Reviewer's report

Title: Barriers and Opportunities for Enhancing Patient Recruitment into Clinical Research: Findings for an Interview Study in an NHS Academic Health Sciences Centre

Date: 19 May 2014

Reviewer: Bryony Soper

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Major Compulsory Revisions

1. Title of the paper

1.1 The title indicates that the paper is about patient recruitment into clinical research. But the repeated mentions of patient retention throughout the paper (i.e. in the conclusion to the abstract on p.1; in the first para on p.4; in the final paragraph on p.6; in the first paragraph on p.7; and in the second paragraph on p.14) suggest that it is also about this related issue, as indeed are many of the papers cited (see, e.g. Fletcher et al who say: “Maintaining recruitment activity over time is also important as it has been shown that enthusiasm for recruiting subjects to RCTs can fade quickly, leading to studies that fail to recruit to target, or which suffer significant loss to follow-up due to difficulties in participant retention for the required study period.” Is this paper meant to cover both issues? If so the title should reflect this.

1.2 An NHS Academic Health Science Centre (AHSC) is the UK government’s description of the research and healthcare structure adopted by many of the world’s leading academic institutions and hospitals:


Six of these centres were designated by the DH in Nov 2013. But the title of the paper uses the term ‘NHS Academic Health Sciences Center’, using the plural ‘sciences’ and the American spelling for ‘centre’. The plural form ‘sciences’ occurs nowhere on the web in relation to the NHS AHSCs other than in the designation of King’s Health Partners, see e.g.

http://www.kingshealthpartners.org/info/academic-health-sciences., who were therefore presumably the site of this work, though not identified as such in the paper. To my mind the plural use and the American spelling are likely to cause confusion.

(There are further confusions in the description of the setting in which this study was conducted on p.7 in the Methods section (see below).)

2. Background (p. 4)

2.1 The first paragraph mentions “poor patient recruitment or retention”, which again raises the issue of what the paper is intended to cover.

2.2 The authors discuss the existing literature on patient recruitment (and
retention), noting that studies “tend to focus on one of three significant and interconnected factors”, procedural, knowledge and resourcing issues (my italics). But while the authors helpfully identify (some of) the different types of recruitment strategy and rightly draw attention to the interconnections between these different types of interventions/strategies, their comment on the focus of the studies they cite does not tally with my reading of this literature. These studies include several large scale systematic reviews (e.g. Watson, Campbell, Treweek, Fletcher) and several detailed descriptions and discussions of recruitment strategies that include all three factors (see, e.g. Table 1 in Watson (which also designates different strategies by type); Table 13 in Campbell (which provides a simple list of various strategies); Fletcher at al, who say that “The reasons for poor or slow recruitment to RCTs can be found at various levels: the patient, the recruiting clinician, the trial centre, the trial organisation and the trial design”;...and Gul et al, who emphasise the “numerous variables that could affect someone’s decision to participate in a research study” and note that these include participant-related factors, monetary compensation, contextual & environmental factors and research related factors). In summary, while the attempt to provide a topology of recruitment interventions/strategies is helpful, this has already been done by other authors and the subsequent discussion in this paper of the literature under three factors does not add much. Indeed the inclusion of some studies (e.g. Jenkins, Fletcher) under more than one of these three factors actually belies the statement at the bottom of page 4 about the narrow focus of these studies.

2.3 The discussion of the literature in this section is also largely a list (under each of the three factors the authors have identified) of the various interventions/strategies identified in different papers as important, significant or potentially successful. The net result leaves the reader with yet another list of factors and no clarification about how they connect. This discussion as it stands would be enhanced, and could possibly largely be replaced, by a table.

2.4 However what is most important in this section is the final paragraph (on p.6) outlining the general conclusions drawn from the preceding summary and the implications for this particular study. A key point is made here about the need for a less piecemeal approach that takes proper account of local contexts. It would help if this thought could be more fully highlighted, and this section expanded to explore more fully what has already been said on these issues in the literature. Thus although the “systematisation of study promotion models” is mentioned in the paper (though not explained) at the top of p.5, and is attributed solely to McDonald et al. (although this approach is earlier described in Campbell), the importance of this innovative model is not further considered, despite the promise McDonald et al suggest that it holds: “The business model is a new approach to trial management and offers something that has been lacking: a consistent framework for planning and managing recruitment. The model seems promising based on results from a small number of case studies. What are needed now are more examples of its use. If the early promise of the model was replicated in other trials, especially those of trialists uninvolved in the development of the model, this would represent a major advance in the conduct and management of
clinical trials.”

2.5 Similarly, Campbell et al. discuss what they call “the unique circumstances potentially relevant to recruitment for each trial”, and note that “a careful empirical exploration of the factors that shape a number of individual trials, to consider their unique challenges and the responses of their research teams to those challenges, could afford important insights that are likely to be to the benefit of other trials.”

2.6 These insights about the importance of context and the uniqueness of each trials are taken further by Jenkins, who cites Berwick’s view about the limitations of RCTs when studying complex social systems (such as an RCT itself) and notes the value of additional qualitative studies that can identify the challenges faced by team members in relation to recruitment to a particular study (see the studies by Paramasivan and Donovan cited by Jenkins). The same theme is subsequently taken up by Fletcher et al., whose systematic review published in 2012 concludes that: “The most promising intervention was the use of qualitative methods to identify and overcome barriers to clinician recruitment activity.”

2.7 In this paper however it is not made clear what the authors think about these issues or whether they were raised with the interviewees.

3. Methods (p.7)

3.1 This is a study of “key organisational barriers and facilitators to patient recruitment work”. It is important therefore that the organisation in which it took place is clearly described. But the description on p.7 makes little sense. If, as the DH website says, there are only 6 NHS AHRCs, how can the AHRC in which this study was undertaken be one of “13 specialised AHRCs operating across these two acute trusts”. Do the authors mean ‘BRC’ not ‘AHRC’?

3.2 Nor do the figures given in this paragraph make sense. The final sentence on p.7 says that “In 2012 this AHSC had 18 Principal or Chief Clinical Research Investigators and had recruited 61 patients from one of the two trusts that year into its 32 publically funded clinical research projects.” If these patients were divided equally between projects this would suggest that 1.9 patients were recruited in 2012 per project, if they are not then some projects would appear to have recruited only one patient that year, or none at all. What do the authors mean here?

3.3 No information is given about the questions the interviewees were asked. Could these be identified – as they were in e.g. the report of the survey undertaken by Spaar and colleagues?

3.4 No information is given on when the study was conducted. Nor is there any information on the type of research projects considered or the clinical field they covered. But both are relevant. The vast majority of previous work on this topic has been undertaken on recruitment to and retention in RCTs: and there is
evidence from previous work (Campbell et al) that recruitment rates are better in cancer and drug studies.

3.5 Interviewee participants were identified through purposive sampling and subsequent snowballing and the authors note that “Sampling was intended to identify those staff with greater experience or expertise in patient recruitment work rather than to capture a numerically representative sample of informants” citing Locock 2011 as an authority. But the Locock study was undertaken to explore the views of patients who all had the same role - that of a participant in a trial, not the views of staff who had, potentially, differing roles in patient recruitment. Campbell et al also describe how they sought their interviewees, and how they deliberately sought to involve all likely interviewees: “The sample was constructed to represent key players who could describe the workings of each of the trials. The intended interviewees were PIs, trial managers, local lead consultants and local recruiters (doctors or nurses according to the trial procedures). As understanding of the processes involved in each trial increased, the list of likely interviewees was expanded to fit the unique circumstances of that trial.”

3.6 A comparison between the number and types of interviewees in the Campbell study (see Table 15 of their paper) and those in this study highlights not only the small size of the sample in this study but also its comparative uniformity - 7/11 (nearly two thirds) of interviewees were research nurses. And again the numbers do not add up: there were 12 interviewees but the roles of only 11 are given (p.8). Presumably this anomaly is related to the unreturned transcript but this should be made clear.

3.7 Could the initials ‘XX’ on p.9 be replaced by those of the relevant team member?

4. Results and discussion (p. 9)

4.1. It takes a lot of effort to understand how the factors described in the first section ‘Descriptive Findings’ relate to those listed in Table 1 and to those discussed in the second section ‘Explanatory Findings’.

4.2 Table 1 is described as “a thematic chart to summarise what staff discussed as the location and direction of influence of these key factors”. What this means is not clear but there are echoes of Fletcher et al’s comment, mentioned above, that “The reasons for poor or slow recruitment to RCTs can be found at various levels: the patient, the recruiting clinician, the trial centre, the trial organisation and the trial design.” Specifically it would help if the section on ‘Descriptive Findings’ used Table 1 to describe more fully not only all the factors that the interviewees mentioned, but also the level at which those factors operate.

4.3 The explanatory account starts with the statement that: “Our explanatory account highlights and examines four key factors that influence recruitment success. These are (a) competition for research participants; (b) personal research benefit; (c) intersections between clinical care and research; (d) wider
responsibilities for enhancing research awareness.” But the account in fact discusses five factors; the one missing from the above list being the clinical research team. This is a particularly strange omission given the final sentence of the preceding paragraph, which highlights the importance of this factor: “Overall, staff identified their research team as the locus of success in recruitment…..”.

4.4 At no point is there any attempt to explore how these four/five key factors relate to the “three significant and interconnected factors” that the paper has previously identified in the literature (see p.4). Nor to explore whether what the interviewees said about these factors confirms or denies similar insights in the many other studies discussed in the Background section.

4.5 In particular there is no attempt to relate the discussion to the point made earlier about the need for a less piecemeal approach that takes proper account of local contexts, although the struggles to access patients described under the section on ‘Competition for research participants’ demonstrate exactly why a more systematic approach that promotes rather than hinders effective collaboration is needed. In this context a significant omission in the paper is the failure to mention the NIHR clinical research networks.

4.6 Another significant omission is the failure to mention the active role that patients can take throughout the research cycle. Throughout the discussion on competition and again on patient costs and benefits the impression given is that the interviewees (and indeed maybe the authors themselves) see research as something done to patients, and not as something with which patients can be actively and positively engaged. This despite the fact that the authors cite the recent AMRC publication “Our Vision for Research in the NHS” at several points; and the need for patient-centred research is stressed throughout that document. As the AMRC document demonstrates, there is growing evidence that patients can be active, effective and much-needed members of research teams. This fact is not, however, mentioned in the discussions of the ‘clinical research team’ or of ‘research awareness’ – although there is a very brief mention of the connection between patient recruitment and patient involvement in research in the conclusion.

5. Conclusion (p. 16)

This is very sketchy. No attempt is made to deliver the promised interconnections between the various factors given (one of which, “current ethical regulatory directives”, has not previously been mentioned in the text), or to return to the point made earlier about the need for a less piecemeal approach that takes account of local contexts, or to draw any practical lessons from the generally negative findings reported.

6. Limitations (p.16)

This section is very short. Other limitations the authors might mention are:

• The small size of the sample. Potential bias of sample (7/11 (nearly two thirds) of interviewees were research nurses; compare with range of types of
interviewee in Campbell (see Table 15 in Campbell et al).

• The type of research projects that the interviewees talking about. Is this paper just about recruitment to trials (like almost all the literature about recruitment to research)?

• Failure to include patients and clinical staff in the study is mentioned – but why were they not included?

Minor Essential revisions

The typos, grammatical infelicities and the references need to be tidied up.

Level of interest: A small study which provides some findings on the difficulties facing patient recruitment in a specific research setting, although the description of that setting is unclear and there is little in the paper about how the findings identified in the study relate to relevant insights in the existing literature.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.