Reviewer's report

Title: Patient experience of the informed consent process during acute myocardial infarction: a sub-study of the VALIDATE-SWEDEHEART trial

Version: 0 Date: 04 Nov 2019

Reviewer: Victoria Shepherd

Reviewer's report:

The authors write on a topic that is important and of great relevance to those designing and conducting research, as well as those involved in the governance and ethical review of research, since low levels of recruitment and retention in clinical trials and other studies is a major issue.

Overall the manuscript is well written, and the study makes a useful contribution to the discussions around the issue of informed consent. There are a few areas of the manuscript that would benefit from further expansion and a revision of English language usage is needed in some areas.

My comments on the manuscript:

Abstract

The abstract (p.2) is overly brief and would benefit from more detail:

Objective - a brief description about VALIDATE-SWEDEHEART and the informed consent approach used would be helpful.

Background - more detail is needed about what aspects of the informed consent procedure are debated, what are these debates? How does this study add to those debates?

Methods - who are the 414 patients enrolled in the sub study (participants and non-participants of the main study?)

Main text introduction

I suggest amending the section heading to 'Introduction' or 'Background'.

P. 3 Line 24 which states 'Several diseases not fulfilling the EFIC criteria pose ethical dilemmas very similar to conditions that do fulfill the criteria.' should be clarified. It is not the disease or condition that is the criteria for an exception to the requirement for informed consent, but the
circumstances under which consent is being sought or is deemed not to be possible or practicable.

P. 4 - the paragraphs require revision as the order of statements is not coherent and the case being made is not clear. The informed consent process 'for this trial' should be made clear that it relates to the previous HEAT PCCI trial.

Patients and Methods

I suggest amending the section heading to 'Methods'.

Data collection

P. 6 line 2 - the term 'professional' research nurses is not a commonly used term (implying there are non- or un-professional research nurses) and is then followed by the use of 'study nurse' in line 5. Specialist, or study-specific research nurse, or describing their affiliation might be more helpful.

Statistical analysis

P. 6 Line 25 - were the exploratory subgroup analyses pre-defined?

Discussion

Informed consent is a complex area which is not fully addressed in the manuscript, and a more considered discussion about the findings from this study in relation to those ethical complexities would strengthen the manuscript. Such as, if EFIC or deferred consent is not supported by the findings from this study, where does that leave the ethical justification for using deferred consent? There are also issues about the different legal frameworks relating to informed consent, and reference to the justification and use of deferred consent in different jurisdictions needs to be included. What are the legal provisions for deferred consent in Sweden where this study was conducted? How do they differ from HEAT PICC, for example?

The Figures listed on p. 16 are not referred to in the text.

Some revision of English language usage is needed, including:

P. 7 Line 47 - there are a few instances throughout the manuscript where 'positive' is not used correctly as a noun, i.e 'more than 80 percent were positive to be asked'. I suggest reviewing the
use of the term and amending e.g 'felt positively about being asked' or 'had a positive attitude towards' (see also P. 9 line 59 and others)

P.7 Line 52-55 - 'Most patients considered information about the study provided in the acute phase as sufficient' suggest amending to be either 'acute phase as sufficient' or 'to be sufficient'.

P. 9 Line 6 - 'A small number of responders expressed a negative feeling of being asked' suggest 'towards having been asked' or 'about having been asked'.

Limitations

Limitations not included were that this was a structured questionnaire (rather than qualitative research) which did not allow for further exploration of participants' attitudes towards the use of deferred consent in general or in this study. The choice of wording of the questions limits the responses, and influences responses. Particularly the fourth question (Would it have been better if you were included in the study without being informed until later?) which may have biased responses through the use of the term 'better'.

There was also no reference to the potential for response bias more generally. For example, whether participants had previously participated in research, or that participants agreeing to participate in this sub-study may have had a more positive attitude towards research than those who did not.

Level of interest

Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English

Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Quality of figures

All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.
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