PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Incidence, contributing factors and outcomes of birth injury among newborns in Africa: a systematic review of quantitative evidence protocol
Update	1b	
Registration	2	Systematic review registration number in PROSPERO: CRD42023123637
Authors:		
Contact	3a	Abera Mersha1, 2* and Shitaye Shibiru1 1School of Nursing, College of Medicine and Health Sciences, Arba Minch University, Arba Minch, Ethiopia 2School of Nursing, Faculty of Health Sciences, Institute of Health, Jimma University, Jimma, Ethiopia
Contributions	3b	AM conceived the research question, wrote the methodology and introduction, and drafted the protocol. SS assisted with the search process, and AM and SS performed the critical revision, reviewed, and approved the final protocol for submission for publication.
Amendments	4	The authors may believe that some amendments or modifications will be needed, but the details of any amendments or discrepancies and the reasons for them will be clearly reported in the systematic review.
Support:		
Sources	5a	The authors did not declare any grant for this research from any funding agency.
Sponsor	5b	N/A
Role of sponsor or funder	5c	N/A
INTRODUCTION		
Rationale	6	A birth injury is any physical injury that a baby sustains before, during, or immediately after childbirth. Birth injuries can range in severity from mild to severe, and can affect any part of the body [1-3]. Some of the more common birth injuries include brachial plexus injury, subconjunctival hemorrhage, caput succedaneum, cephalohematoma, facial nerve palsy and fractures. Most birth injuries are minor and resolve on their own without treatment. However, some birth injuries can be serious and require ongoing medical care [4-7]. Globally, an estimated 2.5 million newborns die each year from birth trauma. This accounts for 46% of all deaths in children under the age of 5[3]. Birth trauma can occur during any stage of labor and delivery, but it is most common during the second stage, when the baby is passing through the birth canal[3, 8]. Birth injury is a significant public health problem in Africa, with a high incidence and associated mortality and morbidity. The incidence varies widely, with the highest reported rates in Ethiopia (12.3-16.9%) [9-14] and Nigeria (67.2%)[15].

		Other studies have reported lower rates, such as 5.7% in Nigeria [16] and 1.84% in Cameroon [17]. A number of factors have been identified as predictors of birth injury in Africa. Maternal and fetal factors including macrosomia [14, 15, 17-19], place of birth [20], short height of the mothers[10], parity[9, 12], educational status[9], place of residence[12], antenatal care[9], occupational status [9], sex of the neonate[10, 14], birth weight[10, 11, 13], gestational diabetic mellitus[10], and night time birth [10]. On the other hand, labor and delivery related factors were duration of labour [10, 11, 15], fetal distress [10, 12], instrumental delivery [10, 11, 13, 14, 17], cord prolapse [10], birth attended by residents [10], shoulder dystocia [11], fetal presentation and position [12-14]. Evidence on the incidence/prevalence of birth injury, contributing factors, and outcomes is essential for policymakers and program planners to integrate into the healthcare system and design appropriate interventions. Given the limited evidence on birth injury in Africa, this systematic review will be the first to fill these gaps and generate evidence to support existing practice and identify areas for improvement. A preliminary search of three electronic databases (MEDLINE, the Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis) was conducted to identify systematic reviews on the topic. The search yielded a single systematic review, which only reported a pooled prevalence and the most common neonatal birth trauma in Ethiopia [21]. This review does not assess the predictors of neonatal birth trauma and included only neonatal birth trauma that happened at health institutions without considering home delivery. However, there is no current or underway systematic review in Africa on this topic.
Objectives	7	The objective of this systematic review is to evaluate the incidence, contributing factors, and outcomes of birth injury among newborns in Africa.
METHODS		
Eligibility criteria	8	The inclusion criteria will be determined by the CoCoPop mnemonic (Condition, Context and Population) as this review will assess prevalence and incidence data. Participants/Population: The participants for this systematic review will be neonates. Condition: This systematic review will consider studies that report on the prevalence and/or incidence, contributing factors and outcomes of state condition. Context: The systematic review will include studies conducted in Africa. Types of studies: This systematic review will include observational studies (such as cohort studies and cross-sectional studies), registry and census data, and experimental studies that report on the prevalence or incidence. Studies published from January 1, 1990 to September 30, 2023 in English language will be included in this systematic review. All the available data sources such as electronic databases, conference proceedings, websites, search engines or other online sources, and contact with study authors will be used to retrieve the needed information.
Information sources	9	The information will be searched in databases including: JBI Database, Cochrane Database, MEDLINE/PubMed, CINAHL/EBSCO, EMBASE, PEDro, POPLINE, Proquest, OpenGrey (SIGLE), Google Scholar, Google, APA PsycInfo, Web of Science, Scopus and HINARI. Unpublished studies and grey literature will be searched from institutional libraries and repositories, preprint websites and personal contact with the authors.
Search strategy	10	**Table 1: Search strategy** **CoCoPop components** | **Inclusion criteria** | **Search terms (keywords/Mesh terms/index terms/Free text words)** | **Limits**

Population	Neonates	neonate* [All Fields] OR newborn* [All Fields] OR baby[All Fields] OR babies[All Fields] OR infant*[All Fields] OR newborn baby*[All Fields] OR pre-term infant*[All Fields] OR preterm bab*[All Fields] OR prematurity[All Fields] OR premature infant*[All Fields] OR premature bab*[All Fields] OR preterm neonate*[All Fields] OR low birth weight[All Fields] OR LBW[All Fields] OR extremely premature bab*[All Fields] OR extremely premature infant*[All Fields] OR postnatal bab*[All Fields] OR term infant*[All Fields] OR term bab*[All Fields]	Language: English Publication date: January 1, 1990 to September 30, 2023
Condition	Prevalence and/or incidence, contributing factors and outcomes for birth injury	prevalence[MeSH Terms] OR incidence[MeSH Terms] OR magnitude [All Fields] OR magnitudes[All Fields] OR contributing factor*[MeSH Terms] OR associated factor*[MeSH Terms] OR risk factor*[MeSH Terms] OR predictor*[All Fields] OR outcome*[MeSH Terms] OR birth injury*[All Fields] OR birth trauma*[MeSH Terms]	
Context	Studies in Africa	Africa	
Combine a single search strategy: ((((((((((((((((((((((((((((((neonate* [All Fields]) OR (newborn* [All Fields])) OR (baby[All Fields])) OR (babies[All Fields])) OR (infant*[All Fields])) OR (newborn baby*[All Fields])) OR (pre-term infant*[All Fields])) OR (preterm bab*[All Fields])) OR (prematurity[All Fields])) OR (premature infant*[All Fields])) OR (premature bab*[All Fields])) OR (preterm neonate*[All Fields])) OR (low birth weight[All Fields])) OR (LBW[All Fields])) OR (extremely premature bab*[All Fields])) OR (extremely premature infant*[All Fields])) OR (postnatal bab*[All Fields])) OR (term infant*[All Fields])) OR (term bab*[All Fields])) AND (prevalence[MeSH Terms])) OR (incidence[MeSH Terms])) OR (magnitude [All Fields])) OR (magnitudes[All Fields])) OR (contributing factor*[MeSH Terms])) OR (associated factor*[MeSH Terms])) OR (risk factor*[MeSH		

		Terms])) OR (predictor*[All Fields])) OR (outcome*[MeSH Terms])) OR (birth injury*[All Fields])) OR (birth trauma*[MeSH Terms])) AND (Africa)) AND (("1990/1/1"[Date - Publication] : "2023/9/30"[Date - Publication]))
		Number of records retrieved by the search: 67, 871
		Database used: MEDLINE (Ovid)
		Search conducted on: Date: September 25, 2023; **Time:** 05:10:58
Study records:		
Data management	11a	JBI SUMARI will be used to manage records and data throughout the review
Selection process	11b	The first step is to find and remove duplicate citations. This can be done using a reference management software like EndNote. Next, two independent reviewers (AM and SS) will look at the titles and abstracts of all the citations to find the ones that might be relevant to the review. The inclusion criteria for the review will be used to decide if the citations are relevant. The full texts of the potentially relevant sources will then be retrieved and their citation details will be imported into the JBI SUMARI software [26]. Two independent reviewers (AM and SS) will look at the full texts of the retrieved studies to decide if they meet the inclusion criteria for the review. If a study is excluded from the review, the reasons for exclusion will be recorded and reported in the systematic review. If the reviewers disagree about whether a study should be included, they will discuss it until they agree. The results of the search and the study inclusion process will be reported in full in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.
Data collection process	11c	To minimize errors during data extraction, two independent reviewers (AM and SS) will use the standardized data extraction tool for prevalence and incidence available in JBI SUMARI to extract data from the studies included in the review [22] (See Table 2 below). The data extracted will include specific details about the condition, populations, study methods, and proportions of interest to the review question and specific objectives. Any disagreements that arise between the reviewers (AM and SS) will be resolved through discussion. Authors of papers will be contacted to request missing or additional data, where required.
Data items	12	The inclusion criteria will be determined by the CoCoPop mnemonic. Participants/Population: The participants for this systematic review will be neonates. Condition: This systematic review will consider studies that report on the prevalence and/or incidence, contributing factors and outcomes of state condition. Context: The systematic review will include studies conducted in Africa.
Outcomes and prioritization	13	Incidence/prevalence of birth injury, contributing or associated factors or predictors, and outcomes
Risk of bias in individual studies	14	Eligible studies will be critically appraised by two independent reviewers (AM and SS) at the study level modify as appropriate if appraisal will occur at the outcome level for methodological quality in the review using standardized critical appraisal instruments from JBI[22]. The Joanna Briggs Institute (JBI) Critical Appraisal Instruments (CAIs) are a suite of tools for appraising the quality of evidence in different types of studies. They are designed to be rigorous and comprehensive, while also being user-friendly and practical. Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements that arise will be resolved through discussion. The results of critical appraisal will be reported in narrative form and in a table. Studies will be scored using a quality appraisal

		checklist, and only studies with a score of 50% or higher will be included in the systematic review and meta-analysis of prevalence. If the two assessors (AM and SS) disagree on a score, they will review the study together to investigate the source of the disagreement. If they are still unable to agree, the average of their scores will be used. Studies that do not meet a quality threshold will be excluded from the systematic review and meta-analysis, but they will be reported narratively and in table form.
Data synthesis	15a	Studies will be scored using a quality appraisal checklist, and only studies with a score of 50% or higher will be included in the systematic review and meta-analysis of prevalence.
	15b	Studies will be pooled in a statistical meta-analysis using JBI SUMARI, where possible. The effect size will be expressed as a proportion with a 95% confidence interval around the summary estimate. Forest plots and the I2 statistic will be used to assess heterogeneity, which is the variation in the results of the individual studies included in a meta-analysis. If there is a lot of heterogeneity, a random-effects model will be used to pool the data. This model takes into account the heterogeneity between the studies and produces a summary estimate that is more generalizable to the wider population.
	15c	Subgroup analyses will be used to explore the potential sources of heterogeneity. This involves dividing the studies into different groups based on certain characteristics, such as the study population, study design, or method of measurement. Then the results of the subgroup analyses will be compared to see if there is a difference in the effect size between the groups. A result will be considered statistically significant if the p-value is less than 0.05.
	15d	If it is not possible to combine the results of the individual studies in a meta-analysis, the findings will be presented in a narrative form, including tables and figures to help visualize the data, where appropriate.
Meta-bias(es)	16	Funnel plots and Egger's regression test will be used to assess publication bias, which is the tendency for studies with positive results to be published more often than studies with negative results.
Confidence in cumulative evidence	17	The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used to assess the quality of the evidence that has been pooled or summarized.

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**