Reviewer's report

Title: Saudi Views on Consenting Research on Medical Records and Leftover Tissue Samples

Version: 1 Date: 17 May 2010

Reviewer: Michael Dunn

Reviewer's report:

Thank you for inviting me to review this paper.

This paper reports a relatively simple empirical questionnaire study exploring Saudi views on consenting procedures, preferences, and norm perception in relation to the use of medical records and leftover tissue samples for medical research.

I agree with the authors that this paper offers a unique perspective on individuals' preferences and perceptions about the place of consent retrospective research using records and tissue samples. It is interesting to be able to compare and contrast a Saudi perspective on this difficult issue in research ethics with other empirical studies undertaken in other countries. In addition, I found the paper easy to follow, well structured, with clear aims, results, and a nice flow that kept the reader engaged.

However, notwithstanding the clear benefits of this paper, I do have some concerns, as follows.

Major Compulsory Revisions

1. Methodological detail and justification. I felt that the authors need to substantiate their methods section, with better justifications for some of the methodological decisions made. First, very little is said about the sample design. What was the rationale for recruiting patients' companions in the study, and what were the criteria for being defined as ‘a companion’? Second, what was the process for pilot-testing, and to what extent did this establish the validity of the measure? Third, on p. 9, the authors clarify that the sample was restricted to those without serious medical/genetic conditions who might bias towards more favourable attitudes towards research, consistent with other studies. However, given that the authors are keen to compare and contrast Saudi perspectives on this issue with empirical data from other countries, is this a valid reason for making such an exclusion? Fourth, the authors provide a rather brief, and oddly placed, paragraph on study limitations on p.12. One of the limitations reported is that the distinction between identifiable and anonymised data/tissue was not explored in the study. Given that this distinction is considered in the literature to be a crucial distinction in making judgements about whether such research is morally acceptable, should the authors not say more to explain their decision to factor this out? The same could be said about the distinction between public and
personal benefit resulting from the research. I believe a stronger justification is needed here.

2. Dynamics of the questionnaire. I found that the questionnaire could have proved problematic when used in practice, and am concerned that these potential problems might have impacted on the data collected. It is unclear what nature of information the participants were given prior to filling out the questionnaire, and whether they had any assistance when completing it. As someone relatively familiar with these issues, I myself found that I had to re-read the questionnaire a number of times in order to understand the subtle distinctions between each item. My concern here is twofold. First, that any difficulties that arise in differentiating between items in the questionnaire, and between the questionnaires, might explain some of the results – for example, the observation on p.10 that no significant differences were found in the distribution of choices between personal preferences and perception of norm. Whilst the different phrases used in the questionnaires on page 4 clarify how the distinction between preference and norm was conveyed, I am not certain that this would have been sufficiently clear for participants, particularly those with less formal education. Second, I am concerned that participants could have struggled to understand some of the concepts in the questionnaire items. For example, the distinction between prior and general consent, or even whether participants understood the meaning of the word 'consent' itself. The same could be said about 'research ethics committee'. This may be an issue that is less problematic in Arabic than English, but I do feel that the authors should give some guidance about how information about the questionnaire was conveyed, and consider whether the complexity of the concepts and items in the questionnaires might have impacted on the data.

3. Analytic approach. The discussion of the findings in the paper is framed entirely by comparing these data with data from comparable empirical studies undertaken in other countries. Whilst this is interesting in its own right, there is almost no ethical analysis of the data, and no attempt to situate the findings within contemporary debates about the use of medical records and tissue samples in research. Indeed, given the exclusions in the study around identifiability and benefit outlined above in comment 1, there would appear to be only limited scope for such an analysis. Additionally, the authors’ attempts to explain some of the observations (e.g. why participants with a lower level of education favour either not using medical records/tissue samples in research, or higher consent standards) requires further qualitative study, and can only be speculative. I feel that the paper would benefit by being framed as an introductory piece that opens up these issues for further study in Saudi Arabia, recognising the limitations of using questionnaire data both for ethical analysis, and for substantiating the reasons behind participants’ reported views/preferences/perceptions.

Minor Essential Revisions

1. I note some minor typos that should be addressed:
a. p.9, paragraph 1: ‘these’ should be ‘three’, I think.
b. p.9, paragraph 1: ‘and did not select population’ should be ‘and we did not select those’
c. p.9, paragraph 2: I don’t think that ‘dispersion’ is the right word here.
d. p.10, paragraph 1: ‘where’ should be ‘were’.
e. p.10, paragraph 2: ‘would not oppose to retrospective research’ should be ‘would not oppose retrospective research’.

2. In Table 2, it would be helpful to be given data about the number of participants in the 5 age groups developed for the purposes for analysis by the authors, as described on page 4.

Discretionary Revisions

1. The authors begin the paper by referencing two professional standards from the UK and USA which state that research can be undertaken without the explicit consent of participants under certain conditions. Given the focus of the study, I think it would be helpful to give a brief outline about the current regulatory approach adopted in Saudi Arabia, and how this relates to the issue under study in this paper.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.