

CENTER FOR ADHERENCE SUPPORT EVALUATION (CASE)

IMPACT OF EVENTS ON PEOPLE WITH HIV/AIDS TAKING HAART: SEPTEMBER 11 EVENTS AND SEQUELAE

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Institutional Review Board, Human Subjects Protocol

STUDY OBJECTIVES

The September 11th terrorist attacks in New York City and Washington, DC were the deadliest to have occurred on U.S. soil, a catastrophe of unparalleled magnitude. Nearly 6,000 people are thought to be dead, a number were injured, and thousands are contributing to rescue and recovery efforts. The attacks induced heightened fear and anxiety throughout the country, but especially in cities that sustained direct attacks. While the financial, bereavement and mental health needs of those directly involved in the attacks are being addressed, attention is also needed to monitor the mental health, economic and social consequences suffered by those who did not directly experience loss or participate in the rescue and recovery efforts. Even people who live outside of New York or Washington may experience stress through media exposure, while continuous television coverage of the aftermath may perpetuate post-traumatic stress (Pfefferbaum, Nixon, Krug, et al., 1999; Pfefferbaum, Seale, McDonald, et al., 2000). Informal discussions with providers at CASE sites suggest that client responses to the events are varied. At two non-New York City sites, investigators received reports of increased anxiety associated with the attacks among clinic staff. At least one New York City emergency room noted increased (non-disaster related) visits in the immediate aftermath, but the increase appears to have tapered off (Personal Communication, Ed Fishkin, MD, Medical Director, North Brooklyn Health Network, 2001).

The purpose of this study is to explore how the September 11th attacks and their aftermath (*e.g.*, military strikes, threats of anthrax or other bio-terrorism, etc.) may have affected the lives and adherence experience of people living with HIV/AIDS who are participating in the CASE/HRSA SPNS cross-site evaluation of interventions promoting adherence to highly active antiretroviral therapy (HAART). To understand such changes, we will investigate the impact of the events on changes in medication-taking practices, overall outlook on life and psychological status, quality of life, social relationships, and

illicit drug use and sexual behavior, and participants' responses and adaptation to these events.

Most studies have investigated the long-term effects of disasters (1-2 years post-event), but relatively few have examined short-term effects. Numerous studies have shown that many people experience symptoms of depression and anxiety, somatization, disrupted social relationships, and post-traumatic stress disorder following natural and man-made disasters, *e.g.*, floods, mudslides, earthquakes, nuclear leaks, dioxin exposure, and bombings (Shore, Tatum, & Vollner, 1986; Davidson, Fleming, & Baum, 1986; Bravo, Rubio-Stipec, Canino, et al., 1990; Smith, North, McCool, et al., 1990; Tucker, Boehler, Dickson, et al., 1999; Pfefferbaum, Nixon, Krug, et al., 1999; Pfefferbaum, Seale, McDonald, et al., 2000).

We hypothesize that intensity of exposure to the attacks will be a factor in adaptation. Intensity of exposure (*e.g.* personal experience; proximity; relationship with those killed, injured, or otherwise directly involved; level of media viewing) was the primary predictor of post-traumatic stress symptoms (accounting for 7% of the variance) among middle- and high-school Oklahoma City youth, following the 1995 bombing (Pfefferbaum, Nixon, Krug, et al., 1999). In a population-based, random-digit dialing telephone survey conducted four months after the bombing, alcohol use and smoking rates in Oklahoma City were double, and the proportion of non-smokers who initiated smoking was four times higher (1.6% compared to 0.4%) than in a control city (Indianapolis). Levels of psychological stress were also higher in Oklahoma City. (Smith, Christiansen, Vincent, & Hann, 1999). Rates of dreams or nightmares about the bombing among Oklahoma City residents persisted one year later, though at a diminished rate. Therefore, we plan to interview clients in both cities that sustained attacks as well as those that did not, to determine whether proximity to the site is a factor in adaptation.

Most participants in the CASE cross-site evaluation are poor, marginalized, and socially disadvantaged, and struggle to maintain stability in many aspects of their lives. The effects of terrorism may exacerbate the uncertainties, chaos and fears already faced by this fragile population, which in turn may impede adherence to HAART or increase sexual risk-taking behaviors. Among those who use illicit drugs, stresses stemming from

emotional and social dislocation are potential triggers for relapse in drug use. Without effective intervention, these deleterious behaviors may endanger clients' health or pose a risk of HIV transmission to others. Study findings will enable us to determine whether clients need enhanced adherence support and/or mental health interventions in the immediate or extended aftermath of these tragic events.

PROJECT PROTOCOL

To maximize participation of the 12 SPNS sites, the study will employ three modules: 1) quantitative analysis of routine quarterly adherence data; 2) supplemental data collection; and 3) in-depth qualitative client interviews. Module 1, the quantitative analysis, will utilize data from all sites, collected during routine quarterly assessments, and will require neither additional data collection nor additional consent from participants. At least four sites will participate in Module 2, which will entail the one-time addition of a supplemental data collection instrument to routine CASE quarterly assessments. Four sites will participate in Modules 2 *and* 3, which consists of a one-time, in-depth client interviews.

Overall study objectives are:

- Determine the degree to which the September 11th attacks may have affected HAART adherence among CASE clients;
- Identify determinants of terrorism-related adverse affects on adherence (*e.g.* proximity, pre-event co-morbidity, etc.)
- Develop programmatic recommendations to assist clients who may be at risk for terrorism-related adverse affects on adherence.

METHODS

MODULE 1: QUANTITATIVE ANALYSIS OF CASE QUARTERLY ADHERENCE DATA

Using data routinely collected as part of the CASE evaluation, we will examine trends in pre- and post-September 11th adherence outcomes. While results from this analysis will not demonstrate a causal link between the September 11 events and changes

in adherence outcomes, trends identified may prove useful in understanding the ways in which adherence patterns may be affected.

1. Sample

This module will consist of additional analyses of data collected from all 12 participating CASE sites.

2. Data Collection

No additional data collection will be required for this module.

3. Data Analysis

Using logistic regression or other types of multivariate analyses, we will compare adherence patterns in the three-month period preceding September 11th to at least the subsequent two three-month periods immediately following the events.

4. Compensation

Because this module entails only additional data analysis, participants will receive no compensation.

5. Informed Consent

Because this module entails only additional data analysis, no additional informed consent is required.

MODULE 2: SUPPLEMENTAL DATA COLLECTION

For this study, we will develop a brief supplemental data collection instrument to be incorporated into routine CASE follow-up interviews. The instrument will be designed to assess individuals' experience of and reaction to the September 11th attacks (see Appendix A). If they do not already do so, sites that participate in Module 2 will also be required to administer CASE data collection supplements K) Depression and N) Substance Abuse.

1. Sample

Four CASE sites will participate in this module: Harlem Hospital Center, Montifiore Medical Center, North Broward Hospital District and Washington University School of Medicine. All clients enrolled at participating sites who have been taking HAART for at least one month are eligible.

2. Data collection

The Supplemental Data Collection instrument will assess individuals' experience of and reactions to the attacks in four domains:

a. *Intensity of Exposure.*

This series of items will explore individuals' personal experiences, including injury to person or loss of property; physical proximity to the incidents; relationship with those killed, injured, or otherwise directly involved; experience assisting in rescue or other disaster mitigation efforts; level of media viewing; frequency and intensity of discussion with family and friends; attendance at funerals, memorials, or other ceremonies or events for victims; etc.

b. *Impact of Events*

This series will comprise the Impact of Event Scale (Horowitz, Wilner, & Alvarez, 1979), a 15-item scale that assesses subjective distress and characteristic experiences associated with any life events, in particular, avoidance and intrusion responses, in the past week. Though a single life event is described prior to administering the items as a referent, the wording of each scale item is not anchored to any particular occurrence. Participants are asked to indicate the frequency (not at all, rarely, sometimes, and often) with which they experienced each item in the last seven days. The scale has demonstrated high split-half reliability scale ($r = .86$) and the sub-scales have high internal consistency reliability ($\alpha = .78$ intrusion and $\alpha = .82$ avoidance). In addition, empirical validity of these sub-scales is adequate, based upon clinical observation, inference, high item relevance, factor analysis, discrimination between patient and non-patient populations, and high internal consistency over time (Zilberg, Weiss, & Horowitz, 1982).

c. *Depression*

Sites that are not already doing so will be required to administer the CASE *Supplement K) Depression* instrument, which is based upon the CES-D (Center for Epidemiologic Studies Depression Scale)

d. *Substance Abuse.*

Sites that are not already doing so will be required also to administer CASE *Supplement N) Substance Abuse* instrument.

3. Data Analysis

Regression analysis will be used to investigate the association between changes in adherence patterns and proximity, impact, intensity of exposure, substance use and depression.

4. Compensation

Individuals will not be compensated for their participation in this study module.

5. Informed Consent

All clients and providers will be asked to sign an informed consent specifically agreeing to participate in Module 2 of the Impact of Events Study (see Appendix B: Client Interview Consent Form). Clients will be informed that their participation in this study is voluntary and that they can chose 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 their respective facilities. All participants will be informed that no personal identifying information will be forwarded to CASE.

MODULE 3: IN-DEPTH QUALITATIVE INTERVIEWS

In-depth qualitative interviews will be conducted one time only with clients at CASE sites that elect to participate in this module. In-depth, unstructured interviewing will allow participants to describe their attitudes and experience regarding global and specific changes in their daily lives since the September 11th attacks. The interview will enable us to broaden our exploration of the impact of terrorism beyond adherence behavior to detect more global and perhaps indirect effects on clients' functioning, which in turn, may affect adherence. The interviews will be conducted by a member of the CASE team.

Domains for investigation include: overall outlook on life and psychological status, quality of life, social relationships, drug use and sexual behavior, smoking

practices as well as changes in medication-taking patterns, adherence to HAART, and use of clinical and adherence support services (see Appendix C: In-Depth Interview Guide).

1. Sample

Four SPNS adherence support intervention sites will participate in this study module. Two are located in New York City (Montefiore Medical Center and Harlem Hospital Center). The remaining sites (Washington University, St. Louis, MO. and North Broward County, FL) are located outside of New York City, and so will serve as comparison groups. Local site staff will utilize convenience sampling used to recruit 20 clients at each site. Client eligibility criteria include enrollment in the SPNS adherence support program and taking HAART for at least one month.

2. Data Collection

CASE staff, consultants and/or local site staff with substantial qualitative interviewing experience will conduct the interviews. These interviews will be initiated immediately after obtaining NYAM and local site IRB approvals. 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. 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 by an experienced CASE consultant. The audiotapes will be sent to CASE for transcription.

3. Data Analysis

The 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. We will use a computerized software program -- Nudist NVivo -- to organize responses and develop matrices to examine salient patterns within and across cases.

4. Compensation

Clients will be given the same amount of financial compensation that the participating sites have given for participation in the CASE cross-site interview.

5. Informed Consent

All clients and providers will be asked to sign an informed consent specifically agreeing to participate in the Impact of Events Study (see Appendix D: Client Qualitative Interview Consent Form). Clients will be informed that their participation in this study 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 their provider institution. 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 determine the need for enhancing adherence support and mental health interventions for persons living with HIV in light of recent terrorist attacks.

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 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 interviews 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 providers at their clinic, unless the client gives written permission to the interviewer. This is essential since some clients may need a referral to mental health services at their institution.

Clients will be told that there is a possibility that the kind of questions they are asked may be upsetting, make them feel sad, or even cry, and that if they become upset, they will be referred to a qualified mental health professional (psychiatrist, psychologist, social

worker) at [NAME OF INSTITUTION]. Each participating institution will be asked to designate a mental health liaison whose name will be noted in the consent form.

Following approval of this protocol, consent forms and interview guide by the New York Academy of Medicine's IRB, each site will secure its own Institutional Review Board approval.

REFERENCES

Bravo, M., Rubio-Stipec, M., Canino, G., et al., (1990) The psychological sequelae of disaster stress prospectively and retrospectively evaluated. *American Journal of Community Psychology* 18: 661- 680.

Davidson, L., Fleming, I., and Baum, A. (1986). Post-traumatic stress as a function of chronic stress and toxic exposure. In *Trauma and its wake*, Figley, C. (Ed), (pp. 57-77)

New York: Brunner/Mazel.

Horowitz, M., Wilner, N., and Alvarez, W. (1979, May). Impact of event scale: A measure of subjective stress. *Psychosomatic Medicine* 41 (3): 209-218.

North, C.S., Nixon, S.J., Shariat, S., Mallonee, S., McMillen, J.C., Spitznagel, E.L., and Smith, E.M. (1999, August 25). Psychiatric disorders among survivors of the Oklahoma City bombing. *Journal of the American Medical Association* 282 (8): 755-762.

Pfefferbaum, B., Seale, T.W., McDonald, N.B., Brandt, E.N., Jr., Rainwater, S.M., Maynard, B.T., Meierhoefer, B., and Miller, P.D. (2000, Winter). Posttraumatic stress two years after the Oklahoma City bombing in youths geographically distant from the explosion. *Psychiatry* 63 (4): 358-370.

Pfefferbaum, B., Nixon, S.J., Krug, R.S., Tivis, R.D., Moore, V.L., Brown, J.M., Pynoos, R.S., Foy, D., and Gurwitch, R.H. (1999, July). Clinical needs assessment of middle and high school students following the 1995 Oklahoma City bombing. *American Journal of Psychiatry* 156 (7): 1069-1074.

Shore, J., Vollmer, W.M., and Tatum, E.L. (1989). Community patterns of posttraumatic stress disorders. *The Journal of Nervous and Mental Diseases* 177 (1): 681-685.

Shore, J., Tatum, E.L., and Vollmer, W.M. (1986). Psychiatric reactions to disaster: The Mount St. Helens experience. *American Journal of Psychiatry* 143: 590-595.

Smith, D.W., Christiansen, E.H., Vincent, R., and Hann, N.E. (1999, April). Population effects of the bombing of Oklahoma City. *Journal of Oklahoma State Medical Association* 92 (4): 193-198.

Smith, E., North, C., McCool, R., et al., (1990). Acute postdisaster psychiatric disorders: Identification of persons at risk. *American Journal of Psychiatry* 147: 202-206.

Tucker, P., Boehler, S.D., Dickson, W., Lensgraf, S. J., and Jones, D. (1999). Mental health response to the Oklahoma City bombing. *Journal of Oklahoma State Medical Association* 92 (4): 168-171.

Zilberg, N.J., Weiss, D.S., and Horowitz, M.J. (1982). Impact of event scale: A cross-validation study and some empirical evidence supporting a conceptual model of stress response syndromes *Journal of Consulting and Clinical Psychology* 50 (3): 407-414.