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Palliative care research protocols: a special case for ethical review?

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Abstract: Between October 2001 and May 2002 the Chairperson and Vice-Chairperson of each Multicentre Research Ethics Committee (MREC) in England, Wales and Scotland took part in a semi-structured interview to ascertain the attitudes of MRECs to palliative care research. Interviews were transcribed and analysed using a grounded theory approach. Most respondents said each protocol was reviewed on its own merits, according to broad ethical principles, but were equivocal as to whether palliative care protocols posed particular or different challenges compared to those from other specialties. Respondents said they reviewed only a small number of palliative care protocols, and that they were less experienced with some of the study methods utilized, particularly qualitative designs. Four main themes emerged from the analysis. Respondents expressed concerns about the protocol itself – in regard to safeguarding the principles of autonomy and justice. There were concerns about how the research would be carried out, especially the protection of patients and the influence and input of the researcher in the process. The third theme concerned the impact of the research on the participant, particularly intrusion, potential distress and the existence of support mechanisms. Fourthly, respondents identified patient groups receiving palliative care (children, the elderly, bereaved families, patients in intensive therapy units, and those from ethnic groupings), who they considered might be particularly vulnerable. *Palliative Medicine* 2003; **17:** 482–490

Key words: ethics committees; palliative care; research

Introduction

Palliative medicine is a relatively new discipline and was only recognized by the UK Royal Colleges in 1987. Palliative care aims to relieve the suffering, while maintaining and promoting quality of life, of dying patients and their families.[1] Caring for the whole person and promoting a multidisciplinary approach to integrate the efforts of a range of health and social care providers are key elements of the palliative care philosophy.[2] However, it has been argued that there is a paucity of data to provide the evidence base for the guidance of treatment decisions within palliative care.[3]

This lack of evidence has been associated with three principal factors. First, there are logistical challenges in conducting research in this area such as the effects of inclusion and exclusion criteria tending to restrict opportunity to participate, and high attrition rates due to the unpredictable nature of malignant disease and poor estimates of life expectancy.[4–8]

Secondly, it has been suggested that there are numerous and unique ethical challenges which constrain research in this field.[9–11] A recent review paper written by authors from the USA identified four specific arguments that have been advanced to support the claim that palliative care research faces unique ethical issues.[1] These were patient vulnerability, obtaining informed consent, dissonance between research and clinical roles and difficulties faced by patients in evaluating the risks and benefits of research and in particular the burden of research upon the participant. The authors concluded that the first three of these arguments were not unique to palliative care research and had been successfully addressed in other areas of medical research. With regard to the final claim, the authors found that this, in part, was supported. They argued that palliative care research was unique because the evaluation and parameters of the risk benefit analysis, as well as the burden of the research upon the patient, may change significantly as patients near death. Nevertheless, the authors stated that these ethical issues were not insurmountable and they advocated a public education campaign, with palliative care providers and investigators taking 'an active role'.

The third factor associated with the difficulty of conducting research in palliative care is that there are

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many groups for whom participation in studies presents distinctive challenges. These groups include children,[12,13] those with mental health problems,[14–16] the elderly,[17] patients from ethnic groupings,[18] patients in Intensive Therapy Units (ITUs)[19,20] and bereaved families.[21]

The requirement for ethical review of research protocols, is also a relatively recent development. It was only in 1991 that the UK Department of Health formally established local research ethics committees (RECs), and not until 1997 that the first Multicentre Research Ethics Committees (MRECs) were formed. In 2002 the first governance arrangements for RECs were formulated. Aristotle noted in *Nicomachean Ethics* that 'nothing is fixed in matters of conduct and of what is useful ... instead the agents must consider what is appropriate to the particular occasion'. It has also been stated that the role of a REC is to help ensure that research studies 'comply with recognized ethical standards',[22] but this is in practice problematic in modern health care, as recent events at Liverpool in regard to organ retention demonstrated. Aristotle's views are echoed in the comments of one of our respondents who said 'if there were right answers we wouldn't need RECs, we could have a computer algorithm' (respondent G). Similarly, the contemporary philosopher de Botton points out that 'arriving at good ethical ideas (belongs) to a troublesome class of superficially simple but inherently complex activities'.[23]

There is some evidence that there are differences in ethical reasoning between various health care professional groups, with nurses tending to be more concerned with the fundamental of caring while medical students tend to be motivated more by the concepts of patients' rights.[24] The overwhelming majority of interviewees in our study were senior clinicians and male. Some commentators have argued the different models that individuals employ to establish their own view of ethics are essentially predicated on gender.[25] Gilligan has also suggested that an understanding of responsibility and truth could be approached from two different perspectives, reflected in two different moral ideologies. On the one hand is a morality of rights, predicated on equality and the understanding of fairness, and on the other, an ethic of responsibility, based on the concept of equity, that is, the recognition of differences of need. Gilligan argues that the ethic of responsibility rests on an understanding that gives rise to compassion and care, that no-one should be hurt, while the ethic of rights balances the claims of other and self, that everyone should be treated the same. Randall and Downie have advanced another typology, arguing that there is a narrow view of ethics referring to codes of procedure or technical factors that have a scientific and social dimension, but also a broader sense of ethics that 'encompasses the professional's overall judgement as to what is for the total good'.[26] In our study, common themes stressed by our respondents were autonomy and justice, reflecting the rights-based model. In contrast, practitioners working within palliative care have tended to stress the responsibility model of compassion and care as central to their practice. This view reflects the definition of palliative care as 'a multidimensional approach to care in the face of mortal illness, which takes into account physical, social, psychological and spiritual elements'.[27] The ways in which individuals develop their own perception of 'good ethics', to what extent it is influenced by background and experience and how this affects their subsequent judgement of ethical issues is at present not fully understood and more research is required in this area.

The aims of the study reported here were to find out whether there were 'numerous and unique ethical challenges' constraining palliative care research, and if they existed, how might they affect protocol review by MRECs. The paper also addresses the overall question of whether MRECs had any concerns about research with patient groups identified in the literature as particularly vulnerable. This study is part of a larger project comparing the attitudes of patients, physicians, nurses and RECs towards palliative care research.

Participants and methods

The Administrators of all Multicentre Research Ethics Committees in England, Wales and Scotland were sent a letter informing them of the study. This was followed up with a telephone call to invite the Chairperson and Vice-Chairperson to take part in the study. A suitable date was then agreed for the interview. All MRECs agreed to take part in the study but in two cases only the Chair was interviewed. As this study was approved by Trent Multicentre Research Ethics Committee it was felt by the Chair of Trent MREC that it would be inappropriate to interview executive members of that REC who had considered this protocol. Thus, two members of Trent MREC who had not been present at the time of the protocol review were interviewed. The interviews were conducted between October 2001 and May 2002. In addition, the Chair of the Central Office for Research Ethics Committees (COREC) was interviewed.

Participants were provided with a copy of the interview schedule prior to the interview. Respondents were assured of their anonymity and it was stressed to the REC members who were interviewed that they were not in the role of spokesperson for their own REC, rather their own opinions were being sought.

The interviews were audio taped with the permission of the interviewee. Tapes were transcribed and the transcription returned to the participant for validation. Interviews lasted between 30 and 80 minutes and focused upon five

broad themes; protection of patients in palliative care research, reviewing palliative care research protocols, informed consent in palliative care research, methodological issues in palliative care research, and quality control of palliative care research.

Analysis followed the systematic principles of the 'Framework' approach developed by the National Centre for Social Research.[28] Key themes and categories were identified from the transcripts and a framework for coding the complete data set was developed. Repeat coding by different members of the research team, including consumer representatives from the North Trent Cancer Research Network's Consumer Research Panel, maintained reliability of the identified categories. Coding validity was monitored using deviant case analysis.[29]

Results

The REC members expressed some divergence of opinion when they were asked the broad question 'Do you have particular concerns about research with palliative care or dying patients?' Some respondents felt that research with palliative care patients posed different ethical issues for RECs but this was a scenario they faced with other patient groups:

> The ethical issues regarding palliative care are different but it doesn't necessarily mean that the REC have more concerns. (respondent Q)

> I'm not sure that palliative care protocols are deserving of especial attention, it's the other way round almost – that each research area is equally important. (respondent O)

Other respondents felt that they did have particular concerns with palliative care research:

> I think the answer is yes and the concerns are mainly to with intruding at a particularly sensitive moment. (respondent A)

> Yes I think we do. We recognize that it is a very stressful and traumatic time, patients are dying and there is the risk that they might cling on to any piece of research, some possible hope, some false expectation and we would want to maintain respect and dignity in dying patients. (respondent E)

Although the distinction between the terms 'particular' and 'different' might seem fairly arbitrary, there may also be some variation between the approaches taken by individual RECs to the review of palliative care research protocols submitted to them. Their approach might vary according to their experience and familiarity with palliative care:

> The REC is made up of quite a varied group of people some of whom deal with dying people and some of whom never do, so you do get quite different responses. . .Certainly sometimes people worry about the distress that is caused to people who are dying but I think they worry according to how much experience they have got. Personally I look after quite a lot of people who are dying so I am probably happier to ask them and I also recognize that patients who are dying don't always mind being asked about dying and about research and are often quite happy to be involved so I'm probably more easygoing about it than other members. (respondent M)

Some respondents said they were unfamiliar with palliative care and many others said they tended to receive very few palliative care research protocols. As one respondent said:

> We haven't had a lot of protocols which is probably reflecting the fact that people don't even bother to submit, so it hasn't actually been seen as a big issue (respondent M).

However, whether RECs perceived palliative care protocols as being 'particular' or 'different', was not necessarily an issue that affected the process of protocol review.

All respondents agreed that the role of their REC was a pragmatic application of ethics – that is, 'general moral principles and rules of conduct',[30] to the proposals they reviewed:

> Many of the ethical issues in research are generic so it doesn't matter whether it's palliative care, mental health or whatever it is, the general ethical issues are common throughout the whole of the ethics review process, but very clearly there are going to be particular issues around particular patient groups. (respondent G)

Respondents tended to argue that each protocol was reviewed on its merits according to broad ethical principles including respect for the autonomy of the participant, justice, nonmaleficence and beneficence. However, many of those interviewed said that they did not work with fixed ethical standards, but the application of these varied according to the nature of the protocol being considered, study design and human judgement, although each REC aimed to work to the highest standards of ethics and rigour.

Many interviewees said that for these reasons, it was not possible, or necessarily desirable, to devise an ethics algorithm that a REC could follow. The REC members interviewed also frequently mentioned that the availability of COREC guidelines and regular training for

members were useful in helping them arrive at their decisions. COREC has suggested that the role of a REC is 'to protect the dignity, safety and well-being of all actual or potential research participants'.[22] Respondents in our study also said there were also five other issues that underpinned every protocol review – is this good science, is there true equipoise, what is the risk/benefit, are patients' rights being fully protected and how can the REC assist the research teams to carry out the study in an ethical way?

Three main themes regarding palliative care research emerged from the analysis. These included concerns about the protocol itself, concerns about the research process and concerns about the impact of the research upon the participant.

Issues raised about the research protocol are included in Figure 1. Most respondents stressed the principle of autonomy and justice. In this respect, respondents felt that palliative care research was not dissimilar to research in any other specialty. Some respondents however (respondent J), approached this issue as a trade-off between individual load and outcome, and argued that this was more problematic in palliative care because of the vulnerability of the patient population. Other respondents (respondent O) pointed out that sometimes they adopted a longer perspective and considered the potential benefit to science likely to accrue from a research study.

Concern for the scientific rigour of the protocol was stressed by many respondents and once this had been established, the ethical issues pertaining to each particular protocol were discussed by the REC. Some respondents felt that the ethical issues they considered during review of palliative care protocols were more complex and one respondent said they felt they were dealing with 'real ethics' (respondent F). A particular issue raised by some respondents concerned recruitment of palliative care patients into studies, and that inclusion and exclusion criteria did not unfairly restrict trial entry or preclude 'active treatment' (respondent P).

RECs also expressed strong concerns about how the research would be carried out (see Figure 2). Their concerns focused upon the protection of patients and the influence and input of the researcher in the process.

Many of our respondents expressed the tension that existed between the protection of patients and their potential exclusion from participation. This was an issue that affected multidisciplinary nursing teams, individual

Autonomy
'For me in clinical terms, the autonomy argument is quite strong, people do of course have a right to choose (respondent J)

Justice
'our concern is justice – here is a very vulnerable population that might be asked to take a particularly high level of load for very little outcome for them' (respondent J)

Load
'we've had a couple of studies where there have been one or two novel approaches which would definitely have resulted in some discomfort to the patient, immediate discomfort, and we said that was ethically ok because we thought that if these novel approaches worked they really would transform care and it's our duty to promote that – we were satisfied about the science, so we approved it' (respondent O)

Valid research question
'we approach things on a case by case basis but within a standardised framework, so you'd look at the validity of the research, how important is the research question and can the research answer the question that is being asked' (respondent C)

Complexity of ethical issues
'the ethical standards can be conflicting…the rights or the autonomy of the subject can conflict with the duty of care' (respondent K)

Recruitment
'our concerns are more likely to be related to the nature of the study and the stage of treatment the patient may be at...the debate might range around are they excluding patients for whom active treatment might be appropriate' (respondent P)

Figure 1 The research protocol

Skills of the researcher:
'it's not just the questions that people ask but who is going to do the asking, so sometimes that causes problems if they are going to ask a distressing question, how is it going to be introduced, what skills have they got, how well known are they to the patient, how well will they be understood' (respondent M)
'we are not only looking at outcomes but also who is conducting it, and one of the things we do look at it what back up there is should the patient suffer distress, what provision is there for a patient to be helped immediately, what experience have the researchers and often who are they' (respondent I)

Patient/doctor(researcher) relationship
'There have been examples of research projects where doctors in particular have declined to let their patients take part in studies without asking the patient even though the study has had ethical review – that's probably a legal issue as well as an ethical one…Generally speaking in terms of cancer treatment and palliative care, a lot of patients are quite altruistic, they want to be able to make some sort of contribution and they shouldn't be deprived of that opportunity. I don't think that's ethical. Absolutely not…On the other hand there are doctors and nurses who regard their patients as their own property in terms of doing research on them' (respondent G)

Protectiveness
RECs:
'I think the REC tends to be over protective as we would want to be very clear that the risk versus benefit equation was in favour of the patient as far as could be anticipated at the outset, that the study was minimally invasive, both for the patient and the family, and that the patient's interests were absolutely to the fore' (respondent H)
'In the past, our problem has been the over enthusiastic researcher and we have to make sure that they are not being carried away by the needs of the research question' (respondent A)
Health professionals:
'Maybe they are over protective and slightly paternalistic. It's a time when you want to look after them and nurse them and see them through their last weeks or months and you want to protect them from things' (respondent E)
'Patients are not made of glass and if properly asked the majority of people are able to say yes or no. Palliative care staff develop a strong and quite therapeutic relationship with their patients for reasons that are quite obvious and I think sometimes that might give them tunnel vision' (respondent J)

Duty of the researcher
'In non-therapeutic studies I think you have a high degree of duty in the sense that you might be causing them considerable distress for no particular benefit (respondent I)

Continuity of personnel
'if you say you are going to interview a palliative care patient every 2 weeks until death then I would want to see in the design of that study, that, barring the death of the researcher, that same researcher will be doing the interviewing' (respondent Q)

Figure 2 The research process

health professionals and RECs themselves. The autonomy argument was voiced strongly here – that although care should be taken to protect patients from the overzealous researcher or from undue pressure to participate, the right of the individual to make their own decision was important.

The influence and impact of the researcher was another theme identified in the analysis. Our respondents felt that the specialty of palliative care presented particular challenges for researchers. Perhaps the most important of these was the closeness of the relationship that frequently develops between patient and their professional carers, especially during the final stages of illness. This may result in professionals being reluctant to ask their patients to take part (because of concerns about potential confusion of role as either researcher or carer) or that patients will feel an obligation to take part in research studies offered to them. Our respondents also expressed concerns that the research process should be sensitive to the patients' position – the researchers should have excellent communication skills and be aware of their moral responsibilities toward those participating in the study.

The third area that respondents expressed concerns about was the impact of the research on the participant (see Figure 3). Again respondents felt that these issues were common to many other fields of research but the particular patient group and the setting of research protocols in palliative care heightened these concerns. Respondents were wary of intruding upon patients, their carers or families and were at pains to assess whether such intrusions were 'excessive' or could be justified. The timing and manner of the approach were also considered to be important factors for a REC to assess.

Patient distress was a common theme identified from the analysis and three principal concerns were noted.

Intrusion
'we would want to ensure that intrusion was not excessive and is justified' (respondent E)

Timing
'one of the most important aspects of all this is the time that you take and the timing' (respondent G)

Distress
Impact:
'To cause distress to a patient is unethical. So if we saw a situation where we thought distress would be caused to a patient we would ask the investigator to justify or to explain what they meant' (respondent O)
Support:
'what back up there is should the patient suffer psychological distress and whether the researcher has the necessary skills to deal with it' (respondent I)
Withdrawal:
'The patient must always be given the option of withdrawing at any stage without in any way affecting the quality of medical care they receive' (respondent N)

Awareness
Hope and expectations:
'this is a very stressful and traumatic time, patients are dying and there is a risk that they might cling on to any piece of research, some possible hope, some false expectation' (respondent E)
Benefit:
'Here is a very vulnerable population that might be asked to take a particularly high level of load for very little outcome for them' (respondent J)
Altruism and coercion:
'there's obviously a concern, and I don't know which way it goes, that patients may be too willing, or easily coerced, into taking part in research' (respondent L)
Side effects:
'Many of the treatments are extremely unpleasant and have very nasty side effects and risks but the stakes are so high, the patient's life is at stake so in that situation an unpleasant risk may become a very acceptable risk' (respondent I)

Maintenance of dignity
'we would want to maintain respect and dignity in dying patients' (respondent E)

Figure 3 The impact of research on the participant

First, respondents felt they had a duty to ensure that potential distress to the patient was minimized, and secondly, that patients were fully aware that they could withdraw from the study at any time should levels of distress become unacceptable. Thirdly, our respondents said that they would want to know the support mechanisms that existed for patients if patients did become upset and whether the researchers would have sufficient expertise to deal with such a situation effectively.

Awareness of their prognosis and the anticipated value of the research to the patient were also common themes cited by respondents. However, respondents tended not to mention symptom control studies that can often take place in the palliative care setting where it would become quickly obvious if a patient was benefiting from a new initiative – for example, to control pain. Our respondents did feel that the underlying motivation of the individual to participate was an issue of concern and they argued that members would want to be reassured that patients were not being coerced to take part or had false hopes of a curative intervention.

Finally, many respondents did feel that research in palliative care was inherently different from research in other specialties in that there had to be clearly expressed mechanisms to maintain the dignity of the participants, who were not solely 'research subjects' but were individuals who were dying.

RECs were also asked if they had any particular concerns regarding research with specific vulnerable patient groups. Their comments are summarized in Figure 4. Many respondents while recognizing that these patients were potentially very vulnerable, were also keen to stress that the autonomy of the patients, that is, their right to decide for themselves, should not be diluted and that patients from these groups should not be negatively stereotyped as being incapable of giving informed consent. For all the groups, most respondents said that RECs would have particular concerns about the skills of the

Children

Autonomy and information:

'The child being Gillick competent and older than 10 or 11 should be approached in the first instance' (respondent A)

'Written information should be available at the appropriate level for the comprehension of the child' (respondent E)

Protection

'The fact that they (the children) could be referred on for extra counselling or support…seems to allow the protocol to go through' (respondent M)

Risks of giving false hope

'parents and guardians…often don't understand the difference between palliative care and a cure' (respondent Q)

Elderly patients

Non-maleficence

'whether their interests are being sacrificed in the interest of science' (respondent A)

Understanding and informed consent

'to be sure that an elder patient fully understood the objects of the research and was competent to give consent' (respondent B)

Protection

'we mustn't be too over protective of an elderly patient who for example is 85 just because they are 85 and their thinking processes might be a little bit slower' (respondent Q)

Bereaved families

'It needs to be handled sensitively using an approach that recognises their loss…it's got to be timed' (respondent E)

Patients in ITU

Environment

'More difficult because of the high pressure nature of the situation…very little time to take consent' (respondent A)

Informed consent

'they (ITU patients) are not competent to give consent…and basically relatives cannot give consent, they can express an opinion' (respondent D)

Patients from different cultures and ethnic backgrounds

Knowledge of religious and cultural practices

'you may be causing immense offence completely innocently' (respondent D)

Information

'make sure they had information in their own language…verbal or written' (respondent B)

Informed consent

'We in the western world believe in individual informed consent some cultures may believe in a consent derived from a broader representation of society' (respondent E)

Health beliefs

'Do they understand our model of disease because different cultures have different concepts of disease and therefore, of research as well' (respondent E)

Figure 4 Vulnerable groups

researchers to appropriately deal with any unexpected, distressing situation, and in making sure that a known and trusted professional would discuss the study with the patient or carers at an appropriate timing and in simple language.

The process of informed consent and the provision of information were regarded as key issues. In the case of children, respondents found it difficult to define the most appropriate way of giving them information and helping them to make a decision about taking part in research studies. Concerns regarding the child's age, maturity and capacity to understand were commonly identified, although there was no consensus as to what principles should be followed. For instance, some respondents favoured the involvement of parents in all stages of the decision-making processes, while others felt that an approach to the child themselves might be appropriate in the first instance.

The main concerns expressed by our respondents in relation to elderly patients and patients in ITUs were also

around similar issues. Our respondents felt that RECs would be particularly concerned that elderly patients would receive accurate and truthful information, would understand what they would be required to do and their choices fully respected. Timing, respectfulness and sensitivity were the most important issues considered by RECs when dealing with research with bereaved families.

Respondents felt that in order to provide patients from different cultural backgrounds and from other ethnic origins with adequate information it was necessary to have an understanding of their customs and beliefs.

Discussion

The results of this study indicate that RECs have a challenging task in ensuring that the 'dignity, rights, safety and well-being'[31] of those taking part in research in this specialty are protected whilst at the same time promoting scientifically valid research.

Research in palliative care is an area that evokes feelings of protectiveness and caution, although many of the participants in our study felt that the ethical issues were no different in essence from those they considered when reviewing protocols from other medical specialties. Ultimately RECs concentrate on the value of the research, balancing potential benefit or gain against the likelihood of risk or discomfort. Many respondents did however recognize some particular concerns in relation to palliative care – the study design, the context and process of the research, and the impact of the research on the participant. Certain patient groups were also identified as particularly vulnerable. Our respondents expressed strong concerns that the design of research studies should explicitly take into account the potential difficulties of recruiting research participants due to their poor clinical condition, high attrition rates and the importance of obtaining informed consent.

Palliative care is by its nature patient focused and professionals are continually developing and adapting their delivery of care to meet the needs of the individual. The patient, in discussion with the multidisciplinary nursing team, is encouraged to decide what is suitable for them at that particular time. This should include being allowed to make decisions regarding involvement in research. Many of our respondents argued strongly in favour of patient autonomy, and recognized the possibility that vulnerable groups could be excluded by being overprotective. Furthermore, in the interests of justice, patients should be able to make their own decision about participation in research, particularly as there is a possibility of benefit, physically and psychologically, from taking part. It is obviously difficult to find the correct balance between looking for important, relevant results from the research that make a difference and an acceptable level of patient discomfort that possibly may occur as a result from participation. This is further complicated by the deterioration of the patient with consequent potential changes in attitude, and a need to recognize the concerns of their family or carers.

RECs have to make very complex decisions within an increasingly limited timeframe. It seems that experience of research with patients who have life-limiting disease, or more general familiarity with this patient group, can have an effect on the way that individual members of RECs perceive palliative care protocols. Although respondents stressed that the process of review for each REC would tend to be grounded in generic ethical principles, further research is required to explore the ways in which individual REC members define 'good' ethical principles and to what extent these influence decisions reached by the REC.

The argument as to whether the ethical challenges inherent in palliative care research are 'unique' or 'different' does not seem to be a debate that preoccupies MREC members. Their approach is more pragmatic, and concerned with the application of ethics to a case by case review of protocols. However, many of our respondents said they review very few palliative care protocols and thus some MREC members may be less familiar with the general issues affecting research in this field. It is a limitation of this study that most of the respondents are speaking hypothetically about their attitudes to palliative care protocols as they reported reviewing very few. In addition, there is evidence from this study that some respondents may view palliative care as care of the dying rather than as a holistic system of supportive care for patients with a terminal disease.[32] In addition to lack of familiarity with reviewing palliative care protocols in general, some of our respondents also said they were less experienced with some of the study methods utilized. Although there is scope to conduct studies within palliative care based on the 'gold standard' of a randomized controlled trial, in comparison to other specialties a greater proportion of study protocols employ qualitative or mixed method designs. Our respondents commonly said that qualitative research tended to be more difficult to review – as one respondent said '(qualitative) studies don't lend themselves to that same mental checklist as a quantitative study' (respondent H). Increasingly MRECs are recruiting experts in qualitative research but many committee members who we interviewed said they tended to be more familiar with quantitative methodologies.

The results from this part of the study indicate that RECs are aware of, and responsive to, the need for research in this area. Health professionals working within palliative medicine should note that if the research profile in this field was increased, RECs would be more familiar

with the issues, the evidence base would expand and patients themselves would benefit.

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