Review protocol for review question: What approach to information giving during antenatal care is effective (including timing and mode of provision)?

Table 3: Review protocol

Field (based on PRISMA-P)	Content
Review question	What approach to information giving during antenatal care is effective (including timing and mode of provision)?
Type of review question	Intervention
Objective of the review	The aim of this review is to determine what the most effective way is of providing topic-specific information, including how it should be delivered, how much of it should be given, and when it should be given.
Eligibility criteria – population	Women who have received information as part of antenatal care, and their partners or families.
Eligibility criteria – intervention(s)	Interventions should be about providing information and support about specific aspects of antenatal care such as screening or preparation for labour. Studies may examine specific aspects of providing information and support such as: • how complex the information provided is (such as inclusion of technical medical terms) • how the information is provided (such as in-person or remotely) • the format of the information (such as support group, pamphlets, electronic media, mix of formats) • specific information provision strategies • when or for how long the information is provided (such as specific trimester or time period, or antenatal appointment)
Eligibility criteria – comparator(s)	Eligible comparators include different: • complexity of information provision • formats of information • information provision strategies • information regimens

Field (based on PRISMA-P)	Content
	• mix of how information is provided • timing(s) of information provision
Outcomes and prioritisation	**Critical** • Anxiety • Increase in knowledge • Satisfaction with information or support • Severe fetal morbidity (including admission to NICU, fetal death) **Important** • Preparedness for labour, birth and parenthood • Satisfaction with maternity care • Self-efficacy
Eligibility criteria – study design	• Systematic review of randomised controlled trials (RCTs) • Randomised or quasi-randomised controlled trials (individual or cluster) Note: For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual.
Other inclusion exclusion criteria	Exclusion STUDY DESIGN: • Case-control studies • Cohort studies • Cross-over studies • Cross-sectional studies • Epidemiological reviews or reviews on associations • Non-comparative studies PUBLICATION STATUS: • Conference abstract LANGUAGE: • Non-English **Inclusion** COUNTRY: • Only studies conducted in high-income countries, as defined by the World Bank, with centrally-funded healthcare systems will be included. For a list of these countries, see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

Field (based on PRISMA-P)	Content
	Note: The use of the World Bank definitions of low-, middle- and high-income countries in this guideline is consistent with its use in the Postnatal care up to 8 weeks after birth (update) NICE guideline CG37.
Proposed sensitivity/sub-group analysis, or meta-regression	Particular attention will be given to the setting of the studies, and the sociodemographic characteristics (such as age, ethnicity) of the samples, in which they were conducted. In the presence of heterogeneity, the following subgroup analyses will be conducted: • Parity status (nulliparous, parous) Statistical heterogeneity will be assessed by visually examining the forest plots and by calculating the I2 inconsistency statistic (with an I2 value≥50% indicating serious heterogeneity, and ≥80% indicating very serious heterogeneity).
Selection process – duplicate screening/selection/analysis	Studies included in the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62), that satisfy the review protocol will be included in this review. 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 perform conduct sifting and data extraction. Pairwise meta-analyses, if possible, will be conducted using Cochrane Review Manager (RevMan5). For details please see Supplement 1: methods. 'GRADEpro' will be used to assess the quality of evidence for each outcome.
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (date, study design): • Date limit: 2000 (date restriction to studies conducted in 'internet-age'). • Apply standard animal/non-English language exclusion • Limit to RCTs and systematic reviews in first instance but download all results.

Identify if an update	This antenatal care update will replace the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) which will be taken down in due course. The following relevant recommendations in the 2008 NICE guideline on antenatal care for uncomplicated (CG62) on what, when and how antenatal information should be provided were made:
	
	1.1.1 Antenatal information
	
	1.1.1.1 Antenatal information should be given to pregnant women according to the following schedule.
	• At the first contact with a healthcare professional:
	  ○ folic acid supplementation
	  ○ food hygiene, including how to reduce the risk of a food-acquired infection
	  ○ lifestyle advice, including smoking cessation, and the implications of recreational drug use and alcohol consumption in pregnancy
	  ○ all antenatal screening, including screening for haemoglobinopathies, the anomaly scan and screening for Down's syndrome, as well as risks and benefits of the screening tests
	• At booking (ideally by 10 weeks):

Field (based on PRISMA-P)	Content
	○ how the baby develops during pregnancy ○ nutrition and diet, including vitamin D supplementation for women at risk of vitamin D deficiency, and details of the Healthy Start programme ○ exercise, including pelvic floor exercises ○ place of birth (refer to intrapartum care NICE guideline CG55) ○ pregnancy care pathway ○ breastfeeding, including workshops ○ participant-led antenatal classes ○ further discussion of all antenatal screening ○ discussion of mental health issues (refer to antenatal and postnatal mental health NICE guideline CG45) • Before or at 36 weeks: ○ breastfeeding information, including technique and good management practices that would help a woman succeed, such as detailed in the UNICEF Baby Friendly Initiative ○ preparation for labour and birth, including information about coping with pain in labour and the birth plan ○ recognition of active labour ○ care of the new baby ○ vitamin K prophylaxis ○ newborn screening tests ○ postnatal self-care ○ awareness of 'baby blues' and postnatal depression. • At 38 weeks: ○ options for management of prolonged pregnancy. This can be supported by information such as 'The pregnancy book' (Department of Health 2007) and the use of other relevant resources such as UK National Screening Committee publications and the Midwives Information and Resource Service (MIDIRS) information leaflets. [2008] 1.1.1.2 Information should be given in a form that is easy to understand and accessible to pregnant women with additional needs, such as physical, sensory or learning disabilities, and to pregnant women who do not speak or read English. [2008] 1.1.1.3 Information can also be given in other forms such as audiovisual or touch-screen technology; this should be supported by written information. [2008] 1.1.1.4 Pregnant women should be offered information based on the current available evidence together with support to enable them to make informed decisions about their care. This information should include where they will be seen and who will undertake their care. [2008] 1.1.1.5 At each antenatal appointment, healthcare professionals should offer consistent information and clear explanations, and should provide pregnant women with an opportunity to discuss issues and ask questions. [2008] 1.1.1.6 Pregnant women should be offered opportunities to attend participant-led antenatal classes, including breastfeeding workshops. [2008] 1.1.1.7 Women's decisions should be respected, even when this is contrary to the views of the healthcare professional. [2008]

Field (based on PRISMA-P)	Content
	1.1.1.8 Pregnant women should be informed about the purpose of any test before it is performed. The healthcare professional should ensure the woman has understood this information and has sufficient time to make an informed decision. The right of a woman to accept or decline a test should be made clear. [2008] 1.1.1.9 Information about antenatal screening should be provided in a setting where discussion can take place; this may be in a group setting or on a one-to-one basis. This should be done before the booking appointment. [2008] 1.1.1.10 Information about antenatal screening should include balanced and accurate information about the condition being screened for. [2008]
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 tool for systematic reviews • Cochrane RoB tool v.2 for RCTs and quasi-RCTs For details please see section 6.2 of Developing NICE guidelines: the manual. The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual.
Methods for analysis – combining studies and exploring (in)consistency	For details please see the Supplement 1: methods.
Meta-bias assessment – publication bias, selective reporting bias	For details please see the 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.

Field (based on PRISMA-P)	Content
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.

CCTR: Cochrane Controlled Trials Register; 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; NGA: National Guideline Alliance; NICE: National Institute for Health and Care Excellence; NIHR: National Institute for Health Research; RCT(s): randomised controlled trial(s); RoB: risk of bias; ROBIS: Risk Of Bias In Systematic reviews tool; ROBINS-I: Risk Of Bias In Non-randomized studies – of Interventions tool.