Using Telemedicine Tools for the Administration of a Multi-site Clinical Trial

ABSTRACT

The VA Cooperative Studies project "Group Treatment of Post Traumatic Stress Disorder," is a randomized clinical trial comparing group PTSD treatments. There are 10 clinical, 2 supervision and 2 administrative sites. Clinical sites (staffed with a PI, 4 therapists, 2 case managers, 1 assessor and research assistant) treat 36 male Vietnam veterans in 3 cycles testing at months 0, 7, 12, 18 and 24.

Clinical supervision and routine administrative functions—which demanded a high degree of accuracy—are done using low-cost telemedical techniques. Because of budget constraints, the system design had to be done with existing technology. The study is guided by national executive, biostatistics, and treatment committees which teleconference weekly. The clinical teams have monthly group teleconferences with weekly individual phone supervision and daily/PRN e-mail supervision.

Communications are stored in searchable, analyzable databases. Routine activities use internet technology.

Data are collected using the DataFax data management system. DataFax manages paper forms faxed from remote sites to a central computer. It reads hand written numbers and check boxes to create a record. Quality control reports are automatically faxed back to clinical sites. Quality control reports identify problems and list expected forms which have not yet been received.
Introduction

Telemedicine is defined as the use of telecommunication technology in the provision of health care (U.S. Department of Commerce [DOC], 1997). Telemedicine tools include devices such as telephones, fax machines, computers, digital radiography, etc. Clinical applications range from informal collegial communication, to formalized professional supervision, direct patient care, management of medical information, and virtual surgery (Basheur, 1997; Coiera, 1997; Institute of Medicine, 1996; Stamm & Pearce, 1995; Stamm, 1997).

Despite changes wrought by telemedicine and informatics in research, supervision, and clinical practice, most telemedicine literature refers to clinical trials of telemedicine. Few reports discuss telemedicine conceptualizations in the support of multisite clinical trials and none deal with distributed information systems to support a clinical trial of a non-telemedical topic.

Generally, telemedicine information concerns medical topics. Clinical trials have evaluated telemedical techniques in surgery (Davies, Hibbers, Timoney & Wickham, 1991; Dunn, Almagro, Choi, Recla & Weinstein, 1997), radiology (Kagetsu, Zulauf & Ablow, 1987), cardiology (Kempner, Ostrow, Fessler & Tucker, 1991), and the application of telemedicine itself (Tangalos, 1995). McKee, Evans & Owens (1996) evaluated the quality of technology, but they tend to assess biomedical engineering or telecommunications and thus are not truly clinical trials.

The closest application of using telemedicine to support multisite clinical trials appears in the evaluation literature for telemedicine. By definition, telemedicine is multisite (Stamm & Perednia, 1998). Thus, much of what applies for evaluation of telemedicine programs also applies to the support of multisite clinical trials of non-telemedicine projects. (IOM, 1997, Perednia, 1995; Stamm & Perednia, 1998).

The Study

Group Treatment of PTSD (Friedman, Schnurr, Hsieh, et al, study in progress) is a multi-site group psychotherapy clinical trial. It is funded by the Department of Veterans Affairs Cooperative Studies Program and housed at the Executive Offices of the National Center for PTSD in White River Junction, Vermont. This randomized clinical trial compares Trauma Focus Group Therapy to Present Centered Group Therapy as a treatment for the symptoms of Post Traumatic Stress Disorder (PTSD). The study spans the continental US and includes 14 sites: 10 clinical, 2 training, 2 administrative (Figure 1). Each clinical site has a staff of nine people, 7 of whom receive remote clinical supervision and adherence monitoring (Figures 2 & 3).

The Chairpersons' office is responsible for the clinical implementation of the study. Day-to-day operations—the majority of what is described in this poster—are overseen at this location. All outcome data are collected by the Cooperative Studies Coordinating Center in Palo Alto, CA. The data are not seen by those in the Chairpersons' office until the completion of the treatment phase of the clinical trial in the spring of the year 2000.

The Telemedical Management System

Design Assumptions

- Clinical needs superceded technology.
- Had to work on lowest current VA standard
- Had to be developed around existing office equipment because there was no dedicated telemedicine funding
- Highly reliable; little transmission degradation
- "Low-Tech"
  - Low cost
  - Low maintenance
  - Easy to operate for non-computer people

Needs Assessment

- Support individual teams at their sites
Develop teams across sites; sense of national

Rigorous training to the treatment protocol

Ongoing clinical and administrative supervision

Ongoing monitoring of protocol adherence

**Technology Used (see Table 1)**

- Desktop computer
  - PC running (P133 with 16 MB Ram)
  - Windows 95 and Microsoft Office Pro

- Telephone & Fax
  - At least one dedicated fax, one dedicated phone with speakerphone capacity if possible

- E-mail
  - Internet access, about 1/2 have Web, document sharing

- Video taping
  - video camera, tripod, external microphone, VCR and monitor wired to simultaneously record multiple tapes

- Audio taping
  - 2 a recorders and 2 personal-sized playback units

- Video teleconferencing
  - Available 1/2 of sites, expensive, used occasionally

**Modes of Information Transfer**

- Clinical data
  - Clinical status data via secure fax
  - Clinical supervision via individual telephone and group audio teleconferences supplemented by e-mail

- General information

- Administrative updates via e-mail
  - Assessment, treatment queries, etc., stripped of identifying information via e-mail, fax or phone

- Committee and training meetings
  - Multiple-user toll-free teleconferences
  - Agendas & minutes via e-mail

- Clinical Supervision
  - Via telephone and mailed video or audio tapes. Case Management faxed records (see case study below).

- Adherence to therapy protocol
  - Mailed video or audio tapes & clinical status fax
  - Monthly audio teleconferences

**Storage and Access to Data**

- Minutes sent in e-form & archived
- E-mails archived by date and by subject
- Incoming faxes and tapes are catalogued by site, patient and clinician number and then filed in physical copy
- Clinical status archived in numerical and narrative form (see below).

**CASE MANAGEMENT EXAMPLE**

Due to the quantity of information generated by this class of data (see Table 1), it is targeted for transfer from fax/paper to purely electronic form as described below.

*Case Management (CM)* is an integral part of the treatment plan for participants in the study (See Figure 1). Each case manager sees each participant at least monthly for the duration of their participation. CMs see 6 patients the first round and add an additional 6 each round culminating at 18 participants. CMs are charged to (a) monitor clinical status, (b) attend to psychosocial problems of veterans, and (c) provide intervention in crisis or emergency situations of veterans

*CM Supervision* ensures that the CMs use problem focused pragmatic interventions and not psychotherapy. It also helps the CMs attend to difficult clinical cases and issues including burnout and secondary traumatic stress (STS). CM supervision (a)
monitors adherence to the protocol, (b) supports crisis management, and (c) helps to prevent burnout and STS of case managers

Thus, the main goal of this project was to use medical informatics to increase the ease and effectiveness of Case Management and CM supervision. The form was judged based on criteria derived from focus groups regarding supervision and adherence monitoring.

**METHOD**

**Participants** The participants in this project consisted of six raters: four expert and two naive. The four expert raters, 2 administrative staff and 2 clinical supervisors, were familiar with the study protocol. The two naive raters were neither administrative nor clinical staff and were not familiar with the protocol.

**Materials** A 10-item test was used to evaluate how well the computerized forms addressed the following goals.

1. Appropriate description of the clinical procedure?
2. Comfort level of the user
3. Ease of use
4. Clinical satisfaction with the forms developed
5. Effectiveness of the procedure

Both qualitative and quantitative data were collected. The quantitative data was used to highlight areas of agreement and disagreement among the raters. The qualitative data was used to enhance positive aspects and remediate perceived deficiencies of the computerized forms.

Five scenarios were designed to represent situations likely to occur in a case management supervision sessions which are often short with multiple issues. Similarly, five scenarios were developed to represent situations that were likely to occur in a case management session with a veteran. These were used with the expert and naive raters to evaluate the final beta version of the forms.

**Record of Case Manager Supervision Form**—This form was developed for the clinical supervisors to record notes from supervision sessions with the Case Managers. The form collected information for both adherence monitoring and clinical supervision (see Record of CM Visit)

**Record of Case Manager Visit Form**—This form was developed for the case managers to assist in clinical supervision and protocol adherence. It helps the case manager during his/her supervision by providing the supervisor with a summary of the status of each patient. It helps in adherence monitoring by providing an outline for the case management sessions, highlighting psychosocial issues to keep case managers focused on the veterans problems in living and pragmatic problem solving.

**Procedure**

The beta versions of the forms were developed through a sequential process. Before the computer versions were attempted, the content and structure of the form was tested in a paper version. The content originated from the treatment manuals and was organized in focus group discussions with the case managers (n=23), administrative staff (n=5), and clinical supervisors (n=2) before computerization was begun. Paper versions of the form were piloted over a 5-month period for completeness and succinctness.

Beta 1 (the first computerized version) was based on the paper version and was computerized using the 5 goals listed above. The form was revised based upon the feedback received from the expert raters. In all, 4 beta versions were completed, each subjected to expert reviews. The qualitative and quantitative input from these ratings were used to make changes to the forms. This process stopped after 5 versions because consensus was reached that the forms were easy, comfortable, reflected the clinical information and could be distributed. At this point, naive raters were asked to evaluate the final beta version of the Case Management form and the Case Management Supervision form.

Data were analyzed using an alpha of .10 due to the small sample size and due to the development nature of the research.

**RESULTS**

Table 2 summarizes the results from the beta testing of the form.

1. Appropriate description of the clinical procedure reported?

This first goal was of quintessential importance. If the information collected was not interpretable later or by other people, the information collected would be worthless negating the value of the electronic data collection. A dichotomous Yes/No answer was used for this question. All of the raters were dissatisfied with Beta 1, the original form. The three subsequent forms (Beta 2, Beta 3, & Beta 4) provided appropriate description of the clinical interactions.

2. Comfort level of the user
Comfort was rated using a five point likert scale that ranged from "1-Not at All Comfortable" to "5-Completely Comfortable." Across time raters reported being more comfortable with the forms (F_5, 5=3.79, p=.059). There was complete agreement at Beta 1 (x=3.00) and Beta 4 (x=5.00). This may suggest comfort with the idea in general (Beta 1) which increased to comfort with the embodiment of the idea in the final form (Beta 4). This increase may also be attributable to either an improvement in the forms, practice effects or an interaction of improvement and practice effects.

3. Ease of use
This was rated on a five point likert scale (1-Not at All Easy to use to 5-Completely Easy to use). Across time raters reported "getting stuck" less (F_5, 4=4.79, p=.034). The most problems occurred at Beta 2. This may be due to the significant changes in the structure of the form from Beta 1 to Beta 2. Subsequent forms were minor modifications of the form used in Beta 2. As with the comfort level, the increased ease of use across trials could be attributable to an improvement in the forms, practice effects, an improvement and practice effects interaction.

4. Clinical satisfaction with the forms developed
Satisfaction was again rated using a five point likert scale (1-Not at All Satisfied” to 5-Completely Satisfied). Overall there were no significant differences between the satisfaction of the four Beta versions of the form.

5. Effectiveness of the procedure
Effectiveness was rated using a dichotomous Yes/No variable. There were no significant differences in belief of the effectiveness of the forms. Beta 1, Beta 2, and Beta 4 were unanimously rated as effective. This suggests a general confidence in the ability of the forms to accurately convey the information gathered during a case management supervision session.

DISCUSSION

This case example illustrates the user-driven nature of this project. The five goals identified by the users were kept at the forefront of the evaluation of the computerized forms. Striving for “customer satisfaction” the users, not the technology, drove the development of the system. In fact, long before the computerization was begun, content and clinical appropriateness were addressed through paper versions of the tasks.

All of the raters reported that the form provided an appropriate description of the clinical interactions, were comfortable, and easy to use. While there were no significant differences in the satisfaction with the form, an examination of the data shows that the mean raters satisfaction increased with each Beta version of the forms. Finally, there was nearly complete agreement at all four assessment points that the forms were effective. These results are in line with the expectations of this project. The forms developed here will be used as prototypes for the other clinical supervisors on this project.

Once fully implemented it will be possible to use the information collected from the forms in a number of ways. First, the forms should increase the supervisors' effectiveness by providing them with a brief summary of previous sessions. This will allow both the supervisors and supervisees to consistently focus on pertinent issues. Second, the forms will simplify the adherence monitoring process by being able to download the information into a common database for statistical analysis. Finally, the computerized forms will allow supervisors to easily communicate with Master Therapists or trainers on difficult cases using e-mail or fax.

REFERENCES


Figure 1 CLINICAL, TRAINING, & ADMINISTRATIVE SITES

Figure 2 CLINICAL SUPERVISION

Figure 3 ADMINISTRATIVE SUPERVISION
Table 1  Estimated Information Flow

<table>
<thead>
<tr>
<th>Modality</th>
<th>Mean # Per Week</th>
<th>Range # Per Week</th>
<th>Average Minutes Per</th>
<th>Peak Number</th>
<th>Peak Average Min. Per</th>
<th>Projected Total Number</th>
<th>Projected Information Hours</th>
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</thead>
<tbody>
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<td>E-Mail</td>
<td>98</td>
<td>71-200</td>
<td>7</td>
<td>87/5 hr</td>
<td>—</td>
<td>20,000</td>
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<tr>
<td>Indivl Phone Conf</td>
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<td>20-35</td>
<td>38</td>
<td>—</td>
<td>—</td>
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<td>1789</td>
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<tr>
<td>Group Phone Conf</td>
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<tr>
<td>Incoming Calls</td>
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<td>15-70</td>
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<td>—</td>
<td>—</td>
<td>1800</td>
<td>—</td>
</tr>
<tr>
<td>Fax Pages</td>
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<td>32-340</td>
<td>2</td>
<td>—</td>
<td>—</td>
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<tr>
<td>CM Tapes</td>
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<td>2100</td>
<td>3500</td>
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<tr>
<td>Totals</td>
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<td>210-820</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>49,745</td>
<td>19,351</td>
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</table>

2 Estimates based on combining actual numbers to date with projections from the study design.

3 Time Estimates are based on a variable number of total weeks depending on research design.

Table 2  SUMMARY OF BETA TESTING CASE MANAGEMENT RECORD FORMS

<table>
<thead>
<tr>
<th>Supervisor Form</th>
<th>CM Form</th>
<th>Form Characteristics</th>
<th>Expert Reviewers' Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta 1</td>
<td>Yes</td>
<td>No</td>
<td>Boxes for information</td>
</tr>
<tr>
<td>Beta 2</td>
<td>Yes</td>
<td>No</td>
<td>Click-on draw down bars</td>
</tr>
<tr>
<td>Beta 3</td>
<td>Yes</td>
<td>No</td>
<td>Click-on radio buttons, meta categories</td>
</tr>
<tr>
<td>Beta 4</td>
<td>Yes</td>
<td>Yes</td>
<td>Forms linked to patient, CM supervisor record</td>
</tr>
</tbody>
</table>