

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Clinical Ethics Support Services in Paediatric Practice: Protocol for a mixed studies systematic review on structures, interventions and outcomes.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-057867
Article Type:	Protocol
Date Submitted by the Author:	20-Oct-2021
Complete List of Authors:	Dittborn, Mariana; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre ; Universidad del Desarrollo, Centro de Bioética Portales, Bernardita; Universidad del Desarrollo, Centro de Bioética Brierley, Joe; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre
Keywords:	PAEDIATRICS, MEDICAL ETHICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts

1

**TITLE**

**Clinical Ethics Support Services in Paediatric Practice: Protocol for a mixed studies systematic review on structures, interventions and outcomes.**

**AUTHORS**

Mariana Dittborn<sup>1,2</sup>, Bernardita Portales<sup>2</sup>, Joe Brierley<sup>1</sup>

<sup>1</sup>Paediatric Bioethics Centre, Great Ormond Street Hospital, London, UK

<sup>2</sup>Centro de Bioética, Facultad de Medicina, Clínica Alemana - Universidad del Desarrollo, Santiago, Chile

**CORRESPONDING AUTHOR**

Mariana Dittborn

Postal Address: Great Ormond Street Hospital, London WC1N 3JH

Email: [mariana.dittborn@gosh.nhs.uk](mailto:mariana.dittborn@gosh.nhs.uk)

**WORD COUNT** 2523

**KEY WORDS**

Paediatrics, Clinical Ethics Committees, Clinical Ethics, Quality Indicators, Systematic Review

2

**ABSTRACT**

**Introduction:** Clinical Ethics Support Services (CESS) have been developing worldwide with growing interest in evaluating their quality. Paediatric-specific CESSs (p-CESS) have received little attention, and evidence from adult services might not be generalisable. Evidence on service models and practices is crucial to inform further research and debate on quality evaluation and minimum standards for p-CESSs. We aim to systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and outcomes.

**Methods and analysis:** We will conduct a mixed-studies systematic review including peer-reviewed empirical studies published in English or Spanish language providing data on the evaluation and/or impact on any aspect of p-CESS. We will search seven electronic databases: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHALL, without filters applied. Search terms will be related to "clinical ethics support" AND "paediatrics" AND "structure/process/outcome". Reference and citation list of included studies will be hand-searched. A 10% random sample of retrieved titles/abstracts and all full texts will be independently dual-screened. We will conduct thematic and narrative synthesis for qualitative and quantitative data, respectively, following a sequential exploratory design guided by Donabedian's framework of structure, process and outcomes. Quality will be assessed using the Mixed-Methods Appraisal Tool (2018). The review will be reported using the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

**Ethics and dissemination:** As a systematic review of published data, no ethical approval is necessary. Results will be published in a relevant academic peer-reviewed journal.

**Registration:** The protocol has been prospectively registered in PROSPERO (CRD42021280978)

**STRENGTHS AND LIMITATIONS OF THIS STUDY**

3

- We will conduct an electronic search using a wide range of electronic databases, including a Latin American database, which will broaden the coverage of publication countries.
- The use of the Donabedian framework will allow an objective assessment of the CESS contribution to the quality of medical care.
- The review will be conducted by a bilingual and international research team, contributing different experiences and perspectives on CESS structures, processes, and outcomes in different contexts (Latin America and the UK).
- However, only English and Spanish language studies will be included with the consequent potential exclusion of relevant articles.

## INTRODUCTION

Clinical ethics support is the provision of support and advice to health professionals, patients and families on ethical issues arising from clinical practice or patient care.(1–3) Accordingly, Clinical Ethics Support Services (CESS) are institutionalised forms of ethics support within healthcare organisations.(2)

CESS were initially developed in the USA in 1970-80 in response to government and medical societies' recommendations,(4) and has since spread progressively worldwide, but in an uneven and very varied way.(1,5–7) Forms of, and access to, CESS varies across different centres, countries, and cultural contexts.(6,8) In some countries, the constitution of institutional CESS is recommended or required by the government and subject to official regulation, while in others, such as the UK, the organisation and function of these services lack official guidance.(1)

Traditionally, four main CESS functions have been described; clinical case consultation, education, institutional policy development, and research.(3,9) Multiple models of CESS have been described, including individual ethical case consultation, clinical ethics committees, individual ethicists, moral case deliberation, ethics rounds and ethics discussion forums.(1,10–12) Informal provision of clinical ethics support has also been reported.(10)

Unlike Research Ethics Committees (REC), CESS have been criticised for lack of standardisation, an absence of regulation of their structures, skill requirements, role and remit and the paucity of formal evaluation of their impact.(13) Even though there has always been an awareness of the need for systematic evaluation of CESS outcomes and effectiveness,(14–16) and there is a growing body of theoretical and empirical literature addressing CESS' evaluation, there remain no agreed standards or quality indicators for these services.(17–19)

Schildmann et al. defined the evaluation of CESS as “the systematic gathering of data with empirical research methods for the purpose of acquiring knowledge about the structure, functioning, quality

5

1  
2  
3 and results of CESS".(p681, 20) Following this definition, in line with the widely used Donabedian  
4 model for evaluating the quality of medical care,(21) a comprehensive evaluation of the quality of  
5 CESS should include three dimensions of care: structure, process and outcomes.(2,21,22) As described  
6 by Donabedian, quality measurement standards derive from both empirical and normative  
7 sources.(21) Considering CESS have an explicit normative character, identifying appropriate quality  
8 criteria is particularly complicated, and this normative feature should be reflected when defining  
9 assessment measures.(23) Widely used outcome measures such as length of stay, mortality, or  
10 financial impact are not be necessarily helpful in evaluating CESS.(22) For example, any evaluation of  
11 ethics consultation services focused on pre-established outcome measures should not ignore the  
12 consultation's central aim of responding to the ethical queries presented by those requesting support  
13 with a particular clinical case. Therefore, an appropriate evaluation system must allow for the context  
14 and particularities of each case to be considered.(24) Additionally, CESS evaluation should involve all  
15 stakeholders, including both those who receive and those who provide ethics support (i.e., healthcare  
16 professionals, patients and relatives, CESS members, hospital management).(25) Moreover,  
17 considering that CESS are, by definition, engaged in complex interventions where multiple  
18 components and interactions impact the final outcome,(2) a clear understanding of how they function  
19 is vital, before attempting any evaluation.(2)

20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42 Paediatric practice raises particular ethical challenges not frequently found in adult patient care.(26–  
43 29) The fundamental principle of respect for patient autonomy has a substantially different  
44 understanding in paediatric practice, with parents taking the responsibility of decision-making until  
45 children are afforded that possibility.(26) Generally, parents' decisions are in coherence with the  
46 child's views and the child's best interest, but conflict might arise when those involved (clinical team,  
47 parents, child) hold different views. Additionally, the child's capacity to understand the information  
48 provided and contribute to, or even make, decisions about their care increases with maturity. Because  
49 of this, careful assessment of the child's competence needs to be made, particularly for decisions with  
50 moral significance.(26) The level of involvement of parents and patients in ethics discussions is a

6

1  
2  
3 controversial point, particularly in a paediatric setting.(30) The paediatric landscape has changed with  
4 technological advances, lower mortality rates in many specialities and an increasing number of  
5 patients with chronic and complex conditions. Uncertainties about prognostication and treatment  
6 outcomes, overall benefits and burdens pose ethical challenges about withholding and withdrawing  
7 life-sustaining treatments.(31) The involvement of multiple teams with different perspectives and  
8 values might add further complexity to the decision-making process.(29) Finally, these significant  
9 technological advances and decreasing mortality rates might strengthen the perception of death,  
10 particularly in children, as a medical failure adding barriers to end of life discussions and decision-  
11 making.  
12

13  
14 Despite ethically challenging situations and consequent divergent opinions being common in  
15 paediatrics, the number of paediatric ethics consultations is relatively low.(32) Many of these  
16 challenges might be opportunely identified and appropriately managed by the healthcare team and  
17 the family,(33) with clinicians receiving support through alternatives to formal ethics consultation.(32)  
18 However, in complex cases, there may either be an impasse or conflict might persist. In these  
19 situations, ethical consultation has been shown to help provide a resolution.(34)  
20

21  
22 Recent controversial cases featured extensively in both print, and social media have increased  
23 international public and academic attention to the ethical challenges of paediatric practice. There has  
24 been an increased interest and debate surrounding the legal and ethical aspects of paediatric practice,  
25 such as parental and clinical teams' disagreements about the child's best interests, emerging child  
26 capacity, innovative treatments, technological dependence and end-of-life decision-making.  
27 Consultant paediatricians, trainees and residents have expressed concerns that these public cases  
28 might negatively impact their relationship with patients and families.(35) Availability of clinical ethics  
29 support services for teams facing ethical challenges has been strongly advocated by professional  
30 bodies,(31) academics(33,36,37) and clinicians.(35,38)  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

7

1  
2  
3 Interest in assessing CESS quality and effectiveness has grown in the past decades. However, most  
4 studies have focused on adult care settings, with relatively little attention paid to p-CESS.(39) Multiple  
5  
6 systematic reviews evaluating different aspects of CESS have recently been published. Nevertheless,  
7  
8 these focus on adult patients; ethical case intervention,(40) adult end of life context,(41) and adult  
9  
10 ICU.(42) Other reviews that did not explicitly focused on adult patients evaluate a specific intervention  
11  
12 (assessment tools for evaluating clinical ethics consultation(17)) or effectiveness of clinical ethics  
13  
14 committees.(18) Generalisation of adult-focused reviews and evidence to paediatric context might  
15  
16 not be appropriate.  
17  
18  
19

20  
21 To our knowledge, no systematic review on Paediatric Clinical Ethics Support Services (p-CESS)  
22  
23 structures, processes, evaluation measures and outcomes has been published. Such a review is  
24  
25 necessary to inform current p-CESS practice and further development. Therefore, we aim to inform  
26  
27 further research and debate on the current quality evaluation and minimum standards for p-CESS by  
28  
29 offering a comprehensive description of current p-CESS models and assessments by responding to this  
30  
31 review question:  
32  
33  
34

35  
36 ***“What is the range of structures, processes, and outcome measures of paediatric CESS***  
37  
38 ***reported in the literature?”***  
39  
40

41 **Aim:**

42  
43 To systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and  
44  
45 outcome measures described in the literature.  
46  
47  
48

49 **Objectives:**

- 50  
51  
52 • To identify and synthesise published data on p-CESS regarding their structures, processes,  
53  
54 evaluation measures and outcomes.  
55  
56 • To explore the impact of p-CESS given the outcomes identified in the review.  
57  
58 • To qualitatively appraise the available evidence.  
59  
60

8

- To develop a preliminary framework for the evaluation of p-CESS based on available evidence.
- To provide recommendations for further research on CESS effectiveness and outcome measures in paediatric practice.

## **METHODS AND ANALYSIS**

We will conduct a systematic review following the PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines(43) to identify and synthesise evidence for Paediatric CESS structures, interventions, evaluation measures and outcomes.

The review protocol has been developed following the recommended items included in the PRISMA-P statement(44) (See Supplemental file 1 for PRISMA-P Checklist) and has been prospectively registered in PROSPERO registry CRD42021280978

### **Eligibility Criteria**

The inclusion and exclusion criteria are summarised in Table 1. The review will include peer-review empirical studies (qualitative, quantitative or mixed-methods), including case studies published in English or Spanish language which provide empirical data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value)(11) of any one or more of the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, and outcome measures of p-CESS. We will include empirical studies of qualitative, quantitative or mixed-methods design reporting both objective and/or subjective measures.

We will include studies reporting on CESS that provide services to adult and paediatric patients only if paediatric data can be extracted separately.

Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces, book chapters will be excluded. Conference abstracts will not be included, but authors will be contacted

9

asking whether the relevant work has been published, with a two-week timeframe allowed for a response. There will be no timeframe or geographical restrictions.

Table 1. Eligibility Criteria		
	INCLUSION CRITERIA	EXCLUSION CRITERIA
Type of participants	<p>CESSs that serve paediatric only or paediatric and adult population, where paediatric data can be extracted separately.</p> <p>The paediatric population will be defined in this review as between 0-18 years old.</p> <p>Study participants include, but are not limited to, referring clinicians, CESS members, patients/children, parents/relatives/careers and hospital administrators.</p>	<p>CESSs that serve only adult patients.</p> <p>CESSs serving paediatric and adult populations, where paediatric data cannot be extracted and analysed</p>
Context/ setting	<p>Articles reporting on established CESS serving paediatric practice in any setting (hospital, community) and country.</p>	<p>Research ethics committees</p>

Issues	Empirical studies reporting data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value) of any one or more of, but not limited to the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, outcome measures of paediatric CESS.	Theoretical analysis or narrative reviews on paediatric CESS.  Studies focusing only on a description of the paediatric CESS without reporting assessment/impact data
Methods	Empirical studies of any methods (qualitative and/or quantitative), including case studies.	Theoretical reviews or analysis.  Systematic reviews  Case reports, narrative reviews.
Timeframe	Any time frame. Searches will be conducted from the database inception date until the search date.	
Type of publication	Peer-reviewed publications in English or Spanish Language	Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces  Conference abstracts
<i>CESS: Clinical Ethics Support Services</i>		

## Search strategy

Electronic searches. The following databases will be searched: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHAL. There will be no methodological, language, geographical or time filters applied to the search strategy. If a non-English paper is considered eligible for inclusion, relevant data and results will be translated to English before analysis.

The initial search strategy was developed considering previously published systematic reviews in paediatrics, clinical ethics and service evaluation. Search terms will be related to "Clinical ethics support", "paediatrics" AND "structure/process/outcome indicators" and adapted to each database requirement. Publications that would match the criteria for inclusion in the review previously known to the research team were successfully retrieved applying the search strategy in Medline online database (See Table 2). The search strategy will be checked and adjusted to the other electronic databases as appropriate.

Table 2. Medline search strategy

1. paediatric.mp.	27. Ethicists/ or ethicist*.mp.	57. structure.mp.
2. paediatr*.mp.	28. bioethicist*.mp.	58. model*.mp.
3. pediatric.mp. or Paediatrics/	29. medical ethics.mp. or Ethics, Medical/	59. process*.mp.
4. pediater*.mp.	30. clinical ethics.mp. or Ethics, Clinical/	60. intervention*.mp.
5. child*.mp. or Child/	31. clinical ethics committee.mp. or Ethics Committees, Clinical/	61. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or assessment*.mp.
6. Adolescent/ or adolescent.mp.	32. bioethics.mp. or Bioethics/	62. evaluation*.mp.
7. adolesc*.mp.	33. bioethical issues.mp. or Bioethical Issues/	63. impact*.mp.
8. infant*.mp.	34. ethical issues.mp. or Ethics/	64. effectiveness.mp.
9. infant.mp. or Infant/	35. ethical challenges.mp	65. Medical Audit/ or Clinical Audit/ or audit.mp.
10. kid.mp.	36. moral review.mp.	66. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or outcome.mp.
11. kids.mp.	37. Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.	
12. baby.mp.	38. moral case consult*.mp.	
13. babies.mp.	39. moral consult*.mp.	
14. toddler*.mp.		
15. childhood.mp.		
16. juvenil*.mp.		
17. youth*.mp.		

12

18. minor.mp. or Minors/ 19. Infant, Newborn/ or infancy.mp. or Child, Preschool/ 20. Infant, Newborn/ or newborn*.mp. 21. Premature Birth/ or Infant, Premature/ or preterm*.mp. 22. prematur*.mp. 23. Puberty/ or pubert*.mp. 24. pubescen*.mp. 25. young person.mp. 26. neonatal.mp.	40. ethic* case review.mp. or Ethics Committees/ 41. ethic* deliberation.mp. 42. ethic* intervention.mp. 43. ethic* round.mp. 44. ethic* support.mp. 45. ethic* service.mp. 46. Ethical Analysis/ or ethic* analysis.mp. 47. ethic* referral.mp. 48. Ethics Committees/ or ethic* committee.mp. 49. bioethic* deliberation.mp. 50. bioethic* intervention.mp. 51. bioethic* round.mp. 52. bioethic* service.mp. 53. bioethic* support.mp. 54. bioethic* analysis.mp. 55. bioethic* referral.mp. 56. bioethic* committee.mp.	67. "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/ 68. indicator*.mp.
69. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 70. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 71. 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 72. 69 AND 70 AND 71		

**Other resources.** Reference and citation list of included studies will be hand-searched. When relevant, we will contact the authors of conference abstracts identified through the search for peer-review publications. We will allow a time frame of two weeks for a response before considering the publication unavailable.

### **Selection process.**

All retrieved records will be managed using Refworks® reference manager software. After deduplication, all titles and/or abstracts will be screened by MD to identify publications that meet the previously established inclusion and exclusion criteria. A random sample of 10% will be independently screened by a second researcher (BP) to test the reliability of the criteria. Any disagreements will be discussed within the research team until agreement, and, if required, eligibility criteria will be adjusted

13

1  
2  
3 and/or clarified to improve the consistency of the screening process. Selected references for  
4  
5 assessment in the full text will be dual-screened, and any disagreements will be discussed within the  
6  
7 research team until agreement. The screening process will be presented as a PRISMA flowchart.  
8  
9

### 10 11 12 13 **Data extraction.**

14  
15  
16 Data from individual studies considered relevant for the review question will be extracted to a pre-  
17  
18 piloted Excel data extraction form by MD and checked by BP. Disagreements will be discussed within  
19  
20 the research team. Data entries will include: Publication details (First author, year of publication, title),  
21  
22 country, study aims, study design, sample description, CESS description (design, delivery, organisation,  
23  
24 function, aims and interventions), study intervention, outcome measures, findings, comments. For  
25  
26 qualitative studies, all data within the results/finding section will be considered as results.  
27  
28

29  
30 MD and BP will independently extract the data, and any disagreements will be discussed within the  
31  
32 team until we achieve consensus. This will include publication details (author, year, title), study design  
33  
34 and instrument, setting (country, healthcare setting), sampling method, and sample characteristics.  
35  
36 Primary outcomes sought in the data set will include; (i) assessed aspects of paediatric CESS as  
37  
38 reported by study authors, including service structures, processes and outcomes; and (ii) assessed  
39  
40 dimensions (i.e., effectiveness, safety and responsiveness) and/or subdimensions of quality of  
41  
42 care(45) as reported by study authors.  
43  
44  
45  
46  
47  
48  
49

### 50 **Quality assessment.**

51  
52 Following our initial scoping review, we expect to find potentially eligible studies with multiple  
53  
54 research designs, including qualitative, quantitative and mixed methods. To allow coherent and  
55  
56 systematic critical appraisal of included studies with different designs, we will use the 2018 Mixed  
57  
58 Methods Appraisal Tool.(46) The tool was developed specifically for the appraisal of complex  
59  
60

14

1  
2  
3 systematic reviews that include empirical qualitative, quantitative and mixed methods studies. It  
4 includes specific criteria depending on the study design category. Each criterion is rated as “yes”, “no”,  
5 “can’t tell” response. As recommended by the authors, for each study, we will present a detailed  
6 description of the rating of each criterion and calculate an overall quality score based on the number  
7 of quality criteria met. There is no recommended cut off score to exclude studies based on quality  
8 appraisal, and therefore no study will be excluded based on that criterion. Instead, we will conduct a  
9 sensitivity analysis during the data synthesis process to assess the impact of low-quality studies in the  
10 review findings and adjust recommendations accordingly.(46) Quality appraisal will be conducted by  
11 MD and checked by BP.

### 27 **Data synthesis**

28  
29 This systematic review is not focused only on the effectiveness of a particular intervention but  
30 addresses a broader range of questions. Therefore we will follow a modified narrative synthesis  
31 approach to synthesise findings.(47) The iterative process will include developing a preliminary  
32 synthesis of findings of included studies, exploring relationships in the data, and assessing the  
33 robustness of the synthesis by considering individual studies’ quality and sensitivity analysis if possible.  
34 Data synthesis will follow a sequential exploratory design by first conducting synthesis of qualitative  
35 data followed and informing synthesis of quantitative data, looking for divergences and/or  
36 convergences and knowledge gaps across the data set. (47) Qualitative data will be analysed by the  
37 thematic synthesis approach,(48) using NVivo software for qualitative data analysis. The synthesis will  
38 include: (i) Free line-by-line coding of the primary study’s findings, and (ii) organisation of these codes  
39 into related areas to construct descriptive themes. After that, the narrative synthesis of quantitative  
40 findings will be integrated into the qualitative synthesis, followed by the development of overarching  
41 themes (48) guided by but not limited to Donabedian’s framework of structure, process and  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

15

1  
2  
3 outcomes. Thematic and narrative analysis will be conducted by MD and checked by BP. The final  
4  
5 synthesis will be discussed within the research team.  
6  
7  
8  
9

### 10 **Ethics and dissemination.**

11  
12  
13  
14 As a systematic review of published data, no ethical approval is necessary. We will present and discuss  
15  
16 our findings in an open-access webinar, including invited experts in the field. A final report will be  
17  
18 published in a relevant academic peer-reviewed journal.  
19  
20  
21  
22  
23

### 24 **Patient and public involvement.**

25  
26  
27 Patients and the public were not involved in the design of this systematic review protocol.  
28  
29  
30  
31  
32

## 33 **DISCUSSION**

34  
35  
36 Interest in assessing CESS quality and effectiveness has grown in the past decades, with little attention  
37  
38 paid to p-CESS. The results of this work will provide us with the first systematic review of evidence on  
39  
40 Paediatric Clinical Ethics Support Services. We hope that our review results will allow for a better  
41  
42 understanding of p-CESS structures, processes, and outcomes, contributing to further research  
43  
44 exploring the normative and empirical basis of p-CESS. We plan to continue this research by  
45  
46 conducting a modified Delphi study based on our review results to explore the most appropriate  
47  
48 quality indicators for evaluating p-CESS. These outputs are vital if we aim to ensure CESS contribute  
49  
50 to better quality care for patients and their families.  
51  
52  
53  
54  
55  
56

57 **Author contributions:** MD and JB conceived the review. MD, JB and BP developed the protocol. All  
58  
59 authors revised and edited the manuscript and approved the final version.  
60

16

**Funding:** This work was supported by the Institute of Medical Ethics “Research in Medical Ethics” grant (No grant number). The funder has had no involvement in the review protocol development.

**Competing interests:** None to declare.

## REFERENCES

1. Slowther A, Johnston C, Goodall J, Hope T. Development of clinical ethics committees. *BMJ* [Internet]. 2004 Apr 17;328(7445):950–2. Available from: <https://pubmed.ncbi.nlm.nih.gov/15087349>
2. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Do we understand the intervention? What complex intervention research can teach us for the evaluation of clinical ethics support services (CESS). *BMC Med Ethics* [Internet]. 2019;20(1):48. Available from: <https://doi.org/10.1186/s12910-019-0381-y>
3. Machin LL, Wilkinson M. Making the (Business) Case for Clinical Ethics Support in the UK. *HEC Forum* [Internet]. 2020; Available from: <https://doi.org/10.1007/s10730-020-09416-6>
4. Courtwright A, Jurchak M. The Evolution of American Hospital Ethics Committees: A Systematic Review. *J Clin Ethics*. 2016;27(4):322–40.
5. Moodley K, Kabanda SM, Soldaat L, Kleinsmidt A, Obasa AE, Kling S. Clinical Ethics Committees in Africa: lost in the shadow of RECs/IRBs? *BMC Med Ethics*. 2020 Nov;21(1):115.
6. Orzechowski M, Schochow M, Steger F. Clinical Ethics Consultation in the Transition Countries of Central and Eastern Europe. *Sci Eng Ethics*. 2020 Apr;26(2):833–50.
7. Hajibabae F, Joolae S, Cheraghi MA, Salari P, Rodney P. Hospital/clinical ethics committees’ notion: an overview. *J Med ethics Hist Med* [Internet]. 2016 Dec 18;9:17. Available from: <https://pubmed.ncbi.nlm.nih.gov/28523118>
8. Slowther A, Bunch C, Woolnough B, Hope T. Clinical ethics support services in the UK: an

17

- 1  
2  
3 investigation of the current provision of ethics support to health professionals in the UK. J  
4  
5 Med Ethics [Internet]. 2001 Apr 1;27(suppl 1):i2 LP-i8. Available from:  
6  
7 [http://jme.bmj.com/content/27/suppl\\_1/i2.abstract](http://jme.bmj.com/content/27/suppl_1/i2.abstract)  
8  
9
- 10  
11 9. Larcher V. Role of clinical ethics committees. Arch Dis Child [Internet]. 1999 Aug;81(2):104–6.  
12  
13 Available from: <https://pubmed.ncbi.nlm.nih.gov/10490512>  
14  
15
- 16  
17 10. Hurst SA, Reiter-Theil S, Perrier A, Forde R, Slowther A-M, Pegoraro R, et al. Physicians' access  
18  
19 to ethics support services in four European countries. Health Care Anal. 2007 Dec;15(4):321–  
20  
21 35.  
22
- 23  
24 11. Haan MM, van Gorp JLP, Naber SM, Groenewoud AS. Impact of moral case deliberation in  
25  
26 healthcare settings: a literature review. BMC Med Ethics [Internet]. 2018;19(1):85. Available  
27  
28 from: <https://doi.org/10.1186/s12910-018-0325-y>  
29
- 30  
31 12. Rasoal D, Skovdahl K, Gifford M, Kihlgren A. Clinical Ethics Support for Healthcare Personnel:  
32  
33 An Integrative Literature Review. HEC Forum. 2017 Dec;29(4):313–46.  
34  
35
- 36  
37 13. Gill AW, Saul P, McPhee J, Kerridge I. Acute clinical ethics consultation: the practicalities. Med  
38  
39 J Aust [Internet]. 2004 Aug 1;181(4):204–6. Available from: [https://doi.org/10.5694/j.1326-  
40  
41 5377.2004.tb06237.x](https://doi.org/10.5694/j.1326-5377.2004.tb06237.x)  
42
- 43  
44 14. Kilham H, Isaacs D, Kerridge I, Newson A. Rethinking Pediatric Ethics Consultations. Am J  
45  
46 Bioeth [Internet]. 2015 May 4;15(5):26–8. Available from:  
47  
48 <https://doi.org/10.1080/15265161.2015.1021970>  
49
- 50  
51 15. Molewijk B, Slowther A, Schildmann J. The European Clinical Ethics Network ( ECEN ): the  
52  
53 professional development of clinical ethics support in Europe and the importance of quality  
54  
55 assessment through evaluation research. Bioethica Forum. 2016;9(2):86–9.  
56  
57
- 58  
59 16. Slowther A-M, Hope T. Clinical ethics committees. BMJ [Internet]. 2000 Sep 16;321(7262):649  
60  
LP – 650. Available from: <http://www.bmj.com/content/321/7262/649.abstract>

18

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
17. Yoon NYS, Ong YT, Yap HW, Tay KT, Lim EG, Cheong CWS, et al. Evaluating assessment tools of the quality of clinical ethics consultations: a systematic scoping review from 1992 to 2019. *BMC Med Ethics* [Internet]. 2020 Jul 1;21(1):51. Available from: <https://pubmed.ncbi.nlm.nih.gov/32611436>
  18. Crico C, Sanchini V, Casali PG, Pravettoni G. Evaluating the effectiveness of clinical ethics committees: a systematic review. *Med Heal Care Philos* [Internet]. 2021;24(1):135–51. Available from: <https://doi.org/10.1007/s11019-020-09986-9>
  19. McClimans L, Pressgrove G, Campbell E. Objectives and outcomes of clinical ethics services: a Delphi study. *J Med Ethics*. 2019 Dec;45(12):761–9.
  20. Schildmann J, Molewijk B, Benaroyo L, Forde R, Neitzke G. Evaluation of clinical ethics support services and its normativity. *J Med Ethics* [Internet]. 2013 Nov 1;39(11):681 LP – 685. Available from: <http://jme.bmj.com/content/39/11/681.abstract>
  21. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q* [Internet]. 2005;83(4):691–729. Available from: <https://pubmed.ncbi.nlm.nih.gov/16279964>
  22. Williamson L, McLean S, Connell J. CLINICAL ETHICS COMMITTEES IN THE UNITED KINGDOM: TOWARDS EVALUATION. *Med Law Int* [Internet]. 2007 Feb 9;8(3):221–38. Available from: <https://pubmed.ncbi.nlm.nih.gov/18270545>
  23. Haltaufderheide J, Nadolny S, Vollmann J, Schildmann J. Framework for evaluation research on clinical ethical case interventions: the role of ethics consultants. *J Med Ethics* [Internet]. 2021 May 17;medethics-2020-107129. Available from: <http://jme.bmj.com/content/early/2021/06/29/medethics-2020-107129.abstract>
  24. Craig JM, May T. Evaluating the outcomes of ethics consultation. *J Clin Ethics*. 2006;17(2):168–80.
  25. Metselaar S, Widdershoven G, Porz R, Molewijk B. Evaluating Clinical Ethics Support: A

19

- 1  
2  
3 Participatory Approach. *Bioethics*. 2017 May;31(4):258–66.  
4  
5  
6 26. Gold H, Hall G, Gillam L. Role and function of a paediatric clinical ethics service : Experiences  
7  
8 at the Royal Children ' s Hospital , Melbourne.  
9  
10  
11 27. Larcher VF, Lask B, Mccarthy JM, Ormond G, Hospitalfor S. Paediatrics at the cutting edge : do  
12  
13 we need clinical ethics committees ? 1997;245–9.  
14  
15  
16 28. Buchanan CA, Bester JC, Bruno B, Delany C, Kennedy KO, Koogler T, et al. Pediatric Ethics  
17  
18 Consultation: Practical Considerations for the Clinical Ethics Consultant. *J Clin Ethics*.  
19  
20 2019;30(3):270–83.  
21  
22  
23 29. Moynihan KM, Taylor L, Crowe L, Balnaves M-C, Irving H, Ozonoff A, et al. Ethical climate in  
24  
25 contemporary paediatric intensive care. *J Med Ethics*. 2021 Jan;  
26  
27  
28 30. Brierley J, Archard D, Cave E. Challenging misconceptions about clinical ethics support during  
29  
30 COVID-19 and beyond: a legal update and future considerations. *J Med Ethics* [Internet]. 2021  
31  
32 Apr 21;medethics-2020-107092. Available from:  
33  
34 <http://jme.bmj.com/content/early/2021/04/21/medethics-2020-107092.abstract>  
35  
36  
37  
38 31. Larcher V, Craig F, Bhogal K, Wilkinson D, Brierley J. Making decisions to limit treatment in  
39  
40 life-limiting and life-threatening conditions in children: a framework for practice. *Arch Dis*  
41  
42 *Child* [Internet]. 2015 May 1;100(Suppl 2):s1 LP-s23. Available from:  
43  
44 [http://adc.bmj.com/content/100/Suppl\\_2/s1.abstract](http://adc.bmj.com/content/100/Suppl_2/s1.abstract)  
45  
46  
47  
48 32. Carter B, Brockman M, Garrett J, Knackstedt A, Lantos J. Why Are There So Few Ethics  
49  
50 Consults in Children's Hospitals? *HEC Forum*. 2018 Jun;30(2):91–102.  
51  
52  
53 33. Linney M, Hain RDW, Wilkinson D, Fortune P-M, Barclay S, Larcher V, et al. Achieving  
54  
55 consensus advice for paediatricians and other health professionals: on prevention,  
56  
57 recognition and management of conflict in paediatric practice. *Arch Dis Child* [Internet]. 2019  
58  
59 May;104(5):413–6. Available from: <https://pubmed.ncbi.nlm.nih.gov/31000533>  
60

20

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
34. Brierley J, Petros A, Linthicum J. Should religious beliefs be allowed to stonewall a secular approach to withdrawing and withholding treatment in children? *J Med Ethics* [Internet]. 2013;39(9):573–7. Available from: <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed14&NEWS=N&AN=1051942353>
35. Avula H, Dittborn M, Brierley J. ‘Who Ya Gonna Call ...?’ Ethical and legal dilemmas in specialist children centres and district general hospitals. *Clin Ethics* [Internet]. 2021 Aug 5;14777509211036648. Available from: <https://doi.org/10.1177/14777509211036649>
36. Huxtable R. Clinic, courtroom or (specialist) committee: in the best interests of the critically ill child? *J Med Ethics* [Internet]. 2018 Jul 1;44(7):471 LP – 475. Available from: <http://jme.bmj.com/content/44/7/471.abstract>
37. Wilkinson D, Savulescu J. Alfie Evans and Charlie Gard-should the law change? Vol. 361, *BMJ* (Clinical research ed.). England; 2018. p. k1891.
38. Archambault-Grenier M-A, Roy-Gagnon M-H, Gauvin F, Doucet H, Humbert N, Stojanovic S, et al. Survey highlights the need for specific interventions to reduce frequent conflicts between healthcare professionals providing paediatric end-of-life care. *Acta Paediatr*. 2018 Feb;107(2):262–9.
39. McDougall RJ, Notini L. What kinds of cases do paediatricians refer to clinical ethics? Insights from 184 case referrals at an Australian paediatric hospital. *J Med Ethics*. 2016 Sep;42(9):586–91.
40. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Ethical case interventions for adult patients. *Cochrane Database Syst Rev* [Internet]. 2019;(7). Available from: <https://doi.org/10.1002/14651858.CD012636.pub2>
41. Haltaufderheide J, Nadolny S, Gysels M, Bausewein C, Vollmann J, Schildmann J. Outcomes of

21

- 1  
2  
3 clinical ethics support near the end of life: A systematic review. *Nurs Ethics* [Internet]. 2019  
4 Nov 19;27(3):838–54. Available from: <https://doi.org/10.1177/0969733019878840>  
5  
6  
7
- 8 42. Au SS, Couillard P, Roze des Ordons A, Fiest KM, Lorenzetti DL, Jette N. Outcomes of Ethics  
9 Consultations in Adult ICUs: A Systematic Review and Meta-Analysis. *Crit Care Med*. 2018  
10 May;46(5):799–808.  
11  
12  
13  
14
- 15 43. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA  
16 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* [Internet]. 2021  
17 Mar 29;372:n71. Available from: <http://www.bmj.com/content/372/bmj.n71.abstract>  
18  
19  
20  
21  
22
- 23 44. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting  
24 items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst*  
25 *Rev* [Internet]. 2015;4(1):1. Available from: <https://doi.org/10.1186/2046-4053-4-1>  
26  
27  
28  
29
- 30 45. Busse R, Panteli D, Quentin W. An introduction to healthcare quality: defining and explaining  
31 its role in health systems. In: Busse R, Klazinga N, Panteli D, Quentin W, editors. *Improving*  
32 *healthcare quality in Europe: Characteristics, effectiveness and implementation of different*  
33 *strategies* [Internet]. Health Pol. Copenhagen (Denmark): European Observatory on Health  
34 Systems and Policies; 2019. Available from:  
35 <https://www.ncbi.nlm.nih.gov/books/NBK549277/>  
36  
37  
38  
39  
40  
41  
42  
43
- 44 46. Hong QN, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, et al. The Mixed  
45 Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers.  
46 *Educ Inf*. 2018;34:285–91.  
47  
48  
49  
50  
51
- 52 47. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al. Guidance on the conduct  
53 of narrative synthesis in systematic reviews. A Prod from ESRC methods Program Version.  
54 2006;1:b92.  
55  
56  
57  
58
- 59 48. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic  
60

1  
2  
3 reviews. BMC Med Res Methodol. 2008;8(45).  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

## 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	Page in text
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	15
Sponsor	5b	Provide name for the review funder and/or sponsor	15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	15
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-9 Table 1
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	11-12
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits such that it could be repeated	11-12 Table 2

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently in duplicate), any processes for obtaining and confirming data from investigators	13
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	13
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	13-14
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	14-15
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I <sup>2</sup> and Kendall's $\tau$ )	14-15
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14-15
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	14-15
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	n/a

**\* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (date 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.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

# BMJ Open

## Clinical Ethics Support Services in Paediatric Practice: Protocol for a mixed studies systematic review on structures, interventions and outcomes.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-057867.R1
Article Type:	Protocol
Date Submitted by the Author:	07-Dec-2021
Complete List of Authors:	Dittborn, Mariana; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre ; Universidad del Desarrollo, Centro de Bioética Portales, Bernardita; Universidad del Desarrollo, Centro de Bioética Brierley, Joe; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre
<b>Primary Subject Heading</b>:	Ethics
Secondary Subject Heading:	Paediatrics
Keywords:	PAEDIATRICS, MEDICAL ETHICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts

1

**TITLE**

**Clinical Ethics Support Services in Paediatric Practice: Protocol for a mixed studies systematic review on structures, interventions and outcomes.**

**AUTHORS**

Mariana Dittborn<sup>1,2</sup>, Bernardita Portales<sup>2</sup>, Joe Brierley<sup>1</sup>

<sup>1</sup>Paediatric Bioethics Centre, Great Ormond Street Hospital, London, UK

<sup>2</sup>Centro de Bioética, Facultad de Medicina, Clínica Alemana - Universidad del Desarrollo, Santiago, Chile

**CORRESPONDING AUTHOR**

Mariana Dittborn

Postal Address: Great Ormond Street Hospital, London WC1N 3JH

Email: [mariana.dittborn@gosh.nhs.uk](mailto:mariana.dittborn@gosh.nhs.uk)

**WORD COUNT** 3505

**KEY WORDS**

Paediatrics, Clinical Ethics Committees, Clinical Ethics, Quality Indicators, Systematic Review

2

**ABSTRACT**

**Introduction:** Clinical Ethics Support Services (CESS) have been developing worldwide with growing interest in evaluating their quality. Paediatric-specific CESSs (p-CESS) have received little attention, and evidence from adult services might not be generalisable. Evidence on service models and practices is crucial to inform further research and debate on quality evaluation and minimum standards for p-CESSs. We aim to systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and outcomes.

**Methods and analysis:** We will conduct a mixed-studies systematic review including peer-reviewed empirical studies published in English or Spanish language providing data on the evaluation and/or impact on any aspect of p-CESS. We will search seven electronic databases: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHALL, without filters applied. Search terms will be related to "clinical ethics support" AND "paediatrics" AND "structure/process/outcome". Reference and citation list of included studies will be hand-searched. A 10% random sample of retrieved titles/abstracts and all full texts will be independently dual-screened. We will conduct narrative and thematic synthesis for quantitative and qualitative data, respectively, following sequential explanatory synthesis guided by Donabedian's framework of structure, process and outcomes. Quality will be assessed using the Mixed-Methods Appraisal Tool (2018). The review will be reported using the adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for reporting systematic reviews of qualitative and quantitative evidence template. Stakeholders will be involved twice in the review process; prior to data extraction and synthesis and after preliminary results.

**Ethics and dissemination:** As a systematic review of published data, no ethical approval is necessary. Results will be published in a relevant academic peer-reviewed journal.

**Registration:** The protocol has been prospectively registered in PROSPERO (CRD42021280978)

**STRENGTHS AND LIMITATIONS OF THIS STUDY**

- We will conduct an electronic search using a wide range of electronic databases, including a Latin American database, which will broaden the coverage of publication countries.
- The use of the Donabedian framework will allow an objective assessment of the CESS contribution to the quality of medical care.
- The review will be conducted by a bilingual and international research team, contributing different experiences and perspectives on CESS structures, processes, and outcomes in different contexts (Latin America and the UK).
- However, only English and Spanish language studies will be included with the consequent potential exclusion of relevant articles and associated bias.

4

## INTRODUCTION

Clinical ethics support is the provision of support and advice to health professionals, patients and families on ethical issues arising from clinical practice or patient care.(1–3) Accordingly, Clinical Ethics Support Services (CESS) are institutionalised forms of ethics support within healthcare organisations.(2)

CESS were initially developed in the USA in 1970-80 in response to government and medical societies' recommendations,(4) and has since spread progressively worldwide, but in an uneven and very varied way.(1,5–7) Forms of, and access to, CESS varies across different centres, countries, and cultural contexts.(6,8) In some countries, the constitution of institutional CESS is recommended or required by the government and subject to official regulation, while in others, such as the UK, the organisation and function of these services lack official guidance.(1)

Traditionally, four main CESS functions have been described; clinical case consultation, education, institutional policy development, and research.(3,9) Multiple models of CESS have been described, including individual ethical case consultation, clinical ethics committees, individual ethicists, moral case deliberation, ethics rounds and ethics discussion forums.(1,10–12) Informal provision of clinical ethics support has also been reported.(10)

Unlike Research Ethics Committees (REC), CESS have been criticised for lack of standardisation, an absence of regulation of their structures, skill requirements, role and remit and the paucity of formal evaluation of their impact.(13)

Even though there has always been an awareness of the need for systematic evaluation of CESS outcomes and effectiveness,(14–16) and there is a growing body of theoretical and empirical literature addressing CESS' evaluation, there remain no agreed standards or quality indicators for these services.(17–19)

5

1  
2  
3 Considering that CESS are, by definition, engaged in complex interventions where multiple  
4 components and interactions impact the final outcome,(2) a clear understanding of how they function  
5 is vital, before attempting any evaluation.(2) Schildmann et al. defined the evaluation of CESS as “the  
6 systematic gathering of data with empirical research methods for the purpose of acquiring knowledge  
7 about the structure, functioning, quality and results of CESS”.(p681, 20) Following this definition, in  
8 line with the widely used Donabedian model for evaluating the quality of medical care,(21) a  
9 comprehensive evaluation of the quality of CESS should include three dimensions of care: structure,  
10 process and outcomes.(2,21,22) As described by Donabedian, quality measurement standards derive  
11 from both empirical and normative sources.(21) Considering CESS have an explicit normative  
12 character, identifying appropriate quality criteria is particularly complicated, and this normative  
13 feature should be reflected when defining assessment measures.(23) Widely used outcome measures  
14 such as length of stay, mortality, or financial impact are not be necessarily helpful in evaluating  
15 CESS.(22) For example, any evaluation of ethics consultation services focused on pre-established  
16 outcome measures should not ignore the consultation’s central aim of responding to the ethical  
17 queries presented by those requesting support with a particular clinical case. Therefore, an  
18 appropriate evaluation system must allow for the context and particularities of each case to be  
19 considered.(24) Additionally, CESS evaluation should involve all stakeholders, including both those  
20 who receive and those who provide ethics support (i.e., healthcare professionals, patients and  
21 relatives, CESS members, hospital management).(25)

22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46 Paediatric practice raises particular ethical challenges not frequently found in adult patient care.(26–  
47 29) The fundamental principle of respect for patient autonomy has a substantially different  
48 understanding in paediatric practice, with parents taking the responsibility of decision-making until  
49 children are afforded that possibility.(26) Generally, parents’ decisions are in coherence with the  
50 child’s views and the child’s best interest, but conflict might arise when those involved (clinical team,  
51 parents, child) hold different views. Additionally, the child’s capacity to understand the information  
52 provided and contribute to, or even make decisions about their care will depend on their age,  
53  
54  
55  
56  
57  
58  
59  
60

6

1  
2  
3 maturity, and the presence of chronic health conditions, physical disabilities and neurodevelopmental  
4 disorders. The United Nations Convention on the rights of the Child (UNCRC) designates a duty to  
5 actively involve children in decision-making on matters that concern them, including their health and  
6 care.<sup>(30)</sup> Thus, regardless of the condition, children must always be involved in the decision-making  
7 process with a careful assessment of the child's competence needs to be made, particularly for  
8 decisions with moral significance.<sup>(26)</sup>  
9

10  
11 The paediatric landscape has changed with technological advances, lower mortality rates in many  
12 specialities and an increasing number of patients with chronic and complex conditions. Uncertainties  
13 about prognostication and treatment outcomes, overall benefits and burdens pose ethical challenges  
14 about withholding and withdrawing life-sustaining treatments.<sup>(31)</sup> The involvement of multiple teams  
15 with different perspectives and values might add further complexity to the decision-making  
16 process.<sup>(29)</sup> Finally, these significant technological advances and decreasing mortality rates might  
17 strengthen the perception of death, particularly in children, as a medical failure adding barriers to end  
18 of life discussions and decision-making.  
19

20  
21 Despite ethically challenging situations and consequent divergent opinions being common in  
22 paediatrics, the number of paediatric ethics consultations is relatively low.<sup>(32)</sup> Many of these  
23 challenges might be opportunely identified and appropriately managed by the healthcare team and  
24 the family,<sup>(33)</sup> with clinicians receiving support through alternatives to formal ethics consultation.<sup>(32)</sup>  
25 However, in complex cases, there may either be an impasse or conflict might persist. In these  
26 situations, ethical consultation has been shown to help provide a resolution.<sup>(34)</sup> Recent controversial  
27 cases featured extensively in both print, and social media have increased international public and  
28 academic attention to the ethical challenges of paediatric practice. There has been an increased  
29 interest and debate surrounding the legal and ethical aspects of paediatric practice, such as parental  
30 and clinical teams' disagreements about the child's best interests, emerging child capacity, innovative  
31 treatments, technological dependence and end-of-life decision-making. Consultant paediatricians,  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

7

1  
2  
3 trainees and residents have expressed concerns that these public cases might negatively impact their  
4 relationship with patients and families.(35) Availability of clinical ethics support services for teams  
5 facing ethical challenges has been strongly advocated by professional bodies,(31) academics(33,36,37)  
6 and clinicians.(35,38) However, there are no standards or guidance on p-CESS structure, functions and  
7 aims. Nor is the, for example, agreement on the level of involvement of patients and parents in ethics  
8 discussions, being this a particularly controversial matter in paediatric setting.(39)  
9

10 Interest in assessing CESS quality and effectiveness has grown in the past decades. However, most  
11 studies have focused on adult care settings, with relatively little attention paid to p-CESS.(40) Multiple  
12 systematic reviews evaluating different aspects of CESS have recently been published. Nevertheless,  
13 these focus on adult patients; ethical case intervention,(41) adult end of life context,(42) and adult  
14 ICU.(43) Other reviews that did not explicitly focused on adult patients evaluate a specific intervention  
15 (assessment tools for evaluating clinical ethics consultation(17)) or effectiveness of clinical ethics  
16 committees.(18) Generalisation of adult-focused reviews and evidence to paediatric context might  
17 not be appropriate. Although many CESSs will support both adult and paediatric patients, their families  
18 and clinical teams, it is likely that, together with the increasing number and complexities of children  
19 hospitals around the globe,(44) many CESS will serve patients and staff of paediatric healthcare  
20 institutions.(45) Moreover, there might be a value in accumulating knowledge and expertise in an  
21 increasingly complex paediatric field. Thus, a better understanding on current models of paediatric  
22 specific CESS will inform further development and research to contribute to the provision of optimal  
23 care for paediatric patients and their families. To our knowledge, no systematic review on Paediatric  
24 Clinical Ethics Support Services (p-CESS) structures, processes, evaluation measures and outcomes has  
25 been published. Such a review is necessary to inform current p-CESS practice and further  
26 development. Therefore, we aim to inform further research and debate on the current quality  
27 evaluation and minimum standards for p-CESS by offering a comprehensive description of current p-  
28 CESS models and assessments by responding to this review question:  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

8

1  
2  
3 ***“What is the range of structures, processes, and outcome measures of paediatric CESS***  
4 ***reported in the literature?”***  
5  
6  
7

8 **Aim:**  
9

10  
11 To systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and  
12  
13 outcome measures described in the literature.  
14

15  
16 **Objectives:**  
17

- 18  
19 • To identify and synthesise published data on p-CESS regarding their structures, processes,  
20  
21 evaluation measures and outcomes.  
22  
23 • To explore the impact of p-CESS given the outcomes identified in the review.  
24  
25 • To qualitatively appraise the available evidence.  
26  
27 • To develop a preliminary framework for the evaluation of p-CESS based on available evidence.  
28  
29 • To provide recommendations for further research on CESS effectiveness and outcome measures in  
30  
31 paediatric practice.  
32  
33  
34  
35

36 **METHODS AND ANALYSIS**  
37

38  
39 We will conduct a mixed studies systematic review to identify and synthesise evidence for Paediatric  
40  
41 CESS structures, interventions, evaluation measures and outcomes. By integrating studies with diverse  
42  
43 research methods, a mixed studies systematic review allows the compensation for the limitations of  
44  
45 qualitative and quantitative evidence and a better the understanding of the complexities of p-  
46  
47 CESS.(46) The review will be reported following the adapted PRISMA for reporting systematic reviews  
48  
49 of qualitative and quantitative evidence template,(47) as recommended by Pluye et al.(48)  
50  
51

52  
53 The review protocol has been developed following the recommended items included in the PRISMA-  
54  
55 P statement(49) and has been prospectively registered in PROSPERO registry CRD42021280978.(50)  
56  
57

58 **Eligibility Criteria**  
59  
60

9

The inclusion and exclusion criteria are summarised in Table 1. The review will include peer-review empirical studies (qualitative, quantitative or mixed-methods), including case studies published in English or Spanish language which provide empirical data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value)(11) of any one or more of the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, and outcome measures of p-CESS. We will include empirical studies of qualitative, quantitative or mixed-methods design reporting both objective and/or subjective measures.

We will include studies reporting on CESS that provide services to adult and paediatric patients only if paediatric data can be extracted separately.

Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces, book chapters will be excluded. Conference abstracts will not be included, but authors will be contacted asking whether the relevant work has been published, with a two-week timeframe allowed for a response. There will be no timeframe or geographical restrictions.

Table 1. Eligibility Criteria

	INCLUSION CRITERIA	EXCLUSION CRITERIA
Type of participants	CESSs that serve paediatric only or paediatric and adult population, where paediatric data can be extracted separately.	CESSs that serve only adult patients.  CESSs serving paediatric and adult populations, where paediatric data cannot be extracted and analysed

	<p>The paediatric population will be defined in this review as between 0-18 years old.</p> <p>Study participants include, but are not limited to, referring clinicians, CESS members, patients/children, parents/relatives/careers and hospital administrators.</p>	
Context/ setting	Articles reporting on established CESS serving paediatric practice in any setting (hospital, community) and country.	Research ethics committees
Issues	<p>Empirical studies reporting data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value) of any one or more of, but not limited to the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, outcome measures of paediatric CESS.</p>	<p>Theoretical analysis or narrative reviews on paediatric CESS.</p> <p>Studies focusing only on a description of the paediatric CESS without reporting assessment/impact data</p>

Methods	Empirical studies of any methods (qualitative and/or quantitative), including case studies.	Theoretical reviews or analysis. Systematic reviews Case reports, narrative reviews.
Timeframe	Any time frame. Searches will be conducted from the database inception date until the search date.	
Type of publication	Peer-reviewed publications in English or Spanish Language	Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces Conference abstracts
<i>CESS: Clinical Ethics Support Services</i>		

### Search strategy

Electronic searches. The following databases will be searched: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHALL. There will be no methodological, language, geographical or time filters applied to the search strategy. If a non-English paper is considered eligible for inclusion, relevant data and results will be translated to English before analysis.

The initial search strategy was developed considering previously published systematic reviews in paediatrics, clinical ethics and service evaluation. Search terms will be related to "Clinical ethics support", "paediatrics" AND "structure/process/outcome indicators" and adapted to each database requirement. Publications that would match the criteria for inclusion in the review previously known to the research team were successfully retrieved applying the search strategy in Medline online

12

database. Please see Table 2 for Medline search strategy and refer to Supplementary file 1 for complete search strategy for all included databases). The search strategy for all other databases is provided in Supplementary File 1.

Table 2. Medline search strategy

1. paediatric.mp.	27. Ethicists/ or ethicist*.mp.	57. structure.mp.
2. paediatr*.mp.	28. bioethicist*.mp.	58. model*.mp.
3. pediatric.mp. or Pediatrics/	29. medical ethics.mp. or Ethics, Medical/	59. process*.mp.
4. pediater*.mp.	30. clinical ethics.mp. or Ethics, Clinical/	60. intervention*.mp.
5. child*.mp. or Child/	31. clinical ethics committee.mp. or Ethics Committees, Clinical/	61. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or assessment*.mp.
6. Adolescent/ or adolescent.mp.	32. bioethics.mp. or Bioethics/	62. evaluation*.mp.
7. adolesc*.mp.	33. bioethical issues.mp. or Bioethical Issues/	63. impact*.mp.
8. infant*.mp.	34. ethical issues.mp. or Ethics/	64. effectiveness.mp.
9. infant.mp. or Infant/	35. ethical challenges.mp	65. Medical Audit/ or Clinical Audit/ or audit.mp.
10. kid.mp.	36. moral review.mp.	66. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or outcome.mp.
11. kids.mp.	37. Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.	67. "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/
12. baby.mp.	38. moral case consult*.mp.	68. indicator*.mp.
13. babies.mp.	39. moral consult*.mp.	
14. toddler*.mp.	40. ethic* case review.mp. or Ethics Committees/	
15. childhood.mp.	41. ethic* deliberation.mp.	
16. juvenil*.mp.	42. ethic* intervention.mp.	
17. youth*.mp.	43. ethic* round.mp.	
18. minor.mp. or Minors/	44. ethic* support.mp.	
19. Infant, Newborn/ or infancy.mp. or Child, Preschool/	45. ethic* service.mp.	
20. Infant, Newborn/ or newborn*.mp.	46. Ethical Analysis/ or ethic* analysis.mp.	
21. Premature Birth/ or Infant, Premature/ or preterm*.mp.	47. ethic* referral.mp.	
22. prematur*.mp.	48. Ethics Committees/ or ethic* committee.mp.	
23. Puberty/ or pubert*.mp.	49. bioethic* deliberation.mp.	
24. pubescen*.mp.	50. bioethic* intervention.mp.	
25. young person.mp.	51. bioethic* round.mp.	
26. neonatal.mp.	52. bioethic* service.mp.	
	53. bioethic* support.mp.	
	54. bioethic* analysis.mp.	
	55. bioethic* referral.mp.	
	56. bioethic* committee.mp.	

69. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
70. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57
71. 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70
72. 69 AND 70 AND 71

Other resources. Reference and citation list of included studies will be hand-searched. When relevant, we will contact the authors of conference abstracts identified through the search for peer-review publications. We will allow a time frame of two weeks for a response before considering the publication unavailable.

#### **Selection process.**

All retrieved records will be managed using Refworks® reference manager software. After deduplication, a random sample of 10% will be independently screened by MD and BP to test the reliability of the criteria. Any disagreements will be discussed within the research team until agreement, and, if required, eligibility criteria will be adjusted and/or clarified to improve the consistency of the screening process. Thereafter, all titles and/or abstracts will be screened by MD to identify publications that meet the previously established inclusion and exclusion criteria... References selected for assessment in the full text will be independently dual-assessed by MD and BP against inclusion/exclusion criteria, and any disagreements will be discussed within the research team until agreement. Reasons for excluding articles after full-text assessment will be recorded and study references and reasons for exclusion will be provided as a supplementary file. A Cohen's Kappa score over 90% will be required at both, the title/abstract and full text screening processes. The screening process will be presented as a PRISMA flowchart.

#### **Data extraction.**

14

1  
2  
3 Data from individual studies considered relevant for the review question will be extracted to a pre-  
4 piloted Excel data extraction form by MD and checked by BP. Disagreements will be discussed within  
5 the research team. Data entries will include: Publication details (First author, year of publication, title),  
6 setting (country, healthcare setting), study aims, study design, sampling method and sample  
7 description. Primary outcomes sought in the data set will include; (i) assessed aspects of paediatric  
8 CESS as reported by study authors, including service structures, processes and outcomes (i.e.,  
9 membership, service's activities, referrers, cases, contexts and reasons for referrals); (ii) assessed  
10 dimensions (i.e., effectiveness, safety and responsiveness) and/or subdimensions of quality of  
11 care(51) as reported by study authors; and (iii) methods and instruments used in the assessment. For  
12 qualitative studies, all data within the results/finding section will be considered as results.  
13 Characteristics of included studies will be tabulated and presented in a Table.

### 34 **Quality assessment.**

35  
36  
37 Following our initial literature review, we expect to find around 10-30 potentially eligible studies with  
38 multiple research designs, including qualitative, quantitative and mixed methods. To allow coherent  
39 and systematic critical appraisal of included studies with different designs, we will use the 2018 Mixed  
40 Methods Appraisal Tool.(52) The tool was developed specifically for the appraisal of complex  
41 systematic reviews that include empirical qualitative, quantitative and mixed methods studies. It  
42 includes specific criteria depending on the study design category. Each criterion is rated as "yes", "no",  
43 "can't tell" response. As recommended by the authors, for each study, we will present a detailed  
44 description of the rating of each criterion and calculate an overall quality score based on the number  
45 of quality criteria met. There is no recommended cut off score to exclude studies based on quality  
46 appraisal, and therefore no study will be excluded based on that criterion. Instead, we will conduct a  
47 sensitivity analysis during the data synthesis process to assess the impact of low-quality studies in the  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

15

1  
2  
3 review findings and adjust recommendations accordingly.(52) Quality appraisal will be conducted by  
4  
5 MD and checked by BP.  
6  
7  
8  
9

### 10 11 **Data synthesis** 12

13  
14 This systematic review is not focused only on the effectiveness of a particular intervention but  
15  
16 addresses a broader range of questions. Data synthesis will follow a sequential explanatory synthesis  
17  
18 following the two-step process described by Pluye and Hong:(46) First, a quantitative synthesis  
19  
20 including results from quantitative studies and quantitative data from mixed-methods studies,  
21  
22 followed by qualitative synthesis of results of qualitative studies and qualitative data form mixed-  
23  
24 methods studies. The qualitative synthesis will be informed by the previously conducted quantitative  
25  
26 synthesis. The integration of the qualitative synthesis into the quantitative one will allow a better  
27  
28 understanding of the quantitative results,(46) also highlighting convergences and divergences  
29  
30 between quantitative and qualitative synthesis to inform future research-  
31  
32  
33

34  
35 As we expect to find great diversity of outcome measures, quantitative data will be synthesised and  
36  
37 tabulated using descriptive statistics where appropriate(53) guided by but not limited to  
38  
39 Donabedian's framework of structure, process and outcomes. For qualitative data, we will conduct  
40  
41 thematic synthesis approach,(54) using NVivo software for qualitative data analysis. The thematic  
42  
43 synthesis will include: (i) Free line-by-line coding of the primary study's findings, (ii) organisation of  
44  
45 these codes into related themes informed by the quantitative synthesis.(54) If the qualitative synthesis  
46  
47 process develops additional themes that are not described in the quantitative synthesis, these will be  
48  
49 included in the integrated synthesis as qualitative results only. To assess the robustness of the  
50  
51 synthesis we will considering individual studies' quality and conduct sensitivity analysis if possible.  
52  
53  
54

55  
56 The synthesis will be conducted by MD and checked by BP. The final synthesis will be discussed within  
57  
58 the research team.  
59  
60

## Timeline

The protocol for this review is published in PROSPERO (date 27 September 2021).(50) Searches on the databases mentioned in the protocol were conducted in August 2021. Retrieved references were screened at title and abstract level during September-October 2021. Screening at full text level is planned for December 2021 – January 2022. We plan to proceed with further stages of the review, including stakeholder involvement, and data extraction and synthesis after the protocol is accepted for publication following the peer-review process. Data extraction and analysis are expected to take 6 months after study selection.

## Patient and public Involvement.

Patients and the public were not involved in the design of this systematic review protocol, but will be involved further at two stages in the process of the research, to ensure the review outcomes are useful and relevant.(55,56) Following Cochrane good practice guidance for people involvement in systematic reviews,(55) we sought to involve views of diverse stakeholders. Since p-CESS are established within healthcare institutions, and provide support to clinicians and patients and their families in making ethically challenging decision, we defined four stakeholders' categories whose collaboration would be valuable to the research process; (i) institutional managers, (ii) p-CESS board members, (iii) clinicians and (iv) parents. We will establish two advisory groups, one Chilean and one UK-based, with one representative for each stakeholder category. We will invite representatives that are already known to the research team to join the advisory group and participate in two one-hour workshops, one before data extraction and synthesis and a second one after preliminary results. Parents' representatives will be or have been previously involved as parent representative in a p-CESS. In the first webinar, participants will be asked to share their views, thoughts, opinions or experiences to

17

1  
2  
3 ensure we will be looking for the appropriate data in the included studies. At the second webinar,  
4 participants will have the opportunity to provide their feedback on the preliminary findings, to add  
5 context and meaning to the findings, contributing to the overall interpretation and recommendations.  
6  
7 Stakeholder involvement will be reported following the GRIPP (Guidance for Reporting Involvement  
8 of Patients and Public) checklist.(44)  
9  
10  
11  
12  
13

### 14 **Ethics and dissemination.**

15  
16  
17 As a systematic review of published data, no ethical approval is necessary. Following Cochrane  
18 guidance,(55) ethical approval for stakeholder involvement in this review would not be required as  
19 workshops would not be audio-recorded and no vulnerable groups will participate.  
20  
21  
22  
23  
24

25 We will present and discuss our findings in an open-access webinar, inviting a broad range of  
26 stakeholders to attend, including hospital managers, clinicians, academic ethicists, and patient  
27 representatives. A final report will be published in a relevant academic peer-reviewed journal.  
28  
29  
30

31 We plan to continue this research by conducting a modified Delphi study based on our review results  
32 to further explore the most appropriate quality indicators for evaluating p-CESS.  
33  
34  
35  
36  
37

### 38 **DISCUSSION**

39  
40 Interest in assessing CESS quality and effectiveness has grown in the past decades, with little attention  
41 paid to p-CESS. The results of this work will provide us with the first systematic review of evidence on  
42 Paediatric Clinical Ethics Support Services.  
43  
44  
45  
46  
47

48 The review team is comprised by a bilingual and international research team that includes a Paediatric  
49 Intensivist Consultant with vast experience in paediatric medical ethics leading the teaching, research  
50 and clinical activities of the p-CESS at a large tertiary children's hospital; a speech therapist, certified  
51 clinical ethics consultant and PhD student in CESSs evaluation and a medical doctor and ethicist with  
52 experience in systematic reviews and ethics research. The researchers' diverse backgrounds will  
53 contribute with their experiences and perspectives on CESS structures, processes, and outcomes in  
54  
55  
56  
57  
58  
59  
60

18

1  
2  
3 different contexts (Latin America and the UK). This will also allow a more comprehensive review both,  
4  
5 by searching a Latin American specific database and the inclusion papers published in English and  
6  
7 Spanish languages. This will enhance the review comprehensiveness, as long as potential bias is given  
8  
9 due consideration in the result interpretation and recommendation development stages. Evidence on  
10  
11 the effect of English-restricted criteria in traditional systematic reviews of randomised controlled trials  
12  
13 with meta-analyses has not shown to result in significant bias.(57,58). However, this review on p-CESS  
14  
15 structures, processes and outcomes will include a broader range of study designs and therefore  
16  
17 potential bias associated with the exclusion of studies published in languages other than English and  
18  
19 Spanish will be considered in the interpretation of results and recommendations.  
20  
21  
22

23  
24 The inclusion of peer-reviewed publications only might result in the omission of relevant publications  
25  
26 (i.e., CESS terms of references and/or reports published in institutional websites). However, focusing  
27  
28 on peer-reviewed publications will ensure validity of data included in the synthesis and also warrant  
29  
30 a balance between the amount of data and the capacity of the research team, without compromising  
31  
32 the review results. Moreover, we aim at mitigating the potential exclusion of relevant data by  
33  
34 including case reports and case studies. The use of the Donabedian model will allow a structured and  
35  
36 objective assessment of p-CESS contribution to patients' care. This is a well-accepted and widely used  
37  
38 framework. However, considering the normative nature of CESS and their interventions and  
39  
40 outcomes, the framework will be used as a guide and adaptation is expected.  
41  
42  
43

44  
45 We hope that our review results will allow for a better understanding of p-CESS structures, processes,  
46  
47 and outcomes, contributing to further research exploring the normative and empirical basis of p-CESS.  
48  
49  
50

51  
52  
53  
54  
55 **Author contributions:** MD and JB conceived the review. MD, JB and BP developed the protocol. All  
56  
57 authors revised and edited the manuscript and approved the final version.  
58  
59  
60

19

**Funding:** This work was supported by the Institute of Medical Ethics “Research in Medical Ethics” grant (No grant number). The funder has had no involvement in the review protocol development.

**Competing interests:** None to declare.

## REFERENCES

1. Slowther A, Johnston C, Goodall J, Hope T. Development of clinical ethics committees. *BMJ*. 2004 Apr 17;328(7445):950–2.
2. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Do we understand the intervention? What complex intervention research can teach us for the evaluation of clinical ethics support services (CESS). *BMC Med Ethics*. 2019;20(1):48.
3. Machin LL, Wilkinson M. Making the (Business) Case for Clinical Ethics Support in the UK. *HEC Forum*. 2020;
4. Courtwright A, Jurchak M. The Evolution of American Hospital Ethics Committees: A Systematic Review. *J Clin Ethics*. 2016;27(4):322–40.
5. Moodley K, Kabanda SM, Soldaat L, Kleinsmidt A, Obasa AE, Kling S. Clinical Ethics Committees in Africa: lost in the shadow of RECs/IRBs? *BMC Med Ethics*. 2020 Nov;21(1):115.
6. Orzechowski M, Schochow M, Steger F. Clinical Ethics Consultation in the Transition Countries of Central and Eastern Europe. *Sci Eng Ethics*. 2020 Apr;26(2):833–50.
7. Hajibabae F, Joolae S, Cheraghi MA, Salari P, Rodney P. Hospital/clinical ethics committees’ notion: an overview. *J Med ethics Hist Med*. 2016 Dec 18;9:17.
8. Slowther A, Bunch C, Woolnough B, Hope T. Clinical ethics support services in the UK: an investigation of the current provision of ethics support to health professionals in the UK. *J Med Ethics*. 2001 Apr 1;27(suppl 1):i2 LP-i8.
9. Larcher V. Role of clinical ethics committees. *Arch Dis Child*. 1999 Aug;81(2):104–6.

20

10. Hurst SA, Reiter-Theil S, Perrier A, Forde R, Slowther A-M, Pegoraro R, et al. Physicians' access to ethics support services in four European countries. *Health Care Anal.* 2007 Dec;15(4):321–35.
11. Haan MM, van Gorp JLP, Naber SM, Groenewoud AS. Impact of moral case deliberation in healthcare settings: a literature review. *BMC Med Ethics.* 2018;19(1):85.
12. Rasool D, Skovdahl K, Gifford M, Kihlgren A. Clinical Ethics Support for Healthcare Personnel: An Integrative Literature Review. *HEC Forum.* 2017 Dec;29(4):313–46.
13. Gill AW, Saul P, McPhee J, Kerridge I. Acute clinical ethics consultation: the practicalities. *Med J Aust.* 2004 Aug 1;181(4):204–6.
14. Kilham H, Isaacs D, Kerridge I, Newson A. Rethinking Pediatric Ethics Consultations. *Am J Bioeth.* 2015 May 4;15(5):26–8.
15. Molewijk B, Slowther A, Schildmann J. The European Clinical Ethics Network ( ECEN ): the professional development of clinical ethics support in Europe and the importance of quality assessment through evaluation research. *Bioethica Forum.* 2016;9(2):86–9.
16. Slowther A-M, Hope T. Clinical ethics committees. *BMJ.* 2000 Sep 16;321(7262):649 LP – 650.
17. Yoon NYS, Ong YT, Yap HW, Tay KT, Lim EG, Cheong CWS, et al. Evaluating assessment tools of the quality of clinical ethics consultations: a systematic scoping review from 1992 to 2019. *BMC Med Ethics.* 2020 Jul 1;21(1):51.
18. Crico C, Sanchini V, Casali PG, Pravettoni G. Evaluating the effectiveness of clinical ethics committees: a systematic review. *Med Heal Care Philos.* 2021;24(1):135–51.
19. McClimans L, Pressgrove G, Campbell E. Objectives and outcomes of clinical ethics services: a Delphi study. *J Med Ethics.* 2019 Dec;45(12):761–9.
20. Schildmann J, Molewijk B, Benaroyo L, Forde R, Neitzke G. Evaluation of clinical ethics support

21

- 1  
2  
3 services and its normativity. *J Med Ethics*. 2013 Nov 1;39(11):681 LP – 685.  
4  
5  
6 21. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q*. 2005;83(4):691–729.  
7  
8  
9 22. Williamson L, McLean S, Connell J. CLINICAL ETHICS COMMITTEES IN THE UNITED KINGDOM:  
10 TOWARDS EVALUATION. *Med Law Int*. 2007 Feb 9;8(3):221–38.  
11  
12  
13  
14 23. Haltaufderheide J, Nadolny S, Vollmann J, Schildmann J. Framework for evaluation research  
15 on clinical ethical case interventions: the role of ethics consultants. *J Med Ethics*. 2021 May  
16 17;medethics-2020-107129.  
17  
18  
19  
20  
21 24. Craig JM, May T. Evaluating the outcomes of ethics consultation. *J Clin Ethics*.  
22 2006;17(2):168–80.  
23  
24  
25  
26 25. Metselaar S, Widdershoven G, Porz R, Molewijk B. Evaluating Clinical Ethics Support: A  
27 Participatory Approach. *Bioethics*. 2017 May;31(4):258–66.  
28  
29  
30  
31 26. Gold H, Hall G, Gillam L. Role and function of a paediatric clinical ethics service : Experiences  
32 at the Royal Children ’ s Hospital , Melbourne.  
33  
34  
35  
36 27. Larcher VF, Lask B, Mccarthy JM, Ormond G, Hospitalfor S. Paediatrics at the cutting edge : do  
37 we need clinical ethics committees ? 1997;245–9.  
38  
39  
40  
41 28. Buchanan CA, Bester JC, Bruno B, Delany C, Kennedy KO, Koogler T, et al. Pediatric Ethics  
42 Consultation: Practical Considerations for the Clinical Ethics Consultant. *J Clin Ethics*.  
43 2019;30(3):270–83.  
44  
45  
46  
47 29. Moynihan KM, Taylor L, Crowe L, Balnaves M-C, Irving H, Ozonoff A, et al. Ethical climate in  
48 contemporary paediatric intensive care. *J Med Ethics*. 2021 Jan;  
49  
50  
51  
52 30. United Nations General Assembly. Convention on the Rights of the Child. 1989.  
53  
54  
55  
56 31. Larcher V, Craig F, Bhogal K, Wilkinson D, Brierley J. Making decisions to limit treatment in  
57 life-limiting and life-threatening conditions in children: a framework for practice. *Arch Dis*  
58  
59  
60

22

- 1  
2  
3 Child. 2015 May 1;100(Suppl 2):s1 LP-s23.  
4  
5  
6 32. Carter B, Brockman M, Garrett J, Knackstedt A, Lantos J. Why Are There So Few Ethics  
7  
8 Consults in Children's Hospitals? HEC Forum. 2018 Jun;30(2):91–102.  
9  
10  
11 33. Linney M, Hain RDW, Wilkinson D, Fortune P-M, Barclay S, Larcher V, et al. Achieving  
12  
13 consensus advice for paediatricians and other health professionals: on prevention,  
14  
15 recognition and management of conflict in paediatric practice. Arch Dis Child. 2019  
16  
17 May;104(5):413–6.  
18  
19  
20 34. Brierley J, Petros A, Linthicum J. Should religious beliefs be allowed to stonewall a secular  
21  
22 approach to withdrawing and withholding treatment in children? J Med Ethics.  
23  
24 2013;39(9):573–7.  
25  
26  
27 35. Avula H, Dittborn M, Brierley J. 'Who Ya Gonna Call ...?' Ethical and legal dilemmas in  
28  
29 specialist children centres and district general hospitals. Clin Ethics. 2021 Aug  
30  
31 5;14777509211036648.  
32  
33  
34 36. Huxtable R. Clinic, courtroom or (specialist) committee: in the best interests of the critically ill  
35  
36 child? J Med Ethics. 2018 Jul 1;44(7):471 LP – 475.  
37  
38  
39 37. Wilkinson D, Savulescu J. Alfie Evans and Charlie Gard-should the law change? Vol. 361, BMJ  
40  
41 (Clinical research ed.). England; 2018. p. k1891.  
42  
43  
44 38. Archambault-Grenier M-A, Roy-Gagnon M-H, Gauvin F, Doucet H, Humbert N, Stojanovic S, et  
45  
46 al. Survey highlights the need for specific interventions to reduce frequent conflicts between  
47  
48 healthcare professionals providing paediatric end-of-life care. Acta Paediatr. 2018  
49  
50 Feb;107(2):262–9.  
51  
52  
53 39. Brierley J, Archard D, Cave E. Challenging misconceptions about clinical ethics support during  
54  
55 COVID-19 and beyond: a legal update and future considerations. J Med Ethics. 2021 Apr  
56  
57 21;medethics-2020-107092.  
58  
59  
60

23

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
40. McDougall RJ, Notini L. What kinds of cases do paediatricians refer to clinical ethics? Insights from 184 case referrals at an Australian paediatric hospital. *J Med Ethics*. 2016 Sep;42(9):586–91.
41. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Ethical case interventions for adult patients. *Cochrane Database Syst Rev*. 2019;(7).
42. Haltaufderheide J, Nadolny S, Gysels M, Bausewein C, Vollmann J, Schildmann J. Outcomes of clinical ethics support near the end of life: A systematic review. *Nurs Ethics*. 2019 Nov 19;27(3):838–54.
43. Au SS, Couillard P, Roze des Ordon A, Fiest KM, Lorenzetti DL, Jette N. Outcomes of Ethics Consultations in Adult ICUs: A Systematic Review and Meta-Analysis. *Crit Care Med*. 2018 May;46(5):799–808.
44. Casimir G. Why Children’s Hospitals Are Unique and So Essential . Vol. 7, *Frontiers in Pediatrics* . 2019. p. 305.
45. Brierley J, Cave E, Archard D. Ethical advice in paediatric care. *Arch Dis Child*. 2021 Nov;
46. Pluye P, Nha Hong Q. Combining the Power of Stories and the Power of Numbers: Mixed Methods Research and Mixed Studies Reviews. *Annu Rev Public Heal*. 2014;35:29–45.
47. Adapted PRISMA for reporting systematic reviews of qualitative and quantitative evidence [Internet]. Toolkit for Mixed Studies Reviews. Available from: [http://toolkit4mixedstudiesreviews.pbworks.com/w/page/66103031/Toolkit for Mixed Studies Reviews](http://toolkit4mixedstudiesreviews.pbworks.com/w/page/66103031/Toolkit%20for%20Mixed%20Studies%20Reviews)
48. Pluye P, Hong QN, Granikov V, Vedel I. The wiki toolkit for planning, conducting and reporting mixed studies reviews. *Educ Inf*. 2018;34:277–83.
49. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting

24

- 1  
2  
3 items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst*  
4  
5 *Rev.* 2015;4(1):1.  
6  
7
- 8 50. Dittborn M, Portales B, Brierley J. Clinical ethics support services in paediatric practice:  
9  
10 protocol for a mixed studies systematic review on structures, interventions and outcomes.  
11  
12 [Internet]. PROSPERO. 2021 [cited 2021 Nov 24]. p. CRD42021280978. Available from:  
13  
14 [https://www.crd.york.ac.uk/prospero/display\\_record.php?ID=CRD42021280978](https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021280978)  
15  
16  
17
- 18 51. Busse R, Panteli D, Quentin W. An introduction to healthcare quality: defining and explaining  
19  
20 its role in health systems. In: Busse R, Klazinga N, Panteli D, Quentin W, editors. *Improving*  
21  
22 *healthcare quality in Europe: Characteristics, effectiveness and implementation of different*  
23  
24 *strategies.* Health Pol. Copenhagen (Denmark): European Observatory on Health Systems and  
25  
26 *Policies; 2019.*  
27  
28  
29
- 30 52. Hong QN, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, et al. The Mixed  
31  
32 *Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers.*  
33  
34 *Educ Inf.* 2018;34:285–91.  
35  
36  
37
- 38 53. McKenzie J, Brennan S. Synthesizing and presenting findings using other methods. In: Higgins  
39  
40 J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. *Cochrane Handbook for*  
41  
42 *Systematic Reviews of Interventions version 62 (updated February 2021).* version 6.  
43  
44 *Cochrane; 2021.*  
45  
46  
47
- 48 54. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic  
49  
50 reviews. *BMC Med Res Methodol.* 2008;8(45).  
51  
52  
53
- 54 55. Cochrane Training. Involving people. A learning resource for systematic review authors  
55  
56 [Internet]. Available from: <https://training.cochrane.org/involving-people>  
57  
58  
59
- 60 56. Pollock A, Campbell P, Struthers C, Synnot A, Nunn J, Hill S, et al. Stakeholder involvement in  
systematic reviews: a protocol for a systematic review of methods, outcomes and effects. *Res*

25

1  
2  
3 Involv Engagem. 2017;3(1):9.  
4  
5

6 57. Moher D, Pham, Klassen TP, Schulz KF, Berlin JA, Jadad AR, et al. What contributions do  
7  
8 languages other than English make on the results of meta-analyses? J Clin Epidemiol.  
9  
10 2000;53(9):964–72.  
11

12  
13 58. Morrison A, Polisen J, Husereau D, Moulton K, Clark M, Fiander M, et al. The effect of  
14  
15 English-language restriction on systematic review-based meta-analyses: a systematic review  
16  
17 of empirical studies. Int J Technol Assess Health Care. 2012/04/26. 2012;28(2):138–44.  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Supplementary file 1. Complete search strategy for all databases

**Embase Classic+Embase**

- 1 paediatric.mp.
- 2 paediatr\*.mp.
- 3 pediatric.mp. or Pediatrics/
- 4 pediatr\*.mp.
- 5 child\*.mp. or Child/
- 6 Adolescent/ or adolescent.mp.
- 7 adolesc\*.mp.
- 8 infant\*.mp.
- 9 infant.mp. or Infant/
- 10 kid.mp.
- 11 kids.mp.
- 12 baby.mp.
- 13 babies.mp.
- 14 toddler\*.mp.
- 15 childhood.mp.
- 16 juvenil\*.mp.
- 17 youth\*.mp.
- 18 minor.mp. or Minors/
- 19 Infant, Newborn/ or infancy.mp. or Child, Preschool/
- 20 Infant, Newborn/ or newborn\*.mp.
- 21 Premature Birth/ or Infant, Premature/ or preterm\*.mp.
- 22 prematur\*.mp.
- 23 Puberty/ or pubert\*.mp.
- 24 pubescen\*.mp.
- 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or  
19 or 20 or 21 or 22 or 23 or 24
- 26 Ethicists/ or ethicist\*.mp.

- 1  
2  
3 27 bioethicist\*.mp.  
4  
5 28 medical ethics.mp. or Ethics, Medical/  
6  
7 29 clinical ethics.mp. or Ethics, Clinical/  
8  
9 30 clinical ethics committee.mp. or Ethics Committees, Clinical/  
10  
11 31 bioethics.mp. or Bioethics/  
12  
13 32 bioethical issues.mp. or Bioethical Issues/  
14  
15 33 ethical issues.mp. or Ethics/  
16  
17 34 ethical challenges.mp.  
18  
19 35 moral review.mp.  
20  
21 36 Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.  
22  
23 37 moral case consult\*.mp.  
24  
25 38 moral consult\*.mp.  
26  
27 39 ethic\* case review.mp. or Ethics Committees/  
28  
29 40 ethic\* deliberation.mp.  
30  
31 41 ethic\* intervention.mp.  
32  
33 42 ethic\* round.mp.  
34  
35 43 ethic\* support.mp.  
36  
37 44 ethic\* service.mp.  
38  
39 45 Ethical Analysis/ or ethic\* analysis.mp.  
40  
41 46 ethic\* referral.mp.  
42  
43 47 Ethics Committees/ or ethic\* committee.mp.  
44  
45 48 bioethic\* deliberation.mp.  
46  
47 49 bioethic\* intervention.mp.  
48  
49 50 bioethic\* round.mp.  
50  
51 51 bioethic\* service.mp.  
52  
53 52 bioethic\* support.mp.  
54  
55 53 bioethic\* analysis.mp.  
56  
57 54 bioethic\* referral.mp.  
58  
59 55 bioethic\* committee.mp.  
60  
56 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or  
42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55

- 1  
2  
3 57 young person.mp.  
4  
5 58 neonatal.mp.  
6  
7 59 25 or 57 or 58  
8  
9 60 structure.mp.  
10  
11 61 model\*.mp.  
12  
13 62 process\*.mp.  
14  
15 63 intervention\*.mp.  
16  
17 64 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
18 assessment\*.mp.  
19  
20 65 evaluation\*.mp.  
21  
22 66 impact\*.mp.  
23  
24 67 effectiveness.mp.  
25  
26 68 Medical Audit/ or Clinical Audit/ or audit.mp.  
27  
28 69 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
29 outcome.mp.  
30  
31 70 "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/  
32  
33 71 indicator\*.mp.  
34  
35 72 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71  
36  
37 73 56 and 59 and 72  
38  
39 74 from 73 keep 7001-7942  
40  
41 75 paediatric.mp. or pediatrics/  
42  
43 76 paediatr\*.mp.  
44  
45 77 pediatric.mp. or pediatrics/  
46  
47 78 pediatr\*.mp.  
48  
49 79 child/ or child\*.mp.  
50  
51 80 adolescent/ or adolescent.mp.  
52  
53 81 adolesc\*.mp.  
54  
55 82 infant\*.mp.  
56  
57 83 infant/ or infant.mp.  
58  
59 84 kid.mp.  
60  
85 kids.mp.  
86 baby.mp. or baby/

1  
2  
3 87 babies.mp.  
4  
5 88 toddler/ or toddler\*.mp.  
6  
7 89 childhood/ or childhood.mp.  
8  
9 90 juvenil\*.mp.  
10  
11 91 youth\*.mp.  
12  
13 92 minor.mp. or "minor (person)"/  
14  
15 93 minors.mp.  
16  
17 94 infancy/ or infancy.mp.  
18  
19 95 newborn/ or newborn\*.mp.  
20  
21 96 prematurity/ or preterm\*.mp.  
22  
23 97 prematur\*.mp.  
24  
25 98 puberty/ or pubert\*.mp.  
26  
27 99 pubescen\*.mp.  
28 100 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or  
29 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99  
30  
31 101 ethicist/ or ethicist\*.mp.  
32  
33 102 bioethicist\*.mp.  
34  
35 103 medical ethics.mp. or medical ethics/  
36  
37 104 clinical ethics.mp.  
38  
39 105 clinical ethics committee.mp.  
40  
41 106 bioethics.mp. or bioethics/  
42  
43 107 bioethic\*.mp.  
44  
45 108 bioethical issues.mp.  
46  
47 109 ethical issues.mp.  
48  
49 110 ethical challenges.mp.  
50  
51 111 moral review.mp.  
52  
53 112 moral case deliberation.mp.  
54  
55 113 moral case consult\*.mp.  
56  
57 114 moral consult\*.mp.  
58  
59 115 ethic\* case review.mp.  
60 116 ethic\* deliberation.mp.

- 1  
2  
3 117 ethic\* intervention.mp.  
4  
5 118 ethic\* round.mp.  
6  
7 119 ethic\* support.mp.  
8  
9 120 ethic\* service.mp.  
10  
11 121 ethic\* analysis.mp.  
12  
13 122 ethic\* referral.mp.  
14  
15 123 ethic\* committee.mp.  
16  
17 124 bioethic\* deliberation.mp.  
18  
19 125 bioethic\* intervention.mp.  
20  
21 126 bioethic\* round.mp.  
22  
23 127 bioethic\* service.mp.  
24  
25 128 bioethic\* support.mp.  
26  
27 129 bioethic\* analysis.mp.  
28  
29 130 bioethic\* referral.mp.  
30  
31 131 bioethic\* committee.mp.  
32  
33 132 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or  
34 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or  
35 128 or 129 or 130 or 131  
36  
37 133 young person.mp.  
38  
39 134 100 or 133  
40  
41 135 neonatal.mp.  
42  
43 136 134 or 135  
44  
45 137 structure.mp.  
46  
47 138 model\*.mp.  
48  
49 139 process\*.mp.  
50  
51 140 intervention.mp.  
52  
53 141 assessment\*.mp.  
54  
55 142 evaluation\*.mp.  
56  
57 143 impact\*.mp.  
58  
59 144 effectiveness.mp.  
60  
145 audit.mp. or clinical audit/  
146 outcome assessment/ or outcome.mp.

- 1  
2  
3 147 quality.mp. or quality assessment tool/  
4  
5 148 indicator\*.mp.  
6  
7 149 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148  
8  
9 150 132 and 136 and 149
- 

10  
11  
12  
13 **Ovid MEDLINE(R) ALL**  
14  
15

- 16 1 paediatric.mp.  
17 2 paediatr\*.mp.  
18 3 pediatric.mp. or Pediatrics/  
19 4 paediatr\*.mp.  
20 5 child\*.mp. or Child/  
21 6 Adolescent/ or adolescent.mp.  
22 7 adolesc\*.mp.  
23 8 infant\*.mp.  
24 9 infant.mp. or Infant/  
25 10 kid.mp.  
26 11 kids.mp.  
27 12 baby.mp.  
28 13 babies.mp.  
29 14 toddler\*.mp.  
30 15 childhood.mp.  
31 16 juvenil\*.mp.  
32 17 youth\*.mp.  
33 18 minor.mp. or Minors/  
34 19 Infant, Newborn/ or infancy.mp. or Child, Preschool/  
35 20 Infant, Newborn/ or newborn\*.mp.  
36 21 Premature Birth/ or Infant, Premature/ or preterm\*.mp.  
37 22 prematur\*.mp.  
38 23 Puberty/ or pubert\*.mp.  
39 24 pubescen\*.mp.  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or  
4 19 or 20 or 21 or 22 or 23 or 24  
5  
6 26 Ethicists/ or ethicist\*.mp.  
7  
8 27 bioethicist\*.mp.  
9  
10 28 medical ethics.mp. or Ethics, Medical/  
11  
12 29 clinical ethics.mp. or Ethics, Clinical/  
13  
14 30 clinical ethics committee.mp. or Ethics Committees, Clinical/  
15  
16 31 bioethics.mp. or Bioethics/  
17  
18 32 bioethical issues.mp. or Bioethical Issues/  
19  
20 33 ethical issues.mp. or Ethics/  
21  
22 34 ethical challenges.mp.  
23  
24 35 moral review.mp.  
25  
26 36 Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.  
27  
28 37 moral case consult\*.mp.  
29  
30 38 moral consult\*.mp.  
31  
32 39 ethic\* case review.mp. or Ethics Committees/  
33  
34 40 ethic\* deliberation.mp.  
35  
36 41 ethic\* intervention.mp.  
37  
38 42 ethic\* round.mp.  
39  
40 43 ethic\* support.mp.  
41  
42 44 ethic\* service.mp.  
43  
44 45 Ethical Analysis/ or ethic\* analysis.mp.  
45  
46 46 ethic\* referral.mp.  
47  
48 47 Ethics Committees/ or ethic\* committee.mp.  
49  
50 48 bioethic\* deliberation.mp.  
51  
52 49 bioethic\* intervention.mp.  
53  
54 50 bioethic\* round.mp.  
55  
56 51 bioethic\* service.mp.  
57  
58 52 bioethic\* support.mp.  
59  
60 53 bioethic\* analysis.mp.  
61  
62 54 bioethic\* referral.mp.

- 1  
2  
3 55 bioethic\* committee.mp.  
4  
5 56 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or  
6 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55  
7  
8 57 young person.mp.  
9  
10 58 neonatal.mp.  
11  
12 59 25 or 57 or 58  
13  
14 60 structure.mp.  
15  
16 61 model\*.mp.  
17  
18 62 process\*.mp.  
19  
20 63 intervention\*.mp.  
21  
22 64 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
23 assessment\*.mp.  
24  
25 65 evaluation\*.mp.  
26  
27 66 impact\*.mp.  
28  
29 67 effectiveness.mp.  
30  
31 68 Medical Audit/ or Clinical Audit/ or audit.mp.  
32  
33 69 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
34 outcome.mp.  
35  
36 70 "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/  
37  
38 71 indicator\*.mp.  
39  
40 72 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71  
41  
42 73 56 and 59 and 72  
43  
44 74 from 73 keep 7001-7942  
45
- 

## Philosopher's Index

Philosophy - journal articles, books, book chapters and book reviews

Subject Area(s): Social Sciences , History , The Arts

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR

"ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

### **APA PsycInfo®**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR "ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

### **VHL Lilacs**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR young person OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR clinical ethics OR clinical ethics committee OR bioethical issue\* OR ethical issue\* OR ethical challenge\* OR moral review OR moral case deliberation OR moral case consult\* OR moral consult\* OR ethic\* case review OR ethic\* deliberation OR ethic\* round OR ethic\* intervention OR ethic\* support OR ethic\* service OR ethic\* analysis OR ethic\* referral OR ethic\* committee OR bioethic\* deliberation OR bioethic\* intervention OR bioethic\* round OR bioethic\* service OR bioethic\* support OR bioethic\* analysis OR bioethic\* referral OR bioethic\* committee) AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*) AND ( db:("LILACS"))

---

### **Web of Science**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR "ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

1  
2  
3 **CINAHL (EBSCOhost Research Databases)**  
4

5 S10 S7 AND S8 AND S9

6  
7 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

8  
9 S9 S4 OR S5 OR S6

10  
11 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

12  
13 S8 S2 OR S3

14  
15 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

16 S7 structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR  
17 effectiveness OR audit OR outcome\* OR quality OR indicator\*

18  
19 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

20  
21 S6 ethic\* referral OR ethic\* committee OR bioethic\* deliberation OR bioethic\* intervention OR  
22 bioethic\* round OR bioethic\* service OR bioethic\* support OR bioethic\* analysis OR bioethic\*  
23 referral OR bioethic\* committee

24  
25 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

26  
27 S5 ethical challenge\* OR moral review OR moral case deliberation OR moral case consult\* OR moral  
28 consult\* OR ethic\* case review OR ethic\* deliberation OR ethic\* intervention OR ethic\* round OR  
29 ethic\* support OR ethic\* service OR ethic\* analysis

30  
31 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

32  
33 S4 ethicist\* OR bioethicist\* OR medical ethics OR clinical ethics OR clinical ethics committee OR  
34 bioethi\* OR bioethical issues OR ethical issues

35  
36 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

37  
38 S3 youth\* OR infancy OR newborn\* OR prematur\* OR pubert\* OR pubescen\* OR young person OR  
39 neonatal

40  
41 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

42  
43 S2 paediatr\* OR pediater\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR  
44 toddler\* OR juvenil\* OR minor\*

45  
46 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

47  
48 S1 paediatric

49  
50 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**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	Page in text
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 9
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	21
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	21
Sponsor	5b	Provide name for the review funder and/or sponsor	21
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	21
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9-10 Table 1
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	12-14
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	12 Table 2

			Supplementary file 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	14-15
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	14
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently in duplicate), any processes for obtaining and confirming data from investigators	14-15
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	14-15
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	15-16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	16-17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I <sup>2</sup> and Kendall's $\tau$ )	16-17
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	16-17
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	16-17
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	n/a

**\* 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.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

# BMJ Open

## Clinical Ethics Support Services in paediatric practice: protocol for a mixed studies systematic review on structures, interventions and outcomes

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-057867.R2
Article Type:	Protocol
Date Submitted by the Author:	19-Jan-2022
Complete List of Authors:	Dittborn, Mariana; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre ; Universidad del Desarrollo Facultad de Medicina, Centro de Bioética Portales, Bernardita; Universidad del Desarrollo, Centro de Bioética Brierley, Joe; Great Ormond Street Hospital for Children, Paediatric Bioethics Centre
<b>Primary Subject Heading</b>:	Ethics
Secondary Subject Heading:	Paediatrics
Keywords:	PAEDIATRICS, MEDICAL ETHICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts

1

**TITLE**

**Clinical Ethics Support Services in paediatric practice: protocol for a mixed studies systematic review  
on structures, interventions and outcomes**

**AUTHORS**

Mariana Dittborn<sup>1,2</sup>, Bernardita Portales<sup>2</sup>, Joe Brierley<sup>1</sup>

<sup>1</sup>Paediatric Bioethics Centre, Great Ormond Street Hospital, London, UK

<sup>2</sup>Centro de Bioética, Facultad de Medicina, Clínica Alemana - Universidad del Desarrollo, Santiago,  
Chile

**CORRESPONDING AUTHOR**

Mariana Dittborn

Postal Address: Great Ormond Street Hospital, London WC1N 3JH

Email: mariana.dittborn@gmail.com

**WORD COUNT** 3534

**KEY WORDS**

Paediatrics, Clinical Ethics Committees, Clinical Ethics, Quality Indicators, Systematic Review

2

**ABSTRACT**

**Introduction:** Clinical Ethics Support Services (CESS) have been developing worldwide with growing interest in evaluating their quality. Paediatric-specific CESSs (p-CESS) have received little attention, and evidence from adult services might not be generalisable. Evidence on service models and practices is crucial to inform further research and debate on quality evaluation and minimum standards for p-CESSs. We aim to systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and outcomes.

**Methods and analysis:** We will conduct a mixed-studies systematic review including peer-reviewed empirical studies published in English or Spanish language providing data on the evaluation and/or impact on any aspect of p-CESS. We will search seven electronic databases: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHALL, without filters applied. Search terms will be related to "clinical ethics support" AND "paediatrics" AND "structure/process/outcome". Reference and citation list of included studies will be hand-searched. A 10% random sample of retrieved titles/abstracts and all full texts will be independently dual-screened. We will conduct narrative and thematic synthesis for quantitative and qualitative data, respectively, following sequential explanatory synthesis guided by Donabedian's framework of structure, process and outcomes. Quality will be assessed using the Mixed-Methods Appraisal Tool (2018). The review will be reported using the adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for reporting systematic reviews of qualitative and quantitative evidence template. Stakeholders will be involved twice in the review process; prior to data extraction and synthesis and after preliminary results.

**Ethics and dissemination:** As a systematic review of published data, no ethical approval is necessary. Results will be published in a relevant academic peer-reviewed journal.

**Registration:** The protocol has been prospectively registered in PROSPERO (CRD42021280978)

**STRENGTHS AND LIMITATIONS OF THIS STUDY**

- We will conduct an electronic search using a wide range of electronic databases, including a Latin American database, which will broaden the coverage of publication countries.
- The use of the Donabedian framework will allow an objective assessment of the CESS contribution to the quality of medical care.
- The review will be conducted by a bilingual and international research team, contributing different experiences and perspectives on CESS structures, processes, and outcomes in different contexts (Latin America and the UK).
- However, only English and Spanish language studies will be included with the consequent potential exclusion of relevant articles and associated bias.

## INTRODUCTION

Clinical ethics support is the provision of support and advice to health professionals, patients and families on ethical issues arising from clinical practice or patient care.(1–3) Accordingly, Clinical Ethics Support Services (CESS) are institutionalised forms of ethics support within healthcare organisations.(2)

CESS were initially developed in the USA in 1970-80 in response to government and medical societies' recommendations,(4) and has since spread progressively worldwide, but in an uneven and very varied way.(1,5–7) Forms of, and access to, CESS varies across different centres, countries, and cultural contexts.(6,8) In some countries, the constitution of institutional CESS is recommended or required by the government and subject to official regulation, while in others, such as the UK, the organisation and function of these services lack official guidance.(1)

Traditionally, four main CESS functions have been described; clinical case consultation, education, institutional policy development, and research.(3,9) Multiple models of CESS have been described, including individual ethical case consultation, clinical ethics committees, individual ethicists, moral case deliberation, ethics rounds and ethics discussion forums.(1,10–12) Informal provision of clinical ethics support has also been reported.(10)

Unlike Research Ethics Committees (REC), CESS have been criticised for lack of standardisation, an absence of regulation of their structures, skill requirements, role and remit and the paucity of formal evaluation of their impact.(13)

Even though there has always been an awareness of the need for systematic evaluation of CESS outcomes and effectiveness,(14–16) and there is a growing body of theoretical and empirical literature addressing CESS' evaluation, there remain no agreed standards or quality indicators for these services.(17–19)

5

1  
2  
3 Considering that CESS are, by definition, engaged in complex interventions where multiple  
4 components and interactions impact the final outcome,(2) a clear understanding of how they function  
5 is vital, before attempting any evaluation.(2) Schildmann et al. defined the evaluation of CESS as “the  
6 systematic gathering of data with empirical research methods for the purpose of acquiring knowledge  
7 about the structure, functioning, quality and results of CESS”.(p681, 20) Following this definition, in  
8 line with the widely used Donabedian model for evaluating the quality of medical care,(21) a  
9 comprehensive evaluation of the quality of CESS should include three dimensions of care: structure,  
10 process and outcomes.(2,21,22) As described by Donabedian, quality measurement standards derive  
11 from both empirical and normative sources.(21) Considering CESS have an explicit normative  
12 character, identifying appropriate quality criteria is particularly complicated, and this normative  
13 feature should be reflected when defining assessment measures.(23) Widely used outcome measures  
14 such as length of stay, mortality, or financial impact are not be necessarily helpful in evaluating  
15 CESS.(22) For example, any evaluation of ethics consultation services focused on pre-established  
16 outcome measures should not ignore the consultation’s central aim of responding to the ethical  
17 queries presented by those requesting support with a particular clinical case. Therefore, an  
18 appropriate evaluation system must allow for the context and particularities of each case to be  
19 considered.(24) Additionally, CESS evaluation should involve all stakeholders, including both those  
20 who receive and those who provide ethics support (i.e., healthcare professionals, patients and  
21 relatives, CESS members, hospital management).(25)

22  
23  
24 Paediatric practice raises particular ethical challenges not frequently found in adult patient care.(26–  
25 29) The fundamental principle of respect for patient autonomy has a substantially different  
26 understanding in paediatric practice, with parents taking the responsibility of decision-making until  
27 children are afforded that possibility.(26) Generally, parents’ decisions are in coherence with the  
28 child’s views and the child’s best interest, but conflict might arise when those involved (clinical team,  
29 parents, child) hold different views. Additionally, the child’s capacity to understand the information  
30 provided and contribute to, or even make decisions about their care will depend on their age,  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

6

1  
2  
3 maturity, and the presence of chronic health conditions, physical disabilities and neurodevelopmental  
4 disorders. The United Nations Convention on the rights of the Child (UNCRC) designates a duty to  
5 actively involve children in decision-making on matters that concern them, including their health and  
6 care.<sup>(30)</sup> Thus, regardless of their health condition, children must always be involved in the decision-  
7 making process with a careful assessment of the child's competence needs to be made, particularly  
8 for decisions with moral significance.<sup>(26)</sup>  
9

10  
11 The paediatric landscape has changed with technological advances, lower mortality rates in many  
12 specialities and an increasing number of patients with chronic and complex conditions. Uncertainties  
13 about prognostication and treatment outcomes, overall benefits and burdens pose ethical challenges  
14 about withholding and withdrawing life-sustaining treatments.<sup>(31)</sup> The involvement of multiple teams  
15 with different perspectives and values might add further complexity to the decision-making  
16 process.<sup>(29)</sup> Finally, these significant technological advances and decreasing mortality rates might  
17 strengthen the perception of death, particularly in children, as a medical failure adding barriers to end  
18 of life discussions and decision-making.  
19

20  
21 Despite ethically challenging situations and consequent divergent opinions being common in  
22 paediatrics, the number of paediatric ethics consultations is relatively low.<sup>(32)</sup> Many of these  
23 challenges might be opportunely identified and appropriately managed by the healthcare team and  
24 the family,<sup>(33)</sup> with clinicians receiving support through alternatives to formal ethics consultation.<sup>(32)</sup>  
25 However, in complex cases, there may either be an impasse or conflict might persist. In these  
26 situations, ethical consultation has been shown to help provide a resolution.<sup>(34)</sup> Recent controversial  
27 cases featured extensively in both print, and social media have increased international public and  
28 academic attention to the ethical challenges of paediatric practice. There has been an increased  
29 interest and debate surrounding the legal and ethical aspects of paediatric practice, such as parental  
30 and clinical teams' disagreements about the child's best interests, emerging child capacity, innovative  
31 treatments, technological dependence and end-of-life decision-making. Consultant paediatricians,  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

7

1  
2  
3 trainees and residents have expressed concerns that these public cases might negatively impact their  
4 relationship with patients and families.(35) Availability of clinical ethics support services for teams  
5 facing ethical challenges has been strongly advocated by professional bodies,(31) academics(33,36,37)  
6 and clinicians.(35,38) However, there are no standards or guidance on p-CESS structure, functions or  
7 aims. Nor is there agreement about the level of involvement of patients, or in paediatrics parents and  
8 children, in ethics discussions.(39,40)  
9

10  
11 Interest in assessing CESS quality and effectiveness has grown in the past decades. However, most  
12 studies have focused on adult care settings, with relatively little attention paid to p-CESS.(41) Multiple  
13 systematic reviews evaluating different aspects of CESS have recently been published. Nevertheless,  
14 these focus on adult patients; ethical case intervention,(42) adult end of life context,(43) and adult  
15 ICU.(44) Other reviews that did not explicitly focused on adult patients evaluate a specific intervention  
16 (assessment tools for evaluating clinical ethics consultation(17)) or effectiveness of clinical ethics  
17 committees.(18) Generalisation of adult-focused reviews and evidence to paediatric context might  
18 not be appropriate. Although many CESSs will support both adult and paediatric patients, their families  
19 and clinical teams, it is likely that, together with the increasing in number and complexity of children's  
20 hospitals around the globe,(45) many CESS will serve patients and staff of paediatric healthcare  
21 institutions.(40) Moreover, there might be a value in accumulating knowledge and expertise in an  
22 increasingly complex paediatric field. Thus, a better understanding on current models of paediatric  
23 specific CESS will inform further development and research to contribute to the provision of optimal  
24 care for paediatric patients and their families. To our knowledge, no systematic review on Paediatric  
25 Clinical Ethics Support Services (p-CESS) structures, processes, evaluation measures and outcomes has  
26 been published. Such a review is necessary to inform current p-CESS practice and further  
27 development. Therefore, we aim to inform further research and debate on the current quality  
28 evaluation and minimum standards for p-CESS by offering a comprehensive description of current p-  
29 CESS models and assessments by responding to this review question:  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

8

***“What is the range of structures, processes, and outcome measures of paediatric CESS reported in the literature?”***

**Aim:**

To systematically identify, appraise and synthesise evidence for p-CESS structures, processes, and outcome measures described in the literature.

**Objectives:**

- To identify and synthesise published data on p-CESS regarding their structures, processes, evaluation measures and outcomes.
- To explore the impact of p-CESS given the outcomes identified in the review.
- To qualitatively appraise the available evidence.
- To develop a preliminary framework for the evaluation of p-CESS based on available evidence.
- To provide recommendations for further research on CESS effectiveness and outcome measures in paediatric practice.

**METHODS AND ANALYSIS**

We will conduct a mixed studies systematic review to identify and synthesise evidence for Paediatric CESS structures, interventions, evaluation measures and outcomes. By integrating studies with diverse research methods, a mixed studies systematic review allows the compensation for the limitations of qualitative and quantitative evidence and a better the understanding of the complexities of p-CESS.(46) The review will be reported following the adapted PRISMA for reporting systematic reviews of qualitative and quantitative evidence template,(47) as recommended by Pluye et al.(48)

The review protocol has been developed following the recommended items included in the PRISMA-P statement(49) and has been prospectively registered in PROSPERO registry CRD42021280978.(50)

**Eligibility Criteria**

9

The inclusion and exclusion criteria are summarised in Table 1. The review will include peer-review empirical studies (qualitative, quantitative or mixed-methods), including case studies published in English or Spanish language which provide empirical data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value)(11) of any one or more of the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, and outcome measures of p-CESS. We will include empirical studies of qualitative, quantitative or mixed-methods design reporting both objective and/or subjective measures.

We will include studies reporting on CESS that provide services to adult and paediatric patients only if paediatric data can be extracted separately.

Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces, book chapters will be excluded. Conference abstracts will not be included, but authors will be contacted asking whether the relevant work has been published, with a two-week timeframe allowed for a response. There will be no timeframe or geographical restrictions.

Table 1. Eligibility Criteria

	INCLUSION CRITERIA	EXCLUSION CRITERIA
Type of participants	CESSs that serve paediatric only or paediatric and adult population, where paediatric data can be extracted separately.	CESSs that serve only adult patients.  CESSs serving paediatric and adult populations, where paediatric data cannot be extracted and analysed

	<p>The paediatric population will be defined in this review as between 0-18 years old.</p> <p>Study participants include, but are not limited to, referring clinicians, CESS members, patients/children, parents/relatives/careers and hospital administrators.</p>	
Context/ setting	Articles reporting on established CESS serving paediatric practice in any setting (hospital, community) and country.	Research ethics committees
Issues	<p>Empirical studies reporting data on evaluation, assessment and/or impact (i.e., effect, evaluation, importance, meaning, value) of any one or more of, but not limited to the following aspects of paediatric CESS: service structure, constitution and membership, service's aims and functions, interventions and processes, outcome measures of paediatric CESS.</p>	<p>Theoretical analysis or narrative reviews on paediatric CESS.</p> <p>Studies focusing only on a description of the paediatric CESS without reporting assessment/impact data</p>

Methods	Empirical studies of any methods (qualitative and/or quantitative), including case studies.	Theoretical reviews or analysis. Systematic reviews Case reports, narrative reviews.
Timeframe	Any time frame. Searches will be conducted from the database inception date until the search date.	
Type of publication	Peer-reviewed publications in English or Spanish Language	Non-peer-reviewed studies, reviews, theoretical works, editorials, letters, opinion pieces Conference abstracts
<i>CESS: Clinical Ethics Support Services</i>		

### Search strategy

Electronic searches. The following databases will be searched: MEDLINE, Philosopher's Index, EMBASE, PsychINFO, LILACS, Web of Science and CINHALL. There will be no methodological, language, geographical or time filters applied to the search strategy. If a non-English paper is considered eligible for inclusion, relevant data and results will be translated to English before analysis.

The initial search strategy was developed considering previously published systematic reviews in paediatrics, clinical ethics and service evaluation. Search terms will be related to "Clinical ethics support", "paediatrics" AND "structure/process/outcome indicators" and adapted to each database requirement. Publications that would match the criteria for inclusion in the review previously known to the research team were successfully retrieved applying the search strategy in Medline online

12

database. Please see Table 2 for Medline search strategy and refer to Supplementary file 1 for complete search strategy for all included databases.

Table 2. Medline search strategy

1. paediatric.mp.	27. Ethicists/ or ethicist*.mp.	57. structure.mp.
2. paediatr*.mp.	28. bioethicist*.mp.	58. model*.mp.
3. pediatric.mp. or Pediatrics/	29. medical ethics.mp. or Ethics, Medical/	59. process*.mp.
4. pediatr*.mp.	30. clinical ethics.mp. or Ethics, Clinical/	60. intervention*.mp.
5. child*.mp. or Child/	31. clinical ethics committee.mp. or Ethics Committees, Clinical/	61. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or assessment*.mp.
6. Adolescent/ or adolescent.mp.	32. bioethics.mp. or Bioethics/	62. evaluation*.mp.
7. adolesc*.mp.	33. bioethical issues.mp. or Bioethical Issues/	63. impact*.mp.
8. infant*.mp.	34. ethical issues.mp. or Ethics/	64. effectiveness.mp.
9. infant.mp. or Infant/	35. ethical challenges.mp	65. Medical Audit/ or Clinical Audit/ or audit.mp.
10. kid.mp.	36. moral review.mp.	66. Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or outcome.mp.
11. kids.mp.	37. Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.	67. "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/
12. baby.mp.	38. moral case consult*.mp.	68. indicator*.mp.
13. babies.mp.	39. moral consult*.mp.	
14. toddler*.mp.	40. ethic* case review.mp. or Ethics Committees/	
15. childhood.mp.	41. ethic* deliberation.mp.	
16. juvenil*.mp.	42. ethic* intervention.mp.	
17. youth*.mp.	43. ethic* round.mp.	
18. minor.mp. or Minors/	44. ethic* support.mp.	
19. Infant, Newborn/ or infancy.mp. or Child, Preschool/	45. ethic* service.mp.	
20. Infant, Newborn/ or newborn*.mp.	46. Ethical Analysis/ or ethic* analysis.mp.	
21. Premature Birth/ or Infant, Premature/ or preterm*.mp.	47. ethic* referral.mp.	
22. prematur*.mp.	48. Ethics Committees/ or ethic* committee.mp.	
23. Puberty/ or pubert*.mp.	49. bioethic* deliberation.mp.	
24. pubescen*.mp.	50. bioethic* intervention.mp.	
25. young person.mp.	51. bioethic* round.mp.	
26. neonatal.mp.	52. bioethic* service.mp.	
	53. bioethic* support.mp.	
	54. bioethic* analysis.mp.	
	55. bioethic* referral.mp.	
	56. bioethic* committee.mp.	
69. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26		

13

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

70. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57
71. 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70
72. 69 AND 70 AND 71

Other resources. Reference and citation list of included studies will be hand-searched. When relevant, we will contact the authors of conference abstracts identified through the search for peer-review publications. We will allow a time frame of two weeks for a response before considering the publication unavailable.

### **Selection process.**

All retrieved records will be managed using Refworks® reference manager software. After deduplication, a random sample of 10% will be independently screened by MD and BP to test the reliability of the criteria. Any disagreements will be discussed within the research team until agreement, and, if required, eligibility criteria will be adjusted and/or clarified to improve the consistency of the screening process. Thereafter, all titles and/or abstracts will be screened by MD to identify publications that meet the previously established inclusion and exclusion criteria... References selected for assessment in the full text will be independently dual-assessed by MD and BP against inclusion/exclusion criteria, and any disagreements will be discussed within the research team until agreement. Reasons for excluding articles after full-text assessment will be recorded and study references and reasons for exclusion will be reported. A Cohen's Kappa score over 90% will be required at both, the title/abstract and full text screening processes. The screening process will be presented as a PRISMA flowchart.

### **Data extraction.**

14

1  
2  
3 Data from individual studies considered relevant for the review question will be extracted to a pre-  
4 piloted Excel data extraction form by MD and checked by BP. Disagreements will be discussed within  
5 the research team. Data entries will include: Publication details (First author, year of publication, title),  
6 setting (country, healthcare setting), study aims, study design, sampling method and sample  
7 description. Primary outcomes sought in the data set will include; (i) assessed aspects of paediatric  
8 CESS as reported by study authors, including service structures, processes and outcomes (i.e.,  
9 membership, service's activities, referrers, cases, contexts and reasons for referrals); (ii) assessed  
10 dimensions (i.e., effectiveness, safety and responsiveness) and/or subdimensions of quality of  
11 care(51) as reported by study authors; and (iii) methods and instruments used in the assessment. For  
12 qualitative studies, all data within the results/finding section will be considered as results.  
13 Characteristics of included studies will be tabulated.

### 31 **Quality assessment.**

32  
33  
34 Following our initial literature review, we expect to find around 10-30 potentially eligible studies with  
35 multiple research designs, including qualitative, quantitative and mixed methods. To allow coherent  
36 and systematic critical appraisal of included studies with different designs, we will use the 2018 Mixed  
37 Methods Appraisal Tool.(52) The tool was developed specifically for the appraisal of complex  
38 systematic reviews that include empirical qualitative, quantitative and mixed methods studies. It  
39 includes specific criteria depending on the study design category. Each criterion is rated as "yes", "no",  
40 "can't tell" response. As recommended by the authors, for each study, we will present a detailed  
41 description of the rating of each criterion and calculate an overall quality score based on the number  
42 of quality criteria met. There is no recommended cut off score to exclude studies based on quality  
43 appraisal, and therefore no study will be excluded based on that criterion. Instead, we will conduct a  
44 sensitivity analysis during the data synthesis process to assess the impact of low-quality studies in the  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

15

1  
2  
3 review findings and adjust recommendations accordingly.(52) Quality appraisal will be conducted by  
4  
5 MD and checked by BP.  
6  
7  
8  
9

### 11 **Data synthesis**

12  
13  
14 This systematic review is not focused only on the effectiveness of a particular intervention but  
15  
16 addresses a broader range of questions. Data synthesis will follow a sequential explanatory synthesis  
17  
18 following the two-step process described by Pluye and Hong:(46) First, a quantitative synthesis  
19  
20 including results from quantitative studies and quantitative data from mixed-methods studies,  
21  
22 followed by qualitative synthesis of results of qualitative studies and qualitative data form mixed-  
23  
24 methods studies. The qualitative synthesis will be informed by the previously conducted quantitative  
25  
26 synthesis. The integration of the qualitative synthesis into the quantitative one will allow a better  
27  
28 understanding of the quantitative results,(46) also highlighting convergences and divergences  
29  
30 between quantitative and qualitative synthesis to inform future research.  
31  
32  
33

34  
35 As we expect to find great diversity of outcome measures, quantitative data will be synthesised and  
36  
37 tabulated using descriptive statistics where appropriate(53) guided by but not limited to  
38  
39 Donabedian's framework of structure, process and outcomes. For qualitative data, we will conduct  
40  
41 thematic synthesis approach,(54) using NVivo software for qualitative data analysis. The thematic  
42  
43 synthesis will include: (i) Free line-by-line coding of the primary study's findings, (ii) organisation of  
44  
45 these codes into related themes informed by the quantitative synthesis.(54) If the qualitative synthesis  
46  
47 process develops additional themes that are not described in the quantitative synthesis, these will be  
48  
49 included in the integrated synthesis as qualitative results only. To assess the robustness of the  
50  
51 synthesis we will considering individual studies' quality and conduct sensitivity analysis if possible.  
52  
53  
54

55  
56 The synthesis will be conducted by MD and checked by BP. The final synthesis will be discussed within  
57  
58 the research team.  
59  
60

## Timeline

The protocol for this review is published in PROSPERO (date 27 September 2021).(50) Searches on the databases mentioned in the protocol were conducted in August 2021. Retrieved references were screened at title and abstract level during September-October 2021. Screening at full text level is planned for December 2021 – January 2022. We plan to proceed with further stages of the review, including stakeholder involvement, and data extraction and synthesis after the protocol is accepted for publication following the peer-review process. Data extraction and analysis are expected to take 6 months after study selection.

## Patient and public Involvement.

Patients and the public were not involved in the design of this systematic review protocol, but will be involved further at two stages in the process of the research, to ensure the review outcomes are useful and relevant.(55,56) Following Cochrane good practice guidance for people involvement in systematic reviews,(55) we sought to involve views of diverse stakeholders. Since p-CESS are established within healthcare institutions, and provide support to clinicians and patients and their families in making ethically challenging decision, we defined four stakeholders' categories whose collaboration would be valuable to the research process; (i) institutional managers, (ii) p-CESS board members, (iii) clinicians and (iv) parents. We decided not to involve children and young people since, to the authors' knowledge, they are rarely involved in ethics consultations themselves, but represented by their parents throughout the process. We will establish two advisory groups, one Chilean and one UK-based, with one representative for each stakeholder category. We will invite representatives that are already known to the research team to join the advisory group and participate in two one-hour workshops, one before data extraction and synthesis and a second one after preliminary results.

17

1  
2  
3 Parents' representatives will be or have been previously involved as parent representative in a p-CESS.  
4  
5 In the first webinar, participants will be asked to share their views, thoughts, opinions or experiences  
6  
7 to ensure we will be looking for the appropriate data in the included studies. At the second webinar,  
8  
9 participants will have the opportunity to provide their feedback on the preliminary findings, to add  
10  
11 context and meaning to the findings, contributing to the overall interpretation and recommendations.  
12  
13 Stakeholder involvement will be reported following the GRIPP (Guidance for Reporting Involvement  
14  
15 of Patients and Public) checklist.(45)  
16  
17

### 18 19 **Ethics and dissemination.**

20  
21  
22 As a systematic review of published data, no ethical approval is necessary. Following Cochrane  
23  
24 guidance,(55) ethical approval for stakeholder involvement in this review would not be required as  
25  
26 workshops would not be audio-recorded and no vulnerable groups will participate.  
27  
28

29  
30 We will present and discuss our findings in an open-access webinar, inviting a broad range of  
31  
32 stakeholders to attend, including hospital managers, clinicians, academic ethicists, and patient  
33  
34 representatives. A final report will be published in a relevant academic peer-reviewed journal.  
35  
36

37  
38 We plan to continue this research by conducting a modified Delphi study based on our review results  
39  
40 to further explore the most appropriate quality indicators for evaluating p-CESS.  
41

### 42 **DISCUSSION**

43  
44  
45 Interest in assessing CESS quality and effectiveness has grown in the past decades, with little attention  
46  
47 paid to p-CESS. The results of this work will provide us with the first systematic review of evidence on  
48  
49 Paediatric Clinical Ethics Support Services.  
50  
51

52  
53 The review team is comprised by a bilingual and international research team that includes a Paediatric  
54  
55 Intensivist Consultant with vast experience in paediatric medical ethics leading the teaching, research  
56  
57 and clinical activities of the p-CESS at a large tertiary children's hospital; a speech therapist, certified  
58  
59 clinical ethics consultant and PhD student in CESSs evaluation and a medical doctor and ethicist with  
60

18

1  
2  
3 experience in systematic reviews and ethics research. The researchers' diverse backgrounds will  
4 contribute with their experiences and perspectives on CESS structures, processes, and outcomes in  
5 different contexts (Latin America and the UK). This will also allow a more comprehensive review both,  
6 by searching a Latin American specific database and the inclusion papers published in English and  
7 Spanish languages. This will enhance the review comprehensiveness, as long as potential bias is given  
8 due consideration in the result interpretation and recommendation development stages. Evidence on  
9 the effect of English-restricted criteria in traditional systematic reviews of randomised controlled trials  
10 with meta-analyses has not shown to result in significant bias.(57,58). However, this review on p-CESS  
11 structures, processes and outcomes will include a broader range of study designs and therefore  
12 potential bias associated with the exclusion of studies published in languages other than English and  
13 Spanish will be considered in the interpretation of results and recommendations.  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

28 The inclusion of peer-reviewed publications only might result in the omission of relevant publications  
29 (i.e., CESS terms of references and/or reports published in institutional websites). However, focusing  
30 on peer-reviewed publications will ensure validity of data included in the synthesis and also warrant  
31 a balance between the amount of data and the capacity of the research team, without compromising  
32 the review results. Moreover, we aim at mitigating the potential exclusion of relevant data by  
33 including case reports and case studies. The use of the Donabedian model will allow a structured and  
34 objective assessment of p-CESS contribution to patients' care. This is a well-accepted and widely used  
35 framework. However, considering the normative nature of CESS and their interventions and  
36 outcomes, the framework will be used as a guide and adaptation is expected.  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 We hope that our review results will allow for a better understanding of p-CESS structures, processes,  
50 and outcomes, contributing to further research exploring the normative and empirical basis of p-CESS.  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

19

**Author contributions:** MD and JB conceived the review. MD, JB and BP developed the protocol. All authors revised and edited the manuscript and approved the final version.

**Funding:** This work was supported by the Institute of Medical Ethics “Research in Medical Ethics” grant (No grant number). The funder has had no involvement in the review protocol development.

**Competing interests:** None to declare.

## REFERENCES

1. Slowther A, Johnston C, Goodall J, Hope T. Development of clinical ethics committees. *BMJ*. 2004 Apr 17;328(7445):950–2.
2. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Do we understand the intervention? What complex intervention research can teach us for the evaluation of clinical ethics support services (CESS). *BMC Med Ethics*. 2019;20(1):48.
3. Machin LL, Wilkinson M. Making the (Business) Case for Clinical Ethics Support in the UK. *HEC Forum*. 2020;
4. Courtwright A, Jurchak M. The Evolution of American Hospital Ethics Committees: A Systematic Review. *J Clin Ethics*. 2016;27(4):322–40.
5. Moodley K, Kabanda SM, Soldaat L, Kleinsmidt A, Obasa AE, Kling S. Clinical Ethics Committees in Africa: lost in the shadow of RECs/IRBs? *BMC Med Ethics*. 2020 Nov;21(1):115.
6. Orzechowski M, Schochow M, Steger F. Clinical Ethics Consultation in the Transition Countries of Central and Eastern Europe. *Sci Eng Ethics*. 2020 Apr;26(2):833–50.
7. Hajibabae F, Joolae S, Cheraghi MA, Salari P, Rodney P. Hospital/clinical ethics committees’ notion: an overview. *J Med ethics Hist Med*. 2016 Dec 18;9:17.
8. Slowther A, Bunch C, Woolnough B, Hope T. Clinical ethics support services in the UK: an investigation of the current provision of ethics support to health professionals in the UK. *J*

20

- 1  
2  
3 Med Ethics. 2001 Apr 1;27(suppl 1):i2 LP-i8.  
4  
5  
6 9. Larcher V. Role of clinical ethics committees. Arch Dis Child. 1999 Aug;81(2):104–6.  
7  
8  
9 10. Hurst SA, Reiter-Theil S, Perrier A, Forde R, Slowther A-M, Pegoraro R, et al. Physicians' access  
10 to ethics support services in four European countries. Health Care Anal. 2007 Dec;15(4):321–  
11 35.  
12  
13  
14  
15  
16 11. Haan MM, van Gurp JLP, Naber SM, Groenewoud AS. Impact of moral case deliberation in  
17 healthcare settings: a literature review. BMC Med Ethics. 2018;19(1):85.  
18  
19  
20  
21 12. Rasoal D, Skovdahl K, Gifford M, Kihlgren A. Clinical Ethics Support for Healthcare Personnel:  
22 An Integrative Literature Review. HEC Forum. 2017 Dec;29(4):313–46.  
23  
24  
25  
26 13. Gill AW, Saul P, McPhee J, Kerridge I. Acute clinical ethics consultation: the practicalities. Med  
27 J Aust. 2004 Aug 1;181(4):204–6.  
28  
29  
30  
31 14. Kilham H, Isaacs D, Kerridge I, Newson A. Rethinking Pediatric Ethics Consultations. Am J  
32 Bioeth. 2015 May 4;15(5):26–8.  
33  
34  
35  
36 15. Molewijk B, Slowther A, Schildmann J. The European Clinical Ethics Network ( ECEN ): the  
37 professional development of clinical ethics support in Europe and the importance of quality  
38 assessment through evaluation research. Bioethica Forum. 2016;9(2):86–9.  
39  
40  
41  
42 16. Slowther A-M, Hope T. Clinical ethics committees. BMJ. 2000 Sep 16;321(7262):649 LP – 650.  
43  
44  
45  
46 17. Yoon NYS, Ong YT, Yap HW, Tay KT, Lim EG, Cheong CWS, et al. Evaluating assessment tools  
47 of the quality of clinical ethics consultations: a systematic scoping review from 1992 to 2019.  
48 BMC Med Ethics. 2020 Jul 1;21(1):51.  
49  
50  
51  
52  
53 18. Crico C, Sanchini V, Casali PG, Pravettoni G. Evaluating the effectiveness of clinical ethics  
54 committees: a systematic review. Med Heal Care Philos. 2021;24(1):135–51.  
55  
56  
57  
58 19. McClimans L, Pressgrove G, Campbell E. Objectives and outcomes of clinical ethics services: a  
59  
60

21

- 1  
2  
3 Delphi study. *J Med Ethics*. 2019 Dec;45(12):761–9.  
4  
5  
6 20. Schildmann J, Molewijk B, Benaroyo L, Forde R, Neitzke G. Evaluation of clinical ethics support  
7 services and its normativity. *J Med Ethics*. 2013 Nov 1;39(11):681 LP – 685.  
8  
9  
10  
11 21. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q*. 2005;83(4):691–729.  
12  
13  
14 22. Williamson L, McLean S, Connell J. CLINICAL ETHICS COMMITTEES IN THE UNITED KINGDOM:  
15 TOWARDS EVALUATION. *Med Law Int*. 2007 Feb 9;8(3):221–38.  
16  
17  
18  
19 23. Haltaufderheide J, Nadolny S, Vollmann J, Schildmann J. Framework for evaluation research  
20 on clinical ethical case interventions: the role of ethics consultants. *J Med Ethics*. 2021 May  
21 17;medethics-2020-107129.  
22  
23  
24  
25  
26 24. Craig JM, May T. Evaluating the outcomes of ethics consultation. *J Clin Ethics*.  
27 2006;17(2):168–80.  
28  
29  
30  
31  
32 25. Metselaar S, Widdershoven G, Porz R, Molewijk B. Evaluating Clinical Ethics Support: A  
33 Participatory Approach. *Bioethics*. 2017 May;31(4):258–66.  
34  
35  
36  
37 26. Gold H, Hall G, Gillam L. Role and function of a paediatric clinical ethics service : Experiences  
38 at the Royal Children ' s Hospital , Melbourne.  
39  
40  
41  
42 27. Larcher VF, Lask B, Mccarthy JM, Ormond G, Hospitalfor S. Paediatrics at the cutting edge : do  
43 we need clinical ethics committees ? 1997;245–9.  
44  
45  
46  
47 28. Buchanan CA, Bester JC, Bruno B, Delany C, Kennedy KO, Koogler T, et al. Pediatric Ethics  
48 Consultation: Practical Considerations for the Clinical Ethics Consultant. *J Clin Ethics*.  
49 2019;30(3):270–83.  
50  
51  
52  
53  
54 29. Moynihan KM, Taylor L, Crowe L, Balnaves M-C, Irving H, Ozonoff A, et al. Ethical climate in  
55 contemporary paediatric intensive care. *J Med Ethics*. 2021 Jan;  
56  
57  
58  
59 30. United Nations General Assembly. Convention on the Rights of the Child. 1989.  
60

22

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
31. Larcher V, Craig F, Bhogal K, Wilkinson D, Brierley J. Making decisions to limit treatment in life-limiting and life-threatening conditions in children: a framework for practice. *Arch Dis Child*. 2015 May 1;100(Suppl 2):s1 LP-s23.
32. Carter B, Brockman M, Garrett J, Knackstedt A, Lantos J. Why Are There So Few Ethics Consults in Children's Hospitals? *HEC Forum*. 2018 Jun;30(2):91–102.
33. Linney M, Hain RDW, Wilkinson D, Fortune P-M, Barclay S, Larcher V, et al. Achieving consensus advice for paediatricians and other health professionals: on prevention, recognition and management of conflict in paediatric practice. *Arch Dis Child*. 2019 May;104(5):413–6.
34. Brierley J, Petros A, Linthicum J. Should religious beliefs be allowed to stonewall a secular approach to withdrawing and withholding treatment in children? *J Med Ethics*. 2013;39(9):573–7.
35. Avula H, Dittborn M, Brierley J. 'Who Ya Gonna Call ...?' Ethical and legal dilemmas in specialist children centres and district general hospitals. *Clin Ethics*. 2021 Aug 5;14777509211036648.
36. Huxtable R. Clinic, courtroom or (specialist) committee: in the best interests of the critically ill child? *J Med Ethics*. 2018 Jul 1;44(7):471 LP – 475.
37. Wilkinson D, Savulescu J. Alfie Evans and Charlie Gard-should the law change? Vol. 361, *BMJ* (Clinical research ed.). England; 2018. p. k1891.
38. Archambault-Grenier M-A, Roy-Gagnon M-H, Gauvin F, Doucet H, Humbert N, Stojanovic S, et al. Survey highlights the need for specific interventions to reduce frequent conflicts between healthcare professionals providing paediatric end-of-life care. *Acta Paediatr*. 2018 Feb;107(2):262–9.
39. Brierley J, Archard D, Cave E. Challenging misconceptions about clinical ethics support during

23

- 1  
2  
3 COVID-19 and beyond: a legal update and future considerations. *J Med Ethics*. 2021 Apr  
4  
5 21;medethics-2020-107092.  
6  
7
- 8 40. Brierley J, Cave E, Archard D. Ethical advice in paediatric care. *Arch Dis Child*. 2021 Nov;  
9
- 10  
11 41. McDougall RJ, Notini L. What kinds of cases do paediatricians refer to clinical ethics? Insights  
12  
13 from 184 case referrals at an Australian paediatric hospital. *J Med Ethics*. 2016  
14  
15 Sep;42(9):586–91.  
16  
17
- 18 42. Schildmann J, Nadolny S, Haltaufderheide J, Gysels M, Vollmann J, Bausewein C. Ethical case  
19  
20 interventions for adult patients. *Cochrane Database Syst Rev*. 2019;(7).  
21  
22
- 23 43. Haltaufderheide J, Nadolny S, Gysels M, Bausewein C, Vollmann J, Schildmann J. Outcomes of  
24  
25 clinical ethics support near the end of life: A systematic review. *Nurs Ethics*. 2019 Nov  
26  
27 19;27(3):838–54.  
28  
29
- 30  
31 44. Au SS, Couillard P, Roze des Ordon A, Fiest KM, Lorenzetti DL, Jette N. Outcomes of Ethics  
32  
33 Consultations in Adult ICUs: A Systematic Review and Meta-Analysis. *Crit Care Med*. 2018  
34  
35 May;46(5):799–808.  
36  
37
- 38 45. Casimir G. Why Children’s Hospitals Are Unique and So Essential. Vol. 7, *Frontiers in*  
39  
40 *Pediatrics*. 2019. p. 305.  
41  
42
- 43 46. Pluye P, Nha Hong Q. Combining the Power of Stories and the Power of Numbers: Mixed  
44  
45 Methods Research and Mixed Studies Reviews. *Annu Rev Public Heal*. 2014;35:29–45.  
46  
47
- 48 47. Adapted PRISMA for reporting systematic reviews of qualitative and quantitative evidence  
49  
50 [Internet]. Toolkit for Mixed Studies Reviews. Available from:  
51  
52 [http://toolkit4mixedstudiesreviews.pbworks.com/w/page/66103031/Toolkit for Mixed](http://toolkit4mixedstudiesreviews.pbworks.com/w/page/66103031/Toolkit%20for%20Mixed%20Studies%20Reviews)  
53  
54 *Studies Reviews*  
55  
56
- 57  
58 48. Pluye P, Hong QN, Granikov V, Vedel I. The wiki toolkit for planning, conducting and reporting  
59  
60

24

- 1  
2  
3 mixed studies reviews. *Educ Inf.* 2018;34:277–83.  
4  
5  
6 49. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting  
7 items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst*  
8 *Rev.* 2015;4(1):1.  
9  
10  
11  
12  
13 50. Dittborn M, Portales B, Brierley J. Clinical ethics support services in paediatric practice:  
14 protocol for a mixed studies systematic review on structures, interventions and outcomes.  
15 [Internet]. PROSPERO. 2021 [cited 2021 Nov 24]. p. CRD42021280978. Available from:  
16 [https://www.crd.york.ac.uk/prospero/display\\_record.php?ID=CRD42021280978](https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021280978)  
17  
18  
19  
20  
21  
22  
23 51. Busse R, Panteli D, Quentin W. An introduction to healthcare quality: defining and explaining  
24 its role in health systems. In: Busse R, Klazinga N, Panteli D, Quentin W, editors. *Improving*  
25 *healthcare quality in Europe: Characteristics, effectiveness and implementation of different*  
26 *strategies.* Health Pol. Copenhagen (Denmark): European Observatory on Health Systems and  
27 Policies; 2019.  
28  
29  
30  
31  
32  
33  
34  
35 52. Hong QN, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, et al. The Mixed  
36 Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers.  
37 *Educ Inf.* 2018;34:285–91.  
38  
39  
40  
41  
42 53. McKenzie J, Brennan S. Synthesizing and presenting findings using other methods. In: Higgins  
43 J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. *Cochrane Handbook for*  
44 *Systematic Reviews of Interventions version 62 (updated February 2021).* version 6.  
45 *Cochrane;* 2021.  
46  
47  
48  
49  
50  
51  
52 54. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic  
53 reviews. *BMC Med Res Methodol.* 2008;8(45).  
54  
55  
56  
57 55. Cochrane Training. Involving people. A learning resource for systematic review authors  
58 [Internet]. Available from: <https://training.cochrane.org/involving-people>  
59  
60

25

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60
56. Pollock A, Campbell P, Struthers C, Synnot A, Nunn J, Hill S, et al. Stakeholder involvement in systematic reviews: a protocol for a systematic review of methods, outcomes and effects. *Res Involv Engagem.* 2017;3(1):9.
57. Moher D, Pham, Klassen TP, Schulz KF, Berlin JA, Jadad AR, et al. What contributions do languages other than English make on the results of meta-analyses? *J Clin Epidemiol.* 2000;53(9):964–72.
58. Morrison A, Polisen J, Husereau D, Moulton K, Clark M, Fiander M, et al. The effect of English-language restriction on systematic review-based meta-analyses: a systematic review of empirical studies. *Int J Technol Assess Health Care.* 2012/04/26. 2012;28(2):138–44.

## Supplementary file 1. Complete search strategy for all databases

**Embase Classic+Embase**

- 1 paediatric.mp.
- 2 paediatr\*.mp.
- 3 pediatric.mp. or Pediatrics/
- 4 pediatr\*.mp.
- 5 child\*.mp. or Child/
- 6 Adolescent/ or adolescent.mp.
- 7 adolesc\*.mp.
- 8 infant\*.mp.
- 9 infant.mp. or Infant/
- 10 kid.mp.
- 11 kids.mp.
- 12 baby.mp.
- 13 babies.mp.
- 14 toddler\*.mp.
- 15 childhood.mp.
- 16 juvenil\*.mp.
- 17 youth\*.mp.
- 18 minor.mp. or Minors/
- 19 Infant, Newborn/ or infancy.mp. or Child, Preschool/
- 20 Infant, Newborn/ or newborn\*.mp.
- 21 Premature Birth/ or Infant, Premature/ or preterm\*.mp.
- 22 prematur\*.mp.
- 23 Puberty/ or pubert\*.mp.
- 24 pubescen\*.mp.
- 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or  
19 or 20 or 21 or 22 or 23 or 24
- 26 Ethicists/ or ethicist\*.mp.

- 1  
2  
3 27 bioethicist\*.mp.  
4  
5 28 medical ethics.mp. or Ethics, Medical/  
6  
7 29 clinical ethics.mp. or Ethics, Clinical/  
8  
9 30 clinical ethics committee.mp. or Ethics Committees, Clinical/  
10  
11 31 bioethics.mp. or Bioethics/  
12  
13 32 bioethical issues.mp. or Bioethical Issues/  
14  
15 33 ethical issues.mp. or Ethics/  
16  
17 34 ethical challenges.mp.  
18  
19 35 moral review.mp.  
20  
21 36 Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.  
22  
23 37 moral case consult\*.mp.  
24  
25 38 moral consult\*.mp.  
26  
27 39 ethic\* case review.mp. or Ethics Committees/  
28  
29 40 ethic\* deliberation.mp.  
30  
31 41 ethic\* intervention.mp.  
32  
33 42 ethic\* round.mp.  
34  
35 43 ethic\* support.mp.  
36  
37 44 ethic\* service.mp.  
38  
39 45 Ethical Analysis/ or ethic\* analysis.mp.  
40  
41 46 ethic\* referral.mp.  
42  
43 47 Ethics Committees/ or ethic\* committee.mp.  
44  
45 48 bioethic\* deliberation.mp.  
46  
47 49 bioethic\* intervention.mp.  
48  
49 50 bioethic\* round.mp.  
50  
51 51 bioethic\* service.mp.  
52  
53 52 bioethic\* support.mp.  
54  
55 53 bioethic\* analysis.mp.  
56  
57 54 bioethic\* referral.mp.  
58  
59 55 bioethic\* committee.mp.  
60  
56 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or  
42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55

- 1  
2  
3 57 young person.mp.  
4  
5 58 neonatal.mp.  
6  
7 59 25 or 57 or 58  
8  
9 60 structure.mp.  
10  
11 61 model\*.mp.  
12  
13 62 process\*.mp.  
14  
15 63 intervention\*.mp.  
16  
17 64 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
18 assessment\*.mp.  
19  
20 65 evaluation\*.mp.  
21  
22 66 impact\*.mp.  
23  
24 67 effectiveness.mp.  
25  
26 68 Medical Audit/ or Clinical Audit/ or audit.mp.  
27  
28 69 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
29 outcome.mp.  
30  
31 70 "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/  
32 indicator\*.mp.  
33  
34 72 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71  
35  
36 73 56 and 59 and 72  
37  
38 74 from 73 keep 7001-7942  
39  
40 75 paediatric.mp. or pediatrics/  
41  
42 76 paediatr\*.mp.  
43  
44 77 pediatric.mp. or pediatrics/  
45  
46 78 pediatr\*.mp.  
47  
48 79 child/ or child\*.mp.  
49  
50 80 adolescent/ or adolescent.mp.  
51  
52 81 adolesc\*.mp.  
53  
54 82 infant\*.mp.  
55  
56 83 infant/ or infant.mp.  
57  
58 84 kid.mp.  
59  
60 85 kids.mp.  
86 baby.mp. or baby/

1  
2  
3 87 babies.mp.  
4  
5 88 toddler/ or toddler\*.mp.  
6  
7 89 childhood/ or childhood.mp.  
8  
9 90 juvenil\*.mp.  
10  
11 91 youth\*.mp.  
12  
13 92 minor.mp. or "minor (person)"/  
14  
15 93 minors.mp.  
16  
17 94 infancy/ or infancy.mp.  
18  
19 95 newborn/ or newborn\*.mp.  
20  
21 96 prematurity/ or preterm\*.mp.  
22  
23 97 prematur\*.mp.  
24  
25 98 puberty/ or pubert\*.mp.  
26  
27 99 pubescen\*.mp.  
28 100 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or  
29 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99  
30  
31 101 ethicist/ or ethicist\*.mp.  
32  
33 102 bioethicist\*.mp.  
34  
35 103 medical ethics.mp. or medical ethics/  
36  
37 104 clinical ethics.mp.  
38  
39 105 clinical ethics committee.mp.  
40  
41 106 bioethics.mp. or bioethics/  
42  
43 107 bioethic\*.mp.  
44  
45 108 bioethical issues.mp.  
46  
47 109 ethical issues.mp.  
48  
49 110 ethical challenges.mp.  
50  
51 111 moral review.mp.  
52  
53 112 moral case deliberation.mp.  
54  
55 113 moral case consult\*.mp.  
56  
57 114 moral consult\*.mp.  
58  
59 115 ethic\* case review.mp.  
60 116 ethic\* deliberation.mp.

- 1  
2  
3 117 ethic\* intervention.mp.  
4  
5 118 ethic\* round.mp.  
6  
7 119 ethic\* support.mp.  
8  
9 120 ethic\* service.mp.  
10  
11 121 ethic\* analysis.mp.  
12  
13 122 ethic\* referral.mp.  
14  
15 123 ethic\* committee.mp.  
16  
17 124 bioethic\* deliberation.mp.  
18  
19 125 bioethic\* intervention.mp.  
20  
21 126 bioethic\* round.mp.  
22  
23 127 bioethic\* service.mp.  
24  
25 128 bioethic\* support.mp.  
26  
27 129 bioethic\* analysis.mp.  
28  
29 130 bioethic\* referral.mp.  
30  
31 131 bioethic\* committee.mp.  
32  
33 132 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or  
34 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or  
35 128 or 129 or 130 or 131  
36  
37 133 young person.mp.  
38  
39 134 100 or 133  
40  
41 135 neonatal.mp.  
42  
43 136 134 or 135  
44  
45 137 structure.mp.  
46  
47 138 model\*.mp.  
48  
49 139 process\*.mp.  
50  
51 140 intervention.mp.  
52  
53 141 assessment\*.mp.  
54  
55 142 evaluation\*.mp.  
56  
57 143 impact\*.mp.  
58  
59 144 effectiveness.mp.  
60  
145 audit.mp. or clinical audit/  
146 outcome assessment/ or outcome.mp.

- 1  
2  
3 147 quality.mp. or quality assessment tool/  
4  
5 148 indicator\*.mp.  
6  
7 149 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148  
8  
9 150 132 and 136 and 149
- 

10  
11  
12  
13 **Ovid MEDLINE(R) ALL**  
14  
15

- 16 1 paediatric.mp.  
17 2 paediatr\*.mp.  
18 3 pediatric.mp. or Pediatrics/  
19 4 paediatr\*.mp.  
20 5 child\*.mp. or Child/  
21 6 Adolescent/ or adolescent.mp.  
22 7 adolesc\*.mp.  
23 8 infant\*.mp.  
24 9 infant.mp. or Infant/  
25 10 kid.mp.  
26 11 kids.mp.  
27 12 baby.mp.  
28 13 babies.mp.  
29 14 toddler\*.mp.  
30 15 childhood.mp.  
31 16 juvenil\*.mp.  
32 17 youth\*.mp.  
33 18 minor.mp. or Minors/  
34 19 Infant, Newborn/ or infancy.mp. or Child, Preschool/  
35 20 Infant, Newborn/ or newborn\*.mp.  
36 21 Premature Birth/ or Infant, Premature/ or preterm\*.mp.  
37 22 prematur\*.mp.  
38 23 Puberty/ or pubert\*.mp.  
39 24 pubescen\*.mp.  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or  
4 19 or 20 or 21 or 22 or 23 or 24  
5  
6 26 Ethicists/ or ethicist\*.mp.  
7  
8 27 bioethicist\*.mp.  
9  
10 28 medical ethics.mp. or Ethics, Medical/  
11  
12 29 clinical ethics.mp. or Ethics, Clinical/  
13  
14 30 clinical ethics committee.mp. or Ethics Committees, Clinical/  
15  
16 31 bioethics.mp. or Bioethics/  
17  
18 32 bioethical issues.mp. or Bioethical Issues/  
19  
20 33 ethical issues.mp. or Ethics/  
21  
22 34 ethical challenges.mp.  
23  
24 35 moral review.mp.  
25  
26 36 Ethical Analysis/ or Ethics Consultation/ or moral case deliberation.mp.  
27  
28 37 moral case consult\*.mp.  
29  
30 38 moral consult\*.mp.  
31  
32 39 ethic\* case review.mp. or Ethics Committees/  
33  
34 40 ethic\* deliberation.mp.  
35  
36 41 ethic\* intervention.mp.  
37  
38 42 ethic\* round.mp.  
39  
40 43 ethic\* support.mp.  
41  
42 44 ethic\* service.mp.  
43  
44 45 Ethical Analysis/ or ethic\* analysis.mp.  
45  
46 46 ethic\* referral.mp.  
47  
48 47 Ethics Committees/ or ethic\* committee.mp.  
49  
50 48 bioethic\* deliberation.mp.  
51  
52 49 bioethic\* intervention.mp.  
53  
54 50 bioethic\* round.mp.  
55  
56 51 bioethic\* service.mp.  
57  
58 52 bioethic\* support.mp.  
59  
60 53 bioethic\* analysis.mp.  
54 bioethic\* referral.mp.

- 1  
2  
3 55 bioethic\* committee.mp.  
4  
5 56 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or  
6 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55  
7  
8 57 young person.mp.  
9  
10 58 neonatal.mp.  
11  
12 59 25 or 57 or 58  
13  
14 60 structure.mp.  
15  
16 61 model\*.mp.  
17  
18 62 process\*.mp.  
19  
20 63 intervention\*.mp.  
21  
22 64 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
23 assessment\*.mp.  
24  
25 65 evaluation\*.mp.  
26  
27 66 impact\*.mp.  
28  
29 67 effectiveness.mp.  
30  
31 68 Medical Audit/ or Clinical Audit/ or audit.mp.  
32  
33 69 Outcome Assessment, Health Care/ or "Outcome and Process Assessment, Health Care"/ or  
34 outcome.mp.  
35  
36 70 "Quality of Health Care"/ or quality.mp. or Quality Indicators, Health Care/  
37  
38 71 indicator\*.mp.  
39  
40 72 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71  
41  
42 73 56 and 59 and 72  
43  
44 74 from 73 keep 7001-7942  
45
- 

## Philosopher's Index

Philosophy - journal articles, books, book chapters and book reviews

Subject Area(s): Social Sciences , History , The Arts

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR

"ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

#### **APA PsycInfo®**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR "ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

#### **VHL Lilacs**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR young person OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR clinical ethics OR clinical ethics committee OR bioethical issue\* OR ethical issue\* OR ethical challenge\* OR moral review OR moral case deliberation OR moral case consult\* OR moral consult\* OR ethic\* case review OR ethic\* deliberation OR ethic\* round OR ethic\* intervention OR ethic\* support OR ethic\* service OR ethic\* analysis OR ethic\* referral OR ethic\* committee OR bioethic\* deliberation OR bioethic\* intervention OR bioethic\* round OR bioethic\* service OR bioethic\* support OR bioethic\* analysis OR bioethic\* referral OR bioethic\* committee) AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*) AND ( db:("LILACS"))

---

#### **Web of Science**

(paediatr\* OR pediatr\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR childhood OR juvenil\* OR youth\* OR minor\* OR infancy OR newborn\* OR prematurity OR preterm OR pubert\* OR pubescen\* OR "young person" OR neonatal) AND (ethicist\* OR bioethicist\* OR bioethic\* OR "clinical ethics" OR "clinical ethics committee" OR "bioethical issue\*" OR "ethical issue\*" OR "ethical challenge\*" OR "moral review" OR "moral case deliberation" OR "moral case consult\*" OR "moral consult\*" OR "ethic\* case review" OR "ethic\* deliberation" OR "ethic\* round" OR "ethic\* intervention" OR "ethic\* support" OR "ethic\* service" OR "ethic\* analysis" OR "ethic\* referral" OR "ethic\* committee" OR "bioethic\* deliberation" OR "bioethic\* intervention" OR "bioethic\* round" OR "bioethic\* service" OR "bioethic\* support" OR "bioethic\* analysis" OR "bioethic\* referral" OR "bioethic\* committee") AND (structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*)

---

**CINAHL (EBSCOhost Research Databases)**

S10 S7 AND S8 AND S9

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S9 S4 OR S5 OR S6

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S8 S2 OR S3

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S7 structure OR model\* OR process\* OR intervention OR assessment\* OR evaluation\* OR impact\* OR effectiveness OR audit OR outcome\* OR quality OR indicator\*

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S6 ethic\* referral OR ethic\* committee OR bioethic\* deliberation OR bioethic\* intervention OR bioethic\* round OR bioethic\* service OR bioethic\* support OR bioethic\* analysis OR bioethic\* referral OR bioethic\* committee

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S5 ethical challenge\* OR moral review OR moral case deliberation OR moral case consult\* OR moral consult\* OR ethic\* case review OR ethic\* deliberation OR ethic\* intervention OR ethic\* round OR ethic\* support OR ethic\* service OR ethic\* analysis

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S4 ethicist\* OR bioethicist\* OR medical ethics OR clinical ethics OR clinical ethics committee OR bioethi\* OR bioethical issues OR ethical issues

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S3 youth\* OR infancy OR newborn\* OR prematur\* OR pubert\* OR pubescen\* OR young person OR neonatal

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S2 paediatr\* OR pediater\* OR child\* OR adolesc\* OR infant\* OR kid OR kids OR baby OR babies OR toddler\* OR juvenil\* OR minor\*

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

S1 paediatric

Expanders - Apply equivalent subjects Search modes - Boolean/Phrase

**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	Page in text
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 9
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	21
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	21
Sponsor	5b	Provide name for the review funder and/or sponsor	21
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	21
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9-10 Table 1
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	12-14
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	12 Table 2

			Supplementary file 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	14-15
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	14
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently in duplicate), any processes for obtaining and confirming data from investigators	14-15
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	14-15
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	15-16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	16-17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I <sup>2</sup> and Kendall's $\tau$ )	16-17
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	16-17
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	16-17
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	n/a

**\* 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.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*