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A 24-Week Education-Support Approach to Increasing Adherence to Therapy in HIV-Infected Adults: Results of a 3 Years Ongoing Pilot Project (Obstacles and Success)

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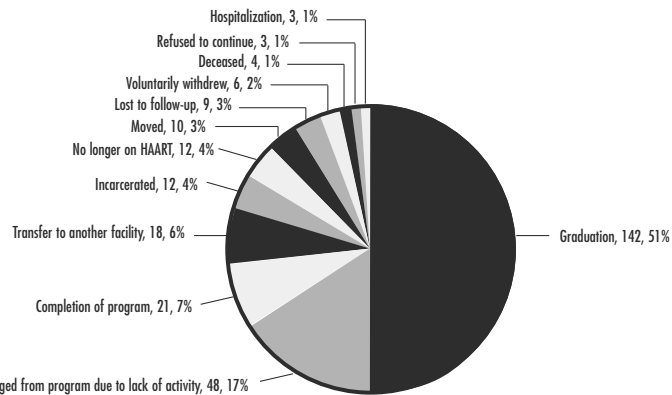
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Introduction: Nassau University Medical Center (NUMC) is a NYS Designated AIDS Center located in Central Nassau County, a region with the highest HIV/AIDS prevalence of any suburban region in the US. Every community in Nassau County has been affected by the AIDS epidemic. Nevertheless, the communities that have shouldered the greatest burden of the disease are Freeport, Hempstead, Inwood, Roosevelt, Uniondale, and Westbury. The residents of these towns also disproportionately suffer from high rates of sexually transmitted disease, teen pregnancy and poverty. This Project (Treatment Adherence Program) is a NYSDOH funded grant, which Provides education and support to the patients from this area who are on retroviral therapy to ensure a high level of treatment adherence. 79% of clients in this program had annual income less than 10,000 dollar per year, 49% without permanent housing and 46% were involved in substance abuse.

Description: 236 patients from August 2003 through August 2006 have been enrolled in treatment adherence program. All clients utilizing the Adherence Program are patients attending the NUMC HIV Primary Care Clinics. Our goal has been to achieve a measurable increase in adherence to antiretroviral treatment with sustained suppression of HIV replication and improved immune reconstitution (At least 3 viral loads and CD4 counts in 24 weeks program period). The adherence counselor meets with each client and explains program goals, makes comprehensive assessment of needs and identifies barriers to adherence. Referral to subspecialty services for addiction, depression and adherence related education is provided and treatment readiness is evaluated. A clear and concrete treatment plan with written instructions is given to the patients when they are ready to initiate treatment. Adherence tools, incentives, specialized pharmacy services, Modified Directly Observed Therapy are utilized as necessary. Upon enrollment in the Adherence Program clients are categorized based on priority. Clients are considered "Highest Priority" when beginning their first HAART regimen. Treatment experienced patients will be enrolled based on need; such as changing their regimen, experiencing virologic failure, or identification of barriers to adherence. "Basic Adherence Services" including education, negotiating a treatment plan, selecting regimens, monitoring adherence, discussion of side effects, and monitoring of HIV viral load is considered for all clients.

The patients have 12 encounters with adherence staff, counselor and primary care provider during this period. 5 onsite visits with Adherence Counselors at weeks 1, 3, 6, 9 and 12, 5 Phone calls with Adherence staff at weeks 2, 4, 5, 10 and 11 and 2 onsite visit with primary care provider at weeks 3 and 12. Patients are evaluated in week 12 for treatment adherence. Based on the results of 12 weeks of monitoring, clients have been categorized as those that need the following levels of intervention: Minimal Intervention - motivated, reliable clients tolerating HAART (>95% adherence rates); Moderate Intervention - clients committed to treatment but continue to miss doses because of regimen problems, work, schedules, and forgetfulness (90- 95% adherence); Intensive intervention - clients with addiction, mental illness, unstable housing, serious co morbid condition, cultural/linguistic barriers, and those with physical/mental handicaps that limit adherence (<90% adherence). Follow-up beyond 12 weeks Frequency of monitoring visits and intensity of supportive treatment adherence services is tailored to individual need. Clients successfully completing the 24-week program would be considered "graduated" and patients who have failed four attempts of encounter over 12 weeks period would be considered "disenrolled."

120 patients (51%) have graduated 142 times (some more than one time). 116 patients (49%) could not graduate from the program; most of them (34%) disenrolled for suboptimal participation in program.



In graduated patients 80% have CD4>200 at the time of graduation (Compare to 65% at the time of enrollment)

Lesson Learned: Despite intensive monitoring suboptimal adherence is common (34% in our patient population). It is hard to design effective interventions to address the nonadherent patient without understanding the patterns of adherence in each individual. Success is the result of good collaboration between the patient and the health care provider in recognizing the barriers for the individual and making the best judgment to intervene. (Lack of participation is the main reason for disenrollment).

Recommendations:

- Identify subset of patients at high risk for adherence.
- Design intensive monitoring based upon adherence need.
- Use objective measure as a benchmark (one log reduction in viral load in 12 weeks) to assess the success.
- Direct energy and resources of adherence program to those that need it most.

Background: Missing doses of antiretrovirals may cause resistance and morbidity and may be due to patient adherence, or system problems. We have noticed that due to system problems, refill requests were not handled promptly at times. The pharmacy felt compelled to issue a 5 day emergency antiviral refill.

In 5/06 our community clinic, serving mainly Latinos, initiated an electronic medical record system (EMR) that, with a mouse click, faxes a prescription to a pharmacy or uses an internet prescription service that communicates refill requests from the pharmacy's software to the EMR and a new or refilled prescription from the EMR to the pharmacy's software. This service is superior to a fax; there are less humans handling and entering the information, reducing time and errors.

Methods: We use the HealthMatics EMR (<http://www.a4healthsystems.com/>), and the internet service, SureScripts (<http://www.surescripts.com/>). In cooperation with 2 locations of MOMS Pharmacy (www.momsparmacy.com). We will compare data from before EMR start date and after 6 months of use: the number of HIV patients on pharmacy service, the number of emergency refills in a month, the response times of the clinic to refill requests.

Results: Data will be presented for pharmacy A and B, and for the 2 time periods.

We will report: 1) The number of emergency refills/HIV patients on service for 2 specific months. The denominator is to normalize the difference of patients on service in case it has changed between the 2 data collection periods. 2) The ranges of the number of days it took for our clinic to respond to refill requests for each patient's prescription during 2 specific months. These will be analyzed by a statistician for significant differences.

Conclusions: We expect to conclude that: 1) There is a clinically significant improvement in the number of times an emergency refill was needed during the after EMR month. 2) There is a statistically significant improvement in the response time to a refill request during the after EMR month.

Introduction: HAART implementation has had an important impact in people living with HIV AIDS (PLWH) morbidity and mortality. Complexity of treatments makes difficult its fulfillment. This program tackles adherence difficulties through a multidisciplinary approach.

Description:

- Objectives:*
- To improve adherence to treatment as indicated.
 - To educate different actors involved in PLWH health care.

Materials & Methods:

1. PLWH who are receiving HAART or about to start treatment.
2. Educational axis: PLWH, health care workers and volunteers who are interested in being trained in HAART optimization strategies.

Methodology: Program looks forward to improve patients' quality of life by adherence optimization. Actions are divided into 2 axis.

1. Operational axis: Action Plan: Individual interviews with pharmacists, physicians and psychologists. Workshops for adherence maintenance. Patient support and assistance by phone. Review of requisitioning list. Search of lost to follow-up PLWH.
2. Educational axis: Action Plan: Training Courses: Basic pharmacology of antiretroviral agents for PLWH. Rotation for pharmacists in training the in pharmacy adherence program. Update on Pharmacological bases of HAART for pharmacists. HIV care update for nurse staff. Health volunteers training.

Lessons Learned: 880 medical charts were reviewed and 126 phone calls to search los to follow-up patients were done. 136 patients attended 414 Workshops. 176 interviews with psychology were performed. 58 patients attended 72 interviews with pharmacists.

- The program is feasible.
- The assistance programs are voluntarily accepted by a significant number of patients.
- The multiplicities of answers not always reply to patients requirements.
- Training Courses are valued for their originality and specificity.
- Continuous efforts should be implemented to obtain information on objective markers of HAART adherence improvement.

Issues: Adherence to antiretroviral therapy continues to be of paramount importance in successful treatment of HIV/AIDS. In an effort to identify, address and overcome barriers to adherence, "Appetite for Adherence: Club Medbox" was incorporated into a Pharmacist-Based Treatment Adherence Program to provide a trusting environment which encourages communication and ultimately increases self-efficacy.

Description: Patients with minimal support or a history of non-adherence were invited to join "Club Medbox." Participants share ownership by developing guidelines, establishing norms and proposing topics. Meeting every other week, patients fill their own medboxes. Accuracy is verified by patient and Pharmacist. A self-administered adherence measurement, the CASE Index, is utilized at each visit as a tool to address individual concerns and barriers. The Pharmacist speaks with a focus on education and understanding the demands of the medication requirements in the context of avoiding resistance. The Behavioral Health Therapist facilitates the development of a therapeutic alliance between patient and provider. An educational component is incorporated into lunch.

Lessons Learned: Essential components include medical, behavioral, educational and psychosocial support. Patients at risk for non-adherence due to substance abuse, psychological issues, lack of social support or limited economic resources receive consistent coaching and modeling by staff and peers. The group allows for the safe examination of casual factors associated with risky behavior and discusses healthy alternatives. Case studies show the group's greatest success is its ability to provide social support and encouragement amongst patients. Patients have built a solid network with one another finding commonality and support which did not exist prior to "Club Medbox." Case studies to be presented.

Recommendations: Providing a non-judgmental, non-punitive, nurturing and educational environment allowing patients to identify with one another can increase adherence. Clinics may need to address cultural influences and diminish barriers such as language, gender or medication experience by implementing multiple groups.

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Electronic Medical Record and Prescription Transmission Reduces HIV Medication Refill Response Time and Emergency Refills in Latino Community Clinic

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Multidisciplinary Program to Improve HAART Adherence

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"Appetite for Adherence: Club Medbox" at Special Immunology Associates, an HIV Outpatient Primary Care Setting

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The CASE Adherence Index: Practical Usage Beyond Adherence Assessment at Special Immunology Associates, an HIV Outpatient Primary Care Setting

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Issues: The CASE Adherence Index, a tool which measures antiretroviral adherence by self-report, was integrated into a Pharmacist-Based Treatment Adherence Program. It was hypothesized that by administering the CASE Index at each consult, the Pharmacist could 1) determine present degree of adherence, 2) assess changes in adherence over time and 3) measure the effectiveness of the program.

Description: The CASE Index contains three easily administered components. Composite scores range from 3 to 16. Scores are calculated dichotomously with scores greater than or equal to 10 indicating high adherence and scores less than 10 indicating poor adherence. The initial assessment (T1) using the CASE Index was administered to 145 patients while 64 patients received a follow-up assessment (T2). At T1, the CASE Index measure had a mean of 11.95, standard deviation 3.17, with 22% of the patients reporting poor adherence. Initial and follow-up data were matched (n=64) and the mean CASE Index measure was 11.66 (T1) and 11.35 (T2), demonstrating a clinically insignificant decrease. Dividing these 64 patients with high adherence (n=46) and low adherence (n=17) at T1, a paired-T test was used to assess differences in T1 and T2 scores between the groups. Both the high and poor adherence groups' scores changed significantly from T1 to T2; 13.34 to 12.11; $p < 0.003$ and 7.12 to 9.29; $p < 0.001$, respectively.

Lessons Learned: The CASE Index is useful in identifying non-adherent patients who warrant immediate interventions. To measure effect and capture change in adherence, long term usage of the tool is necessary. The CASE Index is a measure of self-report; therefore, the initial score may be inflated due to social desirability: Once rapport and trust is established the score may actually decline and then plateau.

Recommendations: The CASE Index should be used at each consultation as an avenue to discuss adherence with the patient.

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Post-Traumatic Stress Impacts Adherence to Medical Care among Youth with HIV

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Background: Our previous research has found a significant relationship between posttraumatic stress disorder and adherence to care among youth with HIV. This study examines how overall and specific symptom severity levels of posttraumatic stress are related to adherence to medical care

Methods: Thirty youth, ages 18-24, were recruited from an urban pediatric hospital HIV clinic. Participants were 70% male, 23% female, and 7% transgender, and reported sexual orientation as 50% MSM, 3% lesbian, 20% bisexual, and 27% heterosexual; most were African American (83%) and unemployed (63%). Participants completed the Post-Traumatic Stress Disorder Checklist twice, first for their self-identified "worst" experience and then for their next "worst" experience or receiving a HIV diagnosis, if that was not named first. Because not all the youth in the clinic are currently receiving highly active retroviral therapy, adherence was measured by percent of clinic visits kept over six months, and a care provider's global rating of adherence.

Results: The association between the two adherence measures was high ($r = 0.607$, $p < 0.001$).

Those youth who named a non-HIV stressor as "worst" showed lower levels of adherence than those who named the HIV diagnosis as "worst." These differences were seen in both percent appointments kept [$t(27) = -2.171$, $p = 0.039$] as well as provider ratings [$t(27) = -2.183$, $p = 0.038$]. Overall, severity level of HIV-associated target symptoms was not associated with adherence. However, non-HIV target symptom severity was associated with reduced adherence ratings ($r = -.366$, $p < 0.05$). Severity of arousal symptoms was associated with poorer adherence to care for both types of trauma reactions.

Conclusions: Traumatic stress, even when related to a stressor other than receiving a HIV diagnosis, impacts adherence to medical care and must be addressed to enhance adherence.

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Integrating Adherence into a Medical Model

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Introduction: Culture and ethnicity play a major role in patient's perception of their own illnesses, feelings of worthiness, and how and if he/she cares for him/herself. Sexual practices and cultural interpretations of sex are essential factors to be considered if patients are to remain healthy while living with HIV. We see few patients who are able to advocate for themselves. Many don't understand the HIV/AIDS disease process, the importance of medical compliance, or know enough about their bodies. With this in mind, adherence programs encompass more than the basic need for patients to take their medications. Literature recognizes effective adherence programs need to address patient's social and psychological factors which may impact their well-being.

Description: Historically, social services and medical models have not been integrated. Incorporating social and medical services appears to be the new model for success. In order to effectively integrate these two models, adherence programs which are primarily social service oriented must be based on social science theory. In our presentation, we plan to share the theoretical foundation and successful outcomes of the incorporation of an adherence program into a medical model.

Recommendations: Garden State Infectious Disease Associates has used a holistic approach to adherence program based on a foundation in both social and medical science. This approach has proved effective in reducing barriers to care for patients and helped educate clinical staff to consider psycho-social factors in their patient's well-being. Through this process, the program learned that standards of care need to be continually assessed and adapted. While each clinic or health setting is unique, the basic elements of developing an adherence program are a matter of adaptation. An understanding of the philosophical clashes between the social science and medical model enables program developers to work through potential difficulties.

Background: We previously reported that data in electronic health records (EHR) can identify predictors of ART treatment failure (TF), where poor adherence was an especially potent predictor. Our objective was to ascertain whether an expanded definition of adherence, a potentially modifiable behavior, better characterized the risk of TF.

Methods: We analyzed data from a cohort of HIV+ patients on ART with ≥ 2 plasma HIV viral loads (VL) and ≥ 2 visits 1/1/03-12/31/04. The primary endpoint was TF, defined as virologic failure (VF; two consecutive VL >400 c/ml or one VL >400 c/ml followed by either stopping ART or loss to follow-up (LTF)), unsanctioned stopping of ART or LTF. For this analysis we expanded EHR-extracted adherence classification to three categories: 'good' (estimated $>85\%$ ART adherence or missed less than one dose/wk), 'poor-but improving' (documentation of improving or trying to improve) and 'poor-not improving'. We tested the association of adherence with new cases of TF in a multivariate proportional hazards model adjusted for age, race, gender and other previously identified predictors of TF.

Results: A total of 614 patients (74% of the clinic) had at least one HIV RNA <400 c/ml, and of these 127 subsequently met the criteria for TF during the 2-year study period. A total of 497 (81%) patients were classified as 'good' adherence, 39 (6%) 'poor-but improving,' 19 (3%) 'poor-not improving' and 59 (10%) unknown. Among the adherence levels the rate of TF was 22%, 67%, 74% and 24%, respectively. In the multivariate model, 'poor-but improving' (HR 2.73, $p<0.0001$) and 'poor-not improving' (HR 3.05, $p<0.0001$) adherence were significant predictors of TF. Patients with 'poor-but improving' adherence were significantly less likely to experience TF than poor-not improving (HR 2.40, $p=0.03$).

Conclusions: Adherence data recorded in an HIV clinic EHR predicted treatment failure. In patients with poor ART adherence, evidence of improvement is associated with a lower rate of treatment failure. The EHR can be used to identify patients at increased risk of treatment failure, who may benefit from targeted adherence interventions.

Background: HIV infection among the African American and Hispanic communities is disproportionate to the overall population of the United States. Highly Active Antiretroviral Therapy (HAART) has greatly enhanced the prognosis for HIV+ persons. However, research indicates that near perfect adherence (95%) is required to fully benefit from HAART, where lower rates have been shown to diminish its effects. Furthermore, research suggests significant problems exist with HAART adherence, and that major depression (MD) and alcohol and/or substance dependence (ASD) negatively impact adherence. This study examined the relationship between MD, ASD, and ethnicity/race on HAART adherence.

Method: One Hundred Thirty-Two HIV+ participants (70 African American, 33 Hispanic, and 27 non-Hispanic white) completed a comprehensive psychiatric and neuromedical evaluation, as well as a clinical assessment of HAART adherence.

Results: Non-Hispanic white, African American, and Hispanic participants did not differ significantly on age, CD4 count, and viral load. Participants did differ significantly on whether or not they had current MD and ASD, such that African Americans exhibited a higher frequency of current MD and ASD. Adherence rates were as follows: 81% for African Americans, 82% for Hispanics, and 97% for non-Hispanic whites. Adherence rates for African Americans and Hispanics significantly differed from the non-Hispanic white adherence rate. A logistic regression analysis was performed predicting 95% adherence with ethnicity/race, current ASD, and current MD. The overall model was significant ($\chi^2 = 12.55$, $p<0.01$). Ethnicity and current ASD acted as unique and significant predictors of 95% adherence ($p=0.049$, and $p=0.01$, respectively).

Conclusions: These findings raise important issues in understanding adherence among African Americans and Hispanics, and suggest that in addition to alcohol/substance dependence, ethnicity alone plays an integral role in adherence. Research needs to examine what it is about ethnicity/race that contributes to suboptimal levels of adherence.

Background: In 1994 Passaic and Bergen Counties (NJ) were designated an eligible metropolitan area (EMA) per the Ryan White CARE Act. In 2004 a web-based data system, eCOMPAS, was implemented to permit quantitative analyses of provider and client data.

Methods: Analysis of the eCOMPAS dataset was conducted of Case Management provider surveys of 3805 clients (8/04-6/06). We examined 4 outcomes: patient skills, HIV regimen adherence, compliance with medical and case management appointments. Bivariate analysis was conducted with the following variables: HIV status, gender, income source, employment, ability to work, race/ethnicity, county of residence, social network, housing, caregiver support, insurance. Significant variables were included in multivariate models for all 4 outcomes.

Results: Sample characteristics were as follows: 21% AIDS (vs. 79% HIV+), 55% male, 69% Black, 75% unemployed, 48% welfare, 70% Medicaid, mean age 43 years. Bivariate analysis revealed several factors associated with poor outcomes: AIDS status, male gender, welfare, no Medicaid. Multivariate analysis revealed several significant covariates for each of the 4 outcomes: 1-Patient Skills: AIDS, no other source of income, White, Passaic county, no private insurance; 2-Adherence to HIV Regimen: AIDS, male, welfare, no other source of income, White, Bergen county, no private insurance; 3-Kept Medical Appointments: AIDS, welfare, White; 4-Kept Case Management Appointments: welfare, no other source of income, unemployment, White, Bergen county, and uncertainty of care-giver support.

Conclusions: Case management outcomes among patients of Ryan White providers vary by distinct characteristics. Specifically, having AIDS, being White, involvement in the welfare system, and not having private insurance were predictive of poor outcomes, suggesting that more attention be paid to structural factors. To our knowledge, this is the first research application of web-based provider data from a Ryan White EMA which can help inform changes in health services and policies, as well navigate allocation of funding.

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Adherence as a Predictor of ART Treatment Failure in an Urban HIV Clinic

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Adherence to HAART in an Ethnically Diverse, Substance Using Population

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Case Management Outcomes among HIV/AIDS Patients: Social, Demographic, and Health-Related Factors

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Developing a Certification Program for Community Pharmacists in HIV Management: A Public/Private Collaborative Initiative to Improve Adherence Outcomes

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Introduction: Although experts recognize the importance of pharmacist involvement in ensuring successful adherence outcomes, community pharmacists do not necessarily have the skills needed for effective partnership in treatment adherence interventions. In early 2006, members of the NY/NJ AIDS Education and Training Center (AETC), PA/Mid-Atlantic AETC and Abbott Laboratories invited pharmacists and educators from industry, retail, academia and professional associations to form a working group charged with developing a method for ensuring standardized adherence counseling knowledge and skills among community pharmacists involved in HIV medication delivery.

Description: An AETC education series that promotes routine medication adherence counseling among community pharmacists was used as the backbone for the development of an HIV certification program for community pharmacists that will be piloted in Newark, NJ and Philadelphia, PA. The primary goals of the pilot are to 1) standardize pharmacist training in HIV disease and adherence counseling; 2) determine if patient adherence outcomes change after program implementation; 3) assess potential for medication cost-savings; and 4) evaluate adaptability of certification program to other settings.

Lessons: 1) Developing a public-private collaboration of stakeholders enhances problem-solving and improves resource-sharing when addressing regional treatment adherence concerns. 2) Other training models can inform the development of an effective HIV treatment adherence certificate program. 3) HIV clinical preceptorships can help standardize HIV treatment adherence intervention experiences. 4) Certification increases likelihood that pharmacists will acquire sufficient knowledge of HIV medication management to impact patient adherence outcomes.

Recommendations: 1) Medicaid, AIDS Drug Assistance Programs and private prescription insurance programs should be approached to participate in an expansion of the certificate program to determine if cost savings can be achieved when HIV-certified pharmacists deliver antiretroviral medications to patients. 2) Research examining differences in additional patient-and provider-level outcomes such as prescription refill patterns and drug error incidences is warranted.

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HIV Case Management Certificate Program: Addressing Adherence Maintenance through Comprehensive Case Manager Training

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Introduction: Early in the epidemic, HIV Case Management was established to help clients effectively navigate complex medical, legal and institutional bureaucracies, and seldom focused on treatment-specific issues. Since the advent of HAART, case managers are increasingly involved in multi-disciplinary HIV care provision by supporting and monitoring adherence to help clients reach therapeutic ARV medication levels.

Case managers must integrate treatment adherence in their goals and practices to ensure continuity of care for their clients. Continuing professional education can be a valuable tool for teaching case managers effective adherence monitoring interventions, and to provide practice and reinforcement for these skills.

Description: There are no national standards for ensuring the incorporation of adherence monitoring across various case management models. UMDNJ was funded by the Newark Department of Health and Human Services to develop an accredited HIV case management certificate program (CMCP) to train case managers with varied educational backgrounds on implementation of the Newark Title I Emergency Metropolitan Area (EMA)'s Case Management Standards of Excellence. The 17 days of CMCP training are divided into four modules: *Case Management Skills*, *Treatment Adherence*, *Addiction/Mental Health Issues* and *Understanding Identity, Beliefs and Behaviors*. Each module trains case managers to support adherence through adherence barrier assessment and intervention.

Lessons: 1) HIV case managers are key partners in addressing adherence concerns because of their traditional role as HIV care access, engagement and retention brokers. 2) Barriers to client adherence are not static, and monitoring offers opportunities for case managers to intervene before non-adherence leads to treatment failure. 3) HIV case managers who are trained to monitor adherence can more effectively promote and improve client adherence, reducing treatment failure.

Recommendations: 1) Design study to examine aggregate adherence rate differences between clients whose case managers who completed the CMCP and those who completed less than 30% of courses. 2) Encourage other EMAs to incorporate adherence monitoring as a core HIV case management responsibility and to track aggregate client adherence rates by case manager.

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Training Community Pharmacists in HIV Medication Adherence Counseling: An Interactive Approach to Improving Pharmacist Participation in Adherence Maintenance

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Introduction: Community pharmacists are integral in the care of HIV+ patients through their ability to provide adherence counseling during medication delivery. Patient outcomes can be compromised when adherence interventions and training do not include these pharmacists. However, community pharmacists are often overlooked as partners in comprehensive HIV adherence planning.

Description: To address this gap, UMDNJ partnered with retail pharmacies and infectious disease practices to implement an HIV education series designed to promote routine medication adherence counseling among community pharmacists. The three-part, modular and accredited continuing education training series focuses on adherence counseling methods, drug interaction issues, medication error avoidance, and adverse effect management. The clinic preceptorship enables participants to observe multi-disciplinary approaches to patient medication counseling at an HIV clinic. The retail preceptorship offers participants an opportunity to assist in medication counseling at a retail store. The case consultation program provides participants an opportunity to review patient adherence concerns within retail settings and appropriately adjust interventions. Outcome measures include pre- and post-testing to quantify changes in participant knowledge and feedback surveys to measure program quality.

Lessons: Participant responses indicated a commitment to adopting medication adherence counseling as standard practice with HIV patients. Responses also indicate that direct participation in adherence counseling has enabled participants to recognize the value of maintaining routine adherence communication with providers for shared patients. Case discussion was viewed as an important quality improvement tool.

Recommendations: Widespread implementation of the series through institutions offering HIV training (e.g. professional pharmacy associations, AIDS Education and Training Centers) will likely enhance pharmacist participation in medication adherence counseling as well as strengthen necessary linkages between HIV clinics and retail pharmacies. Research to quantify changes in patient adherence outcomes in communities implementing the series is warranted.

Introduction: Hudson Pride Connections has provided HIV services in Hudson County since 1995. *Hudson Buddies* was first established to connect isolated consumers with volunteer companions who would serve as support. Over time, the program began to serve as an observational feedback mechanism for monitoring ART adherence. Adherence maintenance is a cognitive-behavioral skill that, once learned, still requires periodic monitoring and reinforcement — especially with isolated consumers. As a result, *Hudson Treatment Adherence Buddies* (H-TAB) was developed to respond to an adherence monitoring need among socially isolated HIV+ consumers.

Description: H-TAB engages volunteers to address treatment adherence. Trainings focus on treatment options and potential side effects. Clinical supervision helps volunteers to assess and monitor consumer adherence in socially non-intrusive ways. Reports assess consumer adherence over time and note changes in adherence barriers. Monthly contact with clinicians by H-TAB incorporates the data on adherence progress within care plans. If data suggests non-adherence, providers are alerted so they can reinforce maintenance. To complete the intervention cycle, volunteers use the H-TAB program infrastructure to support interventions at the community level by encouraging consumer attendance at adherence support groups.

Lessons:

- Adherence maintenance is a complex process that is most effectively monitored by a cyclical feedback partnership between consumers, clinical care providers and community supports.
- Developing volunteer community support for isolated consumers is key to improving adherence outcomes.
- Volunteers with ongoing supervision and training can be effective partners in adherence monitoring and intervention.

Recommendations:

- Expand feedback to incorporate consumers managed by non-Title 1 providers
- Pilot project to examine impact of volunteer-driven adherence interventions
- Examine long-term health outcomes for H-TAB monitored consumers

Background: Evidence in the literature suggests that HIV+ individuals who are depressed have faster disease progression (Olatunji *et al*, 2006). However, the mechanisms are not well understood (Sledjeski *et al*, 2005); suggestions include lower adherence to medication (Weiser *et al*, 2005) and immunological changes associated with depression itself (Cruess *et al*, 2005).

Methods: 138 sero-positive African American men and women were interviewed up to 8 times each over a period of 3 years. At each interview self-reported adherence was evaluated through the use of a 3-day recall, a single-question 90-day adherence estimate and 3 fixed response questions ("I was unable to follow my MD's treatment plan," "I follow my MD's instructions exactly", "how often over the past 4 weeks were you able to follow your treatment plan"). As well, a number of standard psycho-social assessments were administered, including the Beck's Depression Inventory.

Results: Reported adherence, while quite variable over time for individuals, remained stable on average over the period of the study (mean at study inception = 92.2; mean at exit interview = 91.8). Depression scores improved from the first interview to the last (from 14.3 to 11.5; $p < 0.05$). In general the 3-day medication recall, and the 90 day adherence estimate were not significantly correlated with depression scores. However, at each interview, stated ability to follow one's treatment plan was significantly and negatively correlated ($p < 0.05$) with depression scores. Compared to those who remained alive, the depression scores of the 11 individuals who died during the study were not significantly different at the first interview but were by the second and third interviews, as were their reported adherence.

Conclusions: Evidence from our study suggests that adherence is lower among depressed individuals. This lower level of adherence may be responsible for their poorer clinical results; thus, treatment of depression may improve long-term outcomes.

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Hudson Treatment Adherence Buddies (H-TAB): A Community-Based Peer Intervention for Monitoring HIV Adherence among Isolated Consumers

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Relationship between Adherence and Depression in a Sample of Sero-Positive African Americans

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Can Hospital Admissions among PLWHA Be Used as an Indicator of Quality of Care?

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Introduction: With the introduction of antiretroviral therapy in Brazil, since 1996, the quality of treatment for people living with HIV/AIDS has greatly improved. As a result, the last few years have seen a significant reduction in the number of hospital admissions, in problems arising from opportunistic diseases and in HIV-related mortality

Description: The marked reduction of hospital admissions, length and complexity of treatment needed, suggesting a significant improvement in patient well-being. It is estimated that 990,000 admissions were avoided between 1997-2005, representing savings of SUS 2,9 billion. Changes in type of services used was also noted, with significant growth in demand for outpatient services and decrease for home and day-care services. Mortality was reduced by 60-80% and a notable reduction in number of main OI were seen.

Lessons Learned: The offer of quality services for HIV/AIDS care and wide access to antiretroviral therapy has significantly contributed to a decline in the number/complexity of hospital admissions and of AIDS related deaths. It has also led to a reduction in demand for general medical care for this patients and in direct and indirect costs overall.

Recommendations: To improve equity of access to treatment and care requires significant financial, technical, social and political support to be sustainable over the time.

Table 1. AIDS Hospital Admissions Data

Year	N° Hospital Admissions	N° Patients in HAART	No. Attendance		Expected N° of Hospital Admissions	N° Avoided Hospital Admissions	In patient AIDS related death (pat. In use of ARV)	Avoided Hospital Admissions Costs (Million US\$)
			Patients (asymptomatic/ HAART)	Hosp. Admissions/ patient				
1996	25458			1.65				
1997	25157	35895	50253	0.81	51511	26354	0.34	76,31
1998	24700	55604	77846	0.56	72491	47791	0.19	138,31
1999	25027	72791	101907	0.43	96542	71544	0.14	207,11
2000	26655	88084	123318	0.38	114876	88221	0.12	255,32
2001	27415	105145	147203	0.26	139144	111728	0.10	323,73
2002	27583	119315	167041	0.28	157896	130312	0.09	377,14
2003	28041	132958	186141	0.26	175950	147908	0.08	428,1
2004	27844	147395	206353	0.24	195056	167211	0.07	484,3
2005	27270	170000	238000	0.20	224970	197700	0.06	572,2
Total	265150	927187	1298062	—	1228436	988769		2862,52

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Effective Delivery of HAART and Opportunistic Infection Prophylaxis for High-Risk Patients in an AIDS-Dedicated Skilled Nursing Facility

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Introduction: It has been a challenge to extend the benefits of HIV therapy to vulnerable patient populations with social, behavioral, and/or psychiatric co-morbidities. New chronic care models are needed to improve adherence with medical regimens in these high-risk patient groups.

Description: Leeway is a freestanding, 40-bed AIDS-dedicated skilled nursing facility in New Haven, CT. To be admitted, patients must be HIV-infected and require skilled nursing care. We reviewed clinical and demographic characteristics and medication receipt/adherence for patients admitted to Leeway from 11/04–11/05. Data were obtained from standardized chart reviews and review of monthly pharmacy quality improvement logs, from 11/04 through 5/06.

Lessons Learned: Of 77 evaluable patients, 40% were female; 64% were African-American, 14% Latino; median CD4+ count at admission was 120/mm³, 64% had entry viral loads >400 /ml, and 58% had a prior AIDS-defining illness. Over 80% had histories of substance abuse, psychiatric illness, and/or homelessness or unstable housing; 70% were admitted from hospitals, 30% from community or correctional settings; 51% were admitted for initiation or stabilization of HAART. Monthly pharmacy data for the follow up period indicate that over 90% of eligible patients were started and/or maintained on HAART; a mean of 75% had undetectable viral loads, with a median CD4+ count of 335/mm³, over the 18 months reviewed; close to 100% of eligible patients received MAC and/or PCP prophylaxis.

Recommendations: Supervised HIV therapy, delivered within a residential skilled nursing facility, can achieve excellent outcomes for vulnerable patient populations. Current challenges include working with other community-based agencies to identify safe and appropriate discharge options, so that high-risk patients can continue to benefit from HIV therapies in less medically supervised settings.

Introduction: The present study attempts to study adherence of ART among HIV patients in Madurai city, Tamilnadu, India. The study attempts to assess and evaluate the perception of HIV patients who have followed the ART treatment and identify the social, socioeconomic, cultural and psychological factors in increasing the compliance among HIV Patients to follow up the treatment regularly and also hurdles of no adherence among some of the HIV patients. Based on the available records the study observe the differences in gender variation, age structure variation, belief factors on the treatment and satisfaction, health care utilization and so on.

Methods: The study was based on the analysis of 400 patients who were under ART and these data were collected from a hospital based survey and the details include about the details of the patients educational status, satisfaction levels of treatment, Patient and provider interaction, compliance aspects, gender and age wise variation adherence assessment and promotion, barriers to adherence if any etc., Psychosocial concerns about adherence, socioeconomic stability and interpersonal relations in the family etc., were also collected and analyzed with the help of multivariate statistical analysis multiple regression analysis.

Results: It was inferred that the patients' compliance towards ART is reported to be very high (93%) and most of the patients expressed their strong belief towards the treatment and perceived an increased hope after taking treatment. The non adherence is noticed in some of patients were due to their deaths and inaccessibility to avail the treatment regularly. CD4 status of patients indicated a noticeable decrease in improvement of the health status. The poor socioeconomic level also contributes for no adherence in some of the cases (7%). Good quality of care and NGOs involvement in health care of the patients (87%) promoted a protective effect.

Conclusions: Adverse effects, low level socio-economic, matrimonial situation and travel influence the adherence. It is necessary to set up consultation of adherence for the unit of the patients of this cohort and to ensure a partnership with the countries bordering to ensure a supply in ART in the event of rupture during travel.

Background: Although highly active antiretroviral therapy (HAART) has been generally available in the United States since the late 1990's, data on access to treatment and levels of adherence among Alaska Natives and American Indians has not been well examined. Given their economic and social vulnerability, as well as high levels of trauma history, Indians living with HIV/AIDS are at risk for poor treatment access and outcomes. Two-spirit (i.e., gay, lesbian, and bisexual) Indians are especially vulnerable given their double or triple minority status and documented history of sexual and physical assault.

Methods: We interviewed approximately 100 HIV+ two-spirit Indians in six urban areas in the U.S., recruited through respondent driven and convenience sampling. In addition to other data, we collected information on length of time since testing positive, preferences for both Western and traditional healing, access to antiretroviral treatment, and medication adherence.

Results: Descriptive information as well as differences according to gender and extent of prior trauma will be reported.

Conclusions: Two-spirit Alaska Natives and American Indians living with HIV/AIDS are a potentially very vulnerable group in terms of antiretroviral treatment access and adherence. Our results will provide useful data for the design of effect treatment delivery strategies for this group.

Introduction: The Center for HIV Education Empowerment Research and Support is the Orange County Health Department HIV Medications Adherence counseling and support program. Understanding the importance of Adherence to current medications as the Key factor to promote the desired positive long term outcomes of viral suppression, reconstitution of the immune system and prevention of resistance development we developed a Peers Educators/mentors development curriculum. The purpose is to develop a force of well trained Peers to provide HIV/AIDS basic education and effective adherence counseling and to their Peers and help them identify and overcome different barriers to adherence in the community. The program is called the CHEERS for PEERS Curriculum.

Description: The CHEERS for PEERS curriculum is 12 comprehensive lectures covering all major aspects of HIV/AIDS:

1. HIV Basics Day # 1
2. Understanding the Labs
3. Adherence and Resistance issues
4. The HAART lecture
5. What I need to know about Opportunistic Infections
6. STD's and HIV
7. Tuberculosis and HIV
8. Hepatitis and HIV
9. Mental Health Issues
10. Nutrition in HIV
11. Substance abuse issues
12. Cultural Diversity, HIPPA and the Peer Mentor model

The curriculum is offered in Spanish and English. The students have to attend 80 % of the lectures and pass with a score of 70% or higher in a final test to graduate and receive a Peer Educator diploma.

Lessons Learned: In general we all learn from our Peers. This learning model has gained the acceptance of many patients that are interested to make a difference in their respective communities. Actually we graduated approximately 80 students as Peer educators or mentors. Many of them are actually working or volunteering with the OCHD and with HIV/AIDS community based organizations providing one on one and group HIV adherence education and support of excellence to HIV positive consumers in the Orlando EMA.

Recommendations: Adherence counseling/education is a key process in the management of the HIV positive individual. In our experience patients prefer and develop a trusting relationship when they receive adherence counseling from one of their Peers. Developing a Peer based HIV adherence training curriculum will provide the community with well prepared Peer educators to serve the community and to provide HIV medications adherence education of excellence.

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Assessment of Antiretroviral Therapy Adherence among HIV Patients in Madurai City, Tamilnadu, India

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Antiretroviral Access and Adherence among Two-Spirit Native Americans Living with HIV/AIDS

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The CHEERS for PEERS Curriculum: An HIV Peers Educators Development Curriculum to provide HIV Medications Adherence Counseling and Peer Support in the Community

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CBT for Medication Adherence and Depression in HIV-infected Methadone Patients: A Case Series

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Introduction: Substance abuse and depression can be comorbid with HIV and interfere with adherence to antiretroviral therapy (ART). We have previously demonstrated that cognitive behavioral therapy for adherence and depression (CBT-AD) was successful in patients with HIV and depression without comorbid substance abuse.

Description: In preparation for a randomized controlled trial, we describe the feasibility and outcome of cognitive behavioral therapy for adherence and depression in five individuals with HIV and depression who were undergoing methadone maintenance therapy for heroin dependence. CBT-AD integrates CBT for depression (activity scheduling, problem-solving, relaxation training, and cognitive restructuring) with CBT to improve adherence (Life-Steps; Safren *et al.*, 2001). Self-report and MEMs measured adherence. Depression severity was assessed by validated clinician-rated and self-report measures. Mean scores improved from baseline to post-treatment. Adherence: mean scores improved 17% (63% to 80%); Case 1: 86% to 61%; Case 2: 79% to 89%; Case 3: 46% to 89%; Case 4: 79% to 100%; and Case 5: 25% to 61%. Overall depression severity also improved in all but one case. Session by session measures of adherence and depression will be presented.

Lessons Learned: A major challenge was balancing main treatment targets (i.e., adherence and depression) with need to address multiple problems and significant stressors in a comorbid population (e.g., housing difficulties, unemployment, and substance abuse).

Recommendations: In employing structured adherence interventions with such a medically and psychiatrically complex population, it is suggested to employ both adaptability within the framework of a manualized treatment and flexibility in sequencing, extending modules, and matching the intervention to individual need.

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Parental Reports of Pediatric Adherence to Medication and Treatment in a Clinical Setting

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Background: Help Understand and Guide Me (HUG-Me) provides medical and mental health services for both children and adults infected with Human Immunodeficiency Virus (HIV). Adherence to medication is always difficult in HIV/AIDS (Acquired Immune Deficiency Syndrome) treatment, especially for children. Children often have to depend on others to provide them with information and their medications for treatment.

Methods: Parents of HIV infected children were surveyed to assess their child's adherence to medication and treatment. Surveys were anonymous. They were distributed by clinical staff at the child's medical appointments and returned by parents to a box in the reception area. The survey consisted of 31 questions requiring a yes/no response. The survey addressed the following: parental adherence to their own HIV medication, missed doses, disclosure to schools/day-cares, side effects, and difficulties administering medication.

Results: A total of 64 parents or primary caregivers responded to the surveys. The mother was the primary caregiver in 50% of the cases. According to parental reports, 60% of the children knew their HIV diagnosis. Out of those who knew their diagnosis, 32% were 5-12 and 68% were 13-18 years old. Disclosure to schools/daycares was only reported by 25% of the respondents. In addition, 83% of the respondents reported that their child had not missed any medications in the past two weeks. For the remaining nine children (14%), possible reasons parents noted for missing doses included side effects, lack of understanding the treatment, confidence in treatment effectiveness, and difficulty administering the medication.

Conclusions: These results must be interpreted with caution. Although respondents were assured anonymity, parents may have feared repercussions if they revealed that their child was not fully adherent. Some of the issues revealed in this survey can be addressed through education of medical staff and clients. Medical staff can find creative ways to teach clients about medication, side effects, and the importance of adherence. Disclosure issues need to be explored further.

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Maintaining the Integrity of the Initial Antiretroviral Regimen through the Use of Observed Therapeutics in Urban Settings

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Introduction: Adherence to antiretroviral therapy remains central to long-term treatment success. Adherence in urban settings can be complicated by a multitude of factors that impede successful treatment outcomes. Data from our clinics has shown a treatment success rate of 24-35% at one year. A novel care delivery model was employed in our urban setting to facilitate long-term success.

Description: The JACQUES Initiative (Joint AIDS Community Quest for Universally Effective Treatment Strategies) has implemented strategies to overcome the barriers to optimizing HIV treatment in the urban poor. This program targets and brings patients and their identified support systems into the treatment process where they receive; treatment preparation prior to the initiation of therapy; highly supportive therapy during treatment induction and customized treatment support. Patients are able to customize and transition through a choice of five treatment support modalities that offer various degrees of intensity, ranging from our most supportive options such as directly observed therapy (DOT) and weekly observed therapy (WOT) to a simple buddy system.

Patient demographics: 93% African American, 60% male, 34% homeless, 67% unemployed, 46% history of illicit drug use in the last 6 months

Results: Analysis of 12 month data: N= 101

Virologic suppression (<400 copies/ml) ITT : 71%, AT : 83%

A closer look at treatment failures:

- 3 deaths
- 15 patients: virologic or genotypic failure
- 11 patients enrolled in DOT and WOT were treatment interrupted by staff while fully suppressed due to debilitating substance abuse/relapse

85% of surviving patients maintain the integrity of their initial treatment option through suppression and interruption while suppressed.

Lessons Learned: Observed therapeutics (DOT/WOT) positively impact viral suppression rates in this urban setting in addition to the providers ability to interrupt therapy in order to maintain the integrity of the initial treatment regimen by avoiding resistance and the loss of future treatment options.

Introduction: Many co-infected patients do not access hepatitis C treatment due to complex regimens and the need to refer out to liver clinics. Making treatment for hepatitis C readily accessible increases the number of co-infected patients treated.

Description: As reported in *Gut*, only 11.8 percent of infected U.S. veterans are treated for hepatitis C. Factors that make people less likely to be treated include having co-morbid conditions or diseases (i.e., HIV) and ethnic minority status. The Ryan Center developed an on site hepatitis C treatment protocol in collaboration with the National Liver Institute and the National Association of Community Health Centers that incorporates adherence education/support with an on site co-infection adherence team lead by the primary care provider. This program allows for patients to be treated for both infections and access adherence support at their medical home without being transferred for off site hepatitis C treatment. Ryan's patients are predominately minority (90% African-American and Latino) and include many co-infected patients.

Lessons Learned: The Center identified 350 hepatitis C infected patients (160 co-infected) and treated five patients to date. Some issues identified that impacted the number of patients evaluated and treated included 1) need for improved communication amongst the team as patient moves through care plan, 2) need for additional treatment adherence staff to accommodate complex hepatitis C adherence interventions, and, 3) need for improved data systems that can aggregate and analyze patient demographics.

Recommendations: 1) Refine treatment protocol to improve communication through standardized medical record charting and an interactive data system to provide up-to-date patient treatment plans. 2) Secure funding for a dedicated Hepatitis C adherence coordinator.

Introduction: South Africa provides antiretroviral treatment (ART) to more people than any other country in the world. Still only one in five South Africans who need treatment receive it. Many of those in need live in poorly resourced rural-based communities.

The Catholic Church in South Africa has a long history of providing health services in needy communities. In response to the HIV epidemic, these services were expanded to include hundreds of care and support programs. Twenty programs now provide ART. The issue is how adherence has been achieved in these settings.

Description: Catholic Relief Services (CRS), the lead agency of the AIDSRelief Consortium, received funds from the President's Emergency Fund for AIDS Relief (PEPFAR) to support the South African Government's rollout of ART in church service programs. Most are church home-based care programs that hire part-time doctors, outsource pharmaceutical and laboratory services, and rely on community-based volunteer carers to provide adherence training, facilitate support groups, and give home-based follow-up care. Laboratory monitoring includes baseline and six-monthly CD4 counts and viral loads. Viral loads at 6-8 weeks provide an early measure of adherence.

Lessons Learned: As of August 2006, there are 8,571 on ART and 21,171 receiving HIV care. Viral suppression, a marker of adherence, was over 90% at 6 months. Adherence is the result of good patient preparation carried out by dedicated counseling teams in church programs with community trust and support. Over 90% of adults treated were maintained on government's first line regimen.

Recommendations: Adherence can be achieved in resource limited settings. Key factors contributing to adherence include the trust of the communities, personalized services, and home-based care and support groups. Continued follow-up will be required to determine if adherence will be achieved in the longer term.

Introduction: The Adolescent Initiative at The Children's Hospital of Philadelphia (CHOP) had to change over the years as HIV disease went from a death sentence to a treatable disease. In spite of the fact that medication regimens have been simplified and pill burden is less, there remain many challenges related to adherence. Some of our success is attributable to our philosophy that includes flexible service taking one youth at a time. Since 1993, the Adolescent Initiative has been a leader in the evaluation, prevention, care, and treatment of adolescents living with and at risk for HIV. The clinic provides comprehensive, interdisciplinary primary and HIV specialty care. This team of professionals provides a seamless continuum of service that continues to address adherence in creative ways.

Description: The Adolescent Initiative provides treatment adherence to every youth who needs antiretroviral therapy based on public health service guidelines. Our multidisciplinary team identifies barriers and develops an individual readiness and treatment adherence plan. Medication schedules as well as potential interventions to troubleshoot side effects are addressed. The utilization of home and community visits as well as frequent telephone contacts is included to help identify other barriers of adherence.

Lessons Learned: We have learned that if youth are not ready to take antiretroviral therapy even though they are prescribed, they will not take them. The work of treatment adherence is breaking down barriers so that youth are ready to take medications successfully. Readiness can take months and even years before the ultimate goal of treatment adherence is achieved.

Recommendations: Treatment adherence programs need to adapt to the developmental milestones of youth and address self-efficacy. A multidisciplinary team approach to treatment adherence is key to a successful treatment adherence program.

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The Future of Treatment Adherence—A Program to Combine HIV and Hepatitis C Treatment and Adherence Education in an Urban Community Health Center

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Adherence in Faith-Based HIV Treatment Programs in South Africa

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A Historical Perspective of HIV Treatment Adherence at the Adolescent Initiative at The Children's Hospital of Philadelphia

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The Evolution of Patient Knowledge on the Cause and Transmission of HIV after One Year of Highly Active Antiretroviral Therapy (HAART)

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Background: Few studies have investigated the impact of knowledge about the cause and cure of HIV among HIV-infected patients in resource-limited countries or whether there are likely to be barriers to treatment adherence. Understanding and addressing misconceptions is one of the key to successful treatment outcome. *Setting:* Infectious Diseases Institute, Kampala, Uganda.

Method: Patients at the Infectious Diseases Institute on ART or about to start on ART were enrolled into a prospective observational study and followed up every six months. During study visits, a structured questionnaire is administered by a trained nurse-counselor to assess knowledge about the cause and cure of HIV. Patients received structured ongoing adherence support, counseling, health education and involvement of a treatment buddy for difficult cases. Baseline and 12 months correlates of non-adherence are examined. Response to Anti retroviral Therapy was measured in terms of reduction in viral load and improvement in immune function and adherence scores by self reports to measure adherence.

Results: A total of 511 and 337 patients were interviewed at baseline and at 12 months respectively; 69.7% and 71.1% were female at the two time points respectively; mean age was 36 years, mean CD4 at baseline was 101.69 cells/ μ l and 241.98 μ l at 12 months. More patients believed in ART effectiveness at 12 months (98.22%) as compared to 40.61% at baseline, there was reduction in belief of HAART as a cure of HIV at 12 months, 13.35% as compared to 65.26% at baseline, more patients reported using condoms at 12 months (57.27%) as compared to 36.59% at baseline. More patients (67.56%) knew how HIV is transmitted at 12 months as compared to 28.58% at baseline. There was significant difference between viral load at baseline and at 12 months ($p < 0.005$), similar improvements were noted in CD4 ($p < 0.005$). There was a 99% mean adherence rate by self report at 12 months.

Conclusion: Structured adherence support and involvement of treatment buddies for difficult cases may help enhance adherence. Effective delivery of HIV therapies however requires an understanding about HAART and addressing of underlying misconceptions about HIV in general. Prevention programs should emphasize equipping patients with knowledge related to their condition during ongoing counseling sessions and education. Further bigger studies are needed especially in resource-limited settings to address the impact of knowledge in HIV care in the era of HAART.

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Personality and Motivational Variables Relate to Medication Adherence in HIV+ Patients in Care

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Background: Previous studies found increased rates of personality pathology among HIV+ samples, yet attempts to identify protective personality traits have been overlooked. This study investigated associations between normative personality traits, motivational variables, and different types of medication adherence in HIV+ patients.

Methods: 122 participants were recruited into a larger investigation from a university infectious disease clinic in the southeast. Participants were 18+ years of age, HIV+, and prescribed combination antiretroviral medication. Participants completed a measure of normal personality traits, measures of motivation to adhere ("Importance" of adhering (I), "Confidence" to adhere (C), "Readiness" to adhere (R)) and various adherence measures ("ran out of meds" (ROM), "noncompliance" (NC), "took as directed" (TAD)). Data were analyzed using independent-measures t-tests, and Pearson correlations.

Results: Participants who TAD endorsed higher levels of C and R. Participants who did not ROM reported higher levels of "Neuroticism" and R. No group differences were associated with the NC variable. "Extraversion" was correlated with I ($r(115) = .23$, $p < 0.05$), C ($r(115) = 0.26$, $p < 0.05$) and R ($r(115) = 0.28$, $p < 0.05$). "Agreeableness" was also significantly related to I ($r(115) = 0.26$, $p < 0.005$), C ($r(115) = .20$, $p < 0.005$, and R ($r(115) = .23$, $p < 0.005$).

Conclusions: These data suggest "Neuroticism" may be associated with not ROM, possibly reflecting increased vigilance. Also, motivational factors, like C and R, may be directly associated with better overall adherence. Future research should investigate protective and detrimental associations between normative personality variables and motivational variables associated with adherence to better target and treat individuals most vulnerable to medication lapses/errors.

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Self-Reported ART Adherence in Central China

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Background: At the end of 2002, the China CARES initiative began offering free ART to all HIV positive individuals with CD4 counts below 200 cells/mm³. As a result, the number of patients receiving ART in Central China expanded rapidly; but pretreatment adherence education for patients, families, and health care workers has been minimal.

Methods: A cross-sectional survey was conducted at 7 China CARES treatment sites in Hunan, Hubei, and Anhui Provinces. An interviewer-administered questionnaire was used to collect demographic and behavioral data. Clinical data was obtained from medical records. Adherence measures included the CPCRA Adherence Self-Report and a 7 day Visual Analogue Scale. Subjects comprised all patients returning for monthly ART follow-up at each site between April and July, 2006.

Results: Among the 308 subjects, 55% had been on ART one year or longer. The most common regimens were d4T/3TC/NVP (39%), AZT/3TC/NVP (19%), and d4T/ddI/NVP (17%). No regimen included a protease inhibitor. 80% reported taking >90% of prescribed doses in the previous 7 days. 64 subjects reported missing at least 1 dose in that period. Reasons for missing doses included being away from home (56%), forgot (50%), busy (48%), and side effects (22%). Subjects who said they were currently using heroin were more likely to report $\leq 90\%$ adherence (OR=3.5; 95% CI 1.5, 8.1, $p = 0.002$). Self-reported use of reminders such as cell phone alarms, wall charts, or TV programs was associated with a decreased risk for non adherence (OR=6; 95% CI 3, 11; $p = 0.001$). No association was seen between receiving peer support and self-reported medication adherence.

Discussion: The level of self-reported adherence to ART in Central China appears similar to that in other parts of the world. The 20% of subjects who reported taking $\leq 90\%$ of doses are of concern in view of the potential for NNRTI resistance and lack of protease inhibitor back-up regimens. Prospective studies are needed to evaluate the efficacy of reminder devices to improve adherence in this population and to describe the prevalence and incidence of ARV resistance.

Introduction: The Adolescent Initiative at The Children's Hospital of Philadelphia (CHOP), Craig-Dalsimer Division of Adolescent Medicine uses a multidisciplinary team approach to support adolescents in their HIV care and medication adherence. As part of the multidisciplinary approach, the social worker and nurse integrate individualized expertise to best impact a patient's adherence success.

Description: The Children's Hospital of Philadelphia Adolescent Initiative provides treatment adherence to youth who need antiretroviral therapy. Each youth works with the multidisciplinary team to develop an individual ongoing treatment adherence plan. This plan is evaluated and amended as needed which includes working with the social worker and mental health team in addition to the medical providers to identify supports in the youth's life and any barriers to taking medications. Through a Case Study example, it is identified that Patient A, a perinatally infected 17-year-old female, has had difficulty maintaining past medication adherence. Supports are identified, past interventions are evaluated, and a new adherence plan is created.

Lesson Learned: We have learned that using a multidisciplinary approach to support adolescents with adherence is crucial to promoting effective adherence. Working with social work and mental health staff to address barriers to taking medications is crucial in working through the initial steps of taking medications. Using the connection the social worker made with patient A through home visits over a three month span allowed the patient to address barriers effecting adherence and helped integrate the nurse in the treatment adherence plan to best impact this patient's success.

Recommendations:

1. A multidisciplinary team approach to treatment adherence is key to a successful treatment adherence program.
2. Identification of barriers by patient and team is necessary before an adherence plan can be developed.
3. Adherence plans need to be flexible and work with the youth outside the clinic setting - in the home or community.

Background: Although treatment, including free medication, is increasingly available to HIV + patients in China, there is an urgent need for research for the development of adherence enhancement programs. To inform future adherence interventions, we conducted a qualitative study with patients, care givers and providers to assess the cultural appropriateness of potential intervention strategies such as electronic reminder device, pill box, peer support, family member DOT, group counseling and one on one nurse counseling.

Methods: At Beijing Ditan Hospital during summer 2005, we conducted semi-structured interviews with persons who had been on HAART for at least 1 month (HAART-experienced, n=21), were starting their first regimen (HAART-naïve, n=8), and family members/care givers (n=11). We also conducted a focus group of 6 providers (4 physicians and two nurses).

Results: There are different levels of endorsement of the 6 proposed intervention strategies. When the patients had reservations or did not endorse these strategies, they described worries about stigma and discrimination. Concerns about stigma affected all kinds of adherence intervention strategies, even for those already using the strategies. The stigma (real or potential) not only affect the patient themselves, the care givers also are affected and the patients are afraid of bringing stigma and discrimination to their family members.

Conclusions: Findings from the qualitative study of HIV-patients, care givers, and providers showed that stigma played a vital role in the current adherence behavior with Chinese HIV patients. In the next phase of the study we are adjusting/tailoring the intervention programs proposed to reflect the need of taking stigma into consideration for intervention program to be successful.

Background: Pill box organizers are inexpensive and easily used; however, research examining their effect on adherence is extremely sparse.

Methods: We examined the effect of pill box organizer use on adherence to antiretroviral medications. Data were drawn from 245 subjects followed between 1996 and 2000 in an observational cohort of HIV-infected individuals in San Francisco, California. The primary outcome, adherence, was measured using unannounced monthly pill counts. Plasma HIV RNA level (viral load) was considered as a secondary outcome. Several marginal structural model estimators were used to estimate the effect of pill box organizer use on adherence and viral suppression, adjusting for confounding by CD4 T cell count, viral load, prior adherence, recreational drug use, demographics, current and past treatment characteristics, and sexual orientation.

Results: All estimators suggested that pill box organizer use resulted in approximately 4.1-4.5% higher adherence. Pill box organizer use was associated with a decrease in viral load of between 0.34 and 0.37 log copies/ml, and a 14.2-15.7% higher probability of achieving a viral load below 400 copies/ml (OR=1.8-1.9). All estimates of effect were significant, and consistent between estimators.

Table 1: Marginal Structural Model Estimates of Effect of Pill box Organizer Use on Adherence and Viral Load Attributed to Pill Box Organizers

	Adherence %		Log VL		Odds Ratio	
	Difference*	95% CI	Reduction†	95% CI	VL<400‡	95% CI
G Computation	4.5%	(2.0, 7.0)	0.34	(0.08, 0.60)	1.81	(1.25, 2.62)
IPTW‡	4.1%	(0.0, 8.3)	0.37	(0.05, 0.69)	1.91	(1.27, 2.90)
Double Robust	4.1%	(1.1, 7.1)	0.36	(0.09, 0.63)	1.91	(1.27, 2.90)

*Among 237 individuals, 2504 person years of follow up (person-months with measurement pill box organizer use, all confounders, and adherence available)

†Among 194 individuals, 2227 person years of follow up (person-months with measurement of pill box organizer use, all confounders, and viral load available)

‡IPTW: Inverse Probability of Treatment Weight

Conclusion: Pill box organizers significantly improve adherence to antiretroviral therapy and virologic suppression. We estimate that pill box organizers may be associated with a cost of \$19,000 per quality-adjusted life year. Pill box organizers should be a standard intervention to improve adherence to antiretroviral therapy.

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Improving Adherence with Adolescents Living with HIV using a Multidisciplinary Approach

Duckett M, Worth T, Tanney M, Ambrose C

The Children's Hospital of Philadelphia

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The Effect of Stigma on HIV Treatment and HAART Adherence in Beijing, China

Zhao H,¹ Huang B,² Chen W,² Lu L,¹ Starks H,² Pearson C,² Simoni J,² Fredriksen K,² Shiu C,² Zhang F³

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Pill Box Organizers are Associated with Improved Antiretroviral Adherence

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Late-Breaker Abstracts

Thursday, March 29, 2007 — 11:00 am-Noon

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Hidden Influence of Client Specific Factors on Adherence to ART Critical Issues Requiring Attention in Uganda's Populous AIDS Clinics

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Background: Antiviral suppression and adequate management of patients with HIV/AIDS highly depends on treatment compliance and this can be ensured by the provision of sufficient quality information and support to the client by the healthcare team. But ART client characteristics and needs vary, necessitating delivery of client centered care package, which is not possible in heavy HIV clinics.

Objective: To establish factors responsible for differences in adherence to ART in clients receiving same drug information and support from healthcare team.

Methods: Case control study of 50 good adherents and 50 poor adherents was done at the ART clinics of TASO Mulago and identify positive deviants amongst the general population receiving ARVs. Secondary data on adherents was obtained from pharmacy records while primary data on socio-demographic factors and the identification of 'positive deviants' were obtained by observation and use of both structured questionnaires and key informant interviews. Data analysis was by comparison of proportions using X² and Fisher's exact test.

Results: Although their impact on adherence was not statistically significant, client compliance to ART was distracted by debility and disability (X²=1.04, p=0.617), heavy work load (X²=2.84, p=0.204), poor social support (X²=4.89, p=0.059), and lack of disclosure to the family (X²=1.89, p=0.362). Others were alcoholism drug addiction, poly pharmacy, adverse effects experience, culture, and religion. Amongst the positive deviants were those who used to scribble down 'what to take' on the walls of their rooms each morning on daily basis.

Conclusion: Although not statistically significant, these results have clinical relevance and should be addressed by healthcare team when administering antiretrovirals and to encourage openness and clubs like people living with HIV/AIDS.

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Medication Adherence During and After Pregnancy among HIV+ Women

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Background: Among women with HIV infection, pregnancy is a time when maintenance of maternal health and reduction of fetal-neonatal HIV transmission are a primary concern. Few studies have examined adherence to antiretroviral medication (ART) during this time.

Methods: 399 pregnant HIV+ women were monitored by the Women and Infants Transmission Study (WITS-IV) at six sites in the United States, including Puerto Rico. Adherence was assessed through a self-report interview during the 3rd trimester and at 6-months postpartum. HIV-1 RNA viral load was also measured to validate self-report of adherence.

Results: 77 % (309/399) of women completed the self-report adherence measure during the 3rd trimester, 61% (188/309) reported complete adherence. Factors associated with non-adherence included advanced HIV disease status, as measured by CDC class, high HIV-1 RNA viral load, more HIV-related symptoms, alcohol use and tobacco use. At six months postpartum, 55 % (220/399) completed the measure; 44% (97/220) of women who remained on ART reported complete adherence. Factors associated with non-adherence during the postpartum period included ethnicity, more HIV symptoms and WITS clinical site. Results of multivariate analyses across the two visits revealed that number of HIV disease symptoms, HIV-1 RNA viral load, alcohol use and WITS clinical site remained associated with ART adherence.

Conclusions: These analyses indicate that medication adherence is more likely during pregnancy than postpartum in HIV infected women who have given birth, perhaps provoked by motivation to reduce fetal-neonatal transmission or intensive antepartum surveillance. Further investigation is necessary to clarify factors implicated in women's decision-making process regarding ART medication adherence.

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Adherence Results for 84 Patients on Anti-Retroviral Therapy for 1 year at Bushenyi Medical Centre, Katungu in Rural South Western Uganda

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Background: Adherence is the most important factor in the success of anti-retroviral therapy (ART). We present the results of 84 patients on ART for 1 year and recommendations for adherence promotion in sub-Saharan Africa.

Methods: Enrollment started in August 2005. An adherence plan was developed. Data collected into hard copy records is entered into a computer database. For this paper, we reviewed patient records and obtained additional information from the database. Analysis was done using SPSS.

Results: 84 patients were analyzed. Mean age was 36 years, 60% were female. 91% were above 14 years. 74% were treatment naïve. 67 (80%) are still active on therapy, 9 have died, 2 have been lost and 6 were transferred out. Of the active patients, 46 (70%) were treatment naïve and 42 (91%) were on a regimen that included Truvada. We estimated adherence for treatment naïve patients. Average adherence to appointments was 85%. Average adherence using self reported missed doses was 99.4% while 88% of the patients had perfect drug refill habits. Average increase in weight was 9.7kg. 65% reported financial problems, 13% transport problems and 2% stigma as barriers to accessing care. None reported fear of disclosure. Aspects of the adherence plan have been changed with time.

Conclusions: Promotion of adherence in rural Africa, presents unique challenges. Adherence in this community ranges from 85% to 99%. Different measures of adherence give different results. Dramatic weight gain occurred. Financial problems are a barrier to accessing care, patients are less concerned about stigma and do not fear to disclose. More research is required to measure adherence, compare measures and investigate factors associated with adherence. Adherence plans in sub-Saharan Africa should be flexible.

Background: Concern about adherence to antiretroviral therapy is at the forefront of HIV care, particularly for HIV infected (HIV+) individuals with methamphetamine dependence. It is possible that adherence training alone is sufficient for improving adherence, or that successful adherence interventions must include training in "relapse prevention," since relapse to drug abuse is prevalent in early recovery, and may cause nonadherence.

Methods: We conducted a randomized, 3-arm, 8-week clinical trial to compare the efficacy of 1) Usual Care (n=20); 2) Adherence Training alone (n=17); and 3) Adherence Training + Stimulant Relapse Prevention (n=36) in HIV+ methamphetamine-dependent individuals in early recovery. Treatments were based on an Information-Motivation-Behavior Change model. Percent adherence determined by Medication Event Monitoring Systems (MEMS) was the primary outcome measure.

Results: An intent-to-treat analysis of all subjects (n=73) showed no significant differences in MEMS-derived percent adherence at Week 8 (end of treatment) across the three groups (p>0.05). Adherence declined in all groups over the 8-week study period (e.g., MEMS therapeutic coverage from Week 4 to Week 8, Usual Care declined from 85% to 67%, Adherence Training from 68% to 64%, and Adherence Training + Relapse Prevention from 74% to 71%). In exploratory analyses, a repeated measures analysis of covariance (ANCOVA) adjusting for baseline MEMS therapeutic coverage revealed a significant Time x Group interaction [Wilks Lambda=0.898; F (1,56)=3.2; p=0.049] suggesting that adherence in Usual Care declined more precipitously over time than did the experimental groups.

Conclusions: Outpatient adherence training using motivational interviewing, with or without relapse prevention training, may be insufficient to improve, but may help sustain, adherence for HIV+ methamphetamine dependant persons. More structured methods to improve adherence may be warranted for this treatment-resistant group.

Introduction: Despite the numerous factors found to contribute to poor ART adherence — such as regimen complexity, side effects, and poor patient/provider relationships — many individuals have gained mastery of medication adherence. Yet there are few studies that explore adherence from the perspective of ART adherence masters. This qualitative study examined the beliefs and behaviors of highly adherent individuals.

Description: Four focus group discussions were conducted with eighteen participants who were on a stable ART regimen for nine months or longer, self-reported <90% adherence, had a stable viral load, and were actively engaged in medical care. Focus group topics included facilitators and barriers to adherence, values and motivations for taking meds, and suggestions on adherence mastery for patients starting medications.

Lessons Learned: Most frequently identified factors that facilitated mastery of taking medications included: understanding how to take meds, believing that HIV medications kept them healthy, having a provider who cared, keeping medical appointments, and having hope about the future. Identified barriers to overcome to maintain adherence included: being tired of taking medications, feeling overwhelmed, being stressed/worried or down, being around negative people, and not being able to afford medications. Factors identified for maintaining adherence despite challenges included: being healthy, spiritual, knowledgeable, and in-control. Participants suggested ART-naive individuals be ready to start medications, be informed, and be responsible and advocate for their care.

Recommendations: Further exploration of the beliefs and behaviors of adherence masters is needed. Understanding facilitators and motivators for adherence among highly adherent persons, even in the face of challenges, may identify new strategies for addressing ART adherence struggles for others.

Background: In 2005, ART Clinics began to open in rural Zambia. We report demographic, clinical, and adherence data for a representative population attending 3 rural clinics.

Methods: A 10% random sample of all registered ART clinic patients was taken at 3 clinics. Inclusion was limited to adults on ARTs excluding transfers out. Data was collected through a retrospective chart review. A second abstractor conducted a 10% quality check. Adherence was categorized as good (missed no appointments and no documented adherence concerns), mixed (attended appointments, but staff documented adherence concerns), intermittent (missed appointments), defaulted (never returned to clinic), and died within 30 days of starting ARTs. Chi-square and t-test analysis were conducted to determine patient factors associated with good adherence.

Results: 484 charts were sampled to identify 255 eligible patients excluding 34 children, 15 transfers, 121 not receiving ARTs, and 59 lost files. The median number of clinic visits was 5 (IQR 4-7), mean age 39.7 years, 44.3% male, 56.5% married, and 45.5% had completed only primary school. 25.5% had a history of TB. 7.5% were on TB treatment at ART initiation. 7.5% received home-based care. 32.2% had complaints consistent with a peripheral neuropathy at enrollment and 18.6% later developed symptoms. 19.6% had HIV+ partners. 37.3% reported disclosing their status to their spouse and an additional 27.8% had informed other family. 36.5% had ART clinic buddies to provide social support and attend visits with them. Adherence rates were 59.2% good, 3.5% mixed, 19.6% intermittent, 13.7% defaulted, and 3.9% died. 60% of defaults and 73% of deaths occurred within 1 month of initiating drug. Only one death was directly related to ART toxicity. Among all demographic and clinical variables including site of care, only disclosure to ones' spouse (p=0.047), knowing your spouses' HIV status (p=0.02) and having a clinic buddy (p=0.01) were associated with good adherence.

Conclusions: Social support is key to ART adherence in rural Zambia. Modifiable factors, such as use of the buddy system, are more important than age, gender, education, and clinical characteristics in determining adherence.

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Efficacy of Motivational Interviewing for Adherence in HIV+ Methamphetamine Users

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Facilitators, Barriers, and Motivators to ART Medication Adherence among Highly Adherent Persons

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Rural ART Adherence in Zambia: A Retrospective Study at 1 Year Post Roll-Out

Birbeck G for the RAAZ Study Team

Michigan State University, East Lansing, MI



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Associations between Adherence and Neurocognitive Performances among HIV-Infected Individuals: Is Near Perfect Adherence Necessary?

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Background: Strict adherence to antiretroviral therapy (ART) is required for maximum immunologic, virologic and survival gains for people living with HIV/AIDS. Neurocognitive impairment among HIV-infected individuals was previously associated with poor ART adherence with a bidirectional relationship wherein HIV-associated neurocognitive impairments resulted in poor adherence and vice versa (Hinkin, 2002). We examined the associations of ART adherence on neurocognitive, clinical and behavioral variables among HIV-infected individuals at baseline and six months.

Methods: Neurocognitive, behavioral and clinical characteristics among HIV-infected individuals were assessed at baseline and at six months. Participants were already enrolled in an ongoing multi-site investigation on effect of ART on the central nervous system (CNS). All participants underwent a standardized neuropsychological test battery (Carey *et al.*, 2004) that generated the Global Deficit Score (GDS) ranging from 0 to 5 (with a cutoff of ≥ 0.50 indicating overall impairment), neurological and medical examination at baseline and at six months evaluation. Participants were considered ART adherent if they met the following three conditions from the ACTG Adherence questionnaire based on a four day recall: participants took the pills prescribed $>95\%$ of the time, always on schedule and always following special dietary instructions, if any.

Results: The analysis included 251 participants prescribed ART at baseline and six months. The participants' characteristics were: mean age 45 years; 80% male, 45% White, 40% Black and 12% Hispanics; mean 12.5 years of education. The participants' mean CD4 cell count was high (502 cells/mm³), plasma viral load log 2.35 copies/ml, and cerebrospinal fluid (CSF) viral load log 2.07 copies/ml. At baseline assessment, 65% of the participants were ART adherent by self-report. Detectable plasma HIV RNA was observed among 34% of the self reported adherent group (median = 0) and 31% of the self reported non-adherent group (median = 5), however without any significant differences. When looking at CSF viral load, 8% of the adherent group had detectable HIV RNA compared to 19% of the non-adherent group ($p = 0.03$). We found no significant differences in neurocognitive, clinical or behavioral characteristics among the participants at baseline. The mean baseline GDS was 0.50 for the adherent group and 0.52 for the non-adherent group, which was non-significant, the global impairment rate in the adherent and non-adherent groups at baseline were 42% and 38% respectively, which was also not significant. At follow-up, complete data was available for 233 participants, where 62% reported ART adherence. Adherent (median = 0) and non-adherent groups differed significantly on clinical outcomes at plasma viral load [$t(232) = -2.66, p = 0.008$], but not CSF viral load. Mean CD4 cell count dropped to 468 cells/mm³ and was not significantly different for the two groups. No difference in neurocognitive status was found between adherent and non-adherents groups though the mean GDS for was lower than baseline at 0.42 and 0.44 respectively as were the global impairment rates at 34% and 25% respectively.

Conclusions: Even with modern HAART and a brief six month period of evaluation, less than strict adherence to HAART resulted in poorer viral control. However, starting with overall lower mean neurocognitive impairment, the group retained similar trends in low neurocognitive status even after noncompliance in our cohort. Longer term evaluations will be important to understand the long-term impact of lapses in perfect compliance with modern HAART therapy.

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Factors Associated with Efavirenz Resistance and Failures

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Background: Several mechanisms have been proposed which contribute to failure of efavirenz (EFV)-based drug regimens. The CYP2B6 (516G>T) polymorphism alters hepatic clearance of EFV, variability in EFV level in different racial groups, central nervous system toxicity, genotypic mutations (K103N/S, G190S/A/E, and Y188L/H/C) and lacking of adherence to EFV especially in African-Americans population. Our objective was to determine which factors were associated with EFV resistance or failure in a non-clinical trial setting.

Methods: This was a retrospective case controlled, cross-sectional study from a single HIV clinic in Akron, Ohio. Patients on EFV-based HAART regimens for over 12 months were included. Demographics (age, race, sex, weight), length of HIV infection, length of EFV exposure, HIV viral load prior to EFV initialization, self reported adherence, side effects, and genotypic resistance data were collected. Two groups were compared: EFV non-responders (Non decrease or increase in HIV-VL from baseline) and responders (HIV-VL <40 copies). Chi square tests, Fisher's exact tests, and independent samples t-tests were used for statistical analysis.

Results: Of the 90 patients analyzed: 22 failures/ non-responders (NR) and 67 responders (R) were identified. Patient population represented 37% African-Americans, 59% Caucasians, 3% Hispanic/Asians and 78% males. No statistical significance was achieved when analyzing age, sex, weight, race, adverse side effects, viral load, and duration of HIV infection or length of EFV exposure. Adherence was the most significant factor associated with failure to EFV base regimen (Responders had 91% adherence to versus 36% of non-responders, $X^2 = 27.01, p < 0.001$).

Conclusions: This study suggests that adherence (take medicine 100% of the time) is the only significant factor associated with EFV resistance and failures. The importance of adherence still remains the cornerstone of patient education and antiretroviral therapy success.

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ART Adherence and Service Utilization among HIV+ Patients Recently Released from Prison

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Background: When incarcerated HIV+ persons re-enter the community they face many competing priorities that may overshadow the critical health-related activities of enrolling in HIV care services, obtaining new antiretroviral prescriptions, and consistently taking medications. This is important because lapses in ART adherence during the transition from prison to community increase the likelihood of a poor treatment response and raise the possibility of drug-resistant HIV strains being transmitted to others.

Methods: While incarcerated in a state prison, 29 HIV+ adults prescribed ART consented to participate in a post-release telephone survey. Surveys were completed by 22 (76%) community residing respondents approximately 1 month following release from prison (M=38 days post-release). Measures included demographics, ART adherence, prescription information, and service utilization.

Results: Sample ethnicity: 50% African-American, 27% White, 5% Hispanic/Latino, 18% Native American or Other. Mean education: 11 years (range=8-14). Half of respondents lived in someone else's home, 14% in their own home, and 36% in a boarding or half-way house. 77% were unemployed, with 27% currently seeking employment. 55% of respondents reported missing any ART doses in the past 30 days. Number of days ART doses were missed ranged from 0 to 15 (M=2, SD=3.4). 50% were released from prison with a 2-week supply of ART (M=3; range 0-8 weeks). 73% reported filling an ART prescription in the community after release. 43% reported AIDS drug reimbursement program enrollment. 73% reported scheduling an HIV care appointment after release, 59% attended a primary care visit, 9% attended a medical visit with a specialist, 9% sought HIV care in an emergency room, and 1 patient was hospitalized. 18% attended mental health visits, 50% received social services, and 31% attended 12-Steps groups for substance abuse.

Conclusions: Programs and policies are needed to promote continuity of care and adherence to ART among persons released into the community from prison.

Background: Medication adherence is a significant issue for patients with HIV. Yet, limited research has examined an adherence promoting intervention, level of adherence, and subsequent health outcomes. This study examined the relationships among amount of intervention received, medication adherence, and health outcomes over time (RO1 NRO4749).

Methods: No significant group differences existed between those randomized to control/usual care (n=101) or intervention (n=99). The sample (n=200) included 66.5% men and 61% white; the mean age was 40.6 years (SD=7.6). Patients randomized to intervention received 12 weekly sessions of a structured telephone intervention guided by social cognitive theory designed to improve medication adherence in patients with HIV plus a 12 week tapered maintenance intervention. Data at baseline, post-intervention (12 weeks), and post-maintenance (24 weeks) were collected using electronic event monitors, the MOS HIV overall health subscale, and CD4 count.

Results: Hierarchical regression analysis of data from baseline and post-intervention with adherence as percent of days with correct dosing showed a positive relationship between dose of intervention and CD4 count (p=0.026); dose of intervention modified the relationship between adherence and overall health (p=0.024). Similar results occurred with adherence as percent of doses taken on schedule for CD4 count. Dissimilar results occurred for overall health and percent of doses taken on schedule. Examining data from post-intervention to post-maintenance showed that change in adherence as percent of days with correct intake rather than amount of maintenance intervention was positively related to CD4 (p=0.009). There was no significant difference related to overall health. For percent of doses taken on schedule, change in adherence and health outcomes yielded dissimilar results.

Conclusions: Dose of intervention may moderate the effect of an adherence intervention on health outcomes. To improve adherence and health outcomes requires delivering the full intervention. Future research needs to address strategies for intervention delivery.

Background: Adherence to antiretroviral therapy (ART) in pregnancy is crucial to optimize its efficacy and minimize mother-to-child transmission. Our objective was to examine adherence patterns to ART and health behaviors antepartum (AP) and 12 weeks postpartum (PP) among pregnant HIV+ women enrolled in A5084, a prospective, observational, multi-site study.

Methods: Women ≥ 13 years enrolled between 20 and 36 weeks gestation and completed at least 1 self-reported adherence questionnaire AP, and were followed through 12 weeks PP. Women completed questionnaires addressing their use of tobacco, alcohol and illicit drugs. Adherence was defined as reporting not having missed any doses for >3 months. Exact McNemar's tests were used for paired binary data and exact logistic regression was used for predictors of non-adherence.

Results: We report on 149 women (55% Black, 26% Hispanic, 32% < 25 yrs, 7% with AIDS (CD4<200), 99% on ART with 51% on PI-based regimens). PP, 31 (21%) women stopped ART and 18 (12%) withdrew from the study. AP, 54% reported adherence to ART (94% with HIV-1 RNA levels <1000 copies). PP adherence rates were 46% (n=90) (80% with HIV-1 RNA levels <1000 copies). AP, 11% reported ongoing alcohol use and 23% tobacco use compared to 37% and 30% PP (p<0.0001, n=103; p=0.07, n=99, respectively). Although 39% had ever used marijuana (n=116) and 25% hard drugs (n=107), few patients reported use during the study. Prior hard drug use and missed prenatal vitamins predicted of non-adherence in multivariate analyses, with those who had ever used hard drugs having 5.95 times higher odds (P=0.002) and those who missed prenatal vitamins with 4.84 times higher odds (P=0.001) of non-adherence, respectively.

Conclusion: Women with a history of substance use and/or having missed prenatal vitamins should be targeted for programs to enhance adherence to ARV during pregnancy.

Background: Although medications have been freely available to those afflicted with Tuberculosis (Tb) in South Africa, adherence has been less than optimal. Given that antiretroviral (ARV) adherence has been shown to be high in resource-limited countries, the question remains as to whether such adherence will remain high as ARVs become more widely available. Thus, the purpose of this study was to investigate factors affecting medication adherence including socio-demographic factors, sense of coherence, social support, symptom status and quality of life.

Methods: Data collection for a sample diagnosed with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) (n=149), and a sample diagnosed with Tuberculosis (n=159), occurred in a number of settings in Durban, South Africa for this descriptive, cross-sectional research design study.

Results: The Tb sample was more economically deprived with significantly (0.001) less education, employment, more days with nothing to eat, more likely to have stick/mud stone housing with no indoor plumbing or refrigeration. The TB sample also had greater symptom frequency and intensity, less social support and a lower sense of coherence and lower quality of life (<0.01). Nonetheless there was no significant difference in medication adherence or missed appointments.

Conclusions Given these findings of no differences in medication adherence, a caution is in order. The members of the two cohorts were those able to negotiate the distances from their homes to the clinics and may not be representative of those with HIV/AIDS or Tuberculosis. As access to antiretroviral medications becomes more widely available in South Africa, the question remains as to whether such high adherence will be maintained over the long term.

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Relationships among Intervention, Medication Adherence, and Health Outcomes

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Prior Drug Use and Missed Prenatal Vitamins Predict Non-Adherence to Antiretroviral Therapy in Pregnancy

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HIV/AIDS and Tuberculosis in South Africa: Adherence to Two Medication Regimens

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Successful Adherence to Concurrent TB and HIV Treatment among Co-Infected Patients in Rural South Africa; The Sizonqoba Study

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Background: More than 80% of TB cases in rural KwaZulu Natal, South Africa are co infected with HIV. Even with TB DOTS program in place, treatment completion rate is <60% and case fatality rate among co infected patients (pts) is 40%. Therapeutic success for both diseases requires high levels of adherence over time. Integration of TB and HIV therapy with innovative culturally appropriate adherence strategies could improve outcomes for both diseases.

Methods: Observational study in pts with active TB and HIV in rural resource-poor setting. After TB diagnosis and HIV diagnosis, pts disclose diagnosis and select family treatment supporter. Both attend 3 session HIV treatment literacy instruction. Pts receive standard TB therapy and with other patients and treatment supporters collectively construct monthly calendar of daily doses of once-daily HIV regimen (ddl+3TC+efavirenz). TB and ART drugs taken concurrently at home assisted by family treatment supporter and volunteer community home based carer with monthly clinic follow-up. Results analyzed after 12 months for clinic and medication adherence and TB and HIV outcomes.

Results: Of 119 TB/HIV patients, half are women, mean age 32.4 yrs, all WHO Stage 3/4, mean CD4 107 cells/mm³. At 12 months: 99 of 119 (83%) pts successfully completed 6-9 mos TB treatment, 5 (4%) defaulted, 15 (12%) died or failed treatment, most with confirmed MDR TB ; 87% achieved undetectable viral loads with mean CD4 increase 196 cells/mm³. Concurrent therapy was well-tolerated and 1088 of 1168 (93%) scheduled monthly clinic follow-up visits kept and standardized self-reported mean adherence 99%.

Conclusions: TB and HIV treatment integration based on innovative adherence program with once daily TB and HIV regimen and family and community support, can achieve high levels of treatment adherence and favorable therapeutic outcomes for both diseases in rural resource limited South Africa.

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Selective Nonadherence to Components of Combination Antiretroviral Therapy is Associated with Virologic Failure and Antiretroviral Resistance

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For the Terry Bein Community Programs for Clinical Research on AIDS (CPCRA)

Background: Adherence may be different for individual drugs in an antiretroviral regimen. The association of selective nonadherence with virologic failure (VF) and antiretroviral resistance has not been evaluated.

Methods: Adherence was assessed every 4 months using the CPCRA 7-day self-report form among participants in the CPCRA FIRST study — a randomized antiretroviral therapy (ART) strategy trial comparing NNRTI, PI, and NNRTI+PI-based initial ART [with background nucleoside(s)] in previously ART-naive individuals (enrollment 1/99 to 1/02). Selective nonadherence was defined as any difference in self-reported adherence to individual regimen components at any time point. It was evaluated as a binary time-updated variable in Cox regression analyses of time to first VF (HIV-RNA>1000 copies/ml) and first VF with genotypic resistance. The Cox models were adjusted for overall adherence, demographics, baseline CD4 count and baseline HIV-RNA. After a report of selective nonadherence, subsequent findings were deemed attributable to that behavior.

Results: Of 1397 FIRST participants, 1379 (99%) with at least one adherence assessment were included. Selective nonadherence was reported by 403 (29%) participants over a median follow-up of 60 months. Selective nonadherence was more commonly reported by participants randomized to the NNRTI+PI 3-class ART strategy (35%) than those in either the NNRTI (28%) or PI (25%) 2-class strategies ($p=0.005$). There were no significant differences in demographics, baseline CD4 count, or baseline HIV-RNA in participants with or without selective nonadherence. In adjusted Cox regression models, selective nonadherence was significantly associated with first VF (HR = 1.28, 95% CI 1.07 – 1.55) and first VF with genotypic resistance (HR = 1.44, 95% CI 1.10 – 1.87).

Conclusions: Selective nonadherence occurred frequently in this ART strategy trial and was associated with an increased risk of VF and VF with antiretroviral resistance.

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Diagnostic Disclosure and Parental Anxiety Predict Medication Adherence in Youth with Perinatal HIV Infection

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Background: Parental disclosure of child's HIV status was explored as a mediator in the relationship among parental psychological functioning and child medication adherence.

Method: IRB approved cross-sectional pilot study. Sixty parents/guardians of children with perinatally acquired HIV in routine pediatric HIV specialty care enrolled. Parents/guardians completed study-specific semi-structured interview about disclosure of their child's HIV status, and provided self-report of depression, anxiety, and anger. Pharmacy provided adherence pill counts. Non-adherence was defined as mean pill count below the clinically acceptable range (<93%).

Results: Univariate logistic regression analyses identified predictors of HIV medication adherence. Significant predictors of non-adherence included: longer time since child diagnosis [$OR = 1.17$; $CI_{0.95} = (1.01, 1.32)$; $p = 0.05$], greater time since last disclosure of child HIV [$OR = 1.19$, $CI_{0.95} = (1.00, 1.40)$; $p = 0.05$], and older child age at interview [$OR = 1.15$; $CI_{0.95} = (1.01, 1.32)$; $p = 0.04$]. In a multivariate model, parental state anxiety [$OR = 1.08$, $CI_{0.95} = (1.00, 1.16)$; $p = 0.04$] and time since most recent disclosure [$OR = 1.26$, $CI_{0.95} = (1.04, 1.54)$; $p = 0.02$] significantly predicted non-adherence. Time since most recent disclosure appears to mediate the relationship among parental state anxiety and child medication adherence [$OR = 1.26$, $CI_{0.95} = (1.04, 1.54)$; $p = 0.02$]. Further analyses will explore this relationship in depth.

Conclusions: More recent diagnosis, more recent disclosure of child HIV, and younger child age related to better adherence. The odds the child's mean adherence falls < 93% increases 18.5% for every year since last disclosure of child HIV. For every year since child diagnosis, the odds of poorer adherence increase 16.9%. When adjusting for time since last disclosure, parent anxiety predicted adherence whereby there is a 7.6% increase in odds of poorer adherence with increased anxiety. Clinical implications and future research directions are discussed.

Background: Adverse drug interactions between opioids and antiretroviral therapies (ART) can result in nonadherence. Adverse interactions of clinical significance with ART have been reported with methadone (M). Buprenorphine (BUP), a newer treatment for opioid dependence, has now been studied in combination with ART.

Methods: Opioid dependent volunteers were maintained on a stable opioid dose for > 2 weeks before study. Pharmacokinetics of opioids were determined prior to and following ART (zidovudine (ZDV), lopinavir/ritonavir (L/R), nelfinavir (NFV), efavirenz (EFV)) given to achieve steady state with blood sampling over 24 hours. Within-subject analysis of the effect of ART on M or BUP was obtained. A between-subjects analysis of the effect of M or BUP on ART compared to matched controls was obtained.

Results: M increased ZDV by 41% (p=.03). 3 of 8 participants reported symptoms of ZDV toxicity at standard clinical doses. BUP had no effect on ZDV. M AUC was decreased (p<.001) associated with opiate withdrawal in some participants receiving L/R, while this ART had no effect on BUP. NFV was associated with decreases in M exposure (p<.001), and rarely, symptoms of opiate withdrawal. NFV had no effect on BUP concentrations. EFV reduced M serum concentrations (p=.037) associated with opiate withdrawal symptoms. EFV reduced BUP exposure (p<.001), but no withdrawal symptoms were observed. L/R, NFV, and EFV concentrations were not altered by M or BUP.

Conclusions: BUP is not associated with drug interactions of clinical significance with ART that have previously been linked to adverse interactions in some M-maintained patients. Knowledge of potential adverse drug interactions may be used to match treatments to patients and enhance adherence to HAART.

Introduction: The Carl Vogel Center (CVC) is a community-based nonprofit organization that provides multidisciplinary and integrated healthcare that responds to existing and emerging public health needs of people with HIV/AIDS. CVC educates and empowers PLWHA to become full partners and informed advocates in the management of their care. This is provided by services from the Treatment Education Adherence Program (TEAP) and other agency service programs which include primary medical care, medical nutritional therapy, mental health, case management, treatment resource library/computer lab and complementary therapy (acupuncture and massage). Treatment adherence is the most critical component to successful HIV disease management and care for those prescribed Highly Active Antiretroviral Therapy (HAART). Optimal adherence of 95% or greater can reduce virologic failure and the development of resistance to medications. Adherence encompasses all areas of health and wellness: appropriate follow-up with providers, keeping scheduled appointments, practicing risk reduction and lifestyle behavior modification. Interventions that support and improve adherence, therefore contribute to overall HIV disease management.

Description: The goal of the Treatment Education Adherence Program (TEAP) is to enhance the quality of life for those living with HIV/AIDS and improve health outcomes by helping participants:

- Understand HIV disease and its impact on their health and immune system;
- Understand their HIV treatment options;
- Understand the crucial role adherence plays in treatment effectiveness when taking HAART.

The program utilizes a client-centered individualized approach to education and counseling ensuring that client needs are met and that information is presented in a nurturing, non-judgmental environment. This approach fosters involvement of the entire multidisciplinary team of clinicians and provides a "safety net of care" for clients.

The program is organized into three phases:

- | | |
|--------------------|--|
| I. Preparation: | Assess readiness |
| | Determine health priorities |
| II. Implementation | Help with implementation |
| | Elicit feedback |
| III. Evaluation | Review adherence measures |
| | Evaluate effectiveness and revise strategies |

A demographic and clinical description of the sample (n=28) program participants are as follows:

Table 1. Total Number of Unduplicated Clients Served by TEAP (May-Dec 2005)

Ethnicity	Number	Percentage
African-American	23	82.2%
Caucasian	4	14.3%
Hispanic	1	3.5%
Stage of Infection	Number	Percentage
CD4 > or = 500	11	39.2%
CD4 > 200	11	39.2%
CD4 < 200	6	21.4%
Gender	Number	Percentage
Male	23	82%
Female	5	18%

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Improving HAART Adherence in Opioid Addicted Patients

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The Benefits of Treatment Education and Adherence Counseling Services in a Multidisciplinary Health Care Environment

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Lessons Learned: The Carl Vogel Center began offering comprehensive primary medical care May 4, 2005. From May–December 31, 2005 a sample of clients were provided TEAP services, allowing CVC to reach the following observational conclusions:

1. Clients more openly discussed non-adherent practices with the Treatment Specialist compared to similar conversations with the physician.
2. Clients were able to develop a better rapport with Treatment Specialist.
3. HIV Knowledge Assessment tool was effective in identifying client knowledge of HIV disease, treatment options and needs for educational enhancement.
4. Clients' knowledge and understanding of HIV and how it affects the body can directly impact their choices and has resulted in reported improvements in adherence.
5. Adherence counseling time spent with clients is critical to foster a relationship in which they are comfortable while discussing their questions and sharing their abilities and barriers to adhere to treatment.

Results: Client satisfaction surveys were completed and returned by 40% of the sample client group. The following information is representative of clients impression of the services they received by participating in the TEAP program.

Table 21.

<i>Treatment Education</i>	<i>Strongly Agree - Agree</i>	<i>Percentage</i>
1. The Treatment Specialist appeared well informed about antiretroviral therapies for HIV.	9	82%
2. The Treatment Specialist and I discussed my health priorities.	8	73%
3. I increased my knowledge about HIV infection.	8	73%
4. I received written information about my medications that included potential drug interactions.	8	73%
5. I participated in developing my care plan and understand the importance of adhering to my treatment regimen.	8	73%
6. I can describe viral load and resistance testing.	6	55%
8. I learned ways to improve my adherence.	8	73%
9. My questions and concerns were answered to my satisfaction and the Treatment Specialist was helpful.	7	64%
10. My Treatment Specialist and my HIV medical provider(s) worked together to help me	8	73%
11. Overall, I am satisfied with the Treatment education/adherence services I received during the past 1 to 6 months.	8	73%

Recommendations: Exploring approaches to improve adherence is a continuous process. Research that is done which correlates clinical findings with behavioral and lifestyle issues the more we, as providers, can learn how to best meet the needs of the clients we serve. The management of HIV disease is complex and the critical element to ensure clients are provided comprehensive quality care that has proven beneficial to Carl Vogel Center's clients is a clinical team of providers that work collaboratively to empower and encourage clients to be proactive in their care plans. This integrated healthcare approach allows CVC clinicians to deliver client-centered services while holding clients accountable for participation in their treatment plans. Facilitating good communication between providers and clients, creating an environment of support services which are safe and non-judgmental has allowed clients to gain the full benefits of multidisciplinary HIV care. CVC has plans to enhance the TEAP program by increasing recruitment, incorporating treatment support volunteer buddies into the program and creating a visible presence in the community.

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Relationships between Symptom Experience, Mental Health, Social Support, Symptom Manageability, Adherence, Quality of Life, and HIV Disease Progression

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Background: The Self-regulatory HIV/AIDS Symptom Management Model (SSMM-HIV) is a conceptual model for understanding how HIV patients' symptom experiences (SxE) relate to management of symptoms, adherence to ART, quality of life, and disease outcomes. It posits that SxE is multidimensional consisting of cognitive and emotional components, and SxE varies according to types of symptoms. The purpose of this exploratory study was to operationalize SxE with a newly developed multidimensional HIV Symptom Experience and Assessment Scale (HIV-SEAS) and describe relationships between variables in the model.

Methods: A cross-sectional descriptive design was used. A convenience sample (N=272) from the Swiss HIV Cohort Study (SHCS) completed questionnaires measuring SxE, anxiety, depression, substance abuse, social support, symptom manageability, adherence, and quality of life. Data abstraction from an existing data base provided HIV disease outcomes. Associations between study variables, overall SxE, and each of the 4 subscales were examined.

Results: Variables were largely associated with overall SxE ranging from alcohol problems ($\chi^2(2)=6.22$, $p=0.05$) to quality of life ($\chi^2(8)=92.05$, $p<0.001$). Unexpectedly, adherence was not associated with overall SxE ($\chi^2(2)=4.13$, $p=.12$). However, further descriptive analyses with the four SxE subscales showed nonadherence was associated with flu-like/stomach discomfort SxE ($\chi^2(2)=6.28$, $p<0.05$). Associations using the HIV-SEAS subscales revealed many complex and varied relationships among the HIV-SSMM variables.

Conclusions: Our findings lend support to the SSMM-HIV and show that different dimensions of SxE relate to certain health-related factors more than others. Further research is needed to better understand the complexities of SxE and symptom management and their effects on adherence, quality of life and disease outcomes.

Background: HIV/AIDS is a growing yet poorly understood problem in China, with antiretroviral therapy (ART) programs still in their infancy. Although extremely high ART adherence is necessary for successful treatment, little is known about adherence among Chinese patients. In particular, we know little about how best to measure adherence in this population.

Methods: As part of a three-phase prospective study of adherence among 70 Chinese HIV-positive patients in Dali, Yunnan Province, China (the Adherence for Life study), we compared patients' self-reported adherence to ARV medication and their actual adherence as measured by electronic drug monitors (EDM). This analysis presents preliminary results.

Results: Patients reported very high adherence in the baseline interview. Of the 41 patients who had completed six months of the study at the time of this preliminary analysis, 36/38 (92%) reported that they "never forgot" to take their ARV medication. 37/39 (95%) reported not forgetting the previous week. Overall, 26/37 (70%) reported 95% or greater adherence in terms of taking all doses in a typical month; 34/37(92%) reported 90% or greater adherence. In contrast, the EDM data document that only 2/37 (5%) never forgot a dose in six months. Only 13/38 (34%) exhibited 95% or higher adherence in terms of doses taken and appropriate timing. Overall, over 90% of patients falsely reported high adherence on several measures of doses taken; 58% falsely reported taking doses on time.

Conclusions: There are large discrepancies between patient self-report and EDM in this Chinese population. Patients tend to over-estimate their actual adherence; self-report therefore appears to be a poor measure of true adherence in this population.

Introduction: Working with people who have both mental health and substance abuse concerns and/or diagnoses is a common and difficult challenge for those working on the front lines of HIV prevention and care. Providers are often unsure about how to identify problems and prioritize goals. These efforts to help clients or consumers access treatment and care often are met with challenges from the very service delivery systems in place to provide care. This may arise from the fact that the relevant service delivery systems (e.g., medical care, mental health care, substance abuse treatment, and prevention services) may well have their own program goals or treatment modalities, unique jargon, and/or a set of assumptions about what is best for the client(s). In many communities, these services have worked in relative isolation. Integrating services is central to ensuring comprehensive, integrated services that meet diverse client needs and ensure supports and resources in place to promote and sustain medication treatment adherence.

Description: Through didactic discussion and case vignettes, the program will review a model — the ADHERE MODEL — for promoting culturally competent, client accessible integrated services. The model helps providers to better understand the complex bio-medical, psychological, and social-behaviors concerns experienced by those living with HIV/AIDS, as well as the co-occurring behavioral health problems, that often challenge a client's medication adherence. Comprehensive services include understanding the impact of trauma, abuse, and stigma, as well as the inter-relationship of co-occurring substance use and mental health disorders on HIV prevention, treatment, and access to care. The ADHERE MODEL addresses assessment, dialoging with clients and support networks, provider self-evaluation of services, and culturally competent practice that focuses on client strengths in working towards and maintaining medication treatment adherence.

Lesson Learned: The behavior change of participants — representing diverse fields of practice and from public and private service providers — can be measured by reviewing five years of program evaluation materials. In addition of better understanding of stigma and related barriers to care, and the need to understand the cultural context of service provision, participants have stated that the workshops has resulted in a "better understanding of why it is important to be concerned about the connection of HIV, mental health, and substance use" (94%); and "now feel more comfortable working with drug using clients with HIV/AIDS related issues (90%); to "learning the importance of utilizing strengths-based skills in HIV mental health treatment (90%) and "better understanding of the importance of using a MODEL in everyday practice" (92%) . Overall, participants state increased knowledge coupled with enhanced practice skills that they will take in to everyday practice or work in promoting medication treatment adherence.

Recommendations: Persons living with HIV/AIDS experience mental health concerns that affect their day-to-day functioning, with a significant number using alcohol or other drugs, and/or having been diagnosed with a mental health problem or disorder. Providers must have knowledge and clinical skills necessary to address these complex clients' needs. The goal is to ensure that providers — whether working solo, in multi-disciplinary teams, or in public or private settings, can help client to access comprehensive services and increase and maintain medication treatment adherence. The ADHERE MODEL provides practical tools — use of which are transferable across fields on health and mental health practice — that providers can then take back to their own communities and use with the clients/consumers living with HIV/AIDS. This approach to prevention — making professionals aware of bio-psychosocial-spiritual, ethical, and community issues, and then giving them tools that they will use in practical ways with any number of clients they may see — has reached a diverse population of providers (many of whom admit they had not previously been comfortable working with HIV+ clients). The use of the ADHERE Model can create opportunities for prevention and early intervention in both traditional and non-traditional medical and behavioral health care settings.

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Self-Report Overestimates Adherence: Electronic Drug Monitoring vs. Self-Report among HIV-Positive Patients in Yunnan, China

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Working with Multiply Diagnosed Clients with HIV/AIDS: Promoting Medication Treatment Adherence through Use of the ADHERE Model

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Evaluation of CD8⁺ T-Cell and Antibody Responses Following Transient Increased Viraemia in Sooty Mangabeys Infected with Live, Attenuated Simian Immunodeficiency Virus

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Introduction: *In vivo* depletion of CD8⁺ T cells results in an increase in viral load in sooty mangabeys chronically infected with simian immunodeficiency virus (SIVmac239nef).

Description: Here, the cellular and humoral immune responses associated with this transient period of enhanced viraemia in mangabeys infected with SIVmac239nef were characterized. Fourteen days after *in vivo* CD8⁺ T-cell depletion, two of six mangabeys experienced a 1–2 log₁₀ increase in anti-gp130 and p27 antibody titres and a three- to fivefold increase in gamma interferon-secreting SIV-specific CD8⁺ T cells. Three other mangabeys had modest or no increase in anti-gp130 antibodies and significantly lower titres of anti-p27 antibodies, with minimal induction of functional CD8⁺ T cells. Four of the five CD8-depleted mangabeys experienced an increase in neutralizing antibody titres to SIVmac239. Induction of SIV-specific immune responses was associated with increases in CD8⁺ T-cell proliferation and fluctuations in the levels of signal-joint T-cell receptor excision circles in peripheral blood cells. Five months after CD8⁺ T-cell depletion, only the two high-responding mangabeys were protected from intravenous challenge with pathogenic SIV, whilst the remaining animals were unable to control replication of the challenge virus.

Recommendations: Together, these findings suggest that a transient period of enhanced antigenaemia during chronic SIV infection may serve to augment virus-specific immunity in some, but not all, mangabeys. These findings have relevance for induction of human immunodeficiency virus (HIV)-specific immune responses during prophylactic and therapeutic vaccination and for immunological evaluation of structured treatment interruptions in patients chronically infected with HIV-1.

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Math and Memory Skills May Be Key for Accurate Understanding of ART Instructions

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Background: Health literacy has received consistent support as an important factor affecting medication adherence in HIV infection. Moreover, our work with HIV/AIDS patients has indicated that errors in daily medication dosing may occur because patients do not understand their prescriptions' instructions. Therefore, if patients are not able to understand medication instructions at the outset of treatment, then they cannot be expected to accurately follow those regimens over time. Furthermore, neurocognitive impairment associated with HIV infection may also contribute to poor regimen understanding. However, no studies of health literacy and medication taking to date have accounted for the effects of cognitive impairment. This study therefore presents preliminary findings of the effects of reading, math and specific neurocognitive skills on understanding of a typical ART regimen.

Methods: Subjects are 25 HIV positive men and women who have started their first ART regimen within the past year. We assessed prose literacy (reading), quantitative literacy, problem solving and immediate memory abilities using standardized assessment batteries. The Medication Management Test- Revised (MMT-R) was used to measure understanding of typical ART instructions.

Results: Due to our presently small sample size, we performed two separate multiple regression analyses testing 1). the association of prose and quantitative literacy with MMT-R performance, then 2). the relation of problem solving and immediate memory with the MMT-R. Both models were significant [Model 1: R² = 0.53, p = 0.001 & Model 2: R² = 0.36, p = 0.015, respectively] and showed that only quantitative literacy (p = 0.019) and immediate memory skills (p = 0.010) were significantly related to the MMT-R.

Conclusions: Although preliminary, these findings help to identify key skills for successful ART medication taking that can be targeted at the outset of ART treatment. As the study progresses, we hope to extend our understanding of the relative contribution of such skills on successful ART treatment.

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Using Qualitative Methods to Examine Adherence Assessment in Resource-Limited Settings

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Background: With global scale-up of HIV/AIDS treatment comes a need for accurate assessment of adherence in resource-limited settings. We are using qualitative interviews to examine missed doses recorded by Medication Event Monitoring System (MEMS) for patients in rural Uganda.

Methods: Sixty patient interviewees are being asked to comment on specific instances of departures from individualized dosing schedules observed in MEMS data.

Results: Explanations offered for departures (both scheduled bottle openings not recorded by MEMS and unscheduled, "extra" bottle openings) include: (1) technical problems in using the bottle (e.g. not "re-locking" it to ensure an opening is recorded); (2) removing multiple doses at a single opening, usually to avoid having to travel with the bottle; (3) opening the bottle only for re-fill or to check the number of pills remaining; (4) taking pills but not storing them in the MEMS bottle; and (5) missed doses. About half of scheduled-but-unrecorded openings examined to date appear to represent missed doses. Unexpected events disrupting adherence routines and forgetting to bring medications when traveling accounted for missed doses. Some interviewees find MEMS promotes adherence by reminding or motivating them to take their pills. A concern for the "safety" of the "special" MEMS bottle was also evident across interviews. The desire to keep the bottle from being lost, "spoiled" or stolen accounts for removal of multiple doses for travel and consequent "missed" openings.

Conclusion: Qualitative data suggest up to one-half of electronically recorded missed doses may not be truly missed but related to device use. Using qualitative data to evaluate adherence assessment methods and interpret the resulting data promises to be feasible and effective. Adherence research in resource-rich as well as resource-limited settings stands to benefit from this integrated approach.

Background: Translation and back translation of adherence survey questions may not reveal problems with wording in the local language. Cognitive interviews offer a technique to understand how target populations in Vietnam process and understand information related to HIV medication adherence

Methods: To cognitively test the translated version of the adherence questions taken from the HIV Cost and Services Utilization Study, ten individual qualitative interviews will be conducted in January 2007 among HIV-positive drug users attending an outpatient AIDS clinic in Hanoi, Vietnam who are enrolled in a NIDA-funded cohort study on nutrition and HIV. An iterative process will be used where 3-5 patients will be interviewed individually during 2 separate interviewing sessions. After the first session, materials will be revised in response to participants' feedback. Questions in the structured interview guide will assess respondent's interpretation, recall of information, judging information's relevance to the question, and editing of response including whether the patient had anxiety over disclosure to interviewer. Content analysis will identify repeated or singular yet insightful comments.

Results: Results will be used to improve wording or phrasing of adherence questions and lay the groundwork for future prospective analysis of determinants of adherence in this cohort.

Conclusions: Conclusions will be made regarding use of cognitive testing in the development of adherence questions for populations in Vietnam.

Background: Annual ramadan fasting is a fundamental religious rite in Islam observed in many sub-Saharan African countries. During the month adult Muslims refrain from eating and drinking for 14 hours from sunrise to sunset daily. For massive, rapid and qualitative Anti-Retroviral Therapy (ART) scale-up to succeed, effects of local practices on adherence should be evaluated.

Methods: Adherence and customary practices were studied among fasting 'FT' and non fasting 'NFT' ART experienced patients at PEPFAR supported Aminu Kano Teaching Hospital, Kano, Nigeria. CD4 cell counts and weights were repeated during ramadhan (23 Sept – 22 Oct 2006) and changes from pre-ramadhan values compared between the groups. Student's t-, wilcoxon rank sum, fishers exact and chi square tests and measures of effect are used for analyses as appropriate.

Results: 142 FT and 101 NFT adult follow up patients on ART were seen. All the FT patients are Muslims while the NFT patients are composed of Muslims 15.8% and Christians 84.2% but the groups were similar in age, gender, marital status, pre ramadhan mean body weights 60.4 vs 63.8 Kg, mean Karnofsky performance status 75 vs 72%, on-ART mean CD4 cell counts per ml 327 vs 301 ($p > 0.05$), mean time on ART regimen 16.4 vs 13.0 months and regimen types ($p > 0.05$). The daily dosing frequency are similar with majority on twice daily regimens 132/142 (93.6%) and 94/101 (93.1%) ($p > 0.05$) respectively. The FT patients altered their habits by: advancing their morning and delaying their evening doses giving a median dosing interval of 16.75 hours (range 14.58 – 22.00 hours); eating heavier, fatty meals at breakfast (78.2%); and changing and reducing their sleep time (40.1%) during the month. The median change in CD4 cell counts per ml in FT and NFT is +173 and +143.5 and median change in weight is -1.0Kg and 0.0Kg ($p > 0.05$) respectively. The proportion who never missed a dose among the FT and NFT patients are 114/142 (80.3%) and 89/101 (88.1%) with [Odds Ratio (95% Confidence Interval)] 0.55 (0.24 – 1.19). Those who missed at least a dose during the month are 6/142 (4.2%) and 2/101 (2.0%) with 2.18 (0.38 – 22.50) respectively. New onset ailments are less in FT 24/142 (16.9%) compared to NFT patients 30/101 (29.7%) ($p=0.018$), but side effects are similar.

Conclusion: FT does not reduce drug taking frequency but results in changes in eating, meal contents, sleeping pattern and dosing interval increases which might compromise pharmacokinetics and effectiveness of medications especially with drugs dosed ≥ 2 daily. Once-daily dose regimens should be advised for FT patients. Viral load and therapeutic drug monitoring should be utilized in similar studies in the future.

Objectives: Long-term retention of patients in Africa's rapidly expanding antiretroviral therapy (ART) programs for HIV/AIDS is essential for these programs' success but has received relatively little attention. We analyzed reported patient retention in ART programs in sub-Saharan Africa.

Methods: We located published and gray literature reports on the proportion of adult patients retained (i.e. remaining in care and on ART) after 6 months or longer in sub-Saharan African, non-research ART programs. Retention rates at 6, 12, and 24 months were estimated for each program (with imputation as needed) and modeled using Kaplan-Meier curves and in sensitivity analysis.

Results: 24 publications reporting on 25 patient cohorts (66,753 patients, 13 countries) were included. For all studies, the weighted average follow-up was 9 months, during which 76% of patients were retained. Loss to follow-up and death accounted for 61% and 33% of attrition, respectively. Weighted mean retention rates, without imputation, were 78.4%, 64.5% and 69.2% at 6, 12, and 24 months respectively. Attrition was higher in studies with shorter reporting periods, leading to monthly weighted mean attrition rates of 3.7%/month, 2.6%/month, and 1.3%/month for studies reporting to 6, 12, and 24 months respectively. In sensitivity analyses, estimated attrition rates ranged from 30-79% by 2 years.

Conclusions: ART programs in Africa are retaining 50-70% of their patients at the end of two years. Better patient tracing procedures, understanding of loss to follow up, the primary cause of attrition, and earlier initiation of ART are needed if retention is to be improved.

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Use of Cognitive Testing in the Adaptation of Adherence Survey Questions in Hanoi, Vietnam

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Adherence to Anti Retroviral Therapy (ART) during Muslim Ramadhan Fasting

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Patient Retention in Antiretroviral Treatment Programs in Sub-Saharan Africa

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