Author’s response to reviews

Title: The dignified approach to care: using the Patient Dignity Question as an intervention to enhance dignity and person-centred care for people with palliative care needs in the acute hospital setting

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Version: 3 Date: 9 March 2015

Author’s response to reviews: see over
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Title: The dignified approach to care: A pilot study using the Patient Dignity Question as an intervention to enhance dignity and person-centred care for people with palliative care needs in the acute hospital setting

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Reviewer's report
Title: The dignified approach to care: using the Patient Dignity Question as an intervention to enhance dignity and person-centred care for people with palliative care needs in the acute hospital setting

Date: 25 November 2014
Reviewer: Miguel Julião

Reviewer's report: Very interesting manuscript in a very important issue - dignity in an acute setting in patients with palliative care needs. I have no negative or constructive comments or possible revisions to make as this paper is cautiously written, with a special attention to the fluid understanding and conclusion within all the manuscript! I therefore commend the authors for this research and give them a special greeting as a clinician and researcher on this area in palliative care
Level of interest: An exceptional article
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: No competing interests

Reviewer's report

Title: The dignified approach to care: using the Patient Dignity Question as an intervention to enhance dignity and person-centred care for people with palliative care needs in the acute hospital setting

Version: 2 Date: 28 January 2015
Reviewer: Melissa J Bloomer

Reviewer's report:
Thank you for the opportunity to review your manuscript. I have included some revisions that I believe are essential to improving the quality of your manuscript:

MAJOR COMPULSORY REVISIONS

- In the background section:-

- Some discussion about how patients with palliative care needs in acute care settings is needed. Such as how are they identified how are their pall care needs addressed in acute care?

  Patients in acute care settings are identified as having palliative care needs by ward staff. They are referred to the Acute Palliative Care Unit (specialist palliative care) for clinical input or one of the two local hospices. This information is now provided under “Setting” (from line 198).

- Are they automatically transferred to a pall care specialist unit?

  Patients are not automatically transferred to specialist care units- they are assessed according to needs. This information is now provided under “Setting” (from line 198).

- Do you have a specialist pall care unit in this hospital?

  Yes- there is a three-bed Acute Palliative Care Unit, and two local hospices. This is now made clear under “Setting” (from line 198).

- Do you have a pall care clinical nurse consultant or other pall care specialist who is available to support your acute care staff in providing pall care?
Yes- the Hospital Palliative Care Team (specialist palliative care team) – led by consultants in palliative medicine with clinical nurse specialists- are available to provide advice and support throughout the hospital. This is now indicated under “Setting” (from line 204).

- How is ‘pall care need’ determined? Do all members of the treating team (doctors, nurses, allied health) have an opportunity to contribute to the determination of pall care need?

  Yes. This is now indicated under “Setting” (lines 201-202) and “Participants” (lines 214-215).

- Can patients with pall care needs still receive active care? The reader needs this information to better understand the context in which the study took place. You also need to talk about families and their role as proxy-decision makers. This is important because you go on to recruit family members. You will also have to talk about their readiness and acceptance of the need for palliative care, and how this might impact upon their appropriateness for this study.

  The clinical team take an individual approach to patients- concurrent treatments are applied if appropriate for the patient’s need. Palliative care can become an extra layer of support for those receiving active treatments for an underlying condition or concurrent acute issues. In other cases, palliative care becomes the only mode of treatment. In all cases goals of care are agreed with the patient. This is now indicated under “Setting” (lines 206-209).

- Line 131 hyphenate patient-centred for consistency

  Done- Now line 158

- Line 137 and 139 - referencing should be before the full stop, not after

  Now referring to the reference in line 166. NB sentence has changed due to editorial suggestions

- Line 166-167 join the two sentences to make one paragraph

  Done- sentence joined on line 193

- Line 176 In the section under the heading ‘Participants’ you need to further explain what you mean by patients with palliative care needs. How was this determined? Is it only applicable to those who were imminently dying, those with an NFR/DNR order? Or those with palliative care needs in a more broader sense? For example, a patient with a new diagnosis of mesothelioma will have obvious palliative care needs but may be many months/year from dying. How was ‘with palliative care needs’ determined?

  Palliative care needs are determined by the teams looking after the patient. Teams work under a broad definition where palliative care needs applies to those with incurable illnesses who have unmet needs, which may be physical, social, psychological and/ or spiritual. There are different levels of palliative care needs, from general to those that require specialist care. This information is now provided under “Setting” (lines 200-211) and “Participants” (line 214).

- Line 180 Were there any patients who were deemed ‘not appropriate’ for inclusion? A patient may be identified as having palliative care needs, but they may not yet be at the point of acceptance. So to approach someone for inclusion in this study, when they have not yet accepted that they may have a terminal diagnosis or need pall care is inappropriate. You need to expand on this
All patients who were approached had an awareness that they had incurable conditions. When asked to participate, there were no occurrences of distress amongst these patients. Moreover, most participants recommended the PDQ to others (line 431), so this indicates that they felt it was appropriate to partake. In the study, the selection of participants included varied levels of palliative care needs. Some patients had specialist palliative care involvement to meet these needs others had general palliative care given to meet needs.

- Line 186 – change ‘health professionals’ to HCP (you have used this elsewhere. This means you can then delete everything else contained in the brackets.
  Done- line 224

- Line 195 - replace ‘outwith’ with another word
  Done- now line 231. The word “outwith” has been changed to “beyond”.

- Line 203-204 Join the sentences to make one paragraph
  Done- sentences now joined on line 239

- Line 204 replace healthcare staff with HCPs
  Done- line 239

- Line 212 what do you mean when you say that the researcher agreed any necessary changes with the patient?? If you ask the patient to answer the PDQ, then their answer should be valid however they choose to respond. Altering a patient's answer so that it is more ‘acceptable’ for the study is not appropriate. You need to explain what you did and why

  Once the PDQ summary was given to the researcher, the researcher checked that the patient was satisfied with the summary. If the patient requested any amendments to be made, then the researcher made these changes. This is now reflected more clearly from line 247.

- Line 212 change the sentence to say 'requested the patients' permission
  Done- sentence changed on line 251.

- Line 213-217 please give some timelines for how quickly the patient had to complete the various measures. More specifically, what time frame was there between the pre and post intervention questionnaires? You talk elsewhere about the short timeline so I think it is important to articulate what sort of time frame you are talking about here. 2 hours?? 2 days?

  The patient was asked to complete the Person-centred Climate Questionnaire- Patient version (PCQ-P) and the CARE Measure pre and post PDQ intervention. The PDQ feedback questionnaire was completed on the same day that the PDQ had been asked. Following the PDQ intervention, PDQ summaries had to be displayed for a minimum of 48 hours before the PCQ-P and CARE questionnaires were completed again post PDQ. This is now reflected more clearly in lines 252- 257.

- Line 223-225 remove blank spaces
  Done- the subheading "Quantitative analysis" is now on line 288

- Line 238 change to members'
Done- line 279

- Line 245 which version of SPSS?
  21- now indicated in line 285

- Line 271 (recruitment section). I am concerned who you only got 4 relatives when you had 30 patients? Is this a result of the short timeline? If you aimed for one relative for every patient, then only recruiting 4 seems quite disappointing. Please elaborate. I know you have identified it as a limitation, but you need to add more detail in the recruitment section as well. What if family members didn’t do the survey because they were not ‘ready’ to accept that their loved one needs palliative care? Did they even know their loved one had a terminal diagnosis? lots of important detail missing here

  All patient participants and nominated family members were aware that the patient had palliative care needs. We have now been clearer in emphasising that this was a pragmatic pilot study (line 168), and have indicated that this might have led to lower numbers of family members participating (lines 477-480).

- Line 400 - join onto line 396 to form one paragraph
  Done- joined on line 437

- Line 402 change to patient participants
  This part is referring to healthcare professional participant (lines 435-444).

- Line 406 join onto line 404 to make one paragraph
  Done (added to line 441)

- Line 406 change to HCPs
  Done- line 441

- Line 427 join on to previous paragraph
  Done- line 459

- Line 446 as detailed earlier, you need to explain what you mean by the short time frame. It sounds like you rushed it and this is a real flaw of the project. You can’t make assumptions or conclusions for family based on only 4. What might the other 26 have said?

  We have now been clearer in emphasising that this was a pragmatic pilot study (line 168), which contributed to the shorter time frame (line 480), and therefore the lower number of family member participants. We have now been clear to indicate that all analyses in this pilot study provide some understanding, rather than conclusions, and that they will help develop the study into a larger multi-site trial where more definitive conclusions can be made (lines 689-691).

- Line 473 - join to previous paragraph
  Done – now line 506

- Line 501 add a space between paragraphs
Done- line 536 now separates the two paragraphs.

- Line 510 add a line between paragraphs
  Done- line 546 now separates the two paragraphs

- Line 513 add to previous paragraph line
  Done- now in line 549

- Line 539 add a space between paragraphs
  Done- line 576 now separates the two paragraphs

- Line 551 ditto
  Done- line 589 now separates the two paragraphs

- Line 551 to 556 - this is weak and a bit presumptuous because you only had 4 relatives

Where we comment that “this was deemed notable” (line 591), we refer to the fact that all patients completed the PDQ themselves, not the fact that information was reinforced by relatives (in the cases where family members participated). We then provide a reason as to why patients were able to complete the PDQ themselves (593-595).

- Line 564, line 577, line 589, line 602, line 612 add a line between paragraphs
  Done- New paragraphs on lines 605, 619, 630, 644, 655

- Line 635 join to previous sentence
  Done- now in line 677

- Line 636 same issue with time constraints. It seems like you cut quality in order to meet deadlines

  We have now been clearer to emphasise that this was a pragmatic pilot study (line 168), and this provides some understanding into why a shorter time frame arose. The time frame was not constructed in order to meet research deadlines; rather it was result of conducting a study pragmatically within a real life busy acute hospital clinical setting and was agreed with the clinical collaborators at the site.

- Discussion - Once the extra detail is added to the intro and other sections (as suggested above) then this needs to be teased out in the discussion

  In our renewed efforts to make clear that this is a pilot study, we have altered some parts of the discussion (lines 528-531) and indicate that the findings can be seen to provide some understanding. We have acknowledged limitations (line 681) and conveyed intentions to develop this research further (lines 688-691).

- Line 663 add a line space
  Done- new paragraph now 709

- Line 666 ditto
Done- new paragraph now 713

• Line 672 ditto.

Done- new paragraph now line 720

• 16 tables is excessive and likely beyond the number that the journal can realistically publish. You need to use your discretion in determining what tables really need to be included. More tables does not value add!

We now have 12 tables and 2 figures (we have taken advice from editorial comments).

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I declare I have no conflict of interests

**Editorial report**

**Section editor:** Miss Maria Merrie Jul Ladag on behalf of Dr Nancy Preston

**Section editor comments:**
Many thanks for submitting this paper on an interesting topic. One of the reviewers has made extensive comments which I think will help the paper. I wanted to just comment upon some aspects too which I think need addressing:

- I think you need to write this up with pilot study aims and results. As a pilot study it is inherently underpowered so is unlikely to result in significant results. Can you make it clear why this was a pilot study rather than a full study? Was any power calculation made? Also how did this differ to the feasibility study you mention on line 116? What findings did you get from the feasibility study? On line 137 you say the pilot was to assess the design but weren't they addressed in the feasibility?

We have now identified that this is a pilot study by explicitly including “pilot study” in the title. We have consulted further literature, including the article by Arain *et al.* (2010) that you recommended. Following this, we have made further changes to the manuscript:

Background from line 106- we explain that the intentions of the pilot study are to help inform the design of the future main trial.

The feasibility study is also discussed briefly here and intentions are made clearer, for example, highlighting that the feasibility study allowed viability to be assessed with regards to recruitment, willingness of participants to be randomised and assessment of a proposed outcome measure.
We now highlight that the feasibility helped inform our decision to include the CARE measure as a second patient outcome measure in order to allow more thorough assessment of dignified care.

Intentions of pilot study are made more explicit and adhere to the guidance offered by Arain et al. (2010). For example, this pilot study was conceived to be a smaller version of the future larger trial, and can be such, now that it uses the CARE outcome measure. We now make clearer that the pilot study focuses on the processes that will be present in the future study as allocation of the participants to the PDQ and the use of the two key outcome measures.

Lines 127-129 now explain why we analysed findings and how this is an appropriate way to use pilot studies.

The first sentence under “Aim” has been modified (line 145) to reiterate that this pilot study is a smaller version of a larger trial.

Slight modifications under “Study Design” again to reiterate modified information provided in the “Background” section (lines 163-170).

- **Line 148 - how did you define frail or ill patients?**

  This refers to patients who were not well enough to participate in the study- i.e. could not fill out the outcome measures, questionnaires, respond to the PDQ, and take part in the interviews.

- **Line 212 what does ‘any necessary changes were agreed’ mean?**

  Following your editorial comments and reviewer 1’s identification of this, we agreed that this term lacked clarity and risked being interpreted incorrectly. Therefore, under “Study Procedures”, we have now clarified the procedure more clearly (from line 244).

- **You are looking at differences and state an increase of 6 (line 315). Is this a minimally clinically important difference (MCID) and how could this be determined?**

  The increase by 6 was not representative of anything particularly significant- it was more the fact that there had been an increase at all. The increase suggests that overall perceptions of dignified care (as relating to person-centred care) improved after the PDQ intervention.

  We have now discussed the significance of this increase but have removed the reference to “an increase of 6”, since it was not an MCID (360).

- **You repeat the descriptive stats (which weren't significant as expected with an underpowered study) in the narrative. Maybe just pick out fewer key examples. What do you think these
The discussion needs to be framed about what the findings mean as a pilot study rather than a definitive study. I think the qualitative results may be more interesting as the numbers are too small for the quantitative tools except to comment on their usefulness in a large scale trial.

Done- line 528 and under “Strengths and Limitations” (lines 688-691).

How do you the changes were about the PDQ intervention and not just becoming more familiar with staff over time? There is no control group?

Because of the nature of the PDQ as a conversational intervention, it was not as viable to have a control group. Although we cannot definitively say that improved patient perceptions of dignified care are down to the healthcare professional asking and responding to the PDQ, we can comment on aspects of the data which strongly suggest that this was the case. In particular, the following elements help support these conclusions, in the absence of a control group:

- The use of baseline data (giving patients the PCQ-P and CARE questionnaires before the PDQ was asked), allow a set of scores that can be referred to for comparison with scores after the PDQ has been asked and the healthcare professional has had time to look at PDQ summaries.

- The PDQ feedback summary directly elicits information relating specifically to the PDQ and provides some context for scores of the post PDQ PCQ-P and CARE measures. For example high percentage of patients believed that the information was important for HCPs and all supported it being displaying in their notes.

- Qualitative data showed that from patient perspectives, they would like healthcare professionals to know them as a person, including their life achievements. The PDQ, explicitly asks for key information that can help the patient to be understood as a person. The key theme “know me as a person” as identified by patients as important, can be considered when looking firstly, at what the PDQ was designed to do, and secondly, at score improvements post PDQ intervention.

Lines 580-88 are quite descriptive
We have deleted references to specific percentages and have chosen instead to comment generally on the trend of HCP data. We keep the reference to Table to allow readers to identify specific percentages if they wish (lines 619-628).

- Line 621 - what is the tie in to advance care planning - perhaps this can be expanded upon in the background which is very brief

The background section is now focused more on the development of this pilot study from an earlier feasibility (lines 106-142). With this renewed focus, reference to Advanced Care Planning would be misplaced here and would therefore be difficult to bring in later on in the manuscript.

- Line 653 what do you mean by 'not possible'?

Apologies- this was an error. It is not the median score that was “not possible”/able to increase, it was the maximum summated score (since 50 was the maximum possible score – 5/5 for each of the 10 CARE items) and this was the score before and after the PDQ intervention. We have now changed this sentence to explain more clearly that although the median score did not increase post PDQ, it also did not decrease, which is a good thing (line 699).

- Tables and graphs need combining in parts: table 1 could be removed, table 2 referred to in the narrative only then removed, table 3 % missing (is this because numbers low?), table 7 IQR could be added to histogram, table 9 combine with histogram - why no IQRs? Table 10 - just describe in narrative and remove, table 12 are % justified with such low numbers?, table 13,14,15,16 - not sure how much these add which isn’t in the narrative. Maybe rationalise? Graphs 2 and 3 are repeated. Need to use same range on the x and y axis for all graphs. Combine pre and post and IQRs on one graph for each measure ie only 2 graphs in total. What is graph 5 saying? Needs more explanation with the graph.

- Table 1 and references to Table 1 have been removed- PROMs sufficiently explained in narrative.

- Table 2 and references to Table 2 have been removed. The stages of Framework Analysis are described in narrative form (lines 301-307).

- Table 3- percentages were missing for Male and Female variables- now added. All percentages are complete for any categorical variables. Since Age, Palliative Performance and Palliative Prognostic Index are continuous variables, only mean and standard deviation are provided. This is now Table 1 in the modified manuscript.

- Table 10 and references to Table 10 have been removed. Correlation between summated PCQ-P score and summated CARE score post PDQ is described sufficiently in lines 418-422.
- Table 12: Regarding use of percentages for HCPs’ responses (lines 422-430) : We feel that reporting this data using percentages is appropriate because it allows a better picture of the proportion of HCPs who found the PDQ an effective intervention than if we were to talk in terms of numbers. Furthermore, despite the fact that the numbers are small, we feel using percentages is justified, because we now make clearer in previous sections, that this pilot study data will contribute to the final analysis which will be undertaken for a larger trial study. In this way, discussing participant data will be consistent with how data from a larger sample will be discussed. This is now Table 8 in the new manuscript.

- Tables 13, 14, 15 and 16 all provide details of the Framework Analysis, regarding patient, HCP and family perspectives. The structure of the tables are such that they succinctly but sufficiently present the essence of each themes with appropriate verbatim examples. To transform this to narrative form only will require us to significantly add to the word count. These are now tables 9, 10, 11, 12 in the new manuscript.

- The statistical software that we have used does not make it possible to produce layered histograms. Moreover, it does not allow us to display IQRs on the histograms themselves. Therefore, we have condensed this information into one table and two figures. We have produced Figure 1 to show Graphs 1 and 2 side by side, so that pre and post PDQ PCQ-P scores can be compared visually. Figure 2 then shows Graphs 3 and 4 side by side to compare pre and post PDQ CARE scores visually. We have produced Table 6 to show the interquartile ranges on PCQ-P (pre and post PDQ) and CARE (pre and post PDQ) data on one table.

- Graph 5 has now been removed as it was not contributing adequately to the manuscript and its absence does not affect the analysis and discussion of HCP data.

I think the overall gist is to write this more as the results of a pilot study not a definitive study and how it changes the full trial design - effect sizes etc if these were your aims. Current aims are for a definitive study. The following paper might be helpful: Arain et al. BMC Medical Research Methodology 2010, 10:67 [http://www.biomedcentral.com/1471-2288/10/67](http://www.biomedcentral.com/1471-2288/10/67)

We have consulted this helpful paper and made changes (indicated under specific points above) to highlight this study as a pilot and have now structured aims, objectives and discussion as in line with pilot study intentions.

- Please add an “Abbreviations” section

    Done- this will be submitted as an Appendix

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