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# Paper vs. Electronic Diaries

## Compliance and Subject Evaluations

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An instrumented paper diary caught subjects filling out their diary entries after the fact. Electronic diaries may work better for subjects and investigators alike.

Subjects in clinical trials are often asked to report on a variety of experiences, including disease-specific symptoms (for example, pain and fatigue), objective events (wheezing or episodes of urinary incontinence), and evaluations regarding their well-being or quality of life.<sup>1</sup> Although subjects' self-reports regarding their experiences are reliable in general, research on memory has shown that recall is unreliable. For example, a large body of literature has shown that a number of complex processes affect recall data. Memory relies on a variety of heuristic strategies to reconstruct past events.<sup>2</sup> Such retrieval or reconstruction is imperfect and affected by a variety of biases.<sup>3-8</sup>

In an attempt to avoid the inaccuracies and biases that affect recalled data, researchers often use diaries to capture subjects' experiences closer to the time of their occurrence. Approximately 25% of all Phase 2-4 clinical trials use diaries.<sup>1</sup> Given the problems associated with recall, the value of diary data is predicated on subjects' completion of the diaries in a timely manner, proximate to the experience being recorded. In studies using paper diaries, anecdotal reports indicate that subjects do not consistently complete their diary entries as required but rather fill them out in batches after the fact (so-called "parking lot compliance"). When this happens, the scientific rationale for using diaries is undermined, as the data are now subject to the very recall biases that diaries were designed to avoid.<sup>9</sup>

Until recently, researchers had no way to measure subjects' compliance with paper diaries. A small literature on instrumented medical devices (such as inhalers, glucometers, and medication dispensers) suggests that many paper

diary entries are not completed as required by the protocol, and that subjects' reported compliance is not consistent with the objective record—that is, subjects often report good compliance when the instrument reveals poor compliance. In some cases, the instrument's objective record reveals the subjects' attempts to fake compliance (for example, discharging the inhaler dozens of times in the minutes before a clinic visit).<sup>10–17</sup> When it comes to compliance with paper diaries, however, we have had only anecdotal evidence that raises concern, but no objective evaluation of compliance to validate or dismiss this concern.

### Subject compliance with paper and electronic diaries

A recent study published in the *British Medical Journal* fills that gap. This study by Arthur Stone and colleagues was sponsored by the National Cancer Institute (NCI), with in-kind support from invivodata, inc., and was designed to document actual subject compliance with paper diaries.<sup>18</sup>

The investigators assessed subject compliance using a newly developed instrumented paper diary that electronically tracked diary use unobtrusively. Photosensors built into the paper diary triggered an electronic record of the date and time of each diary opening and closing. Compliance rates from this instrumented paper diary (IPD) were compared with those achieved using an electronic diary (ED) implementing unique measurement principles based on the science of ecological momentary assessment (EMA).<sup>19</sup> EMA encompasses methods for collecting valid and reliable subject self-report data in real time and in the subjects' natural environment.<sup>20</sup>

The primary objective of the study was to quantify compliance with paper diaries. The electronic diary condition was included to provide a benchmark comparator of what could be accomplished with a system developed explicitly to enhance compliance. This also served to benchmark compliance rates in this particular population, with this protocol, and at this research site.

Eighty chronic pain subjects were assigned to use an IPD or an ED to record their pain over a three-week period. The IPD was designed to be as user-friendly as possible and to mirror best practice in use of paper diaries. The paper diary cards were locked into a small DayRunner Organizer binder and case (DayRunner, Fullerton, CA), which included a belt loop to facilitate portability. The size and weight of the paper diary (17 cm × 11 cm × 3.5 cm, weighing 240 grams) was very similar to the Palm handheld devices used for the EDs (13 cm × 8 cm × 3 cm, weighing either 170 grams [Palm Vx] or 213 grams [Palm IIIxe]) (Palm, Inc., Santa Clara, CA). The assessment items, identical to those used in the paper diary, were presented on the ED screen and responses were made on a touch-sensitive screen. Figure 1 shows the devices.

All subjects were asked to complete a pain assessment on three occasions each day (10 A.M., 4 P.M., and 8 P.M.). Two types of compliance were analyzed: reported compliance (based on the time and date written on completed diary cards) and actual compliance (based on the time and date record that was automatically recorded by the devices). The EDs allowed entries to be made only during a window of ±15 minutes around the scheduled assessment times, and incorporated features to enhance compliance, such as an audible alarm at the time of assessment



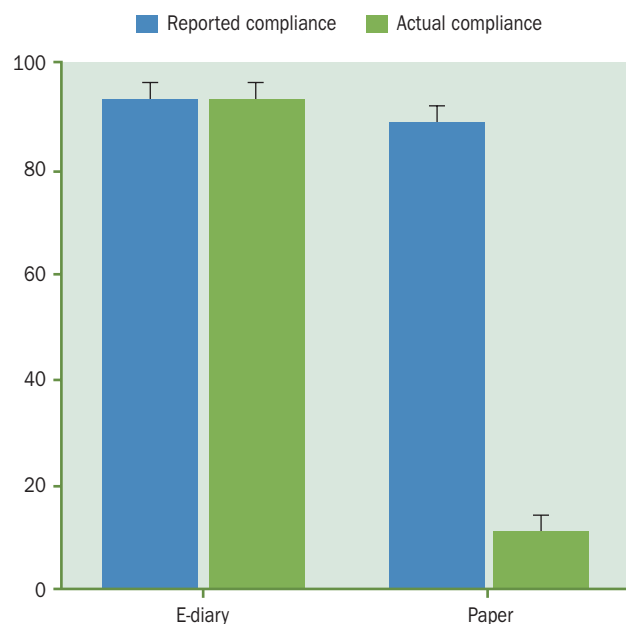
**Figure 1.** The instrumented paper diary (left) and the electronic diary (right). (Not to scale.)

and on-screen feedback if an assessment was missed.<sup>9</sup> The diary data were collected from the IPD and ED subjects at weekly clinic visits, and clinic personnel gave subjects feedback and instructions based on their evident performance. For subjects

## Subjects falsified 79% of paper diary cards.

using the IPDs, feedback was given regarding their submitted diary cards. Subjects using the EDs received feedback regarding their compliance with timely completion of the diary, as well as use of the diary's livability features.<sup>9</sup>

As shown in Figure 2, reported compliance in the IPD group was very high; subjects submitted diary cards corresponding to



**Figure 2.** Subject compliance with paper and electronic subject experience diaries. Note that reported compliance is equivalent to actual compliance for the electronic diary subjects because the electronic diaries used in this study allowed pain entries only within the 30-minute window as required by the protocol.

**Table 1** Questions about the diary completed by subjects at the end of the study.

| Questions  | Response options |
|--|------------------|
| Was the [PPD/ED]* easy to use?   | 1 = Not at all   |
| Was the text easy to read?   | 2 = Somewhat     |
| Were the interviews easy to complete?  | 3 = Moderately   |
| How clear was the [PPD/ED] training?   | 4 = Very much    |
| How easy was it to keep the [PPD/ED] with you at all times?  | 5 = Extremely    |
| We originally asked you to make regular diary entries at 10 A.M., 4 P.M., and 8 P.M. How successful do you think you were at doing this? |                  |

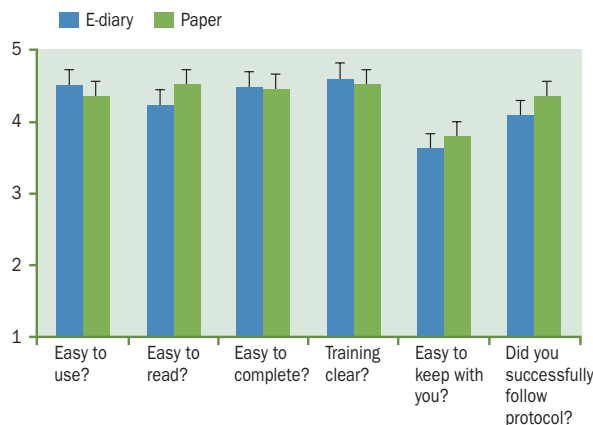
\*Subjects using the IPD saw only the abbreviation PPD (Paper Patient Diary), and subjects using the ED saw only ED (Electronic Diary). These terms were consistent with the training materials for each group.

an average of 90% of assessment occasions. This is consistent with the existing literature on reported compliance with paper diaries. The objective record told a different story, however: actual compliance was much lower, averaging only 11% (95% CI: 8%–14%). Thus, 79% of paper diary cards were falsified.

The pattern of noncompliance is informative. On 32% of study days, the IPD had not been opened at all, so subjects had neglected their task for the entire day. However, subjects submitted 94% of the required cards for those days.

How did the subjects who used the EDs perform? In this group, actual compliance was 94% (95% CI: 91%–96%). In other words, subjects completed each pain report within the required 30-minute window 94% of the time. These high rates of subject compliance are consistent with findings from several peer-reviewed studies using a compliance-enhancing electronic diary system.<sup>21–24</sup>

The unique IPD used by Stone and colleagues allowed for an objective assessment of paper diary compliance for the first time. The compliance findings from this study showed that subjects were very noncompliant with the protocol when using paper diaries. Further, it demonstrated that subjects often fake compliance using paper diaries, giving the false impression of good compliance. In contrast, the ED system delivered very high rates of compliance, demonstrating that the poor compli-



**Figure 3.** Subjects' ratings of the paper and electronic subject experience diaries.

ance seen in the paper diary group was not a function of the study population.

It is easy to be noncompliant with the timely completion of paper diary entries. Without cues to structure subjects' behavior and incentives to establish, reward, and maintain it, compliance with any paper diary is likely to be very poor. The findings from this study raise serious doubts about the veracity of data collected using paper diaries in clinical research.<sup>18</sup> In contrast, high rates of subject compliance can be achieved through a combination of proven scientific principles and robust technology.<sup>9</sup>

### Subjects' evaluations of paper and electronic diaries

The compliance data from this study demonstrates the ability of a science-based electronic diary to provide reliable, real-time diary data. However, some people have had concerns about the acceptability and ease of use of electronic diaries. To examine this question, Stone and colleagues asked the IPD and ED subjects to evaluate their diary at the end of their three-week monitoring protocol.

During their final site visit, subjects completed a questionnaire evaluating the diary (see Table 1). Subjects also could provide open-ended written responses to questions asking what they liked and disliked the most about their diary, and how the diary could be improved.

### Subjects using the electronic diaries rated them as just as easy to use, read, and carry with them as the paper diaries.

As shown in Figure 3, subjects found the electronic diary as easy to use as a paper diary. No significant differences were found between the diaries in terms of ease of use, convenience, legibility, and so on.

In the open-ended responses, 43% of ED subjects explicitly noted that the electronic diary was easy to use. For example, one subject wrote, "Very easy to use, because of problems with my hands, sometimes it's hard to write, with ED just touch and go. Simple." Aspects of the electronic diary that subjects disliked included a variety of comments related to the compliance features used to drive compliance to the protocol (such as programmed reminder beeps). In sum, the open-ended responses from the ED subjects reflected that they found the electronic diaries easy to use and that adhering to the protocol meant completing real-time assessments of their pain, which was not always convenient.

Subjects in the IPD group liked that the paper diaries were portable and easy to use. Twenty-five percent of IPD subjects reported that they found "nothing" to dislike about the paper diary. In sum, subjects using the paper diary found it easy to use, and many found very little that could be improved. This helps to confirm that the paper diary was made adequately portable and easy to use. No subjects using the IPD used the open-ended questions to note that they had exaggerated compliance to the protocol.

These findings are consistent with what has generally been

found when investigators have compared response to paper and electronic diaries.<sup>25,26</sup> For example, Rabin and colleagues<sup>27</sup> explored subject preference for electronic diaries relative to paper diaries after allowing urinary incontinence subjects to self-monitor with each type of diary for one week. Over 98% of their subjects and over 80% of their control group explicitly expressed preference for the electronic diary over the paper diary.

## Summary

Our review of the data and the results from our recent study suggest a sobering conclusion. Data from subjects using instrumented paper diaries that recorded their actual compliance with the protocol confirmed long-held suspicions regarding the veracity of paper diary data. Subjects falsified a majority of their paper diary entries, keeping missed diary cards and back-filling them after the fact. In contrast, subjects assigned to use a science-based electronic diary were highly compliant with the protocol, replicating compliance results obtained in a variety of electronic diary studies.<sup>21-24</sup> Subjects using the electronic diaries in this study rated them as just as easy to use, read, and carry with them as the paper diaries.

Limitations of this study include the fact that only subjects with chronic pain were studied. The empirical literature on subject compliance does not suggest that compliance varies according to the therapeutic category being studied,<sup>28</sup> but this single study cannot rule out that other subjects might demonstrate a different pattern of compliance. More broadly, there is a research-infrastructure burden attendant on conducting electronic diary studies. It is clear that technology alone is insufficient to obtain high rates of subject compliance with the protocol. For example, several studies that did not adequately address the user interface and other programming issues saw high rates of technical failure and patient noncompliance.<sup>29,30</sup>

Given the importance of diary data in many clinical trials, researchers need to capture diary data in a way that is known to be reliable, and to feel comfortable asserting to the reviewing regulatory agencies that the data are timely and valid. A large body of peer-reviewed literature, including data reviewed in this article, confirms that, unlike paper diaries, science-based electronic diaries can be used to collect reliable diary data in the real world, in real time.<sup>22-25</sup>

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