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Interventions, outcomes and outcome measurement instruments in stillbirth care research: A systematic review to inform the development of a core outcome set

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Running Title: Systematic review of stillbirth care outcomes

Abstract

Background

A core outcome set could address inconsistent outcome reporting and improve evidence for stillbirth care research, which has been identified as an important research priority.

Objectives

To identify outcomes and outcome measurement instruments reported by studies evaluating interventions after the diagnosis of a stillbirth.

Search strategy

Amed, BNI, CINAHL, ClinicalTrials.gov, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Embase, MEDLINE, PsycINFO, and WHO ICTRP from 1998 to August 2021.

Selection criteria

Randomised and non-randomised comparative or non-comparative studies reporting a stillbirth care intervention.

Data collection and analysis

Interventions, outcomes reported, definitions and outcome measurement tools were extracted.

Main results

40 randomised and 200 non-randomised studies were included. 58 different interventions were reported, labour and birth care (52 studies), hospital bereavement care (28 studies), clinical investigations (116 studies), care in a multiple pregnancy (2 studies), psychosocial support (28 studies) and care in a subsequent pregnancy (14 studies). 391 unique outcomes were reported and organised into 14 outcome domains: labour and birth; postpartum; delivery of care; investigations; multiple pregnancy; mental health; emotional functioning; grief and bereavement; social functioning; relationship; whole person; subsequent pregnancy; subsequent children and siblings and economic. 242 outcome measurement instruments were used, with 0-22 tools per outcome.

Conclusions

Heterogeneity in outcome reporting, outcome definition and measurement tools in care after stillbirth exists. Considerable research gaps on specific intervention types in stillbirth care were identified. A core outcome set is needed to standardise outcome collection and reporting for stillbirth care research.

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Tweetable abstract

Systematic review identifies paucity of interventions and variation in outcome reporting in stillbirth care research

Keywords

Stillbirth, Core outcome set, Systematic Review, Patient and public involvement, Stillbirth care

Main Text

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Introduction (400 words)

In 2019, an estimated two million babies were stillborn[1]. Previous research has documented the devastating negative medical, social and psychological impact of stillbirth on families[2,3]. Studies have found that the care parents receive after the diagnosis stillbirth is inconsistent and often suboptimal [4,5]. There is a consensus amongst the stillbirth research community and bereaved parents that there needs to be more evidence-based care available to improve care following stillbirth for families worldwide[4,6,7].

There is a range of potential interventions that tackle different aspects of care after a stillbirth across the life course, from the initial diagnosis of the death of a baby; bereavement care; and interventions to understand why a baby has died, to long-term psychosocial support and care in a subsequent pregnancy. Cochrane reviews exploring these aspects of care have unanimously found few randomised controlled trials to guide clinical practice and improve care after a stillbirth has been diagnosed[8–10]. The lack of evidence is further compounded by heterogeneity in outcome reporting, leading to a difficulty in synthesising and appraising the results of previously conducted studies.

Perhaps it is unsurprising that heterogeneity exists, given the array of interventions available at different timepoints, addressing different aspects of the stillbirth. Nonetheless, it is important to identify and measure outcomes consistently when investigating mental, physical and social health care and impacts associated with the experience of stillbirth care[2]. This is particularly important in order to build a comprehensive evidence base on the interventions that are most likely to be effective. By developing a core outcome set, a minimum set of outcomes that should be collected and reported in a given study, the same outcomes could be measured using the same measurement tools, minimising outcome reporting bias[11]. Similar outcomes can therefore can be compared and combined, and thus strengthening the evidence base and statistical power to inform best practice and improve care[11].

An international survey in 2019, nominated the development of a core outcome set for stillbirth research as an 'important and urgent' top five priority to inform clinical practice in a pregnancy subsequent to stillbirth[12]. The iCHOOSE study is addressing and expanding these priorities by developing a core outcome set for stillbirth care research[13]. Here we report on a systematic review that aims to identify what interventions and outcomes have been reported as an initial step in core outcome set development.

Methods

The systematic review was prospectively registered on PROSPERO International prospective register of systematic reviews (CRD42018087748) and adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines **(See Appendix S2 for PRISMA checklist**)[14]. The full protocol for the development of the core outcome set for stillbirth care research is published elsewhere[13].

Study identification

As very few randomised trials of care after stillbirth exist, we felt it was necessary to include observational studies in our methods. This approach was designed to facilitate the development of a comprehensive 'long-list' of potential outcomes for inclusion in a core outcome set for stillbirth care research. With assistance from a clinical librarian (KB), electronic searches of Amed, BNI, CINAHL, ClinicalTrials.gov, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Embase, MEDLINE, PsycINFO, and WHO ICTRP databases were conducted with a date limit of 1998 to 2019, updated in August 2021. For pragmatic reasons, the research team decided to limit the search to a generation's worth of research data (approximately 20 years) to ensure results included seminal stillbirth care research and relevant contemporary outcomes. Free text and subject heading terms were searched such as stillbirth, fetal death, perinatal mortality or fetal mortality and methodological filters were applied. A detailed search strategy is included in the **Appendix S1.** Reference lists of extracted articles and relevant systematic reviews were searched.

Study eligibility

See Table 1 for inclusion and exclusion criteria for systematic review.

Study selection process

The identified publications were uploaded to Covidence systematic review software and duplicates removed [15]. Prior to abstract and full-text screening, all review authors had training on the study's objectives, eligibility criteria and outcome extraction. All titles and abstracts were screened independently by at least two members of the review team (two of DB, AM, AD, CS, KB) with previous experience of systematic review methodology. Full text articles identified from the screening process were then assessed for eligibility by two reviewers. Due to the large number of studies a team of reviewers were involved in the full text review and data extraction process (DB, AM, AD, CS, KD, KB, ES, AL, CB).

Quality assessment

Risk of bias assessment was initially included in the protocol, however quality assessment was not relevant in the context of identifying reported outcomes, as the aim of this study was to create a 'long-list' of outcomes and identify outcome measurement tools for stillbirth care research, not to synthesise any measured effect. Therefore, we do not report on risk of bias.

Data extraction

Data were extracted into a standardised data extraction sheet using Google Forms, which was directly inputted into a Microsoft Excel spreadsheet. The data extraction form was developed and piloted with members of the review team prior to its use. Extracted data were basic publication details (author and date of publication); study setting; study population; details of intervention; study methodology; outcomes measured, their definition (if stated), their relevant outcome measurement tool (if applicable) and patient and public involvement in the research design. Outcomes were extracted verbatim from the published abstract, methods or results including tables. Data extraction from all publications was conducted by the primary author (DB), and team members conducted independent data extraction on 50% of these to ensure reliability of extraction. All disagreements were resolved through a third senior reviewer (CB).

Classification and analysis of outcomes

Following data extraction, true duplicate outcomes were removed. Subsequently, to ensure methodological transparency, a further process was conducted where by two reviewers (a clinician - DB and an experienced researcher - AD) organised and classified the outcomes into outcome domains independently using the Cochrane reviews and COMET core outcome set database taxonomy[16]. This organisation process allowed for outcomes described using the same terminology to be identified and grouped together to enable identification of truly unique outcomes. The Cochrane reviews and COMET taxonomy had more clinical domains than required and therefore the outcomes were further grouped into an adapted stillbirth care research outcome taxonomy **(See Table S2 for the Cochrane and adapted stillbirth taxonomy of outcomes)**[16]. The adapted taxonomy was created to better reflect the needs of stillbirth care research and was developed from ongoing qualitative research and bereaved parent input.

Similar interventions were grouped into the following categories: labour and birth care, postpartum bereavement care, investigations into causes of stillbirth, psychosocial support, multiple pregnancy and interventions in a subsequent pregnancy. Heterogeneity in outcome reporting was assessed in randomised controlled trials according to intervention category. We calculated the number of different definitions and outcome measurement tools described for an individual outcome. The frequency of outcomes assessed at specific time intervals post-stillbirth is reported. An infographic was produced to illustrate the types and timings of interventions after stillbirth **(See Figure 1: Types and timing of interventions for stillbirth care research).**

Patient involvement

Parents who experienced a stillbirth were involved in the design of the research question through to the analysis of the results and review of the manuscript. The parent involvement panel included 11 bereaved parents and had global representation (including Africa, Australasia, Europe, North America) through the iCHOOSE collaborative group.

Results

Our initial searches identified 21,893 records (Search strategy – **Appendix S1**). After excluding 6,398 duplicate records, 15,495 titles and abstracts were screened. An additional 217 articles were identified from searching the reference lists of identified articles and relevant systematic reviews. A total of 1,492 studies were included for full text review. From this, 240 studies met the inclusion criteria, representing approximately 298,762 participants[17-256].

See **Table S1** for detailed characteristics of included studies and **Appendix S3** for PRISMA flow diagram.

Studies from 64 different countries were included. One hundred and eighty-three studies conducted research in high-income, 24 from upper-middle income, 28 from lower-middle and five from low-income countries. The majority of studies were conducted in Europe (111 studies), followed by North America (52 studies) and Asia (42 studies). Only 23 studies included fathers in their interventions. Lastly, of 240 studies, only 10 involved patients and members of the public in the study design and selection of their outcomes and/or outcome measurement tools. A summary of included study details is shown in **Table 2 Study Characteristics.** 58 different types of interventions were identified. See **Figure 1 and Table 2** for an illustration of the types and timing of interventions available for stillbirth care research.

A total of 817 outcomes were reported; after de-duplication and classification of outcomes, 391 unique outcomes remained. The 391 unique outcomes were organised into 14 outcome domains. See **Table 3** for a summary of the number of outcomes per domain and the number of times that an outcome was reported.

See **Table S3** for a comprehensive list of outcomes reported across all studies, by outcome domain and study design. No outcome was reported in all studies of a specific intervention type. A further analysis of outcome reporting in RCTs only **(See Table S4)** indicated variability in outcomes reported and no outcome was reported by every RCT of a specific type.

Labour and birth care: interventions and outcomes

Interventions included in this category were induction of labour (46 studies), mode of birth (3 studies) and neural axial analgesia (1 study). The five most commonly reported outcomes in studies reporting on labour and birth interventions were induction to birth interval reported by 65% of studies (34 out of 52 studies), complications or side effects of treatment reported by 39% of studies (20 out of 52 studies), successful induction reported by 31% of studies (16 out of 52 studies), use of analgesia during labour and birth reported by 25% of studies (13 out of 52 studies) and dose of misoprostol required reported by 15% (8 out of 52 studies). Only one study reported maternal death as an outcome of interest, and only two studies (4% of labour and birth interventions) reported satisfaction with intervention or care. No studies reported psychological (e.g., grief, anxiety) outcomes.

Bereavement care: interventions and outcomes

15 studies were identified evaluating multiple components of bereavement care (e.g., at least two seeing and holding baby, making hand or footprints, photos and mementos, including children or family members in care, care or support from healthcare professionals). The greatest number of outcomes was reported within the delivery of care outcome domain (15 outcomes) followed by the emotional functioning domain (15 outcomes). The most frequently reported outcomes included experience of intervention or care reported by 32% (9 out of 28 studies), depression reported by 29% (8 out of 28 studies), anxiety reported by 21% (6 out of 28 studies, post-traumatic stress disorder reported by 17% (Post-traumatic stress disorder (PTSD) - 5 out of 28 studies) and grief reported by 18% (5 out of 28 studies). There were no studies that measured the impact of postnatal hospital care on parents' role e.g., returning to work or parenting or impact of care on existing older children.

Investigations to understand cause of stillbirth: interventions and outcomes

Interventions included 41 studies evaluating multiple component investigation protocols (e.g., at least two of review of the medical history, post-mortem pathological examination, placental examination, post-mortem imaging, laboratory blood testing for mother or baby). Outcomes were most frequently reported in the investigation domain (127 outcomes). The six most frequently reported outcomes were identification of cause of death reported in 41% (47 out of 116 studies), proportion consenting to post-mortem reported by 16% (18 out of 116 studies), uptake of post-mortem reported by 12% (14 out of 116 studies), identification of fetal congenital abnormality reported by 10% (11 out of 116 studies), identification of a placental cause of death and identification of acquired or inherited thrombophilia reported by 6% (7 out of 116 studies respectively). Only one study measured parents' experience of an intervention to understand why a baby died and only one study reported on parents' perceived understanding of the cause of their baby's death.

Psychosocial support: interventions and outcomes

Psychosocial support interventions evaluated included bereavement support interventions (5 studies), cognitive behavioural therapy (4 studies), counselling (4 studies), and yoga (3 studies). Outcomes were most frequently reported in the mental health domain (10 outcomes). The most commonly reported outcomes were experience of intervention/care reported by 43% (12 out of 28 studies), depression reported by 29% studies (8 out of 28 studies), grief reported by 29% studies (8 out of 28), PTSD 25% of studies (7 out of 28 studies), and anxiety reported by 14% (4 out of 28 studies). Only two studies within this category reported on relationship outcomes and no studies assessed the effect of a psychosocial intervention on existing children or family.

Multiple pregnancy: interventions and outcomes

There were only two interventions and two studies included in this category. One study assessed the impact of intrauterine rescue transfusion and the other focused on bereavement care for a stillbirth in a multiple pregnancy. The study related to intrauterine rescue transfusion reported solely on medical outcomes related to the surviving twin e.g., abnormalities on cranial ultrasound, fetal acidemia or neurodevelopment outcome of the surviving twin. No psychosocial, experiential or grief outcomes were reported.

Care in subsequent pregnancy: interventions and outcomes

Interventions in this category primarily focused on the medical treatment of women in a subsequent pregnancy, including 6 studies on thromboprophylaxis in a subsequent pregnancy. Only 3 studies evaluated

care and 1 study on psychological support interventions in a subsequent pregnancy. The most frequently reported outcomes were live birth in a subsequent pregnancy reported in 29% of studies (4 out of 14 studies), complications during a subsequent pregnancy reported in 21% (3 out of 14 studies), birth weight in a subsequent pregnancy reported in 21% (3 out of 14 studies) and anxiety reported in 21% (3 out of 14 studies). Only two studies reported on experience of care and one study on prenatal attachment in a subsequent pregnancy. No studies reported on the frequency of post-traumatic stress disorder (PTSD) or grief in a subsequent pregnancy.

Outcome measurement

Table S5 lists all outcomes, their definitions and measurement instruments used (if applicable). There was variation in the definition of reported outcomes (range of definitions 0-35). For example, for postpartum complications there were five different definitions. For 247 outcomes no definition was provided. 242 outcome measurement tools were identified. There was variation in the type of outcome measurement tools used to measure the same outcomes, with a range of 0-22 tools used for a single outcome. Outcomes were measured at different timepoints relative to the stillbirth and were dependent on the type of intervention **(Appendix S4**). 190 outcomes were measured during labour and birth, 76 outcomes in the postpartum period (Up to six weeks postpartum), 246 outcomes following investigations, 66 outcomes within the first year, 101 outcomes in the first five years and 24 at five years or more.

Discussion and conclusion

Main Findings

The objective of this systematic review was to generate a comprehensive long-list of outcomes to inform the development of a core outcome set for stillbirth care research; we identified 391 unique outcomes. We demonstrated the wide variation of interventions implemented and assessed, and outcomes reported. Where studies reported the same outcome, there was considerable variation in the reporting of the outcome definition and measurement tool used. Outcomes were measured at different time points relative to the stillbirth, with few studies measuring long term outcomes, i.e., within the first year or beyond five years.

We identified a diverse range of interventions after stillbirth. However, there is a paucity of evidence on a number of specific types of intervention, for example, counselling, specific psychological therapy or targeted

interventions in a subsequent pregnancy. Interventions after stillbirth address different aspects of care, including medical, psychological, social and long-term health. We found that the majority of studies did not measure the effect of interventions or care on parents' perceived experience, grief or psychosocial outcomes.

Strengths and Limitations

A strength of this study is its comprehensive inclusion of both non-randomised, non-comparative and RCTs, allowing for a wide range of interventions and outcomes to be identified. Previous systematic reviews on stillbirth care have only focused on RCTs or interventions targeting physical or mental health of parents, rather than broader outcomes e.g. social, economic or experiential outcomes[8–10,257]. Robust methods have been utilised in the review, including independent duplicate screening, double extraction and extensive reference searching. An inclusive approach was adopted and high, middle- and low- income countries have been included in the systematic review increasing global relevance of the review. An international steering group, including parents with lived experience of stillbirth, have informed the scope, study design and development of the outcome domains and long-list.

A limitation is that for resource reasons, non-English language articles were excluded, which in turn could have limited the number studies identified from low- and middle- income countries. We found that very few studies have been conducted in low-income countries (which have the highest burden of stillbirth). Therefore, the outcome list generated from this review, may omit outcomes most relevant to these settings. Engaging low- and middle- income countries in future core outcome set development will be vital to ensure a globally representative core outcome set is created.

Only studies published over the last 24 years were included. Older publications may describe different interventions or outcomes; however, they might not have been as relevant for informing a contemporary outcome inventory, as stillbirth bereavement care has advanced in recent times[258]. Case studies, conference abstracts, protocols and dissertations were excluded. This could have led to the omission of newer interventions and novel outcomes evaluated in research yet to be published in full manuscript form. Furthermore, this review found that only 23 studies included fathers or non-birthing partners in the assessment of their outcomes, even though the impact of stillbirth has a dyadic (couple) context for many[259]. We identified only 10 studies that included parents or members of the public in their study design. This underlines the need for a future core outcome set to incorporate the viewpoints of patients and members of the public in the selection of the most important outcomes.

Interpretation

This systematic review highlights the wide variation in research studies relating to stillbirth care, by identifying the heterogeneity of interventions and outcomes measured and reported. The lack of standardisation and the frequent failure to report on important outcomes such as maternal mortality, psychosocial outcomes and to assess long term effects in many studies hampers progress towards providing optimal care after stillbirth. The problems for stillbirth care evidence are not unique; previous systematic reviews conducted in obstetrics and gynaecology and other specialties, have found similar heterogeneity in outcome reporting, definitions and outcome measurement tools [260–268]. The outcomes identified in this systematic review have contributed to the development of an outcome long-list and are being used in an international Delphi consensus process to define a minimal core outcome set for stillbirth care research[13].

More studies with robust methodology are needed to improve the clinical evidence for care after stillbirth. For example, there were no RCTs identified for interventions to improve hospital or follow up bereavement care. This could be due in part to the ethical challenges of performing trials in this field, such as the perceived fear of causing harm to bereaved parents and the appropriateness of RCT methodology to evaluate psychosocial support interventions after stillbirth[12]. Studies have found bereaved parents feel positive about participating in research and good recruitment rates have been demonstrated when the approach has been guided by patient and public involvement[225,248,269].

There appears to be several significant evidence-practice gaps into specific interventions after stillbirth. Surprisingly, no interventions were identified on lactation care (e.g., breast milk suppression or milk donation) and personalisation of care at any stage. Several interventions related to subsequent pregnancy have not been studied, including continuity of care; pre-pregnancy counselling; targeted antenatal interventions for women with modifiable risk factors (e.g., diabetes or smoking) and additional antepartum ultrasound surveillance[12]. Moreover, no interventions were identified to support parents from minority ethnic and socioeconomic backgrounds following stillbirth, which could be intensifying health inequalities[270]. Interestingly, we identified no studies were found on interventions to support the LBTQ+ (lesbian, gay, bisexual, transgender, queer/questioning, asexual and others) community. Future research should focus on an exploration of potential interventions in these contexts and populations.

Conclusion

This systematic review has highlighted the large variation in outcomes assessed, and outcome definitions and outcome measurement instruments used. These inconsistencies limit the utility of primary research and of evidence synthesis, and impact adversely on quality of decision making in the field of stillbirth aftercare. Considerable research gaps on specific intervention types in stillbirth care were also identified. The findings of this systematic review strongly support the need to develop a core outcome set for stillbirth care research.

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Disclosure of interests

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Contribution to authorship

Study concept: DB, CB, AF, AD, DS, LH, JMND. Study Design: DB, CB, AF, AD, DS, LH, JMND, AM, KB & iCHOOSE Collaborative Group. Drafting of the article: DB. Development of search strategy and electronic searches of the medical literature databases: DB & KB. Screening of titles, abstracts and full texts: DB, AM, AD, CS, KB. Data extraction: DB, AM, AD, CS, KD, KB, ES, AL, CB. Data analysis: DB, AD, CB & AF. Critical revision of the article for important intellectual content and approval of final manuscript: DB, CB, AF, AD, DS, LH, JMND, AM, KB, ES, CS, KD, AL & iCHOOSE collaborative group. Study supervision: CB, AF, DS, LH & AD

Ethical approval

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Table/Figure Caption lists

Table 1: Inclusion and exclusion criteria for systematic review of interventions, outcomes and measurement instruments

Figure 1: Types and timing of interventions for stillbirth care research *Number illustrates number of studies – Infographic by Anni King Senior Research Associate in Medical Imaging, Bristol, United Kingdom

Table 2: Study characteristics for included studies in the systematic review

Table 3: Summary table of outcomes and domains from systematic review

Supplementary files

Appendix S1: Search strategy for systematic review

Appendix S2: PRISMA Checklist

Appendix S3: PRISMA flow diagram

Appendix S4: Timepoints of outcome measurement

Table S1: Detailed characteristics of included studies

Table S2: Cochrane and adapted stillbirth taxonomy of outcomes

Table S3: Outcomes long-list from systematic review

Table S4: Heterogeneity in outcome reporting in randomised controlled trials

Table S5: Outcomes, definitions and measurement instruments