Reviewer's report

Title: Electronic monitoring of non-adherence to medication therapy: examining underlying assumptions

Version: 1 Date: 1 August 2007

Reviewer: Cynthia L Russell

Reviewer's report:

The purpose of this study was to identify and test assumptions of internal and external validity for electronic monitoring of medication taking. Specifically, the Medication Event Monitoring System (MEMS V) was evaluated in a sample of renal transplant subjects for 3 months. Internal validity was tested by examining the functioning of electronic monitors, the correspondence of events to actual drug ingestion, and the influence of electronic monitoring on the subject's medication taking behavior. External validity was tested by examining the impact of electronic monitoring on sample representativeness. The authors should be commended for addressing an extremely important issue in medication adherence research.

I offer the following considerations for the authors to enhance the manuscript for readers. These suggestions include minor essential and discretionary revisions.

When the quality tests of the MEMS are discussed on page 3 further details should be presented on the testing performed by the manufacturer. In the variables and measurement section, explanation how testing performed in this study was different than in previous studies and why this approach is superior.

Page 4, 2nd para, should assumption 2 include patients who “trigger” their bottles while removing the meds from another source which may likely over estimate non-adherence since they may not take the cap off for the required 3 seconds that are needed for an opening (event) to be recorded by the cap?

Page 6, 1st para, describe the guidelines underlying correct EM use (resulting in unreliable data) for the reader when they are first mentioned here. Were these guidelines used to instruct the patients when they received verbal and written instructions on how to use the EM system (page 7 2nd para)?

In the section on “Variables and Measurement” consider including a clear description and labeling of a priori operational definitions for each of the 3 measures for internal validity and the one measure for external validity. For example, was a non-functioning cap defined as a cap that didn’t record any events, extra events, some events? Why were these operational definitions selected instead those that had been previously used, e.g. by the manufacturer?

Page 7, 3rd para, describe how the 5-point scoring criteria were developed e.g. from the literature, from experts?
Page 8, 2nd para, describe whether the subjects recorded the date of the dropped caps since this seems important to know for data scanning. Were the subjects asked to record any other cap trauma such as temperature or moisture changes?

Page 11, first para, was the manual check of the cap completed by the researcher?

Page 11, 2nd para, were the 44761 records of raw EM data the events of documented cap openings?

References 5 and 6 should be clarified. When I googled the references, they lead me to the author’s dissertation where references for this information appear to be from 2 other sources.

The first time that Figure 1 is references in the text, it should be described in some detail so that the reader is oriented to the figure since it is quite complex.

Clearly identify Figure 4 as it is labeled as Figure 1 in the lower left corner. The figure is important by is difficult to understand. Consider using the same words in the text that as used in the figure and clearly define them for the reader.

Spelling and grammar: Page 2 under “Methods”, last sentence, “dropped” should be “drop”. Page 8 1st para, last sentence should be “were” instead of “was”. Page 13 2nd para, 3rd to last sentence “data” should be “date”. Page 14, 1st para, 2nd sentence should read “The absence of a control group prevents drawing firm conclusions...” Same para, 2nd to last sentence delete “the” after “whole”.

Thank you for asking me to review this manuscript which will make a significant contribution to our developing knowledge regarding validity of electronic monitoring.

What next?: Accept after minor essential revisions

Level of interest: An article of outstanding merit and interest in its field

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.