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Use of Electronic Monitoring in Clinical Nursing Research

Rita L. Ailinger,

Georgetown University, Washington, D.C.

Patricia L. Black, and

George Mason University, Fairfax, Virginia

Natalie Lima-Garcia

Johns Hopkins University, Baltimore, Maryland

Abstract

In the past decade, the introduction of electronic monitoring systems for monitoring medication adherence has contributed to the dialog about what works and what does not work in monitoring adherence. The purpose of this article is to describe the use of the Medication Event Monitoring System (MEMS) in a study of patients receiving isoniazid for latent tuberculosis infection. Three case examples from the study illustrate the data that are obtained from the electronic device compared to self-reports and point to the disparities that may occur in electronic monitoring. The strengths and limitations of using the MEMS and ethical issues in utilizing this technology are discussed. Nurses need to be aware of these challenges when using electronic measuring devices to monitor medication adherence in clinical nursing practice and research.

Keywords

electronic monitoring; Medication Event Monitoring System; MEMS; adherence

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Adherence to medications has long been a concern because it often affects the outcome of treatment. In a recent review of 63 studies over a 30-year period, the authors reported that “the odds of a good outcome if the patient is adherent are almost three times higher than the odds of a good outcome if the patient is non-adherent” (DiMatteo, Giordani, Lepper, & Croghan, 2002, p. 802).

A new method for monitoring adherence to medications is the use of an electronic monitoring device. One example of this is the Medication Event Monitoring System (MEMS; AARDEX Ltd., Zug, Switzerland), which is a computerized monitoring system that is used to indirectly measure medication adherence. With MEMS, a computer chip that fits a standard prescription pill bottle is built into the cap and records each date and time the bottle is opened (de Bruin, Hospers, van den Borne, Kok, & Prins, 2005; Feinn, Tennen, Cramer, & Kranzler, 2003). MEMS has been cited as an effective tool to measure medication intake, and it allows the data to be downloaded and examined on a computer (Claxton, Cramer, & Pierce, 2001; de Bruin et al., 2005; Feinn et al., 2003).

Purpose

The purpose of this article is to describe the advantages, disadvantages, technical and ethical issues in using the MEMS. In addition, we provide several examples of MEMS data and self-report data in the monitoring of adherence in patients on isoniazid for latent tuberculosis infection (LTBI). Adherence to LTBI therapy is problematic because patients feel well, they do not have symptoms, and the medication can produce side effects. Treatment of LTBI is

recommended for high-risk groups, such as immigrants, because most cases of tuberculosis in the foreign born are because of LTBI activation (Cain et al., 2007). A key component of the national strategy to prevent active TB is treating high-risk groups who have LTBI (Horsburgh, 2004). This treatment consists of 9 months of isoniazid 300 mg once per day. Monthly clinic visits for monitoring of adherence and side effects are standard procedure. The usual way that LTBI adherence is documented in the medical record is from patient self-report to the public health nurse. Patients are asked how many pills remain in the bottle they received the previous month, and the nurse records the number as the pill count.

Background and Significance

MEMS has been used to measure treatment adherence in many settings. In a review of studies from 2000 to 2006 in which electronic monitoring devices were used to measure the association between dose frequency and medication adherence, the authors reported that using MEMS allowed them to record consistency in daily dose taking and dose timing. Compliance with dose taking decreased as the number of daily doses increased (Claxton et al., 2001). MEMS technology has been used to track medication adherence in highly active antiretroviral therapy (HAART) studies (de Bruin et al., 2005; Hinkin et al., 2002; Samet, Sullivan, Traphagen, & Ickovics, 2001). de Bruin et al. (2005) used MEMS data as an effective tool for HAART patient education and feedback; however, patients expressed a desire for a smaller MEMS container that looked less like a pill bottle and was more conducive to use in public.

In another HAART study, Williams et al. (2006) speculated that use of MEMS might have altered adherence behavior because participants were aware that information would be uploaded from the container. They further suggested that MEMS could be helpful in understanding types of patients that best adhere to specific interventions. In a separate study, the authors concluded that MEMS may be limited as an effective monitoring tool because drug regimens may be complex and patients may use pill boxes with complicated dosing schedules (Samet et al., 2001).

Bova and colleagues (2005) used MEMS electronic monitoring to measure adherence to medication with HIV-infected adults. They suggested that researchers need to continue to work with electronic monitoring devices and to report the benefits and limitations of using them. Those authors concluded that researchers will find the true measure of patients' adherence to medication by using multiple measurement strategies, including electronic monitoring, self-report, pill counts, refill records, and biological measures. In their study on testing a nurse-tailored adherence intervention for HIV medications, Holzemer and colleagues (2006) used the MEMS caps with four other adherence measures including a pharmacy refill, a self-report instrument, a pill count, and a tool for measuring reasons for missing medications. They found that correlations were moderate within each adherence measure over time; however, there was minimal correlation among the five different adherence measures.

In a study of medication adherence in hypertensive patients, Hamilton (2003) used MEMS as a primary measurement tool for medication adherence. Secondary measurement was done via urinary potassium levels, capsule count, patient's self-report, and physician estimate of adherence. According to Hamilton, MEMS was well accepted by patients, and the adherence rates matched those of self-report. Though MEMS is well accepted, researchers are cautioned to be attentive to the fact that it measures how often the bottle was opened but does not ensure that the medication was consumed.

Adherence to LTBI Therapy

A number of studies have focused on adherence to treatment for LTBI. Measures of adherence included self-report (Ailinger, Moore, Nguyen, & Lasus, 2006; Blumberg et al., 2005), urine

assays (Eidlitz-Markus, Zeharia, Baum, Mimouni, & Amir, 2003; Perry et al., 2002), and directly observed preventive therapy (White, Gournis, Kawamura, Menendez, & Tulsy, 2003). There was only one study in which an electronic measuring system, the MEMS, was used to measure adherence in LTBI therapy. In that study, the authors reported that the number of doses and dose intervals during the first month were related to treatment completion. They suggested targeting interventions toward patients with poor adherence in the first month (Menziez et al., 2005).

Based on current literature, electronic monitoring devices may be an effective choice for measuring medication adherence in LTBI patients, especially when it is used in combination with other reporting measures.

This study was approved by a university human subjects review board. Participants signed an informed consent outlining the procedures used in the study, including the use of a “special” cap, and nondisclosure of the electronic monitoring device until the patient completed the study. The latter deception was approved.

Sample

The setting for the study was a chest clinic in a county public health department. The county has a population of almost 200,000 people, of whom approximately 20% are Latinos. A convenience sample of 86 Latino immigrant patients for whom LTBI therapy was recommended was included in the larger study from which the MEMS examples are drawn. The sample included 55 females and 31 males, from various countries in Latin America, including 28 each from El Salvador and Bolivia. The mean age was 26 ($SD = 6.84$), the mean number of years education was 10.5 ($SD = 3.35$), and the mean number of years in the United States was 4 ($SD = 4.09$).

Procedure

When therapy was started, patients were given their 30-day supply (30 pills) of isoniazid (INH) in the manufacturer's bottle with the cap removed and a MEMS cap used as a replacement. Patients were instructed to bring their bottle with them when they came to subsequent clinic visits. When the patients came to the clinic each month, they gave the INH bottle with the MEMS cap to the research nurse, who took the bottle to a separate area of the clinic, where she placed the cap on a monitor connected to a laptop for reading. The patients were not told that the MEMS cap was recording the bottle openings. Patients did not see the nurse monitoring the MEMS cap report in the clinic, and she did not mention the report nor intervene in any way based on the MEMS report. This was a considered decision at the start of the study, that there would be no intervention based on the MEMS report, because the purposes of the study were to assess the feasibility of using the special caps in the clinic and to perform a reliability check on self-report of adherence at the end of the study.

The MEMS produced a calendar plot of the patient's dosing history displayed in a monthly calendar in which a number was exhibited for each time the bottle was opened. For example, if the patient opened the bottle daily as recommended, the number 1 appeared on the date. If the patient did not open the bottle, a 0 was recorded on the calendar plot.

Clinical Research Examples With LTBI Patients

Three examples from our study illustrate the disparity between patients' self-report and the MEMS report. The total number of doses recommended for LTBI therapy is 270 doses in 12 months (Centers for Disease Control and Prevention [CDC], 2005). In the first case, the patient reported in monthly visits that she had taken 208 doses in 9 months, and the MEMS documented

211 bottle openings (99%). This difference of 3 doses is minimal and is clinically acceptable. However, in the second case, the patient reported that he had taken 250 doses, and the MEMS report showed that the bottle had been opened only 120 times in the 9 months. This is a difference of 130 possible doses, or almost half of the recommended therapy. In a third case, the patient reported having taken 270 doses, although the MEMS recorded 189 doses (70%). The latter is equivalent to 6 months of INH therapy, which is considered acceptable but not preferred by CDC guidelines.

Discussion

When patients forgot to bring the medicine bottle with the special cap, there was no way to electronically monitor adherence for that month. However, because the record was cumulative, it was recorded the next time the patient brought the bottle to the clinic.

Several possible explanations for the discrepancy between the patient's self-report and the MEMS data in the second case include (a) the patient took out a number of pills when he opened the bottle and therefore opened the bottle fewer times than expected or (b) the patient reported taking more pills than what he really did. These are limitations of using the electronic monitoring devices. However, the discrepancy also points to the lack of reliability of using self-report alone as a measure of adherence.

Ethical issues related to this study and the use of the MEMS caps included not divulging to patients that there was a special cap on their INH bottle nor indicating that there was a computer chip in the cap that recorded when they opened the bottle. Because these patients had low literacy and were in unskilled and skilled labor occupations, it was assumed that they were not computer literate and were not cognizant of the computer data generated by the "special" cap. At the end of the patients' participation in the study, we told them about the cap and its recording device.

Another ethical issue in using electronic monitoring devices is whether the nurse tells the patient what the MEMS cap recorded at each clinic visit. In one scenario, the nurse may want to mention how many times the bottle was opened and ask the patient why there is a discrepancy between the number of pills the patient said were taken and the number of bottle openings recorded by the MEMS. This situation could then be used as a stimulus to discuss ways of improving adherence, barriers to adherence, and benefits of adherence. Because this was a research study, we chose not to tell the patients what we saw on the MEMS record, that is, how many times the bottle had been opened each month. The way that the electronic monitoring device is used depends on the purpose for using it. Nurses in practice and research need to make considered decisions on these ethical issues prior to using monitoring devices.

Technical problems can occur when using electronic monitoring devices. For example, during the course of our study, the manufacturer stopped making the cap we were using and upgraded the MEMS cap. This meant that we had to use two different monitors to read the different caps. Because we were using a laptop, there was only one USB port, and we had to switch back and forth between monitors and reconfigure the monitor each time.

One of the other challenges was the learning curve required to use the system. Because there are different options available for recording information, practitioners and researchers need to learn what is available and determine what is best suited for the particular study. In addition, access to a computer is necessary to read the caps on the monitor. In our study, we used a small laptop that did not require much space in the clinic and was out of view of the patients.

Application

The use of an electronic measuring device as an adjunct in clinical nursing research on adherence is a valuable tool. Examples from our study illustrate that some self-reports are reliable with the MEMS report, whereas others are not. Because this was a research study, we chose not to confront the patients about the discrepancy. That is the choice of the researcher and depends on the purpose of the study.

When using the MEMS or other electronic devices, it is important to consider the costs associated with its use. Each MEMS cap cost \$110; additional costs included the monitor and software. This high cost is certainly a challenge that may impede the use of electronic monitoring for adherence in many clinical settings.

In addition, there is the possibility that patients may forget or lose their “special” bottle. Interventions by the research nurse to decrease this problem included putting a sticker on the bottle to remind the patient to bring the bottle to clinic, reinforcing with the patient the need to bring the bottle during telephone clinic visit reminders, and praising the patient when he or she brought the bottle to clinic. In our study, the MEMS cap fit on the supplier's brand of INH. However, this may not be true of other medications.

Practice in using the monitoring device is recommended prior to initiating a study so that the data collector is proficient with the equipment. Because space is often an issue in a clinical setting, the use of a small laptop to attach to the monitor and provide ready accessibility can be convenient. Prior to purchasing the MEMS or other electronic monitoring device, the researcher should ascertain whether there will be a sufficient quantity of the same caps available for the duration of the research study.

Ethical issues about deception must be addressed by the nurse investigator in the informed consent and with the human subjects review board. The use of an electronic monitoring device in clinical nursing research is a tool that can enhance perspectives in research studies on adherence.

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Biographies

Rita L. Ailinger, PhD, RN, is a professor in the School of Nursing & Health Studies at Georgetown University.

Patricia L. Black, MSN, APRN, BC, is a doctoral student at George Mason University.

Natalie Lima-Garcia, BSN, is an MPH student at Johns Hopkins University.

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