Author's response to reviews

Title: Qualitative Inquiry: A Method for Validating Patient Perceptions of Palliative Care While Enrolled on a Cancer Clinical Trial

Authors:

Christina Slota (cslota@nursing.upenn.edu)
Connie M Ulrich (culrich@nursing.upenn.edu)
Claiborne Miller-Davis (CDavis@cc.nih.gov)
Karen Baker (KBaker@cc.nih.gov)
Gwenyth R Wallen (gwallen@cc.nih.gov)

Version: 2
Date: 21 July 2014

Author's response to reviews: see over
Date: July 21, 2014

To: Dr. Catia Cornacchia  
Editor-in-Chief of BMC Palliative Care

From: Gwenyth R. Wallen, PhD  
National Institutes of Health, Clinical Center

Subject: Submission of revisions to manuscript titled “Qualitative Inquiry: A Method for Validating Patient Perceptions of Palliative Care While Enrolled on a Cancer Clinical Trial”

Please accept our revisions of a qualitative analysis entitled “Qualitative Inquiry: A Method for Validating Patient Perceptions of Palliative Care While Enrolled on a Cancer Clinical Trial”. We appreciate the thorough reviews provided and have addressed each of the reviewers’ comments as follows:

1. The sentence, Palliative care clinical trials (PCCT) are one approach to evaluate the quality of care in palliative care programs and can also serve to better understand how palliative care services can assist patients enrolled in a variety of biomedical clinical trials? is quite confusing. I’m not sure how clinical trials can evaluate quality of care. Further, I’m not sure that this generalization for Palliative care clinical trials is accurate, since most PC trials involve symptom management and not health service delivery.

   The following revision was made to clarify that this was an evaluation study of palliative services provided to patients enrolled in a cancer clinical trial:
   Palliative care is a vital component of patient-centered care. It is increasingly seen as central to the management and care of seriously ill patients by integrating physical, psychological, spiritual, and other types of supportive services [1]. Studies that evaluate the process and outcomes of palliative care services for patients enrolled in clinical trials are one approach to quantifying the quality of care in palliative care programs and can also serve to better understand how palliative care services can assist patients enrolled in a variety of biomedical clinical trials.

2. Overall, the structure of the Introduction as one long paragraph is hard for the reader to digest. I would suggest breaking apart, likely into three paragraphs. Also, there is not natural progression of the argument that the reader can easily find. Is the paper about cancer treatment trials, palliative care clinical trials, palliative care services, or a combination? I had to read the Introduction several times to try to understand.

   The introduction was divided into 3 paragraphs as recommended.

3. The second and fourth sentences are repetitive within the introduction.

   The fourth sentence was deleted and the citation was attributed to the second sentence which remains.

4. I’m not sure that the average reader will understand that all patients seen at the NCI are enrolled in a cancer treatment trial.

   The following clarification was added under the sample section on page 6:
   …to evaluate the efficacy of the Palliative Care Service intervention compared to usual care for patients with advanced malignancies who were enrolled in cancer clinical trials that included undergoing surgical procedures in National Cancer Institute (NCI) Surgery Branch clinical trials.
5. It's interesting to me that the authors stress the interdisciplinary and multi-domain nature of palliative care (the second sentence of the introduction), yet the scripted question calls the C team the Pain team.

The open-ended questions referred to the PC team as the pain team at the beginning of the question since this is what the patients used particularly since often they activated the team post-surgery for pain control. The complete question which included the full name of pain and palliative care team was as follows: 1) Do you feel that you are more likely or less likely to complete the protocol knowing that the Pain and Cancer teams are working together? Can you put into words your sense of security (with having a pain and palliative care team)?

6. Can the authors describe how the 34 participants were selected?

The following clarification was added on page 6:
All 34 participants who received palliative care services and provided responses to the open-ended questions were included in the analysis.

7. Is there some foundational knowledge or heuristic that guided the investigators choosing of these two particular questions?

The following was added in the beginning of the discussion:
Researchers and clinicians often express concerns related to the potential burden that participation in clinical trials may present for patients nearing the end-of-life, but there are limited empirical studies that explore what patient-participants experience at the EOL particularly if they are enrolled in a cancer clinical trial. Our goal was to open these discussions that exist around interdisciplinary communication between the patient-participant, their research and their clinical teams. We further wanted to explore how the communication might affect a patient-participant’s potential to remain enrolled in their cancer clinical trial even at the end of life.

8. The discussion seems to leave the reader wanting to still know the answer. Are patients more or less likely to complete the protocol? There seems to be a disconnect between the scripted question (which seems to imply a Yes/No answer) and the thematic analysis, which seems to answer the question what characteristics predict?

The thematic analysis was driven by the responses where the patient participants did seem to have specific characteristics that they found to be positive or negative. The follow-up probes in each of the questions allowed participants to describe their own experiences regarding participation and communication as seen in the table of quotes.

We also added under limitations section the following:
This study was also limited in that we did not directly examine whether individuals who felt positively about communication and were satisfied with their palliative care services remained enrolled the cancer clinical trial. Future studies are needed to quantify whether there is a relationship between the early introduction of integrated palliative care services and retention in cancer clinical trials.
9. Overall, the verbiage around a trial within a trial is quite confusing. Sounds like you have delivery of usual palliative care services, which are provisioned by a clinical trial, for cancer patients who are on a cancer treatment clinical trial. I’m not sure how the PC clinical trial was any different than a PC consultation for those patients who are already on a cancer trial.

As in reviewer comment #1 the following revision was made to clarify that this was an evaluation study of palliative services provided to patients enrolled in a cancer clinical trial: Palliative care is a vital component of patient-centered care. It is increasingly seen as central to the management and care of seriously ill patients by integrating physical, psychological, spiritual, and other types of supportive services [1]. Studies that evaluate the process and outcomes of palliative care services for patients enrolled in clinical trials are one approach to quantifying the quality of care in palliative care programs and can also serve to better understand how palliative care services can assist patients enrolled in a variety of biomedical clinical trials.

Sincerely,

Gwenyth R. Wallen, RN, PhD
10 Center Drive Room 2B09, MSC-1151
Bethesda, MD 20892-1151
(301)-496-0596
gwallen@cc.nih.gov