

Maintenance of Subject Adherence to Daily Diary Entry Facilitated by use of a Mobile Application in the WEPOD Study

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Rationale

Clinical trials in epilepsy historically depended on paper diaries for reporting seizures and adverse events. Since written diary entries can be made at any time between study visits, paper diaries cannot assess the time interval between clinical event occurrence and the diary documentation, or if there is evidence of data entry fatigue. Electronic diaries may facilitate reporting by subjects and enable monitoring of the interval from occurrence of event to entry time as a marker of validity and accuracy. Electronic reporting also allows for constant monitoring of adherence, which can be particularly important in long-term clinical trials.

The WEPOD (Women with Epilepsy: Pregnancy Outcomes and Deliveries) study is a 3-site prospective, observational study evaluating fertility in women with epilepsy (WWE) and healthy controls (HC) as they transition from preconception planning through pregnancy and delivery. This interim analysis assessed subjects' use of an electronic diary and whether data entry fatigue occurred over the course of subject participation in the fertility phase, which could be up to one year.

Methods

Women with epilepsy and healthy controls, ages 18-40 years, seeking pregnancy are enrolled within 6 months of stopping birth control. IRB approval was obtained at all sites. We developed a customized mobile Application (the WEPOD App™) for daily data tracking. The WEPOD App™ is connected to a web-based program that allows for data entry and provides central data monitoring. Subjects were given a 4th generation iPod Touch, which they could also use with the web-based program, or choose to use a paper diary. Subjects recorded menstrual bleeding and sexual activity daily (fertility diary). WWE also tracked seizure occurrence and medication compliance; they were instructed to track anti-epileptic drugs (AEDs), but tracking other medications was optional. The WEPOD App™ includes a "pop-up" reminder asking the subject to make their daily diary entry. Subjects track fertility data daily until conception or until 12 months elapses, creating a potentially long duration for study participation.

Figure 1: WEPOD application

Epilepsy Group Diary
Menses
Sexual Activity
Seizures
Medications
Mood (optional)



Control Group Diary
Menses
Sexual Activity

Both groups have a daily reminder to use application

Results

Demographics: 119 participants were enrolled by May 01, 2012. Eight WWE and six controls have withdrawn from the study. All subjects used the WEPOD app and/or the web; no subjects chose paper diaries. Demographics for all participants are listed in Table 1.

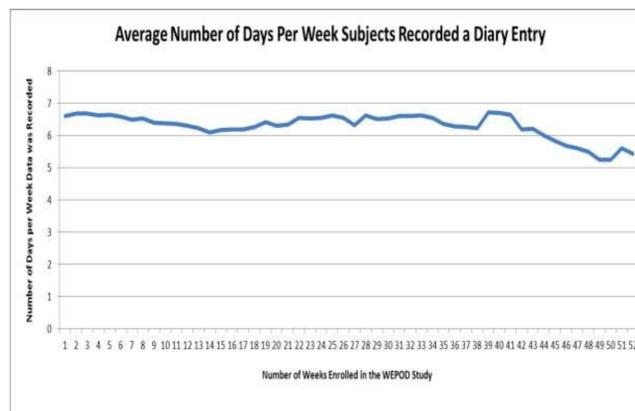
Table 1: Demographic characteristics of participants in the WEPOD study

	Total Subjects (n=119) % (n); mean ± std dev
Age (years)	31.3± 5.1
Race	
American Indian or Alaska native	0.84 (1)
Asian	14.29 (17)
African American/ Black	14.29 (17)
White	65.55 (78)
Other/ Mixed	5.04 (6)
Ethnicity	
Hispanic or Latino	13.45 (16)
Not Hispanic or Latino	86.55 (103)
Education	
High School	8.40 (10)
Some College	10.08 (12)
Associate's Degree	5.88 (7)
Bachelor's Degree	36.13 (43)
Advanced Degree	38.66 (46)
Missing	0.84 (1)
Employment	
Student	7.56 (9)
Unemployed	17.65 (21)
Part-time	10.92 (13)
Full time	62.18 (74)
Missing	1.68 (2)

Fertility diary entry:

- Total number of days fertility data provided was 17,191.
- Average number of days fertility data was entered was 145.6± 111.9 (range 0-365).
- Average completion of the fertility diary was 90% + 0.21 (minimum 0%).
- Average number of days per week a fertility diary entry was made: 6.30.

Figure 2: Average number of days per week subjects recorded fertility data

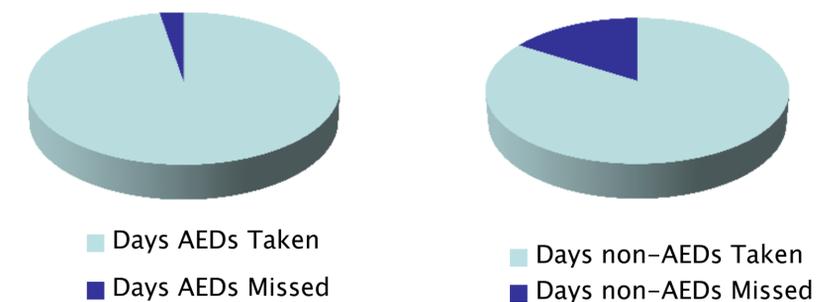


Results

Medication adherence in WWE:

- Among 46 WWE who were enrolled, the total number of days possible for tracking AED dosing information was 9212. No medication data was recorded on 349 days. Subjects indicated that at least one dose of AED was missed on 237 days.
- Of the 46 WWE, 20 also tracked non-AED medication use (medications largely consisted of folic acid and other vitamins). They collectively tracked a total of 4109 days, and there were 658 days on which subjects indicated missed doses of non-AED medications.
- Percentage of days that AED data was logged is 96.2%.
- Overall AED medication adherence rate was 97.4%.
- Non-AED medication adherence rate was 84.0%.

Figure 3: Proportion of days on which doses were missed (AEDs and non-AEDs)



Conclusions

- Subjects preferred an electronic diary for fertility and AED data in the WEPOD study.
- Adherence with fertility diary use was high and stable over time without showing signs of substantial diary entry fatigue.
 - A slight reduction in mean number of days diary data was recorded did appear after 44 weeks in the 20 subjects still in the fertility phase.
- AED adherence was excellent among WWE in the WEPOD study.
- Patients were more adherent with AEDs than with non-AEDs such as folic acid or prenatal vitamins.
- Electronic diary use as a data capture tool has the potential to be used across different disease populations and clinical trials.

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