ABSTRACT: Targeted Literature Review of Medication Event Monitoring Systems to Evaluate Adherence in Observational Real-World Studies

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Objectives

To identify and review methods employed to evaluate medication adherence in studies of oral antineoplastic agents, with particular interest in the opportunities and challenges associated with medication event monitoring systems (MEMS) implemented in observational studies.

Methods

A targeted literature review was conducted to identify studies that have measured adherence with antineoplastic agents. Our review included studies that were published between January 1990 and May 2014. Key data abstracted from each study included patient characteristics, study design and duration, cancer type, treatment, and adherence methodology and results. Based on preliminary results, a second targeted review was conducted to evaluate the literature on the risk of the Hawthorne effect in observational studies utilizing MEMS in any therapeutic area.
Results

We identified 69 studies that evaluated adherence to oral chemotherapy; 6 studies were interventional and excluded from further review. Of the remaining 63 studies, 28 (44%) were prospective, 25 (40%) were retrospective, and 10 (16%) were cross-sectional. A total of 15 studies used MEMS to evaluate medication adherence. Among observational studies that utilized MEMS and evaluated the Hawthorne effect (n=3), mixed results were observed. In two studies, patients reported their behavior was affected by their awareness of being evaluated. This was demonstrated by a significant decrease in adherence between months 1–3 in one study but not measured in the second. The third study showed no change in adherence scores over time and concluded there was no Hawthorne effect. Potential ways to minimize the Hawthorne effect include: study duration >3 months, blinding patients and physicians to results of MEMS downloads, and use of a patient–completed ‘debriefing form’ to assess behavior modifications.

Conclusions

MEMS have been utilized in observational studies evaluating oral antineoplastic agents. The Hawthorne effect may be present with MEMS caps, but can be minimized and is not prohibitive to study conduct.