



eMedonline Medication Management System for Clinical Trials

Grant Number: HHSN261200644005C

Abbreviated Abstract

The National Cancer Institute and the Clinical Center at NIH recognize the need for technologies that support clinical trials. A study of the “state of the science” revealed that cancer centers need systems that automate data collection for the benefit of clinical and research staff. Poor patient compliance with drug regimens in clinical trials can make it difficult to detect the therapeutic effect of drugs that have potential benefit to patients, and can affect the ability to make a rational clinical decision about further therapy. Systems that cost-effectively and accurately track dosing times and missed doses, and that eliminate costly uncertainty and the need for data entry from patient diaries are needed. This contract resulted in the development of a medication management system that integrates health and behavioral informatics, cell phone technology, and radiofrequency identification (RFID) to improve compliance among patients participating in clinical trials. Phase I feasibility and functional tests of such a system in a sample of drug clinical trial patients demonstrated that compliance-related data can be accurately collected, analyzed, and exported for use in other clinical monitoring systems. Furthermore, patient acceptance and value of such a system is high. Phase II assesses the overall acceptability and feasibility of the approach in a larger sample of clinical trial patients. Compliance and patient satisfaction will be evaluated.

Primary Investigator

Barbara A. Rapchak, B.S.
Leap of Faith Technologies, Inc.
23 Brink Street
Crystal Lake, IL 60014
(815) 356-1767
Fax: (815) 356-1780
brapchak@leapoffaith.com
Company Web Site: www.leapoffaith.com
Product Web Site: www.emedonline.com

Research Team & Affiliations

Leap of Faith Technologies, Inc.:

Barbara Rapchak, PI
James Hopkinson, Ph.D., Senior Computer Scientist

Consultants:

Robert Wehbie, M.D., Oncology & Infectious Diseases, Cancer Centers of North Carolina & the U. of North Carolina
Robert Grammling M. D., University of Rochester School of Medicine and Dentistry



Total Budget

\$983,593

Research Objectives

AIMS

- 1) Develop a pre-production prototype of the eMedonline system to enhance medication compliance for patients and facilitate data collection and record keeping for research staff.
- 2) Assess the acceptability of the system among patients and research staff.
- 3) Evaluate effects on medication compliance and self-efficacy.

Theory/Hypothesis

- 1) We hypothesize that subjects in the test group who use eMedonline will report better self efficacy relative to managing their medications as compared to subjects in the control group.
- 2) We hypothesize that the eMedonline system will have a positive effect on medication compliance for subjects in the test group as compared to subjects in the control group.

Experimental Design

Leap of Faith Technologies is conducting the Phase II study jointly with the Radiation Therapy Oncology Group (RTOG) in a controlled pilot at multiple sites. This is a randomized, controlled study with a crossover design. Patients are randomized to one of two groups: use pill counts (control condition) for 1 month, followed by 1 month of the eMedonline system plus pill counts (test condition), or vice versa. Order is randomly assigned.

Final Sample Size & Study Demographics

Subjects are randomized to, and expected to complete treatment on, one of the concurrent temozolomide/radiotherapy arms of RTOG 0834 (i.e., Group 2 or Group 4). N = 26

Data Collection Methods

Data collection is by means of survey instruments, and by the telehealth device (smartphone). The following data is collected via the telehealth device:

- Medication Time — date and time when the patient scans the medication in preparation for taking it
- Compliance Time — the difference between the patient's scheduled time and that the actual time that he/she scanned the medication
- e-Diary — report of compliance, general well-being, coping, and specific side effects.

Outcome Measures

Primary Endpoints

- 1) To determine whether the eMedonline medication management system has a positive effect on medication compliance as measured by data collected from pill counts.
- 2) To compare measures of medication compliance using the telehealth device and eMedonline system vs pill counts.
- 3) To evaluate changes in measures of self-efficacy in one's capacity to comply with the medication regimen and health-related functioning.

Secondary Endpoints



- 1) To assess the overall acceptability of eMedonline among patients as measured by the User Experience Survey.

Evaluation Methods

Compliance

Given the randomized design for this study, we will assume that base rates of compliance will be similar across study groups (~68%) as defined by the proportion of the group taking 100% of the prescribed doses.⁴ Our main study outcome will be the compliance at follow-up as measured by pill counts in both groups. Our main objective for this measure is to estimate the potential effect size. We will follow an intention-to-treat paradigm for all analyses.

Given 13 subjects per randomized arm of this study, we would need to observe an average of 96.5% of doses taken in the intervention group to obtain 80% power with an alpha of 0.05. This is based upon the following assumptions: mean of 85% of doses taken in the control arm, standard deviation of 10 in both groups, normal distribution of the doses taken. This is based upon a 2 sample, 2-sided t-test for equality of means.

Self-efficacy

Self-efficacy, or confidence, is a major predictor of habitual health behavior. We are assessing self-efficacy via 2 items (convenience and capacity to comply with medication regimens). Each item is reported on a 5-point ordinal scale (0-4). Global self-efficacy will be the additive sum of responses, with a potential range of 0 to 8. We consider a 2-point improvement in global self-efficacy to represent a clinically relevant difference. We will evaluate the proportion of participants reporting an improvement in self-efficacy within each study group. Difference in proportion will be determined by standard chi-square analyses.

Research Results

Phase I

- Patients responded positively to their experience with the system, finding it to be easy to use, helpful in understanding what medications they were taking and why they were taking them, and would recommend eMedonline to others.
- The medication compliance rate was 96% as calculated using data collected from the eMedonline device.
- The compliance rate was corroborated by self-report data from e-Diary entries.
- Compliance was timely. 91% of the patients confirmed that they had the medication in hand within five minutes of the scheduled time.
- e-Diary compliance was 100% and timely. Diary entries were made within two minutes of the e-Diary prompt 96% of the time.

Phase II

eMedonline was validated in usability testing at NCI's User-Centered Informatics Research Lab. Clinical trial patients and clinical trial coordinators were recruited to use and evaluate the eMedonline system. Patients reported that the technology makes them feel more confident that they will be able to manage their medications. They said that the system was reassuring, kept them aware and in touch, and prevented them from disregarding important



symptoms. Clinicians participating in the testing also gave the technology high marks. It was credited with being “a great boon for the research nurse or clinical trial coordinator.”

Usability and workload were evaluated using the System Usability Scale (SUS) and Cooper-Harper Ratin. The technology received optimum scores on both scales, indicating high usability and minimal workload. SUS scores range from 0-100, with 100 indicating optimal usability. eMedonline had a mean SUS score of 84.7. Cooper-Harper values range from 1-10, with 10 indicating minimal perceived mental workload. eMedonline had a mean score of 9.4.

The RTOG trial is ongoing.

Barriers & Solutions

A key criterion in the software design and system architecture was that it had to be able to accommodate ever-evolving cell phone and RFID hardware, as well as other platforms. By implementing a very careful, thorough, iterative design and review process, by engaging end users and stakeholders early on, and by inventing new paradigms to describe the way people live with technology relative to prescribed therapies, we were able to achieve this.

Product(s) Developed from This Research

eMedonline