

Short Communication

Palliative Care Research and Ethical Challenges

Monika Pandey^{1*}¹ Australia, University Trobe La, Health Public & Psychology of School, Engineering & health, Science of College* Corresponding Author: monika.pandey@gmail.com

Citation: Pandey M.(2017) Palliative Care Research and Ethical Challenges. ScholReps 2(2).

Copyright: © 2017 Pandey M. This is an open access article distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited

Received: Aug 27, 2017

Accepted: Dec 10, 2017

Published: Dec 28, 2017

Subject Areas: Public Health and Care

Conflict of interest: The author have read the journal's policy and declare that there is no conflicts of interests regarding the focus, interest or any of the contents of this work. This does not alter our adherence to SCHOLARS REPORT policies on sharing data and materials.

Funding: The authors received no specific funding for this work

Abbreviations: EOL, end of life

Keywords: Palliative Care; End of Life; Ethical Challenges

Introduction

In late 1960s, Palliative Care was started as a multidisciplinary approach for delivering quality care to terminally ill people, to help them 'live until they died'. [1] [2] There is a significant need for research in palliative care to assess the needs of the carers and care-recipients as well as the services utilised by them because of the increasing care-recipient population and burden on caregivers. [3] The word 'research' can be defined as '*an investigation to gain knowledge and understanding [and insight of the issue under study] or to train researcher*'. [4] However, after decades of research in the field of palliative care still there is lack of practically generalizable evidence base and a need for further research. [5] This is credited to the ethical constraints and challenges faced during palliative care research by the researcher because of the over-protective institutional ethics committee. [1] Thus, instead of a paternalistic attitude a democratic approach should be sought to mend the gaps in the evidence base of palliative care research, keeping autonomy, beneficence, justice and non-maleficence under consideration.

Literature Overview

It has been observed that palliative care research created numerous ethical challenges for researchers as well as the participants. Research involving end of life (EOL) patients or caregivers as a participant has been observed to build a relationship between the participant and the researcher. According to *de Raeve* (1999), such palliative care research relationship not only morally harms the participant but also the researcher, who unconsciously suffers. [6] **National Health and Medical Research Council** (2015) has built some guidelines according to the requirements of non-maleficence, beneficence, justice and autonomy for palliative care research to protect the EOL patients as a vulnerable group. [4] Scholarly articles researching palliative care have mentioned ethical consideration and stringent inclusion or selection criteria as a reason that have led to limitations in their research sampling, methodology and generalizability. [7][8] There is limited data related to normal conditions and outcomes of unexpected death or bereavement for vulnerable group of caregivers for contrasting or highlighting abnormal events during a research. Figure 1 shows a table from *Aoun & Nekolaichuk* (2014) listing out most of the challenges faced during palliative care research along with proven study references. [9][10]

Challenges of Conducting Palliative Care Research		
Domain	Challenge	References
Patient	● Defining the palliative care patient (timing and terminology)	8,64-66
	● Heterogeneity of the population	12,15,30
	● Frailty	7
	● Unpredictable clinical course and declining health	15
	● Increased prevalence of cognitive impairment, particularly with advancing disease	15
System or organization	● Individual patient preferences to participate in disease-modifying research rather than symptom management research	39
	● Complicated or complex processes for obtaining ethical and administrative approval for research studies	7
	● Undeveloped research culture or lack of awareness of relevancy of research	9
Context or setting	● Service delivery of palliative care services, which is not integrated or which has undergone substantial change	48,49
	● Funding challenges	40,41
	● Gate keeping by clinicians or family members	29,50
	● Clinical practice does not align with protocols	48,49
	● Increased workload for clinicians (e.g., medical assessments by clinicians required)	48,49
Study design	● Limited or unavailable staff on weekends (research and clinical staff)	48,49
	● Lack of engagement by site investigators	48,49
	● Patient eligibility and recruitment	10,14,30
	○ Complex inclusion and exclusion criteria, which may prevent many patients from being eligible for the study	30
	○ Recruitment of "super patients"	30
	● Patient attrition	14,30,76,77
	○ High attrition rates because of progressive disease	76,80,81
	○ Dealing with missing data	12
	● Randomization	12
	○ Patients unwillingness to be part of a comparison group	12
	● Blinding and use of placebos	12
	○ Use of placebo cannot be justified	12
	● Interventions	30
	○ Patients in control arm or comparison arm may perform better because of participation in study or benefit of intervention	12,30
	○ Difficulty standardizing complex interventions, particularly psychosocial spiritual interventions	37
○ Difficulty controlling for nonspecific therapeutic factors, such as the therapeutic relationship	12	
○ Difficulty designing appropriate interventions because of lack of understanding of complex pathophysiology	10,30,36	
● Selection of appropriate outcomes	10,30,36	
○ Lack of appropriate outcome measures that adequately capture complex concepts, such as psychosocial spiritual issues	10,30,36	
Research team	● Recruitment, training, and turnover of research staff	30
	● Lack of specific training of research staff in clinical trials	48,49
	● Lack of availability of research staff over weekends	48,49
Ethics	● Obtaining patient consent and patient safety	12
	● Unable to withhold treatment	12

Figure 1: 'Challenges of Conducting Palliative Care research'. Taken from 'Improving the evidence base in palliative care to inform practice and policy: Thinking outside the box' 1226. [10]

Cochrane systematic review has stated that good evidence for clinical practice has yet not been achieved in palliative care because of the small, fewer number, poor quality, clinically heterogeneous, and insignificant of external validity of primary studies.[8] Small sample size and lack of evidence base has been criticized to lead to lack of generalizability and assumptions are made for certain interventions to be successful. [8] [11]]Hence, external validity of the research is lost that can also be credited to homogeneity in samples or selective sampling. To maintain ethical conduct and integrity, researchers do selective sampling from the target population rather than random sampling and end up studying a homogenous sample. Homogenous sample in palliative research has less practical or clinical applicability in the heterogeneous world and wide range of factors are either underestimated or missed out.[3] Similarly, selective sampling leads to over-representation of the case, such as death, under study in a community.[8]

Critical Analysis

End of life (EOL) patients are classified as vulnerable population and it is this vulnerability that raises a question whether a study should be conducted involving them as participants. EOL patients are a vulnerable population with less energy to actively participate and their participation can lead to burden for them and their caregivers but many studies have highlighted patients' interest in participating in a study for their benefit.[9][11][12] The word vulnerable determines the moral status of bioethics but it also functions to stereotype and overly protective. There are three types of vulnerability: Extrinsic (associated with hospitalization, imprisonment etc), Intrinsic (associated with age, psychosis, etc) and Relational (for example, patient, doctor and family relationship).[11] Relational vulnerability is also associated with

conducting a research because during a research a patient and a researcher tend to develop a relationship, which can be a cause of distress later on to both of them.[5] These points tend to raise a question on the validity of principle of non-maleficence in palliative care research method because of which the institutional ethics and the investigator remain uncertain about a research ethical limit. But does this mean that research for improving the quality of life end of life patients should stop?

Research should be conducted weighing the benefits to the adverse effects. Stringent institutional and clinical gatekeeping violates three ethical principles autonomy, beneficence and justice for the EOL patient and their caregivers.[9] Direct involvement of EOL patients or their caregivers in studying the end of life care process would produce an exact picture of the condition. Many researchers have recommended participation of EOL patients and their caregivers would not only benefit the patient but also improve the autonomy of the patient and help the researcher and his project stand true to the principle of beneficence.[7][9][13] Pettit (1995) has stated that limited or lack of recourse regarding decisions by ethics committee discourages the researcher and leads him in resorting to easier paths to avoid issues raised by the ethics committee.[1] Therefore, leading to disruption of autonomy and beneficence of EOL patient, their caregivers and researcher.

Discussion & Application

After significant literature review, a particular pattern for research in palliative care is observed that is most studies lack generalizability due to small sample size and homogenous samples. The institutional and clinical gatekeeping makes it difficult for the researcher to access a large sample. For my project I had elected to study the factors associated with mental health of EOL patients or their caregivers during transition from hospital to the community. After going through ethical guidelines and consulting my seniors I was made to restrict my project to a population with similar characteristics and try not to encompass multiple organisations or EOL patients or their caregivers as participants as ethics approval would take time and there are chances that the project might not get approved. If considering EOL patients or their caregivers, as participants then no direct question should be asked related to their problems and methods like observation, maintaining a diary, questionnaire and other indirect approach should be used, as it would not cause burden on them. I also came to know that every institute has its own ethics committee with different protocols. This means we need to design a project according to ethics committee not as per the needs of the target population and even then it is not sure that the project approved by one committee would be preferred by the other or not. These restrictions to my plans and thoughts have raised the following questions:

- Isn't this compromising my rights as a researcher?
- What about the autonomy and beneficence of the EOL patient or caregivers?
- Would it be justified to conduct multiple studies with similar outcomes in different ways and still are never get a generalizable result?
- Isn't the institutional ethics committee acting in an authoritative manner?
- Is it justified to make assumptions for a strategy effective for a population after study rather than evidence based approach?
- Who has the authority to decide whether the questions framed in a questionnaire are culturally appropriate?

According to Pessin et al (2008) and Hudson (2003) majority of the EOL patients find participating in a research beneficial and less burdensome.[9] There are many benefits in involving such a vulnerable population that outweigh the burden produced by research participation and thus a study should be approved by measuring the benefits from study rather than the burden produced. Autonomy of the researcher can be maintained by improving communication between the ethics committee and the researcher. There is a need for consulting the representative sample of target population or conducting a pilot study during formulation

and designing of a research study to improve autonomy of the participants as well as the researcher. A grading system should be designed in which a study should be approved according to its generalizability, outcomes and benefit to the sample population under study. It is better to research something ethical and practically beneficial rather than something ethically justifiable but inapplicable.

Acknowledgment

None.

Declaration

The authors report no conflicts of interests. The article is not published or under consideration for publication in any other journal..

Authorship (contribution or attribution)

All the authors have contributed equally.

References

1. Lee, S., & Kristjanson, L. Human research ethics committees: issues in palliative care research. *International Journal of Palliative Nursing* 2003; 9(1), 13-18. doi: <http://dx.doi.org/10.12968/ijpn.2003.9.1.11040>
2. Keesing, S., Rosenwax, L., & McNamara, B. 'Doubly deprived': a post-death qualitative study of primary carers of people who died in Western Australia. *Health & Social Care in the Community*. 2011; 19(6), 636-644. doi: 10.1111/j.1365-2524.2011.01005.x
3. National Health and Medical Research Council (NHMRC). *National Statement on Ethical Conduct in Human Research 2007*. Commonwealth of Australia, Canberra. 2015. Retrieved 18 May 2015 from: https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf
4. Jubb, A. M. Palliative care research: trading ethics for an evidence base. *Journal of Medical Ethics*. 2002; 28(6), 342-346. doi: 10.1136/jme.28.6.342
5. de Raeve, L. Ethical issues in palliative care research. *Palliative Medicine*. 1994; 8(4), 298-305. doi: 10.1177/026921639400800405
6. Ervin, K., & Reid, C. Service utilisation by carers of people with dementia in rural Victoria. *Australasian Journal on Ageing*. 2014. Retrieved 18 May 2015 from: <http://onlinelibrary.wiley.com/doi/10.1111/ajag.12162/epdf>
7. Aoun, S. M., Breen, L. J., Rumbold, B., & Howting, D. Reported experiences of bereavement support in Western Australia: a pilot study. *Australian and New Zealand Journal of Public Health*. 2014; 38(5), 473-479. doi: 10.1111/1753-6405.12177
8. Breen, L. J., Aoun, S. M., O'Connor, M., & Rumbold, B. Bridging the gaps in palliative care bereavement support: An international perspective. *Death Studies*. 2014; 38(1), 54-61. doi: 10.1080/07481187.2012.725451
9. Aoun, S. M., & Nekolaichuk, C. Improving the evidence base in palliative care to inform practice and policy: Thinking outside the box. *Journal of Pain and Symptom Management*. 2014; 48(6), 1222-1235. doi:10.1016/j.jpainsymman.2014.01.007
10. Williams, A. M., Wang, L., & Kitchen, P. Impacts of care-giving and sources of support: a comparison of end-of-life and non-end-of-life caregivers in Canada. *Health & Social Care in the Community*. 2015. Retrieved 18 May 2015 from: <http://onlinelibrary.wiley.com/store/10.1111/hsc.12205/asset/hsc12205.pdf?v=1&t=ia6nypl7&s=d7631ca172986116483e1159c05d4f051218c58b>
11. Dean, R.A. and McClement, S.E. Palliative care research: methodological and ethical

challenges. *International Journal of Palliative Care*. 2002; Vol. 8. No. 8. pp 376-380.

12. Abernethy, A. P., Capell, W. H., Aziz, N. M., Ritchie, C., Prince-Paul, M., Bennett, R. E., & Kutner, J. S. Ethical Conduct of Palliative Care Research: Enhancing Communication Between Investigators and Institutional Review Boards. *Journal of Pain and Symptom Management* 2014; 48(6), 1211-1221. doi: <http://dx.doi.org/10.1016/j.jpainsymman.2014.05.005>
13. Hudson, P. The experience of research participation for family caregivers of palliative care cancer patients. *International Journal of Palliative Nursing*. 2003; 9(3), 120-123. doi:10.1016/j.jpainsymman.2014.01.007