Evaluating *a Clinical Ethics Committee (CEC) implementation process in an Oncologic Research Hospital. A process evaluation study using Normalization Process Theory*

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1. BACKGROUND

The consequence of illness and health care decisions, including healing, death, suffering, and disability, are issues of great importance in the lives of interested patients and their familiars. They are often complex and difficult to resolve due to complicated concepts, unavoidable uncertainty about consequences, and deep-seated value differences. Patients and families may seek advice about ethical issues from their clinicians, who, in turn, may strive to provide informed and well-reasoned responses to such requests (ASBHC). It can also create considerable conflict between different stakeholders and moral distress in clinical practice (Duval 2004). In response to the needs of patients, families, and health care professionals (HPs) for assistance in addressing the ethical issues they encounter in the health care setting, the practice of clinical ethics consultation (CE) and related services providing it has increasingly been implemented over the past thirty years. (ASBHC)

Ethics consultation (EC) is defined as 'a service provided by a committee, team, or individual to address the ethical issues involved in a specific clinical case (Tulsky and Fox 1996; Fletcher 1996). The services providing ethics consultation are called Clinical Ethics Support Services (CESSs).
A CESS represents an ethical case intervention that aims to promote a personalized care approach and to improve the process and outcome of patient's care by a) reducing conflicting situations; b) promoting the ability of HPs to recognize and manage the needs of ethically vulnerable patients; and c) supporting decision-making in ethical complex situations (Aulisio 2000).

Despite a general positive perception of EC and CESS from both HPs and users, a lack of robust evidences to determine CESS's effectiveness with certainty has recently emerged (Shildman et al 2019) along with the need of further research to provide a better understanding of the mode of action of each CESS and, consequently, to identify and measure outcomes which reflect the goals of different types of CESS. (Cochrane Review 2019).

In the last decades, CESSs have been implemented worldwide, with different approaches and forms. Important examples are individual Clinical ethics consultant, that is one-to-one EC provided by an individual ethicist with skills and competencies in ethics (Yarmolinsky R. 2016). Moral case deliberation (MCD), which consist of a collaborative, systematic reflection on real clinical case through a 'deliberationist' approach (Janssens 2015). Finally, Ethics Reflection Group (ERG) is a form of facilitator/ethicist-led refection, aiming to stimulate ethical reflection and promote mutual understanding between professionals groups. (Molewijk et al 2015) Finally, one of the most common forms of CESS are Clinical Ethics Committees (CEC) (Rasoal 2017, Hajibabaee F, 2016)

CEC is characterized as a body of persons established by a health care institution and assigned to consider, debate, take action on, or report on ethical issues that arise in patient care (Aulisio 2008, Hajibabaee et al, 2016) while ensuring good health care decision-making practices and assisting patients. It is a standing, independent, and multi-professionals committee, aiming specifically to a) maximize benefit and minimize harm to patients, families, HPs, and institutions by fostering a fair and inclusive decision making process; b)

to increase shared decision making in the resolution of an ethical problem in individual patient care; c) to facilitate resolution of conflicts; d) to inform institutional efforts at quality improvement, appropriate resource utilization, and policy development, promoting practices consistent with the highest organizational ethics; and e) to assists individuals in handling current and future ethical problems (Fletcher and Siegler 1996, Unesco 2005)

In the light of these goals, a CEC should provide the following functions 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 health care 'institution's policies concerning the rights and welfare of patients (*policy development*); 3) bioethics education in clinical ethics for clinicians, patients, surrogates and the larger community (*bioethics education*); 4) establishing CEC networks (UNESCO 2005; Powell et al., 2007, Furlan 2015).

CECs are now well established in many Western countries especially among European countries, such as UK , Norway and Spain (Hurst 2007). However, at the European level there is no formal legal o regulatory governing framework for CEC, which is in contrast to research ethics committee worldwide (Furlan 2015, Rasoal 2017, De Panfilis 2019). Consequently, in several European countries like Poland and Italy, there is no legal requirement for establishing CECs in health care facilities, despite the need to implement CEC to support HPs have been highlighted, especially during Covid19 pandemic and its ethical implications (Dittborn et al 2021, Perin et al. 2021).

In Italy CECs still represent spontaneous and unregulated experiences, resulting in a general underestimation of the service and the activity carried out (De Panfilis, 2019).

On 2020, a new CEC was established at the local Health Autority of Reggio Emilia, called *Comitato per l'Etica nella Clinica dell'Azienda USL-IRCCS di Reggio Emilia*. At the moment, the CEC represents one of the few experiences of implementing CEC among Italian health care setting and the first, experimental, CEC in the Emilia Romagna Region as well.
The CEC was developed and implemented by the Bioethics Unit (BU) of the same Local Health Authority. The BU is responsible for the development of empirical bioethics research projects, provides ethics consultation to individual HPs and equips, and promote ethics education and training among HPs .
The CEC was prompted by two main reasons: a) the need to provide HPs and health care institutions with a dedicated ethics support service in response to the Covid-19 pandemic outbreak and its ethical implications (De Panfilis L et al., 2020, Dittborn et al 2021, Perin et al. 2021); b) the need to integrate the ethics consultation service already promoted by the ethicist working at the Bioethics Unit of the same Local Health Authority.

Establishing and evaluating a CEC in a health care facility can be seen as a complex intervention, according to the MRC framework for developing and evaluating complex intervention (Magelssen et al., 2020, Shildmann 2019, Craig et al, 2019). CEC is characterized by multiple related components and actors that

potentially contribute to the success of the intervention itself, among which the multiplicity of organizational levels involved, the need for flexibility in tailoring the intervention and the implementation support; and the potential range of outcomes (Craig et al, 2019)

The MRC framework has a phased approach, from a pre-clinical research phase to a final phase in which the intervention is introduced into the health service leading to a theory-driven intervention (Development, Feasibility, Evaluation, Implementation). It also provides a "bottom up" development which guarantees to enter a phase III trial (Evaluating the intervention's effectiveness) with an appropriate theory and pilot work (Craig et al., 2019; Dowding et al., 2017).

In order to better design a controlled study to evaluate our CEC's effectiveness, the MRC framework recommends to develop previous study on the CEC's implementation process at the local level to better understand the intervention. The MRC framework specifically recommends feasibility and piloting phase after an intervention has been developed through Process Evaluation (PE).
PE aid to explore the way in which the intervention under study is implemented, can provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. (Craig 2019). Moreover, PE can be used to assess fidelity and quality of implementation, clarify causal mechanisms, and identify contextual factors associated with variation in outcomes (Oakley 2006). Then, PE is pivotal in understanding the feasibility of the intervention and optimizing its design and evaluation, how the intervention was delivered, how it might be replicated, and generalizable knowledge on how to implement complex interventions. (Moore 215).

PE is composed by three components (1.implementation or delivery; 2. mechanisms of impact; and 3. contextual factors), and 4 implementation outcomes: a) fidelity (defined as whether the intervention was delivered as intended); b) dose (the quantity of intervention implemented); c) investigate how the intervention was delivered; d) the "reach" of interventions (whether the intended audience comes into contact with the intervention, and how) (Moore 2015).
To measure these implementation outcomes, a combination of quantitative and qualitative methods on crucial process variables from all sites or participants purposively selected along dimensions expected to influence the functioning of the intervention are required, to appraise better the effects of the (complex) intervention both as a whole and on its components (Moore and al. 2015)

Previous studies dealing with CEC's implementation showed that CECs vary in diffusion, functions, internal structure and goals. These variations are mainly related to the model of implementing and delivering the service (Crico, 2021), and, at the local level, to various political, institutional, and social factors, among which: local culture, trust relations, dominating model of patient-physician relationship, and existing legal and administrative frameworks (Vollman 2013, Czarkwski 2021, Gaucher 2013).
Other studies demonstrated that the mere establishment of CEC often does not imply that physicians working in health care facilities actually have access and/or willing to use CECs, and several barriers have been related to the top-down approach of CEC, from HPs perspectives, resulting in low referral rates.

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Reported barriers are for examples: low organizational awareness of ethics difficulties, low perceived need for ethics support, difficulties in the deliberation process and HPs involvement (Magelssen 2018, Pedersen 2009).

Based on the above, the successful implementation of a CEC in a hospital setting presents many challenges, due to the multiple dimension of complexity, uncertainty, and local variation involved in the design and implementation of the CEC itself.
Consequently, a growing number of studies emphasize the need of a more in depth comprehension of the intervention before it is evaluated on a larger scale in a controlled study, to explore more in detail what a CEC exactly does, its barriers and facilitators, what outcomes it aims explicitly for, and how it brings about change to clinical practice (Shildmann 2019, Magelssen and al. 2021).

By exploring the barriers and promoters in the implementation process of this CEC, along with the overall perceived significance of CEC from the perspective of clinicians, CEC's members and ward managers, new insight are sought in order to further qualify the development of CEC implementation strategy.

This study presents a first process evaluation of the CEC implemented in an Oncological research Heath Care Company in the North of Italy, identifying aids and hindrances to implementation of this complex intervention into routine practice.

2. AIMS

2.1 Primary aim

This study aims to evaluate the process of a CEC development after 16 months from its implementation.

2.2 Secondary aims

Quantitatively, we aim at assess the activity of the CEC and its diffusions, knowledge and utilization among HPs, while qualitatively, the opinions/perspectives on it from users and providers health professionals in terms of barriers/facilitators, expectations and needs.

2.3 Practical implications

-To improve the ongoing intervention with data collected from the study;
-To identify tool to further evaluate the CEC's impact on the local context

4. STUDY DESIGN

Mixed-method study with retrospective quantitative assessment and prospective qualitative evaluation

3. MATERIALS AND METHODS

1. Intervention set-up

Italian Context

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In Italy, CECs are mainly slowly growing entities, resulting from voluntary local efforts rather than regional or national impetus (Hurst 2007). The last national survey on the current role and practices of ethics consultations among Italian ethics committees in both clinical and research settings demonstrated that very few CECs are available in some Italian hospitals. . Still, they represent local, spontaneous and unregulated experiences (De Panfilis et al., 2019). 'CECs' role, functions and establishment have not been regulated by any national recommendation yet, despite an intense debate is ongoing on the development of national recommendation regarding ethics consultation (Italian Committee for Bioethics, Motion, January,30 2020; Furlan 2015; Italian Committee for Bioethics, Opinion, March,31,2017; draft law on *Disposizioni in materia di morte volontaria medicalmente assistita* , 2021).

On July, 13, 2020, the Clinical Ethics Committee (CEC) was deliberated by the General Directorate of the Heath Care Company of Reggio Emilia. CEC is an ethical intervention promoted by the BU of the Local Health Authority of Reggio Emilia. The BU is an experimental research unit implemented in 2016 by the Scientific Directorate to promote quality of care for patients, familiars, and HPs through research activity on daily clinical practice's ethical issues. The BU research activities already integrated the development, implementation and evaluation of ethics interventions in clinical practice.

The evaluation study is part of a larger PhD research program related to developing, implementing, and first evaluating a CEC. The PI of the study is a Ph.D. candidate in Bioethics with a Master in Philosophy and documented expertise in qualitative research. The co-PI is a health researcher with a Ph.D. in Bioethics and established expertise in research, ethics consultation, and ethical education and training in clinical practice. The intervention is targeted to all the HPs employed by the Local Health Authority of Reggio Emilia.

Description of the intervention: the CEC

The CEC's composition, and task were delineated with a 'top-down' approach, accordingly with data from the scientific literature (Schildmann et al., 2019) and the Recommendations of the Italian Committee for Bioethics,(Italian Committee for Bioethics, Opinion of Mar 31 2017). Composition and Regulations were also deliberated by the General Directorate on November 11, 2020.

-Composition:

The CEC is composed of 15 members representing the different professionals and figures involved in the decision-making process. Of these, 9 are internal and 6 are external to the Health Care Company to guarantee the 'CEC's independence. The stable core is composed of 8 HPs in adult and pediatrics care, 1 representative of patient associations, 2 jurists and 4 experts in bioethics. Occasionally, other members will take part in ethics consultation but only in decisions whose presence appears necessary, according to the patients' needs (e.g. religious, cultural mediators, psychologists, social workers). Due to the experimental feature of the CEC, components were selected personally by the Head of the BU due to their competencies and expertise in the field.

-Role, tasks and Procedures

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The Regulation states the 'CEC' nature, aims, tasks and procedures. CEC is responsible for
a) the evaluation of clinical cases that are not part of the clinical and pharmacological experimentation by ethics consultation targeting HPs or health care team (*ethics consultation*);
b) the proposal and conduction of institutional ethics training program, bioethical awareness of citizenship (*ethics education*) and
d) the analysis of moral problems related to clinical practice (e.g. choice criteria in the allocation of resources, suspension oftreatments, request for medically assisted suicide, minors, and consent, substitute decision-makers, ethical aspect of communication, immigration issues) and the development of policy on specific moral issues (*policy development*).

CEC meets once a month through online meetings. Each HP employed by the Health Care Company of Reggio Emilia can ask for ethics consultation by an online request. Ethics consultation can be discussed during regular meetings by all 'CEC's members or, in a specific case, by a small sub-group, identified by the 'CEC's President on the evaluation of their particular competencies. If necessary, external experts can participate in the CEC meetings for specific advice on the 'President's specific recommendation.
CEC is also provided by a Secretariate, responsible for the back-office activities.

2. **Process evaluation study using Normalization Process Theory**

Implementation of CEC in a hospital setting is a complex intervention.
In order to perform a rigorous evaluation of the implementation process of the CEC of the Local Health Authority of Reggio Emilia, we applied the Noralization Process Theory (NPT) as the methodological research strategy .
Accordingly with a recent survey on the use of NPT, it has been mainly used in reporting the implementation of complex health care intervention prior to the development of a randomized control trial to test their effectiveness.
NPT is a general, generalizable, middle-range theory of implementation that seeks to explain the process of implementation, embedding, and integration of material practices in formally, defined context (May, 2009). It identifies, characterizes and explains mechanism that have been empirically demonstrated to motivate and shape implementation process and affect their outcomes (May et al 2018).
NPT has been developed to identify, characterize and explain empirically identifiable mechanism that motivate and shape implementation process (May et al. 2009), offering a valuable set of conceptual tools to aid understanding of implementation as a dynamic process, effectively assist in the explanation of the success or failure of specific implementation projects (May et al., 2018).
Consequently, NPT provides a means of apprising factors that might promote and inhibit the routine incorporation of complex intervention in everyday life, focusing on the work that people need to ensure interventions become normalized . (Brooks et al; May 2018)

NPT comprises 4 main concepts and identifying these concepts at work during implementation will help to understand the process itself (May and Finch 2009). These components are considered to be dynamic and

interact within the wider context of the intervention, such as existing organizational structures and procedures [May 2018].

Table 1. NPT's 4 core concepts

concept	Key attribute	Working definition
Coherence	Sense-making	The extent t which individuals really understand all the elements of the intervention and the reasons for adopting t 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 operationalized
Reflexive monitoring	Apprisal	The act of keeping an innovation under review and adapting it intelligently to changing circumstances

NPT will be used as methodological framework to perform PE of the CEC implemented at the Local Health Authority of Reggio Emilia.

3. The evaluation study

PE of complex interventions usually requires a combination of basic quantitative measures of implementation with in-depth qualitative data to provide detailed understandings of intervention functioning on a small scale [Moore 2014].

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 [Craig 2008].

I) Quantitative evaluation will include of CEC's activities performed within 16 months since its implementation and survey among all the HPs employed at the Local Health Authority of Reggio Emilia to understand the spread, use and knowledge of the service. These will be used to examine aspects of 'dose' (the quantity of intervention implemented); and the 'reach' of interventions (whether the intended audience comes into contact with the intervention, and how) (Moore 2015).
II) Qualitative methods (semi-structured interview and cognitive survey) will be used to investigate mechanisms of impact and contextual factors among several groups of stakeholders, differently involved in designing, promoting, delivering, and benefitting the intervention. We will use Normalization Process Theory to determine if, and in what ways, the CEC can be successfully 'normalized' (embedded) into clinical practice [Murray 2010, May 2018).

Then, the study has several components and includes data from different stakeholders of the CEC (HPs, CEC's members, Managers and Heads of Departments), as reported in the following table:

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Table 1. Data sources in the project and the main topics they address

Outcome	**Type of data**	**Data collection**	**Population**
Evaluation of CEC's structure - 'top down' approach			
To quantify -the amount of activities performed by CEC in 16 months; - the amount of resources required by the CEC; To assess: - how much the CEC worked; - how much CEC has been used by HPs	Quantitative	Internal database	-
To explore the opinion on CEC functioning, role within the health care facility and expectation	qualitative	Semi-structured interview	Managers/Heads who formally supported and promoted the intervention
To explore the opinion on CEC functioning, role within the health care facility and expectation	qualitative	Semi-structured interview	CEC's members
Evaluation of CEC's activities - 'bottom up' approach			
To assess spread, use and knowledge of CEC among HPs in terms of: -knowledge; -spread within health care facility -access -reception of activities provided by the CEC (training, EC, policy guideline) -interest to the service -eventual impact of policy guideline developed by CEC on clinical practice	quantitative	Anonimous survey	All HPs employed at the Health care Authorithy of Reggio Emilia.
To explore opinions from HPs on: -comprehension of the CEC role; -utility of the service, -expectations and needs; -barriers and facilitators;	Qualitative and quantitative	Cognitive survey	HPs who partecipated to the training on ethics consultation provided by the CEC
To explore te experience with EC provided by CEC	qualitative	Semi-structured interview	HPs who submitted an ethics consultation request

This is the first study to explore how an ethical case intervention, the CEC, is implemented in practice and the first to use a rigorous approach as NPT to do this. A range of methods of data collection enabling triangulation of data sources and analysis, will be used. Large sample of participants from all the HPs working at the Health Care Authority of Reggio Emilia, and all staff types and grades who were involved in designing, commissioning and delivering the intervention will participate. NPT will inform the interview and survey schedule questions.

It will be used also as a framework for data analysis.
Further, we will use data to identify required modifications and to develop practical strategies for enabling and sustaining the CEC delivery in clinical settings.

QUANTITATIVE EVALUATION

The quantitative evaluation aims to assess the implementation process of the CEC by evaluating:
-spread, use, knowledge of the CEC among HPs employed at the Local Health Authority of Reggio Emilia by an anonymous online survey;
- the amount of activities performed by CEC in 16 months and the resources required by the CEC by internal database

Population

For the quantitative evaluation, we chose to focus our study population on all the HPs employed at the Local Health Authority of Reggio Emilia, as CEC is a cross- institution body, dedicated to all the HPs within the health care facility.

Participant eligibility

HPs will be included if they are employed at the Health Care Authority of Reggio Emilia

Recruitment Procedure

The survey will be disseminated among HPs employed at the Local Health Authority of Reggio Emilia. The email will containing all the information related to the study's objectives and a link to the online survey. The email will specify that any personal data will be required to fulfill the survey, which will be anonymous.

Data collection

1) Anonymous survey

We will design, pilot and disseminate an online anonymous survey to assess the spread, use, knowledge of the CEC among HPs employed at the Local Health Authority of Reggio Emilia. The survey will be developed with Google Form with multiple options and closed-ended questions. The surveys' results will be collected in the related Microsoft Excel. The survey will regard HPs' consideration on:

-knowledge
-spread within health care facility
-access to CEC
-reception of activities provided by the CEC (training, EC, policy guidelines)
-interest to the service

-eventual impact of activities developed by CEC on clinical practice(especially regard policy guideline).

2) Internal database

A Microsoft Excel dataset will be created to collect data relating to the activities carried out by the CEC from October 2020 to February 2022. The data will be collected from the internal database of the CEC's Secretariate and by IT application, provided by the Health Care Company, and used by the CEC to save and share the activities carried out.

The following aspects will be analyzed for each of the activities carried out:

CEC's activities	**outcomes**
CEC's meetings	number of meetings carried out; the presence of CEC's components, duration, topics discussed
Ethics consultation (EC):	number of EC provided, who required the EC, topic of the EC, process and modalities of EC, date of the 'CEC's response, time spent to prepare 'CEC's response
Ethics Training course	hour spent in ethics education; number of participants to the course and their characteristics; procedure/type of education provided; questions/comments by participants
Policy-guidelines published	number of policy guideline published; topic; hours spent to publish the document
Resource employed	time spent related to 'CEC's written report preparation; back-office activities.

It is specified that any sensitive data will be anonymized.

Data analysis

The quantitative data collected by the dataset will be represented using descriptive techniques; that is, they will be summarized in terms of frequency and percentages for categorical variables, mean and standard deviation 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 summarized by their mean and SD, or median and interquartile range; categorical variables will be summarized as numbers and percentages.

QUALITATIVE EVALUATION

The opinions/perspectives on the process implementation of the CEC from users and providers health professionals in terms of barriers/facilitators, expectations and needs will be assessed by using qualitative methods with large samples of participants from all staffs types and grades who were involved in designing, promoting, delivering and benefitting the CEC. Specifically, we will:

a) interview Managers/Heads who formally supported and promoted the intervention

b) interview CEC's members who delivered the intervention

c) interview HPs who benefitted the intervention by ethics consultation
d) perform a cognitive anonymous survey targeting all the HPs who benefitted the intervention by attending the training course promoted by the CEC

Population

The qualitative evaluation is targeting to HPs (physicians, therapists, nurses, social workers) employed by the Local Health Authority of Reggio Emilia, and specifically to:
- Local Managers/Heads of Departments who have been contacted during the dissemination process
-CEC's member
- HPs who submitted an ethics consultation request,
- HPs who attended the training on ethics consultation provided by CEC;

Participant eligibility

Participants will be included if they:

-are working as a Head of Departments / local Manager at the Local health company of Reggio Emilia, who have been contacted by the CEC's president during the dissemination process

-have been a member of the CEC in the last 16 months;

- submitted at least 1 ethics consultation request;

- participated to at least 1 of 5 training courses on ethics consultation promoted by the CEC

-are HPs actually employed at the local Health Authority of Reggio Emilia
- Gave written consent

Recruitment Procedure (Interviews)

The center PI will contact by telephone or e-mail eligible participants, explaining the aims and procedures of the study and providing them with a document containing all the information related to the study's involvement (Attached 1). Participants expressing their interest in participation will be then contacted by telephone by the interviewer/facilitator who, after obtaining written informed consent to participate to the study (Attached 2) and to personal data treatment (Attached 3), will schedule an appointment for the interview.
Personal interviews will be held via video teleconference (Lifesize system) or in presence, audio-recorded and transcribed in full.

Recruitment Procedure (cognitive survey)

All the HPs who registered to 1 of the 5 training course on ethics consultation will be recruited from the database of the Training Office. To guarantee HPs' anonymity, the PI will contact the Head of the Training Office who, on behalf of the PI, will sent an email to all the HPs attended the course. Since any further contact will be between the PI and the Head of the training office, it will not possible for the PI to identify who answer the survey. The email will contain all the information related to the study's objectives and a link to the online

survey and it also specifies that any personal data will be required to fulfill the survey, which will be completely anonymous.
Participants are expected to submit the survey in two weeks from the first invitation. Then a reminder will be sent to submit responses within another week.

Data collection

Semi-structured interview

The semi-structured interview is a social interaction between two subjects: the interviewer and the interviewee. It has a cognitive purpose with the primary purpose of collecting data. The semi-structured interview guide includes a series of questions that must be asked to all interviewees without the need for a pre-established order, leaving space for any further investigation.
It will be the interviewer's concern to create a climate based on non-judgmental listening and mutual trust (Bichi 2007, Cocci 2005).
Therefore, the interviews will be conducted by the members of the research team, who have received special training in this regard and the place of the interview will be by the selected participating members.
The expected duration of the interview is between 30 and 50 minutes; the interview will be audio-recorded.

Interview's topic guide are informed by NPT four concepts.

Table 3: topic of Interviews' topic guide accordingly with NPT core concepts

concept	**Key attribute**	**Topics of the interview are:**
Coherence	Sense-making	motivations/ expectations to implement the CEC and understanding of its role within the Health Care Facility
Cognitive participation	engagement	understanding of personal commitment to the service
Collective action	enacting	understanding the experience with the CEC in terms of facilitators, problems, and perceived outcomes
Reflexive monitoring	Apprisal	Critical appraisal on the service delivered and further suggestions to improve CEC

The interview's topic guides are reported in Appendix 1. Specific interview questions were designed for - Local Managers/Heads of Departments; CEC's member; HPs who submitted an ethics consultation request.

Participants' informed consents to the study and data treatment, and interviews' transcription will be collected and archived by a Smarty Web, an online tool provided by the Local Health Authority of Reggio Emilia to collect and archive the personal data of participants involved in research activities.

1) Cognitive survey

To identify factors which might shape the implementation of CEC, we design, pilot and disseminate an online survey through HPs who attended at least 1 of 5 training course 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 to the prospect of the development of the CEC at the Local Health Authority of Reggio Emilia (the tool is provided in Appendix 2).

We chose the NoMAD tool as it is the first quantitative measure based on NPT. NoMAD can be used to describe participants' views about how an intervention impacts on their work, and their expectations about whether it could become a routine part of their work and as a way of improving implementation by identifying areas needing further work to progress an implementation project. The survey is composed by 20 implementation assessment items reflecting the constructs of NPT, from the professionals directly involved in the work of implementing complex interventions in healthcare (Finch 2013).

We used the NoMad Italian validated version available at : https://www.implementall.eu/NoMAD_Italian.pdf
According with the italian version provided, any personal data is included in the survey, which is completely anonymous. The developers suggest adapting and customize the tool for specific use by replacing the word "intervention" with a term that would be more familiar to study participants [Finch 2013]. For this study, "intervention" will be replaced with "Comitato per l'Etica nella clinica (CEC)."

Finally, the survey will be integrated with open questions free text to assess acceptability of elements of the CEC, including activities performed, the process of working with CEC and further improvements for the CEC developments.

The survey will be developed with Google Form with multiple options and the following open-ended questions:

How can this CEC be improved?
What issues would you like to address in a future CEC?
What has CEC brought to the health care facility?
Do you have other general/supplemental remarks?

Open ended questions will elicit HPs' views on their opinion, experience with the CEC and expectations.
The surveys' results will be collected in the related Microsoft Excel.

5.3.3. Data Analysis

Semi-structured interview

Interviews will be audio-recorded and transcribed verbatim.

Data analysis will be conducted by two researchers with experience in qualitative research. Interviews' transcriptions and free text from qualitative survey will be analyzed using thematic analysis [Braun 2006], whose analytical stages can be summarized as follows:

- Each researcher will read the transcriptions and write comments and initial thoughts in a memo.

- Each researcher will extract portions of the text individually and then share their work to reach an initial agreement. During this stage, they will conduct the thematic analysis inductively [Braun V 2006] providing their insights.
- Researchers will independently review themes and allocate portions of the text to the newly reconfigured themes.
- Together, they will re-define themes and re-name them to achieve internal consistency.
- One researcher will extract from the interviews and draft the final report, which will be checked and amended by the other two.

The methodological rigor of the analysis will be further guaranteed by the supervision of a third, independent researcher.
After a first, inductive analysis of qualitative data, the construct of NPT will be applied to the emerging themes to interrogate, challenge, confirm or refine the themes. (McNaughton 2020).

Cognitive survey
The quantitative data collected by cognitive survey will be represented using descriptive techniques; that is, they will be summarized in terms of frequency and percentages for categorical variables, mean and standard deviation for symmetric quantitative variables and median and IQR for the remaining ones.
Free text from surveys will be analysed by thematic analysis described.

The study will be developed within 10 months since the CE AVEN approval.

6. ETHICAL CONSIDERATION

This clinical study was designed and shall be implemented and reported in accordance with the ICH Harmonized Guidelines for GCP, with applicable local regulations, and with the ethical principles laid down in the Declaration of Helsinki.

6.1 Ethics Committee Approval
The protocol, Subject Information Sheet, Informed Consent Form will be approved by the Ethics Committee (CE AVEN), as required in chapter 3 of the ICH E6 Guideline.

6.2 Subject Information and Informed Consent
Eligible subjects may only be included in the study after providing written (witnessed, where required by law or regulation), EC-approved informed consent. Informed consent must be obtained before conducting any study-specific procedures (i.e. all of the procedures described in the protocol). No study procedure can be performed before the written informed consent has been provided.

6.3 Confidentiality
The investigator must ensure participant anonymity. On database and other documents, participants must not be identified by name but by participant number and a code. The investigator must keep a separate log of

'participants' codes, names and addresses, and signed informed consent forms, all of which must be kept strictly confidential.
Data generated by this study must be available for inspection upon request by representatives of the national and local health authorities, monitors, representatives, and collaborators, and the EC for each study site, as appropriate.

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Appendix 1
Interview's topic guide

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

The semi-structured interview with the Managers/Department Heads who promoted the intervention will reflect the following themes:

A. Perception of the role of CEC in the local context, and motivations behind the implementation of CEC.
B. Understanding of their own activities in support of CEC.
C. Understanding the strengths and critical aspects related to the service
D. Reflection on their perceived impact in the local context

Opening
Good morning, thank you for the time you dedicated to participate in this study. Regarding the purpose of the research, do you have any questions or concerns to clarify? Is it clear to you why we are here?

-Would you like to tell me what was your experience with Clinical Ethics Committee (CEC)?

Topic A - coherence :
-In your opinion, what is the role of the CEC within the Local healthcare Authority?
-How, in your opinion, is it 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 prompted 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 CEC to your work and your colleagues?

Topic C - collective action
-Thinking about the activities carried out by the CEC, how have they been integrated into the local context?
-Were there any limitations (organizational? Internal? External to the service? Economic?) that you perceive with respect to the CEC? If yes, which ones?
-Were there potentials instead with respect to the service that was implemented? If yes, which ones?

Topic D - reflexive monitoring
-Considering what has been done in these 16 months, how do you evaluate the service?
- In what ways could the CEC be improved?

Conclusion
Do you have any additional thoughts, examples, comments to share?

The semi-structured interview with CEC's members will reflect on the following themes:

A. Perception of the CEC's role in the local context and motivations for participating in it
B. Understanding of their own activities in support of the CEC
C. Understanding of strengths and critical issues related to the service
D. Reflection on service use and perception of the impact produced in the local context

Opening
Good morning, thank you for your willingness to participate in this study. Regarding the purpose of the research, do you have any questions or concerns to clarify? Is it clear to you why we are here?

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

Topic A - coherence
-In your opinion, what is the role of the CEC within the local Health Care Authority?
-How, in your opinion, is it 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?
-What are your motivations for taking part in this service?

Theme B - cognitive participation.
-What does your work in this service consist of?
-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 were they integrated into the local context?
-Were there any limitations (organizational? Internal? External to the service? Economic?) that you perceive with respect to the CEC? If yes, which ones?
-Were there strengths with respect to the service that was implemented? If yes, which ones?

Topic 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 CEC be improved?

Conclusion
Do you have any additional thoughts, examples, comments to share? Are there any important things that did not come up during the interview?

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The semi-structured interview with professionals who required an ethics consultation to the CEC will reflect on the following themes:

A. Motivations and factors that prompted the request
B. Evaluation of their own experience in terms of: perceived support, impact in their own Clinical case, impact on their daily experience;
C. Evaluation of the CEC activity in terms of: access, satisfaction with the service; strength aspects, critical aspects related to counseling, clarity and comprehensibility of response, availability...
D. Suggestions and overall opinion about the CEC.

Opening
Good morning, thank you for the time you dedicated to participate in this study. Regarding the purpose of the research, do you have any questions or concerns to clarify? Is it clear to you why we are here?

Topic A - coherence
1. Would you like to tell me how you came to know 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 ask for a support to the CEC?

Theme B - cognitive participation
1. With respect to the case you told me about, did you feel supported by CEC? If yes, how?
2. What impact did the CEC's advice have on the case?
3. What differences did you perceive in your daily clinical practice as a result of this case and the CEC's involvement?

Topic C - collective action
1. How do you rate your experience with the counseling service offered by the CEC? Was it easy to access?
2. What do you think are the strengths of this service?
3. What do you think are the critical aspects of this service?

Topic D - reflexive monitoring
1. What do you take home from this experience?
2. What is your overall assessment of the ECC?

Conclusion
Do you have any additional thoughts, examples, comments to share? Are there any important things that did not come up during the interview?

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Appendix 2
Guide and Track of the survey to participants of the training course pomoted by the Clinical Ethics Committee

This survey is designed to better understand how to apply and integrate complex interventions into daily clinical practices. Specifically, this survey asks questions about the implementation process of the Clinical Ethics Committee (CEC) at the Local Health Authority of Reggio Emilia.

The survey is composed by 2 parts. The first part contains a series of more detailed questions about the implemented intervention through closed-ended questions. The second, on the other hand, contains some open-ended questions concerning 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.

This Survey was developed 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: mplementation measure based on Normalization Process Theory. [Measurement instrument]. Accessed at: http://www.normalizationprocess.org.

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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	Continuerò a supportare l'utilizzo del CEC					
9	I will continue to support the use of CEC					
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					

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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?					

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Normalization Measure Development Questionnaire (short NoMAD)

(Adapt the questionnaire to your purposes by specifying [the intervention] you are using inside the brackets)