


# BMJ Open Evaluating a clinical ethics committee (CEC) implementation process in an oncological research hospital: protocol for a process evaluation study using normalisation process theory (EvaCEC)

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## ABSTRACT

**Introduction** A Clinical Ethics Committee (CEC) is a multi-professional service whose aim is to support healthcare professionals (HPs) and healthcare organisations to deal with the ethical issues of clinical practice.

Although CEC are quite common worldwide, their successful implementation in a hospital setting presents many challenges.

EVALuating a Clinical Ethics Committee implementation process (EvaCEC) will evaluate the implementation of a CEC in a comprehensive cancer centre in Northern Italy 16 months after its establishment.

**Methods and analysis** EvaCEC is a mixed-method study with a retrospective quantitative analysis and a prospective qualitative evaluation by a range of data collection tools to enable the triangulation of data sources and analysis. Quantitative data related to the amount of CEC activities will be collected using the CEC's internal databases. Data on the level of knowledge, use and perception of the CEC will be collected through a survey with closed-ended questions disseminated among all the HPs employed at the healthcare centre. Data will be analysed with descriptive statistics.

The Normalisation Process Theory (NPT) will be used for the qualitative evaluation to determine whether and how the CEC can be successfully integrated into clinical practice. We will perform one-to-one semistructured interviews and a second online survey with different groups of stakeholders who had different roles in the implementation process of the CEC. Based on NPT concepts, the interviews and the survey will assess the acceptability of the CEC within the local context and needs and expectations to further develop the service.

**Ethics and dissemination** The protocol has been approved by the local ethics committee. The project is co-chaired by a PhD candidate and by a healthcare researcher with a doctorate in bioethics and expertise in research. Findings will be disseminated widely through peer-reviewed publications, conferences and workshops.

**Trial registration number** NCT05466292.

## INTRODUCTION

Healthcare decisions are often challenging to make due to unavoidable medical uncertainty

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study applies a rigorous methodology (mixed-method and the normalisation process theory) to explore which elements contribute to the normalisation of the service.
- ⇒ Study results will inform the improvement of the service itself, the development of practical strategies to enable and support clinical ethics committee (CEC) delivery in clinical settings and the development of appropriate outcomes for further evaluation.
- ⇒ A limitation is that 16 months is likely not long enough to achieve full implementation. A follow-up study with similar methods at a later stage will therefore be valuable.
- ⇒ Because this CEC has many competencies in clinical ethics and ethics consultation, the same results may be difficult to achieve within 16 months in settings without these competencies.

about the consequences of treatment and disease progression and to the deep-seated values of the persons involved in making the decisions. It is not unusual that moral conflicts between different stakeholders and moral distress among healthcare professionals (HPs) arise in clinical practice.<sup>1</sup> According to the literature, end-of-life issues, patient autonomy issues, resource allocation issues and conflicts with patients are the most frequently perceived ethical dilemmas.<sup>2</sup> Other factors of moral distress have also been identified in the hierarchical relationship between coworkers and with superiors, such as caring for highly demanding patients and caregivers as well as poor communication and organisational constraints.<sup>3</sup>

In response to the ethical issues and needs of patients, their families and HPs, clinical ethics support services (CESS) have increasingly been implemented over the past 30 years.<sup>1,4</sup>

CESS are ethical case interventions to promote a personalised care approach and

**Box 1 Description of clinical ethics committee (CEC) activities and tasks****CEC aims**

- ⇒ To maximise benefit and minimise harm to patients, families, healthcare professionals and institutions by fostering a fair and inclusive decision-making process.
- ⇒ To increase shared decision making in the resolution of an ethical problem in individual patient care.
- ⇒ To facilitate the resolution of conflicts.
- ⇒ To inform institutional efforts for quality improvement, appropriate resource utilisation and policy development by promoting practices consistent with the highest organisational ethics.
- ⇒ To assist individuals in dealing with current and future ethical problems.

**CEC tasks**

1. Ethical case review and analysis regarding active and retrospective cases (ethics consultation).
2. Development of institutional guidelines and policies and analysis of the bioethical aspect of the healthcare institution's policies concerning the rights and welfare of patients (policy development).
3. Bioethics education in clinical ethics for clinicians, patients, surrogates and the broader community (bioethics education).
4. Establishment of CEC networks.

to improve the process and outcome of a patient's care. They aim to resolve the ethical conflicts that arise in the clinical setting, promote the ability of HPs to recognise and manage the ethical needs of vulnerable patients and support decision making in ethically complex situations.<sup>5</sup>

The clinical ethics committee (CEC) is a kind of CESS. It is a standing, independent body established by a healthcare institution whose task is to consider, discuss and promote educational initiatives and to ensure good healthcare decision-making practices<sup>6,7</sup> on ethical issues arising in patient care. The CEC performs several activities: ethics consultation (EC) for HPs and citizens, ethical policy development and bioethics education for HPs.<sup>8,9</sup> A detailed description of CEC activities and tasks is provided in [box 1](#).

There is no standard legal or governing regulatory framework at the European level for CECs, in contrast with research ethics committees worldwide.<sup>9–11</sup> Consequently, in several European countries such as Poland,<sup>12</sup> France and Italy, there is no legal requirement to establish CECs in healthcare facilities.<sup>7</sup> In Italy, CECs still represent spontaneous, unregulated experiences, resulting in a general underappreciation of the service and the activity carried out.<sup>13</sup> According to a review of CESS in Italian healthcare facilities, only 4 regions out of 20, with a total of 10 centres, had dedicated services (called CEC, Ethics Group or Ethics Committee for Healthcare), which dealt specifically with EC.<sup>11</sup> However, a growing need to implement CEC within healthcare facilities has been highlighted by healthcare organisations, mainly due to the COVID-19 pandemic and its ethical implications.<sup>14,15</sup>

After reviewing the literature and collecting evidence-based data, the bioethics unit (BU) of the local health

authority (LHA) of Reggio Emilia<sup>16</sup> promoted the establishment of a CEC in 2020, the Comitato per l'Etica Nella Clinica (CEC) dell' Azienda USL-IRCCS di Reggio Emilia, the first CEC in the Emilia Romagna region.

Two main reasons prompted the development of the CEC: the need to provide HPs and healthcare institutions with a dedicated multidisciplinary CESS in response to the outbreak of the COVID-19 pandemic<sup>14,15,17</sup> and the need to integrate the EC service, already provided by the individual ethicist working at the BU of the same LHA, with a multiprofessional institutional service.<sup>16</sup>

EVALuating a Clinical Ethics Committee implementation process (EvaCEC) is a project designed to evaluate the implementation process of a CEC.

Evaluation research is an important step towards the further development of CESS. According to Haltaufderheide *et al*, evaluating a CESS means to 'develop a notion of what ought to be expected by an intervention and to assess whether or to what extent these expectations have been met by means of empirical research'.<sup>18</sup> Consequently, evaluating a CEC requires linking empirically measurable endpoints with normative theory. For this reason, we adopted so-called 'empirical bioethics' as the theoretical framework of the project.

Empirical bioethics is a generic, broad term increasingly used to describe a particular kind of research that seeks to ask and answer questions of bioethical interest in a way that draws on the strengths of both philosophical and empirical analysis.<sup>19</sup> It consists in the effort to study how the normative and the empirical can and should coalesce to answer research questions of ethical significance.<sup>20</sup> Research in empirical bioethics requires the development of new methodologies that provide both practical and theoretical solutions to the problem of how to develop normative claims that are richly informed by the empirical world.<sup>21</sup>

A CEC is a complex intervention because it is characterised by multiple related components and actors that interact to effect change, by the multiple organisational levels involved, by a need for flexibility in tailoring the intervention and the resources needed for its implementation and by the range of potential outcomes.<sup>21–24</sup> Consequently, we chose the Medical Research Council (MRC) framework for developing and evaluating complex interventions as our methodological framework.<sup>25</sup> The MRC framework aims to help researchers to identify the key questions about complex interventions and to design and conduct research with a diversity of perspectives and an appropriate choice of methods.<sup>25,26</sup> It has a phased, though not necessarily sequential, approach, from a preclinical research phase to a final phase in which the intervention is introduced into the healthcare service (development or identification of an intervention, assessment of the feasibility of the intervention and evaluation design, evaluation of the intervention and impactful implementation), resulting in a theory-driven intervention.<sup>25,26</sup> This framework emphasises the importance of understanding processes, including a model of the evaluation process,

**Table 1** Core NPT concepts

Concept	Key attribute	Working definition
Coherence	Sense-making	The extent to which individuals understand all the elements of the intervention and the reasons for adopting a new intervention
Cognitive participation	Engagement	The extent to which individuals believe in the innovation provided by the intervention and start to prepare for it
Collective action	Enacting	What happens when the intervention is operationalised
Reflexive monitoring	Appraisal	The act of keeping an innovation under review and of adapting it intelligently to changing circumstances

NPT, normalisation process theory.

and gives greater attention to the contexts in which interventions take place.

Moreover, the framework recommends a process evaluation (PE) study to assess the intervention's feasibility and piloting. A PE study helps to understand how the intervention has been delivered and how it can be replicated, to optimise the intervention's design and evaluation and to provide generalisable knowledge on implementing complex interventions.<sup>27</sup> Furthermore, a PE of complex interventions usually requires a combination of basic quantitative implementation measures with in-depth qualitative data to provide a detailed understanding of an intervention functioning on a small scale.<sup>27</sup>

To perform a rigorous PE study, we applied the normalisation process theory (NPT) as the methodological research strategy. NPT is a theory of implementation developed to identify, characterise and explain empirically identifiable mechanisms that motivate and shape implementation processes and affect their outcomes.<sup>28</sup> It provides a means of appraising factors that might promote or inhibit the routine incorporation of a complex intervention into clinical practice by focusing on what is needed to ensure that interventions become normalised.<sup>28,29</sup> NPT comprises four main concepts (table 1); identifying these concepts at work during implementation will help to understand the process itself.<sup>29</sup>

We expect that this study will identify the relevant components that contribute to the successful implementation of the CEC and its integration into everyday practice. Our findings will also identify modifications needed to improve the service and will be used to develop practical strategies to enable and support CEC activities in clinical settings.

## THE CEC: DESCRIPTION OF THE SERVICE

### Italian context

As mentioned above, the role, functions and establishment of CECs in Italy have not yet been regulated by any national recommendation, despite intense ongoing

debate on the establishment of national recommendations regarding EC.<sup>30–33</sup>

### The local context: the Local Health Authority-IRCCS of Reggio Emilia

On 13 July 2020, the CEC was established by the general directorate of the LHA–Azienda USL-IRCCS of Reggio Emilia, which is the single public healthcare company in the province of Reggio Emilia, Italy. The LHA is a part of the Regional and National Health Service; in Reggio Emilia, the LHA, organised into six healthcare districts, provides health and social care, hospital services and primary care. The LHA Hospital Service consists of six hospitals (one for each district), which work together to coordinate, develop and provide high-quality services. Finally, a Scientific Institute for Research, Hospitalisation and Healthcare (IRCCS) in Advanced Technologies and Care Models in Oncology is incorporated into the Reggio Emilia hospital. A total of 1500 beds are provided by the LHA, with 180 beds dedicated to oncology patients. The CEC intervention targeted all the HPs employed by the LHA of Reggio Emilia.

Before the CEC, a BU was set up in 2016 by the scientific directorate. This research unit was developed to promote quality of care for patients, their families and HPs through research activity on the ethical issues arising in daily clinical practice.

This study is part of a larger PhD research project related to developing, implementing and evaluating a CEC.

### Description of the intervention: the CEC

The composition and tasks of the CEC were delineated with a top-down approach, in line with the data from the scientific literature<sup>34</sup> and the Recommendations of the Italian Committee for Bioethics.<sup>31</sup> Composition and Regulation were also deliberated by the General Directorate on 11 November 2020.

### Composition

The CEC is composed of 15 members representing the different professionals and figures involved in the decision-making process. Of these, nine are internal and six are external to the LHA; these latter guarantee the CEC's independence. The core is composed of eight HPs in adult and paediatric care, one representative of patients and citizens, two jurists and four experts in bioethics. Occasionally, others will take part in EC but only in decisions where their presence appears necessary according to the patient's needs (eg, religious leaders, cultural mediators, psychologists and/or social workers). Due to the experimental nature of the CEC, the members were selected personally by the head of the BU according to their competencies and expertise in their field.

### Role, tasks and procedures

The CEC regulation states its nature, aims, tasks and procedures. The CEC is responsible for



- ▶ Evaluating clinical cases that are not part of clinical and pharmacological experimentation. These case evaluations are done by means of EC with HPs or healthcare teams (ethics consultation).
- ▶ Proposing and conducting institutional ethics training programmes (ethics education).
- ▶ Raising bioethical awareness in the community.
- ▶ Analysing the moral problems related to clinical practice (eg, choice criteria for the allocation of resources, suspension of treatments, requests for medically assisted suicide, consent for minors, substitute decision making, the ethical aspect of communication, immigration issues) and developing policies on specific moral issues (policy development).

The CEC meets once a month online. Each HP employed by the LHA of Reggio Emilia can request an EC online. EC requests are discussed during regular meetings by all the CEC members or, in specific cases, by a subgroup formed by the CEC President based on the members' particular competencies. If necessary, the President can specifically recommend that external experts attend the CEC meetings to provide their qualified advice.

The CEC also has an administrative office responsible for writing up meeting minutes, facilitating the production of written CEC case deliberations and other back-office activities.

## METHODS AND ANALYSIS

The study protocol (in-house prot. n. 2022/0026554 of 24/02/2022) was designed following the MRC framework for developing and implementing complex interventions. This is a mixed-method study with a retrospective quantitative assessment and prospective qualitative evaluation of the CEC service, 16 months after its establishment. It was registered on ClinicalTrials.gov on 27 July 2022 (NCT05466292).

Research on complex interventions requires a combination of quantitative and qualitative methods to collect crucial data on the implementation process variables. These data come both from all the settings where the intervention was implemented and from participants purposely selected from those settings who are likely to influence the functioning of the intervention. This combination of methods enables an appraisal of the effects of the (complex) intervention both as a whole and of its components.<sup>27</sup> We will, therefore, use a range of data collection tools to enable the triangulation of data sources and analysis. A comprehensive description of the methodologies we applied, the target population and related interventions are provided in [table 2](#).

Our referral framework is the mixed-methods approach which, by integrating the quantitative findings with the qualitative findings, aims to provide a more comprehensive picture of the intervention than either method can do alone.<sup>24</sup>

## Quantitative evaluation

The quantitative evaluation will assess the activities performed by the CEC within 16 months since its implementation and the spread, use and knowledge of the service among all the HPs employed at the LHA of Reggio Emilia.

### Data collection

Quantitative data will be collected:

- ▶ From the internal database of the CEC Administrative Office from October 2020 to February 2022 and by IT application provided by the LHA of Reggio Emilia and used by the CEC to save and share the activities carried out. For each of the activities carried out, several aspects will be analysed, as presented in [table 3](#).
- ▶ A closed-ended survey aiming to collect information on the level of knowledge, use and dissemination of the CEC among all the HPs employed at the LHA of Reggio Emilia. The survey is composed of the following three sections: (A) the participant's personal information; (B) the participant's previous experience in complex ethical situations and (C) the participant's evaluation of the service in terms of diffusion, knowledge, access and personal attitude and further suggestions. The answers are organised into Yes/No or free text space.

Population and eligibility criteria: The target population is all the HPs (physicians, therapists, nurses, social workers) employed at the LHA of Reggio Emilia, as the CEC is a cross-cutting service dedicated to all the HPs within the LHA. Participants will be included if they are employed at the LHA of Reggio Emilia. The survey will be online and disseminated by institutional email.

### Data analysis

The quantitative data will be analysed using descriptive techniques, that is, they will be summarised in terms of frequency and percentages for categorical variables, the mean and SD for symmetric quantitative variables and median and IQR for the remaining ones.

Descriptive statistics will be calculated for general variables. Specifically, continuous variables will be summarised by their mean and SD or median and IQR; categorical variables will be summarised as numbers and percentages.

## Qualitative evaluation

The qualitative evaluation will investigate mechanisms of impact and contextual factors among several groups of stakeholders who were differently involved in designing, promoting, delivering and benefitting the intervention. NPT will be used to determine whether and how the CEC can be successfully integrated into clinical practice.<sup>28</sup>

### Data collection

The opinions and perspectives on the process implementation of the CEC in terms of barriers/facilitators, expectations and needs will be assessed among different

**Table 2** Description of data sources and tools and their related aims and target population

Aims	Type of data	Data collection/ intervention	Outcome measures	Population
<b>Evaluation of CEC structure – ‘top down’ approach</b>				
To assess: how well the CEC worked in terms of the number of activities carried out by CEC in 16 months and the resources used by the service (see <a href="#">table 3</a> for further details)	Quantitative	Internal database	–	–
To explore the opinions of local managers on CEC functioning, role within the healthcare facility and expectations	Qualitative	Semistructured interview_1	Semistructured one-to-one interviews to explore the opinions and perspectives on the CEC in terms of barriers/facilitators, expectations and needs from the perspectives of Local Health Authority’s Managers/ Department Heads who were involved in the design and delivery of the service.	Managers/heads who formally supported and promoted the intervention
To explore the opinions of the CEC components on CEC functioning, role within the healthcare facility and expectations	Qualitative	Semistructured interview_2	Semistructured one-to-one interviews with CEC members on their concerns about their motivations and expectations as a member of the CEC, personal attitude towards the service, experience with CEC in terms of facilitators, problems and critical evaluation of the service delivered.	CEC members
<b>Evaluation of CEC activities – ‘bottom up’ approach</b>				
To assess the spread, use and knowledge of CEC among HPs in terms of: ▶ Knowledge ▶ Spread within healthcare facility ▶ Access ▶ Reception of activities provided by the CEC (training, ethics consultation, policy guidelines) ▶ Interest in the service ▶ Any impact of policy guidelines developed by CEC on clinical practice	Quantitative	Survey 1 ( <i>7 - issues CEC Survey</i> )	Closed-ended survey aiming to collect information on the level of knowledge, use and dissemination of the CEC among all the HPs employed at the Local Health Authority of Reggio Emilia. It is composed of 3 sections: section A asking the participant for personal information; section B asking the participant about previous experience in complex ethical situations; section C asking participants to evaluate the service in terms of diffusion, knowledge, access and personal attitude and further suggestions. The answers are organised into yes/no or free text space.	All HPs employed at the Local Health Authority of Reggio Emilia.
To explore opinions from HPs on: ▶ Comprehension of the role of CEC ▶ Usefulness of the service ▶ Expectations and needs ▶ Barriers and facilitators	Qualitative and quantitative	Survey_2	The NoMAD survey is a set of 20 survey items to assess implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare. This version comprises 20 multiple-choice questions, supplemented by 4 open questions. Answers are organised into 5 options: (1) I do not agree, (2) I partially do not agree, (3) I neither agree nor disagree, (4) I partially agree and (5) I totally agree. Higher scores mean better outcomes.	HPs who participated in the training on ethics consultation provided by the CEC
To explore the experience with EC provided by CEC	Qualitative	Semistructured interview_3	Semistructured interview concerning participants’ experiences with the ethics consultation service provided by the CEC	HPs who submitted an ethics consultation request

CEC, clinical ethics committee; EC, ethics consultation; HPs, healthcare professionals.

**Table 3** Description of quantitative data collected from the CEC administrative office internal database

CEC activities	outcomes
CEC meetings	No of meetings held; the presence of CEC members, duration, topics discussed
Ethics consultation (EC)	No of EC provided, who requested the EC, topic of the EC, process and modalities of EC, date of the CEC response, time spent preparing CEC response
Ethics training course	Hours spent in ethics education; the no of participants in the course and their characteristics; procedure/type of education provided; questions/comments by participants
Policy guidelines published	No of policy guidelines published; topic; hours spent to publish the document
Resources utilised	Time spent writing CEC reports; back-office activities
CEC, clinical ethics committee.	

HP populations involved in the use and provision of the service by means of:

1. Semistructured one-to-one interviews with LHA's managers/department heads who were involved in the design and delivery of the service to explore their opinions and perspectives on the CEC in terms of barriers/facilitators, expectations and needs.
2. Semistructured one-to-one interviews with CEC members focusing on their motivations and expectations as a member of the CEC, personal attitudes towards the service, experience with CEC in terms of facilitators and problems and critical evaluation of the service delivered.
3. Semistructured interview with HPs who requested EC, focusing on their experiences with the EC service provided by the CEC.
4. Normalisation Measure Development questionnaire (NoMAD) for HPs who attended at least one of five training sessions on clinical ethics promoted by the CEC. The survey will be developed using a modified version of the NoMAD instrument (based on NPT) and will explore attitudes towards the prospect of developing a CEC at the LHA of Reggio Emilia (the tool is provided in online supplemental appendix 1). This version comprises 20 multiple-choice questions reflecting the constructs of NPT, supplemented by four open-ended questions to assess the acceptability of elements of the CEC, including activities performed, the process of working with CEC and further improvements in the CEC development. Answers are organised into a range of five options: (1) I do not agree, (2) I partially

do not agree, (3) I neither agree nor disagree, (4) I partially agree and (5) I agree. Higher scores mean better outcomes. We used the Italian version of the NoMAD questionnaire, which was validated in 2018 by ImplementAll partners.<sup>35</sup>

Participants will be included if they meet, respectively, at least one of the following criteria: (1) is a department head/ local manager at the LHA of Reggio Emilia, (2) has been a member of the CEC in the last 16 months, (3) has submitted at least one EC request and (4) has attended at least one of the five training sessions on EC promoted by the CEC or is an HP employed at the LHA of Reggio Emilia.

Specific interview questions were designed for local managers/department heads, CEC members and HPs who submitted an EC request. All the interview topic guides are informed by the four NPT concepts. The interview's topic guides are reported in online supplemental appendix 2.

### Data analysis

Interviews will be audio recorded and transcribed verbatim. Data analysis will be conducted by two researchers with experience in qualitative research. Interview transcripts and free-text answers from the qualitative survey will be analysed using inductive thematic analysis,<sup>36</sup> and the methodological rigour of the analysis will be strengthened further by the supervision of a third, independent researcher. Analysts will generate themes across the data by defining labels and by grouping the labels into categories.

After this first inductive analysis of the qualitative data, the NPT will be applied to discuss the generated categories.<sup>37</sup>

In contrast, the quantitative data collected by the NoMAD survey will be represented using descriptive statistics, that is, the data will be summarised in terms of frequency and percentages for categorical variables, mean and SD for symmetric quantitative variables and median and IQR for the remaining ones.

Free-text answers from the surveys will be analysed thematically.

### Patient and public involvement

This protocol describes the evaluation of a service targeting HPs and healthcare organisations. Neither patients nor the general public were therefore involved in the design, conduct, reporting or dissemination of our research.

### ETHICAL CONSIDERATIONS

This clinical study was designed and shall be implemented and reported following the ICH Harmonised Guidelines for Good Clinical Practice, in accordance with applicable local regulations and with the ethical principles laid down in the Declaration of Helsinki. The protocol, subject information sheet and informed consent form have been

approved by the ethics committee (N. Protocol:AUSLRE Protocollo no 2022/0026554 of the 24 of February 2022). The project is co-chaired by a PhD candidate and a healthcare researcher. The principal investigator (PI) of the study is a PhD candidate in bioethics with a masters in philosophy and expertise in qualitative research. The co-PI is a health researcher with a doctorate in bioethics and expertise in research, EC and ethical education and training in clinical practice. Eligible subjects may only be included in the study after having provided written (witnessed, where required by law or regulation) and approved informed consent. Informed consent must be obtained before conducting any study-specific procedures (ie, all of the procedures described in the protocol). No study procedure can be performed before the written informed consent has been provided.

Findings will be disseminated widely through peer-reviewed publications, conferences and workshops.

Participants' informed consent to the study and data treatment as well as interview transcripts will be collected and archived by Smarty Web, an online tool provided by the LHA of Reggio Emilia to collect and archive the personal data of participants involved in research activities.

## DISCUSSION

CESS are becoming increasingly common in healthcare settings. Several studies have provided insight from their users, showing generally positive perceptions of the service and the support it provides. However, according to a recent literature review, 'it is not possible to determine the effectiveness of ethical case interventions' such as CEC, and 'further research to identify and measure outcomes which reflect the goals of different types of ethical case intervention is required'.<sup>34</sup> Consequently, a growing number of studies have started emphasising the need for a more in-depth understanding of these ethical interventions before their evaluation to explore more in detail precisely what they do, their barriers and facilitators, what outcomes they explicitly aim to achieve and how they bring about change to clinical practice.<sup>34 38</sup>

Previous studies have shown that CECs vary in diffusion, functions, internal structure and goals. These variations mainly relate to the model of implementing and delivering the service<sup>39</sup> and to various political, institutional and social factors, including local culture, trust relations, dominating model of the patient–physician relationship and existing legal and administrative frameworks.<sup>40–42</sup> These differences make it difficult to identify criteria to measure CEC effectiveness, still the core of research on these services.

Some studies have demonstrated that establishing a CEC is not enough to encourage physicians to access and/or be willing to use a CEC. Several barriers have been found to be associated with the top-down approach of CEC, for example, low organisational awareness of

ethics difficulties, low perceived need for ethics support and difficulties in the deliberation process.<sup>38 43</sup>

Based on the above, the successful implementation of a CEC in a hospital setting presents many challenges due to the multiple dimensions of complexity, the uncertainty and the local variations involved in the design and implementation of the CEC itself. Because several aspects of CEC functioning must still be elucidated,<sup>39</sup> there is a lack of shared processes and tools to understand, first and foremost, whether and how the CEC can be integrated into clinical practice.

To fill this knowledge gap, we conceived the present study, which adheres to the MRC framework for developing and evaluating complex interventions and to the NPT as the methodological research strategy. The present study is in line with the latest version of the MRC framework, which stresses a broader conception of complexity, leading to a shift in focus 'from the binary question of effectiveness'<sup>25</sup> to whether and how the intervention will be acceptable, implementable, cost-effective, scalable and transferable across contexts.

In other words, the focus of complex intervention research should include the development, identification and evaluation of a whole system of interventions and the assessment of how interventions contribute to a change in the system itself. These interventions can affect changes in relationships within an organisation, for example, the introduction of policies, changes in social norms or normalisation of practices.<sup>25</sup> In this regard, NPT and the MRC framework are particularly appropriate because CEC struggle to become a 'normal' part of the hospital system. Furthermore, the quantitative and qualitative methods are integrated to collect crucial variables of the implementation process from all settings and selected participants who are expected to influence the functioning of the intervention. The integration of these two research methods leads to a more accurate appraisal of the effects of the (complex) intervention, both as a whole and of its components.<sup>27</sup>

Our findings overcome context and study variations, the heterogeneity in assessments and the difficulties in making straightforward comparisons by shifting the core of the research onto the 'normalisation' of the whole service within the local context. The research findings may be useful to illustrate the implementation process of a CEC in a completely different context. Moreover, collecting data from different stakeholders, managers/department heads who formally support and promote the intervention at the organisational level could be helpful to collect valuable data to define the outcome. As Kok *et al* argued, providing evidence of quality is essential to furnishing healthcare organisations with solid justification for investing their time and effort in developing forms of CESS.<sup>44</sup>

Finally, we expect our results to contribute to the ongoing debate on the identification of appropriate outcome criteria to assess whether ethical case



interventions improve healthcare, both at the individual level and at the organisational level.

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## Appendix 1 Topic Guide Interviews

Coherence of the CEC	What is the process?	how participants who benefitted from CEC's activities perceive the CEC and whether they experienced the CEC as valuable to them and agreed about its usefulness and purpose.
Cognitive participation	Who performs the process?	whether participants saw the CEC as a legitimate part of their work and whether they supported it over time
Collective action	(How is the process performed?)	how the CEC was provided within the existing context, how the embedding and integration had proceeded, and what factors promoted or inhibited the work
Reflexive monitoring	(How is the process understood?)	how participants individually and collectively evaluate the CEC

### Themes of the interview to Ward Managers

- A. Perception of the role of the CEC in the local context and reasons for implementing the CEC.
- B. Understanding of its own activity in support of the CEC.
- C. Understanding of strengths and weaknesses related to the service.
- D. Reflection on service utilization and perception of impact in the local context

#### *Opening*

Good morning, thank you for your time to participate in this study. Regarding the purpose of the research, do you have any questions or concerns that you would like to clarify?

-Would you like to tell me about your experience with the CEC?

#### *Theme A – coherence:*

- In your opinion, what is the role of the CEC within the Health Care Company of Reggio Emilia?
- How, in your opinion, it is different from other services and what is its specificity?
- What is the goal of the CEC and how does it act in the local context?
- Are there any motivations that led you to support/promote this service?

#### *Theme B – cognitive participation*

- How do you help promote to this service?
- What do you think about the value of a service like the CEC to your work and to your colleagues?

#### *Theme C – collective action*

- Thinking about the activities carried out by the CEC, how have they been integrated into the local context?

-Are there any limitations (organizational? Internal? External to the service? Economic?) that you perceive with respect to the CEC? If so, which ones?

-Have there been any potentialities with respect to the service that has been implemented? If yes, which ones?

#### ***Theme D – reflexive monitoring***

-In light of what has been done in these 16 months, how do you evaluate the implemented service?

- In what ways could the ECC be improved?

#### ***Conclusion***

Compared to what was covered in this interview, do you have any additional thoughts, examples, comments to share? Are there any important things that did not come up during the interview?

#### ***Closing***

Thank you very much for your availability. I would like to ask you if I can contact you again if, there are points to deepen.

### **Themes of the interview to CEC's members**

- A. Perception of the role of the CEC in the local context and reasons for being a member of the CEC.
- B. Understanding of its own activity in support of the CEC.
- C. Understanding of strengths and weaknesses related to the service.
- D. Reflection on service utilization and perception of impact in the local context

#### ***Opening***

Good morning, thank you for your time to participate in this study. Regarding the purpose of the research, do you have any questions or concerns that you would like to clarify?

-Would you like to tell me about your experience with the CEC?

#### ***Theme A – coherence***

-In your opinion, what is the role of the ECC within the Company?

-How, in your opinion, is it different from other promoted services and what is its specificity?

-What is the goal of the CEC and how does it act in the local context?

-What are the motivations that led you to take part in this service?

#### ***Theme B – cognitive participation***

-What does your work involve in this service?

-What do you think about the value of a service like CEC to your work and your colleagues?

#### ***Theme C – collective action***

-Thinking about the activities carried out by the CEC, how have they been integrated into the local context?



-Are there any limitations (organizational? Internal? External to the service? Economic?) that you perceive with respect to the CEC? If so, which ones?

-Have there been any potentialities with respect to the service that has been implemented? If yes, which ones?

#### ***Theme D – reflexive monitoring***

-In light of what has been done in these 16 months, how do you evaluate the implemented service?

- In what ways could the ECC be improved?

#### ***Conclusion***

Compared to what was covered in this interview, do you have any additional thoughts, examples, comments to share? Are there any important things that did not come up during the interview?

#### ***Closing***

Thank you very much for your availability. I would like to ask you if I can contact you again if, there are points to deepen.

### **Themes of the interview to Health care professionals who required ethics consultation by the CEC.**

- A. Reasons and factors for requiring ethics consultation to the CEC.
- B. Evaluation of its own experience in terms of: perceived support, impact in its own on clinical case, impact on the daily experience;
- C. Evaluation of the CEC activities in terms of: access, satisfaction with the service; strengths, critical aspects related to counselling, clarity and comprehensibility of response, availability.
- D. Suggestions and overall opinion of the CEC.

#### ***Opening***

Good morning, thank you for your time to participate in this study. Regarding the purpose of the research, do you have any questions or concerns that you would like to clarify?

#### ***Theme A - coherence***

1. Would you like to tell me how you learned about CEC?
2. Would you like to tell me about the case that prompted you to contact the CEC?
3. What were the reasons that convinced you to contact the CEC?

#### ***Theme B – cognitive participation***

1. Considering the case you mentioned, did you feel supported in approaching the CEC? If so, in what way?
2. What impact did the CEC's advice had on the case?
3. What differences did you perceive in your daily clinical practice after the CEC's involvement?

#### ***Theme C – collective action***

1. How do you evaluate your experience with the counselling service offered by the CEC? Was it easy to access?
2. What do you see as the strengths of this service?
3. What do you think are the critical aspects of this service?

***Theme D – reflexive monitoring***

1. What do you take home from this experience?
2. What is your overall evaluation of the CEC?

***Conclusion***

Compared to what was covered in this interview, do you have any additional thoughts, examples, comments to share? Are there any important things that did not come up during the interview?

***Closing***

Thank you very much for your availability. I would like to ask you if I can contact you again if, there are points to deepen.

## Appendix 2

*Guidance of the survey to health care professionals who participated in the training on ethics consultation provided by the Clinical Ethics Committee of the Azienda USL-IRCCS di Reggio Emilia*

This survey is designed to better understand how to apply and integrate complex interventions into care practices. Specifically, this survey asks questions about the implementation process of the Clinical Ethics Committee of the Local health Authority Azienda USL-IRCCS di Reggio Emilia.

The survey has 2 parts. The first part contains a series of more detailed questions about the implemented intervention, through closed-ended questions. The second one, instead, some open-ended questions of in-depth analysis with respect to some aspects of this intervention. Please take the time to decide which answer best fits your experience for each statement and check the appropriate box.

The survey has been elaborated following the model of Finch, T.L., Girling, M., May, C.R., Mair, F.S., Murray, E., Treweek, S., Steen, IN, McColl, E.M., Dickinson, C., Rapley, T. (2015). Nomad: implementation measure based on Normalization Process Theory. [Measurement instrument]. The Italian version is available at: <http://www.normalizationprocess.org>.

n.	Question	Agree	Partially Agree	Neutral	Partially disagree	Disagree
1	I'm able to distinguish CEC from the usual hatreds of working					
2	Staff in this organization have a shared understanding of the purpose of CEC					
3	I understand how CEC affects the nature of my work					
4	I am able to see the potential value of CEC to my work					
5	There are managers in place to ensure the delivery of the intervention and to engage other practitioners					
6	I believe that participating in the dissemination of the CEC is a legitimate function of my role					
7	I am willing to work in new ways with my colleagues to use CEC					
8	I will continue to support the use of CEC					
9	I am able to easily integrate the use of CEC within my work					
10	Turning to CEC disrupts working relationships					
11	I have confidence in the ability of other practitioners to use CEC					
12	The work is assigned to professionals who possess					



	adequate skills to use CEC					
13	Sufficient training has been provided to enable staff to implement CEC					
14	Sufficient resources are available to support the delivery of CEC					
15	Management adequately supports the delivery of the ECC					
16	I am aware of scientific reports on the effects of CEC					
17	Staff agree that using CEC is fruitful.					
18	I appreciate the effects the delivery of CEC has had on my work					
19	It is possible to use the feedback collected on the CEC to improve the tool in the future					
20	I can modify the way I work with the CEC					
A	In what ways can the CEC be improved??					
B	What aspects would you like CEC to address in the future?					
C	What has CEC brought to the health care facility where you work?					
D	Do you have additional opinions and/or suggestions with respect to the way this service operates?					