Reviewer's report

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

Version: 1 Date: 08 Jan 2020

Reviewer: Victoria Shepherd

Reviewer's report:

The authors have responded to the reviewers' comments and the revised manuscript is much improved. However, some areas require further revision and there are still some areas where a revision of English language usage is needed.

In general, the authors need to clearer about the limits to the study and how the findings relate to consent models used previous trials such as HEAT PPCI, and more careful when referring to research governance (clinical trials legislation and ethical requirements). This is a difficult and complex area, particularly given the different jurisdictions referred to, but an important one and so care must be taken when making claims about the study findings.

Specific comments:

Introduction

P. 4 line 23 The use of the word 'motivated' should be amended e.g permitted or justified

P.4 line 33 citation missing (et. al)

P.5 line 20 (and also P. 11 line 45) the phrase 'ethical committee' is usually referred to as an ethics committee or a research ethics committee

P.5 line 23 'In accordance to the study protocol' should be 'in accordance with'

P.5 line 25 It is important to add that in HEAT PPCI, when approached to provide consent after randomisation, they are being asked to provide informed consent to remain in the study. This is not equivalent to prospective consent to participate.

Methods

P.6 line 54 Thank you for clarifying in your comment to the reviewers that participants were consecutively enrolled in the sub-study. However, this detail should be included in the manuscript.
Discussion

P. 11 line 16 the terms 'delayed consent' and 'deferred consent' are used inconsistently

P. 11 line 24 The authors state that 'Thus, our findings do not support the use of delayed consent in patients with AMI who are capable of answering at the time of the IC process.' However, the question asked in the study (Would it have been better if you were included in the study without being informed until later?) does not explore deferred consent. Deferred consent (as used in HEAT PPCI for example) is used where obtaining patient consent is not feasible and there is also insufficient time to seek informed consent from the patient's representative). The question asked in this study does not appear to include any explanation as to why the patient would be included without being informed and what other ethical oversight/safeguards would be in place (trial presents minimal risk, risk of delaying treatment to obtain consent etc) and so cannot be said to 'investigate deferred consent'. The authors do not make clear that the essential elements of informed consent (being informed about the nature of the trial and the risks and benefits, retaining and understanding the information, coming to a reasoned decision, communicating that decision etc) are more than just being capable of 'answering' or recalling being in the study.

P. 12 'assent' is not equivalent to informed consent and when referring to the Declaration of Helsinki, paragraph 29 (which refers to non-emergency situations) should also include the provisions in the following paragraph 30 which does refer to emergency situations and does not include the requirement for 'assent'. The 'd' in Declaration should be capitalised.

p. 12 line 26 The phrase 'Most of the STEMI patients are awake' requires rewording. Are the authors referring to patients being conscious, or having decision-making capacity? The difference between patient populations in terms of the likelihood of having capacity to provide informed consent is the crucial criteria for the use of a deferred consent model. Are there differences between the patients and the urgency of the treatment in HEAT PPCI and the VALIDATE-SWEDEHEART trial that would justify (or not) the use of deferred consent?

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