

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Percutaneous coronary intervention patients' and cardiologists' experiences of the informed consent process in Northern England: A qualitative study.
AUTHORS	Probyn, Joy; Greenhalgh, Joanne; Holt, Janet; Conway, Dwayne; Astin, Felicity

VERSION 1 - REVIEW

REVIEWER	Fiona Wood Cardiff University, UK
REVIEW RETURNED	22-Nov-2016

GENERAL COMMENTS	<p>I very much enjoyed reading this paper and I think the authors bring out some important insights. Its refreshing to see a Grounded Theory study described so well with a central category.</p> <p>The abstract mentions that nurse delegated consent may offer an alternative approach. I may have missed it, but I can not find any mention of nurse delegated consent in the results or discussion that might support this statement.</p> <p>The cardiologists were invited to audio-record a consent discussion. Did all of them do this? Was this used as a starting point for the interview?</p> <p>The authors state that all cardiologists and all eligible patients were invited to participate, but we are not told how many that was. Consequently we don't know the response rate to the invitation to participate. If this was a low response rate it is possible that the participants held non-typical views.</p>
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REVIEWER	Kerry Woolfall University of Liverpool
REVIEW RETURNED	27-Jan-2017

GENERAL COMMENTS	<p>This is a well designed mixed method study. The use of COREQ helps to assess the quality of this research, which is very good. Audio recorded consent provides good insight into patient-doctor communication. However, the stage at which the conversation was recorded seems to be crucial for this paper and the conclusions which can be drawn. This is acknowledged by the authors at various points, however I am still slightly unclear at which stage the recruitment conversation was recorded- was it stage 3? Could this be clarified in the methods section? Is it possible that patients had discussions with clinicians at earlier stages of the consent process in</p>
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	<p>which they took a less passive role? It seems insufficient to claim that a passive role was taken when audio recordings were limited to the end stage of consent (form completion). If there are data from interviews which indicate this passive role at earlier stages in the consent process (and not just at the box ticking stage) this would help to underpin the main findings.</p> <p>Table 1: are the quotations from interviews or audio recorded consent discussions?</p> <p>Currently there is a lack of data to help illustrate findings. Table 1 would benefit from further quotations, possibly structured under sub themes discussed in the paper.</p> <p>The first quote (Theme 1) seems to be about the patients' hospital admission journey and nothing to do with consent.</p> <p>The second quote (theme 3) seem to be about restricted choice/decision making and not about paternalism 'You're the doctor'.</p> <p>Table 3: was the detailed risk description read directly from a PIS or some other form of written information? Please clarify and perhaps consider whether 'reading out' written information can make a difference in the risk information communicated to patients.</p>
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VERSION 1 – AUTHOR RESPONSE

Comment

Response

Reviewer 1

The abstract mentions that nurse delegated consent may offer an alternative approach. I may have missed it, but I can not find any mention of nurse delegated consent in the results or discussion that might support this statement.

This was an editorial error and has subsequently been deleted.

The cardiologists were invited to audio-record a consent discussion. Did all of them do this? Was this used as a starting point for the interview?

All participating cardiologists audio-recorded their informed consent discussion during which the consent form was signed, with participating patients. We then subsequently interviewed these patients and their cardiologists, using the consent discussion as a starting point for the interview. Please see highlighted changes on pg 5.

The authors state that all cardiologists and all eligible patients were invited to participate, but we are not told how many that was. Consequently we don't know the response rate to the invitation to participate. If this was a low response rate it is possible that the participants held non-typical views.

98 participants were invited to participate in total, giving a response rate of 42%. This has been added on pg 6 (highlighted).

Reviewer 2

Audio recorded consent provides good insight into patient-doctor communication. However, the stage at which the conversation was recorded seems to be crucial for this paper and the conclusions which can be drawn. This is acknowledged by the authors at various points, however I am still slightly unclear at which stage the recruitment conversation was recorded- was it stage 3? Could this be clarified in the methods section?

Is it possible that patients had discussions with clinicians at earlier stages of the consent process in which they took a less passive role? It seems insufficient to claim that a passive role was taken when audio recordings were limited to the end stage of consent (form completion). If there are data from interviews which indicate this passive role at earlier stages in the consent process (and not just at the box ticking stage) this would help to underpin the main findings.

Table 1: are the quotations from interviews or audio recorded consent discussions? Currently there is a lack of data to help illustrate findings. Table 1 would benefit from further quotations, possibly structured under sub themes discussed in the paper.

The first quote (Theme 1) seems to be about the patients' hospital admission journey and nothing to do with consent.

Please see highlighted changes on pgs 11 and 18. The discussion was recorded at Stage 3 at Hospital 1 and Stage 4 at Hospital 2 which reflects the different patient journeys at the participating organisations. Box 1 has been amended to show the requested detail and additional information added in the methods section as requested (see pg 5).

We agree that patients are likely to have had other discussions but unfortunately we were unable to study all of the communication interactions involved in the consent process. This is acknowledged as a limitation on pg 18. The in-depth patient interviews did indicate a high level of passive behaviour.

We have now clearly marked and distinguished between quotations from interviews and consent discussions in Table 1 (pgs8-10). We have added additional quotations as requested presented in a way that reflects the themes and categories that emerged from the data. We would prefer to retain this structure which we believe is grounded in the data. We have added notes in the text to show the links between the descriptions of the themes and quotes in the table to improve clarity.

On reading this again we understand why the relevance of the quotes might not have been immediately obvious. The quotes we selected aimed to illustrate the 3 different types of patient journey (see page 11 for a description). The different journeys shaped the participants consent experiences. We have added quotes Theme 1, category 1 'Diverse patient journeys' to strengthen the representation of the 3 journeys.

The second quote (theme 3) seem to be about restricted choice/decision making and not about paternalism 'You're the doctor'.	This quote has been removed and replaced with quotations that better reflect the theme (pgs9-10).
Table 3: was the detailed risk description read directly from a PIS or some other form of written information? Please clarify and perhaps consider whether 'reading out' written information can make a difference in the risk information communicated to patients	We acknowledge that the delivery of the information could potentially influence comprehension but did not record this information. We felt that the presence of a Researcher during the consent discussion would influence the discussion and therefore we were not present to observe this. Additional information has been added on page 12 regarding the presentation of risk on the consent forms at the two different hospitals and this difference has also been acknowledged in the discussion on pg 19.

VERSION 2 – REVIEW

REVIEWER	Fiona Wood School of Medicine, Cardiff University
REVIEW RETURNED	15-Mar-2017

GENERAL COMMENTS	Thank you for making appropriate changes to address the comments of the reviewers. There are a few typos remaining, (eg. page 14, line 12; page 12, line 46; page 6, line 15) but I am sure they will be ironed out in the proof reading stage.
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