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# Clinical ethics support services in paediatric practice: protocol for a mixed studies systematic review on structures, interventions and outcomes

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## 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, PsycINFO, LILACS, Web of Science and CINHAL, 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 handsearched. 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 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.

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## 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 clinical ethics support services (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 1970–1980 in response to government and medical societies' recommendations,[4] and have 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, 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]

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

Paediatric practice raises particular ethical challenges not frequently found in adult patient care.[26–29] The fundamental principle of respect for patient autonomy has a substantially different understanding in paediatric practice, with parents taking the responsibility of decision making until children are afforded that possibility.[26] Generally, parents' decisions are in coherence with the child's views and the child's best interest, but conflict might arise when those involved (clinical team, parents, child) hold different views. Additionally, the child's capacity to understand the information provided and contribute to, or even make decisions about their care will depend on their age, maturity and the presence of chronic health conditions, physical disabilities and neurodevelopmental disorders. The United Nations Convention on the rights of the Child designates a duty to actively involve children in decision-making on matters that concern them, including their health and care.[30] Thus, regardless of their health condition, children must always be involved in the decision-making process with a careful assessment of the child's competence, particularly for decisions with moral significance.[26]

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

Despite ethically challenging situations and consequent divergent opinions being common in paediatrics, the number of paediatric ethics consultations is relatively low.[32] Many of these challenges might be opportunely identified and appropriately managed by the healthcare team and the family,[33] with clinicians receiving support through alternatives to formal ethics consultation.[32] However, in complex cases, there may either be an impasse or conflict might persist. In these situations, ethical consultation has been shown to help provide a resolution.[34] Recent controversial cases featured extensively in both print, and social media have increased international public and academic attention to the ethical challenges of paediatric practice. There has been a growing interest and debate surrounding the legal and ethical aspects of paediatric practice, such as parental and clinical teams' disagreements about the child's best interests, emerging child capacity, innovative treatments, technological dependence and end-of-life decision-making. Consultant paediatricians, trainees and residents have expressed concerns that these public cases might negatively impact their relationship with patients and families.[35] Availability of CESS for teams facing ethical challenges has been strongly advocated by professional bodies,[31] academics[33 36 37] and clinicians.[35 38] However, there are no standards or guidance on Paediatric (p)-CESS structure, functions or aims. Nor is there agreement about the level of involvement of patients, or in paediatrics parents and children, in ethics discussions.[39 40]

Interest in assessing CESS quality and effectiveness has grown in the past decades. However, most studies have focused on adult care settings, with relatively little attention paid to p-CESS.[41] Multiple systematic reviews evaluating different aspects of CESS have recently been published. Nevertheless, these focus on adult patients; ethical case intervention,[42] adult end of life context[43] and adult Intensive Care Unit (ICU).[44] Other reviews that did not explicitly focus on adult patients evaluate

a specific intervention (assessment tools for evaluating clinical ethics consultation[17]) or effectiveness of clinical ethics committees.[18] Generalisation of adult-focused reviews and evidence to paediatric context might not be appropriate. Many CESSs provide support for both adult and paediatric patients, their families and clinical teams. However, given the increase in number and complexity of children's hospitals around the globe,[45] it is likely that many CESS will serve patients and staff of paediatric-specific healthcare institutions.[40] Moreover, there might be a value in accumulating knowledge and expertise in an increasingly complex paediatric field. Thus, a better understanding on current models of paediatric specific CESS will inform further development and research to contribute to the provision of optimal care for paediatric patients and their families. To our knowledge, no systematic review on p-CESS structures, processes, evaluation measures and outcomes has been published. Such a review is necessary to inform current p-CESS practice and further development. Therefore, we aim to inform further research and debate on the current quality evaluation and minimum standards for p-CESS by offering a comprehensive description of current p-CESS models and assessments by responding to this review question:

> '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 p-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 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (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-Protocols statement.[49 50]

### 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 (ie, effect, evaluation, importance, meaning, value)[11] of any one or more of the following aspects of p-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. There will be no timeframe or geographical restrictions.

### Search strategy

#### Electronic searches

The following databases will be searched: MEDLINE, Philosopher's Index, EMBASE, PsycINFO, 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. Please see table 2 for Medline search strategy and refer to online supplemental file 1 for complete search strategy for all included databases.

#### Other resources

Reference and citation list of included studies will be handsearched. 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 2 weeks for a response before considering the publication unavailable.

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.<br>The paediatric population will be defined in this review as between 0 and 18 years old.<br>Study participants include, but are not limited to, referring clinicians, CESS members, patients/children, parents/relatives/careers and hospital administrators. | CESSs that serve only adult patients.<br>CESSs serving paediatric and adult populations, where paediatric data cannot be extracted and analysed |
| Context/ setting | Articles reporting on established CESS serving paediatric practice in any setting (hospital, community) and country. | Research ethics committees |
| Issues | Empirical studies reporting data on evaluation, assessment and/or impact (ie, 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.<br>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.<br>Systematic reviews<br>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<br>Conference abstracts |

CESS, Clinical Ethics Support Services.

## 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 flow chart.

## Data extraction

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

## Quality assessment

Following our initial literature review, we expect to find around 10–30 potentially eligible studies with multiple research designs, including qualitative, quantitative and mixed methods. To allow coherent and systematic critical appraisal of included studies with different designs, we will use the 2018 Mixed Methods Appraisal Tool.[52] The tool was developed specifically for the appraisal of complex systematic reviews that include empirical qualitative, quantitative and mixed methods studies. It includes specific criteria depending on the study design category. Each criterion is rated as 'yes', 'no', 'can't tell' response. As recommended by the authors, for each study, we will present a detailed description of the rating of each

**Table 2** Medline search strategy

1. paediatric.mp.
2. paediatr*.mp.
3. paediatric.mp. or Paediatrics/
4. pediatr*.mp.
5. child*.mp. or Child/
6. 6adolescent/ 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. young person.mp.
26. neonatal.mp.
27. ethicists/ or ethicist*.mp.
28. bioethicist*.mp.
29. medical ethics.mp. or Ethics, Medical/
30. clinical ethics.mp. or Ethics, Clinical/
31. clinical ethics committee.mp. or Ethics committees, Clinical/
32. bioethics.mp. or Bioethics/
33. bioethical issues.mp. or Bioethical Issues/
34. ethical issues.mp. or ethics/
35. ethical challenges.mp
36. moral review.mp.
37. ethical analysis/ or Ethics Consultation/ or moral case deliberation.mp.
38. moral case consult*.mp.
39. moral consult*.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.
57. structure.mp.
58. model*.mp.
59. process*.mp.
60. intervention*.mp.
61. outcome assessment, Healthcare/ or "outcome and process assessment, Healthcare"/ or assessment*.mp.
62. evaluation*.mp.
63. impact*.mp.
64. effectiveness.mp.
65. Medical Audit/ or Clinical Audit/ or audit.mp.
66. Outcome Assessment, Healthcare/ or "Outcome and Process Assessment, Healthcare"/ or outcome.mp.
67. "Quality of Healthcare"/ or quality.mp. or Quality Indicators, Healthcare/
68. indicator*.mp.
69. 1 or 2 or three 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

criterion and calculate an overall quality score based on the number of quality criteria met. There is no recommended cut-off score to exclude studies based on quality appraisal, and therefore no study will be excluded based on that criterion. Instead, we will conduct a sensitivity analysis during the data synthesis process to assess the impact of low-quality studies in the review findings and adjust recommendations accordingly.[52] Quality appraisal will be conducted by MD and checked by BP.

## Data synthesis

This systematic review is not focused only on the effectiveness of a particular intervention but addresses a broader range of questions. Data synthesis will follow a sequential explanatory synthesis following the two-step process described by Pluye *et al*[46]: First, a quantitative synthesis including results from quantitative studies and quantitative data from mixed-methods studies, followed by qualitative synthesis of results of qualitative studies and qualitative data form mixed-methods studies. The qualitative synthesis will be informed by the previously conducted quantitative synthesis. The integration of the qualitative synthesis into the quantitative one will allow a better understanding of the quantitative results,[46] also highlighting convergences and divergences between quantitative and qualitative synthesis to inform future research.

As we expect to find great diversity of outcome measures, quantitative data will be synthetised and tabulated using descriptive statistics where appropriate[53] guided by but not limited to Donabedian's framework of structure, process and outcomes. For qualitative data, we will conduct thematic synthesis approach,[54] using NVivo software for qualitative data analysis. The thematic synthesis will include: (1) free line-by-line coding of the primary study's findings, (2) organisation of these codes into related themes informed by the quantitative synthesis.[54] If the qualitative synthesis process develops additional themes that are not described in the quantitative synthesis, these will be included in the integrated synthesis as qualitative results only. To assess the robustness of the synthesis we will considering individual studies' quality and conduct sensitivity analysis if possible.

The synthesis will be conducted by MD and checked by BP. The final synthesis will be discussed within the research team.

## 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: (1) institutional managers, (2) p-CESS board members, (3) clinicians and (4) 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 1 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 ensure we will be looking for the appropriate data in the included studies. At the second webinar, participants will have the opportunity to provide their feedback on the preliminary findings, to add context and meaning to the findings, contributing to the overall interpretation and recommendations. Stakeholder involvement will be reported following the Guidance for Reporting Involvement of Patients and Public checklist.[45]

## Ethics and dissemination

As a systematic review of published data, no ethical approval is necessary. Following Cochrane guidance,[55] ethical approval for stakeholder involvement in this review would not be required as workshops would not be audio-recorded and no vulnerable groups will participate.

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

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

## DISCUSSION

Interest in assessing CESS quality and effectiveness has grown in the past decades, with little attention paid to p-CESS. The results of this work will provide us with the first systematic review of evidence on p-CESS.

The review team is comprised by a bilingual and international research team that includes a Paediatric Intensivist Consultant with vast experience in paediatric medical ethics leading the teaching, research and clinical activities of the p-CESS at a large tertiary children's hospital; a speech therapist, certified clinical ethics consultant and PhD student in CESSs evaluation, and a medical doctor and ethicist with experience in systematic reviews and ethics research. The researchers' diverse backgrounds will contribute with their experiences and perspectives on CESS structures, processes, and outcomes in different contexts (Latin America and the UK). This will also allow a more comprehensive review both, by searching a Latin American specific database and the inclusion of papers published in English and Spanish languages. This will enhance the review comprehensiveness, as long as potential bias are given due consideration in the results interpretation and recommendations development stages. Evidence on the effect of English-restricted criteria in traditional systematic reviews of randomised controlled trials with meta-analyses has not shown to result in significant bias.[57 58] However, this review on p-CESS structures, processes and outcomes will include a broader range of study designs and therefore potential bias associated with the exclusion of studies published in languages other than English and Spanish will be considered in the interpretation of results and recommendations.

The inclusion of peer-reviewed publications only might result in the omission of relevant publications (ie, CESS terms of references and/or reports published in institutional websites). However, focusing on peer-reviewed publications will ensure validity of data included in the synthesis and also warrant a balance between the amount of data and the capacity of the research team, without compromising the review results. Moreover, we aim at mitigating the potential exclusion of relevant data by including case reports and case studies. The use of the Donabedian model will allow a structured and objective assessment of p-CESS contribution to patients' care. This is a well-accepted and widely used framework. However, considering the normative nature of CESS and their interventions and outcomes, the framework will be used as a guide and adaptation is expected.

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

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**Contributors** 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.

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