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Impact of an Adherence Program on the Health and Outlook of HIV-Infected Patients Failing Antiretroviral Therapy

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Impact of an adherence program on the health and outlook of HIV-infected patients failing antiretroviral therapy.(HIV Adherence Program).

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Background: We prospectively studied the impact of an adherence counselor on the outcome of patients failing antiretroviral therapy because of nonadherence. **Methods:** Forty-six patients, identified as chronically nonadherent were enrolled. Individual attention was provided using the information, motivation and behavioral methodology. HIV RNA (viral load, in copies/mL), CD4 count (in cells/[mm.sup.3]), and body weight before and after the adherence counselor were measured. Qualitative outcome and patient satisfaction were assessed by deidentified third-party interviews. **Results:** Over half completed at least 1 year; only 8 patients were lost to follow-up. Mean CD4 counts increased significantly ($P < .05$) for completers at 6 and 12 months. Viral loads decreased between baseline and 6 months. Most clients reported subjective benefit from working with the adherence counselor. **Conclusion:** Although few clients showed complete virologic suppression, the value of an adherence counselor was validated. Longer term adherence programs should be evaluated.

Keywords: adherence; failure of medical management; compliance; counseling; HIV outcomes

Once the decision to start therapy has been determined, adherence to antiretroviral therapy is essential for the clinical management of HIV infection. Yet multiple studies have revealed poor adherence to antiretroviral regimens resulting in failure to suppress HIVRNA values, the emergence of drug-resistant strains, and more rapid progression of illness to clinical and surrogate end points. (1-8) This problem is not new. Poor adherence to medication has been recognized as problematic since the writings of Hippocrates (460-377 BC) who advised that physicians should "be alert to the faults of patients which often make them lie about the taking of medicines prescribed." (9) Consequently, increased attention has been paid to the problem of adherence and methods for promoting good adherence in recent HIV literature.

Adherence to highly active antiretroviral therapy (HAART) is a challenge for even the motivated client. Multiple drugs, complex dosing schedules, dietary restrictions, and significant short-term and long-term side effects are frequent complaints. Clients themselves have comorbidities that impact adherence: mental illness, poor relationships with providers, transportation and access issues, poverty, substance abuse, social environment and living conditions, personal belief systems, and concomitant physical illnesses. Social prejudices against HIV/AIDS may create further obstacles, as patients may not want colleagues, friends, or family to know about the

illness, thereby making it hard to maintain complex medication regimens. Poor relationships with providers result in less than optimal clinical results: more than any other factor in urban HIV clinics, missed clinic appointments correlate with unsuccessful treatment. (10)

Roberts (11) identified 5 main barriers to adherence in a series of client interviews: forgetfulness, social and physical environment, antiretroviral regimen complexity, medication side effects, and inadequate patient knowledge. She concluded that patients might overcome some of these barriers by receiving better education about the nature of HIV/AIDS and the need for medication adherence, professional and lay support, and mechanical reminders such as alarm clocks and medisets. These results also indicate the need for additional research into how psychosocial factors and personal beliefs impact adherence in HIV/AIDS. (12-17)

This study utilized the information, motivation, and building skills methodology (IMB) (18) and was designed to assess whether the introduction of an adherence counselor has a positive impact on adherence characteristics and clinical outcomes in a cohort of patients with a history of poor adherence to medical treatment. Others have shown that success may be achieved in such populations by assuring readiness and finding the right provider. (19) In addition to measuring quantitative end points, we assessed qualitative information from clients about the effectiveness of the adherence counselor to determine whether this type of program will benefit other clients, providers, and support service agencies. Qualitative methods help to demonstrate the humanistic perspective and are beneficial in answering psychosocial questions about how individual patients cope with the demands of taking antiretroviral medications and living with HIV infection. At least 95% adherence to antiretroviral therapy is necessary to limit the risk of resistance to medications. Recognizing this, the investigators undertook this study to determine the impact of individualized holistic attention, in the form of an adherence counseling intervention, on the health and outlook of clients identified as recalcitrant by the study investigators.

Methods

Study Overview

The adherence counselor position was created to provide individual attention to adherence issues for HIV-positive clients attending the immunology (HIV) clinic at the Stamford Hospital, a 300-bed community teaching hospital in southwestern Connecticut. The clinic serves approximately 400 clients; at any given time about 200 are consistently and regularly using clinical services. Of the clients using the clinic, 50% are African American and 27% are Hispanic or Latino. Greater than 35% are drug users or former drug users, and 6% are homeless. The clinic serves a predominantly indigent clientele. Requirements for the adherence counselor position included excellent communication skills, compassion, spirituality, flexibility in scheduling, awareness of the community, and an in-depth knowledge of HIV and its medical management. Funding for the position was obtained from federal Ryan White Title II care funds provided through the State of Connecticut Department of Public Health to Stamford CARES, a not-for-profit HIV service organization.

From March 2000 to February 2001, 46 HIV-infected individuals older than 21 years were consecutively identified by the infectious diseases physicians and/or the HIV nurse practitioner

as having long-standing difficulty adhering to antiretroviral therapy. Patients had been diagnosed as HIV infected from 1985 through 1999, with a mean infection duration of 6.8 years. Adherence to HIV management is difficult to measure, (20) but for this study, nonadherence was defined by persistently high HIV viral load values (Roche Amplicor HIV RNA polymerase chain reaction values of more than 10 000 copies/mL) despite prescribed antiretroviral treatment, frequently occurring together with poor clinic attendance and self-reported poor adherence. These clients were referred to the adherence counselor. Table 1 details the plan for implementation of adherence counseling.

On referral, the adherence counselor, who was also a registered nurse and family therapist, performed a comprehensive medical and psychosocial assessment of each client for his or her ability to adhere to therapy. The assessment occurred in a location identified by the client as comfortable for him or her. The adherence counselor provided intense, full-time, one-on-one education, nursing support, and comprehensive adherence resources (eg, directly observed therapy, phone calls, pharmacy pickups, pillboxes) tailored to the individual needs of the client and as agreed to by the client. A client-centered plan was developed based on the individual client's strengths and weaknesses, level of understanding, psychosocial situation, and motivation. Necessary referrals were made to maximize support. Weekly progress and achieved adherence goals were recorded in a client record. Pill counts as well as self-report were used to determine adherence to regimens. Medical aspects of the client's care were not purposefully manipulated.

The IMB (18) methodology was used to structure care plans and encourage behavior change. This model incorporates provision of information and intense education about the disease and medication used for treatment and includes a motivational component to reinforce the importance of adherence and to offer support and encouragement while providing follow-up immediately after the client starts taking medication or changes medication. The client is then helped to build behavioral self-care skills such as accurately filling a pillbox, reordering medication from the pharmacy, and identifying cues during activities of living to serve as reminders of scheduled doses. Vital to the care plan were interventions including assessment of adherence barriers, reinforcement of importance of adherence, and support encouragement at follow-up visits.

Quantitative measurements were performed 6 months before baseline (obtained retrospectively), at baseline (first contact with the adherence counselor), and then prospectively at 6 and 12 months after the introduction of the adherence counselor. CD4 counts, HIV RNA (viral load) values, and patient weights were recorded using codes for each client. Treatment regimens were selected by the infectious disease clinicians providing care for all patients, using contemporary AIDS treatment guidelines. (1)

A one-on-one confidential client interview was conducted after the study was completed at 12 months. Clients discussed their experiences and evaluated the benefit of the Adherence Counselor Program. To prevent bias, a trained interviewer who was previously unknown to the client and was never involved in the client's care conducted the interviews. The interviewer followed a scripted format of questions to provide consistency. The questions focused on views

and feelings of living with HIV/AIDS before the intervention, working with the adherence counselor, medication taking, the quality and success of the treatment plan, the value of the program, the least helpful components of the program, and advice the client would offer other HIV-positive clients and practitioners working with HIV-positive clients. All clients, completers and noncompleters, who were reachable by phone were invited to participate in the confidential interview. Interviews were held either in a room within the hospital complex or at the client's home, according to the client's preference. Interviewee comments were deidentified by the interviewer before transmission to the investigators. Each client who completed the interview process was given \$25.00 for his or her time. Interviews were audiotaped, transcribed verbatim, and reviewed for common themes. Clients were given the opportunity to review the transcribed data to ensure accuracy in transcription. Informed consent was obtained before enrollment pursuant to institutional review board approval of the study.

Data Analysis

Forty-six nonadherent HIV-infected adults were entered in the adherence program study. Twenty-eight patients (61%) completed 1-year follow-up in the program, 8 were lost to follow-up or refused follow-up, and 5 died during the course of the year. Four patients elected no antiviral therapy, and 1 patient was eliminated because of a lack of a complete set of data before the start of the study. Mean values of serial CD4, HIV RNA, and weight for all 28 completers were compared over time; statistical conclusions were drawn by analysis of variance with a priori contrasts. Individual clients were further evaluated with respect to changes in viral load using the following definitions: patients were arbitrarily categorized as likely to be either adherent (viral load less than 400 copies/mL), moderately adherent (viral load of 400-10 000 copies/mL), or nonadherent (viral load greater than 10 000 copies/mL). Changes in individual CD4 counts over time were also categorized as likely to be either nonadherent (increase relative to baseline less than 25%) or adherent (increase greater than 25%). Changes in these parameters were evaluated by the Wilcoxon signed rank test.

Results

As Treated

After the introduction of the adherence counselor, mean CD4 counts increased significantly ($P < .05$) from baseline counts (mean [\pm 1 SD; 244 [\pm 240 cells/ μm^3]) to 6 month (290 [\pm 268 cells/ μm^3]) and 12 month counts (306 [\pm 272 cells/ μm^3]) (Figure 1A). Viral load values decreased significantly only between baseline and 6-month assessments (147 880 [\pm 200 423 vs 61 190 [\pm 137 296 copies/mL]) (Figure 1B). The percentage of patients with at least moderate adherence based on viral load increased significantly ($P < .05$) between baseline and 6 months (7% vs 57%) and between baseline and 12 months (7% vs 43%) (Table 2). Patients with at least moderate adherence were more likely than nonadherent patients to experience an increase of at least 25% in CD4 counts at 6 months (68% vs 25%). No statistically significant change in patient weight was appreciated, despite a trend to increase (Figure 1C). Viral load values, more than even CD4 counts, demonstrated wide variability (range, <50-750 000 copies/mL), resulting in high standard deviation values (Figure 2).

Intent to Treat

Although mean CD4 counts rose (Figure 3), only 61% of the 46 patients who entered the program completed a full year of follow-up, and only one quarter (26%) had become at least moderately adherent by the end of 1 year. Based on more stringent criteria, only 4 (8.7%) of 46 patients had become fully adherent by all 3 measures: self-report, investigators' consensus, and viral load values less than 400 copies/mL. Eight patients were lost to follow-up or had moved, 5 patients died, 4 patients elected to discontinue HAART, and 1 patient was eliminated because of an incomplete data set before study entry.

Qualitative Data Analysis

Qualitative data from 10 patient interviews were transcribed and separated into 4 types of data: perceptions before the intervention, perceptions at the beginning of the intervention, perceptions during the program, and reflective advice from the patient. The authors and the interviewer identified themes for each of these periods. In the first stage, feelings of denial and isolation were a common theme. Denial is a way of protecting oneself from the shock of the disclosure of a terminal illness. For some patients, denial is needed until death. For many patients, denial provides the needed time to understand the diagnosis and organize more lasting coping mechanisms. Most participants described the time period before this intervention, which ranged from a few years to more than a decade, as a time of denial, fear, depression, and shock. Some examples of comments to support this theme of denial were "I didn't want to be around nobody; I was all by myself"; "I didn't understand it; I tried to hide myself"; and "I was ashamed and embarrassed." Some clients recognized the denial and told the interviewer "Big denial"; "It wasn't reality"; "It was something they were just saying"; "I wasn't facing that I had it"; and "It was hectic, shocking; I was in denial for a long time with it." In our study group, we saw evidence of clients' using illicit street drugs to avoid dealing with the HIV diagnosis. Excerpts from interviews include the following: "I was still running the streets/drugging, because I wanted to forget" and "I was into drugs, cocaine, and drinking."

Difficulty with medications was another theme during the interval before the intervention. All of the subjects made statements regarding various aspects of medication taking that impeded the ability to adhere to regimens, including references to side effects, number of pills, and pill fatigue. In fact, one client stated, "I just hate taking medication." Other examples of statements relating to this issue included side effects and the amount of pills: "Pills made me sick, I hurt, felt better not taking them"; "Made me nauseous, it affected my attitude, felt funny and woozy"; "Never took my meds before [the adherence counselor], I couldn't--there were too many"; and "I was taking like 16 drugs a day, and I was tired of it."

In the beginning of the intervention, once the patient agreed to work with the adherence counselor, an individualized plan was prepared (see Methods above). At first, some of the patients resisted the efforts of the counselor. Such patients are often perceived as difficult and ungrateful and frequently provoke undesired reactions from those who try to care for them. One subject commented on the value of persistence on behalf of the adherence counselor: "At first I

didn't want to work with nobody because I didn't feel like I needed to." Other comments included the following: "When she was calling me, I kept flushing her off, but she kept calling, which was cool"; "At first I didn't want to work with her, because I didn't want nobody to get into my business, then I came around"; and even "She gave me the pillboxes, showed me how to lay them out, but when I got home, I would throw them in the garbage."

The HIV education portion of the program was well received. Excerpts to verify this finding include the following: "I started learning about it and taking it more seriously"; "The more I learn, the better it helps me"; "I got a book to see what each pill means, a pamphlet to read up on it, a card to write it down, so I didn't forget"; and "I realized, no more fooling around." A benefit of working one-on-one with a caring counselor was the improvement in communication. Even though the counselor asked a lot of questions, clients felt this questioning was helpful because they started communicating with someone about their disease.

During the study, subjects revealed 3 things that challenged them in adhering to the medication program. One issue was the medications: the antiretroviral pills, the amount, the need to eat or not to eat with medications, the size of the pills, and the side effects. Another challenge was peer pressure to do illicit drugs and drink alcohol. A third challenge was apathy and depression, mentioned by almost every interviewee. One participant stated, "Sometimes I think I am going to die, too much stuff in my head."

Every participant in this study made positive statements about the qualities of the Adherence Counselor Program. The words strength and power were noted throughout this part of the interview. Patients felt the program helped them improve their situation. Spirituality was also a common thread; most clients expressed a belief that God would continue to help them cope with life. Having someone professional and confidential to share information with gave the clients a better outlook on the future. Many patients stressed the value of confidentiality. The adherence counselor's ability to be a good listener and to inspire was important to the interviewees, helping them improve their outlook on the future and of their own abilities.

Cost

Program expenses were primarily attributable to salary and fringe benefits for the adherence counselor. These expenses totaled approximately \$61 350. Travel, telephone, and pager expenses were approximately \$1500. Adherence tools were mostly provided free by separately funded state or local programs and pharmaceutical companies. Out-of-pocket expense for these items was about \$400. Meetings, staff education, and supplies expenses were budgeted at \$1200. There were no significant additional space or secretarial expenses. The total annual program cost, \$64 450, benefited more than the 28 clients who completed this study. It included more than 1000 client contacts (including 300 patient visits in the immunology clinic) and at least monthly contact with all the study clients, for an average cost per client contact of \$48. Additional testing and medical care attributable to better adherence was not factored into these computations.

Discussion

Poor adherence to HAART is common. Patients may miss up to one third of all medication doses, and up to one fifth of the patients never fill their initial prescriptions. (10) Studies have shown that for optimal viral suppression, patients must take more than 95% of prescribed doses. Lesser degrees of adherence are associated with higher rates of virologic failure, immunologic deterioration, and progression of clinical disease.

Multiple patient-focused interventions to increase adherence have been reported elsewhere to be of value and were incorporated into our program. (21-27) These interventions included providing financial counseling and support, providing free medication, streamlining medication schedules to once or twice daily, and coordinating medication taking into the patient's daily living schedule. The need to establish trust, provide spiritual support, utilize peer groups, provide access to nonphysician caregivers, link viral load and CD4 counts to therapy, monitor and aggressively treat adverse events, and share results with patients are all acknowledged and were utilized by this program. Strategies also involved intense education regarding the purpose of the medications, anticipated outcomes, importance of a medication schedule, and reportable side effects. Directly observed therapy, medication boxes, handouts with times and medications, and cue cards were used for each individual patient, as appropriate. Positive feedback and sharing laboratory results with graphic displays and flowcharts also motivated patients' continued adherence. It is crucial that patients and clinicians work together to achieve successful adherence to medication therapy. (19,28)

Attempting to incorporate multiple adherence interventions into the context of a busy practice or clinic may not be possible. A poorly motivated client becomes lost in this scenario; therefore, we prospectively designed our study to add a dedicated adherence counselor to the care of a historically nonadherent group. Our concept was to provide customized, individual attention to each of the 46 clients enrolled in this program. Such attention was not limited to clinic time but was completely flexible to fit in with the client's availability and perceived individual needs. This program benefited all the clients using the immunology clinic as well as the 28 clients participating in the study, averaging \$48 per client contact and \$64 450 annually.

After intense adherence management for 1 year, we were able to recruit about one quarter of these clients into improving their behavior into what we judged at least moderately adherent, and 8.6% actually achieved full virologic suppression. Perhaps also noteworthy, 60% actually became compliant enough to allow serologic follow-up every 3 to 6 months. Because we did not assess for preexisting drug resistance, it is possible that a larger percentage would have become virologically suppressed if treatment had been customized according to viral genotype or phenotype. In our qualitative evaluation, many clients clearly expressed that their improved performance was attributable to the adherence counselor.

This study illustrates the value that a dedicated adherence counselor may have in promoting clients' adherence to antiretroviral therapy and, in the very least, to maintain connection to their health care. Only 8, or 17%, of the 46 clients we identified as recalcitrant were lost to follow-up;

61% completed the program. Although there may be features unique to our study site and to our adherence counselor, there are some clients who will always refuse treatment options and support. There is certainly value to dedicated adherence counseling time in HIV management, which may help reduce the risk of loss to follow-up and improve patient monitoring. Success in such programs will undoubtedly promote better clinical outcomes and should retard the development of antiretroviral drug resistance.

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Table 1. Plan for Implementation of Adherence Counseling

1. Medical provider refers client to adherence counselor.
2. On receipt of referral, schedule an appropriate time to do initial assessment (medical and psychosocial). Assessment is done at the client's home, the hospital, by phone contact, or any appropriate site where the client is comfortable.
3. Assess clients' strengths and weaknesses to enhance adherence,

level of understanding of the disease and the need for medication, physical, and psychosocial situation that may influence adherence, skills to effectively master adherent practices, and client motivation.

4. Develop a client-centered care plan.
5. Provide adherence tools (eg, phone calls, pillboxes, beepers, picture charts, written instructions, rewards or incentives, home visits).
6. Offer daily contact with client at onset (telephone, visits) to include directly observed therapy, if appropriate, and taper as tolerated according to adherence achieved.
7. Assist client with obtaining necessary support for maximizing adherence to medication and/or treatment (eg, referral to Ryan White case manager, pharmacist, drug counseling, medical and social programs, community resources, pastor, family, friends, peer support groups).
8. Track progress of meeting medication adherence goal in client record at least weekly.
9. Meet weekly with care team, including HIV nurse practitioner, physicians, Ryan White case manager.

Table 2. Ranges of Viral Load and CD-4 Count Values in Patients Who Completed 1 Year of Follow-up With the Adherence Counselor *

HIV RNA, copies/mL

Range	Baseline	6 mo	12 mo
0-10 000	2 (7)	16 (57)	12 (43)
10 000-100 000	14 (50)	8 (29)	10 (36)
>100 000	12 (43)	4 (14)	6 (21)

CD4 absolute counts, cells/[mm.sup.3]

Range	Baseline	6 mo	12 mo
<200	14 (50)	11 (39)	12 (43)
201-350	6 (21)	10 (36)	9 (32)
>350	8 (29)	7 (25)	7 (25)

* Values are presented as no.(%).

Figure 1 A, mean CD4 count values for the group of 28 patients completing 12 months of treatment. B, mean HIV RNA values (viral load, in copies/mL) for the group of 28 patients completing 12 months of treatment. C, mean patient weight, in pounds, for the group of 28 patients completing 12 months of treatment.

A	Mean CD4 count
6 months prior	261
Immediately prior	244
6 months after	290
12 months after	306

