Review protocol for review question: How can the views of babies, children and young people be best represented by independent advocates?

Table 4: Review protocol

Field	Content
PROSPERO registration number	CRD42019159564
Review title	Independent advocacy in healthcare for children and young people
Review question	How can the views of babies, children and young people be best represented by independent advocates?
Objective	The Care Act 2014 and Mental Health Act 1983/2007 place a duty on UK Councils to provide an independent advocate to a child or young person who has substantial difficulties being involved in their own healthcare and who may not have an appropriate person to represent them. The aim of this review is to establish what babies, children and young people find beneficial from having an independent advocate to support them. To help determine good practice for the advocate, in the view of babies, children and young people.
Searches	The following databases will be searched: • CCTR • CDSR • Embase • MEDLINE • MEDLINE IN-Process • PsycINFO One broad, guideline-wide, search will be conducted for qualitative questions, capturing the population and the settings. A UK filter will be applied to identify relevant UK studies and a systematic review filter will be applied to the remainder of the results to identify relevant reviews that include evidence from non-UK high-income countries. If no systematic reviews of this type are identified, then a more focused search may be conducted to identify studies conducted in the following high-income countries: Australia, Austria, Belgium, Canada Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and USA.

Field	Content
	Searches will be restricted by: • Date: 2009 • Language of publication: English language only • Publication status: Conference abstracts will be excluded because these do not typically provide sufficient information to fully assess risk of bias • Standard exclusions filter (animal studies/low level publication types) will be applied For each search (including economic searches), the principal database search strategy is quality assured by a second information specialist using an adaption of the PRESS 2015 Guideline Evidence-Based Checklist
Condition or domain being studied	• Babies, children's and young people's experience of healthcare
Population	• People <18 years-old who have experience of healthcare • Studies that use the views of parents or carers as proxies will be included only if they are responding on behalf of their child or charge, and o The baby or child of the parent or carer is under-5 years-old, or o There is a clear rationale provided as to why the study is using parents' or carers' views on and experiences of healthcare as proxies for their child. Note: Studies where part of the population is <18 years-old and part of the population is ≥18 years-old will only be included if it is clear that the themes are supported by evidence from the former group only.
Phenomenon of interest	• Children's experience of independent advocates who have represented their views and interests in decisions about healthcare. For example, when a child or young person has been supported by an independent advocate did they feel more confident/involved in decisions about their healthcare? When was it helpful to the child or young person to have support from the advocate? • Children's views on what elements of advocacy they found beneficial, for example how did the child feel that the advocate represented their views? What did the advocate do which they found useful and supportive to their care? Note: An 'independent advocate' in this context is a person who helps the child or young person to find information relevant to a healthcare decision and to support them in making and communicating healthcare decisions, or who is empowered to speak on the child or young person's behalf when they cannot do so themselves.
Comparator/Reference standard/Confounding factors	Not applicable

Field	Content
Types of study to be included	• Systematic reviews of qualitative studies • Studies using qualitative methods: focus groups, semi-structured and structured interviews, observations • Surveys conducted using open ended questions and a qualitative analysis of responses Note: Mixed methods studies will be included but only qualitative data will be extracted and risk of bias assessed. Systematic reviews that include evidence from countries not listed in the search strategy will be excluded if the sources of the themes and evidence from high-income countries cannot be clearly established. Evidence from individual qualitative studies conducted in the high-income countries listed in the search strategy will be included only if no relevant systematic review evidence is identified.

Other exclusion criteria	STUDY DESIGN
	• Studies using quantitative methods only (including surveys that report only quantitative data)
	• Surveys using mainly closed questions or which quantify open ended answers for analysis
	
	TOPIC OF STUDY
	Studies on the following topics will also be excluded:
	• Experience of independent advocates whilst child or young person is receiving non-NHS commissioned health promotion interventions
	• Non-NHS commissioned health promotion interventions
	• UK Law and legal protections relating to independent advocacy for babies, children and young people. This will include (but will not be limited to) Care Act 2014, Mental Capacity Act 2005, and Child Abuse and Prevention Act 1974
	• Views and experiences of healthcare professionals and service managers
	• Views and experiences of people reporting on shared decision making in the context of social care planning. Where a study covers both health and social care advocacy, the study will be excluded unless there are clear and relevant responses relating to support received within the healthcare system independent from the views on social care advocacy.
	
	Studies that focus explicitly on the following topics rather than focussing on the views on and experiences of babies, children and young people in healthcare will be excluded as they are covered by the following NICE guidelines:
	• Child abuse and maltreatment:
	  ○ Child abuse and neglect (NG76)
	  ○ Child maltreatment: when to suspect maltreatment in under 18s (CG89)
	• Community engagement
	  ○ Community engagement (NG44)

Field	Content

	• Drug misuse in children and young people:
	  ○ Alcohol: school-based interventions (PH7)
	  ○ Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence (CG115)
	  ○ Alcohol-use disorders: prevention (PH24)
	  ○ Drug misuse prevention: targeted interventions (NG64)
	• End of life care for infants, children and young people with life-limiting conditions: planning and management (NG61)
	• Immunisations: reducing differences in uptake in under 19s (PH21)
	• Oral health promotion: general dental practice (NG30)
	• Physical activity and weight management:
	  ○ Maternal and child nutrition (PH11)
	  ○ Obesity prevention (CG43)
	  ○ Physical activity for children and young people (PH17)
	  ○ Weight management: lifestyle services for overweight or obese children and young people (PH47)
	• Pregnancy, including routine antenatal, intrapartum or postnatal care:
	  ○ Antenatal and postnatal mental health: clinical management and service guidance (CG192)
	  ○ Antenatal care for uncomplicated pregnancies (CG62)
	  ○ Intrapartum care for healthy women and babies (CG190)
	  ○ Intrapartum care for women with existing medical conditions or obstetric complications and their babies (NG121)
	  ○ Multiple pregnancy: antenatal care for twin and triplet pregnancies (CG129)
	  ○ Postnatal care up to 8 weeks after birth (CG37)
	  ○ Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors (CG110)
	• Self-harm:
	  ○ Self-harm in over 8s: long-term management (CG133)
	  ○ Self-harm in over 8s: short-term management and prevention of recurrence (CG16)
	• Sexual health and contraception
	  ○ Contraceptive services for under 25s (PH51)
	  ○ Sexually transmitted infections and under-18 conceptions: prevention (PH3)
	  ○ Harmful sexual behaviour among children and young people (NG55)
	• Smoking prevention:
	  ○ Smoking: preventing uptake in children and young people (PH14)

Field	Content
	○ Smoking prevention in schools (PH23) ○ Stop smoking interventions and services (NG92) • Transition from children's to adults services for young people using health or social care services (NG43)
Context	UK studies from 2009 onwards will be prioritised for decision making by the committee as those conducted in other countries may not be representative of current expectations about either services or current attitudes and behaviours of healthcare professionals. The committee presumes that due to their development, particular circumstances and/or condition, there are some topics that babies, children and young people may not be in a position to pronounce on, and that in these circumstances, it may be necessary to treat the 'indirect' views of their parents or carers as proxies for their own views on and experiences of healthcare in order to make recommendations. The guideline committee will be consulted on whether a study should be included if it is unclear why parents' or carer's views are being reported instead of their child or charge, and reasons for exclusion if appropriate will be documented. The topic about which the BCYP are talking about should be generalizable to the wider healthcare context (e.g. a study on the views on and experience of communication with healthcare professionals whilst receiving chemotherapy would be included, whilst a study on experience of chemotherapy would be too narrow and not generalizable to wider healthcare context and therefore excluded). Recommendations will apply to those receiving care in all settings where NHS- or local authority- commissioned healthcare is provided (including home, school, community, hospital, specialist and transport settings). Specific recommendations for groups listed in the Equality Considerations section of the scope may be also be made as appropriate.
Primary outcomes (critical outcomes)	Themes will be identified from the literature. The committee identified the following potential themes (however, not all of these themes may be found in the literature, and additional themes may be identified): • Access to records of healthcare staff discussions • Adequate training for independent advocates including knowledge about developmentally-appropriate approaches • Appeal to, or use of, advocacy groups • Availability and accessibility of appropriate advocacy services (e.g. drop-in centres, ease of referral to advocacy services, mental health advocacy) • Awareness of independent advocate services • Encouraging and supporting self-advocacy when possible • Sensitivity and responsiveness of independent advocate to feedback from child or young person • Views on timing of support provided from the independent advocate, establishing views regarding where and when advocacy is beneficial, including continuity of support
Secondary outcomes (important outcomes)	Not applicable

Field	Content
Data extraction (selection and coding)	• All references identified by the searches and from other sources will be uploaded into STAR and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. • Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies, including study reference, research question, theoretical approach, data collection and analysis methods used, participant characteristics, second-order themes, and relevant first-order themes (i.e. supporting quotes). One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer.
Risk of bias (quality) assessment	Risk of bias of individual qualitative studies will be assessed using the CASP Qualitative checklist. Risk of bias of systematic reviews of Qualitative studies will be assessed using the CASP (Critical Skills Appraisal Programme) Systematic Review checklist. See Appendix H in Developing NICE guidelines: the manual for further details. The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	• Extracted second-order study themes and related first-order quotes will be synthesised by the reviewer into third-order themes and related sub-themes. • The GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research; Lewin 2015) approach will be used to summarise the confidence in the third-order themes or sub-themes synthesized from the qualitative evidence. The overall confidence in evidence about each theme or sub-theme will be rated on four dimensions: methodological limitations, coherence, adequacy, and relevance. • Methodological limitations refer to the extent to which there were problems in the design or conduct of the studies and will be assessed with the CASP checklist for qualitative studies or systematic reviews as appropriate. Coherence of findings will be assessed by examining the clarity of the data. Adequacy of data will be assessed by looking at the degree of richness and quantity of findings. Relevance of evidence will be assessed by determining the extent to which the body of evidence from the primary studies are applicable to the context of the review question with respect to the characteristics of the study population, setting, place and time, healthcare system, intervention, and broader social, policy, or political issues.
Analysis of sub-groups	If there is sufficient data, views and experiences will be analysed separately by the following age ranges: • <1 year-old (i.e. 364 days-old or less) • ≥1 to <12 years-old (i.e. 365 days-old to 11 years and 364 days-old • ≥12 to <18 years-old (i.e. 12 years and 0 days-old to 17 years and 364 days-old) The committee are aware that children can experience substantial cognitive and developmental change during the ages of 1 and 12, and that there may be (though not necessarily) substantive differences between children in this group depending on the topic about which they are being asked. The committee

Field	Content			
	will therefore be consulted regarding whether data regarding further subgroups within this age range (e.g. 1-5, 6-11) should be used. Subgroup analysis according to any of the groups listed in the Equality Considerations section of the scope will be conducted if there is sufficient data. Of particular relevance to this question will be the differing views of those living In care			
Type and method of review	☐	Intervention		
	☐	Diagnostic		
	☐	Prognostic		
	☒	Qualitative		
	☐	Epidemiologic		
	☐	Service Delivery		
	☐	Other (please specify)		
Language	English			
Country	England			
Anticipated or actual start date				
Anticipated completion date	07/04/2021			
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			☑
Named contact	**5a. Named contact** National Guideline Alliance **5b. Named contact e-mail** infant&younghealth@nice.org.uk **5c. Organisational affiliation of the review**			

Field	Content	
	National Institute for Health and Care Excellence (NICE) and National Guideline Alliance	
Review team members	NGA Technical Team	
Funding sources/sponsor	This systematic review is being completed by the National Guideline Alliance, which receives funding from NICE.	
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.	
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: https://www.nice.org.uk/guidance/indevelopment/gid-ng10119/documents	
Other registration details	-	
Reference/URL for published protocol	https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019159564	
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.	
Keywords	Advocacy; advocacy groups; babies; children; experience; healthcare; independent advocacy; independent advocate; young people.	
Details of existing review of same topic by same authors	Not applicable	
Current review status	☒	Ongoing
	☐	Completed but not published
	☐	Completed and published
	☐	Completed, published and being updated

Field	Content	
	☐	Discontinued
Additional information		
Details of final publication	www.nice.org.uk	

CASP: critical appraisal skills programme; CDSR: Cochrane Database of Systematic Reviews; CCTR/CENTRAL: Cochrane Central Register of Controlled Trials; GRADE-CERQual: Grading of Recommendations Assessment, Development and Evaluation – Confidence in the evidence from reviews of qualitative research; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence