Reviewer’s report

Title: Integrating the results of user research into medical device development: insights from a case study

Version: 3 Date: 13 March 2012

Reviewer: Beverley Norris

Reviewer’s report:

Minor Essential Revisions

1. General points:
   a. Add some very brief description of the case study to the abstract to give it some context
   b. What steps were taken to get the development team to look at the results of the user research? As it stands it just sounds as if they didn’t engage with the team or encourage them to use the results, which I’m sure is not the case.

2. Page 8, paragraph ‘The Device’: Please explain why healthcare staff were considered the primary users of the device and why patients as users weren’t considered at this stage, along with other users such as maintenance staff, porters etc.

3. Page 14, first paragraph: Was the timing of the user research the only reason that the results weren’t used? If not, perhaps the reasons can be suggested or if it was, Can this be explored a little further in terms of how to avoid this situation? This is an important issue in the paper, how the technological and user research phases can be better coupled?

4. Page 24, first paragraph: The authors seem to be suggesting that having user research as a requirement for funding is undesirable, but I think the message is that the way the requirement needs to be specified better. So the timing, form and integration of the user research are key to its success. The findings of this paper could help our understanding of how user research should be carried out as part of the MDDP.

5. Page 26, final sentence of conclusions: What about commercial medical device development and not just funded research? Are there any recommendations about how the findings of this study can be exploited by industry?

Discretionary Revisions

6. Page 11, 2nd paragraph: Do the potential clinical application areas reflect those that were consulted i.e. renal and oncology? If the initial scoping work had looked at other areas e.g. neonatal medicine, neuro., could applications have
been found there also? Whilst the study couldn't look at all possible areas it would be worth mentioning if you think other applications areas might exist if scoping work was extended. This is an important issue for the initial product development stage, that possible applications and therefore design requirements will only reflect the areas where scoping work has been done.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**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