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MORECare research methods guidance development: Recommendations for ethical issues in palliative and end-of-life care research

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Abstract

Background: There is little guidance on the particular ethical concerns that research raises with a palliative care population.

Aim: To present the process and outcomes of a workshop and consensus exercise on agreed best practice to accommodate ethical issues in research on palliative care.

Design: Consultation workshop using the MORECare Transparent Expert Consultation approach. Prior to workshops, participants were sent overviews of ethical issues in palliative care. Following the workshop, nominal group techniques were used to produce candidate recommendations. These were rated online by participating experts. Descriptive statistics were used to analyse agreement and consensus. Narrative comments were collated.

Setting/participants: Experts in ethical issues and palliative care research were invited to the Cicely Saunders Institute in London. They included senior researchers, service providers, commissioners, researchers, members of ethics committees and policy makers.

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Results: The workshop comprised 28 participants. A total of 16 recommendations were developed. There was high agreement on the issue of research participation and high to moderate agreement on applications to research ethics committees. The recommendations on obtaining and maintaining consent from patients and families were the most contentious. Nine recommendations were refined on the basis of the comments from the online consultation.

Conclusions: The culture surrounding palliative care research needs to change by fostering collaborative approaches between all those involved in the research process. Changes to the legal framework governing the research process are required to enhance the ethical conduct of research in palliative care. The recommendations are relevant to all areas of research involving vulnerable adults.

Keywords

Ethics, research, guidance development, expert workshop, consensus methods, online consultation, palliative care, end-of-life care

Introduction

There is limited research investment in the development and evaluation of interventions in palliative care.^{1,2} Research is required to develop quality palliative care.^{3–7} This will provide evidence to address deficits in care, to establish whether unproven therapy helps patients and to ensure that palliative care can secure the resources required.⁴

Research in palliative care raises particular ethical concerns,⁶ which have generated intense debate with little consensus of views.^{8,9} The ethical decisions regarding the design and conduct of research determine the nature and quality of the research undertaken. Whether patients at the end of their lives should be invited to participate in research is a key issue widely discussed in the literature.¹⁰ On this issue hinges the moral justification of research in palliative care.¹¹ These views further impact research ethics committees (RECs), which are known as Institutional Review Boards (IRBs) in the United States,^{12–14} whose judgments determine the quality and safety of interventions detailed in researchers' ethics applications.¹² Informed consent is challenging in palliative care research as one has to work in circumstances where time is restricted, and patients experience fluctuating/declining physical and mental capacity.¹⁵ In addition, the concerns of family members require consideration as their views are likely to influence patient participation.¹⁶ Given the divergent ideas about the ethical conduct of palliative care research and the lack of empirical evidence, there is a need to identify and arrive at best practices in this field.

The MORECare project aims to identify, appraise and synthesise 'best practice' methods to develop and evaluate palliative care, particularly focusing on complex service-delivery interventions and reconfigurations.¹⁷ A main intended output is Methods Guidance on Developing and Evaluating Palliative Care (<http://www.csi.kcl.ac.uk/morecare.html>). This guidance is underpinned by systematic reviews of the evidence^{10,18} and, in areas of contentious evidence, expert consensus on best methodological practice. A series of expert 'think tank' workshops were held to generate recommendations and

build consensus on best practice on identified gaps in the evidence base and issues of particular significance. We held such a workshop in the summer of 2011 regarding ethical issues in research in this area. This article aims to present the process and outcomes of the workshop and consensus exercise on agreed best practice to accommodate ethical issues in research on palliative care.

Methods

The workshop

Design. A one-day closed workshop with invited experts, who were identified through the published literatures on ethical issues in palliative care, the networks of the members of the Project Advisory Group, and searches on the Internet. The participants included senior researchers (epidemiologists, ethicists, social scientists and lawyers), service providers (palliative care consultants and allied health professionals in palliative care), commissioners (from hospital trusts and hospices), members of RECs or research governance bodies, and policy makers (national organisations in palliative care). They all had expertise in palliative care and the ethical issues involving research in this area, and they came from different parts of the United Kingdom. The workshop aimed to debate the ethical challenges of undertaking research in palliative care and to generate recommendations on best ethical practices. A systematic literature review on participation in palliative care informed the design of the workshop.¹⁰

Content. The workshop focused on three topics that were identified as particularly challenging in palliative care research: research participation, informed consent, and applications to RECs. These topics were derived and informed by the systematic review, which was undertaken in preparation of the workshop. Their suitability for the focus of the workshop was discussed in a meeting with the Project Advisory Group. Participants were asked to consider specific questions on these areas (see Box 1).

Box 1. Questions discussed in the work groups of the workshop.

Research participation

- What is best practice to enable patients to participate in research on palliative and end-of-life care (P&EoLC) and protect them from harm?
- How can we capture the willingness of individuals to participate in research on P&EoLC, and how can we balance the interests of families with those of the patient?

Applications to RECs

- How can we overcome the challenges in relation to REC members' review processes and evaluations of EoLC research?

Informed consent

- What is best practice in obtaining and maintaining consent for patients and family caregivers who participate in EoLC research?
- How can we enable individuals with fluctuating or declining capacity (or those who lack capacity) to participate in research on P&EoLC?
- How should we balance the need to give potential participants time to consider participation with the particular time constraints of research at the end of life associated with nearness to death?

Format. Three presentations were held to provide an overview of the state of the science of these three topics of the workshop, and this was followed by discussion. Participants were divided according to their expertise and interest into three work groups that focused on one of the three topics. We used nominal group techniques¹⁹ to structure the process of generating recommendations and forming a consensus on their priority ordering. The work groups discussed the questions asked and then individually wrote down recommendations. The participants then shared in turn their recommendations presenting the most important first, and their rationales. Recommendations were recorded

on a flip chart and discussed by the group combining duplicates. The recommendations written down individually were scanned, and together with the recommendations combined in groups, were sent to the MORECare team members undertaking the analysis. All discussions were audio-recorded and transcribed. We used all data gathered in the workshop for the analysis.

Online consultation

Following the workshop, all the recommendations were entered into an Excel spreadsheet. We then combined duplicates, identified those specific to palliative care research and checked the wording for clarity. Doubts were resolved by discussion among the team members. A set of recommendations was agreed on among the project researchers and posted as an online survey to participants in the workshop and members of the MORECare Project Advisory Group comprising senior representatives from academia, service providers, commissioners, policy makers, the voluntary sector and lay members (see Acknowledgements).

Participants in the online survey were asked to rate how much they agreed with the recommendations on a scale from 1–9, where 1 was strongly disagree and 9 strongly agree. A space for comments was provided for each recommendation, and there was a general comments section. The ratings were analysed using descriptive statistics to permit analysis of consensus and rated importance (see Figure 1). The comments were read and considered in the light of the quantitative results.

Ethics approval

The University of Manchester REC approved the MORECare study (ref no. 10328). The online consensus recommendations were presented to the chair for approval prior to posting.

Results

The workshop comprised 28 participants (ethicists, academics in palliative care, members of RECs, service

Rating	Median	Range	Code
Strong agreement/high consensus	≥8	<2	1
Strong agreement/low consensus	≥8	≥2	2
Moderate agreement/high consensus	<8 - >6	<2	3
Moderate agreement/low consensus	<8 - >6	≥2	4
No agreement/high consensus	≥4 - ≤6	<2	5

Figure 1. The classification of recommendations.

providers and commissioners). In all, 25 participants took part in the work group discussions: eight in group 1, seven in group 2 and eight in group 3. Sixteen recommendations were included in the online survey. From the 61 people (24 attendees and 37 project advisory group members) who were invited to the online consultation, 26 responded.

The workshop

Group 1 discussion: participation in research on palliative care. The starting point of the discussion concerned the general perception that it is inappropriate to involve people with palliative care needs in research and how this hampers the development of the evidence base informing palliative care. A workshop participant summed up the prevailing view regarding research with this population:

The culture within our society and especially health care, is that research is extra to treatment, burdensome and unnecessary. (participant G106)

These ideas can be challenged by integrating research into routine health care. Participants recommended that while conducting their studies, researchers can use the opportunity to document barriers and facilitators to research. This can then provide further evidence of the impact of research on researchers and the experiences of patients and carers. The evidence generated should be inclusive of all research participants who consent to participate.

Participants discussed the specific nature of research in palliative care and identified the following: the research process needs to be sensitive to the changing characteristics of the population associated with advancing disease, there needs to be attention to the challenges researchers face in palliative care research and supervision and support for researchers in the field is essential.

Careful consideration of a study is required to accommodate the problems associated with research in this field (e.g. recruitment, attrition, missing data). Studies need sufficient resources, flexible designs and research procedures, preferably with mixed methods. Collaborative approaches and participative designs were recommended where all the different participants are involved in the research process.

Group 2 discussion: seeking REC approval. This group shared experiences about the difficulties of obtaining ethical clearance as one of the greatest challenges of the research process in palliative care research. RECs apply criteria that are relevant for research in general, but these may not be attuned to the specificities of palliative care. The Health Research Authority's standardisation of the National Health Service's ethical review process was

considered to exacerbate these challenges. Standardisation was viewed as directed towards protecting RECs from liability and as stifling common sense in concrete research situations.

As researchers need to operate within established ethical frameworks, they should join RECs to inform decisions and promote understanding of research on palliative care. A way of enhancing discussion at RECs was for researchers to ensure greater involvement of project user representatives within the research and application process, for example, by attending REC meetings with researchers. This could further validate the research proposal, demonstrating the involvement of users in the study design and the acceptability of the methods proposed to users:

... "RECs [...] are not unusual in being more risk averse in their decision making for others than they would be for themselves" [...] So they need to be persuaded to balance that 'natural' paternalism with evidence of how [...] people who are dying can be treated as responsible autonomous beings capable of taking risks and burdens. (participant G2010)

Participants recommended that mutual education should be a priority. RECs require training on conducting palliative care research, and researchers require greater knowledge about the legal framework within which these committees operate. Participants noted that RECs should have clear codes, standards and competencies on palliative care. Participants agreed that the establishment of a Research Ethics Network specifically for palliative care could further develop the essential competencies, resources (such as manuals, templates for participation information sheets) and support for researchers.

Group 3 discussion: informed consent. Consent needs to be embedded in a research culture. Participants observed that this could be cultivated in care settings by informing patients on admission that the facility conducts research. At this early stage, 'consent to consent' can be sought, which is a way of screening people to identify those who are interested in research and thereby minimise gatekeeping.

Participants agreed that the format of participant information sheets can increase the burden of the consent process. The level of detail needs to be proportional to the risks and burdens involved. Participant information sheet templates for palliative care could be developed and made available from central repositories.

The often fluctuating capacity of the palliative care population presents serious challenges to the consent process. The participants proposed advance consent (early informed consent when the patient still has capacity) as a solution to the problem of fluctuating capacity. Participants recommended that such advance consent should be legally effective for *all* research, rather than limited to Clinical Trials of an Investigational Medicinal Product (CTIMPs).²⁰

Currently, the Mental Capacity Act 2005 (the relevant legislation in England and Wales governing health and welfare decision-making in relation to incompetent adults) does not permit research involving incompetent adults on the basis of advance consent.²¹ Instead, necessity and risk/benefit criteria are imposed, and assent must be obtained from a non-professional carer based on what the patient's wishes and feelings about participation in the project would be were the patient competent.²²

As a matter of good practice, participants also recommended that if advance consent were to be relied upon for all trials, contemporaneous assent from someone who is close to the patient and knows whether they would have wished to participate in the research project should *also* be obtained, as is currently required for non-CTIMPs under the Mental Capacity Act 2005, s. 32.

In the absence of such legal change, participants recommended that when obtaining consent from a competent participant for a non-CTIMP study, the researchers should anticipate the potential loss of capacity and in addition, fulfil the requirements of the Mental Capacity Act²¹ by obtaining assent from someone close to them and by meeting the risk/benefit criteria in the Mental Capacity Act. This would provide 'belt and braces' (in the words of participant G3018) for consent for patients with fluctuating/declining capacity.

Consent should be a continuous process to ensure sensitivity to changes in an individual's attitude to participation and signs of distress, especially when capacity is rapidly declining. Further research is necessary on how and when to assess capacity.

Limited time characterises research at the end of life (EoL), while time is also needed to consider consent. In some situations, it is important to allow patients to participate in studies, without having 24 h to consider their decision to enrol, which is often required by RECs. These circumstances require anticipation and specification in the study protocol to avoid coercion.

The online consultation

Table 1 presents the recommendations by subject area. A box and whisker plot shows the ratings of the recommendations in Figure 2.

Research participation. The median scores and narrow inter-quartile ranges show strong agreement on four recommendations of research participation. Especially, recommendation 1 received strong agreement and high consensus. However, recommendations with wider ranges indicate divergence and likely areas of contention. Recommendation 7 triggered most disagreement and low consensus about the combination of clinician–researcher roles.

Applications to RECs. The median scores and range indicate moderate to high agreement on the recommendations

in the area of making applications to RECs. However, recommendation 10 triggered only moderate agreement and low consensus about the idea of establishing a research ethics network in palliative care. The concern here expressed in the narrative comments was that research in palliative care could be set apart from other research.

Obtaining and maintaining consent. The recommendations on obtaining and maintaining consent from patients and families were the most contentious. They had the largest divergence in priority ordering. Concerns especially related to recommendation 16 about the continuous process of informed consent, which entails the risk of making research impossible if there would be too many regulatory requirements.

Respondents expressed uncertainty regarding recommendation 14 in terms of its feasibility and implications. This was due to respondents' lack of expertise on legal issues, which they also admitted with regard to recommendation 15. Here, objections were made to the mechanism of assent. In addition to the requirements of this recommendation, one respondent pointed out that ethical approval would need to be obtained from a REC authorised to approve projects under the Mental Capacity Act.

Table 2 presents the final recommendations, which were refined in light of the narrative comments from the consultation. We did not change all recommendations for the following reasons: when the comments raised questions about operationalisation that went beyond the purpose of the recommendation, if respondents reported a lack of expertise about the recommendation or if issues were already covered by other recommendations.

Discussion

Although the ethical debate on whether patients near the EoL should be considered 'too vulnerable' to be involved in research is far from settled, the participants in this workshop started from the idea that research is needed in palliative care. They therefore concentrated on best practices of research participation to foster scholarship in this area. Participants recognised that the idea that research with this population is not justified underlies the two other issues of this workshop. It determines REC members' attitudes towards palliative care research and the difficulties of conducting research in care settings that complicate the consent process. A change in culture surrounding palliative care research was viewed as the most important recommendation, which can lead to new ways of thinking about research and can open up new ways of approaching this area. Although the guiding question for this workshop focused on the patient, the workshop participants recognised the involvement of all those involved in the research process. They were not considered as separate entities, but the reality of their interaction was taken into account.

Table 1. List of recommendations with mean and median scores ($n = 26$).

	Recommendations on topic: research participation	Mean	Median	IQR
1	To enhance participation in research on palliative and end-of-life care (P&EoLC), closer working and open communication between practitioners, researchers and users is required to increase awareness and understanding of P&EoLC research.	7.9	8.5	7.75–9
2	Practitioners, members of research ethics committees (RECs) and researchers need adequate training in order to address the practical and ethical challenges associated with assessing and conducting research at the EoL.	7.3	8	7–9
3	Research protocols require flexibility to accommodate the fluctuating symptoms or levels of competence often experienced by patients receiving palliative care (e.g. flexible recruitment strategies and data collection methods).	7.0	7	6–8.25
4	Respect is required for autonomous decisions of patients and carers regarding their participation in research to avoid limiting their participation through inappropriate gatekeeping and paternalistic attitudes.	7.9	9	7–9
5	To incorporate wide inclusion criteria in studies on P&EoLC, a sensitive approach to recruitment is required that demonstrates empathy, is responsive to an individual's level of understanding and emphasises the voluntary nature of participation.	7.6	8	7–9
6	Further evidence (especially qualitative) is needed on why patients (and practitioners) may hold positive or negative attitudes towards participation in research and the reasons behind, for example, gatekeeping.	6.8	7	6–8
7	Greater development of roles that combine clinical and researcher activities is needed in order to improve research–practice interface and aid recruitment.	5.6	6	4.75–7
Recommendations on topic: making ethical and governance applications to RECs and Research Governance bodies				
8	Ethical and governance applications are enhanced by collaborative working between researchers and lay user representatives throughout the project by jointly developing Participant Information Sheets (regarding proportionality and the clarity and acceptability of language), developing/reviewing the suitability of data collection tools, a lay summary in the ethical application and by accompanying researchers to the REC review on the application for P&EoLC research.	7.0	7	6.75–8
9	RECs require clear codes of conduct, standards and competencies for assessing research in P&EoLC.	7.3	8	7–9
10	The establishment of a Research Ethics Network for P&EoLC research could further develop methods and guidance on undertaking research at the EoL.	6.5	7	6–8
11	Providing feedback to REC members on participants' experiences of their involvement in P&EoLC research could widen the discussion on the degree patients are burdened, or not, by the research process.	7.3	7	7–9
Topic: obtaining and maintaining consent from patients and families				
12	To enhance processes of consent requires P&EoLC organisations to create a research-aware culture for practitioners by informing practitioners and patients on admission to a service that the organisation is actively involved in research.	7.0	7	6–9
13	To enhance processes of consent requires P&EoLC organisations to create a research-aware culture for practitioners by adopting a policy of consent to consent (consent to be approached about a research study).	6.3	7	5–8
14	Seek to change the law, so that advance consent is legally effective for all research and not limited to Clinical Trials of Investigational Medicinal Products (CTIMPs).	6.3	7	5–8.25
15	When obtaining consent from a competent participant for a non-CTIMP study, anticipate the potential loss of capacity and fulfil the requirements of the Mental Capacity Act 2005 by obtaining assent from a carer and meeting the risk/benefit criteria for non-therapeutic projects.	6.8	7	5–8.25
16	A continuous process of consent is required to ensure sensitivity to changes in an individual's attitude, ability to participate and careful monitoring of signs of verbal or non-verbal distress.	6.5	7.5	5–9

IQR: inter-quartile range.

*The participants were asked how much they agree with each recommendation, where 1 was 'strongly disagree' and 9 'strongly agree'.

RECs are often especially cautious to grant ethical approval to research applications in palliative care.¹² This relates to societal concerns about involving people with life-limiting conditions in burdensome research

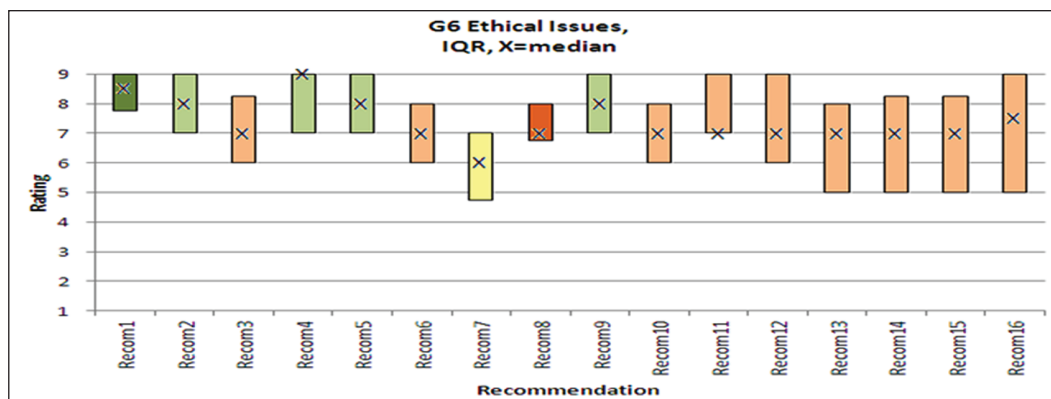


Figure 2. Box and whisker plot of participants' ($n = 26$) ratings of the 16 recommendations for the ethical issues in palliative and end-of-life care research.

with limited individual benefit. RECs may be less familiar with the issues that are particular to this field^{14,23} and with research designs required to accommodate complexities associated with varying deteriorating illness trajectories.^{12,14,23} The involvement of a user representative in the process of REC review of the application could greatly enhance mutual understanding between REC members and those conducting the research (recommendation 8). Submitting decisions made by RECs to external peer review could increase accountability and transparency on their decision-making processes (recommendation 10).

The work group on informed consent addressed the importance of undertaking the consent process in a way that enables individuals with fluctuating/declining capacity to participate in research. A way forward is for advance consent to be legally effective for all research, rather than limited to CTIMPs.²⁰ The recommendation to change the law is a first step in the development of standards for research on palliative care. Such legal change could provide an example for other regulatory contexts relating to the involvement in research of people who have impaired capacity, both in Europe and the United States, where policy guidance is either lacking or diverging in a mixed legal framework.^{24–26} The wider use of advance consent could reduce attrition and missing data, which are common challenges in palliative care research. A separate recommendation¹⁵ situates this change in the current legal framework for medical research by specifying the requirements from other legal provisions that are directly related to this new measure, such as the Mental Capacity Act, so that it is fully operational.

The recommendations were generated in a think-tank involving discussion and consensus of expert views on undertaking research with individuals requiring palliative care and priority rating. The online consultation allowed anonymous rating and commentary from a broader group of experts. Recommendation 4 concerned the importance of patients' autonomous decision-making to counter

gatekeeping and paternalism. This recommendation had the highest score, showing the priority of allowing and enabling individuals to consider participation in research. This is consistent with most patients' experiences of participating in research, which can bring direct benefits, shown by a systematic review conducted in preparation for the think-tank.¹⁰

Recommendation 1 on the need to enhance awareness and understanding of palliative care research through closer working between different parties scored second highest and reached greatest consensus. The comment this recommendation received of being 'self-evident' underscores that this is the main target to which one should work in this field. The third highest rated recommendation shows the importance given to inclusiveness of a population (older people, the bereaved, those with fluctuating capacity) who are often excluded from designs that generate high-level evidence according to criteria used in evidence-based medicine,²⁷ but who are of most relevance to palliative care.

Recommendation 7 on the development of combined clinical and researcher roles received the lowest scores. The comments outlined the advantages of working separately within clearly defined roles. This recommendation does not prescribe complete combined training, but rather an understanding of situations when care takes priority, and a sense for research opportunity. Within a collaborative model, people with clinical or researcher roles acquire insight into the aims and procedures of one another's expertise. Active engagement enhances a sense of ownership of a study, which improves the research–practice interface. The narrative comments to recommendation 13 showed that there was confusion about the term 'consent to consent' as it suggests an additional layer of bureaucracy before the actual consent process. However, it refers to a screening process of patients upon admission to a service, by which they show their willingness to be approached to participate into future studies. In addition, the low score of recommendation 14 was due to the commentators'

Table 2. Summary of narrative comments and final refined recommendations.

No.	Summary of narrative comments for each draft recommendation	Recommendation (<i>changes from draft recommendations in italics</i>)
R3	Flexibility was recognised to be important in palliative and end-of-life (EoL) care, but respondents qualified it by stating that the issues that needed flexibility needed to be carefully considered in the protocol, rather than allowing ad hoc changes when things do not work as expected.	Research protocols require <i>carefully considered</i> flexibility to accommodate the fluctuating symptoms or levels of competence often experienced by patients receiving palliative care (e.g. flexible recruitment strategies and data collection methods).
R5	Although this recommendation was highly rated, some comments showed that responders did not consider it sufficiently specific to palliative and EoL care. Comments show that the link between the wide inclusion criteria and the recruitment approach needs clarification.	Wide inclusion criteria in studies on palliative and EoL care <i>are needed in order to include those who are more difficult to reach (e.g. older people, the bereaved, those with fluctuating capacity)</i> . Therefore a sensitive approach to recruitment is required that demonstrates empathy, is responsive to an individual's level of understanding and emphasises the voluntary nature of participation.
R7	This recommendation triggered disagreement about the combination of clinician–researcher roles. The advantages of working separately were outlined. One comment mentioned the need for documenting resistance to collaboration between clinicians and researchers.	Greater development of <i>clearly defined</i> roles that combine clinical and researcher activities is needed in order to improve research–practice interface and aid recruitment.
R8	As research needs to fit with clinical practice, two comments mentioned the benefit of having a clinician involved. Two comments focused on the need to shorten the sentence. One respondent warned to be mindful of the burden to lay users. Another one pointed out the competencies of the user representative that are required to advocate for the interests of users to ethics committees. Their power of persuasion towards regulatory committees was acknowledged.	Ethical and governance applications are enhanced by collaborative working <i>with competent</i> lay user representatives throughout the project, by developing Participant Information Sheets (regarding proportionality and the clarity and acceptability of language), developing/ reviewing the suitability of data collection tools, a lay summary in the ethical application and by accompanying researchers to the research ethics committee (REC) review on the application for EoL care research.
R9	This recommendation raised doubt in most comments about the benefit of considering palliative and EoL care research as different from other medical research, as this implies the danger that patients get categorised as ‘vulnerable’, which can lead to paternalistic attitudes. One comment pointed at the specific and sensitive nature of palliative care research for which particular expertise needs to be developed. Another comment stated that RECs need guidance regarding palliative and EoL care in order to overcome their over-protective attitudes towards patients.	RECs require clear codes of conduct, standards and competencies for assessing <i>and facilitating</i> research in palliative and EoL care.
R10	One respondent is not in favour of the idea of establishing a research ethics network in palliative and EoL care, again because it could shield it off from other areas of research. This idea led to two questions on its purpose and operationalisation.	The establishment of a Research Ethics Network for palliative and end-of-life care (P&EoLC) research could further develop methods and guidance on undertaking <i>and facilitating</i> research at the EoL.
R12	The value of a research-aware culture was confirmed. Information-giving to patients should take account of patients' specific need for information.	To enhance processes of consent requires P&EoLC organisations to create a research-aware culture for practitioners by <i>sensitively</i> informing practitioners and patients on admission to a service that the organisation is actively involved in research.
R13	This recommendation provided confusion due to respondents' unfamiliarity with the term ‘consent to consent’. One respondent wrote: ‘consent to consent!!’, expressing his/her disbelief at the thought of another formal requirement in order to be able to approach patients.	To enhance processes of consent requires P&EoLC organisations to create a research-aware culture for practitioners by adopting a policy of consent to consent (<i>a screening procedure to identify people interested in taking part in a research study</i>).
R16	Respondents cautioned against the further bureaucratisation that this recommendation could imply if consent would mean the repetition of the formal written consent process and thus make research impossible. The need for a sensitive and well-trained researcher is emphasised.	A continuous process of consent, in <i>which the original written consent does not necessarily needs to be repeated</i> , is required to ensure sensitivity to changes in an individual's attitude, ability to participate and careful monitoring of signs of verbal or non-verbal distress.

unfamiliarity with the legal framework. These findings again underscore the need for collaborative interdisciplinary practice and research.

Limitations

The recommendations may not be exhaustive of all the ethical challenges encountered regarding the three topics. This is related to the particular format of a one-day closed workshop with the aim of developing best practice guidance among experts in palliative care research, which limited the number and range of experts who could be invited. Therefore, in addition, the workshop needed to focus on three topics, which were identified as key to the concerns in palliative care research. Only experts from the United Kingdom participated in this workshop. For the online consultation, a 43% response rate was achieved (26/61) following a reminder at 2 weeks. This workshop was the fourth workshop in the project, which took place at the end of July, and the consultation was open for response in the month of August, which is the holiday month for most people. This may be an explanation for the relatively low response rate. The lay members on the Project Advisory Group were not able to attend this workshop, but they were involved in all stages before and after the workshop, and they were invited to the online consultation.

Conclusion

The results of this workshop and consensus exercise provide guidance for ethical issues in palliative care research. The culture surrounding palliative care research needs to change, which will lead to new ways of thinking about research and open up new ways of approaching this area. This can best be realised by fostering collaborative approaches between those involved in the research process. Changes to the legal framework governing the research process are required to enhance the ethical conduct of research in palliative care. The recommendations are relevant to all areas of research involving vulnerable adults.

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