A Data Management System Integrating Web-based Training and Randomized Trials

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ABSTRACT

This article describes a data management system (DMS) developed to support a large-scale randomized study of an innovative web-course that was designed to improve substance abuse counselors’ knowledge and skills in applying a substance abuse treatment method (i.e., cognitive behavioral therapy; CBT). The randomized trial compared the performance of web-course-trained participants (intervention group) and printed-manual-trained participants (comparison group) to determine the effectiveness of the web-course in teaching CBT skills. A single DMS was needed to support all aspects of the study: web-course delivery and management, as well as randomized trial management. The authors briefly reviewed several other systems that were described as built either to handle randomized trials or to deliver and evaluate web-based training. However, it was clear that these systems fell short of meeting our needs for simultaneous, coordinated management of the web-course and the randomized trial. New England Research Institute’s (NERI) proprietary Advanced Data Entry and Protocol Tracking (ADEPT) system was coupled with the web-programmed course and customized for our purposes. This article highlights the requirements for a DMS that operates at the intersection of web-based course management systems and randomized clinical trial systems, and the extent to which the coupled, customized ADEPT satisfied those requirements. Recommendations are included for institutions and individuals considering conducting randomized trials and web-based training programs, and seeking a DMS that can meet similar requirements.

Keywords
Data management system, Web-based training, Randomized trials, Systems development, Systems requirements

Introduction

The World Wide Web makes interactive web courses available to anyone with a computer and Internet connection. Businesses, universities, non-profit organizations, health plans and governmental organizations favor such courses because this type of instruction provides access to cutting edge knowledge, transcends state and national boundaries, and is a means to maintain a trained workforce. Research findings on educational technology show promising results. For example, physicians participating in internet-based continuing medical education had significant knowledge and skill gains comparable or superior to physicians attending in-person workshops (Fordis, King, Ballantyne, Jones, Schneider, et al. 2005). These findings are echoed in a study of interns completing computer-based learning whose knowledge gains were equal to those of interns attending in-person lectures (Davis, Chryssafidou, Zamora, Davies et al., 2007). Computer engineering supervisors’ knowledge of ways to support mental health-troubled subordinates improved following web-based training (Kawakami, Kobayashi, Takao, & Tsutsumi, 2005), as did the knowledge and skills of raters conducting efficacy evaluations in depression studies (Kobak, Engelhardt et al., 2006). Counselors were more able to link clients to 12-Step Programs following web-training (Sholomskas & Carroll, 2006) and web-training was superior to a manual-only approach for educating counselors in cognitive behavioral therapy (CBT) (Sholomskas, Syracuse-Siewert, et al., 2005). Another recent study of CBT showed an increase in substance abuse counselors’ knowledge and confidence in applying this treatment method following completion of a web-course and a small number of weekly supervision meetings (Weingardt, Cucciare, Bellotti, & Lai, 2009). However, findings from studies of on-line courses and e-learning systems (Chan & Robbins, 2006; Weingardt & Villafranca, 2005) show the need to address the “goodness of fit” between the technology and learners’ needs as well as organizational needs.

Our research and training team was faced with such a challenge when we received a five-year grant from the National Institute on Drug Abuse (NIDA) to develop and deliver an innovative web-course to trainees across the country, and conduct a large-scale randomized study of the course’s effectiveness. We designed the multi-module
A DMS was needed to support all aspects of the study: web-course delivery and management, as well as randomized trial management. A review of the literature and exploration of systems in development revealed no system that was appropriate for our needs. We subsequently participated in the development of a system that met most of our needs.

In the following pages, we describe the innovative web-course we developed, the randomized trial that evaluated the effectiveness of the web-course, the other data management systems we reviewed, and the requirements for the DMS needed to support our project as a whole. The major focus is on the requirements for a DMS that operates at the intersection of web course management and randomized trial systems, and the extent to which the system we developed satisfied those requirements. Our goal is to help organizations who seek to do similar research (a) examine the types of systems requirements for such randomized trials, (b) compare their own systems requirements to those of our project, (c) think creatively about how a system can meet their needs or how it must be customized for their particular study, and perhaps, (d) build a system that best fits their needs.

Innovative CBT Web-Course

The authors led the development of a training innovation called Technology to Enhance Addiction Counselor Helping--Cognitive Behavioral Therapy (TEACH-CBT), a web course to improve the knowledge and skills of substance abuse counselors in using cognitive behavioral therapy (CBT). CBT is one of a small number of therapeutic approaches with overwhelming evidence of effectiveness in treating substance abuse problems (Carroll, 1998; Kadden et al., 1992).

TEACH-CBT contains eight instructional modules focusing on the principles and techniques of CBT for treating substance abuse. The modules highlight issues such as using a functional analysis to understand client patterns, behavioral skills training, cognitive skills training, applying CBT to a case, and applying CBT to HIV/AIDS concerns. The curriculum for the e-learning program was developed by project faculty and experts in the areas of CBT and addiction. (A CBT Therapist Manual from NIDA (Carroll, 1998) was used as the outline for content scope.) Curriculum designers developed CBT content that would match desired behaviors in counselor knowledge, attitudes and skills. Specific outcomes to be measured and methods for measuring them were: (a) changes in the counselors’ knowledge, attitudes and confidence, assessed with pre- and post-training and follow-up questionnaires, (b) changes in the counselors’ level of competence in CBT delivery, assessed by independent ratings of audio-taped counseling sessions pre- and post-training, and (c) the counselors’ maintenance of CBT skills at three-month follow-up, assessed by independent ratings of audio-taped counseling sessions.

Randomized Controlled Trial of the TEACH-CBT Web-Course

The study recruited counselor-supervisor teams from addiction treatment programs, requiring one supervisor and two counselors per team plus an agency liaison to support data collection. The randomized controlled trial, which employed a control group design, consisted of 54 treatment program teams (181 participants total: 54 supervisors and 127 counselors) that were randomly assigned to either the web-course or to training with a printed copy of NIDA’s CBT Therapist Manual (Carroll, 1998) to evaluate training effectiveness. Both study arms were offered supervisor training and support to encourage practice of skills developed through training.

As shown in Figure 1, the study proceeded through a number of discrete phases, beginning with announcements and agency recruitment and extending through enrollment, randomization, training participation and data collection and analysis, with management, reporting and monitoring of project activities occurring throughout the project. All human subjects procedures were approved by NERI’s Institutional Review Board and complied with a data safety monitoring plan. Throughout the study, modest payments were made to participants.
To accomplish this work, it was realized that a system would be required that could respond to the multiple needs of the project: (a) Design, develop and deliver an innovative web-course to teach and practice new knowledge and skills, (b) give feedback to web-learners on their mastery of module material, (c) promote communication among web-learners (d) collect and report out data on intervention and study progress, and (e) manage the data collection protocol aspects of the randomized trial.

Other Data Management Systems for Web-Course Functions and Randomized Trials

Data management systems have been developed that facilitate distance-education courses, many web-enabled and others accessed through the web although not web-interactive, and/or assist in evaluating the effectiveness of those courses. Although there are similarities in their functioning, the systems are not interchangeable and they each have their own strengths and limitations. A review of the documentation for these systems revealed large gaps in their capabilities to satisfy the requirements of our project. Our purpose is not to include a detailed comparison of their capabilities to the system we customized (ADEPT) but rather to highlight ways they have been utilized.

Course/Curriculum Focused

Web Course tools (WebCT): WebCT has been used in a number of web-based training studies, including the evaluation of continuing medical education courses (Curran, Lockyer, Sargeant, & Fleet, 2006), a pharmacology course for nursing students (Tse, Pun, & Chan, 2007), a course on postpartum emotional distress for community nurses (Ingadottir & Thome, 2006), a medicine course for preclinical medical students (Srinivasan et al., 2002), a course on self-change and health interventions for physicians (Robinson, Francis, Simpson, & Rutledge, 2006), a mental health course for social workers (Knowles, 2001), and a course on the elderly for health professionals (Juntunen & Heikkinen, 2004). Tools for course management included quizzes, pre- and post-course surveys, bulletin-board postings, and tallies of utilization of other course materials and activities.

ACCESS: ACCESS, used for the National Center for Suicide Prevention Training (NCSPT), monitors training participation by tracking the number and results of learner visits to the NCSPT web site, the number and type of registrants, the number of pre-tests, posttests, and evaluations completed, and comments posted on the web board (Stone et al., 2005).

eMed: A “web-enabled database-driven curriculum management system,” eMed was used to support an undergraduate medicine program and interrelates with WebCT (Watson et al., 2007, p.353). eMed “contains information about the learning content, graduate capabilities that learning activities develop, teaching activities, resources, schedules, assessment types, and assessment records (including peer assessments)… [and] manages information across all years of an educational program (Watson et al., 2007, p.353).”
e-Coach: The MD Health e-Coach was used to support web-based training in self-change for physicians. The goal was to assist physicians in improving their own health by increasing their awareness of psychological aspects of their health and showing them how to use psychological techniques to address health concerns (Robinson et al., 2006). Elements of e-Coach included tracking health related self-assessments, personalized plans for health change, individualized health reports, visits to the site, and email reminders for assessments.

Other curriculum systems include ANGEL (A New Global Environment for Learning), Blackboard, Desire 2 Learn and Sakai (Benjamin, Robbins, & Kung, 2006); E-learning or web-conference companies include Placeware, WebEx, Centra, Interwise, and Hewlett-Packard (Weingardt, 2004, p.318).

In summary these systems fulfill many of the needs for course development, delivery and management, but were not designed to support clinical trials.

Research/Clinical Trials Focused

Several proprietary systems exist to monitor implementation of clinical trials, such as the system described by Unutzer and colleagues (2002) to support a multi-center trial of a disease management program for late-life depression in primary care (Project IMPACT) (Unutzer, Choi, Cook, & Oishi, 2002). Its capacities include a recruitment entry and monitoring system, enrollment and dis-enrollment tracking, and storage of contact information, baseline and follow-up data and laboratory data.

Other systems support multi-site data collection absent a randomized design. PEMS: The Program Evaluation and Monitoring System (PEMS) used for an HIV prevention program “is a national data reporting system that includes a standardized set of HIV prevention data variables, web-based software for data entry and management, data collection and evaluation guidance and training, and software implementation support services” (Thomas et al., 2006, abstract). It is funded by the Centers for Disease Control and Prevention. BioDBx: BioDBx is a database application that manages clinical and epidemiologic data, tracks inventory using a linked barcoding system, and analyzes laboratory operations and test results. (https://biodbx.med.umich.edu/). It is currently being used in a research study examining an internet enhanced cognitive behavioral treatment for patients with fibromyalgia (http://www.averasacredheart.com/amck/research/researchpatients/studyfibromyalgia.aspx).

Other systems that support clinical trials include Clinical Trials Management Application (CTMA; http://www.dbmi.pitt.edu/services/ctma.html) and Velos e-Research.

These systems fulfill many of the requirements for clinical trial management, but offer no capabilities for web-course delivery and management.

We found systems built to handle distance or web-based training programs and accompanying data collection or monitoring, and systems built to handle randomized trials (most built for clinical trials of medications and other medical procedures, so they track issues such as patient morbidity and mortality). We found no system described in the literature or identified through explorations of systems in development at the time our project was initiated that satisfied our unique requirements for both randomized trials management and web-based training and evaluation, and using two separate systems was deemed unworkable given our project goals.

Customized DMS to Meet Project Needs: Study Requirements and System Support

Advanced Data Entry and Protocol Tracking (ADEPT) System

In order to have a system that supported both randomized trials management and web-based training and evaluation, the study staff programmed a web course utilizing HTML and Javascript that interacted with a specialized DMS that utilized the New England Research Institutes (NERI) proprietary Advanced Data Entry and Protocol Tracking (ADEPT) system. All technology elements were designed by NERI’s technology development staff. NERI’s media and e-programs (www.neriscience.com) had already trained medical clinicians on the research aspects of the studies of pain and other symptoms (http://symptomresearch.org/) with an e-book, and provided Continuing Education
Credit-approved ethics training for nurses (i.e., https://www.nursingethicsce.com). ADEPT data management systems are developed and hosted by NERI for clinical trials and registries and can be accessed from anywhere in the world using a standard browser and the Internet (see http://www.NERIScience.org). Current clinical trials and registries include a) Society for Vascular Surgery (SVS) - Vascular Registry, b) Trial of Aldosterone Antagonist Therapy in Adults with Preserved Ejection Fraction Congestive Heart Failure (TOPCAT), c) Hepatitis C Antiviral Long-term Treatment Against Cirrhosis (HALT-C), d) The Pediatric Heart Disease Clinical Research Network (U01HL68270).

ADEPT was customized to integrate the functions of course management and data collection for this randomized controlled trial. (Use of the term ADEPT here means ADEPT plus customized elements). The software design is multi-tiered, and utilizes Oracle 8 database servers and Microsoft IIS 4.0 Web servers. ADEPT employs secure access via assigned user names and passwords, and is monitored and restricted using a firewall. All communication is encrypted using secure socket layer protocols. Routine web-page technology was employed for user interfaces.

Figure 2 illustrates the overall project technology structure and the interfaces between the participating community agencies, NERI, ADEPT and the Worldwide Web. The primary NERI and participating agency functions are also shown.

In the following figures, we identify the system requirements at each study phase (what the study needed), then describe how ADEPT satisfied those requirements (how the need was fulfilled). Except for those noted as performed manually, all requirements were implemented in ADEPT and all were evaluated as equally critical.

**Systems Requirements at Each Project Phase**

*Agency Recruitment:* Figure 3 illustrates the activities within the Agency Recruitment phase, and the system requirements associated with each activity. The screening of supervisors and counselors was asynchronous, with some agencies taking only one week to be accomplished, others requiring multiple new counselor or supervisor applications when some applicants failed eligibility criteria, left the agency, or became too busy to participate.
Using routine web-page technology, the system supported recruitment activities through web-based announcements and e-mails. Potential applicants were directed to a recruitment web-page (periodically updated by staff) that explained the training opportunity and study requirements, and provided a study e-mail address and 1-800 phone number. Through an interface with ADEPT, interested persons could fill-in and submit a form requesting additional information, which went into a study database. Although the project began with two months of traditional US postal mail activity (sending to all New England-based addiction agencies colorful study brochures, one-page flyers, and applications), all subsequent recruitment was conducted via the Internet and web.

Ultimately, the recruitment web-page was the primary communication source and was supplemented over time with sample screen shots of the web course, a section for Frequently Asked Questions (FAQs), and inspirational quotes from current participants about the ease of study participation and their enthusiasm for the web-course www.teachcbt.org. Early on the website was modified so that potential participants could download .pdf versions of all application forms rather than request that an application be sent by US mail or e-mail. One advantage of the recruitment web page was that the project monitored visits or “hits” to this recruitment page. When activity diminished, project staff sent brief e-mail ‘blasts’ to state agencies, addiction associations, and networks of clinics to inform or remind them of the training opportunity and the web address.

NERI staff entered application and screening information into ADEPT, which then automatically created user accounts on the project web site and generated notification e-mail announcements to participants. One manual step was telephone screening of each applicant. (In a small subsequent “spin-off” study for a stand-alone product, this screening step was also accomplished on-line). ADEPT automatically generated a contact record for each counselor or supervisor who needed to be screened; this screening was asynchronous within study teams. Once two or more counselors and a supervisor met the study eligibility requirements the study Research Associate (RA) was notified to verify complete agency information (e.g., no outstanding local IRB review was required). RA approval resulted in automatic emails of registration information to each participant and they were notified to log onto the web site using their individual user account information and read and “sign” an informed consent by checking a box indicating that they understood and agreed to the study. They then proceeded on the web to provide demographic information, and complete a multiple screen pre-test questionnaire (assessing knowledge, attitudes, behavior, and confidence in using certain treatment methods). Data collection occurred via the web for both intervention and comparison group members. Participants who exited prior to complete data collection were directly returned to the incomplete form.
Out-of-range values could not be entered. These data were transferred directly from the web form into an Oracle database that stored data by study ID only for subsequent analyses.

Baseline Taping and Randomization: Figure 4 illustrates the activities within the Baseline Taping and Randomization phase, and the system requirements associated with each activity.

Once permissions were obtained from clients to audiotape their sessions, ADEPT generated random ID numbers and labels for the tapes that would be used. ID numbers were cross-referenced to agency and counselor and whether the counselor had completed the pre-test or post-test. Forms were generated by ADEPT with pre-filled names and ID numbers, and these forms were packaged with the tapes and a gift for the client and sent to the agency. Counselors filled in the dates of the sessions when the taping was complete, and the tapes were returned to NERI for independent rating. The mailing date was recorded in ADEPT, and the return date of materials was shown as ‘expected’ until they were received at NERI or they were determined to be dropped. All information related to taping (e.g., ID numbers, session forms, client permissions) were maintained by ADEPT in a database that allowed tracking of tapes sent to agencies as well as status of each counselor in the unit. After baseline taping, modest payments were made to counselors and liaisons.

The RA periodically generated simple tabulations of each data form using a pre-programmed report so the investigators could examine the sample profile. Random assignment of agencies to study conditions required first pooling agencies by state location and other characteristics to ensure balance on a small number of stratification variables. This complexity meant random assignment was done manually by the study statistician based on agency information in ADEPT, with the randomization result stored in ADEPT.

Training Participation: Participants utilized either the TEACH-CBT web course or the NIDA training manual according to the randomization outcome. This phase of the study imposed a number of requirements on the support system, as shown in Figure 5.

Training participation included: returning on multiple occasions to learn the 8-module web-course (or read the NIDA manual content), and if web-course, completing a quiz linked to each web-course module, engaging in module specific assignments to practice skills and post on the study bulletin board. For all participants, submitting base-line, post-training, and follow-up audio-taped sessions, and completing pre-test, post-test and follow-up forms. Web programming supported participants by ensuring accurate and timely completion of study forms (e.g., consent forms,
pre-test, post-tests, follow-ups, self-monitoring forms, etc.), web-module quizzes (indicating completion of module), web-practice assignments, and audiotape submissions. Such functions included sending automated e-mails to participants to introduce the course and the schedule, sending timely automated ‘gentle prods’ to web-course participants via e-mail reminder when 14 days had elapsed since they last logged-on or when the next data collection event was scheduled, and sending e-mail prompts to the RA regarding scheduled research tasks. Thus, throughout the TEACH-CBT study, ADEPT was also used to monitor and report participants’ activity on the web site.

System Requirements Implemented in ADEPT

| Maintain a record of supervisor workshop attendance (performed manually) | Generate email advising of course availability & access method |
| Generate supervisor workshop attendance status report (performed manually) | Track progress and page-hit activity |
| Generate email notifications to return web course based on days elapsed from log-in | Maintain a database of post-test results |
| Report counselors out-of-allowed-time for web-course completion | Automatically generate email notifications and reminders of post-test |
| Automatically enable and administer web-based post-tests | Automatically enable and administer web-based post-tests |
| Maintain bulletin board to post end-of-module assignments | Maintain a database of post-test results |
| Permit downloading of .pdf client and counselor session handouts | Send e-mail to those neglecting post-tests |
| Generate CED certificate at web-course end with completion date | Permit research staff to “force” to post-test completion counselors with delays |

Figure 5: Training Participation

System Requirements Implemented in ADEPT

| Same requirements as for baseline taping, plus | Enable double data entry of each tape rating |
| Activate TEACH-CBT course access for counselors and supervisors in comparison agencies | Generate frequency statistics on tape ratings |
| Generate emails to supervisors and counselors in comparison agencies advising of TEACH-CBT course and credit availability | Assign individual tapes to raters, balancing by group and time point (performed manually by statistician) |

Maintain databases of:
- tape rater (project investigator) information
- tape rating

Generate reports of:
- tape tracking and inventory by group assignment and agency

Figure 6: Post-training Activities

Post-training Activities: This phase of the study involved the random selection of three audiotapes out of the eight audiotaped client sessions (or the number recorded as ‘fair or good audio quality’) of each counselor. These
randomly selected tapes were assigned to one of five study raters for independent rating to determine the extent to which counselors employed CBT techniques in their client sessions. Figure 6 illustrates the requirements of the support system for the Post-training phase.

For rating audio tapes, the authors developed a Rating Guide that covered eight core counseling skills and multiple sub-skills taught in the course. Five trained raters rated the sessions; each rater was blind to whether tapes came from the web-course or NIDA manual participants and whether tapes were from baseline, post-training or follow-up. The study investigators pre-defined a passing algorithm using the ratings across all eight counseling skills. Investigators subsequently performed statistical analyses of the audiotape ratings to determine the percentage of intervention and comparison group counselors who received passing scores at baseline and again at the post-training periods.

Summary of Trial Management

Nearly all data was collected remotely via web data entry forms designed for easy and direct completion by the participants. Other study monitoring, tracking data, and tape rating data were directly entered by the RA. ADEPT provided easy export of formatted datasets for further statistical analysis in SAS. ADEPT also monitored elapsed time from the point of randomization for all participants to indicate when new data collection was due, and provided automatic delivery of e-mail prompts both to participants about the date to begin the next data collection event and to the RA to begin the mailing of audio-taped materials.

Using ADEPT reports, the NERI staff monitored the timely completion of the dozens of study steps that were expected of each participant. Investigators monitored and could reconstruct information on how the participants made use of the web course. Statistics that could be reported for each participant and aggregated for analyses included:

- Numerical counts of: log-on sessions, pages visited, links used, discussion board posts
- Modules completed, end-of-module quiz scores, days elapsed between quizzes and log-ins
- Time spent on course activities, per visit, per module, and total

As outlined above, ADEPT also collected data to allow the tracking of:

- Agency progress, including nested applications for multiple participants’ enrollment and screening forms
- Screening and status of each participant; at some points participants progressed as a group; at other points as individual participants
- Randomization goals and balanced groups of randomized agencies
- Accurate, complete, timely web data entry of counselor and supervisor data forms
- Receipt of three forms necessary for each audiotape submission
- Completion of module quizzes
- Completion of participants’ self-monitoring of CBT application in session
- Completion of web-administered pre-test forms and post-test forms

Further, ADEPT provided automatic notification of out-of-window status (failure to comply with the timeline) (e.g., regarding the need to start post-test data collection, the need to determine if a participant was still active in the study).

Empirical Trial Findings

The development of the customized DMS led to successes in some aspects of trial implementation and also eased the burden on project staff as the recruitment stage eventually spanned 18 months. We recorded over 3,000 inquiries on the web page where potential applicants could download application materials or request additional information. Using ADEPT support, over 180 counselor and 65 supervisor applicants were screened. We randomly assigned to the training condition 127 counselors and 54 supervisors at 54 agencies (LoCastro, Larson, Smith, Amodeo, Muroff, 2008). Project staff monitored for each applicant and study participant the timely completion of the dozens of study steps expected of each participant. In all, in addition to the traditional function of storing study-acquired research data, ADEPT assisted the study staff to track more than 10,000 unique research events (50 events per counselor
participant and 27 events per supervisor) over the course of the full study. One illustration of these research events is the multi-form asynchronous data collection required for participant audiotape data collection. Each audiotape submission required pre-labeling by ADEPT of a unique linked number on a consent form, session form, and audiotape. The project received 855 consents to audiotape individual counseling sessions and later received 819 usable (not blank) session audiotapes and session forms. The research assistant could easily confirm with the agency when a missing tape was the result of a missed appointment (no tape expected) or a tape was still outstanding. Collection of audiotapes spanned three waves and ultimately the number of tapes and forms tracked in ADEPT at baseline, post-training and 3-month follow-up were 251, 313, and 255, respectively.

A second illustration of ADEPT findings is related to the tracking of web usage of participants. Of the 62 counselors randomly assigned to the Web course, 57 ultimately started the course (92%). Of those who started, 82 percent (47/57) completed 6 or more of the 8 modules. From log-on information captured by ADEPT, we computed that web course completers averaged, 70.6 days between their first log-on and last log-on to the course. We tracked that non-completers, on average, completed 2.3 modules and averaged 49.0 days from first to last log-on. The DMS also captured web course postings resulting from module assignments. There were 178 assignments posted or on average 3.1 assignments per web course starter. Statistics showed that modules varied in intensity and scope, with the average days between the start and completion of one module ranging from 3.4 days to 10.6 (behavioral skills module and cognitive skills module, respectively) (LoCastro, Larson, Smith, Amodeo, Muroff, 2008).

Recommendations: Using a DMS for Training, Research and Clinical Projects

Choosing a DMS

It is imperative that individuals and institutions interested in developing or utilizing a DMS such as the one described here develop a complete list of their specific needs (i.e., system requirements) before evaluating the various systems available. A key question is, “What should the ideal DMS do?” This question should be considered from four points of view: (1) the learner, (2) the web administrator, (3) the researcher/evaluator, and (4) the course instructor (in some settings). In this project, the study investigators served the roles of web administrator and researchers. One novelty is that this web course had no formal instructor other than automated feedback, although it had two faculty monitoring the content of the bulletin board assignments and offering group telephone sessions for agency supervisors.

Other considerations are the type of reports or outputs needed from the system and the frequency with which they will be needed; the type of data that will be entered into the system, whether the system needs to maintain a history of the data, and if so, for how long; and the speed with which the system needs to respond to user inquiries or transactions.

In addition to the specific requirements, a number of general factors should be considered in evaluating systems of any sort. In particular, Abowd (1994) has compiled a list of usability factors that should prove helpful either in evaluating existing systems or in designing a new system.

- **Visibility of system status:** The system should always keep users informed about what is going on, through appropriate feedback within reasonable time. We did this in ADEPT by providing a visual timeline of the study steps accomplished and remaining in our automated emails to participants. Web course participants also had visual cues to remaining pages in a module. Study investigators had reports showing participant progress against weeks enrolled and a report of all counselors by a flow-diagram of study steps.

- **Match between system and the real world:** The system should speak the users' language, with words, phrases, and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in natural and logical order. We violated this in ADEPT by assigning random log-in ID numbers, for study purposes, but these IDs were only four digits long. When assigning passwords, the system generated two concatenated short words for easy recall (e.g., cakewalk).

- **User control and freedom:** Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo. We accomplished this in ADEPT in the web course and 'saved' the participant’s screen location so he/she could jump back to that spot.
• **Consistency and standards:** Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions. *In our project, each module followed a well thought-out template, had colorful logos designating the type of optional material (advanced, review), and screen icons indicating the type of screen (activity, quiz, content).*

• **Error prevention:** Even better than good error messages is a careful design which prevents a problem from occurring in the first place. *Our web data forms had built in validation so that only valid answers could be provided.*

• **Recognition rather than recall:** Make objects, actions and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate. *The customized ADEPT options for project staff were difficult to understand for all but one project staff most familiar with the system.*

• **Flexibility and efficiency of use:** Accelerators - unseen by the novice user - may often speed up the interaction for the expert user to such an extent that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions. *In data collection for a research study, speed must be balanced with data quality. For the participants, ADEPT recorded pages visited and returned the user to the previous page; content had hot-links to module sections. However, all users were forced to start at the same beginning and take the same path in order to record course progress.*

• **Aesthetic and minimalist design:** Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility. *Web pages became less dense as we designed more modules. Dialogue was limited to 30 second segments after pilot evaluation of the prototype module.*

• **Help users recognize, diagnose, and recover from errors:** Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.

• **Help and documentation:** Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

### Anticipating the Need for Customization

While this article focused on one of ADEPT's applications, the dissemination and evaluation of an EBP to community-based organizations, it and similar systems may be customized to support essentially any type of research inquiry (e.g., on learning, teaching, clinical and non-clinical interventions). However, despite the best efforts to define system requirements, project staff should anticipate that requirements can almost never be fully known at the beginning.

For example, in addition to the usual considerations of the computer literacy of the learners and their access to computers, this study also encountered special issues.

• We received very few complaints that the learners could not navigate the web course or the data collection modules, however the questionnaire data was on several forms requiring periodic submission and some users were unfamiliar with submission of data within certain time constraints before continuing onto another form.

• The learners were inside agencies with spam software, and tests of automatic emails generated by ADEPT were needed for each new participant to ensure receipt. NERI staff needed to advise agency staff on how to change their servers to accept automatically-generated emails.

• Research project staff was decentralized and changed over time; new staff and non-RA’s required substantial orientation to the ADEPT system. The system had complex triggers and logic; customized features were not well documented for newcomers; the logic behind custom reports was not obvious.

• Design of custom reports occurred before the research staff were fully aware of their project management needs, and changes to the reports was awkward and time-consuming.

• The system requirements for web course and research purposes may place competing demands on the system. For example, for learning purposes we wanted the participants to go at their own pace; however, for study purposes, we needed to force participants to take the post-test before too much time elapsed and we risked losing post-test data. Learners were sometimes frustrated by the need to provide data before they had completed training. This study also had added complexity because at times participants progressed in a group and at other
times as individuals. Learners would prefer to navigate freely among modules and pages whereas the research required a more linear progression through materials.

Institutions and individuals anticipating the use of such a system should remember that, in spite of the impressive capacity of such a system to deal with complexity, some customization will still be necessary. Typically, these systems are developed to meet a set of requirements dictated by the project for which they will be used. To the extent that projects, and thus requirements, are different, the system must be modified to accommodate the differences.

Conclusions

This article has described a specialized data management system which married web course materials with a DMS (ADEPT) that was customized to provide real-time information for both the management of web-based educational courses and the collection of a large volume of reliable, valid data at multiple stages for a randomized research trial of training program outcomes. ADEPT was invaluable in its ability to manage ambitious and challenging recruitment and enrollment steps which required that participants be embedded inside of agencies but at the same time screened asynchronously with additions and drops before a set of participants enrolled as part of three-person or larger teams. Participation in Web-training was participant-driven, with some finishing in four weeks and others being prompted at seven weeks to finish.

Educational, health, and human service organizations should consider integrating the innovative data management functions described here into their web-courses if they are planning to engage in: (a) research on learning outcomes, as we did in the study discussed here, (b) research on teaching, that is, examination of effective pedagogical methods, (c) clinician applications such as counselor tracking of whether or not his/her clients complete the homework assigned each session, which handouts are used in a session, and which handouts were given to clients. Longitudinal tracking could identify areas which could be enhanced through additional supervision; or (d) clinical supervisor applications, for example, monitoring print outs of counselor self-ratings and identifying CBT strategies that are being underused and which might benefit from supervision.

Since this project, we have further customized ADEPT and our web programming approach for a commercial version prototype of the course. In this second generation we have automated additional recruitment and screening steps, automated randomization to group based on screening data, and created a ‘case-oriented’ navigation system through the web content. A DMS such as ADEPT is critical for accurate and efficient research data support. This technology exists and is underutilized. Given researchers’ need for such sophisticated systems for research project support, those individuals who are building systems need to focus on how to create similar systems and make them accessible to a wider audience.

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