

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	How Are Decisions Made in Cancer Care? – A Qualitative Study Using Participant Observation of Current Practice
AUTHORS	Hahlweg, Pola; Härter, Martin; Nestroriuc, Yvonne; Scholl, Isabelle

VERSION 1 – REVIEW

REVIEWER	Richard Thomson and Susan Hrisos Institute of Health and Society Newcastle University UK
REVIEW RETURNED	31-Mar-2017

GENERAL COMMENTS	<p>Overall, the findings are intriguing, but the paper lacks some detail to allow the reader to fully understand and appraise the results.</p> <p>Abstract This is clear on the purpose of the study, and provides a reasonable summary of the results. One key issue throughout the paper is the description of this as “participant observation”; it would seem to be non-participant observation. The strengths and limitations are listed together on P2 – it is not always clear which are strengths and which limitations. This could be more thoroughly addressed in the discussion.</p> <p>Introduction This gives a succinct overview and justification for the study, and briefly places it within the context of work to aid development of an implementation strategy for SDM in this area. The aims are clearly stated.</p> <p>Methods As above, this would seem to be non-participant observation and this should be changed. There were three observers, using semi-structured field notes, with subsequent qualitative content analysis and descriptive statistics. It would help readers considerably in critical reading of the paper if the data forms were included as an appendix or online supplement (or as a table within the paper). How were these designed? Did they draw on other observational tools like the OPTION tool (see below in results)? It would help to know why the decision was taken to use hand-written notes rather than video or audio record (outpatient consultations in particular), and there should be subsequent appraisal of the limitations of the method in the discussion. Page 5 How were the wards and clinics selected in order to provide “diverse</p>
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	<p>settings" (P4)? Are they diverse? More is needed on the details of the settings. A key issue is whether there are multidisciplinary team meetings to discuss treatment options, as happen throughout the UK and in many other countries. In our work in head and neck cancer this is a critical and problematic component of the decision making process (See D W Hamilton, B Heaven, R G Thomson, J A Wilson, C Exley. Multidisciplinary team decision-making in cancer and the absent patient: a qualitative study BMJ Open Jul 2016, 6 (7) e012559; DOI: 10.1136/bmjopen-2016-012559). If such meetings don't happen, that should be stated. If they do, this raises the question as to whether they were observed and, if not, was their influence on SDM seen in either the OP or IP setting? On P8 are lines 34-36 referring to formal or informal discussion?</p> <p>Line 16 onwards –was the inpatient data linked to the outpatient data? To what extent are preference sensitive decisions (such as treatment decisions) made as an inpatient compared to the outpatient setting. The methods state that the purpose was to “gain insight into [clinician] workflows” More description of the approach to data collection quality/reliability could be provided (current lines 40-46 on P5). For example were there any shared guidelines for what should be recorded in the ‘observation memo’ or was this just purely descriptive of what was going on? What was the experience and/or training in observation for the three observers and was there any testing of agreement in observing phenomena of interest? Line 42 –what were the challenges and how did you overcome them or, if not, how did that impact on the data collection/outcomes? Line 33 – how did you minimise the Hawthorn effect? Line 35 - ‘we then expanded our notes after the consultations were finished’ – at the end of each consultation or at the end of the clinic, and how much additional detail, any standardised or minimum length or content etc? Whilst stating that “descriptive statistics were calculated” (line 20), the presentation of these results seems limited (see below).</p> <p>Results There are times when terms such as many, few, several are used in the results without numbers despite expressed use of descriptive stats in the methods. Whilst there is an argument about the value of such data within qualitative studies, if analysed as part of the methods, they should be presented appropriately in the results. Throughout the results could be enhanced by use of more illustrative quotes and examples At times in the results it is not clear if the findings are from OP or IP observation, nor how the findings from these settings throw light on one other (if at all).</p> <p>Page 6 Line 46-53 – shouldn't the numbers presented add up to 57? Currently, only 52 OP observations accounted for. Line 53 – It would help if there was a definition of what constituted a “clinical treatment decision” and how the judgements were made on presence of absence of a decision. Is it problematic that the observers ‘got the impression that no decision had to be made ...’? Is it not a decision to ‘renew a script’ for example?</p> <p>Page 7 Lines 31 & 52 (and then subheadings throughout results section) – are these subheadings representing emergent themes from the</p>
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	<p>qualitative content analysis or are they summarising data collected using pre-structured headings?</p> <p>Line 33 – how are you defining ‘patient-centred behaviour’? – these attributes were observed in ‘many consultations’ (if descriptive stats were used, the authors should say in how many)</p> <p>Line 40 –how are ‘good communication skills’ defined here? - these attributes were only observed in ‘some consultations’ (how many?)</p> <p>Line 46 – ‘other physicians used a lot of jargon ...’ – presumably they are not included in previous categorisations of person centred or good communication? (the authors need to be clear whether they are describing behaviours within a series of consultations or of separate physicians, since the physicians are contributing more than one consultation each and their behaviour is varying across patients)</p> <p>Line 59 – ‘observers felt that ...’ the use of phrases like ‘observers felt’ is problematic as it implies a subjective judgement on the part of the observer. It may well be due to writing in a second language (though the English used is generally excellent), but there is then no description of why the observer got that impression other than ‘physician explains little, patient and husband do not SEEM able to follow ...’ What are patient and husband doing that suggests this? How does the observer know what is and what isn’t sufficient explanation? (see also comments on method above)</p> <p>On line 57 it is stated that “More than one treatment option was rarely discussed in detail”. N =? Does this mean that one treatment option was usually discussed in more detail than others or that more than one option was rarely discussed? And the reasons could be manifold and could be consistent or inconsistent with SDM.</p> <p>Page 8</p> <p>Line 45 – were the clinicians only discussing the one option that they had decided on (earlier statement at lines 53-57 on page 7 suggests so)</p> <p>Line 46 – so clinicians made the decision, then went to the patient to discuss option/s in detail, but the outcome was to go with the decision the clinician (appeared to have) made before discussion with the patient? These statements require more descriptive field note data to support them.</p> <p>There is something generally about the findings from the different settings being intertwined in the interpretation/discussion – the context might be influencing the different approaches but it is hard to unpick if there is a context effect. Presumably the clinical status of those who are inpatients is going to be more severe than those who are attending an outpatient appointment?</p> <p>It also feels, generally, that more context needs to be given to support examples of what is thought to be happening from the perspective of the observer. Since there is no second observer of the same consultation etc it is difficult to establish any level of standardisation of what it actually being observed. Might be just a language thing but observers can only describe what they see, they cannot assume what those being observed are thinking or feeling.</p> <p>Page 9</p> <p>Line 12 – this section is more interesting reading and describes what people are doing in more detail. The authors indicate a very minimal role for nursing staff within the physician-patient interaction itself but they appear to be doing a lot of deliberate advocating on the behalf of patients outside of that situation. This isn’t really commented on much. It would be valuable to observe nurse-patient interactions to explore this relationship, how they develop and how they function, and whether this is a routine way of doing or enabling a level of SDM in the settings involved in the study.</p>
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	<p>Line 43 – again an interesting section with sufficient description to facilitate understanding of the behaviours observed in patients, though this would still be greatly strengthened by an example or two quoted directly from the field notes of what the patient did and how the clinician responded (or vice versa as appropriate). The format of field note data might not lend itself easily to this however.</p> <p>Some results seem peripheral to SDM e.g. blood sampling on P 10 lines 19-21</p> <p>Discussion</p> <p>A key finding is that ‘active’ patients instigate SDM, although this is still limited in terms of depth of analysis and lack of descriptive context. Also, how do we know that this is patient driven or might it occur as a result of different approaches to different patients by clinicians? This should be discussed since it also leads to conclusions that patient mediated interventions are required. That is likely so, but the consultation is still often driven by clinician behaviour and that may foster or inhibit the patient role.</p> <p>It is not always clear how conclusions derive from the findings. This could be improved in the discussion but would also be clearer with more detail in methods particularly the results section.</p> <p>There is first mention of comparison with an existing model of SDM in the discussion –should this form part of the methods?</p> <p>There is little consideration of the limitations associated with the approach they used (non-participant observation) - how this may have influenced the behaviour of those being involved, potential observer bias (e.g. existing assumptions, understanding of SDM) and how this was mitigated. (in the COREQ checklist the authors have suggested consideration of observer bias is ‘NA’, likely because the checklist item refers to ‘interviewer bias’)</p> <p>Also how they managed consistency in description and quality or nature of phenomena observed – analysis is of hand scribed notes taken in real-time - this limits detailed and comprehensive data capture for example (note takers can use their own short hand, terminology and so on, and whilst making notes it is possible to ‘miss’ or under-appreciate other relevant phenomena).</p> <p>The section on p 11-12 on intervention development should be removed and the discussion expanded around the key results of this study</p> <p>Overall conclusions</p> <p>This is a really interesting study and a potentially important contribution to the field. The authors could do more to present their methods and findings to further strengthen the paper.</p> <p>In particular:</p> <ul style="list-style-type: none"> • More detail on the methods used, including any frameworks for analysis, and how the quality and reliability of the findings and their interpretation was assured. • More examples and more details on how conclusions were reached from the field notes/data collected. Overall the analysis and discussion would benefit from more depth (dropping the discussion on the intervention development would enable this). • More descriptive stats (or alternatively, drop these and present more detail on analysis/interpretation). • More context for the setting of the observations and particularly whether there is any multidisciplinary team meeting to discuss treatment options • Clarity of definitions and the application of key terms such as “patient-centred behaviour” and “good communication skills”
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REVIEWER	Associate Professor Sarah Lewis The University of Sydney, Australia
REVIEW RETURNED	30-Apr-2017

GENERAL COMMENTS	<p>Abstract:</p> <ul style="list-style-type: none"> • A couple of missing words: “Shared decision-making HAS...” and “Few studies HAVE”. • The abstract needs to mention the method of data analysis for the notes and observations (qualitative tradition or coding method). <p>Introduction:</p> <ul style="list-style-type: none"> • Awkward opening sentence grammatically: “Patient-centeredness in health care has significantly gained in importance over the last years”. Consider “patient-centered health care has gained importance over the last few years” • Improve the readability of the sentence “emphasized the importance to also take the organizational level (i.e., the meso level)” by replacing it with “the importance of also taking into account the organizational” • Overall, a very sound opening that covered most theoretical concerns and past literature however a couple of sentences exploring the dynamics and power imbalance of doctor-patient relationships within the western biomedical model of health care would be helpful. <p>Methodology:</p> <ul style="list-style-type: none"> • Awkward grammar with “In- and outpatient clinics to include in the data collection were identified”. This should read “The In and Out clinics that were included in the data were identified”. • Please list the clinics included as this will provide better readability to a diverse health care audience. • More information about the patient’s clinical situation is necessary. What stages of cancer or diagnosis were the patients in. This would impact upon the results as terminally ill patients or those receiving palliative care may want different SDM or models of care. • Could the researchers please explain why the physicians were not required to give informed consent as they were being observed and recorded. • Was any opposition to being included in the study from either patients or physicians? Was there any attrition rate? • Please make note of any exclusion criteria, such as language difficulties and were interpreters offered? Were family or support persons with the patients at the time of the consultations that would have allowed them to feel more empowered? • For 57 encounters, how many patients did this represent? What was the average age of the patients, as older patients are less likely to engage in SDM. • Were any SDM/consultations around lesser understood therapies like radiation therapy? Or were they all drug related? Were any around allied therapies? <p>Results:</p> <ul style="list-style-type: none"> • Please change “In 25 of the 57 consultations main cancer treatment-related decisions” to “in 25 of the 57 consultations, the primary cancer treatment” • Please provide some examples for “other physicians used a lot of jargon and strong wording such as “you must” or talked about the patient rather than with the patient” • Poor grammar and typing error “This was sometimes caused by the patient voicing his preferences on his own, other times the physician asked for the patients preferneces”. Please correct spelling of preferences and consider word change “This was sometimes in reaction to the patient”
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	<ul style="list-style-type: none"> • It is unclear if the sub-headings were the key themes of the study, could this be clarified <p>Discussion:</p> <ul style="list-style-type: none"> • Line 36, page 11: the word “especially” is not necessary and represents incorrect grammar • Line 4/5, page 12: reports on another study that follows the current study under review. It gives the impression that the focus group study has already been published with linked methodology. Please consider removing this section, it is hard to read and, as there is limited information, it appears that the reader must also consider this new information directly after reading the new article. It is also not the right place to be discussing new studies. • There is no discussion on any bias by the researchers or social desirability of the observed doctors and patients. This is a real possibility and needs to be considered. What information was given to the physicians before the observations that may have affected their behaviour. Likewise for patients.
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Reviewer Name: Richard Thomson and Susan Hrisos

Institution and Country: Institute of Health and Society, Newcastle University, UK

Please state any competing interests or state ‘None declared’: none declared

--> Thank you for the thorough and constructive review of our manuscript. We appreciate your valuable comments and suggestions and acknowledged them in the revised manuscript.

This paper reports on a qualitative observational single site study to better understand the processes, barriers and facilitators to shared decision making (SDM) in cancer care. This involved observations in both outpatient and inpatient (ward) settings. This is an important study since in depth observational work in this area is scant, we know little about the reality of what happens within the consultation, and we currently largely rely on self-completion measures from patients and clinicians to assess SDM (despite well-known problems with such measures).

Overall, the findings are intriguing, but the paper lacks some detail to allow the reader to fully understand and appraise the results.

Response:

Thank you for your overall positive assessment. We revised the manuscript and addressed your concern about the lack of detail. Please see the comments below for more details on the revision.

Abstract

1. This is clear on the purpose of the study, and provides a reasonable summary of the results. One key issue throughout the paper is the description of this as “participant observation”; it would seem to be non-participant observation.

Response:

After careful consideration of your suggestion, we decided to maintain the term “participant observation”. Following Spradley’s terminology, we think the term participant observation with passive participation fits our methodology best (cp. Spradley JP. Participant observation. New York: Holt, Rinehart and Winston; 1980.). To further clarify, we added this information about the passive level of participation in the “methods – study design” section of the manuscript.

2. The strengths and limitations are listed together on P2 – it is not always clear which are strengths and which limitations. This could be more thoroughly addressed in the discussion.

Response:

Thank you for pointing this out. We revised the section accordingly. (cp. editor comment 2)

Introduction

3. This gives a succinct overview and justification for the study, and briefly places it within the context of work to aid development of an implementation strategy for SDM in this area. The aims are clearly stated.

Response:

Thank you for the positive appraisal of this section.

Methods

4. As above, this would seem to be non-participant observation and this should be changed. There were three observers, using semi-structured field notes, with subsequent qualitative content analysis and descriptive statistics.

Response:

Please cp. our response to comment 1. Since the observers were present during the observations to write the field notes, we think this is best described as participant observation.

5. It would help readers considerably in critical reading of the paper if the data forms were included as an appendix or online supplement (or as a table within the paper). How were these designed? Did they draw on other observational tools like the OPTION tool (see below in results)?

Response:

Thank you for this suggestion. We added information and the English translation of the German observation scheme in the appendix.

6. It would help to know why the decision was taken to use hand-written notes rather than video or audio record (outpatient consultations in particular), and there should be subsequent appraisal of the limitations of the method in the discussion.

Response:

We added information on the rationale for this decision in the “methods – data collection” section of the manuscript.

Page 5

7. Setting

a. How were the wards and clinics selected in order to provide “diverse settings” (P4)? Are they diverse? More is needed on the details of the settings.

Response:

We revised the sentence accordingly.

b. A key issue is whether there are multidisciplinary team meetings to discuss treatment options, as happen throughout the UK and in many other countries. In our work in head and neck cancer this is a critical and problematic component of the decision making process (See D W Hamilton, B Heaven, R G Thomson, J A Wilson, C Exley. Multidisciplinary team decision-making in cancer and the absent patient: a qualitative study BMJ Open Jul 2016, 6 (7) e012559; DOI: 10.1136/bmjopen-2016-012559). If such meetings don't happen, that should be stated. If they do, this raises the question as to whether they were observed and, if not, was their influence on SDM seen in either the OP or IP setting?

We completely agree with you on the importance of multidisciplinary team meetings for decision-making in cancer care. We reported the results of observations in multidisciplinary team meetings in a separate publication: Hahlweg P, Hoffmann J, Harter M, Frosch DL, Elwyn G, Scholl I. In absentia: An exploratory study of how patients are considered in multidisciplinary cancer team meetings. PLoS One. 2015;10(10):e0139921. We added a sentence to inform the reader of the existence of this paper in the “introduction” section of the manuscript.

c. On P8 are lines 34-36 referring to formal or informal discussion?

Response:

Thank you for pointing out that this needs clarification. We added “informal” to the sentence.

8. Line 16 onwards –was the inpatient data linked to the outpatient data? To what extent are preference sensitive decisions (such as treatment decisions) made as an inpatient compared to the outpatient setting. The methods state that the purpose was to “gain insight into [clinician] workflows”

Response:

Thank you for this suggestion. We agree with you that it would be very interesting to gather additional information on what decisions are made within which setting. Due to our analysis' focus on how decisions are made rather than the comparison of the two settings, we cannot answer this question at this point. We added to the discussion section that this issue could benefit of further investigation in future studies.

9. More description of the approach to data collection quality/reliability could be provided (current lines 40-46 on P5). For example were there any shared guidelines for what should be recorded in the 'observation memo' or was this just purely descriptive of what was going on? What was the experience and/or training in observation for the three observers and was there any testing of agreement in observing phenomena of interest?

Response:

Thank you for pointing this out. We added information on the development of a guideline and prior experiences with observations within the manuscript.

10. Line 42 –what were the challenges and how did you overcome them or, if not, how did that impact on the data collection/outcomes?

Response:

The challenges are mentioned in brackets within the sentence. For example, we discussed how much information about our observations we had to give the physicians in order to make them feel comfortable with us observing, without giving too much information, in order to keep the situation as close to routine care as possible. Due to limited space within the manuscript we decided to only add "as well as ways to overcome those" within the respective sentence.

11. Line 33 – how did you minimise the Hawthorn effect?

Response:

We added a sentence concerning this issue to the revised manuscript.

12. Line 35 - 'we then expanded our notes after the consultations were finished' – at the end of each consultation or at the end of the clinic, and how much additional detail, any standardised or minimum length or content etc?

Response:

We expanded the notes directly after each consultation. We used the time between two consultations to expand the notes to keep distortion minimal. Due to the explorative nature of the study, the memo field of the field notes form was not structured (cp. line 31 and 32 on page 5 of the unrevised manuscript).

13. Whilst stating that "descriptive statistics were calculated" (line 20), the presentation of these results seems limited (see below).

Response:

As written in the last paragraph of the "methods – data analysis" section, "in addition to qualitative analysis, descriptive statistics were calculated to determine the mean duration of the consultations and the mean number of people present during consultations." This was the sole purpose of the calculation of descriptive statistics. Other than this, data were analysed qualitatively.

Results

14. There are times when terms such as many, few, several are used in the results without numbers despite expressed use of descriptive stats in the methods. Whilst there is an argument about the value of such data within qualitative studies, if analysed as part of the methods, they should be presented appropriately in the results.

Response:

Cp. comment 13. The sole purpose of the calculation of descriptive statistics was to determine the duration of the consultations as well as number of people present. Otherwise, we used a qualitative approach and hence did not report numbers.

15. Throughout the results could be enhanced by use of more illustrative quotes and examples

Response: We selected more illustrative quotes in the revised manuscript and added explanatory words in parentheses..

16. At times in the results it is not clear if the findings are from OP or IP observation, nor how the findings from these settings throw light on one other (if at all).

Response:

Thank you for pointing this out. We made sure to clarify which setting the quotes come from throughout the manuscript. Regarding the interconnections between findings from the two settings, please compare comment 8.

Page 6

17. Line 46-53 – shouldn't the numbers presented add up to 57? Currently, only 52 OP observations accounted for.

Response:

Thank you for pointing this out. We carefully re-evaluated the numbers, added information to clarify, and the numbers add up to 57 now.

18. Line 53 – It would help if there was a definition of what constituted a “clinical treatment decision” and how the judgements were made on presence of absence of a decision. Is it problematic that the observers ‘got the impression that no decision had to be made ...’? Is it not a decision to ‘renew a script’ for example?

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Response:

We revised this section according to your comment.

Page 7

19. Lines 31 & 52 (and then subheadings throughout results section) – are these subheadings representing emergent themes from the qualitative content analysis or are they summarising data collected using pre-structured headings?

Response:

Except for the first heading within the “results” section the headings reflect a mixture of emergent higher-order categories from the coding system (e.g., “Information exchange before making the decision” and “Making the decision after information exchange”) as well as pre-structured headings that were derived from the research questions (i.e., “Facilitators and barriers for SDM”). After careful consideration, we added clarifying information about this in the “methods – data analysis” section.

20. Line 33 – how are you defining ‘patient-centred behaviour’? – these attributes were observed in ‘many consultations’ (if descriptive stats were used, the authors should say in how many)

Response:

We added information on how we defined “patient-centred behaviour” in this context. However, we did not use descriptive statistics for this part of the analyses (cp. comment 13).

21. Line 40 –how are ‘good communication skills’ defined here? - these attributes were only observed in ‘some consultations’ (how many?)

Response:

We added information in the manuscript to explain what we see as good communication skills within this context.

22. Line 46 – ‘other physicians used a lot of jargon ...’ – presumably they are not included in previous categorisations of person centred or good communication? (the authors need to be clear whether they are describing behaviours within a series of consultations or of separate physicians, since the physicians are contributing more than one consultation each and their behaviour is varying across patients)

Response:

Thank you for pointing this out. We revised the sentence according to your suggestions.

23. Line 59 – ‘observers felt that ...’ the use of phrases like ‘observers felt’ is problematic as it implies a subjective judgement on the part of the observer. It may well be due to writing in a second language (though the English used is generally excellent), but there is then no description of why the observer got that impression other than ‘physician explains little, patient and husband do not SEEM able to follow ...’ What are patient and husband doing that suggests this? How does the observer know what is and what isn’t sufficient explanation? (see also comments on method above)

Response:

We agree that some of the quotes could be strengthened by more detail. We added more information regarding this example.

24. On line 57 it is stated that “More than one treatment option was rarely discussed in detail”. N =? Does this mean that one treatment option was usually discussed in more detail than others or that more than one option was rarely discussed? And the reasons could be manifold and could be consistent or inconsistent with SDM.

Response:

We added an explanation of what is meant by this sentence. Please compare comment 13 regarding our decision not to use numbers within the qualitative analyses.

Page 8

25. Line 45 – were the clinicians only discussing the one option that they had decided on (earlier statement at lines 53-57 on page 7 suggests so)

Response:

Unfortunately, we cannot make this connection with certainty within the data set at hand. We therefore decided to leave this sentence out.

26. Line 46 – so clinicians made the decision, then went to the patient to discuss option/s in detail, but the outcome was to go with the decision the clinician (appeared to have) made before discussion with the patient? These statements require more descriptive field note data to support them.

Response:

Since we agree with you that it is hard to follow this conclusion in the current form, we decided to delete this sentence from the manuscript.

27. There is something generally about the findings from the different settings being intertwined in the interpretation/discussion – the context might be influencing the different approaches but it is hard to unpick if there is a context effect. Presumably the clinical status of those who are inpatients is going to be more severe than those who are attending an outpatient appointment?

Response:

We agree with you that connecting an observational study with more clinical information and analysing possible context factors and their determinants would be very interesting. However, we cannot draw those conclusions from the current explorative data set. We added a sentence to the “discussion” section to point out the need for additional research.

28. It also feels, generally, that more context needs to be given to support examples of what is thought to be happening from the perspective of the observer. Since there is no second observer of the same consultation etc it is difficult to establish any level of standardisation of what it actually being observed. Might be just a language thing but observers can only describe what they see, they cannot assume what those being observed are thinking or feeling.

Response:

Thank you for pointing this out. We carefully re-evaluated the entire “results” section in order to avoid conclusions and stick to observable behaviour where possible. If we did report conclusions drawn from our observations during the qualitative analysis, we made sure to clearly state that we are reporting a conclusion rather than observation at this point.

Page 9

29. Line 12 – this section is more interesting reading and describes what people are doing in more detail. The authors indicate a very minimal role for nursing staff within the physician-patient interaction itself but they appear to be doing a lot of deliberate advocating on the behalf of patients outside of that situation. This isn’t really commented on much. It would be valuable to observe nurse-patient interactions to explore this relationship, how they develop and how they function, and whether this is a routine way of doing or enabling a level of SDM in the settings involved in the study.

Response:

Thank you for your positive appraisal and the suggestion. We added this idea to the “discussion” section.

30. Line 43 – again an interesting section with sufficient description to facilitate understanding of the behaviours observed in patients, though this would still be greatly strengthened by an example or two quoted directly from the field notes of what the patient did and how the clinician responded (or vice versa as appropriate). The format of field note data might not lend itself easily to this however.

Response:

Thank you for your positive appraisal of this section. We added one more quote to the section.

31. Some results seem peripheral to SDM e.g. blood sampling on P 10 lines 19-21

Response:

We decided to change the quote.

Discussion

32. A key finding is that 'active' patients instigate SDM, although this is still limited in terms of depth of analysis and lack of descriptive context. Also, how do we know that this is patient driven or might it occur as a result of different approaches to different patients by clinicians? This should be discussed since it also leads to conclusions that patient mediated interventions are required. That is likely so, but the consultation is still often driven by clinician behaviour and that may foster or inhibit the patient role.

Response:

We added a sentence about this in the "discussion" section.

33. It is not always clear how conclusions derive from the findings. This could be improved in the discussion but would also be clearer with more detail in methods particularly the results section.

Response:

After revising the manuscript according to your comments, we hope that this became more clear.

34. There is first mention of comparison with an existing model of SDM in the discussion –should this form part of the methods?

Response:

Since we did not compare our field notes to the "three talk collaborative deliberation model" during analyses but only afterwards, we think that this should not be part of the methods section.

35. There is little consideration of the limitations associated with the approach they used (nonparticipant observation) - how this may have influenced the behaviour of those being involved, potential observer bias (e.g. existing assumptions, understanding of SDM) and how this was mitigated. (in the COREQ checklist the authors have suggested consideration of observer bias is 'NA', likely because the checklist item refers to 'interviewer bias')

Response:

Thank you for pointing this out. We added some information about this at the end of the "discussion" section. Also, we added some reasons for using this approach within the "methods" section.

36. Also how they managed consistency in description and quality or nature of phenomena observed – analysis is of hand scribed notes taken in real-time - this limits detailed and comprehensive data capture for example (note takers can use their own short hand, terminology and so on, and whilst making notes it is possible to 'miss' or under-appreciate other relevant phenomena).

Response:

We added some information about this throughout the "methods" and at the end of the "discussion" section.

37. The section on p 11-12 on intervention development should be removed and the discussion expanded around the key results of this study

Response:

Following your suggestion, we removed the section on the development of the intervention program.

Overall conclusions

38. This is a really interesting study and a potentially important contribution to the field. The authors could do more to present their methods and findings to further strengthen the paper. In particular:

- a. More detail on the methods used, including any frameworks for analysis, and how the quality and reliability of the findings and their interpretation was assured.
- b. More examples and more details on how conclusions were reached from the field notes/data collected. Overall the analysis and discussion would benefit from more depth (dropping the discussion on the intervention development would enable this).
- c. More descriptive stats (or alternatively, drop these and present more detail on analysis/interpretation).
- d. More context for the setting of the observations and particularly whether there is any multidisciplinary team meeting to discuss treatment options
- e. Clarity of definitions and the application of key terms such as “patient-centred behaviour” and “good communication skills”

Response:

Thank you for your valuable feedback on our manuscript. We think that our revision further strengthened the manuscript.

Reviewer: 2

Reviewer Name: Associate Professor Sarah Lewis

Institution and Country: The University of Sydney, Australia

Please state any competing interests or state ‘None declared’: None declared

Dear Authors,

Thank you for submitting your work for review and I congratulate you on a fine study. The manuscript reads mostly well and is an important addition to the current literature on SDM. However, it could be improved in a number of ways, primarily related to a larger section on methodology and discussion. These areas lack a little transparency and one needs to be careful not to link this research work to future/additional work already published by the same authorship team - it needs to stand alone, but supported by peer review studies around it. Please see below for more specifics and best of luck.

Response:

Thank you for your overall positive assessment. We revised the manuscript according to your comments. Please see the comments below for more detail on the revision.

Abstract:

1. A couple of missing words: “Shared decision-making HAS...” and “Few studies HAVE”.

Response:

Thank you for drawing our attention to this. We revised the abstract accordingly.

2. The abstract needs to mention the method of data analysis for the notes and observations (qualitative tradition or coding method).

Response:

We added information on this to the abstract.

Introduction:

3. Awkward opening sentence grammatically: "Patient-centeredness in health care has significantly gained in importance over the last years". Consider "patient-centered health care has gained importance over the last few years"

Response:

Thank you for this suggestion. We revised the sentence accordingly.

4. Improve the readability of the sentence "emphasized the importance to also take the organizational level (i.e., the meso level)" by replacing it with "the importance of also taking into account the organizational"

Response:

Thank you. We revised the sentence accordingly.

5. Overall, a very sound opening that covered most theoretical concerns and past literature however a couple of sentences exploring the dynamics and power imbalance of doctor-patient relationships within the western biomedical model of health care would be helpful.

Response:

Thank you for this positive appraisal. We added one more sentence on the power imbalance as you suggested.

Methodology:

6. Awkward grammar with "In- and outpatient clinics to include in the data collection were identified". This should read "The In and Out clinics that were included in the data were identified".

Response:

We revised the sentence accordingly.

7. Please list the clinics included as this will provide better readability to a diverse health care audience.

Response:

After careful consideration, we decided not to list the clinics. Due to relatively small teams within some of the clinics, we could not sufficiently assure anonymity if we did so.

8. More information about the patient's clinical situation is necessary. What stages of cancer or diagnosis were the patients in. This would impact upon the results as terminally ill patients or those receiving palliative care may want different SDM or models of care.

Response:

We completely agree with you that this would be interesting additional information. However, such information is not part of our data. Please also compare reviewer 1, comment 27.

9. Could the researchers please explain why the physicians were not required to give informed consent as they were being observed and recorded.

Response:

In accordance with the Ethics Committee of the Medical Association Hamburg (Germany), consent from physicians was waived. The observed clinics and hence the physicians working in those clinics were seen as collaboration partners of the study. Still, physicians would have had the opportunity to opt out of being part of the observations.

10. Was any opposition to being included in the study from either patients or physicians? Was there any attrition rate?

Response:

We added some information about this in the beginning of the “results” section.

11. Please make note of any exclusion criteria, such as language difficulties and were interpreters offered? Were family or support persons with the patients at the time of the consultations that would have allowed them to feel more empowered?

Response:

We added information about inclusion and exclusion criteria for patients within the “methods – setting and subjects” section. Since our aim was to observe routine care and interfere with processes as little as possible, no interventions such as interpreters or support persons were offered as part of the study. As can be read in the “results” section, we observed some consultations where other people than physician and patient were present and drew conclusions on the effects this had on the observed situation.

12. For 57 encounters, how many patients did this represent? What was the average age of the patients, as older patients are less likely to engage in SDM.

Response:

We cannot answer this from the data we have (anonymous field notes, no patient information collected).

13. Were any SDM/consultations around lesser understood therapies like radiation therapy? Or were they all drug related? Were any around allied therapies?

Response:

We observed all consultations taking place within the time and place of our observation, i.e. they were not only drug related (chemotherapy or anti-hormonal treatment), but also included other major forms of cancer treatment like surgery or radiation. Please compare the “results – characteristics and description of observed consultations” section for more information on the decisions observed.

Results:

14. Please change “In 25 of the 57 consultations main cancer treatment-related decisions” to “in 25 of the 57 consultations, the primary cancer treatment”

Response:

Thank you. We changed the sentence accordingly.

15. Please provide some examples for “other physicians used a lot of jargon and strong wording such as “you must” or talked about the patient rather than with the patient”

Response:

We added a quote to this statement.

16. Poor grammar and typing error “This was sometimes caused by the patient voicing his preferences on his own, other times the physician asked for the patients preferneces”. Please correct spelling of preferences and consider word change “This was sometimes in reaction to the patient”

Response:

We changed the sentence accordingly.

17. It is unclear if the sub-headings were the key themes of the study, could this be clarified

Response: Please compare reviewer 1, comment 19.

Discussion:

18. Line 36, page 11: the word “especially” is not necessary and represents incorrect grammar

Response:

Thank you for pointing this out. We deleted the word.

19. Line4/5, page 12: reports on another study that follows the current study under review. It gives the impression that the focus group study has already been published with linked methodology. Please consider removing this section, it is hard to read and, as there is limited information, it appears that the reader must also consider this new information directly after reading the new article. It is also not the right place to be discussing new studies.

Response:

After careful consideration, we decided to delete this section of the discussion. Please also compare reviewer 1, comment 37.

20. There is no discussion on any bias by the researchers or social desirability of the observed doctors and patients. This is a real possibility and needs to be considered. What information was given to the physicians before the observations that may have affected their behaviour. Likewise for patients.

Response:

Thank you for pointing this out. We added information on this throughout the “methods” and the “discussion” section. Please also compare our replies to relevant comments from reviewer 1. We think this issue is sufficiently addressed now.

VERSION 2 – REVIEW

REVIEWER	Susan Hrisos and Richard Thomson Newcastle University UK
REVIEW RETURNED	19-Jul-2017

GENERAL COMMENTS	<p>We have a couple of remaining issues.</p> <p>1) We are still unclear about the numbers, perhaps more so now given the changes made on pp 7 and 8. On p7 it states that there were 57 observed consultations, but that three were excluded from further analysis because the patients didn't have cancer. However, in the same paragraph it is also said that "In 26 of the 57 consultations, decisions about the primary cancer treatment (e.g., chemotherapy, surgery, radiation etc.) were made. In 13 consultations, secondary decisions related to the treatment process (e.g., management of treatment induced side effects such as pain or nausea) were made. In 15 consultations, no clinical treatment decisions were observed (e.g., follow-up examination after surgery, regular follow-up care, renewal)." This adds up to 54. Furthermore, table 1 continues to have 57 consultations. This still needs clarifying.</p> <p>2) Whilst the authors make the case for calling this participant observation (and we accept that this is a term that can be variably applied) it is of note that their previous paper which they quote (reference 23, observation of the MDT) calls a very similar approach non-participant observation.</p> <p>3) With regard to the MDT, whilst the authors have referred to their previous work (and apologies that we hadn't remembered that paper), it is still unclear whether the clinic appointments (or even patients seen on the ward) in this current paper included patients who were being seen to receive an MDT recommendation. Perhaps none were included, in which case it should be stated. If there were significant numbers who were receiving the MDT recommendation, then this will in itself have had an impact on the type of discussion and, given their previous paper, would merit consideration in analysis and interpretation.</p> <p>4) There are a number of typos throughout that still need cleaning up. A careful proof read is needed</p>
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REVIEWER	Associate Professor Sarah Lewis The University of Sydney, Australia
REVIEW RETURNED	23-Jul-2017

GENERAL COMMENTS	<p>Thank you for your hard work in revising the manuscripts. There are a small number of revisions that still remain.</p> <ol style="list-style-type: none"> 1. Please explain the Hawthorne Effect (page 6/45): this may be an unfamiliar term with some readers and needs expansion. 2. There is a typing error on page 7/line 6-7 in "overcomechallenges" typed as one word. 3. There is still a little work to do on limitations. As I have previously raised, the nature and staging of a patients' cancer has a profound effect on their ability to engage in SDM. I note in your response that you have no knowledge/record of the patient's extent of illness/staging and this is a clear limitation when commenting on SDM action. Please address this in the limitations that this is unknown and the impact it would have. 4. In results, it is stated that "3 patients" did not have cancer out of the 57 observations. If the paper is ONLY about cancer patients' SDM, how can these interactions be included in the original data collection numbers. Can you please explain or revise as it does not make sense to me.
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1

Reviewer Name: Richard Thomson and Susan Hrisos

Institution and Country: Institute of Health and Society, Newcastle University, UK

Please state any competing interests or state 'None declared': none declared

The authors have responded to the great majority of the comments and the paper is stronger as a result.

Response:

Thank you for your overall positive appraisal of our manuscript.

We have a couple of remaining issues.

1. We are still unclear about the numbers, perhaps more so now given the changes made on pp 7 and 8. On p7 it states that there were 57 observed consultations, but that three were excluded from further analysis because the patients didn't have cancer. However, in the same paragraph it is also said that "In 26 of the 57 consultations, decisions about the primary cancer treatment (e.g., chemotherapy, surgery, radiation etc.) were made. In 13 consultations, secondary decisions related to the treatment process (e.g., management of treatment induced side effects such as pain or nausea) were made. In 15 consultations, no clinical treatment decisions were observed (e.g., follow-up examination after surgery, regular follow-up care, renewal)." This adds up to 54. Furthermore, table 1 continues to have 57 consultations. This still needs clarifying.

Response:

Thank you for pointing this out. We decided to completely leave out the three cases we excluded because they were not cancer patients and only report findings on the 54 outpatient consultations with cancer patients now. Cp. page 7 and table 1.

2. Whilst the authors make the case for calling this participant observation (and we accept that this is a term that can be variably applied) it is of note that their previous paper which they quote (reference 23, observation of the MDT) calls a very similar approach non-participant observation.

Response:

After careful consideration, we decided to stick to the term "participant observation" (for our reasons please compare response to previous reviewer comment within the first revision). Compared to observations in multidisciplinary team meetings (i.e., several physicians/health care professionals in one room with several rows of chairs, often dim lighting, observers sitting in the back rows), the observations within this study (i.e., one-on-one consultations between patients and physicians) were more obvious and hence should be called participant observations in our opinion.

3. With regard to the MDT, whilst the authors have referred to their previous work (and apologies that we hadn't remembered that paper), it is still unclear whether the clinic appointments (or even patients seen on the ward) in this current paper included patients who were being seen to receive an MDT recommendation. Perhaps none were included, in which case it should be stated. If there were significant numbers who were receiving the MDT recommendation, then this will in itself have had an impact on the type of discussion and, given their previous paper, would merit consideration in analysis and interpretation.

Response:

We completely agree with you that linking multidisciplinary team (MDT) recommendations to patient-physician-interactions through longitudinal observations is a crucial next step in order to understand decision-making processes in cancer centres. However, we cannot link our observations of MDT meeting and our observations of patient-physician-encounters within the data described. During our observations of in- and outpatient consultations, only some physicians explicitly mentioned the MDT discussion to the patients. However, we expect many more cases to have been discussed in MDT meetings (as this is an obligation for certified cancer centres in Germany), but physicians to not have identified the discussed treatment recommendation as a MDT recommendation. We expanded the discussion section by stating that linking data from MDT meetings and individual encounters would be a valuable next step.

4. There are a number of typos throughout that still need cleaning up. A careful proof read is needed.

Response:

Thank you for pointing this out. We carefully proofread and revised the manuscript. We also changed from US to UK spelling.

Reviewer: 2

Reviewer Name: Associate Professor Sarah Lewis

Institution and Country: The University of Sydney, Australia

Please state any competing interests or state 'None declared': None declared

Dear Authors, Thank you for your hard work in revising the manuscripts. There are a small number of revisions that still remain.

Response:

Thank you for your overall positive appraisal of our manuscript.

1. Please explain the Hawthorne Effect (page 6/45): this may be an unfamiliar term with some readers and needs expansion.

Response:

We revised the sentence to make it understandable for readers unfamiliar with the Hawthorne effect.

2. There is a typing error on page 7/line 6-7 in "overcomechallenges" typed as one word.

Response:

Thank you. We corrected the typo.

3. There is still a little work to do on limitations. As I have previously raised, the nature and staging of a patients' cancer has a profound effect on their ability to engage in SDM. I note in your response that you have no knowledge/record of the patient's extent of illness/staging and this is a clear limitation when commenting on SDM action. Please address this in the limitations that this is unknown and the impact it would have.

Response:

We added another sentence to the "discussion" section to clarify this limitation.

4. In results, it is stated that "3 patients" did not have cancer out of the 57 observations. If the paper is ONLY about cancer patients' SDM, how can these interactions be included in the original data collection numbers. Can you please explain or revise as it does not make sense to me.

Response:

Thank you for pointing this out. We revised the manuscript accordingly. Cp. response to reviewer 1, comment 1.

VERSION 3 – REVIEW

REVIEWER	Richard Thomson/Susan Hrisos Newcastle University England
REVIEW RETURNED	04-Aug-2017

GENERAL COMMENTS	This is now ready for publication having had all concerns addressed. A valuable paper
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REVIEWER	Associate Professor Sarah Jayne Lewis The University of Sydney Australia
REVIEW RETURNED	14-Aug-2017

GENERAL COMMENTS	Thank you authors, I have no further comments and wish you the best in your research field.
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