CASE REPORT

Case Report: The use of advanced consent methodology and healthcare professional consultee to facilitate research participation in dying patients [version 1; peer review: 2 approved with reservations]

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Abstract

As the need for palliative care increases, it is essential for research opportunities to be offered to patients with palliative care needs to ensure patients can receive evidence-based treatments and services to improve care. Although it is recognised that palliative, and in particular end of life, research can be both methodically and ethically challenging it is important to note that palliative patients are keen to be involved with research.

Over the past three years, patients in Marie Curie Hospice Liverpool have been recruited to a research study evaluating hydration, where advance consent methodology is used to facilitate participation at the end of life. In this study, participants provided 'advanced consent' to receive research assessments, in anticipation of the deterioration of their health and loss of the ability to provide consent to ongoing research participation. During this process, recruiting participants will nominate a consultee (who can be any family member, friend or healthcare professional), who is contacted by the researcher prior to completion of research assessments. Participants will generally choose a caregiver or friend to act as a personal consultee; however, there may be some instances where a healthcare professional is chosen.

In this, we share our experiences using advanced consent methodology and a healthcare professional acting as a consultee, to facilitate research assessments in a patient who was lacking capacity at the end of life.

Keywords

Palliative Care, End of Life, Research, Consent

Open Peer Review

Approval Status ? ?

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1. Dorte Toudal Viftrup , University of Southern Denmark, Odense, Denmark 2. Nicola White , University College London, London, UK		
Any reports and responses or comments on the article can be found at the end of the article.		

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Competing interests: No competing interests were disclosed.

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Plain language summary

There is an increasing need for palliative care, and it is important that we offer the chance to participate in research to palliative patients. This will help to ensure that treatment is evidence-based, and enables us to improve care.

Over the past three years, Marie Curie Hospice Liverpool have offered patients the opportunity to participate in a research study evaluating body water. In this study, participants provided 'advanced consent' to receive research assessments should their condition deteriorate and they lose the ability to provide consent to continue in the research study.

As part of the 'advanced consent' process, participants will nominate a consultee (this can be any family member, friend or healthcare professional), who is contacted by the researcher before any research assessments are carried out. Participants will usually choose a caregiver or friend to act as consultee; however, in some cases a healthcare professional is chosen

In this case report we share our experiences of using advanced consent methodology with a healthcare professional acting as a consultee, to continue research assessments in a patient who was lacking capacity at the end of life.

Introduction

As the need for palliative care increases¹, it is essential for research opportunities to be offered to patients with palliative care needs to ensure patients can receive evidence-based treatments and services to improve care. Although it is recognised that palliative, and in particular end of life, research can be both methodically and ethically challenging it is important to note that palliative patients are keen to be involved with research².

Over the past three years, patients in Marie Curie Hospice Liverpool have been recruited to a research study evaluating hydration, where advance consent methodology is used to facilitate participation at the end of life. In this study, participants provided 'advanced consent' to receive research assessments, in anticipation of the deterioration of their health and loss of the ability to provide consent to ongoing research participation. During this process, recruiting participants will nominate a consultee (who can be any family member, friend or healthcare professional), who is contacted by the researcher prior to completion of research assessments. Participants will generally choose a caregiver or friend to act as a personal consultee; however, there may be some instances where a healthcare professional is chosen. In this case report, we share our experiences using advanced consent methodology and a healthcare professional acting as a consultee, to facilitate research assessments in a patient who was lacking capacity at the end of life.

Case report

A male in his 60s participated in the study during the COVID-19 pandemic. At the time of recruitment, the hospice

was closed to visitors due to the pandemic. We discussed research participation and provided an explanation of the consultee process. He explained that he had little family and had one close friend who was in poor health. He did not want this individual to visit the hospice due to concerns that they would contract COVID-19. He consented to participate in the study, but only if there was no involvement of his family or friends. The participant named his medical consultant as his nominated consultee, based on the belief that this individual would understand his desire to continue to participate in this research. All aspects of this discussion and the decision-making process were documented in the electronic patient record.

Following discharge from the hospice, the patient was re-admitted due to deterioration in his clinical condition. He met with the research team and expressed his eagerness to continue participation in the study.

Two days later he was dying, unconscious and lacking capacity. We facilitated the consultee process in partnership with the medical consultant (the nominated consultee) who was responsible for his care. We reviewed the case note documentation from study recruitment to the study to present day to ensure there were no reasons that research participation should be stopped. Furthermore, we asked other clinical team members for their opinion during this process. We agreed that the participant had previously expressed their desire to remain a research participant during this phase of their illness, and there was no evidence available that would change this. Therefore, the consultee was satisfied to provide assent for ongoing research participation for the patient. We completed these assessments and documented the process.

Discussion

Summary

This case report describes our experiences of using advanced consent methodology using a healthcare professional consultee process in palliative care.

Strengths/lessons learnt

Our experience demonstrates how a healthcare professional can act as a consultee to facilitate research assessments at the end of life. It is important for researchers to know that such processes may be necessary when requested by participants, particularly if there are there limited people who can act as a consultee for the individual.

Comparison with previous work

Although previous studies have described use of advanced consent methodology²⁻⁵, there has been little documentation of the practical experience of this process; when healthcare professionals act as a nominated consultee for participants who lose the ability to provide ongoing consent for research participation. It is important to describe these approaches, to support researchers use of the advance consent process to provide opportunity for enable people to participate in end of

life care research if they wish to. The COVID-19 pandemic was a key factor that influenced the participant's approach to the advanced consent process. It is important therefore to acknowledge how factors, which may restrict visitors, may influence research recruitment, from both patient, caregiver and healthcare professional perspectives.

Limitations

A limitation of this report is that the experience of one participant cannot be generalisable to a wider population. Also, the research participation took place during the COVID-19 pandemic, which influenced his decision making regarding the consultee.

Implications to policy, practice and research

Our case demonstrates how researchers can practically use the advanced consent and nominated consultee process to facilitate research participation. This may be useful in situations where there are challenges involving friends or family of study participants, or if their preference is for healthcare professionals to act in the role as consultee in the first instance. However, it is important for researchers to consider ethical challenges that may emerge if participants don't feel it is safe for their

friends and family to participate in research, as this could create greater problems for research participation and retention in the future.

Conclusion

Our experience provides an example of how the nominated consultee process was used to facilitate research participation of a dying patient during the pandemic. However, we identify methodological and ethical challenges around research at the end of life particularly during the pandemic as a consequence of visitor restrictions. It is important for researchers to consider the implications of these developments in design of research studies to ensure that patients and their families feel safe to participate, and to enable research participation at the end of life.

Consent

As part of the advanced consent process, written informed consent was obtained from the patient for publication of articles related to this research study.

Data availability

All data underlying the results are available as part of the article and no additional source data are required.

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Open Peer Review

Current Peer Review Status: ? ?

Version 1

Reviewer Report 11 November 2021

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? Nicola White

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I would like to applaud the authors for their continuing contribution to the building evidence base of the consent process in end-of-life care research. It is much needed and of interest to other researchers looking at advanced consent methods.

Overall, I think the aim and case report of the review are clear. There are a couple of suggestions I would recommend:

1. The introduction is sufficient for this specific issue of imminent death, although it might benefit from a wider discussion of capacity and research, and where this research sits in this. For example, Scott *et al.* (2011)¹ adopted a similar methodology due to the fast-paced and unpredictable nature of hospital admissions and dementia. Whether this is in the introduction or discussion, is for the authors to decide.
2. The case study indirectly highlights a few potential ethical issues – particularly the role of the family in end-of-life decision making. Whilst this specific case was during a pandemic and there was limited visiting, post-pandemic (if such a world exists!) will introduce more complexities. I think it would be helpful to address this in the discussion. I agree that the use of professional consultees can facilitate participation, but there are unintended complications.
3. It would be useful to add some sort of conclusion to the plain language summary.

References

1. Scott S, Jones L, Blanchard MR, Sampson EL: Study protocol: the behaviour and pain in dementia study (BePAID). *BMC Geriatr.* 2011; **11**: 61 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the background of the case's history and progression described in sufficient detail?

Yes

Are enough details provided of any physical examination and diagnostic tests, treatment given and outcomes?

Partly

Is sufficient discussion included of the importance of the findings and their relevance to future understanding of disease processes, diagnosis or treatment?

Partly

Is the case presented with sufficient detail to be useful for other practitioners?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Palliative research, end-of-life, prognosis, decision making.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 27 January 2021

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Dorte Toudal Viftrup

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Thank you for publishing this interesting and highly relevant case report. I believe it will contribute to enhancing research opportunities being offered to patients at the end of life. I particularly find the presentation of your experiences of using advanced consent methodology where a healthcare professional acting as a consultee for the patient a highly relevant contribution to the field. My comments concern emphasizing this contribution in the case report by presenting it more thoroughly in abstract and summary as well as discussing it in relation to other studies and ethical challenges.

Summary:

To ensure patients can receive evidence-based treatments and services to improve care at the end of life, palliative patients should also be offered the chance to participate in research at the end of life.

In a research study on evaluating hydration, patients from Marie Curie Hospice Liverpool were recruited. Participants provided 'advanced consent' to receive research assessments, in

anticipation of the deterioration of their health and loss of the ability to provide consent to ongoing research participation. Participants usually choose a caregiver or friend to act as consultee; however, in some cases a healthcare professional is chosen.

Although previous studies have described use of advanced consent methodology, there has been little documentation of the practical experience of the process of when healthcare professionals act as a nominated consultee for patients.

In the presented case report, the researchers share their experiences of using advanced consent methodology where a healthcare professional acting as a consultee for the patient. The case report concerns a male patient in his 60s who only consented to participate in the study if there was no involvement of his family or friends. The case report describes how the patient named his medical consultant as his nominated consultee based on a discussion and decision-making process. This was also documented in the electronic patient record. When the patient was dying, they facilitated the consultee process in partnership with the nominated consultee. They reviewed the case note documentation and ensured there were no reasons that research participation should be stopped.

The case report suggests that a healthcare professional may act as a consultee to facilitate research assessments at the end of life, if there are limited people who can act as a consultee for the patient (e.g. during a covid-19 pandemic). However, it is important that researchers design the research studies so it's ensured that patients and their families feel safe to participate, and to enable research participation at the end-of-life.

Comments:

I believe the background of the case's history and progression is described in sufficient detail for the reader to gain a thorough understanding of the practical experience of the process of when healthcare professionals act as a nominated consultee for patients.

The authors do not provide details of physical examination and diagnostic tests, treatment given and outcomes, as it is not relevant for the present case report. Instead, they provide details on the advanced consent process of the specific case, and the case is presented with sufficient detail to be useful for other practitioners.

However, I believe the authors only partly include sufficient discussion of the importance of the findings and their relevance to future understanding of advanced consent processes where healthcare professionals act as a nominated consultee for patients. The authors only 'lightly' address/discuss the ethical challenges that may emerge if participants don't feel it is safe for their friends and family to participate in research.

The manuscript would benefit from a more thorough discussion on these ethical challenges as well as previous studies use of advanced consent methodology in relation to the main contribution of the case report. In the discussion, the authors write: "Although previous studies have described use of advanced consent methodology, there has been little documentation of the practical experience of this process; when healthcare professionals act as a nominated consultee for participants who lose the ability to provide ongoing consent for research participation." However, it would still be highly relevant to discuss these studies use of advanced consent methodology in relation to the presented case.

The main contribution of the manuscript is the authors' experiences of using advanced consent methodology with a nominated consultee. The usefulness of this contribution for other practitioners would be increased if this main contribution was thoroughly discussed in relation to ethical concerns and other studies on advanced consent methodology.

Furthermore, these other studies describing the use of advanced consent methodology should also be presented in the introduction together with some thoughts on the methodically and ethically challenges of research in the end of life. If this is done, these topics can function as a red thread on the main contribution throughout the manuscript.

I also recommend the abstract and plain language summary are rewritten based on the structure of the manuscript: Introduction, case report (results), discussion, and conclusion. As it is now, abstract and summary are presented more as an introduction with a line of arguments for the advanced consent process, instead of an actual summary of the content and results of the case report.

For example, in the end of the abstract the authors write: "In this, we share our experiences using advanced consent methodology and a healthcare professional acting as a consultee, to facilitate research assessments in a patient who was lacking capacity at the end of life." However, these experiences are the 'findings' and main contribution of the case report and these should also be presented in the abstract and summary.

Even though the report only presents the experience of one participant and therefore I may not be generalizable to a wider population, the contribution of the report is still highly relevant.

Is the background of the case's history and progression described in sufficient detail?

Yes

Are enough details provided of any physical examination and diagnostic tests, treatment given and outcomes?

Partly

Is sufficient discussion included of the importance of the findings and their relevance to future understanding of disease processes, diagnosis or treatment?

Partly

Is the case presented with sufficient detail to be useful for other practitioners?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health psychology, qualitative research, end of life, spiritual care

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.