European Journal of Obstetrics and Gynecology 307 (2025) 61–70

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.journals.elsevier.com/european-journal-of-obstetrics-and-gynecology-and-reproductive-biology

Full length article

Variations in caesarean section outcome reporting in low- and middle-income countries: A systematic review

Amie Wilson [a,b,*], Harpreet Kaur [c], Ahmed Ali Hassan [d], Bernard Mbwele [e,f], Soha Sobhy [a], Gabriel Ruiz Calvo [g], Sergio Olmos Piñero [g], Javier Zamora [g,h], Shakila Thangaratinam [a,i]

[a] Department of Metabolism and Systems Science, WHO Collaborating Centre for Global Women's Health, College of Medicine and Health, University of Birmingham, United Kingdom
[b] Centre for Women's and Newborn Health, International Public Health, Liverpool School of Tropical Medicine, Liverpool, United Kingdom
[c] All India Institute of Medical Sciences (AIIMS), Bilaspur, India
[d] Public Health Physician -Independent Researcher- Khartoum, Sudan
[e] Department of Epidemiology, Biostatistics and Clinical Research, University of Dar es Salaam - Mbeya College of Health and Allied Sciences (UDSM-MCHAS), Hospital Hill Road, P.O Box 608, Mbeya, Tanzania
[f] Vijiji Tanzania, Block T, Mbeya, Tanzania
[g] Ramon y Cajal Biomedical Research Institute (IRYCIS), Madrid, Spain
[h] CIBER Epidemiology and Public Health (CIBERESP), Madrid, Spain
[i] Institute of Life Course and Medical Sciences, University of Liverpool, United Kingdom

ARTICLE INFO

Keywords:
Caesarean section
Maternal death
Maternal morbidity
Perinatal death
Global maternal health
Low-income country
LMIC, Caesarean section interventions

ABSTRACT

Objective: To explore the variation and quality of the outcomes reported using descriptive analysis and interactive network visualisation of CS outcomes of comparative studies conducted in low-and middle-income settings.
Study Design: Systematic review of comparative studies to reduce caesarean section complications in low- and middle-income countries and outcome assessment using the modified Harman questionnaire, assessing for the presence of a clear primary outcome, an explanation of how the outcomes were analysed and a description of the methods used to enhance the quality of these measures.
Results: 102 comparative studies were included. Studies of interventions to improve maternal and perinatal outcomes after caesarean section reported 466 outcomes with 15 % of these outcomes appearing only once across the outcomes reviewed (n = 73). The most common outcome categories reported were maternal death, disability and bleeding. Psychological and injury outcomes were less commonly reported. The overall quality of outcome reporting varied between studies but was particularly low for reporting on methods to improve outcome measures. Very few outcomes scored a maximum of three points when assessed according to the modified Harman score, with only 15 of the primary outcomes (16 %) achieving 3 points and 40 of the secondary outcomes (11 %) achieving 3 points. The median quality of reporting was 2 (range 0, 3) for all outcomes, for a maximum score of 3. Quality of outcome reporting was associated with the type of outcome (primary or secondary), the region in which the study was conducted in, and journal characteristics such as impact factor and journal type.
Conclusions: There was wide variability in both the outcomes reported and the frequency in which they were reported. Overall, very few primary and secondary outcomes achieved the maximum score of three on the modified Harman score, highlighting the need for a core outcome set for caesarean section intervention trials to improve the consistency and synergy of future research outcome definition, measurement and synthesis.
Trial registration: The protocol was registered (PROSPERO CRD42022353939)

* Corresponding author.
E-mail address: amie.wilson@lstmed.ac.uk (A. Wilson).

https://doi.org/10.1016/j.ejogrb.2025.01.039
Received 24 October 2024; Received in revised form 22 January 2025; Accepted 23 January 2025
Available online 25 January 2025

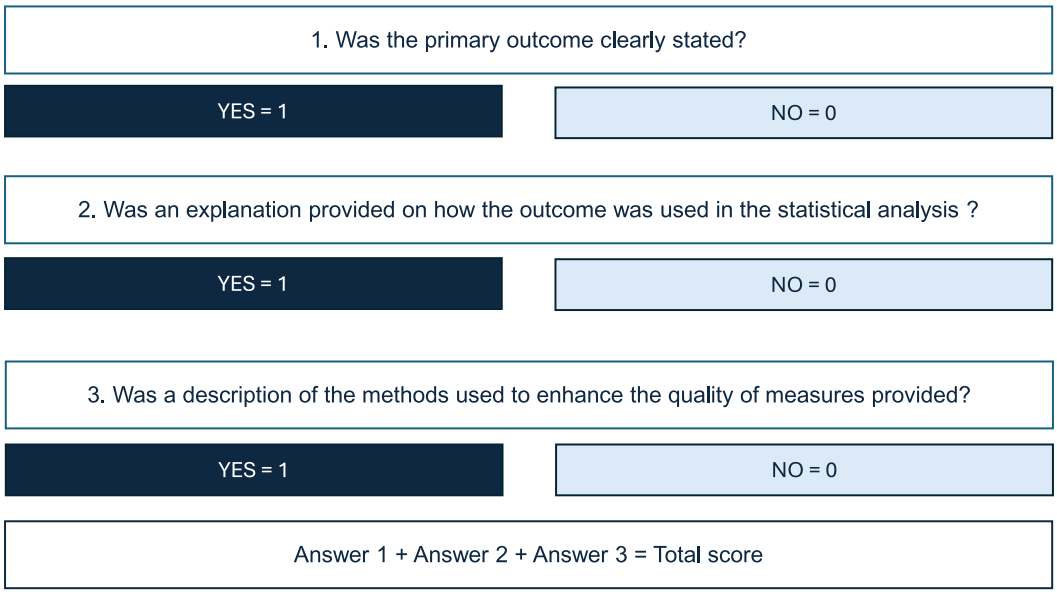

Fig. 1. Modified Harman questionnaire.

Introduction

Background

There are growing concerns about the rise in caesarean section (CS) rates globally, with almost one in five (21 %) births being a caesarean birth. [1] CS can be a lifesaving operation when performed at right time and for the right indication, but the procedure is not without risk.[2–7] The risk of maternal death and disability following caesarean section is disproportionately higher in low- and middle-income countries (LMIC), due to more limited access to timely, good quality comprehensive obstetric care [2].

A wide range of surgical and medical interventions have been studied to reduce risks associated with caesarean section and improve maternal and perinatal outcomes such as skin cleansing, adhesive drapes, different types on incisions and surgical techniques and the use of different fetal extraction methods, closure materials and methods [8–11]. However, in the absence of an existing core outcome set for caesarean section, there is often wide variability in the outcomes that are reported and how these outcomes are measured in caesarean section trials around the world.

Appropriate selection of primary and secondary outcomes a priori, is an essential part of a well-designed clinical trial [12,13]. Consistency in how outcomes are defined, measured, and reported can facilitate appropriate comparison across studies, such as in meta-analysis [14]. Selective reporting of trial outcomes can increase bias within the results [13 15] and seriously impair the ability to synthesise such evidence and inform clinical practice [16].

We conducted a systematic review of comparative studies in LMICs focussing on caesarean section related mortality and morbidity, and interventions to reduce these outcomes in low- and middle-income countries. We explored the variation of outcomes that were reported across studies conducted in low- and middle-income countries and the quality of the primary and secondary outcomes that were reported.

Methods

Protocol registration

Our study followed the steps recommended in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist. The protocol was published in PROSPERO in August 2022 (CRD42022353939).

Search strategy

EMBASE, MEDLINE, Scopus and Web of Science, and the WHO library, were searched without language restriction from October 1990 to February 2024 for studies set in healthcare settings in low and middle-income countries that focused on maternal mortality and morbidity and examined interventions to reduce these outcomes following caesarean section. Low and middle-income countries were defined according to world bank regions. We used the key words combinations/ MeSH heading as: caesarean section, low-and middle-income country, LMIC, maternal, pregnancy, anaesthesia, caesarean interventions (supplementary file 1).

Selection Criteria

We included comparative studies of clinical interventions set in low- and middle-income countries, delivered to reduce maternal mortality and morbidity following caesarean section. Case series and non-comparative studies were excluded. Studies set-in high-income countries were excluded.

The study selection was performed in a two-stage process using Covidence [17]. Titles and abstracts of studies were screened by at least two independent reviewers (AAH, HK, BM). In the second stage, full texts of those deemed suitable for inclusion were assessed independently for eligibility by at least two reviewers (AAH, HK, BM), any disagreements were resolved by discussion with a third reviewer (AW).

Data extraction

A standardised, pre-piloted form was used to extract data from the included studies for assessment of study quality and evidence synthesis. Extracted information included: study design, study setting, study population/maternal characteristics and demographics, caesarean section rate, number of caesarean section deaths and reasons, details of the interventions, type of journal, impact factor and the outcomes reported. The journals were classified as general or specialist, and as obstetrics-focused or other. Where possible, we tried to retrieve the journal impact factor in the publication year. The outcomes reported were grouped into either maternal, perinatal or resource categories; they were then further grouped by outcome type such as infection, wound

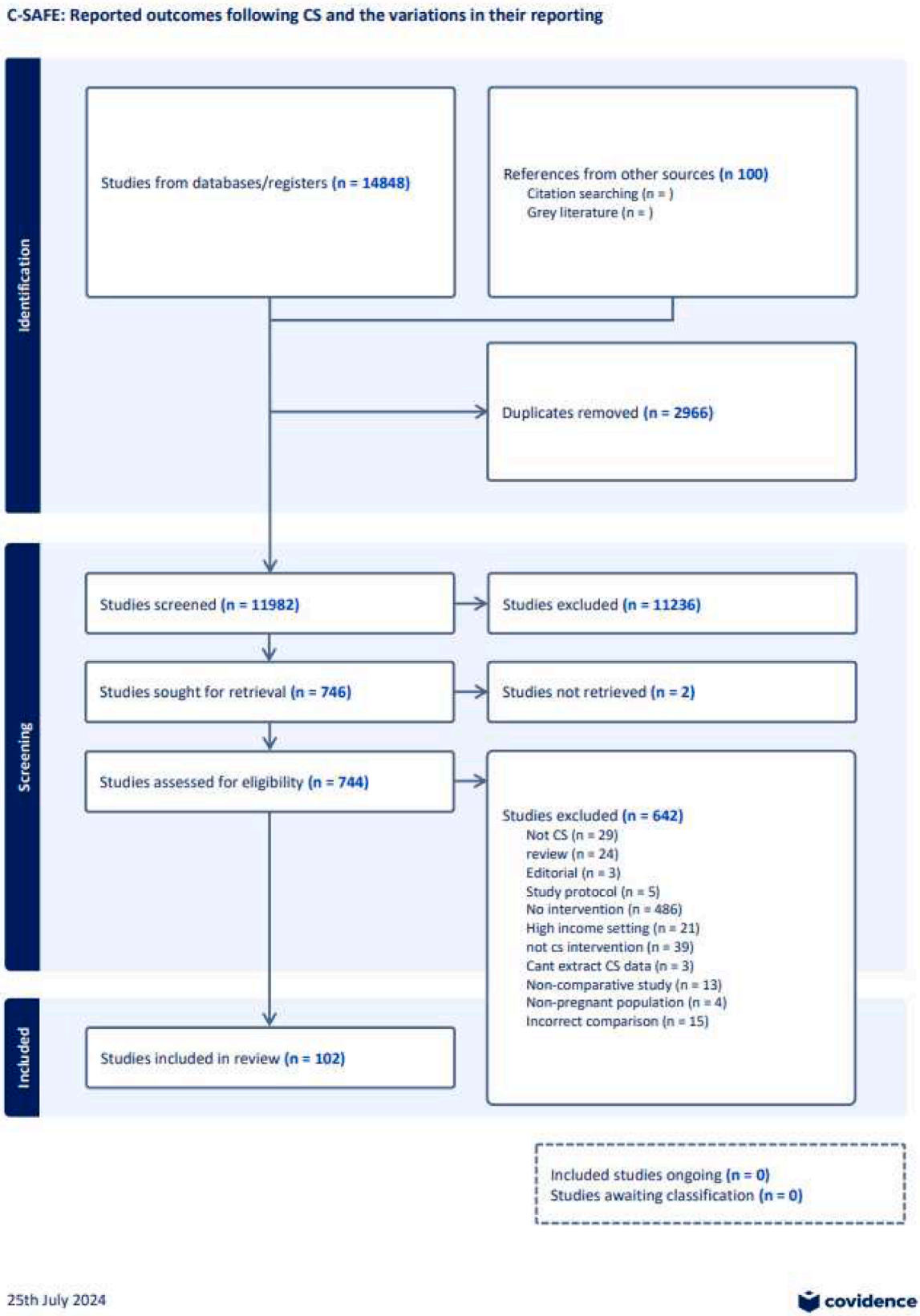
C-SAFE: Reported outcomes following CS and the variations in their reporting
Identification
Studies from databases/registers (n = 14848)
References from other sources (n 100)
Citation searching (n =)
Grey literature (n =)
Duplicates removed (n = 2966)
Screening
Studies screened (n = 11982)
Studies excluded (n = 11236)
Studies sought for retrieval (n = 746)
Studies not retrieved (n = 2)
Studies assessed for eligibility (n = 744)
Studies excluded (n = 642)
Not CS (n = 29)
review (n = 24)
Editorial (n = 3)
Study protocol (n = 5)
No intervention (n = 486)
High income setting (n = 21)
not cs intervention (n = 39)
Cant extract CS data (n = 3)
Non-comparative study (n = 13)
Non-pregnant population (n = 4)
Incorrect comparison (n = 15)
Included
Studies included in review (n = 102)
Included studies ongoing (n = 0)
Studies awaiting classification (n = 0)
25th July 2024
covidence

Fig. 2. PRISMA.

Table 1
Table of study characteristics.

Author, Year	Intervention type	Delivery	Country	Region	Income group	Journal type	Impact factor
Kanwal 2020	Clinical	During Birth	Pakistan	South Asia.	Lower-middle	General	0
Okucu 2021	Clinical	During Birth	Turkey	Europe & Central Asia	Upper-middle	specialist Other	1.052
Arif 2020	Nutrition, Other	Before Hospital Discharge	Pakistan	South Asia.	Lower-middle	General	0
Suliman 2020	Health system	Health system	Sudan	Africa	Low	General	0.6
Thakur 2019	Lifestyle, Other	Before Hospital Discharge	India	South Asia.	Lower-middle	General	0
AlZubaidi 2022	Drug	Before Hospital Discharge	Iraq	Middle East & North Africa	Upper-middle	Specialist Obs	2.48
Fahmy 2021	Drug	During Birth	Egypt	Middle East & North Africa	Lower-middle	specialist Other	0
Khatoon 2021	Health system	Health system	India	South Asia.	Lower-middle	General	0.3
Kansouh 2019	Drug	Before Hospital Discharge	Egypt	Middle East & North Africa	Lower-middle	General	0
Onu 2021	Clinical	After Hospital Discharge	Nigeria	Africa	Lower-middle	General	3.246
Cecilia 2018	Drug	Before Hospital Discharge	India	South Asia.	Lower-middle	specialist Other	2.833
MacDonald 2021	Health system	Health system	Haiti	Latin America & Caribbean	Lower-middle	Specialist Obs	0.96
Yousefi 2019	Lifestyle, Other	Before Hospital Discharge	Iran	Middle East & North Africa	Lower-middle	Specialist Obs	1.298
Iqbal 2022	Drug	During Birth	Pakistan	South Asia.	Lower-middle	General	2.26
Nautiyal 2020	Clinical	During Birth	India	South Asia.	Lower-middle	General	0.1
Ahmed 2018	Lifestyle, Other	Before Hospital Discharge	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	1.361
Kintu 2019	Drug	Before Hospital Discharge	Uganda	Africa	Low	General	1.987
Kabir 2019	Drug	During Birth	Bangladesh	South Asia.	Lower-middle	General	0
Sengupta 2019	Surgery	During Birth	India	South Asia.	Lower-middle	General	0.1
Onwudiwe 2021	Surgery	During Birth	Nigeria	Africa	Lower-middle	General	0
Nooh 2018	Neonatal	During pregnancy	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	1.493
Gupta 2022	Clinical	Health system	India	South Asia.	Lower-middle	Specialist Obs	0
Abbas 2022	Drug	During Birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Other	2.217
Sweed 2018	Drug	During Birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	2.11
Sammour 2019	Nutrition, Other	Before Hospital Discharge	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	2.1
Ogah 2021	Infection	During Birth	Nigeria	Africa	Lower-middle	Specialist Obs	4.544
Bansal 2018	Drug	Before Hospital Discharge	India	South Asia.	Lower-middle	Specialist Obs	0
Walker 2020	Health system	Health system	Kenya	Africa	Lower-middle	Specialist Other	27.427
Tahir 2020	Surgery	During birth	Pakistan	South Asia.	Lower-middle	General	0.48
Sadiq 2019	Neonatal	During pregnancy	Pakistan	South Asia.	Lower-middle	General	0
Yilmaz 2019	Education, Other	During pregnancy	Turkey	Europe & Central Asia	Upper-middle	Specialist Obs	0
Ozovali 2022	Education, Other	Before Hospital Discharge	Turkey	Europe & Central Asia	Upper-middle	General	0
Bahadur 2019	Drug	Before Hospital Discharge	India	South Asia.	Lower-middle	Specialist Obs	0.79
Nyamtema 2021	Health system	Health system	Tanzania	Africa	Lower-middle	Specialist Other	1.211
Boriboonhirunsarn 2022	Health system	Health system	Thailand	East Asia & Pacific	Upper-middle	Specialist Obs	1.226
Jyothi 2019	Infection	During Birth	India	South Asia.	Lower-middle	General	0.51
Ali 2020	Surgery	During Birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Other	1.108
Sudjai 2022	Drug	Before Hospital Discharge	Thailand	East Asia & Pacific	Upper-middle	General	0.15
Kabore 2019	Health system	Health system	Burkina Faso	Africa	Low	Specialist Other	8.775
Metogo 2021	Surgery	During birth	Cameron	Africa	Lower-middle	Specialist Other	2.217
Berna Aslan 2019	Clinical	During birth	Turkey	Europe & Central Asia	Upper-middle	Specialist Obs	1.674

(*continued on next page*)

Table 1 (*continued*)

Author, Year	Intervention type	Delivery	Country	Region	Income group	Journal type	Impact factor
Puchakala 2022	Surgery, Clinical, Drug	During birth	India	South Asia.	Lower-middle	Specialist Other	
Wei 2020	Clinical	During birth	China	East Asia & Pacific	Upper-middle	General	1.889
Kwikiriza 2019	Surgery, Drug	Before Hospital Discharge	Uganda	Africa	Low	Specialist Other	6.955
ShiqinXu 2019	Surgery, Drug	During birth	China	East Asia & Pacific	Upper-middle	General	1.1
Elkhouly 2021	Surgery,	During birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	2.729
Mohta 2018	Drug	During birth	India	South Asia.	Lower-middle	Specialist Other	6.955
Ibrahim 2020	Drug	During birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	1.192
Mangala 2021	Drug	During birth	India	South Asia.	Lower-middle	Specialist Obs	0.552
Ahmadi 2018	Drug	During birth	Iran	Middle East & North Africa	Lower-middle	Specialist Other	
Ralhan 2022	Clinical	During birth	India	South Asia.	Lower-middle	General	0.261
Nur Şahin 2018	Surgery,	During birth	Turkey	Europe & Central Asia	Upper-middle	Specialist Other	1.727
Buthelezi 2020	Clinical	During birth	South Africa	Africa	Lower-middle	Specialist Other	12.893
Faiza 2021	Surgery,	During birth	Pakistan	South Asia.	Lower-middle	General	2.26
Sanad 2020	Drug	During birth	Egypt	Middle East & North Africa	Lower-middle	General	0
Kanza Gul 2021	Lifestyle, Other	Before Hospital Discharge	Turkey	Europe & Central Asia	Upper-middle	Specialist Obs	1.25
Weerasinghe 2022	Lifestyle, Other	During pregnancy	Sri Lanka	South Asia.	Lower-middle	Specialist Other	0
Li 2022	Drug	Before Hospital Discharge	China	East Asia & Pacific	Upper-middle	Specialist Other	1.143
Bakker 2020	Health system	Health system	Malawi	Africa	Low	General	2.96
Arora 2021	Drug	Before Hospital Discharge	India	South Asia.	Lower-middle	General	0
Shi 2019	Clinical	Before Hospital Discharge	China	East Asia & Pacific	Upper-middle	Specialist Other	1.785
Sallam 2019	Surgery,	During birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Other	2.323
Prajith 2020	Clinical,	During birth	India	South Asia.	Lower-middle	Specialist Other	0.869
Onur 2021	Clinical,	During birth	Turkey	Europe & Central Asia	Lower-middle	General	0.11
Mohamed 2022	Neonatal	During pregnancy	Egypt	Middle East & North Africa	Lower-middle	General	0
Sweed 2019	Drug	During birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	0.64
Hosni 2021	Drug	During birth	Egypt	Middle East & North Africa	Lower-middle	General	0
deHolandaAraujo 2020	Drug	Before Hospital Discharge	Brazil	Latin America & Caribbean	Upper-middle	Specialist Other	3.161
Bagga 2022	Infection	During pregnancy	India	South Asia.	Lower-middle	General	0
Yan 2021	Drug	Before Hospital Discharge	China	East Asia & Pacific	Upper-middle	General	4.22
Ogah 2022	Drug	During birth	Nigeria	Africa	Lower-middle	General	0.948
Kamel 2018	Clinical	During birth	Egypt	Middle East & North Africa	Lower-middle	Specialist Obs	1.569
DiketeEkanga 2022	Health system	Health system	Democratic Republic of Congo	Africa	Low	General	3.24
Singh 2020	Surgery,	During birth	India	South Asia.	Lower-middle	Specialist Obs	0
Sunda 2020	Drug	During birth	India	South Asia.	Lower-middle	Specialist Obs	0
Ghaffari 2018	Surgery,	During birth	Iran	Middle East & North Africa	Lower-middle	General	0
Elbohoty 2020	Neonatal	During pregnancy	Egypt	Middle East & North Africa	Lower-middle	General	0
Gentilotti 2020	Health system	Health system	Tanzania	Africa	Lower-middle	Specialist Other	4.887
Lumbiganon 2020	Surgery,	During birth	LMICs	Various LMICs across Africa, South Asia	Lower-middle and Low	Specialist Other	4.38
Wurdeman 2022	Health system	Health system	Tanzania	Africa	Lower-middle	Specialist Other	3.282
Esthiet 2003	Surgery,	During labour	Mali	Africa	Low	General	
Diawara 2014	Health system	During labour	Nigeria	Africa	Lower-middle	General	0.169
Rukewe 2014	Surgery	During labour	Nigeria	Africa	Low	Specialist Obs	2.27

(*continued on next page*)

Table 1 (*continued*)

Author, Year	Intervention type	Delivery	Country	Region	Income group	Journal type	Impact factor
Zongo 2015	Clinical, Drug, Neonatal	After hospital discharge	Taiwan	East Asia & Pacific	Upper-middle	Specialist Obs	8.661
Chang 2011	Surgery	During labour	Mozambique	Africa	Low	Specialist Obs	4.663
Pereira 1996	Surgery,	During birth	Tanzania	Africa	Lower-middle	Specialist Obs	2.938
Nelissen 2013	Health system	Health system	Nigeria	Africa	Lower-middle	Specialist Obs	8.661
Gori 2007	Surgery	During labour	Burkina Faso	Africa	Lower-middle	Specialist Obs	4.447
Riachard 2008	Health system, Clinical, Drug,	During labour	Malawi	Africa	Low	General	3.192
Chilopora 2007	Health system,	During labour	Chad	Africa	Low	General	0
Madoue 2015	Health system,	During labour	Burkina Faso	Africa	Low	General	3.192
Hounton 2009	Health system,	During labour	Indonesia, Malaysia, The Philippines and Thailand	East Asia & Pacific	Lower-middle	Specialist Obs	2.938
Nwafor 2014	Surgery, Clinical,	During labour	Nigeria	Africa	Lower-middle	General	0.294
Fyaneface-Organ 2008	Surgery, Clinical,	During birth	Nigeria	Africa	Lower-middle	General	0.25
Adisso 2006	Surgery, Clinical,	During birth	Benin	Africa	Low	General	0
Sørbye 2007	Health system,	During birth	Tanzania	Africa	Low	Specialist Obs	3.105
Briand 2012	Health system,	During labour	Mali and Senegal	Africa	Low	Specialist Obs	3.752
Festin 2008	Infection, Clinical	During labour	Indonesia, Malaysia, The Philippines and Thailand	South Asia.	Lower-middle	Specialist Obs	3.85
Ali 2017	Surgery, Clinical,	During labour	Pakistani	East Asia & Pacific	Lower-middle	Specialist Other	
Asefa A2020	Health system,	During labour	Ethiopia	Africa	Low	Specialist Other	0.287
Meng 2019	Health system,	Health system,	China	East Asia & Pacific	Upper-middle	Specialist Other	4.545
Al Husban 2021	Clinical	Before Hospital Discharge	Jordan	Middle East & North Africa	Upper-middle	General	0

complications, perinatal morbidity, guided by the CS core outcome sets on infectious morbidity [18] and systematic review on pregnancy and childbirth core outcome sets [19].

Data were extracted by two reviewers independently (HK, AAH, BM). Any differences were clarified through discussion with a third reviewer.

Outcome assessment

Study outcome assessment was undertaken by two reviewers. The quality of describing and reporting outcomes were evaluated using the modified Harman-questionnaire [20,21]. The points were assigned as indicated out of a total score of three; Fig. 1: primary outcome clearly stated (one point), an explanation of the use of the outcome in the statistical analysis (one point) and a description of methods to enhance quality of measures (one point). We had defined the quality of outcome reporting score as the proportion of points out of three, as all studies were assessed for each criterion. Studies were grouped by outcome score, with scores of 0 or 1 classed as low quality, and scores of 2 or 3 classed as high quality. If a study did not clearly state which outcomes were primary and which were secondary, they were assessed as secondary outcomes.

Data analysis

We analysed the data using descriptive statistics to summarise the frequency of the outcomes reported in the studies and their associated quality by primary and secondary outcomes.

We developed an interactive network visualisation of outcomes using the R programming language (version 4.3.1). Specifically, we harnessed the capabilities of the visNetwork package (version 2.1.2), which relies on the JavaScript library vis.js (version 4.21.0). This powerful combination is well-suited for handling extensive datasets, enabling dynamic data manipulation and interaction [22].

Table 2
Differences in the total quality score by variables of interest.

	Outcomes / studies	Median (p25-p75)	P-value *
Type of outcome			
Primary	92 / 72	2 (1–2)	<0.001
Secondary	368 / 82	1 (1–2)	
Region			
Africa	122 / 32	2 (1–3)	<0.001
East Asia & Pacific	72 / 11	2 (1–2)	
Europe & Central Asia	31 / 8	1 (1–2)	
Latin America & Caribbean	7 / 2	2 (2–2)	
Middle East & North Africa	93 / 21	2 (1–2)	
South Asia	133 / 27	1 (0–2)	
Income			
Low	61 / 16	2 (1–3)	0.014
Lower-middle	290 / 66	1 (1–2)	
High / Upper-middle	107 / 19	2 (1–2)	
Journal type			
General	225 / 43	1 (0–2)	<0.001
Specialist Obs	138 / 32	2 (1–2)	
Specialist Other	103 / 27	1 (1–2)	
Impact factor	459 /98	2 (1–2)	<0.001 (rho = 0.296)

* The association between categorical and continuous variables was analysed using the U-Mann Whitney test or the Kruskal-Wallis test according to the number of categories. The association between two continuous variables was measured with Spearman's correlation, the value of Spearman's rho is also given in this case.

Our approach involved defining data frames using the dplyr package (version 1.1.3) and the tidyverse package (version 2.0.0) [23]. We created these data frames to represent unique identifiers (ID) as network

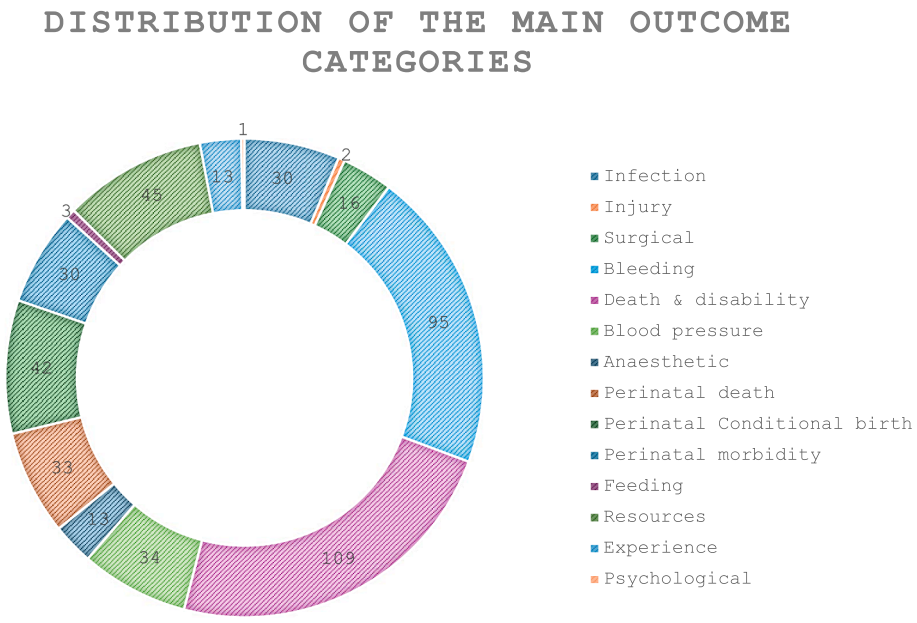

Fig. 3. Distribution of the main categories of the outcomes.

nodes, while a separate data frame was used to define the interactions between these nodes. The network's structure was carefully crafted to incorporate various dimensions, including trial outcomes, study author and publication year, the intervention being studied, world geographical region, and the income level of the country. The result is an interactive representation where the outermost nodes of the network correspond to the outcomes of the trials, facilitating the extraction of insights guided by the stratification factors.

Results

From 14,948 potential citations identified, 102 comparative studies were included (Fig. 2); Table 1 provides details of these included studies. Ninety percent of the studies were published after the 2010 CONSORT update (n = 92). Half of studies were randomised controlled trials (n = 51/102), four were quasi-randomised controlled trials, five were cross-sectional studies and 42 were cohort studies; of which 18 were retrospective and 24 were prospective, with a total of 608,437 birthing people. Over half of the studies were conducted in low-middle income countries (n = 66), with the majority set in Africa (n = 32); this is demonstrated in the first column of Table 2. Most studies included were published by authors in low-income countries (n = 90) and were published in general medical journals (n = 43) such as the British medical journal rather than specialist obstetrics and gynaecology journals (n = 32) such as the European journal of obstetrics & gynecology and reproductive biology, or other specialist journal (n = 27) such as the Journal of anesthesia. The median impact factor of this cohort of studies was 2 (IQR 1, 2).

All studies examined the effect of interventions to improve maternal and perinatal outcomes after caesarean section, but there was a wide range of interventions being examined across the studies. The most common type of intervention included in these studies were uterotonic drugs (n = 19 studies) and anaesthetic techniques (n = 14 studies), and the most common time of administration (time that the intervention was delivered) was during birth (n = 45 studies), after birth and before hospital discharge (n = 21 studies).

Variation in outcome reporting

Studies of interventions to improve maternal and perinatal outcomes after caesarean section reported over 400 outcomes (n = 466). Seventy-two studies reported 92 primary outcomes, and 82 studies reported 368 secondary outcomes. Fifteen percent (n = 72) of the outcomes reported appeared only once across the 466 outcomes reviewed.

There was wide variability in both the outcome and the frequency of which it was reported. The most common outcome category reported was maternal death and disability (n = 109, 23 %). However, this category was heterogeneous with 21 different outcomes. Bleeding was a commonly reported outcome category, containing 20 % of all outcomes (n = 95). Compared to maternal death and disability, this outcome category was less heterogeneous, with eleven different outcomes. Outcome categories less commonly reported were psychological (n = 1;), injury (n = 2) and neonatal feeding (n = 3). Fig. 3 describes the distribution of the main categories of the outcomes.

Quality of outcome reporting

A total of 466 outcomes were assessed for quality from 102 different studies. Only 51 % (n = 236) of the included outcomes clearly defined which outcome was the primary outcome among all other outcomes reported. Only half of the total outcomes (n = 238: 51 %) were assessed as reproducible by the clear definition of the measurement provided, 64 % (n = 298) of the total outcomes reported were mentioned in the statistical analysis and described how the outcome would be analysed, but less than a quarter of outcomes (n = 111; 24 %) reported a description of methods to enhance the quality of measures (such as averaging repeated measures or using validation procedures). Only 20 % (n = 97/466) of all outcomes reported the outcomes in a published study protocol, many did not publish a study protocol.

Primary and secondary outcomes

Overall primary outcomes received a higher score (median 2, IQR 1,2), than secondary outcomes (median 1, IQR 1,2) when assessed using the adapted Harman scale; this is demonstrated in Table 2. Almost double the number of primary outcomes were assessed as reproducible (n = 74;80 %) when compared to secondary outcomes (n = 164; 44 %). Seventy three percent (n = 67) of the primary outcomes reported were mentioned in the statistical analysis (how the outcome would be analysed), compared to 62 % (n = 231) of secondary outcomes. Even fewer primary and secondary outcomes reported a description of methods to enhance the quality of measures (such as averaging repeated measures

Table 3
Differences in the total quality score (grouped) by variables of interest.

	Type of outcome Low quality (N = 225)	High quality (N = 241)	P-value*
Type of outcome			
Primary	29 (12.9 %)	63 (26.8 %)	<0.001
Secondary	196 (87.1 %)	172 (73.2 %)	
Region			
Africa	48 (21.3 %)	74 (31.8 %)	<0.001
East Asia & Pacific	23 (10.2 %)	49 (21.0 %)	
Europe & Central Asia	23 (10.2 %)	8 (3.4 %)	
Latin America & Caribbean	0 (0.0 %)	7 (3.0 %)	
Middle East & North Africa	39 (17.3 %)	54 (23.2 %)	
South Asia	92 (40.9 %)	41 (17.6 %)	
Income			
Low	30 (13.3 %)	31 (13.3 %)	0.33
Lower-middle	149 (66.2 %)	141 (60.5 %)	
High / Upper-middle	46 (20.4 %)	61 (26.2 %)	
Journal type			
General	127 (56.4 %)	98 (40.7 %)	<0.001
Specialist Obs	46 (20.4 %)	92 (38.2 %)	
Specialist Other	52 (23.1 %)	51 (21.2 %)	
Impact factor	**N = 221**	**N = 238**	
	0.95 (0.10–2.32)	1.78 (0.29–3.10)	<0.001

*The association between categorical variables was analysed using the Chi-square test. The association between categorical and continuous variables was analysed using the U-Mann Whitney test.

or using validation procedures) (19 %; 18 primary outcomes; and 25 %; 93 secondary outcomes). Very few outcomes scored a maximum three points when assessed for quality according to the modified Harman score, with only 15 of the primary outcomes (16 %) and 40 of the secondary outcomes (11 %) achieving a maximum of 3 points. When outcomes were assessed for selective reporting bias; over 80 % of primary outcomes (n = 73) and 63 % of secondary outcomes (n = 296) reported either did not publish a study protocol or did not state within the published protocol the outcome reported in study results.

When outcomes were grouped and analysed by the pre-defined variables of region, income group and journal characteristics, there was an association with outcome score and the region in which the study was conducted, the journal type, and the impact factor ($p < 0.001$). There was no association with the income group in which the study was conducted (0.014). This is demonstrated in Table 2. When studies were grouped by quality, these associations continued to be observed; this is demonstrated in Table 3.

Discussion

Main findings

Studies of interventions to improve outcomes from caesarean section in low and low to middle income countries report a variety of different outcomes. Outcomes that were grouped into the death and disability category and the bleeding category were reported more often that other outcomes, this may be due to these complications being the most common causes of mortality and morbidity in caesarean section [2]. Outcomes that were grouped into the psychological, feeding or injury

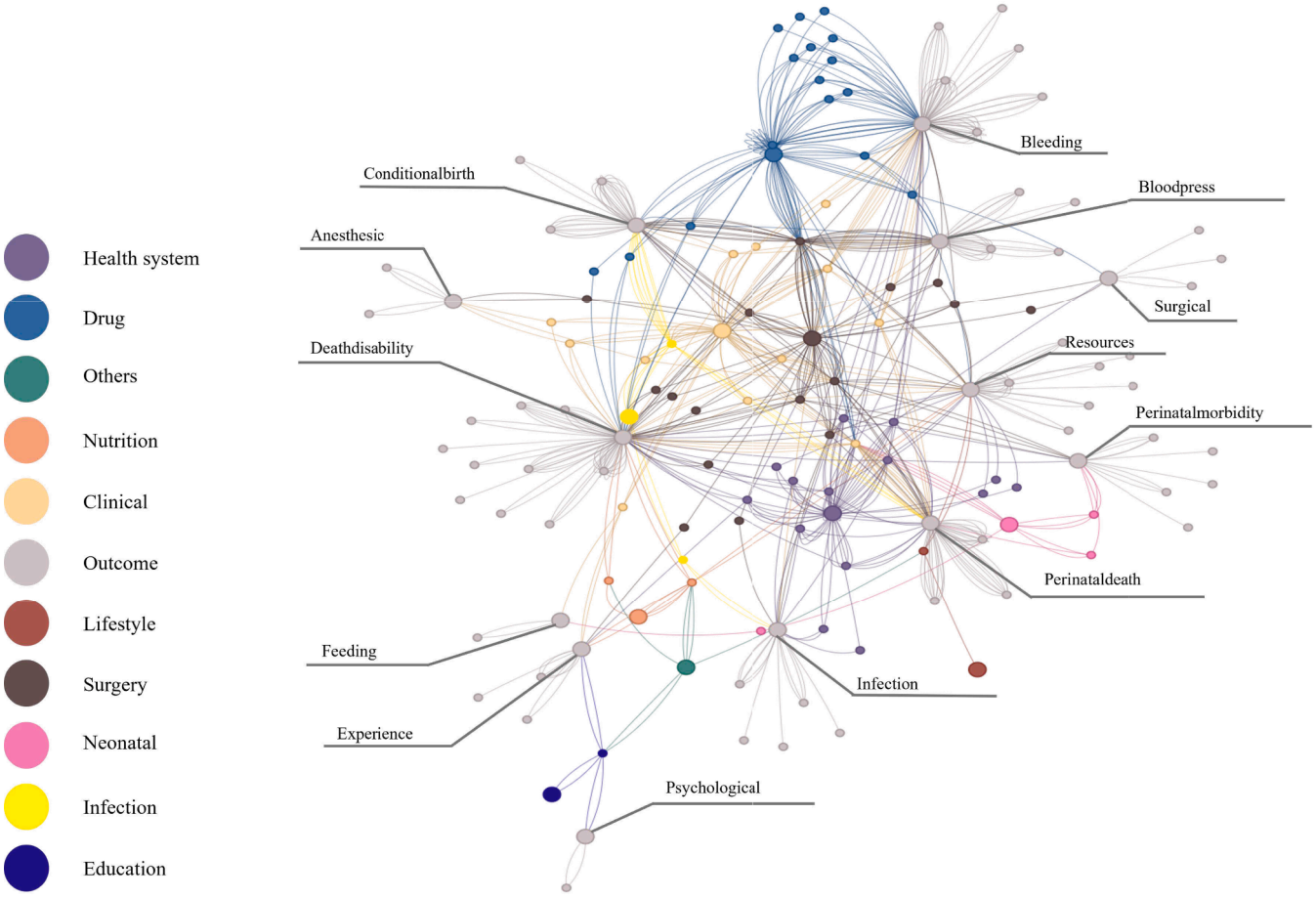

Fig. 4. Visualisation outcomes by intervention type. The node and spoke colours denote the type of study intervention or study setting.

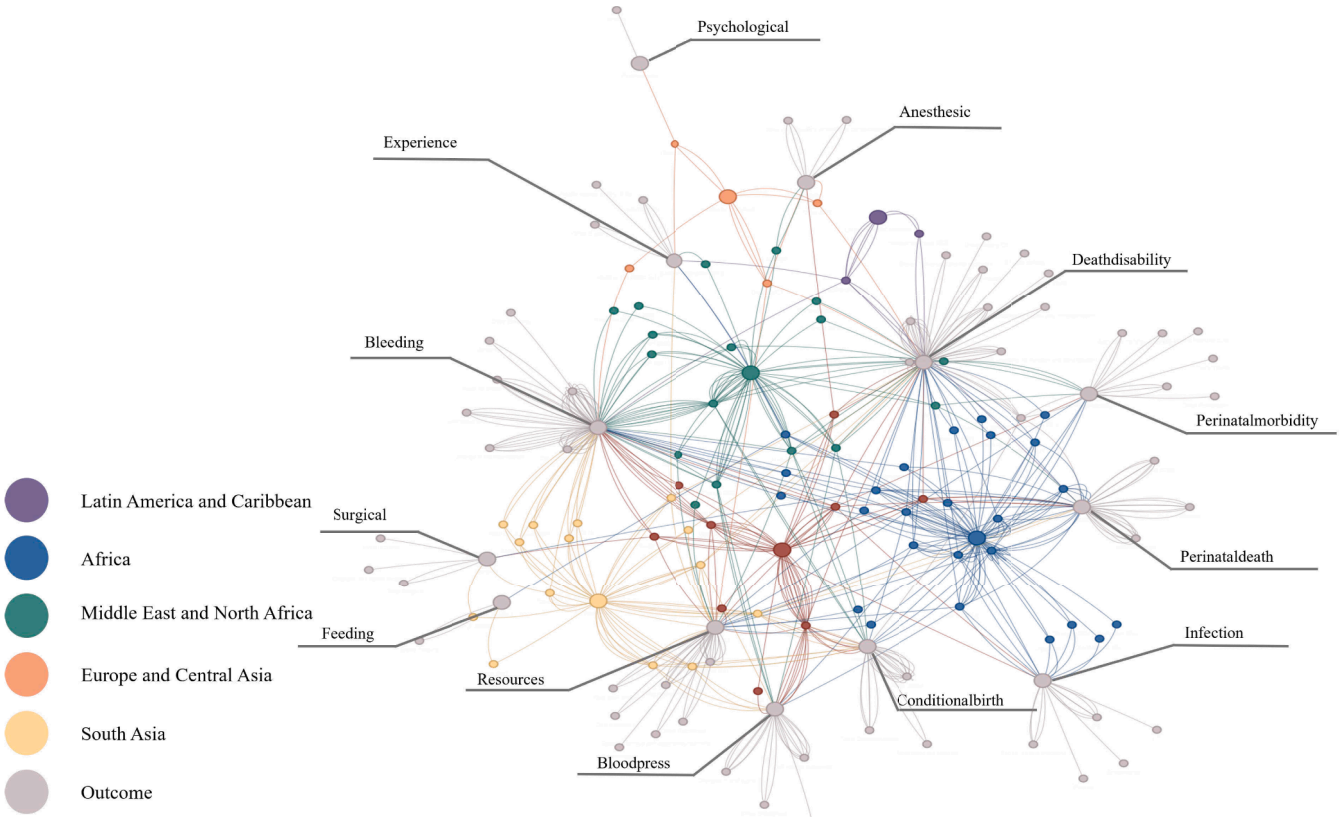

Fig. 5. Visualisation outcomes by region. The node and spoke colours denote the type of study intervention or study setting.

categories were rarely reported within these studies. The overall quality of outcome reporting varied between studies but was particularly low for reporting on methods to improve outcome measures. The quality of reported outcomes was influenced by type of outcome (if primary or secondary), region and journal-specific factors such as impact factor or journal type.

Interpretation

The included figures are an interactive network visualisation of outcomes. These figures demonstrate the grouping of outcomes with different elements of interest in our analysis: the intervention being studied, world geographical region, and the income level of the country.

When outcomes are visualised by the types of interventions (Fig. 4), we can see a concentration of studies examining pharmacological interventions (denoted by the blue nodes and spokes) reporting maternal bleeding outcomes. A less linear concentration of outcomes can be seen with surgical interventions (denoted by brown nodes and spokes), reporting maternal death and disability related outcomes, perinatal outcomes such as death and disability, condition at birth and, and resource outcomes.

When outcomes are visualised by the region of study conduct (Fig. 5), we can see a diverse spread of studies conducted in South Asia, the Middle East and North Africa, Africa, and East Asia and the Pacific (denoted by the yellow, green, blue and red nodes and spokes respectively) reporting bleeding outcomes. Similar diversity can be seen with death and disability outcomes, however, there appears to be substantially more of these outcomes visualised in studies conducted in Africa. Similarly, infection outcomes appear to be concentrated in studies conducted in Africa, with a small proportion in East Asia and the Pacific. The outcomes can be visualised via this link Core Outcome Set (shinyapps.io) (publicly available).

Strengths and limitation

Our work assesses the variation and quality of outcome reporting in studies of interventions to improve outcomes after caesarean section. We used existing literature to support the groupings of the outcomes and followed the established standards for evidence synthesis [18,19]. This systematic review was conducted with no language limits and gives a thorough overview of global research. Although we limited the studies included to those published after 1990, most studies exploring the effect of interventions to improves outcomes after caesarean section were published in the last decade.

We used an adapted version of Harman et al.'s questionnaire to assess the quality of outcome reporting, which has been used in other reviews to assess variation and quality of outcomes [1420,21].

Implications for research

Reproducibility is a fundamental principle of any scientific research. The rationale behind the CONSORT requirement for the reporting of primary and secondary outcomes is to allow other researchers to use the same outcomes [24,25]. Based on the reporting of the outcomes, it would not be possible to reproduce the primary outcome for more than 16 % of cases and secondary outcomes for more than 11 % of cases. The weakest component of outcome reporting was the infrequent availability of information about the description of methods used to enhance quality of measurement. This might not affect outcomes such as maternal or perinatal death but may reduce the reliability of outcomes where a consistent measurement is vital to determine the outcomes presence or absence, such as blood loss measurement in postpartum haemorrhage or psychological assessment using a postnatal depression scale interpretation. Issues identified in our study are not limited to caesarean section studies or obstetrics and gynaecology research. Variation in outcome reporting and the use of multiple measures are

highlighted as a hindrance to research informing clinical practice, regardless of medical specialities [13,21,26–29].

This variability in outcome reporting makes it challenging to synthesise the evidence from trials on the same topic and highlights the urgent need for the development of core outcome measures. The COMET Initiative has been promoting the development of core outcome sets since it was launched in 2010. The crown initiative [30] was also set up in response with fifty-six of the top journals in obstetrics and gynaecology leading an international effort to encourage researchers to collect and report core outcome sets in studies of key conditions in women's health. The Grade group, World Health Organization, and the Cochrane Collaboration are also committed to supporting, developing and implementing core outcome sets [13]. This work further highlights the importance of this and is the first step in developing a minimum data set to be selected, collected, and reported in all future clinical trials on interventions to reduce poor maternal and perinatal outcome following caesarean section.

Conclusion

Our systematic review has highlighted the disparity within and scarce reporting of outcomes in studies on caesarean section interventions. The quality of outcome reporting drastically needs to be improved. Development of a core outcome set to be reported in studies, with standardised measurements is vital to facilitate reliable and useful evidence synthesis.

CRediT authorship contribution statement

Amie Wilson: Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Harpreet Kaur:** Writing – review & editing, Writing – original draft, Data curation. **Ahmed Ali Hassan:** . **Bernard Mbwele:** Writing – review & editing, Data curation. **Soha Sobhy:** Funding acquisition, Conceptualization. **Gabriel Ruiz Calvo:** Writing – review & editing, Software, Methodology, Formal analysis. **Sergio Olmos Piñero:** Writing – review & editing, Visualization, Software, Formal analysis. **Javier Zamora:** Writing – review & editing, Validation, Supervision, Methodology, Funding acquisition, Conceptualization. **Shakila Thangaratinam:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding

This study was funded by the Medical Research Council, research grant MR/V035282/1. The funding body had no input in the design of the study and collection, analysis, and interpretation of data or in writing the manuscript.

Author Roles

AW and SS designed the search strategy. AW and SS conducted the searches. AW, JV, ST designed the data extraction form. HK, AAH, AW and BM extracted data and assessed quality. GRC, JZ, SOP conducted the analysis, AW wrote the manuscript. HK, ST, JZ and SS provided critical feedback on the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejogrb.2025.01.039.

References

[1] WHO, *Caesarean section rates continue to rise, amid growing inequalities in access.*, in *Caesarean section rates continue to rise, amid growing inequalities in access.*. 2021.
[2] Sobhy S, et al. *Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis*. Lancet 2019;393(10184):1973–82.
[3] Esteves-Pereira AP, et al. *Caesarean Delivery and Postpartum Maternal Mortality: A Population-Based Case Control Study in Brazil*. PLoS One 2016;11(4):e0153396.
[4] Ologunde R, et al. *Assessment of cesarean delivery availability in 26 low- and middle-income countries: a cross-sectional study*. Am J Obstet Gynecol 2014;211(5):504 e1–504 e12.
[5] Keag OE, Norman JE, Stock SJ. *Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis*. PLoS Med 2018;15(1):e1002494.
[6] Villar J, et al. *Maternal and neonatal individual risks and benefits associated with caesarean delivery: multicentre prospective study*. BMJ 2007;335(7628):1025.
[7] Kietpeerakool C, et al. *Pregnancy outcomes of women with previous caesarean sections: Secondary analysis of World Health Organization Multicountry Survey on Maternal and Newborn Health*. Sci Rep 2019;9(1):9748.
[8] Albarqouni L, et al. *Low-Value Surgical Procedures in Low- and Middle-Income Countries: A Systematic Scoping Review*. JAMA Netw Open 2023;6(11):e2342215.
[9] Gialdini C, et al. *Evidence-based surgical procedures to optimize caesarean outcomes: an overview of systematic reviews*. EClinicalMedicine 2024;72:102632.
[10] Dahlke JD, et al. *Evidence-based surgery for cesarean delivery: an updated systematic review*. Am J Obstet Gynecol 2013;209(4):294–306.
[11] Hadiati DR, et al. *Skin preparation for preventing infection following caesarean section*. Cochrane Database Syst Rev 2020;6(6).
[12] Iwashyna TJ, McPeake J. *Choosing outcomes for clinical trials: a pragmatic perspective*. Curr Opin Crit Care 2018;24(5):428–33.
[13] Williamson PR, et al. *Developing core outcome sets for clinical trials: issues to consider*. Trials 2012;13:132.
[14] Rogozinska E, et al. *Methods used to assess outcome consistency in clinical studies: A literature-based evaluation*. PLoS One 2020;15(7):e0235485.
[15] Webbe J, Sinha I, Gale C. *Core Outcome Sets*. Arch Dis Child Educ Pract Ed 2018;103(3):163–6.
[16] Chan AW, Altman DG. *Identifying outcome reporting bias in randomised trials on PubMed: review of publications and survey of authors*. BMJ 2005;330(7494):753.
[17] Covidence. *Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia.*. 2022; Available from: www.covidence.org.
[18] Briscoe KE, Haas DM. *Developing a Core Outcome Set for Cesarean Delivery Maternal Infectious Morbidity Outcomes*. Am J Perinatol 2020;37(4):436–52.
[19] Osterberg M, et al. *Core Outcome Sets (COS) related to pregnancy and childbirth: a systematic review*. BMC Pregnancy Childbirth 2021;21(1):691.
[20] Harman NL, et al. Trials 2013;14:70.
[21] Rogozinska E, et al. *Variations in reporting of outcomes in randomized trials on diet and physical activity in pregnancy: A systematic review*. J Obstet Gynaecol Res 2017;43(7):1101–10.
[22] Team, v., *visNetwork: Network Visualization using 'vis.js' Library* in *version 2.1.2*. 2023.
[23] Wickham H, A.M., Bryan J, Chang W, McGowan L, François R, et al, *Welcome to the Tidyverse*. J Open Source Softw, 2019. **21**(4): p. 1686.
[24] Begg C, et al. *Improving the quality of reporting of randomized controlled trials. The CONSORT statement* JAMA 1996;276(8):637–9.
[25] Moher D, et al. *The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials*. JAMA 2001;285(15):1987–91.
[26] Opondo D, et al. *Standardization of patient outcomes reporting in percutaneous nephrolithotomy*. J Endourol 2014;28(7):767–74.
[27] Kapadia MZ, et al. *A Core Outcome Set for Children With Feeding Tubes and Neurologic Impairment: A Systematic Review*. Pediatrics 2016;138(1).
[28] Marks M, et al. *Outcome measures and their measurement properties for trapeziometacarpal osteoarthritis: a systematic literature review*. J Hand Surg Eur 2013;38(8):822–38.
[29] Benstoem C, et al. *Evaluating outcomes used in cardiothoracic surgery interventional research: a systematic review of reviews to develop a core outcome set*. PLoS One 2015;10(4):e0122204.
[30] Khan, K. and C.I. Chief Editors of Journals participating in The, *The CROWN Initiative: journal editors invite researchers to develop core outcomes in women's health*. BJOG, 2016. **123 Suppl 3**: p. 103-4.