Reviewer's report

Title: An international survey of physicians and dentists regarding clinical trials: A comparison between Kyoto University Hospital and Seoul National University Hospital

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Reviewer: zelda tomlin

Reviewer's report:

This article reports findings from a comparative survey of Japanese and South Korean ‘physicians and dentists’ on their attitudes to clinical trials; the work is set in the context of ‘insufficient’ clinical trial activity in Japan compared to higher levels in South Korea. This is an interesting and useful study. However, there are several problems with the reporting which are detailed below. Additionally, the paper reports on findings of a questionnaire survey while the remit of the journal is methodology. I could not see any aspects in this paper that would contribute to or advance the methodological body of knowledge.

• Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1) The aim of the survey is given as: understanding how the different clinical trial environments (in the two countries) influence physicians’ attitude to trials. I find this formulation a little odd. Physicians’ attitudes may indeed be influenced by the environment and levels of trial activity but the reverse may also be true, i.e. attitudes may be one factor that explains the different levels of trial activity. The authors may want to reflect on and incorporate this duality in their statement of objective.

2) The language would benefit from some revision, to eliminate some clumsy syntax.

• Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

3) The title and abstract state that the survey was sent to physicians and ‘dentists.’ However, the demographic data refer to ‘dental surgeons.’ If these were medically trained surgeons, then it would be more appropriate not to make a distinction between physicians and dentists as dental surgeons would be classified as physicians.

• Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

Methods:

4) The authors do not say how they define 'clinical trial' – whether they are
referring to randomised trials only or both randomised and non-randomised designs. Equally, they do not specify whether the study concerns publicly funded or industry-sponsored trials or both.

5) The authors do not make clear how the questionnaire was developed. The questionnaire was a modified version of a previous one designed with the involvement of one of the authors (Sumi et al, 2009) which, in turn, was a modified version of an earlier questionnaire (Yanagawa et al, 2006). This is not adequate to explain to the reader how the questions were developed (based on what – literature review?), tested and piloted. The explanation on each question in the methods section is unnecessary.

6) I do not have statistical expertise, therefore cannot judge the appropriateness and adequacy of the statistical analyses conducted; however, the brief reporting gives the impression that these were very basic and may be inadequate.

Results/Discussion:

7) In terms of the sample, can the authors clarify which two KUHP departments refused participation and any reasons given. The absence of two KUHP departments from the sample means that the responding physicians at KUHP represented 27.5% of the total number of staff there while the same figure for SNUH was 45%. The quoting of the KUHP response rate as 64% without this information is misleading.

8) The meaning of some of the questions is unclear/overlapping. For example, what are ‘infrastructure’ related problems and how do they differ from ‘systemic support from hospital?’ Similarly, how do problems with ‘enrolment of subjects’ (incidentally, the preferred term these days is ‘participants’) differ from problems with ‘obtaining informed consent?’ What were the problems/merits identified in the ‘others’ option in these sections?

9) A distinction is made between barriers/problems associated with ‘trials’ and industry-sponsored multinational trials with different answer options (Q 10 and Q16). What was the rationale for this? Many of the factors could apply to both kinds of trials. Quality of (multinational) trials was seen as a bigger problem at KUHP than at SNUH; as it is unlikely that there is a big difference in the quality of trials that two hospitals are exposed to, this may need explaining: is it, for example, that the expectations of KUHP doctors are higher?

10) Q17 was for free-text ‘comments.’ The results for this question are not reported. Is this because this question was left blank?

11) There is a general problem with the reporting of the results and their discussion: many of the interesting responses shown in the tables are not flagged up in the text and/or contextualised, with the result that the reporting appears unbalanced and fails to reflect the whole study:

11.1 The designation by SNUH physicians of board certification as a major benefit of trial participation is important, both on its own, but also in comparison with the insignificance of this for KUHP physicians. Thos may go a long way in accounting for the greater enthusiasm of SNUH physicians for trial participation. This is not acknowledged or flagged up.
11.2 There is a striking difference between the two sites in terms of opportunities for and sources of information on trials. It seems that there is little information provided at SNUH, compared to KUHP. And yet, there is more trial activity at SNUH. Comment is needed from the authors on the possible reasons but also the implications of this. For example, is it possible that SNUH physicians are participating in trials without adequate information about them?

11.3 The higher percentage of trials terminated due to adverse events at SNUH compared to KUHP (26% v 8%) may need a comment. Furthermore, the other reasons given by SNUH doctors are intriguing and troublesome and also need comment: adverse events (a higher percentage than at KUHP), sponsor’s request, protocol violation, publication of similar trial results elsewhere, unfeasible research design. Some of these appear to be avoidable shortcomings, with implications for resource use in trials.

11.4 While the Discussion addresses the infrastructural and operational factors in limiting the number of trials in Japan, it does not address other findings. For example, the authors explain the higher tendency of KUHP physicians to refer to recruitment problems in terms of the limited availability of eligible patients to any single hospital in Japan, compared to South Korea. However, they offer no explanation for the higher percentage of Japanese physicians referring to problems in obtaining informed consent compared to those in South Korea.

12) In the Discussion, the authors state that ‘financial gain’ was the second to last merit reported at KUHP and last at SNUH. Financial gain is not a category in any of the tables and is not mentioned in the results section.

13) The discussion is a little diffuse and repetitive. The ‘resolutions’ section repeats findings; it should focus on suggested solutions. A paragraph (or possibly bullet points) on the main recommendations to emerge from the study would be welcome. The section on ‘patients’ perspectives’ is irrelevant, uninformative and not justified, as this was not covered by the survey and should be removed.

Limitations

14) The questionnaire was explained and handed out to staff by departmental directors. This may have compromised the independence of the research and, despite the offer of anonymity, staff may have been under the impression that participation was preferred by management. Conversely, staff may have been reluctant to respond because of this. Additionally, this method may have been less reliable than direct posting in ensuring that each potential respondent received the questionnaire.

15) There was no ‘other’ option provided in many of the questions, raising the possibility that important opinions and attitudes may not have been elicited.

16) The ethics of trials was not covered by the questionnaire. While there is a knowledge test regarding the Declaration of Helsinki, there are no questions on how doctors feel about trials and possible conflicts of interest, a prominent issue in the literature especially in relation to randomised trials (Hales et al, 2001 Sackett and Hoey, 2000, Garcia et al, 2004).

These limitations need to be acknowledged.
Reference:

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

Declaration of competing interests:
I declare that I have no competing interests