

Minimising gate-keeping in palliative care research

Peter Hudson, Sanchia Aranda, Linda Kristjanson and Karen Quinn on the particular problems of recruiting patients to palliative care studies and ways to overcome these hurdles

Research into palliative care has the same benefits as for any patient population; it aids understanding of the illness experience of patients and family members, informs clinical care and provides a foundation for evidence-based guidelines to improve practice. Unfortunately, poor recruitment and sample attrition limit the quality of research. Many projects have failed to recruit sufficient participants,¹ weakening the validity of the results and contributing to type II errors. One problem is gate-keeping, the process whereby healthcare providers prevent access to patients for research recruitment.¹ We would extend this definition to include gate-keeping by the patient or family members, as well as by institutional bodies. Therefore, a more complete definition is the process by which people's capacity to be invited into a research project, or to make an informed decision regarding research participation, is inhibited by others.

We are concentrating on its context in palliative care. The problem has been acknowledged in the literature,² although there has been minimal exploration of its extent, little documentation of its negative effects or analysis of why and how it happens. Moreover, there are few published strategies for minimising the impact of gate-keeping in palliative care research.

Levels of gate-keeping

Gate-keeping occurs when researchers attempt qualitative or quantitative studies. There are three levels: institutional, professional, and patient and family gate-keeping.

Institutional gate-keeping

Although ethics committees play a vital role in assessing the appropriateness of projects, some researchers have encountered gate-keeping at this level,³ with patients and their families denied the chance to participate. Some ethics

committees may perceive a lack of patient benefit from the research,⁴ and may inappropriately consider it potentially harmful.² In addition, Lee and Kristjanson³ report that ethics approval is sometimes denied on the premise that palliative patients should not be approached because they are dying.

We have also experienced management boards who block or delay ethical approval and access to patients and families for recruitment into projects. Although these boards have a role in protecting patients, there is a danger that they may be unnecessarily protective.

Professional gate-keeping

Healthcare professionals (HCPs) who practise gate-keeping often do so in a desire to 'protect' the patient and family.¹ In our experience, they either do not advise them of the research project or suggest they are already too overburdened to consider participation. This paternalistic approach is usually unnecessary, given the scrutiny required to obtain ethics approval. It also denies the patient or family member the right to decide whether to be involved. Our experience and emerging evidence^{5,6} suggests that patients and families are able to make such decisions, are comfortable declining to participate, and most often report a feeling of satisfaction in being able to contribute.

Many projects have failed to recruit sufficient participants

Key points

- Protective or obstructive approaches by healthcare professionals, institutional committees, or patients and families may limit a person's access to participation in research studies.
- Gate-keeping threatens the representativeness of research samples and thus the ability to generalise from the research.
- Overcoming gate-keeping is vital if we are to establish a rigorous tradition of research in palliative care.

Patient and family gate-keeping

A patient eligible for a research project may be excluded because their spouse says the research would be too onerous. The spouse is motivated by a desire to protect the patient, but may deny the patient the chance to make an independent, informed choice. This may occur in reverse, with the patient denying access to a family member because of a wish to protect that person and a reluctance to burden them.

This is the most challenging area because of family difficulties, relationship concerns, or a need to limit involvement. In such cases, researchers should ensure the merits and purpose of the study are explained, and if denied access, should respect this.

Impact of gate-keeping

Gate-keeping has two main consequences: restriction of autonomy and the reduction of research quality. Restriction of autonomy occurs when the patient or family are denied their right to informed choice regarding research participation.¹⁸ Patients and families may not be given the opportunity to gain a sense of satisfaction associated with having contributed to improvements in knowledge.³

Research quality is reduced when gate-keeping causes selection bias, restricting the representativeness of the sample and thus the ability to generalise from the findings.⁹ Research studies with insufficient samples are more likely to result in type II errors, potentially leading to premature dismissal of promising interventions. It may also lead to over-representation of more 'robust' populations, or exclusion of participants more likely to benefit from the intervention. Consequently, researchers and clinicians draw conclusions based on biased samples. It also contributes to a misuse of valuable resources, time and effort on the part of all involved. Ethics committees may take a long time to review proposals as they negotiate benefit versus harm with the investigators.

When patients or families participate in a study weakened by gate-keeping that prevents sound conclusions, their time and energies are misused. Given the limited life expectancy, it is imperative their contributions are worthwhile.

Issues arising from a controlled trial

The recruitment experience in a recent randomised controlled trial exemplifies some of the issues common in this field. The study evaluated a new intervention focused on



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enhanced support and information for primary family carers of patients dying of cancer at home.¹⁰ A screening form was developed to capture data on each patient admitted to two metropolitan community palliative care services (CPCS) to identify a sample of potential participants. Forms were sent to the researcher, and eligible carers were sent a letter about the research, inviting their involvement. The carer was then contacted by phone and explained the research using a standardised approach. If carers agreed to be involved, a home visit was set up to provide an information sheet and explanation of the study and to get written consent.

No direct input into recruitment was required from the CPCS nurses, which it was hoped would minimise any gate-keeping.¹¹ The investigator sent a letter about the research to all HCPs at both CPCSs to try to minimise gate-keeping and data contamination. This was followed up with face-to-face discussions. However, following ethics approval, both implemented a protocol whereby, at admission, nurses assessed the willingness of all patients and family carers to be involved in research projects approved by the organisation's ethics committees. The CPCSs sought written patient consent before their contact details could be forwarded to researchers conducting studies approved by the ethics committees.

In a year, a third of carers (305 out of 989, 31%) could not be considered for participation because they or the patient declined to be approached by a researcher. In about 90% of cases, it was the patient who determined if the carers' contact details could be forwarded to a

researcher. Some patients may have decided that involvement in research was too onerous for their family member and denied them access to it. This meant that some carers were precluded from being invited to partake in the research. Several nurses reported 'assisting' patients and family members to decide that they should not make themselves available, as the nurses felt the research might be too burdensome. Hence, it was presumed that a considerable proportion of carers were denied a chance to make an informed choice about participation. In one care team, 56% of patients refused to have their contact details forwarded to a researcher, while in another team refusal rates were 16%. It seems likely that HCP gate-keeping occurred more frequently in the team with high refusal rates.

Strategies to overcome gate-keeping

Dispel misconceptions

There has been much debate about whether this patient group is more vulnerable, and some have advocated that research warrants specific attention given the ethical considerations unique to this population. However, having a limited prognosis is not sufficient reason to exclude patients.¹⁴ There is no legitimate argument for not using standard ethical principles and guidelines in palliative care research.^{12,13} People with a life-threatening illness are still autonomous individuals and, unless proved otherwise, have the capacity to decide for themselves whether they wish to take part in approved research studies.¹

Exploring psychosocial issues is a core research agenda and excluding those who might be confronted with psychosocial issues may be based more on fear than on the likelihood of adverse reactions.¹⁴ Paternalistic protection of this population has had the paradoxical effect of limiting progress in evidence-based care and intruding on the rights of people to participate voluntarily in research.¹³ There is emerging evidence that patients and families are not harmed by research and, conversely, commonly derive benefits.^{4,6,14-16}

Researchers need to educate HCPs and ethics committees about the potential benefits and risks of research involvement. The rights associated with patient autonomy and self-determination may be enunciated as part of the ethical considerations section of ethics application forms. This might include evidence of potential benefits associated with research participation described in palliative care research.

A practical approach may be to offer information sessions. Key articles could also be forwarded; Lee and Kristjanson's³ recent critical review of ethics committees' approaches to research is a good example. Where possible, a face-to-face dialogue between researchers and committees when studies are being reviewed can enable early resolution of ethical concerns.

Gather data on attitudes and recruitment

An additional way to minimise gate-keeping would be to obtain empirical data to document the attitudes of HCPs and ethics committees. Published reports of recruitment barriers, refusal rates, reasons for refusal and possible effects are needed to reveal the magnitude of the problem. Researchers should also include data in published reports about the proportion of potentially eligible patients. Such monitoring will give a more accurate assessment of the extent to which research findings are limited by this. This information could also be used so that shared responsibility for both recruitment and patient protection is created.

Involve clinicians in research

Gate-keeping may be lessened if HCPs are kept up-to-date with research activities in their organisation. Researchers could also engage clinicians as consultants to projects or as co-investigators, to allow them an opportunity to contribute to the work, understand how ethical considerations can be addressed within a study protocol, and incorporate their advice regarding clinically sensitive issues related to the research.

It may also be helpful if the principal researcher or clinical leader sends a letter to all staff of the relevant clinical service providing them with an overview of the study. Brief face-to-face updates, including discussion of emerging issues, by the research team to clinical staff are recommended. Opportunities to elicit team concerns about the research also offer chances to explore potential solutions. Researchers should provide HCPs and ethics committees with a summary of project findings, offer information sessions and thank relevant staff for their assistance. In this way, research can be viewed more as a partnership between investigators and clinicians.

Develop appropriate inclusion criteria

To lessen potential gate-keeping, researchers should think carefully about the inclusion criteria for potential participants. It has been

There is emerging evidence that palliative care patients and families are not harmed by research

Box 1. Proposed strategy for informing palliative care patients/families about research

Dear [insert Service/organisation's name and healthcare professional's name]

Please read out and provide a copy of the following information to all newly admitted patients and record your own details below. If the patient is unable to make a decision because they are too cognitively impaired please liaise with their next of kin/principal family carer. This form will need to be placed in the patients' medical record.

[insert Service name] promotes enhancing quality of care through involvement in research projects which have been approved by our Research and Ethics committee/board. We seek your permission to allow your name, contact details, medical information and principal next of kin details (via your medical record) to be made available to research staff. By doing so you may also be contacted by a researcher to seek your and/or your next of kin/principal family carer's permission to be involved in a research project. If this were the case, the researcher would explain the study and provide you with written information and seek your written consent. However, it is important for you to know that if you were contacted your involvement would be optional and your decision would not impact upon the care provided by [insert Service name].

If you would prefer that your details are not made available to a researcher please sign below.

Patient/ Next of kin (please circle)

Name Signature Date

Reason for refusal if willing to provide

Healthcare professional

Name Signature Date

Discussion of above was conducted with the patient , the next of kin/carer or both (please tick).

Obtaining informed consent is crucial in recruitment and has received increasing attention in the literature

postulated that HCPs will usually be extra protective of the most vulnerable patients.¹ Therefore, if the study aim does not require feedback from patients who are significantly unwell or very close to death, researchers are encouraged to exclude them from recruitment. The RCT example cited above excluded patients from research participation if the assessing nurse deemed them likely to be within four weeks of death or if they had a high-dependency score. On 75% of occasions, this approach proved successful in predicting patients that would die within four weeks and would not be able to complete study requirements. This meant that many patients and carers were not inappropriately invited to participate. Clearly, concern for patient and carer wellbeing is necessary and can be partially addressed through sensible and ethically sound inclusion and exclusion criteria.

Promote continuing assessment of consent

Obtaining informed consent is crucial in recruitment and has received increasing attention in the literature.^{4,17} There has been a tendency to employ a process of repeatedly obtaining informed consent for participation.¹⁸ Although this may be appropriate for protocols that involve long-term, repeated data collection, this must be balanced with the overload that repeated informed consent discussion may create. We do not recommend formally assessing informed consent at every data

collection point but, rather, suggest research staff remain alert to the need to discuss consent at all times. For example, if the researcher senses that a participant is feeling overwhelmed or hesitant, they could ask if the research is causing additional burden and remind them of the opportunity to withdraw from the study. HCPs could also be reminded that if they are concerned about a participant's capacity to give ongoing consent, they should contact the researcher. If these approaches are made clear to HCPs, ethics committees and key family members, some recruitment concerns may be alleviated and gate-keeping lessened.

Approach to informing patients and families

Accessing patients and families is likely to become even more difficult given recent changes to privacy legislation in many countries. Although these initiatives are important, we advocate an approach (Box 1), which may not be in keeping with current legislation in some countries, whereby patients and relevant family are advised (verbally and in writing) on admission by an HCP that ethically approved research studies are conducted within the health service from which they are receiving care. The alternative strategy described previously in the RCT example lacks a consistent approach and relies on busy HCPs who may not necessarily be best placed to assist patients/families to determine if they should partake in research.

Do not involve HCPs in direct recruitment

Unless there is no other alternative, HCPs who are in a care-giving relationship to the patient/family should not have a direct recruitment role. This is because patients/families receiving care from an HCP are in a 'one-down' power relationship to the clinician and may feel less inclined to decline if they believe that their refusal may lead to a diminished quality of care.⁶ The National Health and Medical Research Council of Australia acknowledges that the relationship between HCPs and patients may lead staff to inappropriately protect patients from what they consider to be unnecessary intrusion.¹⁹ For this reason, an invitation to participate by a 'neutral' person that circumvents this power relationship may be more appropriate in allowing freedom to make an informed choice about involvement. Not involving clinicians in recruitment prevents overburdening them with additional work, may lessen the potential for gate-keeping, and prevents an inconsistent approach to recruitment caused by multiple clinicians attempting to recruit and explain the study to patients.

Consider the projects undertaken

We encourage research and ethics committees to continually evaluate the number, type and potential impact of palliative care projects undertaken in their organisation. Gate-keeping may increase if clinicians are involved with multiple research projects where an environment of competition for recruitment ensues. There is also a legitimate need for ethics committees to monitor the number of projects occurring in one care setting to prevent undue burden on the same group of patients or families.

Informed decision-making

Ethical review of all research is essential to ensure that any potential for harm to participants is minimised, and that the principle of beneficence is respected.²⁰ Decisions made by ethics committees in relation to research in palliative care should be guided by the same ethical principles as are used with any other area of practice. This paper in no way diminishes the importance of respecting a person's refusal to be involved in research, as HCPs and researchers have a moral obligation to respect their refusal.²¹ However, it is essential that individuals be given an opportunity to make an informed decision.

Unless strategies are developed to minimise the impact of gate-keeping on research,

researchers will continue to be frustrated in their attempts to conduct sound research that is able to be generalised. Sample sizes will continue to be small and possibly biased, raising concerns about the quality of research. Well-designed and sensitively conducted research is essential to the advancement of practice. The presence of gate-keeping needs to be acknowledged and addressed to minimise its detrimental effects. We hope that the recommendations described may lessen gate-keeping at all levels.

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The presence of gate-keeping needs to be acknowledged and addressed to minimise its detrimental effects

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COMMENT

- 139 Taking up the EAPC challenge
Marilène Filbet

CLINICAL MANAGEMENT

- 141 Spinal cord compression requires early detection
Marie Joseph and René Tayar
- 144 Use of atypical antipsychotic olanzapine as an anti-emetic
Mairi-Clare Fleming and Colette Hawkins
- 147 Percutaneous nephrostomy in patients with cervical cancer
Dorothy Dulko, Jane Duffy-Weisser and Paul Sabbatini

THE CASE STUDY MASTERCLASS

- 150 Case 21. A patient with multiple medical problems
Anjali Mullick, Caroline Lucas, Sabrina Bajwah and Bernadette Lee

REVIEW

- 152 The modern history of morphine use in cancer pain
Jane Seymour and David Clark

ORGANISATION OF SERVICES

- 156 The patient-professional partnership in supportive care
Pippa Winton and Gill Thomas

PSYCHOSOCIAL ISSUES

- 160 The ethical approach to the caress at the end of life
Eytan Ellenberg

162 NOTICEBOARD

RESEARCH

- 165 Minimising gate-keeping in palliative care research
Peter Hudson, Sanchia Aranda, Linda Kristjanson and Karen Quinn

NATIONAL VIEWPOINT

- 170 Palliative day care in Belgium: first observations
Wim Distelmans, Sabien Bauwens, Guy Storme and Louis Tielemans

PSYCHOTHERAPY

- 174 Cognitive behavioural therapy in the palliative care setting
Simon Dein

177 EAPC NEWS AND VIEWS

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