Lessons Learned in the Early Phase of the MI-HEART Clinical Trial

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Objective. To provide guidelines for enhancing the patient accrual process in clinical trials using community-based Web-based Information Technology (WebIT).

Background and Significance. Previous IT-administered education studies have been conducted in controlled environments: the computers are usually 1) supplied to the patients[1], 2) in an setting where a research facilitator can assist patients using the IT-based education[2,3,4,5] or 3) are supplied by the patient but the software does not feedback measures of efficacy to the investigators[6]. In contrast, the MI-HEART Clinical Trial education is a randomized study that measures the changes in cognitive variables of community-based patients exposed to tailored or non-tailored self-administered Web-based and paper-based education[7]. The education is self-administered, without assistance, using patient's accessible WebIT, at non-controlled times and locations. The MI-HEART System feeds back process and efficacy measurements to the investigators. 62 patients have applied to join the MI-HEART clinical trial, 19 of which have already completed the pre-intervention cognitive test.

Content Covered. 1) The presentation will first address the **barriers to recruitment** and the observed patient accrual rates resulting from several patient enrollment strategies covering a period of eight months will be presented. 2) The **lessons learned** from interesting and unexpected preliminary demographics, process variables and findings will also be presented **to foster enhanced recruitment strategies for clinical studies involving WebIT**.

Enrollment Strategies.

1) Direct patients solicitation
2) Repetitive brochure distribution in clinics
3) Patients Educational Events
4) Public Announcements
5) National and International Recruitment
   a) Internet Interest Group
   b) Electronic Medical Record –Based Qualification
   c) Personal Contact with Peers

Some Lessons Learned. (1/2)

1) Self-enrollment of patients that are required to use WebIT may favor a subset of wealthy, knowledgeable and self-efficacious individuals with a low belief in treatment efficacy. This group may only portray a subset of the assortment of health education needs of a non-biased patient population. (figure 1, table 1).
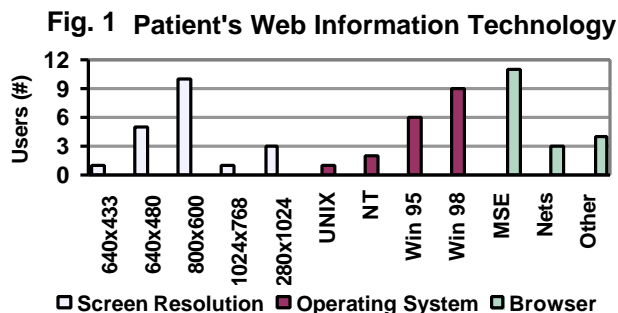
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Fig. 1 Patient's Web Information Technology

Table 1 – Preliminary Findings Baseline Questionnaire (n=19)

Measured Cognitive States	Linkert Scale (min. to max. score)	Score of the answer ranked at the specified quartile		
		25%	50%	75%
Knowledge	0 to 1	1	1	1
Emotional Awareness	1 to 6	6	6	6
Perceived Threat	1 to 5	4	4	5
Treatment Efficacy Beliefs	1 to 10	1	1	1
Self-Efficacy	1 to 10	6	8	10
Response-Efficacy	1 to 10	6	8	9

Some Lessons Learned. (2/2)

2) Supervised or assisted kiosk-based education may provide an opportunity to reach the non-users or novice users of WebIT.

References

1. Brennan PF, Caldwell B, Moore SM, et al. Designing HeartCare: custom computerized home care for patients recovering from CABG surgery. JAMIA Suppl. 1998:381-5.

2. Helwig AL, et al. . An office-based Internet patient education system: a pilot study. J Fam Pract 1999 48(2):123-7.

3. Henderson J, Noel J, Reeves T, et al. Developers and Evaluation of Interactive Health Communication Applications. *Am J Prev Med* 1999;16(1):30-42.

4. Shegog R, Bartholomew LK, Parcel GS, et al. Asthma Self-management Behavior. JAMIA 2001;8:49-61.

5. Lehmann ED. Interactive educational diabetes simulators: future possibilities. Diabetes, Nutrition & Metabolism - Clinical & Experimental 1999; 12(6):380-7.

6. Kukafka R[§], Lussier YA[§], Cimino JJ: "Modeling Patient Response to Acute Myocardial Infarction: Implications for a Tailored Technology-Based Program to Reduce Patient Delay". *JAMIA suppl.* 1999:570-5.

7. Scherrer-Bannerman A, Fofonoff D, Minshall D,et al. Webbased education and support for patients on the cardiac surger waiting list J of Telemed&Telecare 2000;6 Suppl2:S72-4.