

12/22/00

**Ruth Finkelstein, ScD, Principal Investigator**  
**CENTER FOR ADHERENCE SUPPORT EVALUATION (CASE)**  
**Institutional Review Board, Human Subjects Protocol**  
**Phase II (Qualitative/Site Assessment)**

**STUDY OBJECTIVES**

The purpose of this study is to assess the effectiveness of interventions designed to increase adherence to highly active antiretroviral therapy (HAART) in 12 AIDS centers in the U.S. funded by the Health Resources and Services Administrations' (HRSA) Special Projects of National Significance (SPNS). In particular, the evaluation seeks to determine the appropriate levels of service utilization for supporting adherence, the impact of different types of providers in supporting adherence, the duration of effectiveness of the different adherence support programs, and the effectiveness of different programs in supporting adherence of populations facing different barriers to their adherence.

This is a cross-site evaluation of 12 locally designed and locally evaluated HRSA SPNS Adherence Support Grantees. (A complete listing of the participating SPNS Adherence Support Grantees is attached to this document). The statistical power gained in the pooled data from the multiple sites of the Adherence Evaluation Grantees (AEGs) make it possible to compare the outcomes of different programs to one another, as well as allow more complex, multivariate analyses identifying predictors of good outcomes for particular populations and characteristics of effective strategies across a range of programs. Results of the cross-site evaluation should provide critical information about what adherence support programs work best for whom, "best practices" guidelines, and replicable models to HIV/AIDS service providers, policymakers, and funders.

**PROJECT PROTOCOL**

The CASE cross-Site Evaluation consists of two data collection phases: (1) Quantitative, and (2) Qualitative.

**Quantitative.** The quantitative component of the evaluation consists of collecting both client-level and health care service delivery system-level data. Client interviews and chart

12/22/00

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abstractions are conducted at quarterly intervals over a 12-month period. Encounter forms that track client adherence services are completed for each adherence visit. Data collection for this phase began in May 2000 and is currently ongoing. The core client interview focuses on clients' socio-demographic characteristics, health status, knowledge of HIV and HIV medications, adherence to HIV combination therapy, support for combination therapy, disclosure of HIV status, and substance use. Sites can elect to ask supplemental questions about HIV medication side effects, depression, substance use, trust in primary HIV medical provider, adherence self-efficacy, and/or beliefs about HIV combination therapy. The chart abstraction form elicits information about demographics, HIV/AIDS status, health status, adherence to medical visits, and clinical psychiatric diagnoses.

**Qualitative.** Phase Two of the cross-site evaluation will entail both client- and site-level data collection. The CASE team will conduct 12 individual site visits and gather data by administering client and provider interviews, as well as a group site assessment done by written survey and interview with key staff.

**Objectives.** Specific objectives of the Qualitative/Site Assessment are to:

- Determine how interventions are actually being implemented and the salient differences in program design, theoretical models, and service delivery across the 12 sites.
- Identify how the context in which interventions are implemented (*e.g.*, organizational and program characteristics (staffing configurations, external service linkages) influence their effectiveness.
- Determine how adherence support provider characteristics, *e.g.*, specialty, training, age, and provider-client demographic matching (by gender, age, ethnicity) with a specific provider, influence effectiveness.

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- Identify clients' reactions to and beliefs about the adherence support program, (e.g., strengths, weaknesses, and satisfaction, and what they consider to be the most critical program facilitators of adherence).
- Define recruitment practices, enrollment criteria and implementation, and follow-up protocol at individual sites to control for differences in cross-site findings.

### **Study Procedures**

Overview. Data will be collected by local site staff, local evaluators, and CASE staff. CASE staff will conduct a site visit to each of the 12 grantees between February and April 2001. Each visit will be conducted over a period of about three to four days. During this visit, the Group Site Interview (Part II) and the Adherence Support and Medical/Clinical Provider Interviews (if done by CASE staff) will be conducted. The Adherence Support and Medical/Clinical Provider Interviews conducted by the local site evaluators may be done either before or after the Site Visit.

Client Interviews. Each site will draw a 10% to 20% sample of the clients enrolled in the CASE cross-site quantitative evaluation study. The exact proportion will be based on the projected sample size based on each site's projected enrollment and will be individually negotiated with the CASE team. The sample will reflect a cross-section of clients in terms of the length of their participation in the adherence support program so as to capture the range of experiences. An attempt will be made to sample equal numbers of clients based on their level of intervention exposure: (1) 1-3 months, (2) 4-8 months, and (3) 9-12 months. Clients will be recruited between February and April 2001 when they present to the clinic for their regular medical or adherence support visits. The total sample across all sites will be comprised of at least 100 clients.

The interviews will help us: (1) ascertain clients' perceptions of the effectiveness of the HAART adherence support program; (2) determine factors that clients perceive enhance their HIV medication adherence; and (3) increase understanding of HIV medication

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adherence problems encountered by clients. Questions will focus on three primary domains: (1) clients' experience with the adherence support program; (2) clients' experience with providers and other program staff; and (3) clients' attitudes and practices regarding HIV medication-taking. Questions will be open-ended to allow participants to describe their expectations and experience with antiretroviral medications and participation in the adherence support interventions in their own terms.

Site staff and/or the local evaluation team working with the site will conduct the client interviews (See Attachment: *Qualitative Client Interview*). These interviews will be conducted after the CASE site visit. The client will be interviewed only once and the duration of the interview will be approximately 25-30 minutes. Informed consent will be obtained prior to the start of the interview (See Attachment: *Qualitative Client Interview Consent Form*). Interviews will be conducted in English and Spanish. The Spanish version of the instrument will be translated from English into Spanish and then back-translated into English. The interviews will be taped and transcribed verbatim. The audio-tapes will be sent to CASE for transcription.

Adherence Support Provider Interviews. All providers (including peers and buddy volunteers) who deliver adherence support services will be asked to complete the Adherence Support Provider Interview. The number of providers will range from four to 10, depending on each site's service delivery model and client caseload.

CASE staff and/or the local evaluation team working with the site will conduct the Adherence Support Provider Interviews (See Attachment: *Adherence Support Provider Interview*). If CASE staff conducts the interviews, the interviews will be scheduled during the site assessment. If local evaluators do, interviews will be conducted either before or after the site assessment. The interview will take approximately 20-25 minutes. Informed consent will be conducted prior to the start of the interview (See Attachment:

12/22/00

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*Adherence Support Provider Interview Consent Form*). The interviews will be audiotaped and sent to CASE for verbatim transcription.

The focus of the Adherence Support Provider Interview is on: (1) providers' attitudes and practices about HIV combination therapy; (2) attitudes and practices about clients' HIV medication adherence; (3) perceptions of the adherence support program and its effectiveness; (4) staff and management issues (human resources, caseload, and staff relations); and (5) provider demographic characteristics.

Individual Interviews with Clinical/Medical Providers. A brief interview will be conducted with the medical providers who are not delivering adherence support services at their clinic. The interview will focus on HAART and medication adherence, provider demographics, and job responsibilities and needs, and will take about 10 minutes (See Attachment: *Clinical/Medical Provider Interview*). Informed consent will be conducted prior to the interview (See Attachment: *Clinical/Medical Provider Consent Form*).

Group Site Assessment Interview. The site assessment form will be administered in two parts. Sites will be asked to describe their program/services, its target populations, staffing composition and level of training required to ensure successful program outcomes, enrollment protocols, eligibility criteria, use of incentives, and evaluation plan (See Attachment: *Site Assessment Part I*). Part I will be completed prior to the CASE visit by local site staff (no later than January 31, 2001). This will allow CASE adequate time to review the data to inform the agenda for the upcoming site visit.

Part II will be an interview conducted in a group format with each site's Principal Investigator, Project Director or Coordinator, the Evaluation team, and other staff as deemed appropriate during the CASE site visit. The interview, which will take about three to three and a half-hours, will be taped and transcribed verbatim. Informed consent

12/22/00

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**Phase II (Qualitative/Site Assessment)**

will be conducted prior to the interview (See Attachment: *Site Assessment Consent Form*).

Part II will focus on: (1) **program overview and enrollment** (changes in adherence support program, perceptions of the client enrollment process, retention of clients); (2) **program implementation** (development of individualized plan, procedures for handling clients who miss appointments, referral process, program resources, barriers to program implementation, perceptions of what works and doesn't work); (3) **staff and management issues** (role of prescribing clinician, communication mechanisms among staff, peer adherence specialists/buddies); (4) **internal monitoring and evaluation** (assessment of adherence, management of client and program data, program changes as a result of monitoring feedback, perceptions of CASE cross-site evaluation); and (5) **information dissemination** (mechanisms for increasing community awareness of your adherence support services (See Attachment: *Site Assessment Part II*).

Data Analyses. The Site Group Interview data will provide detailed information about each site's adherence support intervention, effective program elements, organizational features, and a descriptive context for understanding client-level data gathered in both the quantitative baseline/follow-up and qualitative interviews.

The Client, Adherence Support Provider, and Medical/Clinical Provider Interview data will be subjected to content analyses. Initially, broad categories of themes, which are not mutually exclusive, will be coded. We will look for the range of variations and prevalence of these themes and the language used by participants to frame their experiences. Data that do not fit the categories will be reviewed systematically over the course of the study for the purpose of adding other codes. Coding of the qualitative data will be entered into a database and frequencies of coded responses will be computed. Matrices will be developed to examine salient patterns.

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The closed-response variables (*e.g.*, the degree to which provider demographics match client demographics, professional background, training) in the Provider Interviews will be used as predictors of client outcomes in the baseline and follow-up interviews, and hence a determinant of intervention effectiveness.

Compensation. Clients will not receive any compensation by CASE to participate in the National Qualitative Phase Evaluation. However, they may receive financial incentives from the local site. Providers will not be compensated for their participation in the Site Assessments, Adherence Support Provider, and Medical/Clinical Provider Interviews.

Informed Consent. All clients and providers will be asked to sign an informed consent specifically agreeing to participate in the Qualitative Phase of the national evaluation study. Clients and providers will be informed that their participation in the national evaluation is voluntary and that they can choose not to be in the study or withdraw consent at any time. Clients will be told that their refusal to participate will in no way affect their care at [NAME OF INSTITUTION], and providers will be told that their refusal to participate will not affect their employment or work at [NAME OF INSTITUTION]. Providers will also be told that all reports of the data will be presented in the aggregate and that all personal identifiers will be removed. Providers who participate in the Site Assessment Group Interview (Part II) will be reminded that whatever they say during the interview will be available to their Supervisor, Program Director, or Principal Investigator if the latter participate in the group interview. All participants will be informed that no personal identifying information will be forwarded to CASE.

**Risks and Benefits**

Clients and providers may not personally derive any benefits from participating in the evaluation. Study findings will be used to better meet the adherence support needs of persons living with HIV across the country.

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Confidentiality of participants will be maintained through the use of unique identifiers, and through password control restricting access to the data set to the Principal Investigator and those working directly with her. No names will appear on any of the interview forms. The data collected from each site will be entered into a CASE database where it will be maintained in an electronically secure environment. Hard copies of completed instruments will be kept in a locked file and will be available only for research study staff. Participants will be told that the information that they give to the interviewer will not be shared with HIV providers at their clinic (with the exception of the Site Assessment Group Interview as described previously). Information from the client interview will be kept completely separate from the clients' medical and other visits.

Clients will be told that there is a slight possibility that the kind of questions they are asked may be upsetting and that if they become upset, they can be referred to a staff member at **[NAME OF INSTITUTION]**.

CASE and each site will secure its own Institutional Review Board approval. In addition, for the cross-site Qualitative Phase of the CASE evaluation, four consent forms have been prepared.