Review protocol for review question: Is there an association between sleep position on going to sleep and still birth or having a small for gestational age baby?

Table 4: Review protocol

Field (based on PRISMA-P)	Content
Review question	Is there an association between sleep position on going to sleep and still birth or having a small for gestational age baby?
Type of review question	Prognostic factors review
Objective of the review	The aim of this review is to evaluate whether specific sleep positions are associated with still birth or having a small for gestational age baby after 24^{+0} weeks gestation.
Eligibility criteria – population	All pregnant women

Eligibility criteria – Risk factors (s)	• Maternal sleep position on going to sleep after 24^{+0} weeks gestation:
	  o Other
	  o Prone (i.e. tummy)
	  o Side
	   ▪ Left lateral
	   ▪ Right lateral
	   ▪ Variable
	  o Sitting/propped
	  o Supine (i.e. on back)
	
	Notes: The position 'other' is intended to capture any other sleep position that is not listed. SGA is defined as having a birth weight below the 10th centile. Some studies will report this as Low Birth Weight (LBW) adjusted for Gestational Age (GA) rather than as SGA. For participants in the case group, sleep position reported may be usual sleep position or sleep position on the night before stillbirth.

Eligibility criteria – Confounding factors	Analysis used by studies must adjust for confounding factors using logistic regression to conduct multivariable analysis.
Outcomes and prioritisation	**Model performance** • Discrimination o Concordance (C) statistic Note: the C statistic is also known as 'area under the receiver operating characteristics curve' (AUC).

Field (based on PRISMA-P)	Content
	Outcomes • Still birth (i.e. fetal death after 24^{+0} weeks but before delivery) • Small for gestational age (SGA) Note: SGA is defined as having a birth weight below the 10th centile. Some studies will report this as Low Birth Weight (LBW) adjusted for Gestational Age (GA) rather than as SGA.

Eligibility criteria – study design	**INCLUDE:**
	 • Systematic reviews of prognostic studies
	 • Prognostic observational studies
	   ○ Prospective cohort studies
	   ○ Retrospective cohort studies
	   ○ Nested case-control studies within a cohort of known size
	 The following types of study design will be considered only if no studies of the above types are identified:
	 • Non-nested case-control studies

Other inclusion exclusion criteria	**EXCLUDE:** POPULATION: • Multiple pregnancy • Pregnancy with congenital anomalies • Women who had stillborn or live-born babies with congenital abnormalities STUDY DESIGN: • Cross-over studies • Cross-sectional studies • Non-comparative studies • Randomised and quasi-randomised controlled trials LANGUAGE: • Non-English PUBLICATION STATUS: • Conference abstract **INCLUDE** COUNTRY: • No restriction
Proposed sensitivity/sub-group analysis, or meta-regression	If the studies are sufficiently similar to merit meta-analysis, subgroup analysis according to World Bank status of country (High-income countries; Low and middle-income countries) in which they were conducted in will be performed (see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups for classification of countries). Statistical heterogeneity will be assessed by visually examining the forest plots and by calculating the I^2 inconsistency statistic (with an I^2 value≥50% indicating serious heterogeneity, and ≥80% indicating very serious heterogeneity).

Field (based on PRISMA-P)	Content
Selection process – duplicate screening/selection/analysis	Review questions selected as high priorities for health economic analysis (and those selected as medium priorities and where health economic analysis could influence recommendations) will be subject to dual weeding and study selection; any discrepancies above 10% of the dual weeded resources will be resolved through discussion between the first and second reviewers or by reference to a third person. All data extraction will quality assured by a senior reviewer. Draft excluded studies and evidence tables will be circulated to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	NGA STAR software will be used to generate bibliographies/citations, and to conduct study sifting and data extraction. Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). For details please see Supplement 1: methods.
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits: • Date limit: none • Apply standard animal/non-English language exclusion • Limit to prognostic studies in first instance but download all results.
Identify if an update	This is a new area in the guideline.
Author contacts	Developer: National Guideline Alliance.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Quality assessment of individual studies will be performed using the following checklists: • ROBIS for systematic reviews of prognostic studies • QUIPS for prognostic studies For details please see section 6.2 of Developing NICE guidelines: the manual. The risk of bias for the evidence for each prognostic factor (i.e. sleep position) will be evaluated using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox': http://www.gradeworkinggroup.org/. For further details as to how GRADE will be adapted, see the following article: • Huguet, A., Hayden, J. A., Stinson, J., McGrath, P. J., Chambers, C. T., Tougas, M. E., & Wozney, L. (2013). Judging the quality of evidence in reviews of prognostic factor research: adapting the GRADE framework. Systematic reviews, 2(1), 71.
Criteria for quantitative synthesis (where suitable)	Meta-analyses will be conducted for this review only if the same confounders are accounted for in the analyses, the same analytical methods are adapted, and the populations assessed are suitably similar. In all other cases, the results will be reported separately.
Methods for analysis – combining studies and exploring (in)consistency	The adjusted Risk Ratio or Odds Ratio and 95% confidence intervals will be plotted in RevMan if appropriate, although the results for each relative measure will be presented separately. Good model performance regarding discrimination will be defined as a C statistic >0.75 as suggested in Debray 2017: • Debray, T. P., Damen, J. A., Snell, K. I., Ensor, J., Hooft, L., Reitsma, J. B., ... & Moons, K. G. (2017). A guide to systematic review and meta-analysis of prediction model performance. Bmj, 356, i6460.

Field (based on PRISMA-P)	Content
	If a meta-analysis is conducted, inconsistency will be assessed by visual examination of the forest plots and the I^2 statistic (with $I^2 \geq 50\%$ indicating serious heterogeneity and $I^2 \geq 80\%$ indicating very serious heterogeneity.
Meta-bias assessment – publication bias, selective reporting bias	For details please see Supplement 1: methods and section 6.2 of Developing NICE guidelines: the manual. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Kate Harding in line with section 3 of Developing NICE guidelines: the manual. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see Supplement 1: methods.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	This protocol is not registered with PROSPERO.

AUC: area under the curve, CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; LBW: Low Birth Weight; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial; RoB: risk of bias; SGA: small for gestational age