review was developed prospectively and was registered before any stage of the systematic review was completed. The Unique Identification number of PROSPERO is CRD42022304239.[4] Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline was followed to report our findings.

The following electronic bibliographic databases were searched: MEDLINE (OvidSP) [1946-present], EMBASE (OvidSP) [1974-present], WHO Global Index Medicus (globalindexmedicus.net), Global Health (OvidSP) [1973–2022 Week 8] and CINAHL (EBSCO-Host) [1982-present]. For unpublished or grey literature, the WHO databases (who.int), Google Scholar (scholar.google.com) and ProQuest Dissertations & Theses Global (proquest.com) were searched, as well as hand searching the reference lists of included studies. MESH terms encompassing "*Clinical Audit", "*Perinatal Mortality", "Pregnancy Complications", and "Stillbirth" were used with Boolean operators. The searches employed sensitive, topic-based strategies designed for each database, and used terms related to or describing "stillbirth review" using relevant Cochrane review's search terms as a guide[5] (see Supplementary material: Appendix 1). The search dates were from the inception of the databases to the 10th of December 2021 and were updated every month to identify any further studies for inclusion. The final search was conducted on the 11th of January 2023, and the references were imported into Covidence software.[6]

The screening was conducted as a two-stage process. Firstly, all titles and abstracts were screened based on inclusion and exclusion criteria followed by a full-text screening. Both stages were carried out independently by three reviewers; the first reviewer (YYB) reviewed all the articles and two other reviewers (UGA and DBT) reviewed 50% each. In both stages, if there was a disagreement, the three reviewers worked to resolve by consensus, and if it was not resolved after the consensus meeting, a senior supervisor (MN) was consulted. Cohen's kappa was used to calculate the level of agreement among reviewers.

Inclusion and exclusion criteria

The systematic review included studies that used a facility-based review process or a review tool to investigate stillbirths (antepartum and/or intrapartum) and explained the methods used. This means, any stillbirth review process in a facility-based setting, whether as a subgroup of perinatal death review or a standalone process to investigate stillbirths, and any other type of review processes such as audit, review/meeting, confidential enquiries or any combination of these were eligible for inclusion. A stillbirth review is more extensive than stillbirth surveillance, and investigates the quality of care, attempts to identify avoidable factors (resulting from suboptimal care), and/or modifiable factors in addition to information about identification of stillbirth, pregnancy progress, and care, and details of the labour and birth. There were no restrictions for age range, ethnicity, or any health status information in terms of the women who were included in the reviews. There were no language or geographical restrictions and all types of studies were considered except systematic reviews, case reports and editorials.

Data extraction and analysis

A data extraction template was developed including four main sections: general information, the facility-based stillbirth review process, outputs and outcomes, and facilitators and barriers to implementation of the stillbirth review (see Supplementary material: Appendix 2). Data were extracted directly into Covidence software by the first reviewer (YYB), and two other reviewers independently reviewed this information (UGA and DBT).

Several tools for risk of bias assessment and different types of frameworks for narrative synthesis were considered and piloted before finalising the most applicable methods to appraise the included studies.

The quality assessment of individual studies was conducted independently by three reviewers (YYB, UGA and DBT) using an adapted version of "The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews: Checklist for Case Series"[7] (see Supplementary material: Appendix 3).

Using the existing template developed by Taylor-Powell et al.,[8] a theoretical logic model was developed *de novo* to present a narrative synthesis of the findings in a useable format of all studies included in the review. The logic model was finalised when a consensus was reached between all co-authors via multiple iterations following several group discussions. The types of stillbirth reviews were categorised by critically appraising the methods described for the review process and comparing them against standard guidance which were informed by an integrative literature review article by Helps et al. (2020), outlining the usual characteristics of perinatal audits, local reviews and confidential enquiries.[9] Helps et al. state that audit involves data collection, case assessment of stillbirth, implementation of changes based on outputs and re-evaluation, whereas, a review includes components of "a collaboration between different specialities in obstetrics, midwifery, neonatology and pathology i.e. a multidisciplinary team", to examine reasons for cases for suboptimal care and/or avoidable factors, and dissemination of key findings and learning points to all relevant clinical staff.[9] In addition, a confidential inquiry consists of all the aspects of a review but is distinguished by cases being identified via "an anonymous review" process.[9] This is different from the usual standards of anonymity; reviewers receive case notes with no prior knowledge or links and, therefore, can offer a fresh pair of critical but fair eyes.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All researchers were independent of the funders and all authors had access to the data and accept responsibility for the decision to submit for publication.

Results

We identified 7258 titles and abstracts eligible for the first stage of screening. After excluding 6860 records, which did not meet the inclusion criteria, 398 full texts were screened in the second stage. After completing the screening process, a total of 68 studies met the inclusion criteria and were finally included in the systematic review (Fig. 1). If there were studies that used the same methods and reports produced annually, the most recent report was included. The inter-rater reliability comparing the percent agreement between reviewers during the title and abstract screening was 0.8 (Cohen's Kappa statistics = 0.11) and full-text screening was 0.9 (Cohen's Kappa statistics = 0.35).

Table 1 summarises the country and its income category as per the World Bank Income Classification (WBIC), time-period of the study, and the level (as described below) at which the facility-based stillbirth reviews were conducted for the 68 included studies. The 68 studies were from 39 countries (Fig. 2). When categorising the countries using the WBIC 2022, 39 studies were from 17 HICs and 29 were from 22 LMICs.[76] There was variation among the studies in the inclusion of these characteristics, and in the ranges included, regardless of the type of country involved.

The level of review was categorised based on the place, and/or the region where the review was conducted. They could include national guidance and tools, but if the review described in the study was conducted at a regional level, it was considered a regional level review. However, if the study conducted its review in different hospitals/regions in more than one country, the study was considered an international review.

Twenty-seven studies were stillbirth reviews conducted at a local or hospital level (not in the entire district), 25 were conducted at a district or state level, 11 were conducted at a national level and two were conducted at an international level. Three further studies that could not be categorised, as one study was conducted at a national level, however, the study focused on a county called Bungoma as it was the only county in the country (Kenya) that had reviewed more than 50% of stillbirths in 2017, whereas other counties had a very low review rate.[67] Another study was conducted at all three levels (district, state, and national), as their process was a three-tiered system.[17] Lastly, one study was a feasibility study to understand if the audit could be performed at a national level and involved three regions in a country.[21]

There were three types of stillbirth reviews as described by the authors of the included studies – audit, review, and confidential enquiry. It is important to note that some studies may have used the word audit and review interchangeably, though they have not explicitly stated that they used the term interchangeably in their studies. Therefore, the types were categorised by critically appraising the methods described for the review process and comparing them against standard guidance which were informed by an integrative literature review by Helps et al. (2020) as described in the methods section. Table 2 presents a comparison of the author definition of type of review in the included studies and the salient features of the usual processes as discussed above, and the results are shown as count and percentage of included studies for which the author definition matched with the salient features described by Helps et al.. Out of 41 studies that defined their review method as an "audit", most included a component of data collection (95%), while re-evaluation (i.e., a

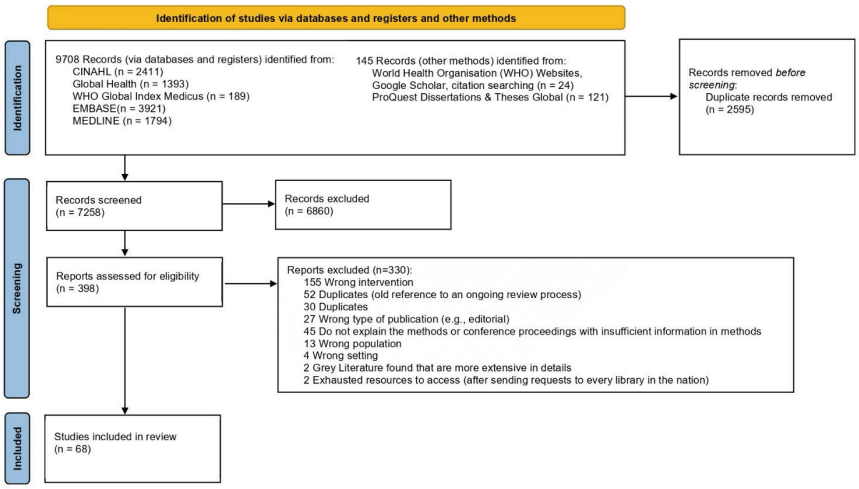


Fig. 1: PRISMA flowchart of study selection. *From:* Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. https://doi.org/10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

continuous cycle) was the most lacking aspect (27%). Many, however, also had components of a review and confidential enquiry (Table 2 and Supplementary material: Appendix 4). A total of 28 studies that defined their review method as a "review" or "confidential enquiry" also showed similar patterns to studies that defined their review method as an "audit"; not all studies contained the desired components of a review/confidential enquiry.

The included studies had one or more of the following aims when conducting a stillbirth review: to prevent stillbirth, to improve all aspects of care by making adequate and informed recommendation guided by clear local/national/international criteria or practices[3,15,17,25,36,39,43,46,51,52,55–57,64,65,69,73,75]; to analyse cause/s of stillbirth and/or any suboptimal care during the pregnancy[3,10,11,15,16,19–24,26,28–32,36–43,45,47,50,53,54,58,59,61,66–74,77]; to evaluate the current review process or tool implemented and what the facilitators or barriers were[18,32,34,44,48,49,53,62,63]; and to compare if there were differences in stillbirth rate between groups of pregnant women that occurred due to systematic differences in quality of care.[12–14,27,33,35]

For 29 out of 68 studies (43%), Government agencies (15 studies[3,14,17,18,24,25,30,32,34–36,38,39,72,75]) or other funding bodies such as non-governmental organisations (9 studies[19,20,22,23,51,62,67,69,73]), universities or professional associations (2 studies[46,47]), and research grants (3 studies[10,11,77]) were solely responsible for commissioning the review process. Fifteen studies[12,15,27,33,43,46,48,50,58,60,63,66,70,71] out of 68 received funding from two or more organisations (22%), but 24 out of the 68 studies (35%) received no funding or did not list any funding information for the stillbirth review process.

Routine data was used as at least one of the data sources to identify eligible stillbirths for review in 44 out of 68 included studies (65%).[10–12,16,19,22–34,38,42–48,50,52,55,57,59,61–65,67,69,71–75,77] Routine data included birth or death registry, hospital records, social care organisations' records, and obstetric records. Four studies (6%) used interviews with care providers as a supplementary source of data, in addition to routine records to identify stillbirths for review.[22,30,63,72] Sixteen studies (24%) implemented a specific data identification system to build a stillbirth database only for the purposes of the review or to enable the review to be started.[3,14,15,17,18,24,25,36–39,53,58,66,67,70] For example, they requested care providers to fill in a form within a reasonable time after the death in the facility and report through an online surveillance system or via phone call/fax to notify the review team to enable a review to be started.[3,17,18,38,39,66,67] Some studies used an existing specific database that was not built for the purpose of the stillbirth review only, but to support research on how to reduce stillbirth. For example, a study utilised a prospective cohort of antenatal attendees' data to identify stillbirth within the cohort for review.[58] Twelve studies (18%) did not state what data source they used to identify stillbirths.[13,20,35,40,49,51,54,56,60,68] Please see Supplementary material: Appendix 5 for the detailed lists of sources of data used for each study.

First author, publication year	Country	Level of review	Duration
High-income countries			
Flenady, 2021[10]	Australia	D	1 Jan 2018–1 Dec 2018
Richardus, 2003[11]	Belgium; Denmark; Finland; Greece; Netherlands; Norway; Spain; United Kingdom	I	1993–1998
Andersen, 1991[12]	Denmark	D	1985–1986
Westergaard, 1997[13]	Denmark; Sweden	I	1991
Sauvegrain, 2020[14]	France	D	1 Jan-31 Dec 2014
de Caunes, 1990[15]	Guadeloupe[a]	N	Nov 1983–Dec 1985
Furst, 1989[16]	Israel	L	Oct 1987–Feb 1988
D'Aloja, 2021[17]	Italy	L; D; N	1 Jul 2017–30 Jun 2019
Alderliesten, 2008[18]	Netherlands	D	1999
Dekker, 2003[19]	Netherlands	L	1986–1995
Eskes, 1993[20]	Netherlands	L	1969–1983
van Diem, 2010[21]	Netherlands	O	Nov 2004–May 2005
van Diem, 2012[22]	Netherlands	D	Sep 2007–Mar 2010
Wolleswinkel-van den Bosch, 2002[23]	Netherlands	D	1996–1997
Eskes, 2014[24]	Netherlands	N	2010-present
PMMRC, 2021[25]	New Zealand	N	2007-present
Berge, 1991[26]	Norway	L	1976–89
Bjellmo, 2019[27]	Norway	N	1999–2015
Fossen, 1999[28]	Norway	D	1989–1997
Han, 2018[29]	Singapore	L	Jan 2004–Dec 2008
De la Puente, 2002[30]	Spain	L	1997–1998
Miranda, 1996[31]	Spain	L	1979–1992
Eksmyr, 1986[32]	Sweden	D	1973–1978
Essén, 2002[33]	Sweden	N	1990–1996
Sterpu, 2020[34]	Sweden	D	2017
Chepkin, 2019[3]	United Kingdom	L	Feb 2018-present
Cross-Sudworth, 2015[35]	United Kingdom	L	2008
Draper, 2017[36]	United Kingdom	N	Nov 2016–May 2017
Hundley, 2001[37]	United Kingdom	D	Not stated (re-review of the review that was conducted during the Aberdeen Trial in 1992–1993)
Maternal and Child Health Research Consortium, 1999[38]	United Kingdom	N	The Confidential Enquiry into Stillbirth and Deaths in Infancy (CESDI) from 1993–2002; the Confidential Enquiries into Maternal and Child Health (CEMACH) from 2003–2008; Centre for Maternal and Child Enquiries (CMACE) from 2009–2011
Mersey Region Working Party on Perinatal Mortality, 1982[39]	United Kingdom	D	1979
Tan, 1999[40]	United Kingdom	D	1991
Tang, 2011[41]	United Kingdom	L	2004–2009
Bausch, 1996[42]	United States	D	1992
Harper, 1977[43]	United States	D	1973
Kieltyka, 2012[44]	United States	D	From 2001
Moawad, 1990[45]	United States	D	1983–1987
The National Center for Fatality Review and Prevention, 2021[46]	United States	N	Late 1980s- present
Vallejo, 1991[47]	United States	D	1988
Upper-middle income countries			
Amaral, 2011[48]	Brazil	D	Oct–Dec 2005
Raman, 2015[49]	Fiji	L	2011–12
Alyahya, 2021[50]	Jordan	L	1 Aug 2019–1 Feb 2020
Stratulat, 2014[51]	Moldova	N	2006–2010
Copenhagen: WHO Regional Office for Europe, 2020[52]	North Macedonia	N	2019

(Table 1 continues on next page)

First author, publication year	Country	Level of review	Duration
(Continued from previous page)			
Govender, 2017[53]	South Africa	L	1 Apr 2014–31 Mar 2015
Pattinson, 1995[54]	South Africa	D	Aug 1991–Jul 1992
Rhoda, 2014[55]	South Africa	N	From the early 1990s, but was not a truly national programme until 2012.
Ward, 1995[56]	South Africa	L	1 Jan 1991–31 Dec 1992
Wilkinson, 1997[57]	South Africa	D	May 1991–Dec 1995
Mo-suwan, 2009[58]	Thailand	D	15 Oct 2000–19 Mar 2002
Low income and low-and-middle income countries			
Demise, 2015[59]	Ethiopia	L	Jun–Nov 2012
Musafili, 2017[60]	Rwanda	L	Jul 2012–May 2013
El Amin, 2002[61]	Sudan	L	May–Aug 2000
Kirabira, 2020[62]	Uganda	L	From 2008
Biswas, 2015[63]	Bangladesh	D	2010–2011
Bhatt, 1989[64]	India	L	Initiated from 1965
Sharma, 2022[65]	India	L	Dec 2018–Nov 2019
Supratikto, 2002[66]	Indonesia	D	From 1994
Bandali, 2019[67]	Kenya	O+	From 2014
Omwodo, 2020[68]	Kenya	L	1 May 2017–31 Aug 2018
Aminu, 2017[69]	Kenya; Malawi; Sierra Leone; Zimbabwe	L	Jan–Sep 2015
Vallely, 2020[77]	Papua New Guinea	D	Jul 2017–Jan 2020
Hinderaker, 2003[70]	Tanzania	D	Not stated
Maaløe, 2016[71]	Tanzania	L	1 Oct 2014–31 Jan 2015
Mbaruku, 2009[72]	Tanzania	L	Jul 2002–Jul 2004
Mdoe, 2022[73]	Tanzania	L	Jan 2019–May 2020
Wilkins, 2015[74]	Timor-Leste	L	Nov 2009–Dec 2010
Kasengele, 2017[75]	Zambia	L	2012–2014

L: local/hospital(s), D: district/state, N: national, I: international. O+ It is implemented nationally. However, this paper focuses on Bungoma country as it is the only country in Kenya that has reviewed more than 50% of perinatal deaths in 2017. Ø Included three regions, therefore between D and N level. [a]Guadeloupe was included as a high-income country as it is a French overseas region.

Table 1: **General information about the included studies.**

There is no universally accepted definition of stillbirth and the definition tends to vary between countries and within countries,[78] an issue also observed in the included studies. Out of the 68 studies, 20 did not list any definition of stillbirth used for case assessment, 29 studies used only one criterion (either gestational age or birthweight) to define stillbirths for case assessment, and three studies used three criteria (gestational age, birthweight, and crown-heel length) (Table 3). Sometimes case assessment was limited to particular interests as the review may focus on one aspect of stillbirth; for example, four studies[13,36,51,72] only focused on intrapartum stillbirth, two studies[10,24] only focused on late gestational stillbirth, and one study[40] only included stillbirths with birthweight above 2500 g considering that these were most likely to be "influenced by obstetric care and management". Excluding seven studies that only focused on a particular type of stillbirth, the minimum gestation age used ranged between 20 and 28 weeks. The minimum birthweight used ranged between 400 g and 1000 g, and minimum crown-heel length used ranged between 25 and 35 cm. When dividing this range by country's income classification, studies that were conducted in LMICs had a narrower gestation age range of 22–28 weeks, a narrower birthweight range of 500–1000 g and crown-heel length of 35 cm. Compared to HICs, in LMICs the minimum gestational age was higher by two weeks, the minimum birthweight was higher by 100 g, and the minimum crown-heel length was also higher by 10 cm. In addition, six studies[13,17,36,38,68,75] used additional definitions to classify antepartum/macerated and intrapartum/fresh stillbirths; all six studies used the "onset of labour" or "onset of care in labour" as a criterion to differentiate the two types of stillbirths.

Abstracting or directly reviewing data from already available data (e.g. hospital notes, social care data, death registry, theatre records) was the most common method of gathering data to facilitate a stillbirth review. This means there was no interview or further additional information sought; 36 out of 68 studies (53%) used this method for data collection.[12,13,18,19,21,23,24,27–34,36–38,42–45,47,48,52,55,56,61,67,71,73,74,75,77] Twenty-six studies (38%) collected

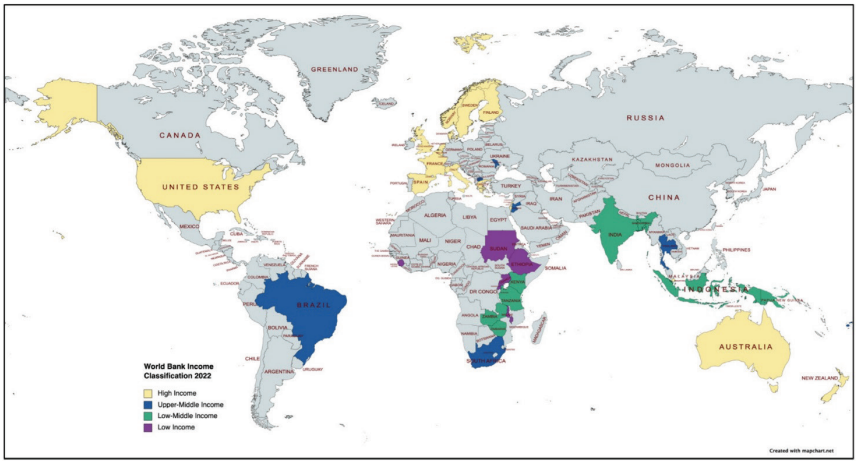


Fig. 2: The geographical distribution of countries of included studies using the World Bank income classification 2022.

additional data for the purpose of the review[3,10,11,14–17,25,35,39,41,46,49,50,57–60,62–66,69,70,72]; for example, by conducting interviews with mothers, health care providers, and family members, by requesting contextual background information about the facilities and mothers, and by carrying out additional tests (e.g. macroscopically examining placenta and cords) that would otherwise not be done. Six studies (9%) did not state how they collected data to facilitate the stillbirth review process.[20,26,40,51,54,68] Please see Supplementary material: Appendix 5 for the detailed data collection methods used for each study.

In addition to the components listed in Table 2, there were other notable components of stillbirth review that were observed in the included studies. Please see Supplementary material: Appendix 5 for the detailed review methods/tools used for each study. These included questions related to: reviewers being trained in the review process[18,24,50]; data needed for the review being delivered to the reviewers prior to the review process to help with their preparation[12,18,36,61,52]; structured forms or checklists to fill in during the review[3,17,18,24,37,49–53,66–69,71,73] versus discussion oriented process[64]; no review meetings (chart review only)[22,26,29,41,46,49,69,73] versus two stage review process; individual judgement (case review) then a collective judgement after a panel discussion to reach a consensus[11,18,19,27,34,47,51,55,61,70,74] versus review meetings only[15,24]; cause of death recorded using well-known classifications and/or selected contributory factors from a framework[14–19,21,24,25,38,39,43,45,47,53,54,56,58–60,62,65,68]; grading of suboptimal care using an established grading system such as the CESDI[3,10,18,19,22,24,30,35,36,47,49,51,53,60,61,65,66,69,70,74,75]; external reviews being conducted for quality assurance[15,18,27,46,61]; creating action plans and follow up plans[3,15–17,24,34,37,40,45,48,50,61,63,67,73,75]; assessing if the death was avoidable, if there was suboptimal care, usually using a grading system or a criteria[3,12,13,15,17,20–22,25–27,29–33,35,36,38,39,42,43,45,47,53,55,58–60,62,65,67,70,72,74,75]; evaluation against criteria/guidelines[24,27,36,44,55,58,71,75] versus evaluation against personal knowledge, experience, and culture[56,61,71]; having separate administrative staff or a chair to facilitate reviews[24,35,36,77]; lead presenter presents the allocated case[10,34,36,45,58,60,61,70,73]; findings distributed in multiple languages[61]; and grade/comment on the quality of clinical notes.[55,62,74]

All included studies produced outputs (data or information) that resulted from the stillbirth review. The themes identified were: risk, protective and modifiable risk factors for stillbirth (maternal, fetal and, obstetric); trends in stillbirth (e.g. changes in stillbirth rate); counts or proportion of causes of stillbirth (cause of death); details and grading of suboptimal care (what, when, who); proportion of stillbirths where post-mortem examinations were conducted; recommendation of actions to be implemented to reduce future stillbirths; and quality of case notes (record-keeping).

Not all reviews led to an outcome. Identified in 14 studies, the following short-term and medium-term outcomes were observed: providing cost-effective ways of increasing mothers' awareness of stillbirth risk factors and level of knowledge about recognising the need to seek care[50]; improving referral pathways and record keeping to streamline the quality management process of providing optimal care[3,25,50,53,59,63,67]; increasing and

Salient features of the usual process as described by Helps et al. (2020)	As described by authors in the included studies		
	Audit (n = 41)	Review (n = 28)	Confidential enquiry (n = 14)
Audit component 1: data collection	39 (95%)	28 (100%)	14 (100%)
Audit component 2: case assessment of stillbirth	33 (81%)	24 (86%)	13 (93%)
Audit component 3: implementation of changes based on outputs	12 (29%)	9 (32%)	3 (21%)
Audit component 4: re-evaluation (i.e., a continuous cycle)	11 (27%)	10 (36%)	3 (21%)
Review component 1: a collaboration between different specialities in obstetrics, midwifery, and pathology (i.e., the multidisciplinary team)	23 (56%)	21 (75%)	13 (93%)
Review component 2: examine reasons (what, when, who) for cases for suboptimal care and/or avoidable factors	33 (81%)	22 (79%)	12 (86%)
Review component 3: dissemination of key findings and learning points to all relevant clinical staff	13 (32%)	11 (39%)	5 (36%)
Confidential enquiry: anonymous in addition to the above three components of a review process	5 (12%)	12 (43%)	11 (79%)

Table 2: **Count and percentage of studies that had the component of relevant stillbirth review depending on the type (audit, review, and confidential enquiry).**

First author and year	Country	Age of gestation (weeks)	Birthweight (g)	Crown-heel Length (cm)
High-income countries				
Flenady, 2021[10]	Australia	≥34[b]	N/A	
Richardus, 2003[11]	Belgium; Denmark; Finland; Greece; Netherlands; Norway; Spain; United Kingdom	≥28	N/A	
Andersen, 1991[12]	Denmark	≥28	N/A	
Westergaard, 1997[13]	Denmark; Sweden	>28[a]	N/A	
Sauvegrain, 2020[14]	France	≥22	N/A	
de Caunes, 1990[15]	Guadeloupe	≥22	N/A	
Furst, 1989[16]	Israel	N/A	N/A	
D'Aloja, 2021[17]	Italy	≥28	N/A	
Alderliesten, 2008[18]	Netherlands	N/A	N/A	
Dekker, 2003[19]	Netherlands	>24	≥500	
Eskes, 1993[20]	Netherlands	N/A	>500	
van Diem, 2010[21]	Netherlands	N/A	N/A	
van Diem, 2012[22]	Netherlands	>22	>500	≥25
Wolleswinkel-van den Bosch, 2002[23]	Netherlands	≥24	N/A	
Eskes, 2014[24]	Netherlands	≥37[b]	N/A	
PMMRC, 2021[25]	New Zealand	≥20	≥400	
Berge, 1991[26]	Norway	≥24	N/A	
Bjellmo, 2019[27]	Norway	N/A	N/A	
Fossen, 1999[28]	Norway	≥22	N/A	
Han, 2018[29]	Singapore	≥28	≥500	
De la Puente, 2002[30]	Spain	≥22	>500	
Miranda, 1996[31]	Spain	N/A	≥1000	
Eksmyr, 1986[32]	Sweden	N/A	N/A	
Essén, 2002[33]	Sweden	N/A	N/A	
Sterpu, 2020[34]	Sweden	≥22 + 0	N/A	
Chepkin, 2019[1]	United Kingdom	≥22 + 0	>500	
Cross-Sudworth, 2015[35]	United Kingdom	≥24	N/A	
Draper, 2017[36]	United Kingdom	≥37[a]	N/A	
Hundley, 2001[37]	United Kingdom	N/A	N/A	
Maternal and Child Health Research Consortium, 1999[38]	United Kingdom	>24	N/A	

(Table 3 continues on next page)

First author and year	Country	Age of gestation (weeks)	Birthweight (g)	Crown-heel Length (cm)
(Continued from previous page)				
Mersey Region Working Party on Perinatal Mortality, 1982[39]	United Kingdom	N/A	N/A	
Tan, 1999[40]	United Kingdom	N/A	≥2500[c]	
Tang, 2011[41]	United Kingdom	N/A	N/A	
Bausch, 1996[42]	United States	N/A	N/A	
Harper, 1977[43]	United States	N/A	N/A	
Kieltyka, 2012[44]	United States	≥24	N/A	
Moawad, 1990[45]	United States	N/A	≥501	
The National Center for Fatality Review and Prevention, 2021[46]	United States	N/A	N/A	
Vallejo, 1991[47]	United States	≥20	≥500	
Low-and-middle income countries				
Biswas, 2015[63]	Bangladesh	N/A	N/A	
Amaral, 2011[48]	Brazil	N/A	≥500	
Demise, 2015[59]	Ethiopia	≥28	≥1000	
Raman, 2015[49]	Fiji	N/A	N/A	
Bhatt, 1989[64]	India	N/A	N/A	
Sharma, 2022[65]	India	≥28	≥1000	
Supratikto, 2002[66]	Indonesia	N/A	N/A	
Alyahya, 2021[50]	Jordan	≥24	N/A	
Bandali, 2019[67]	Kenya	N/A	N/A	
Omwodo, 2020[68]	Kenya	≥22	≥500	
Aminu, 2017[69]	Kenya; Malawi; Sierra Leone; Zimbabwe	≥28	≥1000	≥35
Stratulat, 2014[51]	Moldova	>37[a]	≥2500[a]	
Copenhagen: WHO Regional Office for Europe, 2020[52]	North Macedonia	≥22	≥500	
Vallely, 2020[77]	Papua New Guinea	N/A	N/A	
Musafili, 2017[60]	Rwanda	≥22	≥500	
Govender, 2017[53]	South Africa	N/A	≥500	
Pattinson, 1995[54]	South Africa	N/A	>1000	
Rhoda, 2014[55]	South Africa	N/A	N/A	
Ward, 1995[56]	South Africa	>28	≥1000	
Wilkinson, 1997[57]	South Africa	N/A	N/A	
El Amin, 2002[61]	Sudan	N/A	≥500	
Hinderaker, 2003[70]	Tanzania	≥28	N/A	
Maaløe, 2016[71]	Tanzania	N/A	≥1000	
Mbaruku, 2009[72]	Tanzania	N/A	≥2000[a]	
Mdoe, 2022[73]	Tanzania	≥28	N/A	
Mo-suwan, 2009[58]	Thailand	≥28–40	N/A	
Wilkins, 2015[74]	Timor-Leste	≥22	≥500	
Kirabira, 2020[62]	Uganda	≥28	≥1000	≥35
Kasengele, 2017[75]	Zambia	N/A	N/A	

[a]Intrapartum stillbirth only. [b]Late gestational stillbirth only. [c]Stillbirth most likely to be influenced by obstetric care and management.

Table 3: **Definition (case assessment of stillbirth) used in included studies.**

improving clinical tests available and medical capacity (equipment, available health care professionals within the department) within the facilities[3,25,30,38,50,51,54,59,62,65,67,75]; and providing training to health care professionals to increase their knowledge and medical skills.[25,38,50,54,59,67] None of the studies reported any impact on the incidence of stillbirth which is difficult to attribute to the review process alone.

Almost all included studies (97%) had clear criteria for inclusion in the review except a study from India by Bhatt[64] and an Indonesian study by Supratikto et al.,[66] which only explained the inclusion criteria of maternal deaths occurring in a facility setting. In order to measure stillbirth in a standard and reliable way for all cases included, the review should use a consistent definition of stillbirth applicable to all cases or consistent experts'

assessment methods. This was seen in 71% of included studies, but could not be determined for 25% of the included studies. Three studies did not measure stillbirth in a standard and reliable way for all cases.[16,43,49] Most of the studies (85%) were able to demonstrate which source of data they used for identification of the stillbirth and 82% of the studies had consecutive inclusion of stillbirths to reduce selection bias. At a minimum, the stillbirth review should collect some important demographic characteristics of the mothers who had a stillbirth to compare against well-known risk factors for stillbirth. However, 46% of the included studies did not include information such as age of the mother, parity, gestational age at birth, pregnancy complications and number of antenatal visits during pregnancy. While all included studies in this systematic review stated that their stillbirth review process evaluated the quality of care and/or avoidable factors, 35% of the included studies did not discuss the details of suboptimal care. In addition, these studies did not explain when the risk factors could have been avoided in relation to the pregnancy period (e.g. antenatal, labour and delivery) and who could have addressed these factors (e.g. obstetric staff, social care staff, mothers). It is important to consider what can be improved in the facility setting to prevent any future stillbirth, and this is one of the main aims of conducting a stillbirth review. While all studies may have identified the weakness in their facilities and made recommendations, most of the studies (79%) did not describe whether they actioned any recommendations as a result of the review outcomes. Lastly, 90% of the studies reported the presenting sites' or clinics' information and 96% used appropriate statistical analysis methods to analyse their data. Quality assessment of the included studies are visualised in Supplementary material: Appendix 6.

Facilitators and barriers in order to successfully implement a stillbirth review were identified from 14 included studies.[3,25,30,38,50,51,53,54,59,62,63,65,67,75] These are described in Table 4. Facilitators and barriers identified from the studies were categorised into three main themes: resources, expertise, and commitment. These three themes are connected in the sense that, the facilities with greater commitment (e.g. leadership buy-in) were more willing to provide resources (e.g. funds, training, administrative staff) to implement and strengthen their stillbirth review process. This further encouraged staff to be more committed to the ethos and aims of the review process. With adequate training provided (resources), staff could gain confidence in communication skills which could enable them to build trust with mothers, as well as focus on a blame-free culture when conducting the reviews. Adequate resources will help to engage experts from different specialities to create a multidisciplinary panel. In addition, with greater commitment from the staff and available tools and guidelines given for the purpose of the stillbirth review, better quality data will be collected, and adequate quality data will be available to conduct a thorough review. Better quality of data collected is important to address barriers such as poor or missing data. Another important barrier identified is poor or

Themes	Facilitators (frequency of studies reporting)	Barriers (frequency of studies reporting)
Resources • Facilitators (n = 22) • Barriers (n = 21)	- Administrative staff and supporting researchers dedicated to the stillbirth review (n = 3) - Training in conducting stillbirth review (n = 3) - Availability of neutral chairs in the meetings to reduce the risk of bias (consistent review methods) and create a safe environment for panels to discuss cases (n = 2) - Data collection and stillbirth review tools or frameworks (n = 6) - Adequate data available (n = 2) - Funding (n = 6)	- Poor or missing post-mortem examination data (n = 3) - Amount of time spent in gathering data from multiple sources and inconsistencies in data between multiple sources (n = 5) - Inadequate capacity and resources (Human Resources, no tools/frameworks to collect data or conduct reviews, or summaries the results of the reviews) (n = 7) - Changes in guidelines since the stillbirth occurred (n = 1) - Lack of training in collecting data and/or conducting reviews (n = 2) - Language barriers between the mothers/families and the health care professionals to collect necessary data (n = 1) - Limited funds for conducting reviews and implementing the action points from the review results (n = 2)
Expertise • Facilitators (n = 13) • Barriers (n = 11)	- Multidisciplinary review teams/panels (MDT) (n = 6) - External reviewers as part of the MDT (n = 2) - Supervision from the senior members of the review team (n = 3) - Trust between hospital staff and mothers/families to collect data required (n = 2)	- Inconsistencies of grading/identification of suboptimal care between reviewers (n = 2) - Poor record keeping to document events adequately (n = 7) - Emotional involvement of the panel in the cases (n = 1) - Lack of confidentiality leading to pressure on certain departments/types of health care professional (n = 1)
Commitment • Facilitators (n = 16) • Barriers (n = 7)	- Equal opportunities to participate regardless of the level of seniority or job titles in the panel (n = 2) - Anonymous, blame-free, no-fault review environment (n = 6) - Strong commitment of the public care/research sectors and participation of the private health care sectors by sharing common aims of reducing stillbirth and improving care (n = 5) - Number of stillbirths (smaller the size, easier to review all cases) (n = 1) - Leadership buy-in (n = 2)	- Perceived differences in status between representatives of different health professionals in the review panel (e.g. midwives vs. senior obstetricians) (n = 1) - Lack of leadership buy-in (n = 2) - Lack of motivation of the health care professionals to reflect their care (n = 2) - The volume of deaths when this is large in number (n = 2)

Table 4: **Facilitators and barriers in implementing a successful stillbirth review.**

missing post-mortem data. Staff training could improve data quality, but engagement with parents will be required to receive approval for a post-mortem. Engaging with parents in the review process will also enable staff to collect more robust demographic data and create opportunity for parents to provide additional relevant information pertinent to the review and find out why their baby died after the review process is concluded.

A logic model was developed after carrying out the narrative synthesis. Fig. 3 maps out how a facility-based stillbirth review can work effectively with inputs and activities (primary output), which result in generated learnings (secondary outputs) and outcomes. However, the relationship between inputs, outputs, outcomes and impact needs to be understood in the context of the facilitators and barriers to implementing a successful stillbirth review. For example, while the "proportion of stillbirth where post-mortem examinations were conducted" is not an output or learning to reduce stillbirth, this was included in the logic model because having poor or missing post-mortem examination data was identified as a barrier in conducting stillbirth reviews in some studies[17,69] (see Table 4). Autopsy and placental histology are important examinations to help identify the cause of stillbirth.[79–81]

The generated learnings (secondary outputs) have the capacity to lead to short-term outcomes such as new training programme for staff, and medium-term outcomes such as improved referral pathway to improve the quality of care in the facilities. However, long-term outcomes or impact on reducing the incidence of stillbirth will take longer to materialise, and it will be difficult to attribute them solely or directly to the review process alone.

Discussion

This systematic review identified different types and methods of facility-based stillbirth review processes around the world and a logic model was built from the extracted evidence to describe what a successful stillbirth review process could look like. The search identified 68 studies that described the methods used to conduct a facility-based stillbirth review from 39 countries (17 HICs and 22 LMICs). There were reviews conducted at various levels (district, state and national), and three types of stillbirth review were identified (audit, review and confidential enquiry) although most reviews did not include the salient features for the review process used, which led to a mismatch between the author description of the type of reviews and as the actual salient features of the process. Reviews from many countries had agreed that the aim of the stillbirth reviews were to prevent stillbirth, and to improve all aspects of care by making adequate and informed recommendation guided by clear local/national/international criteria or practices.

In terms of data sources for identifying stillbirths for the review, routine data was the most popular method. Some studies additionally conducted interviews with care providers, and many studies implemented a specific data identification system to build a stillbirth database only for the purposes of the review. Case assessment using stillbirth definition was used in 48 out of 68 studies. However, there was variation among the studies in the inclusion of these characteristics, and in the ranges included, regardless of the type of country involved. All stillbirth review processes identified in this study generated outputs that can lead to outcomes. Short-term and medium-term outcomes were reported in 14 studies, but the impact of the review process on reducing stillbirth, which is more difficult to establish, was not reported in any study. Facilitators and barriers identified from 14 studies focused on three main themes: resources, expertise, and commitment. The generated learnings from the stillbirth review processes inform the action plans and allow facilities to consider

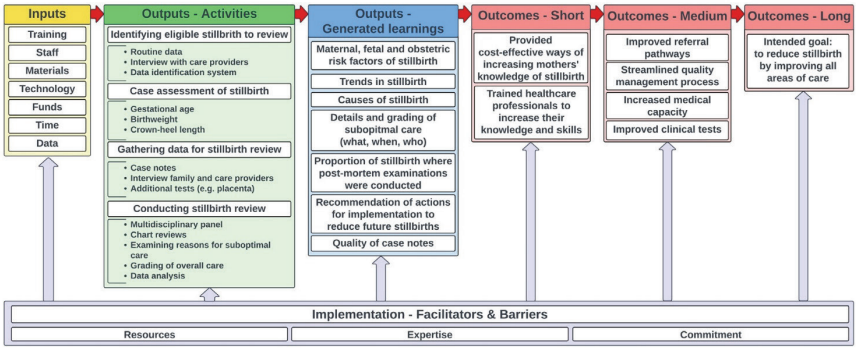


Fig. 3: Logic model of stillbirth reviews.

where the changes should happen to improve the quality of care in the facilities, enabling positive short-term and medium-term outcomes.

Stillbirth review process is not standardised in many countries at a local/national level, despite the known value of such review programmes in reducing stillbirth rates over time and identifying gaps in care.[82] Although it was important to have a standard process across all regions in a country, this might nevertheless be only possible in a small country like the UK with not much variation in the healthcare system and healthcare provision across the regions. Standardisation might not be possible in large countries with variable systems such as the United States, India, and others, which do not have a standard care provision system for all in health facilities. This was evident in a national programme, the Fetal Infant Mortality Review Program from the United States, as guidelines existed at the national level, yet different States were implementing the stillbirth review using different methods that uniquely work for each State.[44,46] This is in contrast to the programme that exists in the UK where the confidential enquiries and review methods employ standardised tools that can be used in any region in order to facilitate standardised national monitoring.[25,36] It was observed, however, that even with a national programme in place, without a robust environment to implement the programme, the uptake of stillbirth review can be very low in areas that do not have adequate resources and support. For example, when perinatal death was added as a component to the National Maternal Death, Surveillance and Response in Kenya in 2016, Bungoma was the only county that reviewed more than 50% of the deaths. A study found that the technical and training support from UKAID was the main reason why the programme could be successfully implemented and strengthened in this county compared to others that did not receive this type of support.[67]

There was a lack of application of core principles of an audit process within studies that defined their review processes as "audits", especially as many studies[13–16,18,20,21,23,26–29,31–34,45,52,57,60,61,64,68,71,72,77] lacked implementation of changes based on outputs and failed to ensure a continuous audit cycle of re-evaluation. Reporting on how changes are made by making adjustments in clinical practices based on stillbirth review outputs can be challenging, as it can be a gradual and time-consuming process that requires both service-level and policy-level support and many other processes and findings may be involved beyond reviews. However, there is a need for clear guidelines on how to measure the impact of such changes. The continuous audit cycle of re-evaluation can be also challenging due to the cost (time and financial) associated with conducting a stillbirth review; particularly compromises to clinical care could be counter-productive if health care professionals are required to spend clinical time participating in the review meetings without providing additional resources to pay for this time.[5]

For the studies that defined their stillbirth review process as "reviews", dissemination of key findings and learning points to relevant staff were not observed in many. The dissemination of information should activate knowledge translation within the hospitals/units which then forms part of the knowledge-to-action cycle, and can support promoting sustainable changes that improve clinical practices.[83] Therefore, it is crucial for studies to enable effective dissemination of learning points in the future and promoting them through training platforms that are already available in their facilities.[84] While the United States Department of Veterans Affairs Root Cause Analysis Tool states that training and dissemination are a weak means of changing either behaviour or outcomes, many studies from LMICs found that these types of actions are an effective ways to change clinical practices to reduce suboptimal care in health facilities.[85] This may be due to differences in health systems and/or provider knowledge and practices in HICs versus LMICs, as LMICs may not usually have the facilities or practices in place to conduct training for the healthcare professionals or disseminate significant information about why a baby died and therefore when this happens it may have more impact. The results of this systematic review also revealed that a stillbirth review process could be an amalgamation of different types rather being confined to the salient features that are thought to be desirable for a specific type, and different processes will most definitively comprise a variable mix of audit, review and confidential enquiry components. It is important, however, to recognise that implementing a stillbirth review in a facility-based setting is a 'test and learn' process and if the desired components of stillbirth review are missing, it does not mean that the review methods are ineffective. As seen in early maternal mortality reviews in Ireland, UK and the United States, from 1920s to 1940s, the processes initially did not examine the standard of care, however, this was later revised and more structured approaches to maternal mortality reviews were established.[9] Understanding that stillbirth review is relatively new compared to maternal mortality reviews, stillbirth review processes are likely to adapt and improve over time. Different countries/districts/hospitals will have different stillbirth review processes to optimise their resources and contextualise their healthcare system, cultural and social norms.

The definition used to assess stillbirth can vary greatly between studies, and there is a need to develop and adopt a universal definition of stillbirth to facilitate meaningful comparison of stillbirth rates between regions and to correctly identify risk, protective, and modifiable risk factors for stillbirth, even in HICs.[86] This has been also discussed extensively in a previous

systematic review by Aminu et al., and in the latest 2023 report by the United Nations Inter-agency Group for Child Mortality Estimation.[87,88] The minimum gestational age, birthweight and crown-heel length ranges used to define stillbirth were lower in HICs than the range in LMICs. This could be because LMICs prefer to use the WHO definition of stillbirth for international comparison and reporting.[89] The rationale for moderating the definition of stillbirth cut-off for international comparison to 1000 g or more at birth, or ≥ 28 completed weeks of gestation, or attainment of at least 35 cm crown-heel length could be to ensure comparability as many LMICs may not capture late fetal deaths accurately and data is limited.[90,91] In addition, in countries where neonatal intensive care units are limited, babies below the gestational age of 28 weeks may not be viable when delivered prematurely, unlike HICs, where facilities are available, and lower gestational age babies can survive with adequate neonatal care and treatment.[92]

There were unique components of stillbirth review in some studies that showed positive effects on achieving their aims which can be utilised in future designs of stillbirth review. Some studies explicitly stated how reviewers were trained in the review process before they started participating in a review panel.[18,50] Effective training will not only reduce measurement errors from between-reviewer variation, but also allows reviewers to prioritise the guiding principles for stillbirth reviews, for example, focusing on improvements to health systems and not individuals (no blame policy). Sharing review-related data a few weeks prior to the panel review is another effective way to promote the review meetings and to stay focused on the agenda without panels feeling unprepared or rushed because they have not had enough time to absorb the amount of information available in the case notes. Allowing review panels to study the cases before the meetings allows them to understand the cases fully and helps them in gaining confidence to participate in the discussion sessions. This may also create a system where there is a lead presenter to present an allocated case in each session to open up the discussion more naturally during the review meeting.

Some facilities may have structured forms or checklists that guide the stillbirth review process, while some only conduct the review via discussion with the panel. Nonetheless, having well-known classifications to assess the cause of death or a framework to select contributory factors, could increase the consistency between the reviewers and the extent to which consensus is reached. Aminu et al., however, notes that there are over 35 classification systems for stillbirth and none of them are adopted globally.[87] In addition, some argue that even the widely known classification systems such as Extended Wigglesworth and Amended Aberdeen are considered limited in classifying stillbirth.[87,93] Since creating action plans and follow-up plans are important steps to implement changes based on stillbirth review outputs, having a clear reporting of suboptimal care (what, when, who), grading suboptimal care using an established grading system (e.g. CESDI[18]) and assessing if it contributed to death could equip review panels to select and justify appropriate action plans successfully.

As identified in the facilitators to implementation of the identified stillbirth reviews, having separate administrative staff or a chair to facilitate reviews could be effective in reducing the workload and increasing motivation and consistency between review meetings. Furthermore, as data quality was identified as one of the barriers to implementation, an opportunity for review panels to grade or comment on the quality of clinical notes can increase awareness among the health care professionals of the importance of accurate and detailed record keeping of cases.

The strength of this systematic review is that this is one of the first, of which we are aware, to critically appraise and synthesise the methods used for facility-based stillbirth review process across the world, in detail. We used a robust methodology by including independent reviewers for screening, extracting and quality assessment. Since there are high levels of heterogeneity between included studies due to the nature of the aim of this systematic review, such as methodological characteristics, as well as clinical heterogeneity such as diversity in the populations (different regions and countries), several tools for risk of bias assessment and different types of frameworks for narrative synthesis were considered and piloted before finalising the most applicable methods to appraise the included studies.

While using a logic model for narrative synthesis was deemed most appropriate for this study, logic models represent a linear model of how processes should work. Since the sequence of implementing a stillbirth review in the real world is not linear, and assumptions are often not met, the logic model proposed in this study should be interpreted with flexibility when designing a stillbirth review process. Moreover, the proposed logic model in this study assumes that this model would apply to all settings within and across countries. Whereas the same audit process in differing contexts may also involve different outcomes, reflecting differing reasons for stillbirth rates being elevated. Therefore, users should critically appraise the logic model and update their methods, if necessary, by considering the contextual settings and understanding the complexity in implementing a stillbirth review in their setting.

In addition, studies reporting on the stillbirth review process may not always reach mainstream sources of literature, and despite efforts made to retrieve studies by searching published and unpublished or grey literature, the systematic review might not have identified every possible method used for facility-based stillbirth review process across the world.

Finally, this study compared different types of reviews using Helps et al.'s interpretation of the desired components of audits, reviews, and confidential enquiries as standard guidance.[9] However, Helps et al. focused on the types and evolution of audits and reviews in HICs alone when deriving the desired components. Considering this study looks at stillbirth review processes in both HICs and LMICs, there are limitations on using Helps et al.'s interpretation of salient features for different types of review processes because their method may not fully reflect LMICs' health systems, which may differ from HIC's systems for standard care provision.

In conclusion, this systematic review identified different types and methods of facility-based stillbirth review processes implemented around the world and a logic model was built from the extracted evidence to describe what a successful stillbirth review process might encompass. The findings this comprehensive review were used to develop a logic model which could be used as a guide or contextually adapted by health facilities to improve their stillbirth review process. This systematic review raises important questions about what the gold standard stillbirth review process is and how this can be achieved, and whether we can reach a global consensus. The logic model developed from this review is the first step in trying to achieve a global standard for stillbirth review. It does however need to be used to assess its utility and usability and reach consensus about its use as a global standard for stillbirth review. Moreover, since most stillbirths (98%) occur in LMICs, there is an urgent need to introduce standardised stillbirth review processes in more LMICs, while considering the facilitators and barriers, resources required, training and support needs.

Contributors

YYB, NR, JJK, ML and MN were responsible for conceptualisation and methodology. YYB was responsible for data curation, funding acquisition, visualisation, and writing the first draft of the paper. YYB, UGA and DBT were responsible for formal analysis, and investigation. NR was responsible for library resources. YYB and MN were responsible for project administration. YYB, NR and MN were responsible for validation. NR, JJK, ML and MN were responsible for supervision. All authors were responsible for reviewing and editing the drafted paper. YYB, UGA, DBT have accessed and verified the underlying data and all authors were responsible for the decision to submit the manuscript.

Data sharing statement

All data relevant related to the study are included in the article or uploaded as supplementary information.

Declaration of interests

MN is a member of data safety and monitoring board for PREVENT study, a multicentre study on fetal brain injury in South Asia led by Prof Sudhin Thayyil, Imperial College, London (2021 onwards). All other authors declare no competing interests.

Acknowledgements

This systematic review is part of YYB's DPhil research which is supported by the Clarendon Fund, Kellogg College Award, and Nuffield Department of Population Health Scholarship, University of Oxford. MN is funded by a Medical Research Council Transition Support Award (MR/W029294/1). ML was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at UCL Great Ormond Street Institute of Child Health/Great Ormond Street Hospital NHS Foundation Trust. NR, JJK and MN are employed at the University of Oxford, a collegiate research university in Oxford, England. The Funding for YYB's DPhil was also received from the University of Oxford, England. ML is employed at University College London (UCL), a public research university in London, England. We would like to thank Femke Maria Ahlers, Camilla Hatling, Diego Aguilar-Ramírez, Julia Vila-Guilera, and Cinja Jostock for helping with the data extraction of articles in a language other than English.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2023.101976.

References

1 Kurinczuk J, Draper E, Field D, et al. Experiences with maternal and perinatal death reviews in the UK–the MBRRACE-UK programme. *BJOG An Int J Obstet Gynaecol*. 2014;121:41–46.
2 World Health Organization. *Making every baby count: audit and review of stillbirths and neonatal deaths*. World Health Organization; 2016.
3 Chepkin S, Prince S, Johnston T, et al. Learning from standardised reviews when babies die. In: *National perinatal mortality review tool: first annual report*. Oxford: National Perinatal Epidemiology Unit; 2019.
4 Boo YY, Gwacham-Anisiobi U, Thakrar DB, et al. A systematic review of facility-based stillbirth review processes used in different countries across the world. *PROSPERO Int Prospect Regist Syst Rev*; 2022. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022304239. Accessed February 11, 2022.
5 Willcox ML, Price J, Scott S, et al. Death audits and reviews for reducing maternal, perinatal and child mortality. *Cochrane Database Syst Rev*. 2020;3(3):CD012982.
6 Veritas Health Innovation. *Covidence systematic review software*. 2022.
7 Munn Z, Barker TH, Moola S, et al. Methodological quality of case series studies: an introduction to the JBI critical appraisal tool. *JBI Evid Synth*. 2020;18:2127–2133.
8 Taylor-Powell E, Henert E. Developing a logic model: teaching and training guide. *Benefits*. 2008;3:1–118.
9 Helps A, 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;250:24–30.
10 Flenady V, Kettle I, Laporte J, et al. Making every birth count: outcomes of a perinatal mortality audit program. *Aust N Z J Obstet Gynaecol*. 2021;61:540–547.
11 Richardus JH, Graafmans WC, Bergsjo P, et al. Suboptimal care and perinatal mortality in ten European regions: methodology and evaluation of an international audit. *J Matern Fetal Neonatal Med*. 2003;14:267–276.
12 Andersen KV, Lange AP, Helweg-Larsen K. A perinatal audit of stillbirths in three Danish counties. *Scand J Soc Med*. 1991;19:127–133.
13 Westergaard HB, Langhoff-Roos J, Larsen S, Borch-Christensen H, Lindmark G. Intrapartum death of nonmalformed fetuses in Denmark and Sweden in 1991. A perinatal audit. *Acta Obstet Gynecol Scand*. 1997;76:959–963.
14 Sauvegrain P, Carayol M, Piedvache A, et al. Understanding high rates of stillbirth and neonatal death in a disadvantaged, high-migrant district in France: a perinatal audit. *Acta Obstet Gynecol Scand*. 2020;99:1163–1173.
15 De Caunes F, Alexander GR, Berchel C, Guengant J-P, Papiernik E. The Guadeloupean perinatal mortality audit: process, results, and implications. *Am J Prev Med*. 1990;6:339–345.
16 Furst AL, Shamba E. Methodological issues associated with an audit of stillbirth in a family medicine practice in Israel. *Fam Pract*. 1989;6:177–181.
17 D'Aloja P, Salvatore MA, Sampaolo L, Privitera MG, Donati S, Group PMSSW. A nationwide surveillance system to reduce perinatal death cases in Italy: implementing a population-based pilot project. Un Sist di sorveglianza Naz per la riduzione della mortalita Perinat Ital implementazione di un Progett Pilot Popul *Epidemiol Prev*. 2021;45:343–352.

18 Alderliesten ME, van Lith JMM, Bleker OP, et al. Design and evaluation of a regional perinatal audit. *Eur J Obstet Gynecol Reprod Biol*. 2008;137:141–145.
19 Dekker CJ, Springer MP, Kanhai HHH. Perinatal mortality in a region where obstetric primary care is provided by the general practitioner: an audit. *Huisarts Wet*. 2003;46:191–195.
20 Eskes M, Van Alten D, Treffers PE. The Wormerveer study; perinatal mortality and non-optimal management in a practice of independent midwives. *Eur J Obstet Gynecol Reprod Biol*. 1993; 51:91–95.
21 Van Diem M, De Reu P, Eskes M, et al. National perinatal audit, a feasible initiative for The Netherlands!? A validation study. *Acta Obstet Gynecol Scand*. 2010;89:1168–1173.
22 van Diem MT, Timmer A, Bergman KA, et al. The implementation of unit-based perinatal mortality audit in perinatal cooperation units in the northern region of The Netherlands. *BMC Health Serv Res*. 2012;12:195.
23 Wolleswinkel-Van Den Bosch JH, Richardus J-H, Mackenbach JP, et al. Substandard factors in perinatal care in The Netherlands: a regional audit of perinatal deaths. *Acta Obstet Gynecol Scand*. 2002;81:17–24.
24 Eskes M, Waelput AJM, Erwich JJHM, et al. Term perinatal mortality audit in The Netherlands 2010-2012: a population-based cohort study. *BMJ Open*. 2014;4:e005652.
25 PMMRC, Fourteenth Annual report of the perinatal and maternal mortality review committee. *Te Pūrongo ā-Tau Tekau mā Whā o te Komiti Arotake Mate Pēpi, Mate Whaea Hoki: Reporting mortality and morbidity 2018*. Te tuku pūrongo mō te mate me te whakamate 2018. Wellington: Health Quality & Safety Commission.; 2021.
26 Berge LN, Rasmussen S, Dahl LB. Evaluation of fetal and neonatal mortality at the University Hospital of Tromso Norway, from 1976 to 1989. *Acta Obstet Gynecol Scand*. 1991;70:275–282.
27 Bjellmo S, Hjelle S, Krebs L, Magnussen E, Vik T. Adherence to guidelines and suboptimal practice in term breech delivery with perinatal death- a population-based case-control study in Norway. *BMC Pregnancy Childbirth*. 2019;19:330.
28 Fossen D, Silberg IE. Perinatal deaths in the county of Ostfold 1989-97. *Tidsskr den Nor laegeforening*. 1999;119:1272–1275.
29 Han JY, Huang EY, Tan KH. Targeted patient education-A critical step toward reducing stillbirth rates. *Perinatology*. 2018;19:41–49.
30 De la Puente ML, Marti A, Pascual E, et al. Analysis of perinatal mortality in Bages (Barcelona). *Rev Calid Asist*. 2002;17:106–110.
31 Miranda JA, Herruzo AJ, Mozas J, et al. Influence of obstetric and perinatal care on perinatal mortality. *Eur J Obstet Gynecol Reprod Biol*. 1996;67:103–107.
32 Eksmyr R, Larssen KE, Bakketeig LS, et al. Perinatal mortality in a Swedish county 1973-1978. Time trends revealed by perinatal audit. *Acta Paediatr Scand*. 1986;75:17–23.
33 Essen B, Bodker B, Sjoberg NO, et al. Are some perinatal deaths in immigrant groups linked to suboptimal perinatal care services? *BJOG*. 2002;109:677–682.
34 Sterpu I, Bolk J, Perers Öberg S, Hulthén Varli I, Wiberg Itzel E. Could a multidisciplinary regional audit identify avoidable factors and delays that contribute to stillbirths? A retrospective cohort study. *BMC Pregnancy Childbirth*. 2020;20.
35 Cross-Sudworth F, Williams M, Gardosi J. Perinatal deaths of migrant mothers: adverse outcomes from unrecognised risks and substandard care factors. *Br J Midwifery*. 2015;23:734–740.
36 Draper E, Kurinczuk J, Kenyon S, on behalf of MBRRACE-UK. MBRRACE-UK 2017 perinatal confidential enquiry: term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. In: *The infant mortality and morbidity studies*. Leicester: Department of Health Sciences, University of Leicester; 2017.
37 Hundley V. *Determining success in the provision of maternity care*. UK Irel: PQDT; 2001. https://www.proquest.com/dissertations-theses/determining-success-provision-maternity-care/docview/301575818/se-2?accountid=13042.
38 Maternal and Child Health Research Consortium. *Confidential enquiry into stillbirths and deaths in infancy: 6th annual report*. London: Maternal and Child Health Research Consortium; 1999.
39 Mersey Region Working Party on Perinatal Mortality. Confidential inquiry into perinatal deaths in the Mersey region. *Lancet (London, England)*. 1982;1:491–494.
40 Tan KH, Wyldes MP, Settatree R, Mitchell T. Confidential regional enquiry into mature stillbirths and neonatal deaths–a multi-disciplinary peer panel perspective of the perinatal care of 238 deaths. *Singapore Med J*. 1999;40:251–255.
41 Tang A-W, Sabir N, Comber K, Liebling R, Pollard J, Roberts D. A pro forma and review process for the assessment of standards of care in stillbirths. *BJOG*. 2011;118:1661–1664.
42 Bausch LC, Smith CV. A focused review of fetal deaths in Nebraska in 1992. *Nebr Med J*. 1996;81:120–121.
43 Harper RG, Sokal MM, Sokal S, Mastrota VF, Davis JG. The high-risk perinatal registry. A systematic approach for reducing perinatal mortality. *Obstet Gynecol*. 1977;50:264–268.
44 Kieltyka L, Craig M, Goodman D, Wise R. Louisiana implementation of the national fetal and infant mortality review (NFIMR) program model: successes and opportunities. *Matern Child Heal J*. 2012;16:353–359.
45 Moawad AH, Lee KS, Fisher DE, Ferguson R, Phillippe M. A model for the prospective analysis of perinatal deaths in a perinatal network. *Am J Obstet Gynecol*. 1990;162:15–22.
46 The National Center for Fatality Review and Prevention. *Fetal and infant mortality review manual: a guide for communities*. Okemos: National Center for Fatality Review and Prevention; 2021.
47 Vallejo BC. Confidential inquiry into perinatal mortality in the Lower Rio Grande Valley, 1988. ProQuest Diss. Theses https://www.proquest.com/dissertations-theses/confidential-inquiry-into-perinatal-mortality/docview/303943485/se-2?accountid=13042; 1991.
48 Amaral E, Souza JP, Surita F, et al. A population-based surveillance study on severe acute maternal morbidity (near-miss) and adverse perinatal outcomes in Campinas, Brazil: the Vigimoma Project. *BMC Pregnancy Childbirth*. 2011;11:9.
49 Raman S, Iljadica A, Gyaneshwar R, Taito R, Fong J. Improving maternal and child health systems in Fiji through a perinatal mortality audit. *Int J Gynecol Obstet*. 2015;129:165–168.
50 Alyahya MS, Khader YS, Al-Sheyab NA, Shattnawi KK, Altal OF, Batieha A. Modifiable factors and delays associated with neonatal deaths and stillbirths in Jordan: findings from facility-based neonatal death and stillbirth audits. *Am J Perinatol*. 2021. https://doi.org/10.1055/s-0041-1730434.
51 Stratulat P, Curteanu A, Caraus T, Petrov V, Gardosi J. The experience of the implementation of perinatal audit in Moldova. *BJOG An Int J Obstet Gynaecol*. 2014;121:167–171.
52 Copenhagen: WHO regional office for Europe. *Perinatal mortality audit: North Macedonia 2019*. World Health Organization; 2020.
53 Govender I. Auditing stillbirths at lower Umfolozi war memorial regional hospital: a 12-month review. *S Afr Med J*. 2017;107:1121–1126.
54 Pattinson RC, Makin JD, Shaw A, Delport SD. The value of incorporating avoidable factors into perinatal audits. *SAMJ (S Afr Med J)*. 1995;85:145–147.
55 Rhoda N, Greenfield D, Muller M, et al. Experiences with perinatal death reviews in South Africa-the perinatal problem identification programme: scaling up from programme to province to country. *BJOG An Int J Obstet Gynaecol*. 2014;121:160–166.
56 Ward HRG, Howarth GR, Jennings OJN, Pattinson RC. Audit incorporating avoidalbility and appropriate intervention can significantly decrease perinatal mortality. *SAMJ (S Afr Med J)*. 1995;85:147–150.
57 Wilkinson D. Reducing perinatal mortality in developing countries. *Heal Policy Plan*. 1997;12:161–165.
58 Mo-suwan L, Isaranurug S, Chanvitan P, et al. Perinatal death pattern in the four districts of Thailand: findings from the prospective cohort study of Thai children (PCTC). *J Med Assoc Thail*. 2009;92:660–666.
59 Demise A, Gebrehiwot Y, Worku B, Spector JM. Prospective audit of avoidable factors in institutional stillbirths and early neonatal deaths at Tikur Anbessa Hospital in Addis Ababa, Ethiopia. *Afr J Reprod Health*. 2015;19:78–86.
60 Musafili A, Persson L-Å, Baribwira C, Påfs J, Mulindwa PA, Essén B. Case review of perinatal deaths at hospitals in Kigali, Rwanda: perinatal audit with application of a three-delays analysis. *BMC Pregnancy Childbirth*. 2017;17:1–13.
61 El Amin S, Langhoff-Roos J, Bødker B, et al. Introducing qualitative perinatal audit in a tertiary hospital in Sudan. *Heal Policy Plan*. 2002;17:296–303.
62 Kirabira VN, Byaruhanga R, Okong P, Dewez JE, Van Den Broek N, Aminu M. Prospective study to explore changes in quality of care and perinatal outcomes after implementation of perinatal death audit in Uganda. *BMJ Open*. 2020;10:e027504.
63 Biswas A, Rahman F, Eriksson C, Halim A, Dalal K. Facility death review of maternal and neonatal deaths in Bangladesh. *PLoS One*. 2015;10:e0141902.

64 Bhatt RV. Professional responsibility in maternity care: role of medical audit. *Int J Gynecol Obstet*. 1989;30:47–50.
65 Sharma B, Aggarwal N, Suri V, Siwatch S, Kakkar N, Venkataseshan S. Facility-based stillbirth surveillance review and response: an initiative towards reducing stillbirths in a tertiary care hospital of India. *J Perinat Med*. 2022. https://doi.org/10.1515/jpm-2021-0440.
66 Supratikto G, ME W, Achadi E, Cohen S, Ronsmans C. A district-based audit of the causes and circumstances of maternal deaths in South Kalimantan, Indonesia. *Bull World Health Organ*. 2002;80:228.
67 Bandali S, Thomas C, Wamalwa P, et al. Strengthening the 'P' in maternal and perinatal death surveillance and response in Bungoma county, Kenya: implications for scale-up. *BMC Health Serv Res*. 2019;19(1):611.
68 Omwodo K. A qualitative perinatal audit at a rural health facility in Eldoret, Kenya, 7. http://imsear.searo.who.int/handle/123456789/202097; 2020
69 Aminu M. *Cause of and factors contributing to stillbirth in Sub-Saharan Africa*. PQDT - Glob; 2017. https://www.proquest.com/dissertations-theses/cause-factors-contributing-stillbirth-sub-saharan/docview/2424363803/se-2?accountid=13042.
70 Hinderaker SG, Olsen BE, Bergsjø PB, et al. Avoidable stillbirths and neonatal deaths in rural Tanzania. *BJOG An Int J Obstet Gynaecol*. 2003;110:616–623.
71 Maaloe N, Housseine N, Bygbjerg IC, et al. Quality of intrapartum care at an East African referral hospital: a case-control study of stillbirths. *BJOG An Int J Obstet Gynaecol*. 2016;123:124.
72 Mbaruku G, van Roosmalen J, Kimondo I, Bilango F, Bergstrom S. Perinatal audit using the 3-delays model in western Tanzania. *Int J Gynecol Obstet*. 2009;106:85–88.
73 Mdoe P, Katengu S, Guga G, et al. Perinatal mortality audit in a rural referral hospital in Tanzania to inform future interventions: a descriptive study. *PLoS One*. 2022;17:e0264904.
74 Wilkins A, Earnest J, Mccarthy EA, Shub A. A retrospective review of stillbirths at the national hospital in Timor-Leste. *Aust N Z J Obstet Gynaecol*. 2015;55:331–336.
75 Kasengele CT, Mowa R, Katai C, et al. Factors contributing to intrapartum stillbirth: a criteria-based audit to support midwifery practice in Zambia. *Afr J Midwifery Women's Health*. 2017;11:67–71.
76 The World Bank. *World Bank country and lending groups*. World Bank; 2022. https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups. Accessed May 22, 2022.
77 Vallely LM, Smith R, Bolnga JW, et al. Perinatal death audit and classification of stillbirths in two provinces in Papua New Guinea: a retrospective analysis. *Int J Gynecol Obstet*. 2020;153:160–168.
78 Da Silva FT, Gonik B, McMillan M, et al. Stillbirth: case definition and guidelines for data collection, analysis, and presentation of maternal immunization safety data. *Vaccine*. 2016;34:6057.
79 Ptacek I, Sebire NJ, Man JA, Brownbill P, Heazell AEP. Systematic review of placental pathology reported in association with stillbirth. *Placenta*. 2014;35:552–562.
80 Scalise C, Cordasco F, Sacco MA, Ricci P, Aquila I. The importance of post-mortem investigations in stillbirths: case studies and a review of the literature. *Int J Environ Res Publ Health*. 2022;19:8817.
81 Miller ES, Minturn L, Linn R, Weese-Mayer DE, Ernst LM. Stillbirth evaluation: a stepwise assessment of placental pathology and autopsy. *Am J Obstet Gynecol*. 2016;214:115.e1–115.e6.
82 Flenady V, Wojcieszek AM, Middleton P, et al. Stillbirths: recall to action in high-income countries. *Lancet*. 2016;387:691–702.
83 Gravel K, Légaré F, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. *Implement Sci*. 2006;1:1–12.
84 Curtis K, Fry M, Shaban RZ, Considine J. Translating research findings to clinical nursing practice. *J Clin Nurs*. 2017;26:862–872.
85 US Department of Veterans Affairs. *Root cause analysis tools*. 2016.
86 Flenady V, Middleton P, Smith GC, et al. Stillbirths: the way forward in high-income countries. *Lancet*. 2011;377:1703–1717.
87 Aminu M, Unkels R, Mdegela M, Utz B, Adaji S, van den Broek N. Causes of and factors associated with stillbirth in low- and middle-income countries: a systematic literature review. *BJOG An Int J Obstet Gynaecol*. 2014;121:141–153.
88 United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). *Never Forgotten: the situation of stillbirth around the globe. New York*. 2023.
89 World Health Organization. *Neonatal and perinatal mortality: country, regional and global estimates*. World Health Organization; 2006.
90 Lawn JE, Gravett MG, Nunes TM, Rubens CE, Stanton C. Global report on preterm birth and stillbirth (1 of 7): definitions, description of the burden and opportunities to improve data. *BMC Pregnancy Childbirth*. 2010;10(Suppl 1):S1.
91 Lawn JE, Yakoob MY, Haws RA, Soomro T, Darmstadt GL, Bhutta ZA. 3.2 million stillbirths: epidemiology and overview of the evidence review. *BMC Pregnancy Childbirth*. 2009;9:S2.
92 Yasmin S, Osrin D, Paul E, Costello A. Neonatal mortality of low-birth-weight infants in Bangladesh. *Bull World Health Organ*. 2001;79:608–614.
93 Flenady V, JF F, Pinar H, et al. An evaluation of classification systems for stillbirth. *BMC Pregnancy Childbirth*. 2009;9:24.

Appendix B: Search terms used for each database

Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to January 11, 2023	
#	Searches
1	(fetal mortality/ or perinatal mortality/) and (clinical audit/ or medical audit/)
2	(Pregnancy Complications/mo or Stillbirth/) and (clinical audit/ or medical audit/)
3	((fetal or foetal or perinatal) adj3 (mortality or death?)).ti,ab. and (clinical audit/ or medical audit/)
4	stillbirth?.ti,ab. and (clinical audit/ or medical audit/)
5	(fetal mortality/ or perinatal mortality/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
6	(Pregnancy Complications/mo or Stillbirth/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
7	(((death? or mortality) adj3 (review* or audit* or meeting? or enquir* or inquir*)) and (fetal or foetal or perinatal)).ti,ab.
8	(stillbirth? adj5 (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.
9	((confidential enquir* or confidential inquir*) and ((fetal or foetal or perinatal) adj3 (mortality or death?))).ti,ab.
10	((confidential enquir* or confidential inquir*) and stillbirth?).ti,ab.
11	(cemach or cmace or cemd or cmde).ti,ab.
12	(saving mothers lives or making pregnancy safer or making childbirth safer).ti,ab.
13	((near miss* or significant event* or critical event* or critical incident?) and (fetal or foetal or perinatal or stillbirth) and (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.
14	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	exp Animals/ not humans/
16	14 not 15
17	(review or meta analysis or news or comment or editorial).pt. or cochrane database of systematic reviews.jn. or comment on.cm. or (systematic review or literature review).ti.
18	16 not 17

Embase 1974 to January 11, 2023	
#	Searches
1	(fetus mortality/ or perinatal mortality/) and medical audit/
2	((*Pregnancy Complications/ and (*"cause of death"/ or *mortality/)) or exp *fetus death/) and medical audit/
3	((fetal or foetal or perinatal) adj3 (mortality or death?)).ti,ab. and medical audit/
4	stillbirth?.ti,ab. and medical audit/
5	(fetal mortality/ or perinatal mortality/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
6	((*pregnancy complication/ and (*"cause of death"/ or *mortality/)) or exp *fetus death/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
7	(((death? or mortality) adj3 (review* or audit* or meeting? or enquir* or inquir*)) and (fetal or foetal or perinatal)).ti,ab.
8	(stillbirth? adj5 (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.
9	((confidential enquir* or confidential inquir*) and ((fetal or foetal or perinatal) adj3 (mortality or death?))).ti,ab.
10	((confidential enquir* or confidential inquir*) and stillbirth?).ti,ab.
11	(cemach or cmace or cemd or cmde).ti,ab.
12	(saving mothers lives or making pregnancy safer or making childbirth safer).ti,ab.
13	((near miss* or significant event* or critical event* or critical incident?) and (fetal or foetal or perinatal or stillbirth) and (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.

14	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	(exp animals/ or nonhuman/) not human/
16	14 not 15
17	(editorial or letter or note or "review").pt. or cochrane database of systematic reviews.jn. or (systematic review or literature review).ti.
18	16 not 17

Global Health <1973 to 2022 Week 52>	
#	Searches
1	(perinatal mortality/ or stillbirths/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
2	pregnancy complications/ and ("causes of death"/ or mortality/) and (review* or audit* or meeting? or enquir* or inquir*).ti,ab.
3	(((death? or mortality) adj3 (review* or audit* or meeting? or enquir* or inquir*)) and (fetal or foetal or perinatal)).ti,ab.
4	(stillbirth? adj5 (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.
5	((confidential enquir* or confidential inquir*) and ((fetal or foetal or perinatal) adj3 (mortality or death?))).ti,ab.
6	((confidential enquir* or confidential inquir*) and stillbirth?).ti,ab.
7	(cemach or cmace or cemd or cmde).ti,ab.
8	(saving mothers lives or making pregnancy safer or making childbirth safer).ti,ab.
9	((near miss* or significant event* or critical event* or critical incident?) and (fetal or foetal or perinatal) and (review* or audit* or meeting? or enquir* or inquir*)).ti,ab.
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9

WHO Global Health Medicus (globalindexmedicus.net)	
#	Searches
1	(fetal OR foetal OR perinatal) AND (death OR deaths OR mortality) AND (audit OR audits OR enquiry OR enquiries OR inquiry OR inquiries OR meeting OR meetings)
2	(death review OR mortality review OR death reviews OR mortality reviews) AND (fetal OR foetal OR perinatal)
3	(stillbirth OR stillbirths) AND (audit OR audits OR enquiry OR enquiries OR inquiry OR inquiries OR meeting OR meetings)
4	confidential enquiry OR confidential enquiries OR "confidential inquiry" OR "confidential inquiries" OR cemach OR cmace OR cemd OR cmde OR saving mothers lives OR making pregnancy safer OR making childbirth safer
5	(near miss OR significant events OR critical events OR critical incidents OR significant event OR critical event OR critical incident) AND (audit OR audits OR enquiry OR enquiries OR inquiry OR inquiries OR meeting OR meetings) AND (fetal OR foetal OR perinatal)
6	1 OR 2 OR 3 OR 4 OR 5

CINAHL (EBSCOHost) [1982 to January 11, 2023]	
#	Searches
S12	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11
S11	TI (("near miss*" or "significant event*" or "critical event*" or "critical incident?") and (foetal or perinatal) and (review* or audit* or meeting? or enquir* or inquir*)) or AB (("near miss*" or "significant event*" or "critical event*" or "critical incident?") and (foetal or perinatal) and (review* or audit* or meeting? or enquir* or inquir*))
S10	TX saving mothers lives or making pregnancy safer or making childbirth safer
S9	TX cemach or cmace or cemd or cmde
S8	TX ((confidential enquir* or confidential inquir*) and (stillbirth*))

S7	TX ((confidential enquir* or confidential inquir*) and ((foetal or perinatal) N3 (mortality or death*)))
S6	TX ((stillbirth*) N5 (review* or audit* or meeting* or enquir* or inquir*))
S5	TI (((death* or mortality) N3 (review* or audit* or meeting* or enquir* or inquir*)) and (foetal or perinatal)) or AB (((death* or mortality) N3 (review* or audit* or meeting* or enquir* or inquir*)) and (foetal or perinatal))
S4	(((MH "Pregnancy Complications+/MO") OR (MH "Perinatal Death"))) AND (TI ((review* or audit* or meeting? or enquir* or inquir*)) or AB ((review* or audit* or meeting? or enquir* or inquir*)))
S3	((stillbirth*)) AND (MH "Audit")
S2	(((foetal or perinatal) N3 (mortality or death*))) AND (MH "Audit")
S1	((MH "Pregnancy Complications+/MO") OR (MH "Perinatal Death")) AND (MH "Audit")

WHO database (who.int)
stillbirth site:who.int.
stillbirth review site:who.int.
stillbirth audit site:who.int
perinatal site:who.int.
perinatal death review site:who.int.
perinatal death audit site:who.int.
confidential inquiries site:who.int.
foetal death review site:who.int.
foetal death audit site:who.int.

Google Scholar (scholar.google.com)
(stillbirth OR perinatal mortality OR perinatal death) (audit OR chart review OR mortality review OR death review OR confidential enquiry)

ProQuest Dissertations & Theses Global (proquest.com)
ab(Stillbirth OR perinatal mortality OR perinatal death) AND ab(audit OR chart review OR mortality review OR death review OR confidential enquiry)

Appendix C: Data extraction template

General information

1. First author and Year

E.g. Boo, 2021

2. Country in which the study conducted

Please HIGHLIGHT the country where the stillbirth review was/has been conducted. Some papers describe several countries, e.g. EuroNatal Working Group, which were Belgium, Denmark, the UK, Finland, Greece, Netherlands, Norway, Spain and Sweden. Please select all that apply.

1. Australia
2. Bangladesh
3. Brazil
4. Belgium
5. Denmark
6. Ethiopia
7. Fiji
8. France
9. Finland
10. Ghana
11. Guadeloupe
12. Greece
13. India
14. Indonesia
15. Israel
16. Italy
17. Jordan
18. Kenya
19. Malawi
20. Moldova
21. Mozambique
22. Netherlands
23. New Zealand
24. Norway
25. Papua New Guinea
26. Rwanda
27. Sierra Leone
28. Singapore
29. South Africa
30. Spain
31. Sudan
32. Sweden
33. Tanzania
34. Thailand
35. Timor-Leste
36. Uganda
37. United Kingdom

38. United States
39. Zambia
40. Zimbabwe
41. Other: specify

3. Notes

If you have any additional notes you want to write down.

The facility-based stillbirth review process

4. Aim

E.g. to present the analysis and assess avoidable factors associated with stillbirths identified in an ongoing trial.

E.g. In 2016, perinatal death was added as a component to the national MDSR guidelines in Kenya

E.g. to improve the quality of care provided by a maternity service in rural Africa and to use the results of the review to inform the design of interventions (structural and functional rearrangement of the maternity service district-wide, writing and implementing protocols of care for local use, and regular in-service education).

5. Funding

E.g. Financed by the Regional Health Agency of Ile-de-France.

E.g. Conducted under the UKAID funded Maternal and Newborn Health Initiative (MANI) project in Kenya. The MANI project and staff members working and funded by UKAID under this project undertook te review as part of documenting learnings.

6. Level

Please HIGHLIGHT your selection (select only one)

1. Local/hospital(s)
2. District/state
3. National
4. International
5. Other

7. Details of the hospital/regions

Name of the hospitals, number of hospitals involved, number of states involved that can be identified. Sometimes, due to the confidentiality and sensitive nature of reporting of stillbirth, the paper may have kept this information vague.

E.g. district hospital and a tertiary referral hospital in Kigali, Rwanda

E.g. midwife-managed unit within the Aberdeen Trial

E.g. 10 peri-urban and rural health centers in East New Britain and Madang provinces

8. Type

Please HIGHLIGHT your selection (select only one) according to how the study described themselves.

1. Audit
2. Review
3. Confidential enquiries

9. What did the process (audit/review/confidential enquiries) entail?

To guide "Examine reasons for suboptimal care or avoidable factors", the review should look into components of care that were judged to be substandard (e.g. detection, resources, organisational or communication). If the review inquired if the suboptimal care occurred or not, but there were no details about what it entailed, then this review does not "Examine reasons for suboptimal care or avoidable factor".

Please HIGHLIGHT your selection (select all that apply)

1. Data collection
2. Case assessment
3. Implementation of changes based on outputs
4. Re-evaluation (i.e. a continuous cycle)
5. A collaboration between different specialities in obstetrics, midwifery, and pathology (i.e. the multidisciplinary team)
6. Examine reasons for suboptimal care or avoidable factors
7. Dissemination of key findings and learning points to all relevant clinical staff
8. Anonymous review
9. Other

10. Duration/Time

E.g. 2020-2021, Jan-July 2021

11. Source of data

Examples, usually applicable if the review was done in a local facility setting and review was conducted prospectively:

E.g. Hospital records and interviews

Examples, usually applicable if the review was done in a confidential inquiry setting or retrospective review as part of a research project:

E.g. the national Swedish Medical Birth Register

E.g. all stillbirths identified in Severe adverse events reports from the Women and Newborn Trial of Antenatal Interventions and Management (WANTAIM) trial

12. Identification of stillbirth

E.g. A stillbirth was defined as a fetal death after at least 22 completed weeks of gestation or weighing 500 g or more at birth.

How the stillbirth was defined. Since stillbirth is quite straightforward to diagnose, some papers might have not listed how they identified stillbirth, and may just state the source of data. If this is the case, please put N/A.

13. Data collection method

E.g. using a questionnaire containing both closed and open-ended questions. The first part of the questionnaire included information on the socioeconomic characteristics of the women and their households. The second part included data on routine antenatal screening and care, pregnancy complications and their management, characteristics of labour and delivery, condition of the baby at birth (alive or stillbirth) and afterwards, Apgar score, management of the newborn's illness that led to a fatal outcome, and time and causes of death. The third part of the questionnaire comprised information obtained from interviews with women and healthcare providers.

E.g. Narratives based on individual records were written for each birth. They contained in-depth descriptions of relevant time-related events, including such elements as medical history, social conditions, communication, surveillance, interventions and outcome.

14. Who collected the data

E.g. one nurse, one midwife, and one doctor

E.g. one member of the research team

15. Who conducted the review

E.g. An expert panel of three obstetricians and one neonatologist

E.g. Audit committee were recruited from the hospitals and included two obstetricians, two paediatricians, and the main investigator, who is also a paediatrician

16. Definition of suboptimal care or avoidable factors

Not all studies have defined the suboptimal or avoidable factors. If this is the case, put N/A.

E.g. An error (e.g. incorrect labour ward management decision) or omission (e.g. failure to test for syphilis at antenatal booking) on the part of a member of the health service team (administrative staff, drivers, and laboratory technicians, as well as doctors and midwives)

17. Review tool or/and review method

Not all papers had a specific review tool or meeting. Some papers might have conducted a review by simply selecting a code in a database which then was reviewed by second or panel reviewers.

E.g. The abstracted chart data were reviewed independently by a panel.

E.g. Firstly, a medical investigator reviewed each death with the team that cared for the pergnant woman. Then, each case was reviewed, after removal of identifying information, by at least one peer assessor from an external panel.

E.g. Once one member of the research team conducted the initial analysis and coding of each case, a second reviewer reviewed and conducted an independent analysis and coding. The differences were resolved through discussion and consensus; adjudication where necessary were undertaken by a third reviewer. To further validate assigned codes, 10% of the cases were randomly selected, assessed, and coded independently by two obstetricians.

Outputs and outcomes

18. Output

Outputs are the data/information that results from the stillbirth review.

E.g. Perinatal Mortality Rate (PNMR), Proportion of death classified as avoidable.

E.g. Proportion and details of demographics/clinical information (e.g. gestational age, maternal condition) of women who had a stillbirth, cause of stillbirth, avoidable factors identified.

19. Outcome

Not all stillbirth reviews led to an outcome. Please state N/A if this is the case. Outcomes are different to outputs as outcomes are the short and medium benefits that a stillbirth review brings.

E.g. The review enabled the design and implementation of specific interventions targeted at areas of care causing unnecessary death.

Facilitators and barriers

20. Facilitators

Not all studies have identified facilitators. In this case, please put N/A.

E.g. awareness and training to mobilise health staff to attach prominence to and conduct reviews.

E.g. ensuring the focus remains on learning and improving quality of care rather than on placing blame or engaging in punitive measures

21. Barriers

Not all studies have identified barriers. In this case, please put N/A.

E.g. poor documentation and missing records led to difficulties in extracting data needed for the review.

E.g. Having the appropriate death review reporting templates in place at the facility level which align with national online forms.

E.g. the volume of deaths.

Appendix D: Quality assessment template

1. Were there clear criteria for inclusion in the review?

The authors should provide clear inclusion (and exclusion criteria where appropriate) for the study participants. The inclusion/exclusion criteria should be specified (e.g. risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

- Yes
- No
- Unclear
- Not applicable

2. Was the condition (stillbirth) measured in a standard, reliable way for all fetus included in the review?

The study should clearly describe the method of measurement of the condition. This should be done in a standard (i.e. same way for all patients) and reliable (i.e. repeatable and reproducible results) way.

- Yes
- No
- Unclear
- Not applicable

3. Were valid methods used for identification of the condition (stillbirth) for all fetus included in the review?

Sometimes stillbirths are not easily diagnosed or defined. If the outcomes (stillbirth) were assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If the outcomes were assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

- Yes
- No
- Unclear
- Not applicable

4. Did the review have consecutive inclusion of stillbirth cases?

The completeness of a review contributes to its reliability. Studies that indicate a complete inclusion are more reliable than those that do not. As stated above, a review that states 'we included all cases with stillbirth who presented to our clinic between March 2005 and June 2006' is more reliable than a study that simply states 'we report a review of 24 stillbirths'.

- Yes
- No
- Unclear
- Not applicable

5. Was there clear reporting of the demographics of the women who had a stillbirth in the review?

Minimum, the stillbirth review should collect the following demographic information of the women. Please select **YES** if there are some or all of the information below reported in the report.

- Age (years)
- Parity (numbers)
- Gestational age at birth
- Pregnancy complications
- Antenatal visits
- live in Rural/urban area
- Any Socio-economic Status (SES) information
  - Yes
  - No
  - Unclear
  - Not applicable

6. Was there clear reporting of "quality of clinical care" of the stillbirth cases?

All included studies in this systematic review stated that their stillbirth review process assesses the quality of care or avoidable factors. Therefore, this question is asking if the review method lists the "quality of clinical care" in detail or not. So, if the quality of clinical care was listed with what kind of sub-optimal care during the pregnancy/labour occurred (details), then the answer to this question is likely to be yes. If it simply says 40% were found to have had components of suboptimal care but not details on what these were (e.g. no checkup for fetal movement).

- Yes
- No
- Unclear
- Not applicable

7. Were the outcomes or follow-up results of having a review process clearly reported?

This question is asking if having a review process allowed the facility to action any recommendations made as a result of the review outcomes (e.g. started providing training about the importance of fetal monitoring for nurses... etc. as this was found to be one of the suboptimal care factors that may contribute to stillbirth).

- Yes
- No
- Unclear
- Not applicable

8. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?

Certain diseases or conditions vary in prevalence across different geographic regions and populations (e.g. sociodemographic variables between countries). However, stillbirth is a sensitive topic and the study might not report in detail where the review was conducted. If the paper has some/any information (e.g. was conducted in 3 hospitals) of the sites, please select Yes.

- Yes
- No
- Unclear
- Not applicable

9. Was statistical analysis appropriate?

If there was any statistical analysis, were the method listed in detail and were appropriate? The methods section of studies should be detailed enough for reviewers to identify which analytical techniques were used and whether these were suitable.

- Yes
- No
- Unclear
- Not applicable

Appendix E: Included studies and the extracted data

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Alderliesten, 2008 [75]	• Perinatal deaths are reported to the investigator by fax	• The investigator fill in the structured case record form (CRF) on site after receiving a perinatal death notification	• All audit members are trained and the case summaries and clinical data (such as cardiotocography) are distributed three weeks prior to each audit session • The review include an individual judgment of each case, using a structured judgment form, prior to the session • A collective judgment of the perinatal audit panel follow after discussion during the audit session • An independent chairman preside over all sessions • The cause of death is recorded during the panel meetings, using three internationally accepted classification methods (Extended Wigglesworth classification, modified Aberdeen classification, fetal and infant classification) • An overall review of the contribution of sub-standard care factors in each case to the occurrence of perinatal death is determined and graded[$] • The component of perinatal care (attributed to the mother or care provider) which was judged to be substandard (detection, therapy, logistics or communication) is recorded, as is the responsible care provider. • Ten cases (7.3%) reviewed by the Amsterdam audit are allocated at random and presented to the external audit committee

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Alyahya, 2021 [107]	• Identified stillbirth among registered births in the five hospitals under study	• A death case review form with key details is filled from hospital notes and interviews from mothers, family members, relatives, and health worker	• The members of each death review committee (DRC) receive training • Each DRC meet on a monthly basis to review all stillbirths and uses a specific form (mortality audit and action items form) to record the main cause of death; identify any critical delays and modifiable factors; identify the specific actions required to address the identified modifiable factors; and devise a follow-up plan
Amaral, 2011 [105]	• Hospital records	• Data are collected from the medical and administrative records • Clinical care provided in each case is compared with the standards defined in the Manuals on Emergencies and Humanized Healthcare (supervised by two research assistants and the principal investigator)	• Committee members identify potential delays in seeking, reaching or receiving care (presented as percentages) and a preventability score (PS) is proposed, based on the potential capacity of each intervention suggested to prevent the situation, ranging from 0 (none) to 5 (max) as judged by committee members in a participatory, consensus-driven process • The mean PS is calculated from PS for each individual intervention, and the total per event is proposed as a product of the mean score of each intervention multiplied by the number of cases for which it was suggested
Aminu, 2017 [126]	• Facility registers • Delivery registers • Surgical theatre registers • Midwives' handover notes	• Data is collected using a specially designed data collection tool, informed by different countries' audit forms and consultation with 22 health care workers from the participating countries. • Date of delivery, maternal sociodemographic characteristics, pregnancy details, obstetric and medical history, baby's characteristics, cause of death, and possible risk	• Health care professionals and the author review cases of stillbirth in batches within one month of death • the completed forms from all participating hospitals are reviewed over several months, and at least one expert reviews each case. 1/4 of the sample is reviewed by a second reviewer • data is entered into the data capture form using the Excel macro algorithms • Standard of care is assessed using the grading system (0-2 only)*

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		factors associated with the death are collected • Other contextual information about the facilities are collected (e.g. signal function available, total deliveries)	
Andersen, 1991 [69]	• Medical records	• Data are entered into a questionnaire • Detailed summary of each medical record is created	• The summaries and the questionnaires are sent to the members of each panel three weeks before the meetings • The panel answer two questions: 1) would a different treatment have improved the infant's possibility of survival and 2) should a different treatment have been given • Cases in which the panel answered "no" to one or both were allocated to "unavoidable deaths" • Cases in which the panel answered "yes" to both were allocated to "potentially avoidable deaths" • The panels are asked to state which suboptimal factor led to potentially avoidable deaths • Suboptimal factors are categorised into suboptimal care in antenatal care or intrapartum care
Bandali, 2019 [124]	• Perinatal Death Notification Form submitted to the facility Health Records Information Officer (HRIOs) • Case notes from the hospitals	• Data extracted using National online forms (DHIS2) for perinatal death review reporting and case notes	• The Maternal and perinatal death surveillance and response (MPDSR) review meetings are held monthly to identify causes of death, avoidable causes, service delivery and quality gaps after the notification of perinatal death • The review team fills out a review form which the HRIOs then submit as members of the review committee • Perinatal death review actions are regularly tracked by the MPDSR committee, with

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			feedback provided on the status of each recommendation.
Bausch, 1996 [99]	• Fetal death certificates	• Data requests for information are sent from the Nebraska Medical Association to the medical records department of the hospital and to the physician singing the certificate of death	• The cases are numerically coded, and the medical information was mailed to reviewers • Reviewers comment on aspects of prenatal care, intrapartum care, fetal data, cause of fetal death and if, in the reviewer's opinion, alteration of care received by the patient could have reduced the likelihood of fetal death
Berge, 1991 [83]	• Antenatal charts • Hospital records	• Not stated	• Chart review • Main cause of death and the avoidability of death are identified
Bhatt, 1989 [121]	• Hospital records	• The unit concerned completes all papers on the deaths and submits the data to the committee, comprised of two members from the teaching staff along with the professor • The committees raises questions and seek clarification on various points and if needed, the resident who managed the case will be called for additional information before it is filed.	• Six to eight meetings are conducted annually to discuss stillbirth • The staff and residents are encouraged to freely express their opinions • Ward nurses hold fortnightly meetings to discuss aspects of complicated obstetric cases
Biswas, 2015 [120]	• Existing records • Recall by visiting the health care providers in the facility who treated or managed the patient before death	• Using the facility death notification form and the death review form	• Senior staff nurses/family welfare visitors perform facility death notifications • Facility death review meetings are conducting quarterly to analyse death cases and create action plans in the district and in upazilas
Bjellmo, 2019 [84]	• Medical Birth Registry of Norway (MBRN)	• Case notes (open review) or a written detailed summary (blinded review)	• For open review, the two authors evaluate if the deliveries were in line with current Norwegian guidelines and if they could have been avoided if a planned caesarean delivery (CD) had been performed

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			• The course of the actual delivery is evaluated against both the guidelines relevant at the time of delivery and the current guidelines and if the delivery was managed suboptimally • To assess the suboptimal care, it is assessed subjectively by the two authors based on their clinical experience and the available written information • For blinded review, the two external examiners independently complete a questionnaire about the course of the delivery • In this questionnaire, they are asked to indicate any deviations from the Norwegian guidelines and whether they considered the management of the delivery to be suboptimal or not • They are also asked to predict whether they would expect the child to die or survive • Regardless of this prediction, they are also asked to indicate whether the planned CD could have prevented death if the child had died • The consensus meeting is conducted with all four authors
Chepkin, 2019 [42]	• Deaths are notified within 7 days of the death and are then available within the Perinatal Mortality Review Tool (PMRT) to be reviewed using the PMRT	• Data is collected in the PMRT • Relevant notes, statements, results of any follow-up investigations and other necessary information about the mother and her pregnancy • Demographic details, pregnancy and medical history from the booking and antenatal information	• Once the data is collected, the PMRT presents the death details and provide *opening up* questions based on the information and responses provided for each question asked • The questions consider the care provided and judgements about the quality of care provided • The issues identified by the PMRT will be listed at the end of the review and the review group identifies the factors which contributed to this issue

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		• Parents' perspectives and any questions they raised • A timeline of the events	• The review team selects contributory factors from the National Patient Safety Agency Contributory Factors Classification Framework • The review team identifies whether that issue was likely to have contributed to the outcome for the baby or the mother • The review group identifies the actions needed to improve care • The review group are asked to consider and grade (0-3)* the quality of care provided for each of the following: 1) "the care provided to the mother and baby up to the point that the baby was confirmed as having died"; 2) "the care provided to the mother following confirmation of the death of her baby"
Copenhagen: WHO Regional Office for Europe, 2020 [109]	• The State Statistical Office (SSO) • Case notes	• Maternal characteristics and information on risk factors during pregnancy, care during pregnancy, social factors and quality of neonatal care is entered into a predesigned database	• Medical records are distributed to the review members • The review members analyse the health care interventions given to the mothers, assess application of standards of care, possible delays in providing adequate care and any action points identified from the review • The classifications and forms were adapted from the WHO, Making every baby count: audit and review of stillbirths and neonatal deaths and the United Nations International Children's Emergency Fund (UNICEF) capacity-building package
Cross-Sudworth, 2015 [92]	• Not stated	• Copies of relevant case notes are obtained • A short risk assessment form is sent to mother's General Practitioner and to named community midwives to	• Each panel has an independent chair and assisted by specialist midwives from the West Midlands Perinatal Institute

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		collect details of the social, psychological and medical risk factors	• The panel discuss and comment on the standard of care and avoidability of outcome based on CESDI criteria (0-3)*
D'Aloja, 2021 [74]	• Each case is reported to the Regional Operational Unit (ROU) and National Operational Unit (NOU) within 48 hours through a web-based system	• During the first stage of the surveillance system (local audit), the SP1 anonymous paper form is filled in to summarise the mother and newborns clinical history, the complete care pathway, and the cause of death • The SO online form describing the facility organisation to verify compliance with the national clinical standards requirements is filled in	• The perinatal mortality surveillance system (SPItOSS) operates via three organisational levels • Local level conducts multiprofessional audits using the Significant Event Audit methodology • Regional level has a ROU subgroup that conducts regional Confidential Enquiries once they are notified of perinatal deaths, where they review by prioritising the most preventable deaths in the following order: 1) intrapartum deaths, 2) neonatal deaths related to intrapartum foetal distress and subsequently other neonatal deaths, 3) antepartum deaths, starting from those occurring from 35 gestational weeks • ROU assess the cause of death, identify clinical or organisational weaknesses in the care system, develop recommendations, and determine death avoidability • The avoidability focuse on four criteria: 1) inappropriate care with avoidable outcome; 2) improvable care with unavoidable outcome; 3) appropriate care with unavoidable outcome; 4) unaccountable outcome • National level revises and re-evaluates the regional Confidential Enquiries up to 100 cases (with the same priority protocol as regional level), and NOU also organises an annual national meeting with the Confidential Enquiries Regional Committee and the

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			Confidential Enquiries National Committee experts to discuss the discordant cases and attain a shared evaluation
de Caunes, 1990 [72]	• Telephone notification to audit process by any medical or paramedical staff member	• Within 24 hours after notification of death, the corpse, placenta cord are macroscopically examined; blood and cerebrospinal fluid are sampled for bacteriological culture; medical charts and hospital records are reviewed • Medical and paramedical personnel and mothers are interviewed • Once the data is compiled, a comprehensive report is sent for corrections to the obstetrician in charge of the delivery	• A meeting is held to discuss each case and complete a perinatal death certificate based on recommendations provided by the WHO • Cause of death and factors amenable through facility's practices are examined • Avoidable deaths are discussed by conducting a critical review of the care involved while considering mothers' socioeconomic environment and perinatal resources available in the region • With avoidable death that did not reach a consensus, an external reviewer is involved
De la Puente, 2002 [87]	• Medical records • the maternal health primary care providers via interviews	• Data is collected using medical records and interview • Based on country of origin, women are categorised as born in Spain or immigrants.	• Obstetric suboptimal care is graded using the CESDI format (0-3)* • Avoidable factors are identified using Mantel classification
Dekker, 2003 [76]	• The National Obstetrics Registration Primary Care (Landelijke Verloskunde Registratie eerstelijn, LVR-1) • National Obstetrics Registration Secondary Care (Landelijke Verloskunde Registratie tweedelijn, LVR-2)	• The status inquiry is made if data was missing or incomplete • A file was created for each death	• The files are sent to the panel members, and they are asked to determine the cause of death using the Aberdeen classification, and determine if there had been suboptimal care, and to which extent this suboptimal care could have caused death • Suboptimal factors is graded (0-3)§ • If there was no consensus when comparing individual grades, panel members can see other members' grades and reconsider their own score.

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			• If there was still no consensus after the second phase, a plenary meeting is organised to discuss the cases
Demise, 2015 [116]	• Hospital's birth register	• Using a standardised data collection form data is abstracted from medical records and data is obtained by conducting interviews with health staff involved in the care of stillbirth, mothers and family members, • The interviews are conducted using a pre-tested and structured questionnaire that incorporated a modified verbal autopsy instrument developed by the WHO	• The Audit Team determines the diagnosis and immediate cause of death, according to Wigglesworth classifications; whether or not the death was preventable; and if preventable, what specific avoidable factors contributed to the death • Determining whether or not a death was avoidable rely upon serious consideration of information derived from multiple inputs and deliberation among members of the Audit Team • When reviewing cases, the Audit Team take particular note of risk factors that are known to be associated with poor outcomes, and how these may have related to missed opportunities to provide standard care practices
Draper, 2017 [93]	• The Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) perinatal mortality surveillance system	• Copies of all relevant case notes are requested to be sent from the local Trust or Health Board teams to the MBRRACE-UK office (except Northern Ireland where they will gain consents from the family and redact records before sending them to the MBRRACE-UK office) • Trusts and Health Boards provide details on notes that were unavailable and add any helpful how to locate them • A research midwife prepares the notes for the inquiry panels in logical	• Panel members receive the anonymised notes three weeks prior to the meeting • A lead presenter is identified for each case from the panel and the lead is responsible for presenting at the meeting and completing a checklist prior to the meeting • Panel meetings are chaired by one of three neutral chairs • The panel's composition depend upon the type of cases being discussed • A general discussion followed by a consensus opinion of the grade of quality of care (0-3)[&], relevance of grade of care to outcome (0-3)[+] and which aspects were suboptimal are noted

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		order, redacting identifiable or removing any irrelevant information and producing a summary	(what, who) for each aspect of care (antenatal, during labour, at birth, post-natal and bereavement, post-mortem/placental histology) • Overall quality is graded (0-2 only)* and a summary comments are given, and the panel evaluates if the overall grade relates to mother's health, care of the baby or both
Eksmyr, 1986 [89]	• the Swedish Medical Birth Registry	• A summary is collated from the medical records	• The panel classifies each case into one of two categories, unavoidable and possibly avoidable deaths and specific details of avoidable factors with reference to the time period (antenatal or intrapartum) is stated • The avoidable deaths are only referred to hospital care and not maternal or social factors • The classification is based on the state of the art and time of delivery is blinded to the panel when making decision
El Amin, 2002 [118]	• Registration of all births at the delivery wards	• Narratives on all cases of perinatal death are prepared in both Arabic and English.	• Audit meetings are held at 2-week intervals, and the last one is an open meeting presenting the results of the process and suggested measures for the future • The narratives of cases for assessment and audit grading forms in English and Arabic are distributed to audit committee members two days before the audit meetings • Based on clinical judgment, all cases are assessed individually by the auditors prior to the meetings • A grading form on each case consisted of pre-structured questions: 1) do pre-pregnant risk factors or events during pregnancy indicate that the woman should have been delivered selectively before labour? 2) according to your

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			judgement, considering the local resources, the death was associated with: optimal care (=1), probably acceptable care (=2), probably suboptimal care (=3) or suboptimal care (=4) • Further comments specifying or discussing suboptimal conditions and care are requested • During the meetings, all cases are presented by the PhD student, after which open discussions led to a consensus on the audit questions of the grading form • An external audit panel of two Danish senior obstetricians who had knowledge about the local structure, organisation and resources in Sudan assessed all cases after the meetings • In Sudan, no explicit criteria are followed, and therefore assessments reflect personal knowledge, experience, and culture
Eskes, 1993 [77]	• Not stated	• Not stated	• The experts subdivide the cases into six groups: (1) unavoidable; (2) probably unavoidable; (3a) insufficient information; (3b) possibly avoidable; (4) probably avoidable; and (5) avoidable. In assessing (un)avoidability and the results were considered against the background of the most ideal circumstances and facilities in the time period concerned
Eskes, 2014 [81]	• Perinatal Registry of The Netherlands (PRN)	• Stillbirths are registered in Perinatal Audit Registry of The Netherlands (PRN-Audit) • Data are gathered from the medical records and registered with specific details needed to construct the narrative that will be used during the audit, including supplementary	• The basic document for the audit meeting is created from the PRN-Audit database • Representatives of the professionals of the perinatal cooperation groups (PCG) analyse the cases, identify substandard care factors (SSF) in delivered care or organisation of care, identify the types of professionals involved and classify mortality according to three different systems

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		information such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum risk selection with their time frames	(Wigglesworth/Hey, Modified Relevant Condition at Death (ReCoDe), and Tulip classifications) • Grades how likely SSF was the cause of death (none/unlikely, possible, (very) probable, unknown) • Specific recommendations for improving the quality of care are formulated • There is a chairperson in the meeting who is independent and from outside of the hospital
Essén, 2002 [90]	• The national Swedish Medical Birth Register	• Narratives based on individual records are written for each birth solely from the data obtained	• Panellists are blind to the country of origin of each woman studied and work with the case narratives to identify suboptimal factors which were likely to have contributed to perinatal death • Primary criteria (explicit and primarily evidence-based) for identifying suboptimal factors are adopted from the EuroNatal study of perinatal mortality in Europe • Other suboptimal factors identified during the audit are categorised as secondary criteria. Suboptimal factors were assigned to one of three categories: maternal factors (which the mother did not realize were detrimental), medical care or communication • To categorise perinatal deaths to ascertain which are potentially avoidable, a modified version of the Nordic-Baltic perinatal death classification scheme is used
Flenady, 2021 [67]	• Queensland Perinatal Data Collection (QPDC), a legislated data collection of all births occurring in Queensland	• Data is collected from the Directors of Obstetrics (or equivalent) or Patient Safety and Quality Officer at	• Cases are summarised by the midwifery project coordinator and presented at the meeting • Using the Perinatal Society of Australia and New Zealand (PSANZ) guidelines tool,

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		the services where the deaths occurred and medical records	contributing factors were assigned to: 1) organisation/management (eg inadequate supervision of staff, lack of appropriate clinical management protocols, lack of communication between services), 2) personnel (eg staff factors relating to professional care and service provision), 3) accessing/engaging with care (e. no, infrequent or late booking for antenatal care, women decline treatment/advice) • The contribution of each identified factor in the death was classified*
Fossen, 1999 [85]	• Hospital evidence	• Data are collected from medical records	• The committee evaluate and assess to find suboptimal care regarding the identified stillbirth
Furst, 1989 [73]	• the Government Central Bureau of Statistics	• Mother's practice and hospital medical files that had satisfactory data entries on selected criteria are included and utilised for the audit • A detailed interview with the practice doctors responsible for the mother's antenatal care before referral to hospital, hospital doctors responsible for the mother's hospital care, and with each mother are conducted	• A detailed chart review of the mother's practice and hospital medical files, as well as a detailed interview with relevant stakeholders (practice doctor, hospital doctor, and mothers) are audited
Govender, 2017 [110]	• Hospital's Perinatal Problem Identification Programme (PPIP) database	• The 'Hands Up' Mortality and Morbidity Extraction Tool (HUMMET) form is used to summarise all cases	• Healthcare workers analyse the case and identify risk factors, avoidable factors, substandard care/missed opportunities, learning opportunities and actions to be taken regarding the patient and the health service • The main factors contributing to each perinatal death are coded according to the PPIP and entered into the electronic PPIP database

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Han, 2018 [86]	• Hospital Stillbirth Registry	• Data of patients' case records, summaries, results of investigations and post-mortem reports are obtained	• Using a prepared structured proforma, level of care, causative factors of stillbirths and whether the case was preventable are recorded by two assessors • The factors of suboptimal care are graded (0-3)* • Responsible personnel are determined for identified factors of suboptimal care • The stillbirths are classified using the KK Hospital Stillbirth Classification
Harper, 1977 [100]	• Death certificates	• Data is collected by abstracting medical records onto a 37-page form	• The abstracted chart data are reviewed by a panel of four physicians, independently • Each reviewer is expected to define the factors which placed the mother and infant at risk and to identify the interventions which might prevent or alleviate problems in subsequent pregnancies by answering these questions: 1) what was the cause of death?, 2) was the death preventable?, 3) what were the factors that contributed to preventability?
Hinderaker, 2003 [128]	• Prospective cohort of antenatal attendees	• Verbal autopsies • Household survey interviews • Hospital and medical records	• The causes of death is grouped into a functional classification developed by Wigglesworth et al. and modified by the International Collaborative Effort on BirthWeight, Plurality, Perinatal and Infant Mortality • The underlying causes of death are grouped into seven functional categories where each group has common features requiring intervention at a specific time • The two reviewers from the panel also assessed whether the deaths are "avoidable" and the factors that were suspected to be responsible

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			for the avoidable deaths, are categorised into patient-oriented and health service provider-oriented
Hundley, 2001 [94]	• Stillbirths identified in the Aberdeen trial in 1992-1993.	• EuroNatal questionnaire is used to extract required data from maternity, neonatal and autopsy records • A narrative summary is written to provide details of chronological order	• The reviewers review the case histories independently and give a grading regarding suboptimal care before the panel meeting • Panel meeting occurs after three weeks after receiving the case histories, observed and documented by the author • One panel member presents the case and discussion follows after to grade the suboptimal care • Suboptimal factors are classified into when it occurred (antenatal, intrapartum, or neonatal), then who was responsible for them (maternal/social, infrastructure/service organisation or care) • Suboptimal factor is judged if it contributed to the stillbirth outcome using a grading system (unlikely, possibly, likely) • Overall grade of the case is given (0-3)*
Kasengele, 2017 [133]	• Case notes • Routine data from the admission and delivery register	• data are collected using the structured checklist adopted from WHO	• A criteria-based clinical audit is conducted (using the criteria adopted from the Integrated Management of Pregnancy and Childbirth (IMPAC) programme • Recommendations are developed to reduce the performance gaps
Kieltyka, 2012 [101]	• Obituaries • Hospital records • Louisiana Vital Events Registry	• Standardised data collection is performed using a web-based data system, BASINET • BASINET automatically strips identifying information from case	• Most of the LaFIMR Network case review team (CRT)s meet quarterly • CRT reviews 3-8 cases per two-hour session

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		summaries and contains de-identified narrative case summaries, including information from maternal interviews	
Kirabira, 2020 [119]	• Maternity registers • Newborn admission register • Hospital notes	• Data is abstract using an audit form • A narrative summary is written for each case	• Each case is presented to the audit team for detailed discussion • The information presented to the team allows for reviewing the cause of death and assigning a more precise cause of death by consensus • Care provided is judged against existing local protocols and national guidelines • The quality of care provided at the hospital is also graded by consensus and classified into four categories* • The overall grading of the care provided to the mother and baby, the identified specific areas of suboptimal care and the recommendations for improvement are documented • The summary of each case included a list of the actions to be taken and during monthly meetings, implementation progress was compared with the action plan by the wider audit team
Maaløe, 2016 [129]	• Admission, delivery, and theatre registers • Case files	• Data is extracted into a structured entry form based on the pre-selected audit criteria	• Case files of stillbirths are reviewed using the criteria of realistic best quality of care
Maternal and Child Health Research Consortium, 1999 [95]	• The Rapid Report Form • National collection of mortality statistics by the Office for National Statistics (ONS)	• Case notes identifying/documenting risk factors and management during antepartum and intrapartum periods	• Confidential inquiry is conducted by a regional multidisciplinary panel • The panels reviews all aspects and record suboptimal care (notable factor) • For each notable factor, panel assigns when, what and when category; grade of the standard

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			of care (0-3)*; grade of the relevance to death (0-3)+ • Panel assigns cause of death according to the pathophysiological classification by Wigglesworth, the fetal and neonatal classification, the revised Aberdeen Obstetric classification and an overall grade relating the care to the final outcome* • Panel comments on the completeness of the record (case notes)
Mbaruku, 2009 [130]	• Interview • Hospital records	• A detailed questionnaire is filled in by one of the authors	• The reviewers audit using the 3-delays methodology which classifies delays as follows: 1) first delay refers to the time spent at home before a decision is made to seek health care; 2) the second delay refers to the inability to get to a health facility after having made the decision to go there (due to problems with transport, money, or poor roads); and 3) the third delay refers to the time spent waiting for adequate management after arrival at a health facility • The reviewers consider mismanagement or incorrect treatment as a third delay • A process audit is undertaken, whereby actual practice is compared with standard practice based on evidence or expert consensus
Mdoe, 2022 [131]	• Patient's case notes	• Data were collected using a designated case review form (CRF) from the patient's case notes	• The CRF is reviewed by a clinician who commented on the possible cause of death and a likely contributing factor(s) based on the reviewed case notes • The research team includes the obstetrician, pediatrician, and senior midwife and reviews the comments made by a clinician

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			• The agreed completed CRF is entered into the database for analysis
Mersey Region Working Party on Perinatal Mortality, 1982 [96]	• Notification of death by telephone to the inquiry office by a senior nursing officer from each maternity unit or each specialist in community medicine	• After each notification, a full-time member of the working party visits the maternity unit within 5 days of death • A questionnaire is completed using the case notes • The professional staff concerned in the care of each case are interviewed • The mother's GP is contacted by telephone and, if necessary, visited. • The mother is interviewed by another member of the working party and the interview helps filling out the questionnaire form	• The assessors (panel) assess which factors were avoidable and is grouped into the following three groups – obstetric; paediatric; and maternal/social • The Scottish perinatal mortality survey classification of death is used to classify cause of death
Miranda, 1996 [88]	• Patient records	• Information obtained from patient records	• The committee carries out a detailed analysis of each case • The committee assess if the suboptimal care was relevant to the outcome
Mo-suwan, 2009 [115]	• The Prospective Cohort Study of Thai Children (PCTC)	• An interview to collect baseline data of pregnant women and their families at 28-36 weeks gestation • Home visits to these women are carried out weekly from 36 weeks onwards • The delivery outcome was retrieved from the hospital records • Interviews with parents and caregivers after the death are also collected	• Causes of death are defined based on Wigglesworths classification • The reviewers are asked to conclude whether death of that case was preventable

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Moawad, 1990 [102]	• Clinical records • Pathologic diagnosis	• Data are entered on a specially designed form • A narrative case summary is prepared	• Audit meetings are held in the hospital where the death had occurred • Avoidable death is identified through clear consensus
Musafili, 2017 [117]	• Not stated, assumed hosptial records	• Using questionnaires, hospital data is abstracted and information is obtained from interviews with mothers and healthcare providers • Narratives summarising the information collated from the different sources are prepared for each case by the main investigator	• The main investigator introduce the study objectives and procedures at the first meeting and present all cases of perinatal deaths discussed in each session, which was scheduled according to the members' availability • These presentations are based on individual narratives and are followed by open discussions to identify the causes of the deaths, the underlying factors, and any potentially avoidable deaths • The discussions aim to evaluate whether the delay had possibly or likely contributed to the fatal outcome • The quality of care provided to mothers and neonates are judged against evidence-based practices, as expressed in local guidelines and protocols or the scientific literature
Omwodo, 2020 [125]	• Not stated, but assumed hospital records	• Not stated	• Presentations are given for each case • Open discussions by the panel to identify the cause of death, the underlying factors, any potentially avoidable deaths and build recommendations for improved care
Pattinson, 1995 [111]	• Not stated	• Not stated	• All stillbirth are classified according to the primary obstetric and neonatal causes of death • Potentially avoidable factors which could have contributed to the death are identified, classified and graded

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			• The avoidable factors are classified into patient-oriented, administrative and medical management-related groups • The patient-oriented category is further divided into an inappropriate response to a complication, non-or late attendance at antenatal clinics, and criminal intervention during the pregnancy • The medical management category is further divided into honest errors, oversight and a gross deviation from accepted practice. • Avoidable factors are classified into two grades: grade 1 - an action which, if avoided or altered, could possibly have modified the outcome, and grade 2 - actions which, if avoided, would probably have altered the outcome, in which case the baby might have survived • All cases are presented by a doctor who is specifically assigned the presentation task to allow the problem to be discussed freely • The final categorisation of avoidable factors are made by one researcher after the assessment of the case notes to ensure consistency
PMMRC, 2021 [82]	• Compilation of data submitted by Lead Maternity Carers, local coordinators, the Ministry of Health and Births, Deaths, and Marriages registry	• Local coordinators oversee the collection of data • Data is submitted to the New Zealand Mortality Review Data Group at the University of Otago • Coordinators are required to submit rapid reporting forms within 48 hours of death • Two forms: one containing information on the mother and one	• Local coordinator initiates local clinical reviews, assign cause of death using Perinatal Society of Australia and New Zealand (PSANZ) Perinatal Death Classification, contributory factors, potentially avoidable deaths • A multidisciplinary team completes the Perinatal and Maternal Mortality Review Committee (PMMRC) classification form

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		form containing information on the baby	• Local coordinator submits the post-mortem and histology reports with the classification form
Raman, 2015 [106]	• Not stated	• A clinician enter the demographic information for each perinatal death onto the datasheet and information on modifiable factors is completed in discussion with a senior doctor	• Death is categorised using the Perinatal Society of Australia and New Zealand perinatal mortality classification • Modifiable factors related to each death is classified according to the three delays model
Rhoda, 2014 [112]	• Hospital data • Birth register in the labour ward	• Data Capturing Form is used to insert basic demographic data and primary obstetric cause of death	• The causes of stillbirths is divided into primary obstetric causes and the final neonatal causes • Each case is categorised as an avoidable or unavoidable death • For avoidable deaths, it is further categorised into the patient, medical- personnel- or administrative-related deaths
Richardus, 2003 [68]	• Student Center Perinatal Epidemiology (SPE) in Flanders • Danish Brith Register • CESDI • Medical Birth Register • 2nd Greek National Perinatal Survey • Hospital case records and midwife case records, Medical Birth Registry of Norway • Aberdeen Maternal and Neonatal Databank, Hospital registers: delivery-, case record- and pathology register • Regional Medical Register "Perinatal Revision South"	• Explicit criteria for standards of care are defined by the Euronatal Working Group and are incorporated into a questionnaire, which is completed in the country of origin • The excerpt, narrative summary and questionnaire are produced from questionnaire data by the co-ordination team	• A grading system is adapted from the CESDI to define suboptimal care • Each case is blinded to the country and distributed randomly to one subpanel • Each subpanel member receives a copy of the questionnaire, the narrative summary and a sheet that identified a lack of compliance with the explicit audit criteria • After reviewing these, the panel member decides whether there were instances of suboptimal care and any such instances are listed on a standard form to mark timing and responsible individual/organisation

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Sauvegrain, 2020 [71]	• Maternity and neonatal unit notification	• Data is abstracted from medical records using a pre-tested structured instrument • Maternal interviews are conducted	• For each case, the reviewers identify suboptimal care factors and provide a citation for the guidelines or standard or an explanation • The reviewers judge whether the factors related to the death and whether acting on them could have prevented it • The reviewers also evaluate whether the information was complete and adequate for their assessment • The reviewers meet as a panel to harmonise definitions and evaluations and to discuss cases flagged for group review
Sharma, 2022 [122]	• Delivery registers • Hospital records	• The information is collected using a pre-structured questionnaire according to the guidance in the WHO, Making Every Baby count. • Interviews with patients and husbands/family members is conducted wherever possible	• The qualitative (identify modifiable or associated factors to stillbirth) and quantitative analysis is carried out every month • Some cases are selected for detailed discussion in the monthly perinatal meeting
Sterpu, 2020 [91]	• Obstetric record system Obstetrix	• The data are collected from the obstetric record system Obstetrix, TakeCare, Swedish Medical Birth Register and hospital records	• The review team assess cause of death, the proportion of preventable/non-preventable stillbirth and the level of delay (patient/caregiver) and details, demographic details, pregnancy characteristics and fetal outcomes
Stratulat, 2014 [108]	• Not stated	• Not stated	• Cases are analysed and the causes of death are examined using the Relevant Condition at Death (ReCoDe) classification • Cases were graded according to the presence of substandard care, and whether that was considered as contributing to the adverse outcome

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
Supratikto, 2002 [123]	• Report to the village midwife or district health office	• The village midwife conducts post mortem and obtain medical record • All forms checked by a senior midwife or a doctor and sent to the district health office	• The village midwife presents the background and the chronology of events and the review participants consider the case, relying on the expertise of an obstetrician or paediatrician from the district hospital to guide discussion on clinical case management • On the basis of the contributing factors identified during the meeting, the audit team at the district level designs management initiatives, proposes additional training, and recommends changes in clinical protocol and policy • The findings and recommendations have discussed at the start of the next audit meeting in order to check on progress made in resolving the problems previously uncovered
Tan, 1999 [97]	• Not stated	• Not stated	• Assessors first work independently using a structured assessment protocol • After collating the assessment forms, the coordinator arrange a meeting of the entire panel for discussion and a panel consensus is reached for each case • Factors of sub-optimal care to clinical practice, staffing, structure, equipment and patient or her family are identified in each case and they are graded*
Tang, 2011 [98]	• Not stated. Assumed hospital records	• Data is recorded on the pro forma prospectively following the event and checked with the hospital records	• The panel review the pro formas anonymously and case notes are consulted where additional information is required • The management of each stillbirth is allocated to one of the four standards of care categories established by CESDI

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
The National Center for Fatality Review and Prevention, 2021 [103]	• Identified deaths to Fetal and Infant Morality Review (FIMR) staff • Hospital/birthing center admission and discharge logs • Obituary columns, through communication with existing local programs, agencies, hospital/birthing center bereavement nurses or counsellors • Local doula providers • Funeral directors • Hospital medical records staff • Medical examiner or coroners's offices, • Emergency medical transport service teams • Community health workers	• Summaries of 3-5 cases from source of data, related social services records, and the parental/family interview, prepared by FIMR staff before the meeting.	• FIMR staff coordinates and schedule meeting with the Case Review Team (CRT) • The multidisciplinary CRT reviews the barriers to care, trends in service delivery and action points improve policies and services • The CRT analyses the information and summarise findings to create recommendation
Vallejo, 1991 [104]	• Texas department of health • Death certificates	• Data of birth and death certificate combined with the maternal/infant clinical notes contained in the hospital or midwife records using the perinatal morality survey tool	• Records review
Vallely, 2020 [127]	• Severe adverse events (SAE) reports	• Using a study-specific SAE form, data is collected for the mother's general health, pregnancy risk factors, and the circumstances around the event including prenatal, labour, and birth events, gestational age at birth, birth weight, and final outcome	• Two members conduct the initial analysis and coding of each case, independently • 10% of the cases are randomly selected, assessed, and coded independently by two obstetricians

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
van Diem, 2010 [78]	• Not stated, assumed hospital records	• Data are entered and described on an anonymous narrative form	• Using the SPSS function "random selection" a subgroup of cases is selected using the case numbers as variables for selection • Blinded to each other, the auditors assess these cases once individually and later at a group discussion • For the classification of the cause of perinatal death, the modified Aberdeen Classification, the Extended Wigglesworth Classification and the Tulip classification is used • Substandard factors (SSF) is graded as: no SSF identified and one or more SSF identified • The avoidability is graded+
van Diem, 2012 [79]	• Hospital/unit records • Narratives of care team	• Anonymous narratives are the basic documents used in the perinatal audit meetings and it includes the cause of death classified by the local core group	• Using the narrative, substandard factors (SSF) are identified during unit based perinatal audit meetings • The audit instrument is based on a root cause analysis as 6 What Questions: 1) what happened and which caregivers were involved, 2) what were the circumstances in which the SSF occurred, 3) what made the SSF occur, 4) what is the relation between the SSF and death, 5) what are the conclusions, 6) what needs to be done to prevent the SSF from occurring again • Members of the project team chair the meetings until other independent chairpersons is found
Ward, 1995 [113]	• Not stated, assumed hospital records	• Scrutinised case records	• The primary obstetric cause of the sequence of events leading to each death is classified using the Whitfield classification

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
			• Each death is assessed for potentially avoidable factors; if found, were graded, categorised and subdivided
Westergaard, 1997 [70]	• Not stated	• Summaries of pregnancy, delivery and foetus are built by reviewing clinical records and discharge letters	• Each review member is given a summary of death and asked to answer three questions: 1) could the fetus already have been dead before admission (1=possibly, 2=less likely, 3=not possible); 2) were dispositions (surveillance and interventions) during delivery suboptimal (1=to a high degree, 2=to a less degree, 3=no) ; 3) could an improved effort during delivery have prevented the intrapartum death (1=yes, certainly, 2=yes, possibly, 3=no, probably not) • Reviewers are asked if anything could have done differently and to provide any additional comments
Wilkins, 2015 [132]	• Hospital birth registry • Maternal records	• Data is collected and entered directly into a spreadsheet, adapted from the WHO Southeast Asia Regional Office stillbirth record form	• The simplified Cause of Death and Associated Conditions (CODAC) classification system, developed specifically for use in low-income settings, is used to classify cause of death • The quality of care is assessed based on the reviewers' knowledge of the available resources and staff training from extensive time spent as an obstetrician in the hospital (no formal tool)
Wilkinson, 1997 [114]	• Case records • Maternity register • The ward death notification book • The mortuary admission book	• Data are collected daily by carefully reviewing case records, discussing the case with the staff involved and interviewing the mother	• The perinatal deaths are assessed and all avoidable deaths are classified
Wolleswinkel-van den Bosch, 2002 [80]	• Gynecology/obstetrics departments and labour ward registers	• Medical records of the identified cases are obtained from the medical archives of the hospitals or the	• For each case, the panel members first note deviations from the criteria and their relationship with perinatal death (unlikely,

Reference	Source of stillbirth data	Data collection method	Review tool or/and review method
		midwives and these records are summarised using a structured questionnaire • A case abstract is written in order to better represent the chronology of events during perinatal care • Doctors and midwives are asked to verify the data as summarised by the investigators.	possibly or probably' related to perinatal death) on a score sheet • The panel members then gave a final score, based on all substandard factors identified[$] • The panel members could also indicate whether sufficient information was available to give a score • A plenary panel meeting is held if the consensus is not reached

[*]0 - No suboptimal care. 1 - Suboptimal care, but different management would have made no difference to the outcome. 2 - Suboptimal care - different management might have made a difference to the outcome. 3 - Suboptimal care - different management would reasonably have been expected to have made a difference to the outcome

[+]0 - Not relevant. 1 - Possibly relevant. 2 - Probably relevant. 3 - Almost certainly relevant.

[&]0 - No suboptimal care. 1 - Minor suboptimal care. 2 - Significant suboptimal care. 3 - Major suboptimal care.

[$]0 - No suboptimal factors. 1 - one of more suboptimal factor, unlikely that this caused perinatal death. 2 - one or more suboptimal factor, possible this caused the death. 3 - one or more suboptimal factor, probable this caused the death.

Appendix F: Consent form

	If yes, please put your initial in this box
1. I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.	
2. I consent to being audio recorded.	
3. I am happy for the audio recordings to be sent to a professional and confidential transcription service (a preferred supplier of the University of Oxford).	
4. I am happy for my personal details and study data to be stored in the University of Oxford servers and I understand that all identifiable and personal information such as audio recordings, will be destroyed, including the signed consent form after five years of publication of the research.	
5. I agree to take part in this study.	

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Appendix G: Participant information sheet – for hospitals that conduct stillbirth reviews

Introduction

We would like to invite you to take part in a **focus group discussion**. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What's the purpose of this research?

We are conducting this research to explore structure and processes of facility-based stillbirth reviews in your hospital and to understand the facilitators and barriers to implementing the stillbirth review process in your hospital. We hope that the findings from this study will improve implementability, scale-up and sustainability of stillbirth review processes in India.

What is a focus group discussion?

A focus group discussion involves a selected group of people discussing their opinions, thoughts and feelings with a facilitator. There are no right or wrong answers in a discussion of this kind.

Why have I been invited to take part?

You are invited because you are a member of your hospital's stillbirth review panel. All members of the panel are invited to be a part of this study.

What's involved for me?

If you would like to participate in our focus group discussion, you will be asked to sign a consent form. You will have a copy of this participant information sheet and a consent form to keep.

The focus group discussion will be conducted at your hospital. You can expect the group to be approximately 6-8 people and it will take around an hour and half. If the focus group discussion is conducted online, you will be given a link to join the Microsoft Teams meeting.

We will request your permission to record the focus group discussion to ensure we capture all you say accurately, but no one will be identified by name on the recording. The recording will be stored on the University of Oxford servers and only the research team members will have access to it. The information recorded is confidential.

We will also ask you to fill out a short form asking your job role, job grade/seniority, age, gender, years of experience in the post and how long you have been involved in the stillbirth review process in your hospital. You can fill out this form before or after the focus group discussion. This form is for us to gain background information on our participants.

What will happen to my data?

Data protection policies require that you know how we intend to use your data. The University of Oxford is the data controller with respect to data collected in this study and is responsible for making sure your information is used properly. We will not collect personal data beyond what is necessary for the focus group discussion.

Research documents such as consent forms which will have your personal information will be kept temporarily in secure cabinets at your hospital at the end of the focus group discussion. They will then be scanned and uploaded to the University of Oxford servers, while the hard copies will be destroyed. Online copies will be destroyed by a designated member of the IT department after five years of publication of the research.

Audio recordings will be stored in the University of Oxford servers and destroyed by a designated member of the IT department after five years of publication of the research.

Other research data like de-identified (anonymous) transcripts and field notes will be archived and stored securely in the University of Oxford servers for an indefinite period of time.

Will my data be shared with third parties?

Depending on the need for an external support on transcriptions, we may send audio files to a professional and confidential transcription service (a preferred supplier of the University of Oxford).

We will ensure data is transferred between parties in a secure manner, and that the third party deletes all audio recordings once the transcription has been returned to us.

Are there any risks in taking part?

We have prioritised participants' comfort in designing this study. We know your time is valuable and we have chosen specific topics to explore which should not exceed the 90 minutes allocated.

It is possible that you may find talking about stillbirths upsetting; especially if you or your loved one has had a stillbirth. You are free to ask the researcher to pause or stop the interview at any time.

The findings from the research will be written up in a dissertation, academic publications, conference presentations and blog posts. It will not be possible to identify any participant in the study as the data will be anonymised and combined with responses from other participants to produce the final research outputs. A copy of the dissertation will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

What are the benefits of taking part?

There are no direct benefits to you for participating in this study. However, there may be indirect benefits as it is hoped that insights from this research will inform policy and guide interventions to prevent stillbirths which will potentially be useful to your hospital.

There will be no payment for taking part in this study. There will be, however, snack and tea/coffee available for the participants during the in-person focus group discussions.

Do I have to take part?

It is up to you to decide whether or not to take part. You can withdraw from the study, without giving a reason, by informing us of this decision. You can withdraw up until the data analysis process begins. If you choose to withdraw before the data analysis process begins, your data will be identified (using the code assigned to you during the interview) and deleted from our records. After this, the data from the study would have been anonymised and combined and it would be difficult to isolate your data, so we will not be able to remove your data after this point.

Has the study been reviewed by an ethics committee?

This study has received an ethical approval from a subcommittee of the University of Oxford Tropical Research Ethics Committee (OxTREC) (reference number: 539-23).

What if I have any questions or want to raise a concern?

If you have a concern about any aspect of this study, please contact Yebeen Boo – yebeen.boo@dph.ox.ac.uk or Manisha Nair – manisha.nair@ndph.ox.ac.uk, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Medical Sciences Interdivisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

Data protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

Appendix H: Participant information sheet – for hospitals that do not conduct stillbirth reviews

Introduction

We would like to invite you to take part in a **focus group discussion**. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What's the purpose of this research?

We are conducting this research to understand what factors can impact implementability, scale-up and sustainability of stillbirth review processes in India.

What is a focus group discussion?

A focus group discussion involves a selected group of people discussing their opinions, thoughts and feelings with a facilitator. There are no right or wrong answers in a discussion of this kind.

Why have I been invited to take part?

You are invited because you are a staff involved in obstetric care in your hospital. Your hospital has agreed for you to be approached regarding participation in the study.

What's involved for me?

If you would like to participate in our focus group discussion, you will be asked to sign a consent form. You will have a copy of this participant information sheet and a consent form to keep.

The focus group discussion will be conducted at your hospital. You can expect the group to be approximately 6-8 people, and it will take around an hour and a half. If the focus group discussion is conducted online, you will be given a link to join the Microsoft Teams meeting.

We will request your permission to record the focus group discussion to ensure we capture all you say accurately, but no one will be identified by name on the recording. The recording will be stored on the University of Oxford servers and only the research team members will have access to it. The information recorded is confidential.

We will also ask you to fill out a short form asking your job role, job grade/seniority, age, gender and years of experience in the post. You can fill out this form before or after the focus group discussion. This form is for us to gain background information on our participants.

What will happen to my data?

Data protection policies require that you know how we intend to use your data. The University of Oxford is the data controller with respect to data collected in this study and is responsible for making sure your information is used properly. We will not collect personal data beyond what is necessary for the focus group discussion.

Research documents such as consent forms which will have your personal information will be kept temporarily in secure cabinets at your hospital at the end of the focus group discussion. They will then be scanned and uploaded to the University of Oxford servers, while the hard copies will be destroyed. Online copies will be destroyed by a designated member of the IT department after five years of publication of the research.

Audio recordings will be stored in the University of Oxford servers and destroyed by a designated member of the IT department after five years of publication of the research.

Other research data like de-identified (anonymous) transcripts and field notes will be archived and stored securely in the University of Oxford servers for an indefinite period of time.

Will my data be shared with third parties?

Depending on the need for an external support on transcriptions, we may send audio files to a professional and confidential transcription service (a preferred supplier of the University of Oxford).

We will ensure data is transferred between parties in a secure manner, and that the third party deletes all audio recordings once the transcription has been returned to us.

Are there any risks in taking part?

We have prioritised participants' comfort in designing this study. We know your time is valuable and we have chosen specific topics to explore which should not exceed the 90 minutes allocated.

It is possible that you may find talking about stillbirths upsetting; especially if you or your loved one has had a stillbirth. You are free to ask the researcher to pause or stop the interview at any time.

The findings from the research will be written up in a dissertation, academic publications, conference presentations and blog posts. It will not be possible to identify any participant in the study as the data will be anonymised and combined with responses from other participants to produce the final research outputs. A copy of the dissertation will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

What are the benefits of taking part?

There are no direct benefits to you for participating in this study. However, there may be indirect benefits as it is hoped that insights from this research will inform policy and guide interventions to prevent stillbirths which will potentially be useful to your hospital.

There will be no payment for taking part in this study. There will be, however, snack and tea/coffee available for the participants during the in-person focus group discussions.

Do I have to take part?

It is up to you to decide whether or not to take part. You can withdraw from the study, without giving a reason, by informing us of this decision. You can withdraw up until the data analysis process begins. If you choose to withdraw before the data analysis process begins, your data will be identified (using the code assigned to you during the interview) and deleted from our records. After this, the data from the study would have been anonymised and combined and it would be difficult to isolate your data, so we will not be able to remove your data after this point.

Has the study been reviewed by an ethics committee?

This study has received an ethical approval from a subcommittee of the University of Oxford Tropical Research Ethics Committee (OxTREC) (reference number: 539-23).

What if I have any questions or want to raise a concern?

If you have a concern about any aspect of this study, please contact Yebeen Boo – yebeen.boo@dph.ox.ac.uk or Manisha Nair – manisha.nair@ndph.ox.ac.uk, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Medical Sciences Interdivisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

Data protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest.

Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

Appendix I: Document analysis worksheet

Documents to request	**Date obtained/reason why it was not obtained**	**Type of document (see MIT example)**	**Date document was produced**	**Document created by**	**Intended audience of the document**	**Short description of content**
Stillbirth review guide/protocol						
Stillbirth notification form						
Stillbirth reporting flowchart						
Stillbirth review data collection form/proforma template						
Stillbirth review training materials						
Stillbirth review meeting minutes						
Action plans/recommendations from stillbirth review meetings						
Report published by the hospital to disseminate stillbirth review findings						
Patient chart template						
Death certificate template						
Post-mortem report template						
Antenatal/delivery register template						
Documents with the following information (for annual figure, from 2019 to 2022, if possible and if not, latest year)*: • Annual births • Number of women receiving antenatal care • Stillbirth number and rate (per 1,000 total births) • Number of staff working in obstetric unit, broken down by obstetrician, obstetric nurses, midwives, and others • Year stillbirth review started • Frequency of stillbirth review meeting						

Documents to request	**Date obtained/reason why it was not obtained**	**Type of document (see MIT example)**	**Date document was produced**	**Document created by**	**Intended audience of the document**	**Short description of content**
*Hospital can aggregate the number themselves, if they prefer.						
Any other relevant documents (specify name)						

Please ensure that all personal identifiable information is removed or obscured before making copies or scanning the document. Please ensure all documents are shared via saving the documents in the project folder within Oxford OneDrive for business.

Appendix J: Observation guide

When entering the observation venue or starting focus group discussions

I will present myself as an observer–researcher to all participants in the meeting. Before the meeting, I plan to introduce myself in a way that is truthful, concise, and understandable in local terms and does not set off alarms or cause offence. For example, I will make it clear to the participants that I am a PhD student (not a government official) who wants to learn about how stillbirth reviews are conducted in India. I will acknowledge the sensitivity of the topic and assure the participants that my intention is to contribute positively to the field. In addition, I will emphasise my commitment to maintaining privacy and confidentiality throughout the research process. Regarding my position as an observer, I plan to ask the review panel where they prefer me to sit. I will mention that I typically sit in a corner or at the side of the table to minimise disturbance and ensure I have a clear view of the meeting.

Observation guide for researcher when attending stillbirth review meetings

This guide serves as a helpful tool to support me when attending stillbirth review meetings as a non-participant observer. I should note that this guide is intended to be a flexible framework and should not be used as a rigid checklist. My role is to observe the meeting holistically, capturing important details and nuances. Rather than focusing on ticking off items from a list, I should engage in active listening and carefully observe the process. It is important for me to document their observations in the form of free-text notes. This means that I should write in their own words and use descriptive language to convey their observations accurately. As soon as the meeting concludes, I should take some time for personal reflection. This reflection should involve capturing my initial thoughts and impressions about the meeting. It is crucial to expand on these reflections while the memory is still fresh, to ensure accuracy and detail in the final notes. To facilitate the organisation of field notes, I may find it useful to use subtitles or headings.

<u>Panel composition</u>

1. Is the panel diverse?

- Age, gender, job role, clinical discipline, seniority etc.

2. What role does each panel member play?
    - Listen to introductions of members, affiliations, qualifications, years of experience.
    - Note who have not attended the meeting. Did they give apologies? Is this a pattern?
    - Is there a facilitator/chair of the meeting? If yes, what's the job role/qualification?

Meeting goals/objectives

1. What are the goals and objectives of the meeting?
    - During the introduction, do panel mention any action plans from previous meeting? What they did re: from the previous meeting?
    - What do they plan to discuss and achieve in this meeting?

Context

1. Are there any resources available for use by panel members?
    - Observe space and basic materials e.g. notepads, pens, tea etc.
2. Is anyone from the administration in attendance?
3. Do the review panel have adequate time to attend the meeting or could they be attending while having other responsibilities during the meeting time?
    - Do all participants sit in the meeting throughout or do they leave to attend other responsibilities?
    - Do we have other members coming in late, when the meeting has already started?

Techniques

1. How does the panel discuss stillbirth cases?
    - Is there sufficient documentation in the chart to enable discussion (ie is the chart of the patient physically present?)
    - Do they discuss if anything went wrong? What factors are they reflecting on (context, patient safety, errors, staffing, resources)?
    - Do they reflect as individuals or as a panel?

- Can they identify action plan – and how do they do this? Think about individual actions vs. actions for system-level changes.
- Do they write minutes?
- Do they assign people to follow up on the action plan?
- How do they plan to achieve the action plan (training, individual conversations, leaflets)?

2. Are their discussions guided by existing national or international guidelines?
    - Are stillbirth review based on national operational guidelines?
    - Are they aware of any national/international guidelines?
    - Do they use any classification/grading system?
3. How are ideas being discussed and differences in opinion is being resolved?
    - Observe if panel members give any feedback and how this is received by other members.
    - Are decisions agreed by all members?

<u>Panel interactions</u>

1. Observe panel interactions – how are members interacting (talking, facial expressions)?
    - What is the tone/mood in the meeting?
    - Are there any differential power issues between and within panel members? (observe interactions, who makes decisions, who talks the most etc)
    - Is there any panel member who seems less engaged than others? If so why?
2. Do all panel members make effort to participate in the discussions or are they called upon, encouraged by the facilitator/chair?
    - Do they have a "no blame culture" and if so, how is this ensured? Is there evidence of failure of "no blame culture"?
    - What methods are used in the meeting? Participatory or structured?

Appendix K: Focus group discussions topic guide – for hospitals that conduct stillbirth reviews

Stillbirth review process

I would like to understand the stillbirth review process that I observed in your hospital in more details. I will ask you more about how each is conducted, who is involved with what and why.

Note: The points noted under each question will be used as probe, if required.

1. Why do you undertake stillbirth reviews?
    - Do you think there is a high rate of stillbirth among the population you look after?
    - Do you think conducting stillbirth reviews is important? Why/why not?
2. Could you please describe how a stillbirth review is planned?
    - Who organises the meeting?
    - Is the venue and agenda of the meeting communicated?
    - Do you receive any resources/information of the cases before the meeting for you to read/prepare?
    - Who is invited to participate? Why?
    - What motivates each member to attend and contribute to the stillbirth review meeting?
3. How do you select cases to review?
    - How do you identify eligible stillbirths to review?
    - Does your hospital review all stillbirths or a sample?
    - What stillbirth definition does your hospital use?
4. Can you please describe how you discuss stillbirth cases?
    - Do you use any guidelines that guides the process and outcomes of stillbirth review? If yes, does it get updated and how?
    - Has the review process changed/evolved over time in your hospital?
    - Do you think all members participate equally during the discussion?

- Do you think panel members support one another in the meeting?

5. How do you use the information or findings (identified learning) of a stillbirth review?
    - Do you communicate/disseminate identified learnings within the hospital?
    - Do you create any reports following the review? Who are the audience of the reports?
    - Do you create any action points to make changes within your hospital because the review identified learnings?
6. Do you think your hospital address action points in response to the learning from the stillbirth review?
    - Can you give an example of action point that was addressed recently?
    - What has been working well to implement action points from generated learnings?
    - What has not been working well and what changes would you like to see in the future?

<u>Facilitators and barriers</u>

Now, I want to ask you about what factors have been impacting stillbirth review processes in your hospital and any insights you would like to share to improve implementability and sustainability of stillbirth review processes in your hospital.

1. What has been working well when conducting stillbirth reviews in your hospital?
    - Reflect what practices have been helpful in your hospital when implementing or sustaining stillbirth review process.
    - What else do you think could be helpful for your hospital moving forward, to sustain and improve the current stillbirth review process?
2. What has been the challenges when conducting stillbirth reviews in your hospital?
    - Can you describe how each challenge affects and which part of the process it affects?
    - Can you give an example how you mitigated/overcame these challenges, if possible to mitigate/overcome?

This is the end of the focus group discussion session. Thank you.

Appendix L: Focus group discussions topic guide – for hospitals that do not conduct stillbirth reviews

Note: The points noted under each question will be used as probe, if required.

1. Do you think stillbirth is a problem in the population you look after?
    - What do you think can be done to reduce stillbirth?
2. What are your views on conducting stillbirth reviews?
    - What do you understand about stillbirth reviews?
    - Are you aware of any guidance?
3. How do you define stillbirth in your hospital?
    - Do you collect any data around stillbirth?
4. What in your opinion could be an ideal process for stillbirth reviews?
    - Who do you think should be invited to participate?
    - How do you think the cases should be selected?
    - What kind of resources/support should be available?
    - What should be the goals/objectives of the reviews?
    - How would you use the information you learned from the stillbirth review process?
5. What are your views on implementing a stillbirth review process in your hospital?
    - What could be helpful in your hospital if you were to start conducting stillbirth reviews in your hospital?
    - Do you foresee any challenges that will arise if you were to start conducting stillbirth reviews in your hospital?
    - Can you describe how each challenge will affect and which part of the review process it will affect?
    - Can you give an example of how you may mitigate/overcome these challenges, if possible to mitigate/overcome?

This is the end of the focus group discussion session. Thank you.

Appendix M: Published article – Maternal and Fetal Factors Associated with Stillbirth in Singleton Pregnancies in 13 Hospitals Across Six States in India

Check for updates

Received: 6 October 2023 | Revised: 25 December 2023 | Accepted: 28 December 2023 | Published online: 17 January 2024

DOI: 10.1002/ijgo.15367

CLINICAL ARTICLE

Obstetrics

Maternal and fetal factors associated with stillbirth in singleton pregnancies in 13 hospitals across six states in India: A prospective cohort study

Yebeen Ysabelle Boo[1] | Amrit K. Bora[2] | Shakuntala Chhabra[3] | Saswati S. Choudhury[4] | Gitanjali Deka[5] | Swapna Kakoty[6] | Pramod Kumar[3] | Pranabika Mahanta[7] | Bina Minz[8] | Anjali Rani[9] | Sereesha Rao[10] | Indrani Roy[11] | Carolin Solomi V.[12] | Ashok Verma[13] | Farzana Zahir[14] | Rupanjali Deka[15] | Jennifer J. Kurinczuk[1] | Manisha Nair[1] | on behalf of the MaatHRI collaborators

[1]National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK

[2]Sonapur District Hospital, Guwahati, Assam, India

[3]Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra, India

[4]Gauhati Medical College and Hospital, Guwahati, Assam, India

[5]Tezpur Medical College and Hospital, Tezpur, Assam, India

[6]Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta, Assam, India

[7]Jorhat Medical College and Hospital, Jorhat, Assam, India

[8]Sewa Bhawan Hospital Society, Basna, Chhattisgarh, India

[9]Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India

[10]Silchar Medical College and Hospital, Silchar, Assam, India

[11]Nazareth Hospital, Shillong, Meghalaya, India

[12]Makunda Christian Leprosy and General Hospital, Karimganj, Assam, India

[13]Dr Rajendra Prasad Government Medical College, Kangra, Himachal Pradesh, India

[14]Assam Medical College (AMC), Dibrugarh, Assam, India

[15]Srimanta Sankaradeva University of Health Sciences, Guwahati, Assam, India

Abstract

Objective: This study aimed to investigate the incidence of and risk factors for stillbirth in an Indian population.

Methods: We conducted a secondary data analysis of a hospital-based cohort from the Maternal and Perinatal Health Research collaboration, India (MaatHRI), including pregnant women who gave birth between October 2018–September 2023. Data from 9823 singleton pregnancies recruited from 13 hospitals across six Indian states were included. Univariable and multivariable Poisson regression analysis were performed to examine the relationship between stillbirth and potential risk factors. Model prediction was assessed using the area under the receiver-operating characteristic (AUROC) curve.

Results: There were 216 stillbirths (48 antepartum and 168 intrapartum) in the study population, representing an overall stillbirth rate of 22.0 per 1000 total births (95% confidence interval [CI]: 19.2–25.1). Modifiable risk factors for stillbirth were: receiving less than four antenatal check-ups (adjusted relative risk [aRR]: 1.75, 95% CI: 1.25–2.47), not taking any iron and folic acid supplementation during pregnancy (aRR: 7.23, 95% CI: 2.12–45.33) and having severe anemia in the third trimester (aRR: 3.37, 95% CI: 1.97–6.11). Having pregnancy/fetal complications such as hypertensive disorders of pregnancy (aRR: 1.59, 95% CI: 1.03–2.36), preterm birth (aRR: 4.41, 95% CI: 3.21–6.08) and birth weight below the 10th percentile for gestational age (aRR: 1.35, 95% CI: 1.02–1.79) were also associated with an increased risk of stillbirth. Identified risk factors explained 78.2% (95% CI: 75.0%–81.4%) of the risk of stillbirth in the population.

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.
© 2024 The Authors. *International Journal of Gynecology & Obstetrics* published by John Wiley & Sons Ltd on behalf of International Federation of Gynecology and Obstetrics.

Correspondence
Yebeen Ysabelle Boo, National Perinatal Epidemiology Unit (NPEU), Nuffield Department of Population Health, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF, UK.
Email: yebeen.boo@ndph.ox.ac.uk

Funding information
Clarendon Fund; Kellogg College, University of Oxford; Nuffield Department of Population Health, University of Oxford; Medical Research Council, Grant/Award Number: MR/P022030/1 and MR/W029294/1

Conclusion: Addressing potentially modifiable antenatal factors could reduce the risk of stillbirths in India.

KEYWORDS
cohort study, India, risk factors, singleton pregnancies, stillbirth

1 | INTRODUCTION

The global burden of stillbirths remains a significant public health concern, with an estimated 1.9 million babies being stillborn annually.[1] In 2021, the global stillbirth rate reached 13.9 per 1000 total births, with a significant concentration of stillbirths in sub-Saharan Africa and South Asia, collectively accounting for three-quarters of all stillbirths.[1] The emotional implications for affected families, coupled with negative consequences for communities, healthcare providers, and economies, underscores the urgency of addressing this issue.[2]

Despite the profound impact of stillbirths, this issue has received inadequate attention on the global health agenda, particularly in comparison to maternal and child mortality.[3–5] Notably, stillbirth-specific targets were conspicuously absent from the 2030 Agenda for Sustainable Development Goals.

In India, the scale of the problem is particularly alarming, with an estimated 286 482 stillbirths in 2021, consistently ranking the nation first in the absolute number of stillbirths for over two decades.[1,5] This is despite commendable progress made in reducing stillbirth rates over the past two decades, with the rate declining from 29.6 per 1000 births in 2000 to 13.9 per 1000 births in 2019.[5] Recognizing stillbirths as a persistent public health challenge, India launched the India Newborn Action Plan (INAP) with the ambitious goal of reducing the stillbirth rate to less than 10 per 1000 births by 2030.[6]

To date, various types of studies, including population surveillance,[7,8] case series,[9] cross-sectional[10] and case–control studies[11] have explored risk factors or spatial patterns influencing stillbirths in India. One of these studies has identified pregnancy complications such as anemia and hypertensive disorders of pregnancy (HDP) as risk factors amenable to interventions.[10] However, these studies adopted study designs susceptible to bias or were primarily descriptive in nature.

To address these limitations, this study focused on a hospital-based cohort of singleton pregnancies to investigate the incidence of and risk factors for stillbirths in an Indian population. The primary objectives of this study were to calculate overall stillbirth (ante- and intrapartum) rates per 1000 total births in 13 hospitals across six states in India and to investigate the maternal and fetal characteristics associated with stillbirths in this population.

TABLE 1 Characteristics of 13 MaatHRI hospitals.

Maternal care functions	*N* (%)
Skilled staff available 24 h	13 (100.0)
Access to operating theater	13 (100.0)
Functional ambulance available	13 (100.0)
Electricity always available	13 (100.0)
Reliable access to clean water	13 (100.0)
Infection control	13 (100.0)
Partograph use	13 (100.0)
Cardiotocography (CTG) monitors	11 (84.6)
Hand-held dopplers	11 (84.6)
Emergency carts	13 (100.0)
Functional blood bank	12 (92.3)
Anesthetic care (by technicians or anesthetists)	13 (100.0)
Fridge for storage of drugs	13 (100.0)
Neonatal Intensive Care Unit (NICU)	12 (92.3)
Removal of retained products	13 (100.0)
Parenteral oxytocin	13 (100.0)
Parenteral magnesium sulfate	13 (100.0)
Manual removal of placenta	12 (92.3)
Parenteral antibiotics	13 (100.0)

2 | MATERIALS AND METHODS

2.1 | Study design

This study was a secondary data analysis of a hospital-based cohort from the Maternal and Perinatal Health Research collaboration, India (MaatHRI). MaaatHRI has 16 collaborating hospitals in six states in India (Assam, Meghalaya, Maharashtra, Uttar Pradesh, Himachal Pradesh and Chhattisgarh) and 13 of these hospitals participate in epidemiological studies.[12] This cohort study was originally designed to investigate the risk factors for postpartum hemorrhage in an Indian population.

The hospital-based prospective cohort study collected data on births between October 2018 and September 2023 in 13 of the MaatHRI collaborating hospitals that participate in

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

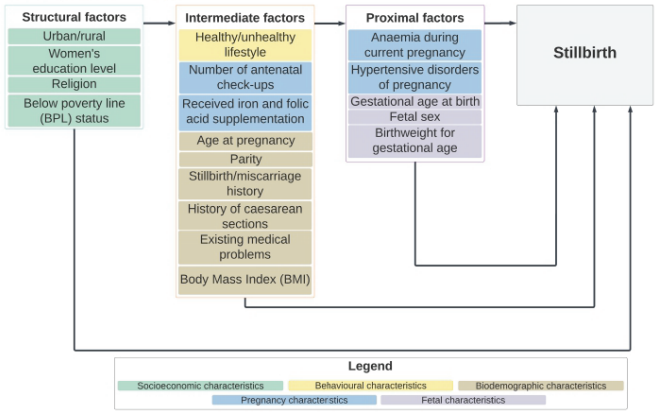


FIGURE 1 Hypothesized relationship between the structural, intermediate and proximal factors and stillbirth.

epidemiological research (9 medical colleges, 4 community hospitals) across six states in India. All 13 hospitals have adequate facilities for providing maternal and newborn care, and Table 1 describes the characteristics of included MaatHRI hospitals. In this cohort study, pregnant women more than 28 weeks of gestational age, aged 18 years or older and planning a vaginal birth in the 13 hospitals were approached to participate. Women were excluded if they were under 18 years of age, if they were unwilling to provide informed consent or were planning a cesarean section at the time of the recruitment.

Out of 10064 women, 99.9% of women ($N = 10056$) consented to participate, and their baseline information including sociodemographic characteristics, previous and current pregnancy problems, medical comorbidities and other pregnancy characteristics were collected by the research nurses. Hemoglobin (Hb) concentration in the third trimester was measured by collecting, processing and analyzing women's blood samples at the time of recruitment and by using their most recent routine Hb record. The women were followed-up during labor and childbirth and up to 48 h postpartum.

2.2 | Inclusion and exclusion criteria

All singleton pregnancies where the outcome of the fetus was available were included in this study. Women with multiple pregnancies and those with missing fetal outcomes, such as due to lost to follow-up were excluded.

2.3 | Outcome variable

The outcome variable was stillbirth, defined as any fetal death that occurred at or beyond 28 completed weeks' of gestation.[13] Stillbirths were categorized into ante- and intrapartum stillbirths and this information was derived from the free text data related to the reasons/indications for cesarean section, induction and augmentation of labor, and/or details of maternal/fetal complications.

2.4 | Exposure variables

Exposure variables were grouped as socioeconomic, behavioral, biodemographic, pregnancy, and fetal characteristics. These variables were selected if there was likely clinical relevance and/or if they were found as significant risk factors for stillbirth in the literature.[7–11,14–16]

For socioeconomic characteristics, below the poverty line (BPL) status was selected as a proxy for assessing income level. The Planning Commission of India defined BPL households as households (average five family members) with a per capita consumption expenditure of Indian Rupees (INR) 816.00 on a monthly basis in rural areas and an expenditure of INR 1000.00 in urban areas using the Tendulkar methodology.[17]

For behavioral characteristics, unhealthy lifestyle during pregnancy was defined as smoking, chewing betel nuts, or consuming tobacco and/or alcohol.

For biodemographic characteristics, women's age at the time of recruitment was categorized into five groups (<20, 20–24, 25–29, 30–34, >34) and age group 20–24 was selected as the reference group to examine the potential associations between teenage pregnancy and stillbirth.

Introduced in 2002, the WHO's Focused Antenatal Care model recommends pregnant women receive at least four comprehensive antenatal check-ups.[18] Thus, the number of antenatal check-ups were categorized into three groups: 0–1, 2–3, and 4 or more, with four or more check-ups serving as the reference group. Levels of severity of anemia were defined using the WHO definition for Hb cutoffs[19]: mild anemia 10–10.9 g/dL, moderate 7–9.9 g/dL, and severe <7 g/dL.

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Gestational age at birth was categorized according to the recommendation by Spong[20] recognizing that the risk of stillbirth can vary even within the "term" pregnancy, with a 5-week gestational age range. Hence, the early term was defined as $37^{0/7}$ to $38^{6/7}$ weeks. Birth weight for gestational age, gender-specific z-scores and centiles were generated using the INTERGROWTH-21st tool.[21]

2.5 | Conceptual framework

Exposure variables were categorized as structural, intermediate and proximal factors informed by the WHO's Commission on Social Determinants of Health (CSDH) conceptual framework[22] and the complex hierarchical inter-relationships between these factors and stillbirth were visualized using a directed acyclic graph (DAG) (Figure 1). Conceptual frameworks are known to provide guidance for statistical analysis and also allow epidemiological studies to take account of the effects of structural and intermediate (more distal) factors.[23]

2.6 | Statistical analysis

The overall stillbirth rate and a confidence interval (CI) per 1000 total births were calculated using the stillbirths and births recorded in the cohort study using Ulm's method.[24]

Frequency distributions for categorical exposure variables and median and interquartile range for continuous exposure variables were compared between stillbirths (overall, ante- and intrapartum) and live births. Univariable analysis using modified Poisson regression models was conducted to observe unadjusted associations between each exposure variable and the outcome.

After initial exploratory analysis, multivariable Poisson regression models were built to estimate adjusted associations between the outcome and exposure variables. Only variables that were associated with the outcome in the univariable analysis at a *P* value of ≤0.05 overall or within the subgroups were included in the regression models using a hierarchical approach starting with the structural factors (model 1), followed by intermediate factors (model 2), and proximal factors (model 3). This was informed by the DAG (Figure 1). Statistical interaction between the women's education level and BPL status was tested for effect modification. Multicollinearity was tested for using the variance inflation factor (VIF). Variables with a value of VIF five or more were not included in the same model. Model prediction was assessed using the area under the receiver-operating characteristic (AUROC) curve.

Patterns and frequencies of missing data were described for exposure variables in Table S1. While there was missing information, the proportion of missingness was very small: almost all the exposure variables had less than 0.4% of missing data, and even the variable with the highest extent of missingness (BMI) had less than 4% of missing data. Therefore, the missing data were presumed to be missing at random and complete-case analysis was used.

All associations were reported as relative risk (RR) or adjusted RR (aRR) with 95% CI and *P* values. All analyses were performed using R version 4.2.2 and RStudio 2023.03.0+386. A two-tailed *P* value ≤0.05 was considered statistically significant.

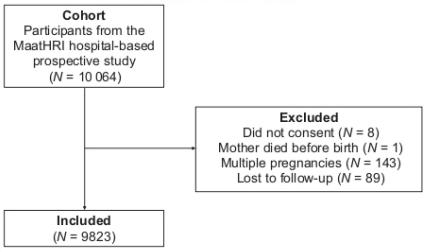


FIGURE 2 Flow diagram of the selection of the study participants.

3 | RESULTS

Based on inclusion and exclusion criteria, 9823 women were eligible for inclusion in the analysis (Figure 2).

There were 216 stillbirths (48 antepartum and 168 intrapartum) in the study population, representing a stillbirth rate of 22.0 per 1000 total births (95% CI: 19.2–25.1). Of these 22.2% were antepartum and 77.8% were intrapartum stillbirths.

Table 2 describes the results of the univariable analysis. Urban/rural and religion from structural factors, unhealthy lifestyle, history of cesarean sections, existing medical problems and BMI category for South Asian from intermediate factors, and fetal sex from the proximal factors had *P* values >0.05 and were excluded from the multivariable analysis. The results of the multivariable analysis are shown in Table 3, and after adjusting for structural, intermediate and proximal factors (full adjustment, model 3), BPL status and parity were not statistically significantly associated with stillbirth.

3.1 | Structural risk factors

Compared with women who had a tertiary or higher level of education (beyond 12th class in the Indian education system), women who could not read or write (illiterate) had almost a three times greater risk of stillbirth when adjusting for only BPL status (aRR: 2.95, 95% CI: 1.84–4.83). After full adjustment for structural, intermediate and proximal factors, the association was attenuated to 1.86 times increased risk of stillbirth (95% CI: 1.13–3.10).

3.2 | Intermediate risk factors

After full adjustment, women who received two or three antenatal check-ups had a 75% increased risk of stillbirth (aRR: 1.75, 95% CI: 1.25–2.47) than women who received four or more check-ups.

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 2 Descriptive statistics of antepartum, intrapartum, and total stillbirths, and live births, and univariate analysis of risk factors associated with stillbirth.

	Antepartum stillbirths (*N* = 48)	Intrapartum stillbirths (*N* = 168)	Total stillbirths (*N* = 216)	Live births (*N* = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	*P* value
Structural factors						
Urban/rural						
Urban/suburban	9 (18.8%)	29 (17.3%)	38 (17.6%)	1419 (14.8%)	1 (Ref)	-
Rural	39 (81.3%)	139 (82.7%)	178 (82.4%)	8188 (85.2%)	0.82 (0.58–1.17)	0.255
Women's education level						
Tertiary or above (beyond 12th class)	9 (18.8%)	18 (10.7%)	27 (12.5%)	1628 (16.9%)	1 (Ref)	-
Up to secondary school (6–12th class)	17 (35.4%)	73 (43.5%)	90 (41.7%)	5070 (52.8%)	1.07 (0.71–1.67)	0.761
Up to primary school (5th class)	13 (27.1%)	41 (24.4%)	54 (25.0%)	2002 (20.8%)	**1.61 (1.02–2.59)**	**0.043**
Illiterate	9 (18.8%)	36 (21.4%)	45 (20.8%)	874 (9.1%)	**3.00 (1.88–4.89)**	**<0.001**
Religion						
Hindu	38 (79.2%)	119 (70.8%)	157 (72.7%)	7059 (73.5%)	1 (Ref)	-
Muslim and others	10 (20.8%)	49 (29.2%)	59 (27.3%)	2548 (26.5%)	1.04 (0.77–1.39)	0.796
Below poverty line (BPL) status						
No	14 (29.2%)	45 (26.8%)	59 (27.3%)	3195 (33.3%)	1 (Ref)	-
Unknown	10 (20.8%)	21 (12.5%)	31 (14.4%)	1594 (16.6%)	1.05 (0.67–1.61)	0.819
Yes	24 (50.0%)	102 (60.7%)	126 (58.3%)	4818 (50.2%)	**1.41 (1.04–1.93)**	**0.031**
Intermediate factors						
Unhealthy lifestyle[a]						
Never	27 (56.3%)	116 (69.0%)	143 (66.2%)	6185 (64.4%)	1 (Ref)	-
Gave up during/prior to pregnancy	3 (6.3%)	11 (6.5%)	14 (6.5%)	353 (3.7%)	1.69 (0.93–2.82)	0.062
Current	18 (37.5%)	41 (24.4%)	59 (27.3%)	3069 (31.9%)	0.83 (0.61–1.12)	0.243
Number of antenatal check-ups (*N*)						
Median [Q1, Q3]	3.00 [2.75,4.00]	3.00 [2.00,3.00]	3.00 [2.00,4.00]	3.00 [3.00,4.00]		
Number of antenatal check-ups						
4 or more	16 (33.3%)	39 (23.2%)	55 (25.5%)	4199 (43.7%)	1 (Ref)	-
2–3	27 (56.3%)	104 (61.9%)	131 (60.6%)	4624 (48.1%)	**2.13 (1.56–2.94)**	**<0.001**
0–1	5 (10.4%)	25 (14.9%)	30 (13.9%)	784 (8.2%)	**2.85 (1.81–4.41)**	**<0.001**
Duration of iron and folic acid supplementation						
More than 180 days	0 (0%)	2 (1.2%)	2 (0.9%)	283 (2.9%)	1 (Ref)	-
90–180 days	21 (43.8%)	97 (57.7%)	118 (54.6%)	7492 (78.0%)	2.21 (0.70–13.38)	0.266
Less than 90 days	22 (45.8%)	44 (26.2%)	66 (30.6%)	1482 (15.4%)	**6.08 (1.91–37.01)**	**0.012**
None	5 (10.4%)	25 (14.9%)	30 (13.9%)	350 (3.6%)	**11.25 (3.40–69.55)**	**<0.001**
Women's age (years)						
Median [Q1, Q3]	25.0 [21.0,29.0]	26.0 [22.0,29.3]	25.5 [22.0,29.0]	24.0 [21.0,28.0]		
Women's age						

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 2 (Continued)

	Antepartum stillbirths (*N* = 48)	Intrapartum stillbirths (*N* = 168)	Total stillbirths (*N* = 216)	Live births (*N* = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	*P* value
<20	4 (8.3%)	11 (6.5%)	15 (6.9%)	852 (8.9%)	0.92 (0.51–1.56)	0.781
20–24	19 (39.6%)	59 (35.1%)	78 (36.1%)	4090 (42.6%)	1 (Ref)	-
25–29	16 (33.3%)	56 (33.3%)	72 (33.3%)	3167 (33.0%)	1.19 (0.86–1.64)	0.292
30–34	6 (12.5%)	25 (14.9%)	31 (14.4%)	1139 (11.9%)	1.42 (0.92–2.12)	0.102
>34	3 (6.3%)	17 (10.1%)	20 (9.3%)	359 (3.7%)	**2.82 (1.68–4.51)**	**<0.001**
Parity (*N*)						
Median [Q1, Q3]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]		
Parity						
Nulliparous	27 (56.3%)	111 (66.1%)	138 (63.9%)	6429 (66.9%)	1.01 (0.75–1.38)	0.945
Para 1–2	18 (37.5%)	41 (24.4%)	59 (27.3%)	2779 (28.9%)	1 (Ref)	-
Para 3 or more	3 (6.3%)	16 (9.5%)	19 (8.8%)	399 (4.2%)	**2.19 (1.27–3.59)**	**0.003**
Stillbirth/miscarriage history						
No	11 (22.9%)	46 (27.4%)	57 (26.4%)	2810 (29.2%)	1 (Ref)	-
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6250 (65.1%)	1.05 (0.77–1.44)	0.767
Yes	10 (20.8%)	15 (8.9%)	25 (11.6%)	533 (5.5%)	**2.25 (1.38–3.56)**	**<0.001**
History of cesarean sections						
No	17 (35.4%)	55 (32.7%)	72 (33.3%)	2846 (29.6%)	1 (Ref)	-
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6250 (65.1%)	0.84 (0.64–1.13)	0.248
Yes	4 (8.3%)	7 (4.2%)	11 (5.1%)	487 (5.1%)	0.90 (0.45–1.62)	0.732
Existing medical problems						
No	45 (93.8%)	164 (97.6%)	209 (96.8%)	9288 (96.7%)	1 (Ref)	-
Yes	3 (6.3%)	4 (2.4%)	7 (3.2%)	318 (3.3%)	0.98 (0.42–1.92)	0.955
BMI category for South Asian						
<18.5	7 (14.6%)	49 (29.2%)	56 (25.9%)	2487 (25.9%)	1.10 (0.79–1.51)	0.555
18.5–22.9	30 (62.5%)	78 (46.4%)	108 (50.0%)	5297 (55.1%)	1 (Ref)	-
23–24.9	8 (16.7%)	17 (10.1%)	25 (11.6%)	892 (9.3%)	1.36 (0.86–2.07)	0.162
≥25	2 (4.2%)	8 (4.8%)	10 (4.6%)	561 (5.8%)	0.88 (0.43–1.59)	0.690
Proximal factors						
Severity of anemia						
Normal (≥11 g/dL)	3 (6.3%)	13 (7.7%)	16 (7.4%)	1463 (15.2%)	1 (Ref)	-
Mild (10–10.9 g/dL)	7 (14.6%)	20 (11.9%)	27 (12.5%)	1169 (12.2%)	**2.09 (1.14–3.96)**	**0.020**
Moderate (7–9.9 g/dL)	28 (58.3%)	77 (45.8%)	105 (48.6%)	5845 (60.8%)	1.63 (0.99–2.87)	0.068
Severe (<7 g/dL)	10 (20.8%)	58 (34.5%)	68 (31.5%)	1130 (11.8%)	**5.25 (3.13–9.36)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						
No	42 (87.5%)	145 (86.3%)	187 (86.6%)	8777 (91.4%)	1 (Ref)	-
Yes	6 (12.5%)	23 (13.7%)	29 (13.4%)	830 (8.6%)	**1.62 (1.07–2.35)**	**0.016**
Gestational age at birth (weeks)						
Median [Q1, Q3]	35.0 [33.0,38.0]	37.0 [34.8,39.0]	37.0 [34.0,39.0]	39.0 [38.0,40.0]		

(Continues)

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 2 (Continued)

	Antepartum stillbirths (N = 48)	Intrapartum stillbirths (N = 168)	Total stillbirths (N = 216)	Live births (N = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	P value
Gestational age at birth						
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	30 (62.5%)	66 (39.3%)	96 (44.4%)	1401 (14.6%)	**5.13 (3.77–7.01)**	**<0.001**
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	8 (16.7%)	35 (20.8%)	43 (19.9%)	2484 (25.9%)	1.36 (0.92–1.98)	0.112
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	9 (18.8%)	60 (35.7%)	69 (31.9%)	5452 (56.8%)	1 (Ref)	-
Late/post term (≥$41^{0/7}$ weeks)	1 (2.1%)	6 (3.6%)	7 (3.2%)	270 (2.8%)	2.02 (0.84–4.10)	0.076
Fetal sex						
Male	27 (56.3%)	87 (51.8%)	114 (52.8%)	5083 (52.9%)	1 (Ref)	-
Female	21 (43.8%)	81 (48.2%)	102 (47.2%)	4524 (47.1%)	1.01 (0.77–1.31)	0.970
Birth weight for gestational age (percentile)						
Median [Q1, Q3]	25.9 [0.398,69.2]	4.01 [0.120,29.6]	6.83 [0.143,39.2]	13.6 [2.92,36.0]		
Birth weight for gestational age						
<10th percentile	19 (39.6%)	93 (55.4%)	112 (51.9%)	4146 (43.2%)	1.46 (1.11–1.93)	**0.007**
10 to 90th percentile	24 (50.0%)	69 (41.1%)	93 (43.1%)	5075 (52.8%)	1 (Ref)	-
>90th percentile	5 (10.4%)	4 (2.4%)	9 (4.2%)	354 (3.7%)	1.38 (0.65–2.58)	0.359

Abbreviations: BMI, body mass index; RR, relative risk. Bold: statistically significant (P value ≤0.05).
[a]Smoking, chewing betel nuts, tobacco consumption, alcohol consumption.

Women who did not take any iron and folic acid supplementation during pregnancy had more than seven times increased risk of stillbirth than women who took them for more than 180 days (aRR: 7.23, 95% CI: 2.12–45.33). Women's age was also associated with stillbirth. The relationship with age was linear with a 6% increase in risk for every 1 year increase in age (aRR: 1.06, 95% CI: 1.03–1.09, *P* value ≤0.001). However, when we examined age as a categorical variable, women aged 35 years or older had a significantly higher risk of stillbirth compared with age group 20–24 (aRR: 2.28, 95% CI: 1.28–3.87). Finally, women with stillbirth/miscarriage history had more than a two-fold increase in risk of stillbirth (aRR: 2.17, 95% CI: 1.32–3.48) than women who did not have a history of stillbirth/miscarriage.

3.3 | Proximal risk factors

Women who had severe anemia had more than three times the risk of stillbirth (aRR: 3.37, 95% CI: 1.97–6.11) than women who did not. Having HDP increased the risk of stillbirth by 1.59 times (95% CI: 1.03–2.36). Preterm birth and early term birth increased the risk by 4.41 times (95% CI: 3.21–6.08) and 1.63 times (95% CI: 1.09–2.39), respectively. Lastly, infants with birth weight below the 10th percentile for gestational age had a 1.35 times higher risk of stillbirth (95% CI: 1.02–1.79) than infants with birth weight between the 10th to 90th percentile for gestational age.

3.4 | Performance of multivariable models

Figure 3 shows the AUROC curve for model 1 (adjusting for structural factors only), model 2 (adjusting for structural and intermediate factors) and model 3 (fully adjusted including proximal factors). Together, the structural and intermediate factors accounted for 70.2% (95% CI: 66.5%–73.9%) of the variance in the data. With the addition of the proximal factors, this increased to 78.2% (95% CI: 75.0%–81.4%).

4 | DISCUSSION

This study showed that the stillbirth rate in 13 hospitals across six states in India was 22.0 per 1000 total births (95% CI: 19.2–25.1) and 77.8% of all stillbirths occurred intrapartum. Women's illiteracy (not being able to read or write) was a significant structural risk factor. Significant immediate risk factors included receiving less than four antenatal check-ups, not taking any iron and folic acid supplementation during pregnancy, being aged 35 or older and having a history

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 3 Multivariable analysis of risk factors for stillbirth.

	Model 1: Adjusted for structural factors[a]		Model 2: Adjusted for structural and intermediate factors[b]		Model 3: Adjusted for structural, intermediate and proximal factors[c]	
Variable/level	aRR (95% CI)	*P* value	aRR (95% CI)	*P* value	aRR (95% CI)	*P* value
Structural factors						
Women's education level						
Tertiary or above (beyond 12th class)	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Up to secondary school (6–12th class)	1.05 (0.69–1.65)	0.816	1.08 (0.71–1.70)	0.731	1.00 (0.66–1.59)	0.982
Up to primary school (5th class)	1.48 (0.93–2.40)	0.102	1.29 (0.80–2.13)	0.309	1.01 (0.62–1.68)	0.977
Illiterate	**2.95 (1.84–4.83)**	**<0.001**	**2.30 (1.41–3.83)**	**0.001**	**1.86 (1.13–3.10)**	**0.016**
Below poverty line (BPL) status						
No	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Unknown	1.13 (0.72–1.75)	0.574	0.93 (0.59–1.44)	0.756	0.90 (0.57–1.40)	0.645
Yes	1.36 (0.99–1.88)	0.058	0.95 (0.69–1.33)	0.766	0.87 (0.63–1.22)	0.416
Intermediate factors						
Number of antenatal check-ups						
4 or more			1 (Ref)	-	1 (Ref)	-
2–3			**1.75 (1.26–2.47)**	**0.001**	**1.75 (1.25–2.47)**	**0.001**
0–1			1.48 (0.90–2.39)	0.114	1.43 (0.87–2.32)	0.149
Duration of iron and folic acid supplementation						
More than 180 days			1 (Ref)	-	1 (Ref)	-
90–180 days			2.11 (0.66–12.83)	0.299	1.97 (0.62–12.03)	0.343
Less than 90 days			**4.88 (1.50–30.05)**	**0.029**	**4.19 (1.28–25.83)**	**0.049**
None			**8.91 (2.63–55.71)**	**0.003**	**7.23 (2.12–45.33)**	**0.008**
Women's age						
<20			0.86 (0.47–1.45)	0.590	0.82 (0.45–1.40)	0.493
20–24			1 (Ref)	-	1 (Ref)	-
25–29			1.27 (0.91–1.77)	0.158	1.22 (0.87–1.71)	0.242
30–34			1.52 (0.97–2.35)	0.062	1.47 (0.93–2.28)	0.088
>34			**2.42 (1.36–4.12)**	**0.002**	**2.28 (1.28–3.87)**	**0.003**
Parity[d]						
Nulliparous			1.17 (0.84–1.64)	0.349	1.16 (0.83–1.63)	0.384
Para 1–2			1 (Ref)	-	1 (Ref)	-
Para 3 or more			1.12 (0.62–1.93)	0.694	1.22 (0.68–2.10)	0.486
Stillbirth/miscarriage history[d]						
No			1 (Ref)	-	1 (Ref)	-
Never pregnant			1.36 (0.97–1.93)	0.083	1.40 (1.00–1.99)	0.056
Yes			**2.34 (1.43–3.73)**	**<0.001**	**2.17 (1.32–3.48)**	**0.002**
Proximal factors						
Severity of anemia						
Normal (≥11 g/dL)					1 (Ref)	-
Mild (10–10.9 g/dL)					**1.92 (1.05–3.65)**	**0.039**
Moderate (7–9.9 g/dL)					1.39 (0.84–2.45)	0.229
Severe (<7 g/dL)					**3.37 (1.97–6.11)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						

(Continues)

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 3 (Continued)

Variable/level	Model 1: Adjusted for structural factors[a] aRR (95% CI)	*P* value	Model 2: Adjusted for structural and intermediate factors[b] aRR (95% CI)	*P* value	Model 3: Adjusted for structural, intermediate and proximal factors[c] aRR (95% CI)	*P* value
No					1 (Ref)	-
Yes					**1.59 (1.03–2.36)**	**0.028**
Gestational age at birth[e]						
Preterm (28^{+0} to 36^{+6} weeks)					**4.41 (3.21–6.08)**	**<0.001**
Early term (37^{+0} to 38^{+6} weeks)					**1.63 (1.09–2.39)**	**0.015**
Full term (39^{+0} to 40^{+6} weeks)					1 (Ref)	-
Late/post term (≥41^{+0} weeks)					2.00 (0.83–4.06)	0.083
Birth weight for gestational age[e]						
<10th percentile					**1.35 (1.02–1.79)**	**0.038**
10 to 90th percentile					1 (Ref)	-
>90th percentile					0.96 (0.45–1.82)	0.919

Abbreviations: aRR, adjusted relative risk; CI, confidence interval. Bold: statistically significant (P value ≤0.05).

[a]Women's education level, BPL status.

[b]Women's education level, BPL status, number of antenatal check-ups, duration of iron and folic acid supplementation, women's age, parity *or* stillbirth/miscarriage history.

[c]Women's education level, BPL status, number of antenatal check-ups, duration of iron and folic acid supplementation, women's age, parity *or* stillbirth/miscarriage history, severity of anemia, hypertensive disorders of pregnancy (HDP), gestational age at birth *or* birth weight for gestational age.

[d]Due to high collinearity between parity and stillbirth/miscarriage history, these variables were not included in the same model together.

[e]Birth weight for gestational age was calculated using gestational age at birth, therefore, these variables were not included in the same model together.

of stillbirth or miscarriage. Additionally, having anemia, experiencing HDP, preterm birth, early term birth and birth weight below the 10th percentile for gestational age were significant proximal risk factors.

The stillbirth rate of 22.0 per 1000 total births in the study population was substantially higher than the 2019 estimate for India's overall stillbirth rate of 13.9 per 1000 total births.[1] This contrast is noteworthy, considering these births occurred in a hospital setting and did not include home births or planned cesarean sections before the third trimester. This could be because nine out of 13 MaatHRI hospitals (69.2%) where the study population was recruited, were medical colleges, which typically serve a higher proportion of high-risk women compared with community hospitals. It is also possible that the estimate for India overall could be a consequence of undercounting.

The majority of the stillbirths were intrapartum (77.8%) having occurred after the onset of labor and prior to birth. Considering that intrapartum stillbirths are more closely related to various measures of obstetric care than antepartum stillbirths,[25] further investigation into the quality of care received by women who experienced intrapartum stillbirths through a stillbirth review process would be beneficial. Such reviews can generate learning to inform the action plans and allow facilities to consider where the changes should be made to improve the quality of care they provide, enabling positive short- and medium-term outcomes, and ultimately reducing preventable stillbirths.[26]

Similar to the findings of Altijani et al. from an analysis of data from 886 505 Indian women from the annual health survey,[10] our study identified women's illiteracy as significantly associated with an increased risk of stillbirth. However, our findings also highlight that improving access to high-quality antenatal care and better management of pregnancy and fetal complications has the potential to attenuate or eliminate the risk of stillbirth associated with socioeconomic inequalities, such as those related to women's low education levels and low-income status.

More importantly, this study emphasizes that several of the major risk factors for stillbirth are potentially modifiable. For instance, ensuring that women receive at least four antenatal check-ups and take iron and folic acid supplementation during pregnancy were identified as interventions that could significantly reduce the risk of stillbirth in India. Pregnancy complications such as having anemia in the third trimester and HDP were also reported as major risk factors that greatly increase the risk of stillbirth, consistent with findings from other studies.[27-31] These complications are also potentially amenable to interventions to enhance their management.

Despite routine iron supplementation being available at no cost to women,[32] overall 84.9% of the cohort had anemia (Hb < 11 g/dL) and 12.2% had severe anemia (Hb < 7 g/dL). Furthermore, even after adjusting for the effects of iron and folic acid supplementation, anemia remained a significant risk factor for stillbirth, and this was especially critical for women with severe anemia who experience over a

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

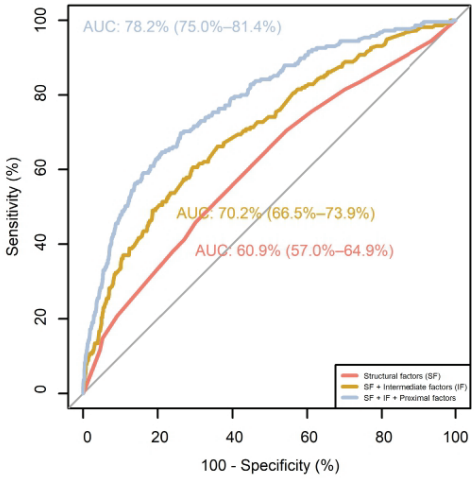


FIGURE 3 Area under the receiver-operating characteristic (AUROC) curve for structural, intermediate and proximal factors.

three-fold increased risk of stillbirth compared with women without anemia.

This suggests that low Hb levels do not necessarily translate into iron deficiency anemia and addressing anemia (especially severe anemia) with iron supplementation alone may not be effective in addressing this important risk factor for stillbirth in India. Understanding the underlying causes of anemia is crucial to developing targeted treatment strategies. The complex, multifactorial relationship between iron supplementation and anemia and risk of stillbirth supports MaatHRI's recent study findings, which emphasized the importance of using iron biomarkers and not relying solely on Hb measurement to facilitate tailored prevention, control, and treatment activities for managing anemia during pregnancy.[33]

Additionally, further analysis should be conducted to explore early term birth (37^{+0} to 38^{+6} weeks) and birth weight below the 10th percentile for gestational age as risk factors for intrapartum stillbirth. While the association between preterm birth and stillbirth is relatively well established,[7,10,34,35] research on the relative risk of intrapartum stillbirth associated with early term birth is limited. Smith[36] suggests there was a 2.2 times increased risk of intrapartum stillbirth at 37 weeks' gestation compared with 38 weeks', while Trudell et al.,[37] advocate for early term birth for small for gestational age pregnancies to minimize the risk of stillbirth. Therefore, it is unclear whether childbirth at early term is beneficial or harmful, especially for small for gestational age babies.

Finally, proximal factors which include pregnancy and fetal characteristics emerged as the important predictors of stillbirth, as evident in the AUROC curve analysis. This finding aligns with the study by Horwood et al.,[38] which found that proximal factors were the primary predictors when focusing on risk factors for maternal mortality in the Indian population. Proximal factors are more likely to be tackled with quality improvement of clinical care, therefore, these findings reinforce the importance of high-quality antenatal care and the availability of basic emergency obstetric care to improve maternal health in India, ultimately supporting efforts to reduce both maternal mortality and the stillbirth rate.

4.1 | Strengths and limitations

The main strength of the present study is that it employed a large prospective design, allowing examination of the relationship between maternal and fetal factors associated with stillbirth. The prospective cohort study design, in combination with an appropriate statistical analysis method, allowed this study to assess the relative risk of identified risk factors associated with stillbirth in India. The findings are potentially generalizable to the wider Indian population as data were collected from 13 hospitals across six states in India, characterized by varying socioeconomic contexts, healthcare facilities, food habits, prevalence of malnutrition and anemia among pregnant women and the burden of pregnancy complications. Rigorous and standardized methodologies were utilized to minimize bias and enhance the validity and reliability of the findings.

Given the limited number of stillbirths and especially the small number of antepartum stillbirths (N = 48), conducting a subgroup analysis to examine risk factors for ante- and intrapartum stillbirths separately was not feasible. A deeper understanding of the differences between the two subgroups' risk factors can contribute meaningfully to shaping India's policy focus regarding prevention, and future studies should seek to enhance the current knowledge. Another limitation of this study relates to the cohort's original research focus, which did not center specifically on stillbirth. The exclusion of women who were planning to undergo a cesarean section at the time of recruitment, therefore, may have introduced selection bias. There is a need for cautious interpretation before extending the study's findings to this particular subgroup.

5 | CONCLUSION

Our findings emphasize the significance of addressing modifiable factors to reduce the risk of stillbirths in India. Improving access to high-quality antenatal care and enhancing the management of pregnancy complications, including the availability of emergency obstetric care, are vital steps toward achieving this goal. The study also highlights the importance of understanding the underlying causes of anemia to develop targeted treatment strategies, recognizing the complex, multifactorial relationship between iron supplementation and anemia. Furthermore, our findings emphasize the need for further investigation into intrapartum stillbirths and the quality of obstetric care provided during labor. By providing obstetric staff and policymakers with practical data and insights, this study could support strategic planning to reduce stillbirths in the Indian population

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

and achieve the proposed INAP target. As we move forward, these insights can inform the planning of targeted interventions and policies aimed at reducing stillbirth rates, ultimately advancing maternal and fetal health in India.

AUTHOR CONTRIBUTIONS

YYB developed the concept and design for the study, obtained, analyzed and interpreted the data, and wrote the first draft of the manuscript. RD is the MaatHRI Project Manager who supervised data collection, contributed to the interpretation of the data, and reviewed the paper critically for important intellectual content. MN developed the concept and design for the study, is the chief investigator of the MaatHRI projects from which the dataset was used, contributed to the interpretation of the data, edited the first draft of the paper and reviewed it critically for important intellectual content. JJK contributed to the development of the concept and design for the study, and the interpretation of the data, edited the first draft of the paper and reviewed it critically for important intellectual content. AKB, SC, SSC, GD, SK, PK, PM, BM, AR, SR, IR, CSV, AV and FZ contributed equally and their names are included in the alphabetical order of their last name. They contributed to the development of the concept and design for the study, are collaborators and investigators of the MaatHRI project from which the dataset was generated, contributed to the interpretation of the data, and reviewed the paper critically for important intellectual content. All authors gave final approval of the current version of the paper to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ACKNOWLEDGMENTS

We would like to thank Monica Lakhanpaul for her supervision of YYB's DPhil research, during which this study was conducted, and Charles Opondo for providing valuable advice on statistical analysis.

FUNDING INFORMATION

This study is part of YYB's DPhil research which is supported by the Clarendon Fund, Kellogg College Award, and Nuffield Department of Population Health Scholarship, University of Oxford. The MaatHRI platform and this study are funded by an MRC Career Development Award to MN (Ref: MR/P022030/1) and a Transition Support Award for MN (Ref: MR/W029294/1). The funders had no role in the study design, data collection, analysis, or writing the paper.

CONFLICT OF INTEREST STATEMENT

All authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Yebeen Ysabelle Boo https://orcid.org/0000-0003-2557-0678
Jennifer J. Kurinczuk https://orcid.org/0000-0001-9554-6337
Manisha Nair https://orcid.org/0000-0003-0660-5054

REFERENCES

1. United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). *Never Forgotten: the Situation of Stillbirth around the Globe*. United Nations Children's Fund; 2023.
2. Heazell AEP, Siassakos D, Blencowe H, et al. Stillbirths: economic and psychosocial consequences. *Lancet*. 2016;387:604-616.
3. Sachs JD, Kroll C, Lafortune G, Fuller G, Woelm F. *Sustainable Development Report 2022*. Cambridge University Press; 2022.
4. de Bernis L, Kinney MV, Stones W, et al. Stillbirths: ending preventable deaths by 2030. *Lancet*. 2016;387:703-716.
5. Hug L, You D, Blencowe H, et al. Global, regional, and national estimates and trends in stillbirths from 2000 to 2019: a systematic assessment. *Lancet*. 2021;398:772-785.
6. Ministry of Health & Family Welfare Government of India. Indian Newborn Action Plan. 2014.
7. Newtonraj A, Kaur M, Gupta M, Kumar R. Level, causes, and risk factors of stillbirth: a population-based case control study from Chandigarh, India. *BMC Pregnancy Childbirth*. 2017;17:1-9.
8. Sharma B, Raina A, Kumar V, Mohanty P, Sharma M, Gupta A. Counting stillbirth in a community - to understand the burden. *Clin Epidemiol Glob Heal*. 2022;14:100977.
9. Goldenberg RL, Saleem S, Goudar SS, et al. Preventable stillbirths in India and Pakistan: a prospective, observational study. *BJOG An Int J Obstet Gynaecol*. 2021;128:1762-1773.
10. Altijani N, Carson C, Knight M, et al. Stillbirth among women in nine states in India: rate and risk factors in study of 886,505 women from the annual health survey. *BMJ Open*. 2018;8:e022583.
11. Neogi SB, Negandhi P, Chopra S, et al. Risk factors for stillbirth: findings from a population-based case-control study, Haryana, India. *Paediatr Perinat Epidemiol*. 2016;30:56-66.
12. Nair M, Bezbaruah B, Bora AK, et al. Maternal and perinatal health research collaboration, India (MaatHRI): methodology for establishing a hospital-based research platform in a low and middle income country setting. *F1000Res*. 2020;9:683.
13. World Health Organization. *Neonatal and Perinatal Mortality: Country, Regional and Global Estimates*. World Health Organization; 2006.
14. Mbah AK, Alio AP, Marty PJ, Bruder K, Whiteman VE, Salihu HM. Pre-eclampsia in the first pregnancy and subsequent risk of stillbirth in black and white gravidas. *Eur J Obstet Gynecol Reprod Biol*. 2010;149:165-169.
15. Gardosi J, Madurasinghe V, Williams M, Malik A, Francis A. Maternal and fetal risk factors for stillbirth: population based study. *BMJ*. 2013;346:f108.
16. Haruyama R, Gilmour S, Ota E, et al. Causes and risk factors for singleton stillbirth in Japan: analysis of a nationwide perinatal database, 2013–2014. *Sci Rep*. 2018;8:1-10.
17. Planning Commission (Government of India). Press note on poverty estimates, 2011-12. 2013.
18. World Health Organization. *WHO Antenatal Care Randomized Trial: Manual for the Implementation of the New Model*. World Health Organization; 2002.
19. World Health Organization. *Haemoglobin Concentrations for the Diagnosis of Anaemia and Assessment of Severity*. World Health Organization; 2011.
20. Spong CY. Defining "term" pregnancy: recommendations from the Defining "Term" Pregnancy Workgroup. *JAMA*. 2013;309:2445-2446.
21. Villar J, Ismail LC, Victora CG, et al. International standards for newborn weight, length, and head circumference by gestational age and

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15567 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

sex: the Newborn Cross-Sectional Study of the INTERGROWTH-21st project. *Lancet*. 2014;384:857-868.
22. WHO. *A conceptual framework for action on the social determinants of health*. WHO; 2010.
23. Victora CG, Huttly SR, Fuchs SC, Olinto MT. The role of conceptual frameworks in epidemiological analysis: a hierarchical approach. *Int J Epidemiol*. 1997;26:224-227.
24. Ulm K. Simple method to calculate the confidence interval of a standardized mortality ratio (SMR). *Am J Epidemiol*. 1990;131:373-375.
25. Goldenberg RL, McClure EM, Bann CM. The relationship of intrapartum and antepartum stillbirth rates to measures of obstetric care in developed and developing countries. *Acta Obstet Gynecol Scand*. 2007;86:1303-1309.
26. Boo YY, Gwacham-Anisiobi U, Thakrar DB, et al. Facility-based stillbirth review processes used in different countries across the world: a systematic review. *EClinicalMedicine*. 2023;59:101976.
27. Basta M, Hanif K, Zafar S, et al. Impact of hypertensive disorders of pregnancy on stillbirth and other perinatal outcomes: a multicenter retrospective study. *Cureus*. 2022;14:e22788.
28. Ngoc NTN, Merialdi M, Abdel-Aleem H, et al. Causes of stillbirths and early neonatal deaths: data from 7993 pregnancies in six developing countries. *Bull World Health Organ*. 2006;84:699-705.
29. Vogel JP, Souza JP, Mori R, et al. Maternal complications and perinatal mortality: findings of the World Health Organization multicountry survey on maternal and newborn health. *BJOG An Int J Obstet Gynaecol*. 2014;121:76-88.
30. Nair M, Churchill D, Robinson S, Nelson-Piercy C, Stanworth SJ, Knight M. Association between maternal haemoglobin and stillbirth: a cohort study among a multi-ethnic population in England. *Br J Haematol*. 2017;179:829-837.
31. Nair M, Choudhury MK, Choudhury SS, et al. Association between maternal anaemia and pregnancy outcomes: a cohort study in Assam, India. *BMJ Glob Health*. 2016;1:e000026.
32. National Health Mission. Anemia Mukt Bharat: Poshan Abhiyaan. PM's Overarching Scheme Holistic Nourishment. 2018. Accessed September 18, 2023. https://anemiamuktbharat.info/
33. Nair M, Choudhury SS, Rani A, et al. The complex relationship between iron status and anemia in pregnant and postpartum women in India: analysis of two Indian study cohorts of uncomplicated pregnancies. *Am J Hematol*. 2023;98:1721-1731.
34. Lawn JE, Gravett MG, Nunes TM, Rubens CE, Stanton C. Global report on preterm birth and stillbirth (1 of 7): definitions, description of the burden and opportunities to improve data. *BMC Pregnancy Childbirth*. 2010;10(Suppl 1):S1.
35. Kc A, Wrammert J, Ewald U, et al. Incidence of intrapartum stillbirth and associated risk factors in tertiary care setting of Nepal: a case-control study. *Reprod Health*. 2016;13:1-11.
36. Smith GCS. Life-table analysis of the risk of perinatal death at term and post term in singleton pregnancies. *Am J Obstet Gynecol*. 2001;184:489-496.
37. Trudell AS, Cahill AG, Tuuli MG, Macones GA, Odibo AO. Risk of stillbirth after 37 weeks in pregnancies complicated by small-for-gestational-age fetuses. *Am J Obstet Gynecol*. 2013;208(376):e1-e7.
38. Horwood G, Opondo C, Choudhury SS, Rani A, Nair M. Risk factors for maternal mortality among 1.9 million women in nine empowered action group states in India: secondary analysis of Annual Health Survey data. *BMJ Open*. 2020;10:e038910.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Boo YY, Bora AK, Chhabra S, et al. Maternal and fetal factors associated with stillbirth in singleton pregnancies in 13 hospitals across six states in India: A prospective cohort study. *Int J Gynecol Obstet*. 2024;165:462-473. doi:10.1002/ijgo.15367

18793479, 2024, 2, Downloaded from https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15367 by Test, Wiley Online Library on [03/08/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Appendix N: Summary of document analysis

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
Birth register (Proforma)	Contains headings of data that are collected once a woman registers in the hospital. Intended audience is for healthcare professionals (HCPs).	• Woman's demographic details are collected. This includes their age, guardian (male), address, contact information, and Scheduled Caste/Scheduled Tribe/Other Backward Class. • Obstetric history are collected, including, estimated due date (EDD), Parity, history of caesarean, Other obstetric complications in the past. • Admission details are collected, including, if the woman is in labour at the time of the admission, blood pressure, fetal health rate, any infections, and any information that may indicate high risk pregnancy. • Details of intrapartum intervention were collected, including, partograph usage, if the woman was induced, blood transfusion, placenta delivered within 30 min, episiotomy. • Details of birth, including, date, time, type of delivery (normal/assisted), caesarean, who was involved, term duration were collected. Baby outcome information was collected as alive, fresh stillbirth, macerated stillbirth and newborn death. • Information about the baby includes, sex, weight, resuscitation method were collected. • Information on complication of women and baby were collected, as well as any referral information if applicable, condition of mother and baby at discharge, postpartum family planning such as counselling, any contraception methods chosen etc.
Hospital statistics (Memoranda)	Contains annual birth (live/stillbirth) from 2019 to Jun 2023. Includes no. of obstetricians and nurses in Jul 2023. Intended for the researcher to understand the background information of the hospital around stillbirth burden.	• Number of live births and stillbirths from 2019 to June 2023 are listed. • Number of obstetricians and nurses as of July 2023 are listed. • Number of total births (sum of live births and stillbirths) are listed.
Stillbirth report (Proforma)	Contains legal and statistical information of each stillbirth in the hospital. Intended for surveillance of stillbirth at higher level (e.g. state level) since the information of this report is to be sent to a registrar and to be added to the	• 'Legal information' section requires data of the woman, such as date of birth of the baby, sex of the baby, name of the father, name of the mother, place of birth (and if at the hospital, name of the facility), informant's name and address.

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
	stillbirth register. Intended for person who is reporting number of stillbirth to higher authority.	• 'Statistical information' section requires data of town or village of the mother, age of the mother at the birth, mother's level of education and type of facility or attention (if birth occurred at home setting), gestational age at birth and cause of death if known. • There is a place to be signed by the Registrar of the town/village at the bottom of the form.
Data of stillbirth cases (Proforma)	Contains headings of data that are collected for the stillbirth review, and each column has case number. Intended for person who is gathering data for stillbirth review.	• Women's demographic information (age, education) and father's age is collected. • Obstetric history such as gravida, parity, abortion status, any other living children, previous stillbirth or caesarean sections are collected. • Present pregnancy's details are collected including, gestation age at birth, iron and folic acid intake, if the women had at least four antenatal check ups, fetal heart rate present at the admission, partograph usage, mode of delivery, indication for caesarean, decision to delivery interval in hours and minutes, birth defects presence. • Cause of death were collected including, if infection was present, if there was any intrapartum complications (e.g. malpresentation, prolong labour etc.,) if there was any fetal cause (e.g. birth defects, isoimmunisation, multiple pregnancy etc.,), if cord complication was present, if placenta causes are present, if maternal causes were present (e.g. hypertension, diabetes etc.,) and if it was a antepartum stillbirth.
Protocol for monthly audit of stillborn and perinatal death (Instructions and procedures)	Contains objectives, definition of terminology and audit procedure including scheduled day, panel members, and activity flows. Intended for stillbirth review panel.	• Objectives of stillbirth review are indicated as to: review incidence of death, determine cause of death, evaluate predisposing factors (both medical and non-medical), root cause analysis and recommendation, submission of data to further review and action • Definition of fresh/intrapartum stillbirth, macerated stillbirth and perinatal death are described. Fresh stillbirth is defined as death after onset of labour and less than 12 hours of birth with no skin changes, more than 1,000g, and more than 28 weeks of gestation, but excludes severe lethal congenital abnormalities. Macerated/antepartum stillbirth is defined as fetus death before the labour has started and shows skin and soft-tissue changes. Perinatal death is defined as death within 24 hours of birth.

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
		• Audit date is first Saturday of following month. • Panel includes superintendent (and noted as Chair), gynaecologist (noted as nodal person), paediatrician, in-charge labour room nurse, in-charge operating theatre nurse, in-charge Special Newborn Care Unit (SNCU) nurse, nursing administrator. • Flow of activity shows any stillbirth to be informed to nodal person as soon as possible, preferably within 1 hour. The nodal person is then responsible for documenting the statement from who has given care of the women and talking to family members (while considering grief of the family). Also, nodal person reviews medical records then create a report. • At the stillbirth review, individual stillbirth is presented to the panel and cross-interview of concerned service provider to be done. Discussion of clinical and managerial issue. • Any recommendation suggested by the panel should be recorded with responsible person and timeframe. This document is signed by the Chair.
Report of stillbirth (Reports)	Contains number of birth and stillbirth and brief detail of each stillbirth. Intended for stillbirth review meeting (resources).	• Total number of birth, stillbirth and perinatal death reported for the month. The summary of stillbirth includes date of admission, date/time of birth, women's gravida and parity, problems at admission, gestational age, birthweight, any medical/obstetric history.
Monthly audit meeting minutes (Meeting documents)	Stillbirth statistics of the month, action points and names and signatures of the attendees are written in this minutes. Intended for dissemination and record keeping.	• Lists names and signatures of stillbirth review meeting attendees. • Stillbirth statistics of the month (e.g. total birth, stillbirth and neonatal death) are described. • Contains details of what was lacking (e.g. medical intervention) and what should be done in future. E.g. follow up should be vigilant in high risk pregnancy, due to pregnancy induced hypertension, absent fetal movements were not communicated.
Operational guidelines for establishing sentinel stillbirth surveillance	National guidelines for establishing sentinel stillbirth surveillance system. Intended for hospital senior management team establishing such system.	• The guidelines gives standard guidance to operationalise sentinel stillbirth surveillance at the medical colleges, large district hospitals and institutions. It uses the following stillbirth definition, 'fetal death

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
system (Instructions and procedures)		weighing at least 1,000g, or gestational age of 28 completed weeks or a crown-heel length of 35cm or more'. • The guidelines describes the Head of department of obstetrics and gynaecology would be designated as the nodal officer and will be responsible for all surveillance related activities. It also describes following job titles should be involved and be trained on standard operating procedure: obstetricians and gynaecologists, paediatricians, resident doctors, medical officers, nurses, other staff including pathologists. • There is a proforma (Annexure 2) that supports the data collection for stillbirth surveillance and recommends the proforma to be filled out using a standard history taking and examination of both mother and the baby. • The guidelines explains the nodal officer should assign cause of stillbirth (using the modified Causes of Death and Associated Conditions (CODAC) classification) once receiving the complete documentation of the mother and baby. It also advises talking to the family to identify the cause if they are uncertain. • The guidelines notes that each facility will report their stillbirth using their registered ID to South-East Asia Region Newborn and Birth Defects (SEAR-NBBD) database and the quality of data will be assessed by National nodal institution. • The role of responsibilities show that designated paediatrician will examine and confirm the diagnosis of stillbirth. Also, pathologist will carry out the autopsy. Lastly, data should be managed electronically. • There is a state child health nodal officer and national nodal centre who will oversee the surveillance activities of each facility, including reporting and training. • There is a guidance on how to approach a family for the autopsy of stillbirth and what kind of topics to discuss when having this conversation.
Case sheet for maternity services –	A proforma used for when a woman is admitted to the hospital. Intended for health care professionals.	• Woman's registration number, referral source, reason for referral, name of Accredited Social Health Activist (ASHA) worker is collected.

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
L3 facility: Admission form (Proforma)		• Woman's demographic details are collected, including age, marital status, and name of companion. • Pregnancy details and admission category are collected, for example, expected delivery date (EDD), diagnosis, contraception history. • Birth outcome is collected, including sex, preterm status, birthweight, immunisation status, date of birth, mode of birth, indication for assisted or caesarean section method of birth, final outcome of the mother. • Any information of past pregnancy and medical history or family history are collected. • Date and time of labour and any gravida/parity/abortion information are collected. • Examination of the mother including height, weight, pallor/jaundice/pedal edema status are collected. • Vitals including temperature, blood pressure, pulse, respiratory rate and fetal heart rate are collected. • Abdominal examination such as presentation of baby and engagement/lie are collected. • Gestational age and fundal heights, antenatal corticosteroid status are recorded. • Vaginal examination information are recorded, for example, cervical dilation, cervical effacement, membranes status, colour of amniotic fluid and pelvis status. • Results from blood investigations such as platelets, serum creatinine, blood group/Rhesus are collected. Also, any other blood sugar level, infections are recorded.
Medical certification of death: international (Proforma)	Death certificate. Intended for health care professionals.	• Information of the hospital, details of woman (age, sex, occupation, religion, address, guardian) are collected. • Cause of death are categorised as immediate cause, antecedent causes and other significant condition. Immediate causes are defined as disease, injury or complication which cased death. Antecedent causes are defined as morbid condition and also any underlying condition for

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
		this morbid condition. Other significant condition is defined as contributing to the death, but not related to the disease or condition causing it.
Labour room register (Proforma)	Contains headings of data that are collected once a woman registers in the hospital. Intended audience is for HCPs.	• Woman's demographic details are collected. This includes their age, guardian (male), address, contact information, and Scheduled Caste/Scheduled Tribe/Other Backward Class. • Obstetric history are collected, including, estimated due date (EDD), Parity, history of caesarean, Other obstetric complications in the past. • Admission details are collected, including, if the woman is in labour at the time of the admission, blood pressure, fetal health rate, any infections, and any information that may indicate high risk pregnancy. • Details of intrapartum intervention were collected, including, partograph usage, if the woman was induced, blood transfusion, placenta delivered within 30 min, episiotomy. • Details of birth, including, date, time, type of delivery (normal/assisted), caesarean, who was involved, term duration were collected. Baby outcome information was collected as alive, fresh stillbirth, macerated stillbirth and newborn death. • Information about the baby includes, sex, weight, resuscitation method were collected. • Information on complication of women and baby were collected, as well as any referral information if applicable, condition of mother and baby at discharge, postpartum family planning such as counselling, any contraception methods chosen etc.
Recommendation and action plan generated by the stillbirth review panel (Reports)	Contains three recommendations and responsible person. Intended for stillbirth review panel, and any important people who should be disseminated the information agreed from the stillbirth review meeting.	• Along with information of when the recommendation was agreed (and at which stillbirth review meeting), the report has three recommendations from June 2023 stillbirth review meeting. • Each recommendation has responsible person. • Each recommendation has details of what the suboptimal factor was (of the stillbirth) and what needs to be done in future to rectify the issue or improve quality of care.

Name (Type)	Summary of document type and objective	Summary of key document analysis findings
Stillbirth report (Proforma)	Contains legal and statistical information of each stillbirth in the hospital. Intended for surveillance of stillbirth at higher level (e.g. state level) since the information of this report is to be sent to a registrar and to be added to the stillbirth register. Intended for person who is reporting number of stillbirth to higher authority.	• 'Legal information' section requires data of the woman, such as date of birth of the baby, sex of the baby, name of the father, name of the mother, place of birth (and if at the hospital, name of the facility), informant's name and address. • 'Statistical information' section requires data of town or village of the mother, age of the mother at the birth, mother's level of education and type of facility or attention (if birth occurred at home setting), gestational age at birth and cause of death if known. • There is a place to be signed by the Registrar of the town/village at the bottom of the form.
Reporting flowchart (Memoranda)	Contains four step guidelines of how to report stillbirth. Intended for stillbirth review panel.	• The reporting flow shows that when filling stillbirth report, women is involved to provide information. • Recording in delivery register is used for filling stillbirth report • Details of the stillbirth report is rechecked. • The stillbirth report is sent to Chief Medical Officer's office within 21 days. • The stillbirth report is also sent to municipal's office, although the timeline for this submission is not stated.
Hospital statistics (Memoranda)	Contains annual birth, women receiving antenatal care and stillbirth from 2019 to 2022. Includes no. of doctors, nurses and other staff in the department from 2019 to 2022. Intended for the researcher to understand the background information of the hospital around stillbirth burden.	• Number of annual births, number of women receiving antenatal care and stillbirths from 2019 to 2022 are listed. • Number of doctors, nurses and other staff from 2019 to 2022 are listed.