Reviewer's report

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

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Reviewer: Ray Ownby

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General

This paper is a welcome addition to the discussion of how to assess medication adherence in various contexts. It highlights the importance of not uncritically accepting electronic monitoring as the gold standard in adherence assessment by focusing on the potential pitfalls of this acceptance. The authors present interesting new data on the reliability of MEMS caps in an actual clinical study (including data on the consequences of patients’ dropping the caps while using them). They also present a useful theoretical framework for evaluating adherence assessments in the four assumptions that they suggest underlie electronic monitoring. I believe that this paper can be strengthened further by consideration of the following issues.

As already mentioned, the four assumptions that the authors argue underlie electronic monitoring are a useful framework for analyzing the MEMS caps’ use in clinical and research studies. The first assumption, that the monitors actually work, may seem obvious but the authors correctly note that the reliability of the MEMS caps has not been routinely assessed in studies, and it is my impression that most users accept the manufacturer’s information on this point. The standard to which the authors appear to hold the device, however, seems to be 100% functioning at all times; when one monitor fails in their study, they argue that the assumption was violated. At one point in the manuscript, they note that “only” 97.5% of the units worked – this gives me the impression that they are being too critical. It would be wonderful if all measurements in research studies were only inaccurate in 2.5% of cases. This standard is thus too strict, particularly in a relatively small sample. While it would be desirable that all electronic devices function with 100% reliability, few do. I’d suggest that the authors reconsider this standard and moderate their conclusions on this point.

Their second assumption, that each time the monitored pill bottle is opened a dose is taken, is also an important issue in the use of electronic monitors. The authors correctly note the limitations of monitors’ use and the importance of assessing whether patients using them are using them correctly. The found a substantial need for adjustments of medication adherence data, and appear to argue that this is a defect in the use of electronic monitors. I’d suggest an alternative interpretation is that while electronic monitors are potentially useful, the way in which individual patients use them is important, too.
Their third assumption is that the monitoring device must have no effect on adherence behavior. Here the authors highlight an extremely important issue, but here again I would suggest that their discussion could be more nuanced. While it is true that under ideal circumstances we would be able to assess any behavioral process without affecting it, in real-world research this is almost never possible. I think the paper might be improved for readers if the authors included a brief discussion of how MEMS caps are different from other methods of assessing adherence, such as self-report, other monitoring methods (e.g., blood levels, pharmacy records) or unannounced pill counts. Each has strengths and weaknesses, but all, it can be argued, may affect patients’ adherence. The result of the authors’ argument, at least for me, is to show that electronic monitoring via MEMS caps isn’t perfect, and I think most thoughtful consumers of research on adherence would agree that’s true.

The authors’ fourth assumption concerns the impact of the use of electronic monitoring on sample characteristics. Here, it is not clear whether the use of MEMS caps affects the composition of a sample because of the necessary elimination of users of pill box organizers. The additional information on this point is welcome.

What next?: Accept after minor essential revisions

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

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 interests