Short Communication

Palliative Care Research and Ethical Challenges

Monika Pandey

1 Australia, University Trobe La, Health Public & Psychology of School, Engineering & health, Science of College

* Corresponding Author: monika.pandey@gmail.com

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]
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. 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. 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 homogeneous 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. Similarly, selective sampling leads to over-representation of the case, such as death, under study in a community.

### 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. 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). Relational vulnerability is also associated with

---

<table>
<thead>
<tr>
<th>Challenges of Conducting Palliative Care Research</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain</td>
<td>Challenge</td>
</tr>
<tr>
<td>Patient</td>
<td>Defining the palliative care patient (terminology)</td>
</tr>
<tr>
<td>System or organization</td>
<td>Complicated or complex process for obtaining ethical and administrative approval</td>
</tr>
<tr>
<td>Context or setting</td>
<td>Gate keeping by clinicians or family members</td>
</tr>
<tr>
<td>Study design</td>
<td>Internal validity of primary studies.</td>
</tr>
<tr>
<td>Patient attrition</td>
<td>High attrition rates because of progressive disease</td>
</tr>
<tr>
<td>Randomization</td>
<td>Dealing with missing data</td>
</tr>
<tr>
<td>Interventions</td>
<td>Patients unwellness to be part of a comparison group</td>
</tr>
<tr>
<td>Selection of appropriate outcomes</td>
<td>Lack of appropriate outcome measures that adequately capture complex concepts, such as psychosocial spiritual issues</td>
</tr>
<tr>
<td>Research team</td>
<td>Recruitment, training, and turnover of research staff</td>
</tr>
<tr>
<td>Ethics</td>
<td>Obtaining patient consent and patient safety</td>
</tr>
</tbody>
</table>

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]
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 dairy, 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

11. Dean, R.A. and McClement, S.E. Palliative care research: methodological and ethical
