

Ruth Finkelstein, ScD, Principal Investigator

**CENTER FOR ADHERENCE SUPPORT EVALUATION
(CASE)**

**Institutional Review Board
Human Subjects Protocol
Revised June 8, 2000**

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 11 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 11 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 evaluation consists of collecting both client-level and health care service delivery system-level data. Client interviews, chart abstraction and encounter forms are the three strategies used to collect information about clients. The core client interview asks questions about socio-demographics, health status, knowledge of HIV and HIV

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medications, adherence to HIV combination therapy, support for combination therapy, disclosure of HIV status, and substance use, and takes about 25-35 minutes to complete.

Supplemental instruments on the side effects of HIV medications, depression, substance use, trust in primary HIV medical provider, adherence self-efficacy, and/or beliefs about HIV combination therapy may be administered by some of the AEGs (AEGs who elect specific supplements will administer them to all enrolled clients). The chart abstraction form solicits information about demographics, HIV/AIDS status, health status, adherence to medical visits, and clinical psychiatric diagnosis. The client interviews and chart abstractions will be conducted at baseline and quarterly intervals over a 12-month period. The encounter form track adherence services delivered to the client and will be completed each time a client receives adherence services.

Phase two of the cross-site evaluation will entail site-level data collection. This will consist of in-depth provider interviews, client exit interviews on a small convenience sample, and observations of the service delivery site and intervention delivery using a combination of quantitative and qualitative methods. Both of the protocols for the provider interviews and client exit interviews as well as additional informed consent forms will be submitted for IRB review within one quarter. Phase two of data collection is not expected to begin until Year 2 of this project (October 2000).

Study Procedures

Clients will be enrolled in the AEG study upon presentation to the project site at the time of the intake visit. Eligibility criteria for each local site are set locally. At the time of informed consent for the local evaluation, all eligible clients meeting eligibility criteria for the local adherence support program will be asked to participate in the national evaluation. The total sample for the national evaluation is estimated to be between 3,300 (300/AEG).

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The client interviews, chart abstractions and encounter forms will be administered by local AEG staff.

CASE will be responsible for the data management and analyses of the core data submitted by the AEGs.

Compensation

Clients will not receive any compensation by CASE to participate in the national evaluation. However, they may receive financial incentives from their local AEG.

Informed Consent

All clients will be asked to sign an informed consent specifically agreeing to participate in the national evaluation study. Clients 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 informed that no personal identifying information will be forwarded to CASE. They will also be told that their refusal to participate will in no way affect their care at [NAME OF INSTITUTION].

Risks and Benefits

Clients may not personally derive any benefits from participating in the evaluation. Study findings will be used to help identify adherence support needs of other persons living with HIV at other centers across the country.

Confidentiality of participants will be maintained through the use of unique identifiers, and through password control restricting access to the data set to the Project Director and those working directly with her. No names will appear on any of the client forms. The data collected from each site will be entered into a CASE SPSS database where it will be maintained in an electronically secure environment. Any hard copies of instruments will be kept in a locked file and will be available only for research staff

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involved in the study. Participants will be told that the information that they give to the interviewer will not be shared with their HIV providers and that the information for this evaluation study will be kept completely separate from their 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 AEG will secure its own Institutional Review Board approval. In addition, CASE has prepared for the New York Academy of Medicine IRB review, a consent form for the cross-site evaluation we would like your consideration of both the full consent form and of the excerpt of the paragraph indicated in italics for inclusion in each AEG consent form.