

Monitoring Medication Adherence Electronically: Considerations and a Case Study

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Overview

- Maximizing treatment exposure critical to understanding impact of treatment
- Monitoring adherence in a clinical trial setting is common but can be challenging
- Currently no industry standard for this process
- Common practices include research staff performing a pill count and participant self-report
- New technologies have been developed allowing for electronic monitoring, which provides a more accurate accounting of adherence

Electronic Monitoring of Medication Adherence

- Examples of methods include eCaps, electronic blisterpacks, multicompartment smart pill boxes, digital swallow pills, and dose text or video submission from the participant to the research staff



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Considerations For Device Selection

- Cost
- Portability
- Durability
- Ability to label per regulations
- Ease of use for the research staff and participant
- User-friendly software to transfer data
- Ability to provide participant feedback
- Lead time for filling the device with drug
- Participant privacy

Factors For Device Selection in a Trial Centrally Coordinated By a Data Center

- **Availability of technical support**
- **Structure and content of the output data set**
- **Ease of data retrieval**
- **Ease of integration with an electronic data capture system (EDC)**
- **Storage of video/text files**

Benefits

- Immediate feedback to participant
- Some systems are capable of sending text reminders to increase adherence
- Higher compliance because participant knows his actions are tracked and receives immediate positive feedback (or additional compensation) from study staff

Risks

- **Expensive, particularly for a population expected to need replacement devices**
- **Can be bulky to carry back and forth to clinic/pharmacy for refill**
- **An accurate accounting of number of bottle openings, which doesn't necessarily correlate with taking the pill**
- **If a circumstance arises where it would be acceptable to manually update data, system may not be able to accommodate**

NIDA Clinical Trials Network

- **Clinical Trials Network (CTN) of the National Institute on Drug Abuse (NIDA)**
- **Multi-site, multi-protocol network designed to study pharmacological and behavioral interventions for the treatment of substance use disorders in community treatment programs**
- **The EMMES Corporation has a contract to serve as the Data and Statistics Center (DSC) for the network**

NIDA CTN-0052 Case Study

Randomized Controlled Evaluation of Bupirone for Relapse-Prevention in Adults with Cocaine Dependence

Medication Adherence Measures

Participant report	Daily records of milligrams of bupirone taken based on self report
Pill count	Tabulations of total pills taken calculated by site staff counting pills dispensed, returned and lost at every study visit
eCAP	Electronic monitoring of whether pill bottle opened twice per day – 6am to noon and 6pm to midnight
Urine positive for 1-PP	Urine sample sent to central lab <u>once per week</u> to measure bupirone (or metabolite)

eCAP

- Basis for contingency management
- Allows electronic storage of time at each bottle opening



eCap

- The eCap was selected for use in this trial because:
 - Time zone of tech support (Canada vs. Switzerland)
 - Cost: **\$70/cap** + \$316/site for the cap reader vs. **\$115/cap** + \$339/site for cap reader and software
 - Child-resistant cap, fits standard, cheap bottle
 - 21CFRpart11 system – no staff input possible
 - Data easy exportable to our electronic data capture system



eCAP Issues Reported

- Software was desktop (not web-based), which lead to problems saving, retrieving, and corrupting files, in addition to concern over lack of a backup.
- Software had a high learning curve for research staff, which resulted in a significant number of wasted caps
- Site assigned cap to wrong participant
- A participant in jail and had his friend open eCap so he could continue receiving money for adherence
- A participant's boyfriend stepped on a cap and broke it
- Similar number of issues at the end of the trial as in the beginning

Conclusions

- High correlation between all 4 measures of adherence
- Suggest only one measure of adherence is needed
- Still no “gold standard” for all trials
- Weighing the pros and cons of each device, determine the best measure based on the need’s of the trial

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