Appendix A – Review protocols

Review protocol for what information and support should be provided for parents and carers of babies with suspected or confirmed late-onset neonatal infection?

ID	Field	Content
0.	PROSPERO registration number	CRD42019158604
1.	Review title	Information and support for parents and carers of babies with late-onset neonatal infection
2.	Review question	What are the perceived information and support needs for parents and carers with babies with suspected or confirmed late-onset neonatal infection?
3.	Objective	To identify the information and support that should be provided for pregnant women or expectant parents with risk factors for late-onset neonatal infection and for parents and carers of babies at risk of late-onset neonatal infection, and those with suspected or confirmed late-onset neonatal infection. The review will synthesise qualitative data on information needs of parents and carers, as perceived by parents and carers themselves and by health-care professionals.
4.	Searches	The following databases will be searched:

		• Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE (including 'in process' and 'E-pub ahead of print') • Database of Abstracts of Reviews of Effect (DARE) • Psychinfo Searches will be restricted by: • English language • Human studies • Conference abstracts • No date limit will be used Other searches: None The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.

		The full search strategies for MEDLINE database will be published in the final review.
5.	Condition or domain being studied	Infection is a significant cause of mortality and morbidity in neonates. It may be late-onset which, for the purpose of this guideline is classified as infection more than 72 hours after birth, although can be considered as infection at greater than 7 days after birth. Late-onset neonatal infection can lead to life-threatening sepsis, which accounts for 10% of all neonatal deaths.
6.	Population	Inclusion: • Expectant parents, and parents and carers of babies aged under 28 days (corrected age) who may or may not be at risk of late-onset neonatal infection • Parents and carers of babies with suspected or confirmed late-onset neonatal infection • Health-care professionals with experiences of caring for babies with suspected or confirmed late-onset neonatal infection Exclusion:

		• Parents and carers of babies with suspected or confirmed non-bacterial infections. • Parents and carers of babies with suspected or confirmed syphilis. • Parents and carers of babies with localised infections. • Parents and carers of babies with suspected or confirmed bacterial infection resulting from therapeutic interventions such as surgery • Parents and carers of babies with suspected or confirmed meningitis who are not receiving care in neonatal units (covered by the NICE guideline on bacterial meningitis and meningococcal septicaemia)
7.	Intervention/Exposure/Test	• Perceived information and support needs of parents and carers of neonates with, or at risk of, neonatal infection among health practitioners and parents and carers.
8.	Comparator/Reference standard/Confounding factors	Not applicable (qualitative review question)
9.	Types of study to be included	Studies using qualitative methods: • Including, semi-structured and structured interviews, focus groups, observations

		• Qualitative data from mixed methods studies will be included. • Data from surveys will not be included Qualitative evidence syntheses of above study types
10.	Other exclusion criteria	Non-English language studies Evidence from non-OECD countries (Non-OECD counties were excluded because the pathogens and risk factors which result in neonatal infection vary between countries. The committee thought that countries who are part of the OECD are likely to have more similar pathogens and standards of care to the UK than those which are not part of the OECD.)
11.	Context	The review will cover all contexts in which information and support is provided to parents and carers who have a child at risk of or who has suspected or confirmed late onset neonatal infection. All settings where care of pregnant women and neonates is provided will be covered including: antenatal care (community or hospital based), postal natal care (community or hospital based), neonatal care (neonatal unit).
12.	Primary outcomes (critical outcomes)	Themes will be identified from the literature and not pre-specified. Relevant themes may include: • Preferred format and content of information provision

		• Decision making • Information sources other than healthcare professionals (e.g. support groups, online resources) • Parent/carer involvement in decision-making • Parental/carer anxiety • Impact on the baby's family • Delivery of support (e.g. nurse, peer groups) • Setting (e.g. community, hospital) • Timing of information provision • Support following discharge of the baby from hospital
13.	Secondary outcomes (important outcomes)	Not applicable
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form

		will be used to extract data from studies. Study investigators may be contacted for missing data where time and resources allow. This review will make use of the priority screening functionality within the EPPI-reviewer software. Included studies will be uploaded to NVivo 11 for coding and identification of themes.
15.	Risk of bias (quality) assessment	The methodological quality of the included studies will be assessed using the CASP qualitative checklist as described in Developing NICE guidelines: the manual.
16.	Strategy for data synthesis	Data extracted from the papers will be grouped together into themes (aggregative coding). These themes will be examined for common factors and differences, which will be reported in the summary of qualitative findings table. The quality of evidence will be assessed used GRADE-CERQual.
17.	Analysis of sub-groups	Stratifications: • Term vs preterm babies • babies who have been admitted to hospital from home

		• Vulnerable women (including non-attenders at antenatal clinics, low socioeconomic status (defined using deprivation quintiles), level of education or low income) • ethnicity • People for who English is a second language • age of parent/carer (under 25s vs older parents) The stratifications listed above will be coded. Within each theme, evidence for each of the stratified groups will be presented separately.
18.	Type and method of review	☐ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)

19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	01/01/2019		
22.	Anticipated completion date	12/08/2020		
23.	Stage of review at time of this submission	**Review stage**	**Started**	**Completed**
		Preliminary searches		
		Piloting of the study selection process		
		Formal screening of search results against eligibility criteria		
		Data extraction		

		Risk of bias (quality) assessment		
		Data analysis		
24.	Named contact	**5a. Named contact** Guideline Updates Team **5b Named contact e-mail** NIupdate@nice.org.uk **5e Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE)		
25.	Review team members	From the Guideline Updates Team: • Dr Kathryn Hopkins • Dr Clare Dadswell • Mr Fadi Chehadah • Mr Wesley Hubbard • Dr Stacey Chang-Douglass		
26.	Funding sources/sponsor	This systematic review is being completed by the Centre for Guidelines which receives funding from NICE.		

27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website.
29.	Other registration details	None
30.	Reference/URL for published protocol	None
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts

		• issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Information, support, late onset neonatal infection
33.	Details of existing review of same topic by same authors	None
34.	Current review status	☐ Ongoing ☐ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35..	Additional information	None
36.	Details of final publication	The guideline with supporting evidence reviews will be published on the NICE website.