Designing Study Nurses’ Training to Enhance Research Integrity:
A Macroergonomic Approach

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Successful field evaluation of informatics initiatives designed to create technology-enhanced professional practice relies on adequate training of experimental participants. However, such training presents design, implementation and evaluation challenges. A macroergonomic approach, focusing on an organizational view of people, technology, task and environment interactions in work systems, provides a framework for training that allows anticipation and compensation for challenges. In the HeartCare II project, we developed a multi-level training program for nurses and patients enrolled in a field trial of an innovative technology-enhanced professional practice model. Using a macroergonomic approach, we designed three waves of training and assessment centered on a train-the-trainer model. Despite planning, a drop-off occurred between training waves, affecting both recruitment and patient training. Evaluation identified people, task, technology, and organizational concerns. Strategies to increase nurse buy-in and improve technical performance are making a difference. Organizational challenges remain the most intractable.

Introduction

Testing innovative interventions through clinical field trials improves analysis of their effectiveness in real world settings, but presents numerous implementation challenges, including ensuring intervention implementation follows study protocol (1). Complex interventions, such as those involving practice changes, add another level of challenge since they require providers to make decisions during implementation which must be based on a clear understanding of the intervention and study. To ensure research integrity, treatment fidelity practices that enhance reliability and validity of interventions should be incorporated into study design (2). One of these practices is training intervention providers. In healthcare clinical field trials, providers are site personnel such as staff nurses. They need excellent initial training and ongoing support. This requires careful attention to a well-planned training design, delivery and evaluation process. The best way to develop and implement training for field evaluation studies remains unclear, however, suggestions range from standardized approaches (2) to theory-driven ones (1). This paper presents a training model, built on macroergonomic theory, which focuses on an organizational view of people, technology, and environment interactions in work systems. The model facilitates anticipating and addressing implementation challenges (3). Results from applying this model to study nurse and patient participants’ training in a large academic-clinical collaborative field trial (HeartCare II) are shared and discussed.

Background

HeartCare II Project:
The HeartCare II project is a collaboration between an academic nursing informatics research team and a home care nursing service to design and deploy a web-based resource to support an innovative nursing practice model, Technology Enhanced Practice (TEP). TEP provides a means to close a gap among consumer health informatics tools, evidence based nursing practice, and home health nursing practice (4). TEP allows nurses to balance interpersonal and technologically-mediated interventions in care of patients with heart disease, thus maximizing their time and effectiveness while supporting patient’s self-management efforts. This multiyear project, conducted within a large integrated health care delivery network in Wisconsin, will involve approximately 30 nursing care delivery teams and 400 patients. The first phase of the study, the design phase, applied human factors techniques to analyze work of home care nurses. It resulted in development of the technology core for TEP, the HeartCare web site, which is housed within the clinical partner’s clinical information system. The second phase of the ongoing study, initiated in September 2005, implements TEP in a randomized field experiment that will examine its impact on nurses’ workflow and patient outcomes including clinical status, quality of life, self-monitoring, satisfaction with care, and health care service utilization (5).
TEP’s technology core, the HeartCare website, is an innovative resource designed to provide services for both nurses and patients within the context of a formal home care nursing delivery system. Nurses use professional judgment to plan individualized TEP for each patient based on their skills, preferences and assessment of patient needs. The actual delivery (e.g., type of service, frequency, and duration) of the TEP may vary within individual nurses between patients, and among nurses due to differences in patients’ needs and nurses’ levels of clinical expertise, preferences, and experience with technology. The HeartCare website provides a standard suite of technology services that will be utilized in different ways to meet specific needs of nurses and patients across time (5).

Treatment Fidelity and Training Approaches
Treatment fidelity refers to methodological strategies used to ensure valid and reliable tests of clinical interventions; recommendations cover study design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills (2). Recommended training strategies include standardization and assurance of intervention provider’s skills acquisition through use of standardized training manuals, videotaping, and measurement of adherence to training protocols, among others (2). Leventhal (6) and Sidani (1) note that these approaches work better in randomized controlled clinical trials than in field trials of intervention effectiveness conducted in natural clinical environments where intervention providers must exercise judgment regarding intervention application across differing patients and contexts. In these more complex settings, they suggest that a theory-based approach to training and intervention implementation offers a better, more realistic test of the intervention’s effectiveness. They stress that the underlying theory comes from the project’s conceptual framework and must be clearly understood by providers to ensure integrity. In the HeartCare II project, macroergonomic theory is an essential part of the study’s conceptual framework and guided the initial design phase of study, thus it supports training for the implementation phase.

A Macroergonomic Approach to Training
A part of human factors, macroergonomics is a top-down sociotechnical systems approach that focuses on the human-organizational interface to design work systems compatible with workers’ psychosocial and skill characteristics (3). A macroergonomic model, the Balance Model, (7) provided a framework for design and implementation planning of the technology core of the HeartCare II project and a theoretical base for the training plan. The model identifies five interactive components of the work system: 1) the individual; 2) tasks; 3) technologies and tools; 4) environment; and 5) organization. An individual uses technologies and tools to accomplish tasks in a local work environment situated within larger organizational systems. Each of the five components has positive and negative elements which interact to synergistically affect individual and organizational functioning and work. Describing the HeartCare II project from a Balance Model perspective, homecare nurses and patients selectively use computer technology and tools found on the study website to perform the task of home management for patients with heart disease. This work occurs in many local environments (patients’ homes) and organizational systems (multiple VNA site offices, Visiting Nurses’ Association organization, and its parent healthcare organization).

Macroergonomics specifies a theoretical basis that can guide training strategy and allow problem anticipation. Robertson (3) developed a training program based on macroergonomic elements. Key training components are: 1) creating a responsive organizational environment; 2) supporting active participation; 3) developing active learning experiences; 4) supporting continuous learning and improvement; 5) providing continuous feedback; 6) ensuring senior management support and commitment; 7) training supervisors and middle managers; and 8) using an instructional systems design approach. We used this training approach in the implementation phase of HeartCare II, capitalizing on several elements initiated in the design phase, including top management commitment and study nurse engagement through active participation in intervention design. We report on lessons learned in planning, delivering, evaluating and troubleshooting study participant training in the HeartCare II project.

Methods
Training Plan and Implementation
Table 1 maps theory-based training elements to phases of the training plan. The training sessions began with the clinical team PI’s presenting an overview of the study at each site, demonstrating senior management support and providing an opportunity for general questions.

We developed a three stage training plan, based on a train-the-trainer model. In the first wave, research team nurses taught mentors (care managers and staff nurse volunteers) methods for training and encouraging study nurses. Mentors then trained study nurses in the second wave, and study nurses trained
homebound patients to use the HeartCare web resources in the third wave. The training plan placed mentors in a central role in which they enabled, empowered, and encouraged home care nurses to use TEP. Mentors and home care nurses had the opportunity to interact regularly within their shared office settings, both formally (through scheduled care meetings) and informally, allowing discussion and reinforcement of the study. This training strategy aimed to increase nurse engagement through active participation and provide opportunity for continuous learning and feedback.

<table>
<thead>
<tr>
<th>Phases</th>
<th>Macroergonomic Training Component (3)</th>
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<tbody>
<tr>
<td>Study Overview</td>
<td>- Ensuring senior management support and commitment</td>
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<tr>
<td></td>
<td>- Training supervisors and middle managers;</td>
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<tr>
<td>Training</td>
<td>- Supporting active participation</td>
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<tr>
<td>Delivery:</td>
<td>- Developing active learning experiences</td>
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<tr>
<td>First wave</td>
<td>- Supporting continuous learning and improvement</td>
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<tr>
<td>Second wave</td>
<td>- Training supervisors and middle managers (some served as mentors)</td>
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<tr>
<td>Third wave</td>
<td>- Using an instructional systems design approach.</td>
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<tr>
<td>Training</td>
<td>- Supporting continuous learning and improvement</td>
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<td>evaluations</td>
<td>- Creating a responsive organizational environment</td>
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<tr>
<td>Ongoing</td>
<td>- Supporting continuous learning and improvement</td>
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<tr>
<td>training</td>
<td>- Providing continuous feedback</td>
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<td>support plan</td>
<td>- Creating a responsive organizational environment</td>
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Using an instructional systems design approach, objectives and content developed for each training wave increased focus and consistency. Training methods emphasized active participation and learning. First wave training included a PowerPoint presentation of the study purpose, protocol, participant roles, intervention (TEP concept and website tools demonstrated by screen capture videos), 2nd and 3rd wave training outlines, tips on teaching elders and practice teaching scenarios. Anticipating a degree of staff turnover and the need for periodic retraining, mentors received a packet of training materials including a handout of presentation slides, a pocket guide to the website tools, a guide mapping website tools to the agency’s home visit guidelines, nurse and patient training outlines, patient care scenarios illustrating use of the website tools during several home visits, and a CD with narrated webcam demonstrations of the website tools. Second wave training was hands-on active learning, with mentors guiding nurses in website use and reviewing patient care scenarios, pocket guide and teaching tips. Nurses and patients use the patient’s computer in their home during 3rd wave training, which could occur over several home visits at the nurse’s discretion. Patients receive a written manual and pocket guide describing website access and use. Training materials at all stages reinforced continuous learning. First wave training was completed during three sessions in July and August 2005. Second wave training was targeted for completion by October 15, 2005 but extended through February 2006. Third wave training is ongoing.

Evaluation tools created for each of the three training waves provided feedback for continuous training improvement. Brief survey tools, administered at the end of each training session, consisted of close-ended Likert scale and open-ended items. The first wave training evaluation assessed mentors’ immediate reactions to the training session: perceptions of the training’s usefulness in understanding their role and teaching activities. Second wave evaluation tools assessed learning: mentors evaluated their training preparation after training home care nurses. Third wave surveys assessed training performance; home care nurses evaluated their satisfaction with training preparation after patient training. The research team trainers used 1st and 2nd wave evaluation findings to improve subsequent mentor training. Mentors received 3rd wave evaluation results and used them to improve their nurse training sessions.

An ongoing support plan designed to ensure momentum builds on existing organizational structures and includes internal and external motivators. Regular monthly care meeting discussions allow active participation and continuous feedback and support through study updates, identifying potential patients, training tips and sharing experiences (success stories and problems). Organizational newsletters feature study updates and successes. The parent healthcare organization’s patient web portal hosts the HeartCare website and help desk staff offer support. Leveraging existing organizational structures helps ensure the study’s ongoing visibility, support and sustainability and demonstrates administrative commitment. Internal and external motivators enhance nurse and patient participation and reinforce active participation through recognition and reward. Nurses received HeartCare caps and lapel pins. Certificates awarded after training recognized nurses’ participation. Sharing success stories and problems at staff meetings highlight individual effort and allow brainstorming. Easy access to patient support materials (either online or print) and online access to
home visit guidelines can enhance nurses’ ability to provide care grounded in best practices. Patient participant motivators included access to self-management resources at any time and a monetary compensation at the end of the study.

Study Nurses Demographics. Approximately 30 registered nurses staff the experimental offices in the HeartCare study. The majority are females; the average age is 43 years old (range approximately 24-60). Racial composition is predominantly Caucasian, with very few African-American, or Hispanic nurses.

Results and Discussion
Despite careful planning, a drop-off occurred between the first and second training waves, which affected recruitment, patient training and intervention implementation. Mentors gave positive feedback after the first training wave, but many delayed starting second wave training. We visited study sites and spoke with mentors and study nurses to identify training implementation barriers. Using the macroergonomics framework, we looked for challenges within each of the elements of the study nurse work system and identified concerns with organizational environment, technology, task and people elements. Challenges and strategies developed to address them are discussed by element.

Organizational environment
The home care nurse teams and supervisors face heavy patient loads and tight schedules. Competing demands for staff time and fluctuations in structure of the clinical teams decreased participation in the project. Implementation of a new computerized documentation system created additional stress to the clinical system and to the staff. This occurred at the time of orienting staff to the website and study protocol, and necessitated renegotiating the launch date of the experiment. Between first and second wave training, a regulatory agency visit resulted in time spent on training and remediation unrelated to the project. High staff turnover in some offices and slow replacement appointments resulted in nurses shifting between offices to cover case load. In some offices, monthly care meetings were held irregularly. All of this disrupted training progress, increasing time between mentor and home nurse training and decreasing opportunities for ongoing support. At the broader organizational level, upper administration turnover resulted in a new administrator who knew little about the study. Creating a responsive organizational environment and ensuring senior management support and commitment presented challenges, especially with complexity of multiple environments (home, six offices, parent health care organization, University). The extent of these organizational challenges was unexpected and largely outside the research team’s control. Strategies to address these included frequent meetings, open communication, mutual troubleshooting, and travel to study sites to ensure communication between research and clinical teams. Study PIs and investigators met with the new incoming administrator, and secured his interest and support.

Technology
Website functionality problems (slow connection times, slow page refreshes, broken links) confused and frustrated some patients and their nurses; they thought the website was not working. Installation contractors’ delays in delivering and installing equipment caused delays in training patients and limited the number of home visits when nurses and patients could collaboratively use TEP. We improved functionality by working with the internet access subcontractor to improve connectivity and with the healthcare organization’s IT director on programming revisions to increase speed. A protocol revision allowed patients to use their personal computer and internet link which increased technology comfort. Finally, the research team began testing the website daily to ensure tools and links were active; malfunctions were reported to agency IT.

People and Task:
Despite participation in the TEP design phase, training overview and first wave training, nurses were slow to engage in the study; they did not readily “buy in”. We identified three interrelated contributing factors: a gap between the agency’s standard of care and actual practice; nurses’ lack of comfort with technology; and nurses’ lack of motivation to use TEP. A few months before the study’s design phase began, the homcare agency developed standard of care guidelines for home visits based on best practices for patients with heart failure. The standard of care specifies what nurses should do during each of nine home visits, organized as: assess, medications, instruct, review/recall, other (consults, etc), and homework (patient education readings). The HeartCare technology core tools and resources were designed to enhance nurses’ ability to deliver this standard of care and training emphasized use of the website’s tools for TEP guided by this standard. However, the agency’s quality assurance results for July 2005 – January 2006 indicate that the standard of care is not firmly entrenched in nurses’ daily practice, with 2/3 of the sites showing low compliance rates with standard of care initiation and documentation (40 – 58%) and only one site achieving 85% compliance. Failure to follow the
standard of care diminishes nurses’ realization of the benefit of TEP using the HeartCare website. Many nurses were uncomfortable using computers, despite having a laptop computer and mandated electronic documentation. Some felt uncomfortable teaching patients how to use their computer and website tools, or thought the academic research team nurses did the patient home training. Some nurses may have perceived participation in a research study as additional work rather than as a means to help them work more efficiently, thus decreasing motivation for use. Several perceived its use as a burden to their sick, functionally limited patients. Combinations of these factors led to reluctance or failure of visiting nurses to effectively prepare and inform their patients about the project, or to convey its potential benefits and importance as part of the patient’s care, decreasing recruitment efforts.

Research team efforts to address these challenges are having an impact on study recruitment and training. Increasing communication and visibility of the research team—“Face time”—gives us the opportunity to increase active participation, develop active learning experiences, support learning, reinforce training and provide continuous feedback. One research nurse was designated as the liaison with the home care nursing offices. She communicates weekly with managers and attends monthly meetings at study sites to review study goals, training, TEP, recruitment, explore nurses’ successes and problems and help with retraining efforts. The liaison nurse, home care managers and administrators reinforced the need for nurses to follow standard of care guidelines to reflect best practices and improve patient care. To help nurses explain the study and recruit patients, we developed a flyer containing a brief overview of the study and patient incentives that nurses can give their patients as well as a short script nurses read to potential patient participants to prepare them for a recruitment telephone call. The script is printed on the back of the liaison nurse’s business card. As an added incentive, the clinical partner provides additional pay for home care nurses on initial TEP visits. As a result of these efforts, we have begun seeing more positive responses from nurses who are recommending particular patients to the study coordinator as candidates to participate in the study, positive responses by patients to the suite of electronic resources, and requests from nurses and patients to expand the use of the communication and patient record-keeping tools to allow the patient to share personal health-management records with his or her physician.

**Conclusion**

A macroergonomic approach to training study nurses in a complex multi-site field evaluation of an innovative consumer health informatics intervention proved helpful for training design, implementation and evaluation. This approach provided a means to anticipate challenges, assess root causes of challenges we had not foreseen, and develop compensatory actions. In the HeartCare II project, strategies to increase nurse engagement and improve task performance and technical functionality are making a difference and may be generalizable to other large informatics field trials. Organizational challenges remain more difficult to anticipate or resolve. Working within organizational constraints is challenging but essential to clinical effectiveness research, and presents a rich area for future research.

**References**

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